Journal of Participatory Medicine

Journal Impact Factorâ ¢ (JIF) (2023): 5.8
Volume 16 (2024) ISSN 1438-8871 Editor in Chief: Gunther Eysenbach, MD, MPH

Contents

Review

Viewpoint

Original Papers

Tutorial

Review

Public Involvement and Engagement in Big Data Research: Scoping Review

Piotr Teodorowski[1], PhD; Elisa Jones[2], MA; Naheed Tahir[3]; Saiqa Ahmed[3], MSc; Sarah E Rodgers[2], PhD; Lucy Frith[4], PhD

[1]Faculty of Health Sciences and Sport, University of Stirling, Stirling, United Kingdom
[2]Department of Public Health, Policy & Systems, University of Liverpool, Liverpool, United Kingdom
[3]National Institute for Health and Care Research Applied Research Collaboration North West Coast, Liverpool, United Kingdom
[4]Centre for Social Ethics and Policy, University of Manchester, Manchester, United Kingdom

Corresponding Author:
Piotr Teodorowski, PhD
Faculty of Health Sciences and Sport
University of Stirling
Pathfoot Building
Stirling, FK9 4LA
United Kingdom
Phone: 44 1786466362
Email: piotr.teodorowski@stir.ac.uk

Abstract

Background: The success of big data initiatives depends on public support. Public involvement and engagement could be a way of establishing public support for big data research.

Objective: This review aims to synthesize the evidence on public involvement and engagement in big data research.

Methods: This scoping review mapped the current evidence on public involvement and engagement activities in big data research. We searched 5 electronic databases, followed by additional manual searches of Google Scholar and gray literature. In total, 2 public contributors were involved at all stages of the review.

Results: A total of 53 papers were included in the scoping review. The review showed the ways in which the public could be involved and engaged in big data research. The papers discussed a broad range of involvement activities, who could be involved or engaged, and the importance of the context in which public involvement and engagement occur. The findings show how public involvement, engagement, and consultation could be delivered in big data research. Furthermore, the review provides examples of potential outcomes that were produced by involving and engaging the public in big data research.

Conclusions: This review provides an overview of the current evidence on public involvement and engagement in big data research. While the evidence is mostly derived from discussion papers, it is still valuable in illustrating how public involvement and engagement in big data research can be implemented and what outcomes they may yield. Further research and evaluation of public involvement and engagement in big data research are needed to better understand how to effectively involve and engage the public in big data research.

International Registered Report Identifier (IRRID): RR2-https://doi.org/10.1136/bmjopen-2021-050167

(J Particip Med 2024;16:e56673) doi:10.2196/56673

KEYWORDS

patient and public involvement; PPI; involvement; engagement; big data; data science; patient engagement; co-design; coproduction

Introduction

Background

The growth of big data allows researchers to use and link large, multisource health data sets for research. Big data is still an evolving field [1], and disagreements remain on precisely what the term stands for in health research [2]. Other terms used include routinely collected data [3] and data-intensive research [1,4]. For clarity, throughout this paper, we will refer broadly to the term big data as it is used in the literature and easily understood by the public. We follow the definition by Aitken et al [1], recognizing that the main feature of big data is the ability to link large data sets for analysis. They name sources for such data as patient records, administrative, registry biobanking, social media, and digital application data. Big data research in health can be used for multiple purposes with the aim of improving health care services and reducing health inequalities [5,6]. These include service management, evaluation or audit of services, statistics, and exploring connections between health and non–health-related outcomes [1]. Often, these purposes differ from the original intent of data collection (eg, health care or statistical purposes). In other words, big data is often used for secondary research purposes.

Big data research offers new opportunities for academics. However, reusing big data for research faces ethical challenges [7]. Previous big data initiatives suggest that the public must have confidence that their data will be used in an acceptable way if they are going to be supportive of big data research [8]. This means moving outside what is legally required and establishing a social license for research [9]. Carter et al [9] proposed 3 conditions for establishing a social license for big data research. First, reciprocity is essential, as there is a need for 2-way communication and improving public awareness of big data research as well as improving researchers' understanding of the public's concerns and expectations. A lack of transparency could make it challenging to secure public trust [10], and the public has a right to be informed about the progress of the research [11]. Second, the process should empower, not disempower, the public; in big data research, this could include members of the public involved in the governance of data linkage and the design of big data projects. Third, big data research should benefit the public; thus, researchers need to understand what the public might perceive as public benefit.

Public involvement and engagement could be used to bridge the gap between researchers and the publics' understandings of the benefits of big data research [12]. There is evidence in the literature (outside big data) that public involvement can provide legitimacy for research [13]. Public contributors could be a part of the process of creating research norms for big data research [14]. Research norms consist of governance and regulation that could guide research. These might not be popular among some academics, but they could help secure a social license for research [15]. Aitken et al [1], in their consensus statement on public involvement with big data research, go a step further and argue that "the public should not be characterised as a problem to be overcome but a key part of the solution to establish beneficial data-intensive health research for all." There is emerging evidence that public contributors can be meaningfully involved in big data research projects [16-18]. However, there is a need to understand how public involvement and engagement takes place in big data research comprehensively.

Objectives

Previous reviews have examined literature around public trust and attitudes toward big data research [19-22]. Despite public involvement and engagement being seen as one of the ways to improve public trust, as far as we are aware, there have not been any previous reviews exploring public involvement and engagement in big data research and there have not been any reviews registered on the PROSPERO and Cochrane databases. Therefore, this review aimed to synthesize what is known about public involvement and engagement in big data research. Using scoping review methodology [23-25], we mapped key issues in the research to find evidence of how public involvement and engagement were carried out in big data research. Understanding how to involve and engage the public in big data research could be used to formulate guidance for researchers and policy makers on how to do this effectively, as there are field-related challenges, especially regarding the abstraction and complexity of big data [26].

Methods

Overview

The protocol for this scoping stage review was published previously [27]. The protocol outlines the parameters of the review and provides a justification and explanation of all the methodological steps and decisions taken. To ensure rigor further, we used the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist [28] and reported it as Multimedia Appendix 1.

Defining Public Involvement

In the literature, the terms involvement, engagement, and participation are used interchangeably, but these do not always have the same meaning [29,30]. This makes research and discussion about public involvement challenging, as it can be difficult to identify papers for review [31-33]. Hence, there is growing recognition that more consistent terminology is needed [13]. The diversity of types of involvement can be seen in the ladder by Arnstein [34] that determines types of involvement by constructing a typology based on the amount of power given to the public. It identifies from the bottom (lowest extent of people's influence) to the top (highest extent of people's influence) the following steps: therapy manipulation, nonparticipation, informing, consultation, placation, partnership, delegation, and full citizen control. The author herself called the ladder "provocative." One of the health-specific definitions of public involvement has been developed by INVOLVE [35]. It has been used broadly by funders and researchers and embedded in the public involvement reporting checklist [33]. It offers a nuanced perspective on 3 types of activities: involvement, engagement, and consultation, which researchers can use when working with members of the public. One is not better than the other, but rather, each offers a different approach. INVOLVE defines involvement as research carried out with or by members of the public rather than to, about, or for them. This recognizes shared ownership of research with members of the public. Engagement is providing information about big data research and disseminating it to the public. Consultation happens when the research is discussed with the public, but there is no shared ownership. Thus, engagement and consultation are "to," "about," or "for" rather than "with" or "by" them. However, these activities can provide an understanding of the public views.

Owing to the diversity of definitions of public involvement and engagement used in the literature, we mapped all included papers using the INVOLVE definition, identifying whether they were involvement, engagement, or consultation.

Public Involvement in the Review

Public involvement in reviews can improve their quality by contributing to defining the scope, appraising the papers, and interpreting results [36,37]. In total, 2 public contributors (SA and NT) were involved in the review from the initial design stage and contributed at each stage (screening, data extraction, and analysis). They are both experienced public contributors and previously copublished papers around public involvement and engagement in big data research. SA and NT ensured the relevance of review results to the public. This was achieved by relating results to their experience as public contributors in other research projects. The details of the involvement process and what was put in place to support them (eg, training) are reported elsewhere.

Searches

Following the search strategy developed with the support of a university librarian, the CINAHL, Health Research Premium Collection, PubMed, Scopus, and Web of Science databases were searched for papers in September 2021. The search strategy, as published in the protocol paper, is included in Multimedia Appendix 2. The search covered papers published after 2010 until the search completion in September 2021. Additional manual searches were conducted. These included the screening of the first 100 results from a Google Scholar search, journals that aim to publish public involvement research (*BMC Research Involvement and Engagement* and *Health Expectations*) or had special editions on public involvement in big data (*International Journal of Population Data Science*), and gray literature (the first 100 results from the Patient Outcome Research Institute database were screened). A call for potential papers to be included was posted on X (previously known as Twitter) to reach experts in the field.

Inclusion Criteria

The review included papers that met the following criteria: (1) discussed public involvement or engagement in big data research (those that appeared more as consultations were not excluded, but a note was taken of this), (2) focused on patient- or health-related research, and (3) were published in English. All study designs and nonempirical discussion papers were included.

Screening and Study Selection

PT took the lead by screening all papers. SA, NT, and EJ jointly screened at least a random 20% of papers at each stage (title, abstract, and full paper). Any discrepancies were discussed by the research team. The reasons for exclusions at a full paper stage were recorded and reported in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.

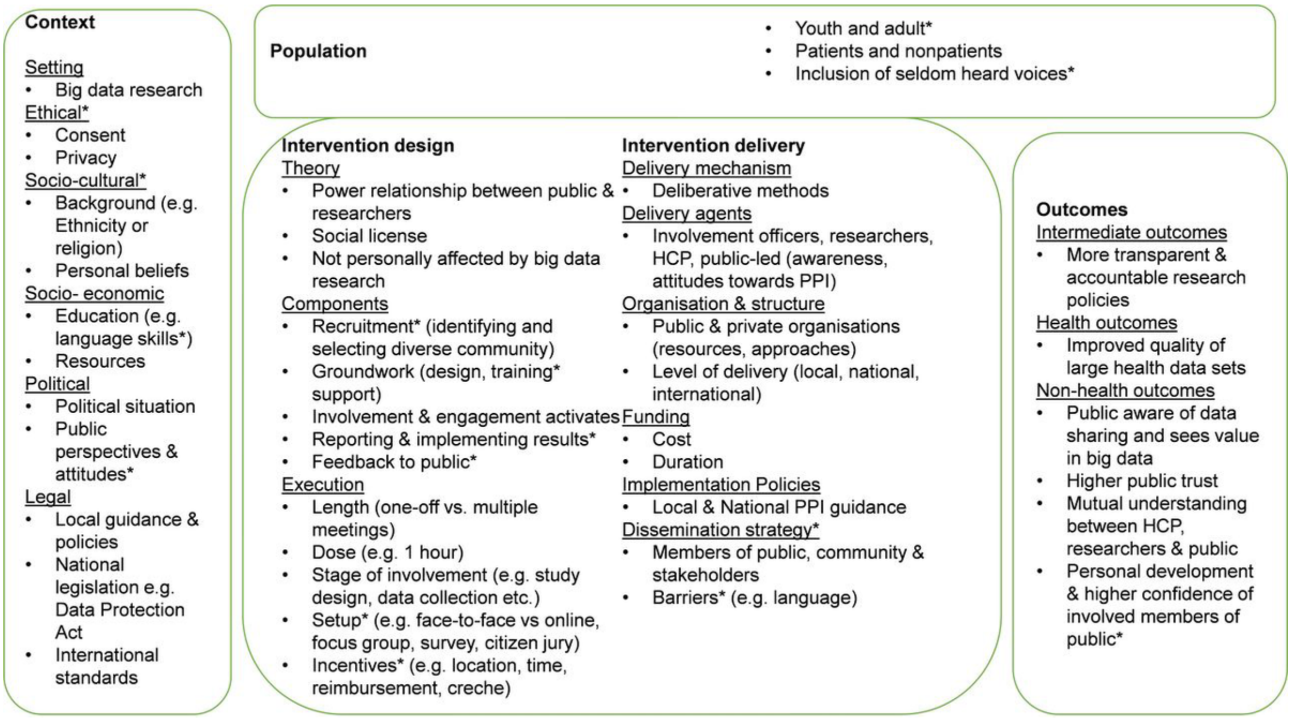
Data Extraction

The data extraction form development was iterative and tested by the whole research team. The final data extraction form is available in Multimedia Appendix 3. PT extracted data from all papers in the first instance. Then, all extraction was double checked by the rest of the research team, thus ensuring each paper was considered by 2 researchers. The research team met regularly to discuss any discrepancies and discuss initial findings. PT organized the extracted data in a descriptive and narrative way under key headings based on the data extraction form. This was discussed with the research team.

Analysis

The analysis was supported by a prior system logic model that we published in the protocol paper (Figure 1 [27]). It was initially developed by a preliminary scoping of the literature, research team discussion, and input from the public contributors. The logic model assisted us in identifying relevant elements of public involvement and engagement in big data research. We mapped our findings under the model and present them using headings from the logic model.

Figure 1. System logic model of public involvement and engagement in big data research (reproduced from the study by Teodorowski et al). HCP: health care provider; PPI: public and patient involvement.



Results

Overview

The database searches produced 4054 papers. Additional manual searches added a further 11 papers. After the removal of duplicates, 3540 articles were screened for inclusion in the review. A total of 3342 papers were excluded based on the title and abstract. The full-text screen took place for 198 papers, and 53 were included in the review. Figure 2 [38,39] shows the PRISMA flowchart of the screening process. We first discuss the study characteristics and thereafter present findings as mapped under the revised system logic model (Figure 3 [27]).

Figure 2. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart. PPIE: patient and public involvement and engagement.

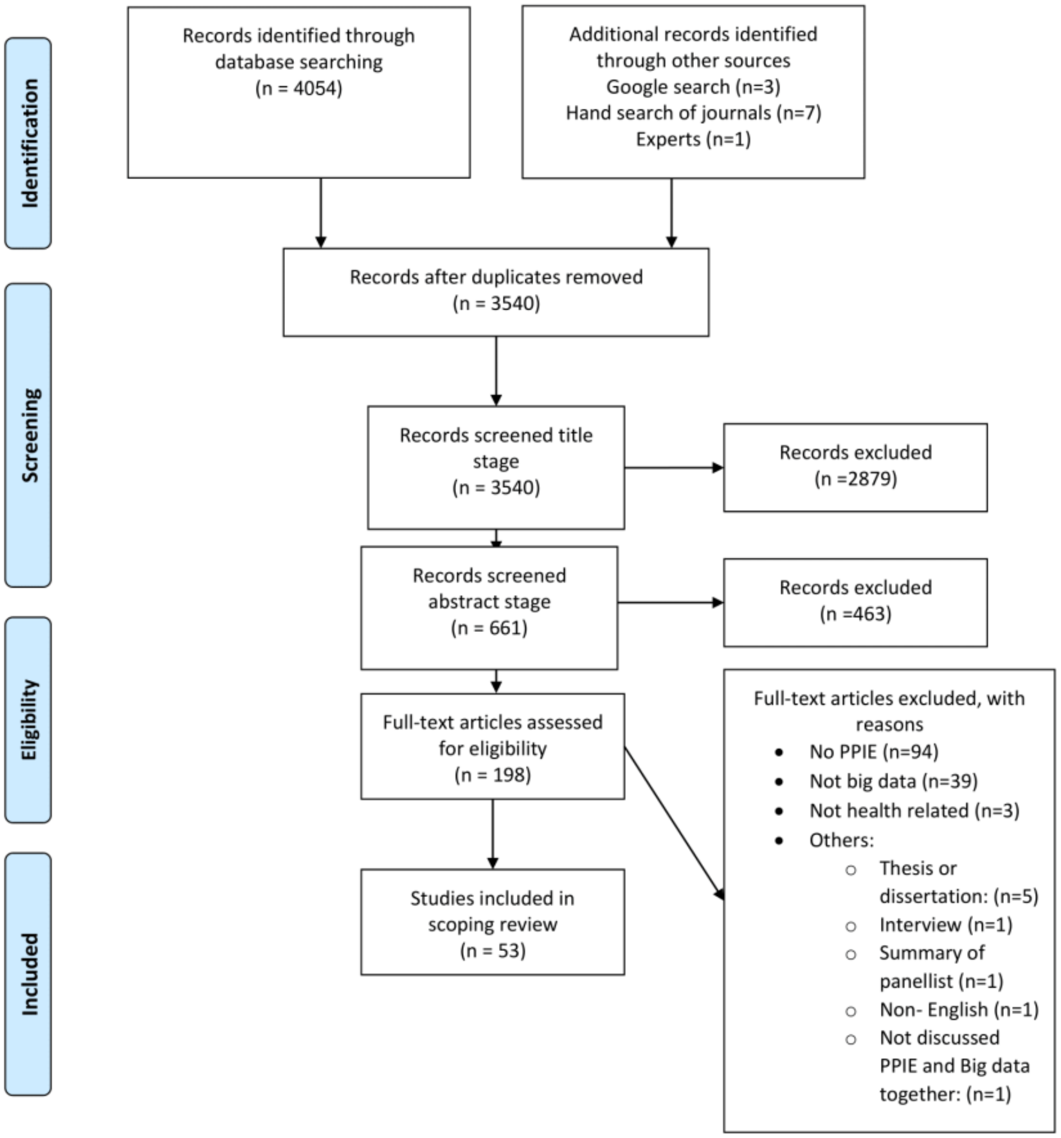
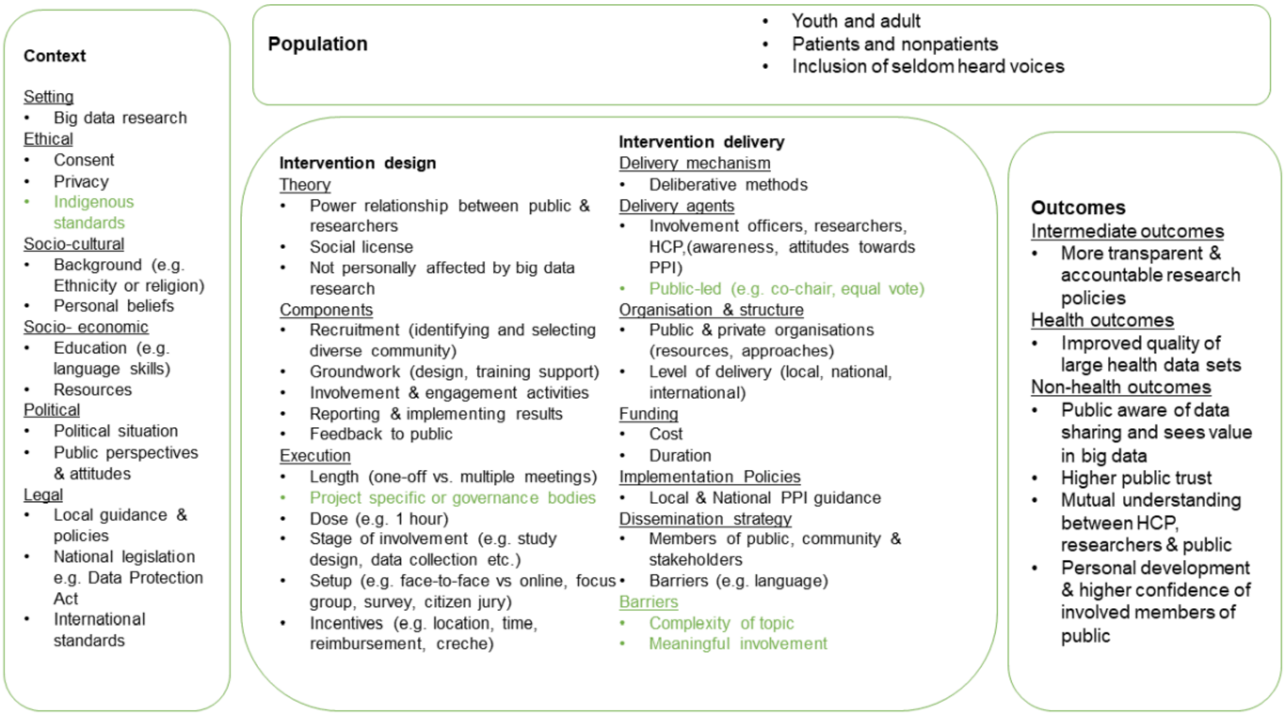


Figure 3. The updated a priori system logic model of public involvement and engagement in big data research (adapted from the study by Teodorowski et al). Green color is used to record new aspects of the model based on the review. HCP: health care provider; PPI: public and patient involvement.



Study Characteristics

The most prevalent type of papers were discussion papers (nonempirical, including conceptual or ethical papers; 28/53, 53%), followed by review papers (5/53, 9%); qualitative study design (5/53, 9%); opinion, letter, commentary, or editorial (4/53, 8%); evaluation (3/53, 6%); protocol (2/53, 4%); ethnographic or descriptive case study (2/53, 4%); public deliberations (1/53, 2%); action research (1/53, 2%); quantitative (1/53, 2%); and mixed methods (1/53, 2%). The papers were from the United Kingdom (19/53, 36%), the United States (10/53, 19%), Canada (7/53, 13%), New Zealand (3/53, 6%), the Netherlands (1/53, 2%), Portugal (1/53, 2%), France (1/53, 2%), South Africa (1/53, 2%), Australia (1/53, 2%), Germany (1/53, 2%), and Africa (1/53, 2%). In total, 12 papers did not specify a geographical location, and some papers included more than one. The most prevalent type of involvement and engagement activities carried out with the public (following INVOLVE definitions) were involvement (45/53, 85%), followed by engagement (25/53, 47%) and consultation (7/53, 13%). Some papers discussed >1 type of activity. Table 1 presents the characteristics of the included papers.

Table 1. Summary of the included papers in the scoping review.

Study; year	Design	Location	Demographics to involve and engage	Types of activities	Area of interest
Baart and Abma [40], 2010	Action research	Netherlands	Not specified	Involvement and engagement	Involvement in psychiatric genomics research
Ballantyne and Style [41], 2017	Discussion	New Zealand	Lay, gender, and Māori representation	Involvement and engagement	Expert health data research ethics committee
Ballantyne and Stewart [42], 2019	Discussion	United Kingdom	Affected group; priority is given to patient groups considered vulnerable	Involvement and engagement	Public and private sectors collaborate to share, analyze, and use biomedical big data
Beyer et al [43], 2010	Qualitative	United States	Caucasian, Hispanic, Taidam or Lao; represented various education, income, and other characteristics	Involvement and consultation	Geocoded health information and experiential geographical information in a GIS[a] environment
Bharti et al [44], 2021	Discussion	United Kingdom	Not specified	Engagement	Securing public trust and the importance of public engagement
Bot et al [45], 2019	Discussion	United States	Underrepresented populations	Involvement	Decentralization of governance
Coulter [46], 2021	Editorial	United Kingdom	General public	Involvement	National Health Services Digital plans to update its systems from patient data from general practitioner records
Dankar et al [47], 2018	Discussion	N/A[b]	Not specified	Engagement	Data governance in population genome projects
de Freitas et al [48], 2021	Protocol	Portugal	Patients and informal carers	Involvement	Coproduction of a people-centered model for the public in decision-making processes about data reuse
Deverka et al [49], 2019	Public deliberations	United States	Diverse geographic and individuals with chronic illness	Involvement and consultation	Recommendations for medical information commons design and management
Duchange et al [50], 2014	Discussion	France (European Union project)	Representatives of patient organizations	Involvement, engagement, and consultation	Ethics committee
Erikainen et al [51], 2020	Qualitative	United Kingdom	Not specified	Involvement	Governance of population-level biomedical research
Evans et al [52], 2020	Qualitative	United States	Individuals with OUD[c] and their families	Involvement and engagement	Reuse of big data on opioid use
Fernando et al [53], 2019	Letter	South Africa	Traditional community leaders	Involvement and consultation	Data governance model in biobanking and data sharing
Fleurence et al [54], 2014	Discussion	United States	Patients	Involvement	National research network (PCORnet)
Funnell et al [55], 2020	Discussion	Canada	Indigenous communities	Involvement	Community-based participatory research methods in a project using previously collected data to examine end-of-life health care
Gallier et al [56], 2021	Discussion	United Kingdom	Not specified	Involvement and engagement	PIONEER infrastructure and data access processes
Goytia et al [57], 2018	Qualitative	United States	Patients	Involvement and engagement	Views on big data research
Henare et al [58], 2019	Opinion	New Zealand	Indigenous people	Involvement and engagement	Road map for neuroendocrine tumor research to reflect the values of Indigenous people
Hudson et al [59], 2020	Discussion	N/A	Indigenous population	Involvement	Indigenous communities' views on the sharing of genomic data
Hurt et al [60], 2019	Discussion	United Kingdom	Not specified	Involvement and engagement	Design of HealthWise Wales

Study; year	Design	Location	Demographics to involve and engage	Types of activities	Area of interest
Jewell et al [61], 2019	Evaluation	United Kingdom	Service users and carers	Involvement	Advisory group
Jones et al [18], 2013	Evaluation	United Kingdom	Consumers; at least 1 representative from an ethnic minority group	Involvement	Consumer panel
Jones et al [17], 2019	Discussion	United Kingdom	Not specified	Involvement and engagement	SAIL Databank
Jones et al, 2020 [16]	Evaluation	United Kingdom	Inclusive of all ages, ethnic groups, cultures, socioeconomic levels, lifestyles, and other definable interests	Involvement and engagement	SAIL Databank and related population data science initiatives
Kalkman et al [62], 2019	Systematic review	N/A	N/A	Involvement and engagement	Ethical guidelines for principles and norms pertaining to data sharing
Kirkham et al [63], 2021	Qualitative	N/A	People with lived experience of mental illness and experience with data science or research methods	Involvement	Best practice checklist for use in mental health data science
Luna Puerta et al [64], 2020	Scoping review	N/A	N/A	Involvement	Reporting the impact of public involvement in biobanks
Manrique de Lara and Peláez-Ballestas [65], 2020	Narrative review	N/A	N/A	Involvement and engagement	Bioethical perspectives of big data
Milne et al [66], 2021	Discussion	United States and North America	Not specified	Involvement	Data trust model in the governance of biobanks
Milne and Brayne [67], 2020	Discussion	N/A	Not specified	Involvement	Data governance in dementia
Mourby et al [68], 2019	Discussion	United Kingdom	Not specified	Involvement and engagement	Obstacles preventing data linkage research from reaching its full potential
Murtagh et al [69], 2018	Ethnographic case study	United Kingdom	Participants of genomic studies	Involvement and engagement	Foundational principles of data sharing infrastructure
Nelson and Burns [70], 2020	Discussion	United Kingdom	Most affected communities by the research	Engagement	ADRC NI[d] approach to public engagement
Newburn et al [3], 2020	Discussion	United Kingdom	Service users; 1 activity targeted ethnic minority groups	Involvement and engagement	Service user participation in a data linkage study
Nunn et al [71], 2021	Mixed methods	Australia	Not specified	Involvement	Involvement in genomic research
O’Doherty et al [72], 2011	Discussion	Canada	Groups considered historically disadvantaged	Involvement and engagement	Biobank governance and principles to form governance structures
O’Doherty et al [73], 2021	Commentary	N/A	Not specified	Involvement	Functions of good governance
Ohno-Machado et al [74], 2014	Discussion	United States	Patients	Involvement and consultation	Setting up of the pSCANNER[e]
Omar et al [75], 2020	Discussion	N/A	Not specified	Involvement, engagement, and consultation	European network of excellence for big data in prostate cancer
Paprica et al [76], 2020	Discussion	Canada	Communities facing long-standing inequalities that are affected by the research	Involvement and engagement	Establishment and operation of data trusts

Study; year	Design	Location	Demographics to involve and engage	Types of activities	Area of interest
Patel et al [77], 2021	Quantitative	United Kingdom	Not specified	Involvement	The use of remote consultation and prescribing of psychiatric medications
Pavlenko et al [78], 2020	Systematic review	N/A	N/A	Involvement	Governance in clinical data warehouses internationally
Rowe et al [79], 2021	Discussion	Canada, New Zealand, and United States	Indigenous people	Involvement	Principles for linking Indigenous population data
Shaw et al [11], 2020	Discussion	United States, Canada, and United Kingdom	General public and specific communities (eg, African Americans, Indigenous people, people with disabilities, and people living with homelessness)	Engagement	Social license for big data initiatives
Sleigh and Vayena [80], 2021	Descriptive case study	Germany and United Kingdom	General public	Engagement	Visual public engagement campaigns
Teng et al [81], 2019	Discussion	Canada	Not specified	Involvement	Public deliberation event on the data linkage and reuse for research
Tindana et al [82], 2015	Review	Africa	People affected by the research	Involvement, engagement, and consultation	Community engagement in biomedical and genomic research
Townson et al [83], 2020	Discussion	United Kingdom	Not specified	Involvement and engagement	A model of public involvement and engagement
Vayena and Blasimme [84], 2017	Discussion	N/A	Patients	Involvement	Models of informational control in data-intense health care and clinical research
Weich et al [85], 2018	Protocol	United Kingdom	Mental health users and carers and people with lived experiences; ensure diversity of age, gender, and ethnicity	Involvement	Spatial and temporal variation in the use, effectiveness, and cost of community treatment orders through the analysis of routine administrative data
Willison et al [86], 2019	Discussion	Canada	Patient representatives with diabetes including Francophone, immigrant, and Indigenous populations	Involvement	Governance model for health data repositories
Xafis and Labude [87], 2019	Discussion	N/A	Not specified	Involvement and engagement	Ethics framework for big data in health and research

[a] GIS: Geographic Information Systems.

[b] N/A: not applicable.

[c] OUD: opioid use disorder.

[d] ADRC NI: Administrative Data Research Centre Northern Ireland.

[e] pSCANNER: patient-centered Scalable National Network for Effectiveness Research.

Population

The demographics of the public or communities involved and engaged in big data research were diverse. These included patients (including consumers and service users; 12/53, 23%); affected groups or groups considered vulnerable (8/53, 15%); Indigenous communities (6/53, 11%); articles focusing on specific characteristics (eg, gender, age, income, education, or geography; 5/53, 9%); carers (4/53, 8%); the general public (3/53, 6%); ethnic minority groups (3/53, 6%); patient representative or community leaders (3/53, 6%); and research study participants (1/53, 2%).

Deciding who should be on advisory boards, how they should be selected, and what their role should be remained a challenge for researchers [82]. An important issue was representativeness; advisory boards were unlikely to represent all the public views [66,69,87]. No single committee could represent all communities (because of their diversity) [58,76]. Identifying the relevant communities was seen to be difficult [82]. This created the challenge of ensuring legitimate group representation [72]. Advisory groups often did not reach a broader population [68];

hence, involvement and engagement need to move away from the “usual suspects” [16,18,66,76]. There was the risk that more vocal individuals could dominate the discussion [82]. Public contributors could be chosen arbitrarily, for example, based on personal contracts, and thus, the process might not be transparent to the public [72]. This could lead to involving financially and politically motivated [49] or well-connected contributors [42]. The way to overcome these issues could be to recruit public contributors from the study participants; for example, participants could elect their own representatives or a marketing company could conduct the recruitment [72,81].

Context

Researchers should respect local and seldom-heard groups’ traditional structures and ethical perspectives. Papers focusing on Indigenous communities showed already existing governance mechanisms supporting research with these groups [59,79]. Researchers should incorporate Indigenous culture, for example, traditional ceremonies, when involving the community [58]. Formalized agreements with Indigenous organizations could improve the relationship with that community [55]. This more nuanced approach to big data research could assist researchers in establishing trust with Indigenous communities rather than merely convincing them that this is the right thing to do [59].

Political situations or public perspectives and attitudes could influence how and why members of the public get involved in big data research. Secrecy could be a challenge [11]. Organizations might not want to share controversial information, and private companies may argue that sharing it might be against their commercial interests [42]. Involvement and engagement could have the potential to improve public trust in big data research but not necessarily in the research institution [51]. There could be historic mistrust from underserved communities, for example, African Americans, Indigenous communities, and people living with homelessness [11]. There was no guarantee that it would always be possible to maintain public trust in big data research [67].

Intervention Design

Theory

Respectful, ongoing, genuine, and nonhierarchical interaction between researchers and the public was seen as necessary to build trust [16,87]. Building a relationship could take time [82]. It included the coownership of research [55] and should concentrate on what the public wants to know [40]. The reciprocal relationship was illustrated by Newburn et al [3], who organized workshops during which they delivered training for members of the public on using social media and research methodology. A clear purpose for the activity leads to realistic expectations [16]. The starting point for involvement might not be about assuming an equal partnership but an exploration of power relationships [40]. Working in smaller groups gave more opportunities for every public contributor to share their opinion [81]. Decisions could be made through consensus [55,86]. However, Ballantyne and Stewart [42] recognized that there would always be disagreements and that all opinions cannot always be acted on; in that case, there might be a need for a clear explanation of why these voices were not included.

Conducting involvement and engagement activities did not mean that public values are incorporated into big data research [72]. Involvement could be tokenistic without effecting real change, but this still could offer some form of legitimacy to researchers and the research [72]. There was a need to ensure a balanced power relationship between public contributors and the research team [48]. When public contributors joined already ongoing research projects, they had limited scope for impact (eg, amendments might not be allowed); thus, their involvement might turn more into consultation [66,82]. Some researchers did not support involvement and would prefer a deficit engagement model where the members of the public were simply informed about the research [40]. Researchers should reflect on how to ensure balance in engagement. It could be about raising awareness of big data research and understanding that it should not be limited to an already agreed outcome but rather an ongoing dialogue [16,17,76]. Public involvement and engagement should take place before any data sharing occurs [11].

Recruitment

Various ways could be used to reach diverse audiences [75,86]. Recruitment of public contributors was mostly through already existing groups such as involvement groups (eg, Jewell et al [61] used an established involvement register that was open for service users and their families or carers), patient organizations [18,61,74,75,85], clinical sites [74], or recruitment via newsletter distributed among study participants [60,83]. Working with intermediaries (eg, charities or community leaders) could improve the reach as they can provide advice about public perspectives or can become gatekeepers [70,82]. Public contributors might be unclear on their role at the beginning [18]. Therefore, clear criteria for the public are needed [66]. Promoting involvement should focus on seeing it as a reciprocal opportunity with benefits for both researchers and public contributors [3]. The recruitment advertisement should include a description of the role and the required skills [61]. The full research protocol with all methodological details should be available on request [3]. There was a perceived need for a transparent process of selecting public contributors to avoid tokenism [49,73]. Candidates could be interviewed to identify individuals with team working skills and the ability to contribute outside their own health situation [18,86], as public contributors’ emotional connection to the research could be both an enabler or a barrier to their involvement [71].

Engagement is about reaching the broader public, especially around dissemination [62,68]. The engagement was mentioned alongside education, as it showed how findings from big data projects were shared with the community [52]. Educating the public could be seen as paternalistic, one directional, and top down; hence, there was a need for 2-way communication [11,86]. Researchers should share any discussion from governance groups with a broader public [11,56]. These could be a brief web-based report of findings and key recommendations [43].

Contribution

Public contributors had various roles in big data research. First, they contributed to specific research projects. In some papers, the public contributors were involved at all stages, from study design and identifying research questions to analysis and dissemination [3,48,52,53,55,57,61,65,82,85,87]. Public contributors also acted as coinvestigators in big data research projects [3].

The other role was around data governance. Public contributors (or representatives of patient organizations) could be involved in (joint) data governance to ensure that research was done ethically (in terms of public interest and sensitivity risk), for example, by advising, cofinding new solutions, or cocreating guidance and policy [16,18,41,42,45,54,56,58-60,62,64,66-69,72-78,86]. Working with the public could offer a lay perspective and ensure that data access and research were in the public interest, and thus, this was argued to potentially pave the way for establishing public trust [17,18,41,56,60,66,68].

One paper reported that public contributors who were members of governance bodies acted as big data advocates [16]. However, their voice should be of equal value as other stakeholders [49]. For example, if the group felt that a big data project did not have enough public input, they could assign a public contributor to support that particular work [86]. The governance bodies could also assist with engaging the general public (eg, by reviewing lay information) and guide the recruitment of new public contributors [16]. The influence of governance groups differs, and O'Doherty et al [72] recommended flexible governance that could evolve as big data research develops. Some papers argued that a one-size-fits-all solution might never work in big data research or for diverse communities [45,58,68,82]. Embedding involvement in the governance of big data research may require novel solutions [51].

The public should receive understandable and educational information on project outcomes [75]. Engagement activities should be proportional to the nature and size of the project around big data research [42]. Therefore, the way these engagement activities looked differed between the papers that were included. The public could be reached through engagement events [16,65]. Events were held with service users [3]. Researchers attended and supported events, for example, during the colorectal cancer awareness month [43]. Interactive elements (graphics, videos, etc) were used during exhibitions to raise public awareness [80].

The consultation approach consisted of surveys [50,75], informal small group meetings (eg, town hall meetings) [82], or qualitative research that aimed to capture the public perspective before setting up the project using that community data [53]. These included focus groups (eg, exploring patients' approach to patient engagement in governance and prioritizing research questions) and interviews (eg, to understand public views toward privacy) [74].

In-person activities could be time restrictive and cost restrictive for some communities [74]. Public contributors might not be able to attend meetings, sometimes without warning because of personal circumstances (eg, health treatment, work, or family responsibilities) [3,81].

Intervention Delivery

Delivery Mechanism

Involvement around governing big data research could also be conducted as a one-off deliberation event [49,81] or a Delphi study [63]. A one-off deliberation process could be particularly beneficial for contentious issues [73].

Delivery Agents

Governance groups could be chaired or cochaired by a public contributor, and most members of these groups could be members of the public [60,66,74,86]. If there was >1 governance group in the organization, public contributors could sit on different panels [16-18,74]. The public could be a part of the engagement process. Townson et al [83] mentioned the role of "Champions" who promoted studies in general practitioner surgeries, large public events (eg, food festivals) reaching schools, and support events organized by researchers. Another role they had was that of "supports." Supports (similarly, to champions) were to promote the research, but it took the form of a pledge; this was more casual, with no formal training or evaluation and no reimbursement. However, both roles were voluntary, with no specific targets to reach [83].

Involvement and engagement should be led by team members experienced in organizing and running these activities [16,48,60,70,76]. Other researchers should dedicate time to these activities (and this time should be embedded in the workload) [16]. Research team members and facilitators should be trained in public involvement [60,81]. Access to specialist training on involvement and engagement should be provided to both staff and the public [16].

Organization and Structure

Using modern technology, researchers could create a registry or website where the public can see who had access to their data and for what purpose or receive newsletters [3,41,47,72]. Newburn et al [3] aimed to share their research on social media (Twitter and Facebook). Nationwide campaigns could explain the benefits of big data research [52,57,80]. This should be done in the language (eg, Indigenous) the public understands [58]. The public could be further reached through patient organizations [3,75], and researchers could share (yearly) updates jointly with them [50].

Funding

Expectations around monetary compensation should be established from the start [82]. These could include reimbursement for time [61,72,81,83], travel [81], and childcare expenses [3]. Researchers should provide lunch [3] and use venues that are easily accessible by public transport [3]. If public contributors are paid equally to professionals in governing bodies, this might improve their involvement [49].

Implementation Policies

A minority of papers directly referred to involvement or engagement guidance. These included the UK National Standards for Public Involvement [16,60,61], National Institute for Health and Care Research (NIHR) definitions of involvement and engagement [3,83], the GRIPP2 (Guidance for Reporting

Involvement of Patients and the Public) checklist [3,61], the consensus statement on public involvement and engagement with data-intensive health research [16], an academic model guiding involvement [40], and local policies or principles [47,79].

Some papers mentioned legal documents to justify involvement and engagement. These include data protection legislation [16,67], government policies [41,45], and legislation or treaties around Indigenous communities' rights [55,58].

Dissemination Strategy

Researchers should communicate clearly, in lay language and without jargon, to ensure transparency [18,49,76]. The examples included jargon-free graphics [80], tailoring academic research to lay audience [40], and postsession informal debrief [69]. When reaching the broader public, researchers should aim to deliver the message themselves rather than through the lens of media to provide more balanced information [3]. Public contributors should receive training introducing them to big data research [18,48,69,83,86]. The availability of good-quality information on big data underpins meaningful public involvement [75,87]. Explanations could include links to Wikipedia [83]. Researchers should send information before activities to give people time to reflect on it [83]. Public contributors might need extra time to consider their responses [16].

Barriers

Meaningfully including public contributors in the governance of big data projects could be challenging. Big data could be a complex topic, and it is difficult to find, involve, and engage public contributors with sufficient big data expertise [18,40,47,49,52,57,65]. Potential contributors might feel apprehensive about contributing to complex research if they do not understand the technical jargon [16,42]. This could be further compounded by language and cultural barriers between researchers and the public [82]. Public contributors should be offered training and additional support as required, especially with complicated topics [61,83]. Support needs to be person-centered and based on each individual's skills and experience [83]. These could include short lectures, group discussions, and opportunities to ask questions [61,66]. For example, Teng et al [81] sent a booklet written by researchers in lay language on big data with a special focus on data collection, regulation, data sharing, and public concerns. Involving people with experience in research could be an alternative [69]. Kirkham et al [63] included public contributors with big data research experience. Still, they recognize that people with a better understanding of big data might have different views than the general public.

Public involvement should be a meaningful process. Included papers suggested several ways to ensure that members of the public would feel comfortable and able to share their views. Before meeting other stakeholders, public contributors could meet first together [48]. When commenting on a new aspect of research, public contributors were invited to comment first [86]. Some papers described the beginning of the involvement process [40,81]. In the study by Teng et al [81], during the first day of activities, presentations were made to provide some background on big data research for public contributors. These were from the perspective of patients and seldom-heard communities. These presentations were not neutral but opinionated to show diverse views on big data research.

Outcomes

Some included papers in the review claimed that involvement and engagement should have clear outcomes. First, it could identify gaps in knowledge and priorities for research [70]. Second, it could align researchers' and institutional perspectives of public interest with public views [44], for example, by bringing together charity workers, service providers, elected politicians, and members of the public [54,70]. Third, public contributors involved in governing bodies could have the effect of improving trust and accountability [84]. Fourth, improving public awareness of big data might democratize health research [62]. For example, Vayena and Blasimme [84] argued further that blending citizen science and participatory models could offer more democracy in governance.

However, measuring the impact of involvement and engagement in big data research was challenging [3,64,82,83]. A scoping review by Luna Puerta et al [64] recognized that there was no consensus about the objectives of public involvement in big data research, which undermines the ability to measure impact. Another review by Tindana et al [82] found that the papers included in their review on community engagement did not evaluate the effectiveness of engagement activities.

Engagement through genuine public debate could help demonstrate that the public sector could be a trustworthy steward of patient data [42]. This should include any negative comments toward the initiative; these should be publicly shared, and justification should be provided as to why their feedback was not implemented [42]. Dankar et al [47], when discussing biomedical databases, suggested that sharing research findings should include reaching individuals with personalized research results; these need to be valuable and benefit individuals (eg, they could go for health tests or make life changes that improve their health).

Discussion

Principal Findings

This scoping review provides an overview of how public involvement and engagement have been used in big data research or how it has been argued that it could be applied. This is the first review exploring this issue. The review has shown that the public can and, many articles argue, should be involved and engaged in big data research in terms of individual initiatives and data governance. However, the findings indicate that there is no one right way to involve and engage the public in big data research. Those responsible for working with the public should consider what type of activities are most relevant to their work and should use multiple approaches (involvement, engagement, and consultations) to reach different communities. Some papers suggested using modern technology when engaging the public (eg, through a website or digital newsletter). However, most included papers were not primary studies.

The review indicates that many believe that public involvement and engagement have the potential to improve public trust and accountability for big data initiatives. However, there is limited literature on how public involvement and engagement might influence it. Future research should attempt to measure the impact of involvement and engagement in securing social license for big data research with the broader public. The initial step to improve this situation could be to ensure reporting by using standardized reporting guidance for public involvement, such as GRIPP2 [88].

References to public involvement and engagement guidance or legal documents in the included papers were limited. The consensus statement on public involvement and engagement with data-intensive health research [1] is relatively new. However, INVOLVE (now incorporated into the NIHR) has been active in the United Kingdom since 1996. This indicates that many included papers replicate similar discussions around principles involving and engaging the public rather than referring to already established standards. However, more big data–specific guidance is being developed by the Public Engagement in Data Research Initiative in the United Kingdom [89].

The findings of this review indicate that some challenges are particularly relevant for involvement and engagement in big data research. However, the review has also shown that public involvement and engagement in big data research are not dissimilar to other research fields, as they share aspects of involving and engaging the public, such as working with seldom-heard communities and addressing power balance. This suggests that big data researchers could also use generic public involvement resources, such as the National Standards for Public Involvement in the United Kingdom [90].

The main challenge is that big data research is a complex topic. It might not be easy to explain it briefly (or in accessible language) to potential public contributors or the public. The papers offered some suggestions on how these barriers could be overcome. Researchers need to ensure that they allocate sufficient time and resources when discussing big data research with members of the public. This finding aligns with another review that examined patient involvement in cancer research, where the authors identified time-consuming involvement as a primary challenge in that context [91]. This review suggests that involving and engaging the public in big data research might be even more time consuming than in other fields. If these challenges are overcome, there is a higher chance that involvement and engagement in big data research is not tokenistic, but this might mean additional time and financial resources. Researchers should budget for these resources as they design any involvement or engagement activities. However, they should be supported to do it by research institutions and funders.

Bailey et al [92] reported that Black and South Asian communities in the United Kingdom have less trust in the health system, and because of this, there might be concerns within these groups about how the public bodies use their data. Researchers need to recognize how trust and attitudes toward big data research could influence public involvement and engagement. This review has offered some indication of how to achieve this from the literature that explored working with Indigenous communities, such as recognizing communities' beliefs and way of life.

The protocol that this review was based on presented the priori system logic model for public involvement and engagement in big data research [27]. On the basis of the review findings, the model was revised. Within the context section, Indigenous standards were added to recognize that big data research needs to consider the perspective and views of Indigenous communities that might differ from previous dominant perspectives. In the intervention theory section, the execution of involvement activities could be divided into project-specific aspects (eg, focusing on 1 big data research project) and governance bodies that look into granting approvals into data linkage (for other projects). These 2 purposes might influence how researchers involve and engage the public. In intervention delivery, the bullet point around public-led activities was added, as some papers suggested that it was important to ensure that the public voice is equivalent to professionals' views during voting and should have equal or even more influence (eg, by cochairing meetings or being coinvestigators). Furthermore, a new bullet point was added in intervention delivery to recognize big data–specific barriers, especially jargon, and how complex big data research could be to members of the public.

Most of the elements included in the model were discussed in the included papers. The only exception is that it does not reflect on the involvement and engagement of people who are not personally affected by big data research (or do not perceive themselves as such). The coverage of most of the issues raised in the papers for involvement and engagement in big data research suggests that the logic model could support researchers who intend to design and deliver these activities to the public.

Textbox 1 provides a summary of the key recommendations around public involvement and engagement in big data research based on the review findings.

Textbox 1. Key recommendations around public involvement and engagement in big data research.

- Ensure that complex and abstract language is explained in lay terms and is understandable to members of the public.
- As public involvement and engagement in big data research might require additional time and resources, these should be planned and budgeted in research plans.
- Trust and public attitudes could influence how and if members of the public get involved in big data research. Public involvement and engagement activities targeting seldom-heard communities should recognize the cultural beliefs held by these groups.
- Following big data research standards could provide researchers with more specific guidance for working with members of the public. These should be used alongside already existing generic guidance.
- Capture and evaluate the impact of public involvement and engagement activities in big data research.

Limitations

The first limitation is the use of terminology. The review explored public involvement and engagement in big data research. These terms are used in different ways by researchers. This parallels the experience of Brett et al [93] in their review, where they found that the variability in wording used to describe involvement complicated literature searching. The search strategy was developed with an experienced librarian and included additional manual searches. However, this did not guarantee that all relevant papers were included. This could have influenced the search results, as potentially some relevant papers might not have been picked up by the search as the authors used different terms. The second limitation was that only information included in the papers was extracted. The authors of included papers were not approached for more details. As academic papers have a word limit, it is possible that some additional information about involvement and engagement may have not been included in the published paper. In contrast to the initial plan, the references of included papers were not screened for potential inclusion. This was because screening of references of included papers in the scoping review was considered impractical because of the high number of papers. Moreover, only papers published in English were included. Finally, owing to the number of papers identified through the searches, only a random sample of 20% was screened by all coauthors.

Conclusions

This review offers a snapshot of evidence on what public involvement and engagement in big data research could look like. It is limited, as it was largely based on discussion papers, but useful, as evidence on how these involvement and engagement activities could be delivered and what type of outcomes they could produce was provided. The field would benefit from further research and evaluation of involvement and engagement activities in big data through primary research. Owing to the ongoing development of big data research, it is likely that these would need to be updated on a regular basis, but nevertheless, such research could provide further insights into how to meaningfully involve and engage the public in big data research.

Acknowledgments

PT was a PhD student supported by the National Institute for Health and Care Research (NIHR) Applied Research Collaboration North West Coast (ARC NWC) and based at the University of Liverpool. SER is partly funded by the NIHR ARC NWC. This report is an independent research study funded by the ARC NWC. The views expressed in this publication are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care. The authors would like to thank Dr Kate Fleming for assisting at the data extraction stage.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist.
[DOCX File , 27 KB - jopm_v16i1e56673_app1.docx]

Multimedia Appendix 2
Search strategy as published in the protocol paper.
[DOCX File , 20 KB - jopm_v16i1e56673_app2.docx]

Multimedia Appendix 3
Data extraction form.
[DOCX File , 23 KB - jopm_v16i1e56673_app3.docx]

References

1. Aitken M, Tully M, Porteous C, Denegri S, Cunningham-Burley S, Banner N, et al. Consensus statement on public involvement and engagement with data intensive health research. Int J Popul Data Sci 2019 Mar 12;4(1):586-512 [FREE Full text] [doi: 10.23889/ijpds.v4i1.586] [Medline: 34095528]
2. Mehta N, Pandit A. Concurrence of big data analytics and healthcare: a systematic review. Int J Med Inform 2018 Jun;114:57-65. [doi: 10.1016/j.ijmedinf.2018.03.013] [Medline: 29673604]
3. Newburn M, Scanlon M, Plachcinski R, Jill Macfarlane A. Involving service users in the Birth Timing project, a data linkage study analysing the timing of births and their outcomes. Int J Popul Data Sci 2020 Nov 02;5(3):1366 [FREE Full text] [doi: 10.23889/ijpds.v5i3.1366] [Medline: 34007886]
4. Aitken M, Porteous C, Creamer E, Cunningham-Burley S. Who benefits and how? Public expectations of public benefits from data-intensive health research. Big Data Soc 2018 Dec 06;5(2):205395171881672. [doi: 10.1177/2053951718816724]

5. Raghupathi W, Raghupathi V. Big data analytics in healthcare: promise and potential. Health Inf Sci Syst 2014;2:3 [FREE Full text] [doi: 10.1186/2047-2501-2-3] [Medline: 25825667]
6. Zhang X, Pérez-Stable EJ, Bourne PE, Peprah E, Duru OK, Breen N, et al. Big data science: opportunities and challenges to address minority health and health disparities in the 21st century. Ethn Dis 2017;27(2):95-106 [FREE Full text] [doi: 10.18865/ed.27.2.95] [Medline: 28439179]
7. Lipworth W, Mason PH, Kerridge I, Ioannidis JP. Ethics and epistemology in big data research. J Bioeth Inq 2017 Dec 20;14(4):489-500. [doi: 10.1007/s11673-017-9771-3] [Medline: 28321561]
8. Taylor M. information governance as a force for good? Lessons to be learnt from Care.data. SCRIPTed 2014 Apr;11(1):1-10. [doi: 10.2966/scrip.110114.1]
9. Carter P, Laurie GT, Dixon-Woods M. The social licence for research: why care.data ran into trouble. J Med Ethics 2015 May;41(5):404-409 [FREE Full text] [doi: 10.1136/medethics-2014-102374] [Medline: 25617016]
10. Spencer K, Sanders C, Whitley EA, Lund D, Kaye J, Dixon WG. Patient perspectives on sharing anonymized personal health data using a digital system for dynamic consent and research feedback: a qualitative study. J Med Internet Res 2016 Apr 15;18(4):e66 [FREE Full text] [doi: 10.2196/jmir.5011] [Medline: 27083521]
11. Shaw JA, Sethi N, Cassel CK. Social license for the use of big data in the COVID-19 era. NPJ Digit Med 2020 Oct 02;3(1):128 [FREE Full text] [doi: 10.1038/s41746-020-00342-y] [Medline: 33083563]
12. Ford E, Boyd A, Bowles JK, Havard A, Aldridge RW, Curcin V, et al. Our data, our society, our health: a vision for inclusive and transparent health data science in the United Kingdom and beyond. Learn Health Syst 2019 Jul 25;3(3):e10191 [FREE Full text] [doi: 10.1002/lrh2.10191] [Medline: 31317072]
13. Manafo E, Petermann L, Mason-Lai P, Vandall-Walker V. Patient engagement in Canada: a scoping review of the 'how' and 'what' of patient engagement in health research. Health Res Policy Syst 2018 Feb 07;16(1):5 [FREE Full text] [doi: 10.1186/s12961-018-0282-4] [Medline: 29415734]
14. Muller SH, Kalkman S, van Thiel GJ, Mostert M, van Delden JJ. The social licence for data-intensive health research: towards co-creation, public value and trust. BMC Med Ethics 2021 Aug 10;22(1):110 [FREE Full text] [doi: 10.1186/s12910-021-00677-5] [Medline: 34376204]
15. Dixon-Woods M, Ashcroft RE. Regulation and the social licence for medical research. Med Health Care Philos 2008 Dec 17;11(4):381-391. [doi: 10.1007/s11019-008-9152-0] [Medline: 18633729]
16. Jones KH, Heys S, Thompson R, Cross L, Ford D. Public involvement and engagement in the work of a data safe haven: a case study of the SAIL databank. Int J Popul Data Sci 2020 Aug 24;5(3):1371 [FREE Full text] [doi: 10.23889/ijpds.v5i3.1371] [Medline: 33644414]
17. Jones KH, Ford DV, Thompson S, Lyons RA. A profile of the SAIL databank on the UK secure research platform. Int J Popul Data Sci 2019 Nov 20;4(2):1134 [FREE Full text] [doi: 10.23889/ijpds.v4i2.1134] [Medline: 34095541]
18. Jones KH, McNerney CL, Ford DV. Involving consumers in the work of a data linkage research unit. Int J Consumer Studies 2013 Oct 07;38(1):45-51 [FREE Full text] [doi: 10.1111/ijcs.12062]
19. Aitken M, de St Jorre J, Pagliari C, Jepson R, Cunningham-Burley S. Public responses to the sharing and linkage of health data for research purposes: a systematic review and thematic synthesis of qualitative studies. BMC Med Ethics 2016 Nov 10;17(1):73 [FREE Full text] [doi: 10.1186/s12910-016-0153-x] [Medline: 27832780]
20. Stockdale J, Cassell J, Ford E. “Giving something back”: a systematic review and ethical enquiry into public views on the use of patient data for research in the United Kingdom and the Republic of Ireland. Wellcome Open Res 2019 Jan 17;3:6. [doi: 10.12688/wellcomeopenres.13531.2]
21. Kalkman S, van Delden J, Banerjee A, Tyl B, Mostert M, van Thiel G. Patients' and public views and attitudes towards the sharing of health data for research: a narrative review of the empirical evidence. J Med Ethics 2019 Nov 12;48(1):3-13 [FREE Full text] [doi: 10.1136/medethics-2019-105651] [Medline: 31719155]
22. Howe N, Giles E, Newbury-Birch D, McColl E. Systematic review of participants' attitudes towards data sharing: a thematic synthesis. J Health Serv Res Policy 2018 Apr 13;23(2):123-133. [doi: 10.1177/1355819617751555] [Medline: 29653503]
23. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol 2005 Feb;8(1):19-32. [doi: 10.1080/1364557032000119616]
24. Colquhoun HL, Levac D, O'Brien KK, Straus S, Tricco AC, Perrier L, et al. Scoping reviews: time for clarity in definition, methods, and reporting. J Clin Epidemiol 2014 Dec;67(12):1291-1294. [doi: 10.1016/j.jclinepi.2014.03.013] [Medline: 25034198]
25. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. Implement Sci 2010;5:69 [FREE Full text] [doi: 10.1186/1748-5908-5-69] [Medline: 20854677]
26. Teodorowski P, Rodgers S, Fleming K, Tahir N, Ahmed S, Frith L. 'To me, it's ones and zeros, but in reality that one is death': a qualitative study exploring researchers' experience of involving and engaging seldom-heard communities in big data research. Health Expect 2023 Apr;26(2):882-891 [FREE Full text] [doi: 10.1111/hex.13713] [Medline: 36691930]
27. Teodorowski P, Jones E, Tahir N, Ahmed S, Frith L. Public involvement and engagement in big data research: protocol for a scoping review and a systematic review of delivery and effectiveness of strategies for involvement and engagement. BMJ Open 2021 Aug 19;11(8):e050167 [FREE Full text] [doi: 10.1136/bmjopen-2021-050167] [Medline: 34413107]

28. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. Ann Intern Med 2018 Oct 02;169(7):467-473. [doi: 10.7326/M18-0850] [Medline: 30178033]
29. Mockford C, Staniszewska S, Griffiths F, Herron-Marx S. The impact of patient and public involvement on UK NHS health care: a systematic review. Int J Qual Health Care 2012 Feb;24(1):28-38 [FREE Full text] [doi: 10.1093/intqhc/mzr066] [Medline: 22109631]
30. Islam S, Small N. An annotated and critical glossary of the terminology of inclusion in healthcare and health research. Res Involv Engagem 2020 Apr 20;6(1):14 [FREE Full text] [doi: 10.1186/s40900-020-00186-6] [Medline: 32337067]
31. Dawson S, Campbell SM, Giles SJ, Morris RL, Cheraghi-Sohi S. Black and minority ethnic group involvement in health and social care research: a systematic review. Health Expect 2018 Feb 15;21(1):3-22 [FREE Full text] [doi: 10.1111/hex.12597] [Medline: 28812330]
32. Harrison JD, Auerbach AD, Anderson W, Fagan M, Carnie M, Hanson C, et al. Patient stakeholder engagement in research: a narrative review to describe foundational principles and best practice activities. Health Expect 2019 Jun 13;22(3):307-316 [FREE Full text] [doi: 10.1111/hex.12873] [Medline: 30761699]
33. Lalani M, Baines R, Bryce M, Marshall M, Mead S, Barasi S, et al. Patient and public involvement in medical performance processes: a systematic review. Health Expect 2019 Apr;22(2):149-161 [FREE Full text] [doi: 10.1111/hex.12852] [Medline: 30548359]
34. Arnstein SR. A ladder of citizen participation. J Am Inst Plann 1969 Jul;35(4):216-224. [doi: 10.1080/01944366908977225]
35. What is public involvement in research? INVOLVE. 2020. URL: https://www.invo.org.uk/find-out-more/what-is-public-involvement-in-research-2/ [accessed 2024-09-21]
36. Boote J, Baird W, Sutton A. Public involvement in the systematic review process in health and social care: a narrative review of case examples. Health Policy 2011 Oct;102(2-3):105-116. [doi: 10.1016/j.healthpol.2011.05.002] [Medline: 21641075]
37. Boote J, Baird W, Sutton A. Involving the public in systematic reviews: a narrative review of organizational approaches and eight case examples. J Comp Eff Res 2012 Sep;1(5):409-420 [FREE Full text] [doi: 10.2217/cer.12.46] [Medline: 24236418]
38. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med 2009 Jul 21;6(7):e1000097 [FREE Full text] [doi: 10.1371/journal.pmed.1000097] [Medline: 19621072]
39. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Syst Rev 2015 Jan 01;4(1):1 [FREE Full text] [doi: 10.1186/2046-4053-4-1] [Medline: 25554246]
40. Baart IL, Abma TA. Patient participation in fundamental psychiatric genomics research: a Dutch case study. Health Expect 2011 Sep;14(3):240-249 [FREE Full text] [doi: 10.1111/j.1369-7625.2010.00634.x] [Medline: 20860783]
41. Ballantyne A, Style R. Health data research in New Zealand: updating the ethical governance framework. N Z Med J 2017 Oct 27;130(1464):64-71. [Medline: 29073658]
42. Ballantyne A, Stewart C. Big data and public-private partnerships in healthcare and research: the application of an ethics framework for big data in health and research. Asian Bioeth Rev 2019 Sep 30;11(3):315-326 [FREE Full text] [doi: 10.1007/s41649-019-00100-7] [Medline: 33717319]
43. Beyer KM, Comstock S, Seagren R. Disease maps as context for community mapping: a methodological approach for linking confidential health information with local geographical knowledge for community health research. J Community Health 2010 Dec;35(6):635-644. [doi: 10.1007/s10900-010-9254-5] [Medline: 20352481]
44. Bharti N, O'Donovan C, Smallman M, Wilson J. Public trust, deliberative engagement and health data projects: beyond legal provisions. Engag Sci Technol Soc 2021 Oct 05;7(1):125-133. [doi: 10.17351/ests2021.1197]
45. Bot BM, Wilbanks JT, Mangravite LM. Assessing the consequences of decentralizing biomedical research. Big Data Soc 2019 Jun 11;6(1):205395171985385. [doi: 10.1177/2053951719853858]
46. Coulter A. Patient trust in plans to share primary care data. BMJ 2021 Jun 04;373:n1413. [doi: 10.1136/bmj.n1413] [Medline: 34088678]
47. Dankar FK, Ptitsyn A, Dankar SK. The development of large-scale de-identified biomedical databases in the age of genomics-principles and challenges. Hum Genomics 2018 Dec 10;12(1):19 [FREE Full text] [doi: 10.1186/s40246-018-0147-5] [Medline: 29636096]
48. de Freitas C, Amorim M, Machado H, Leão Teles E, Baptista MJ, Renedo A, et al. Public and patient involvement in health data governance (DATAGov): protocol of a people-centred, mixed-methods study on data use and sharing for rare diseases care and research. BMJ Open 2021 Mar 15;11(3):e044289 [FREE Full text] [doi: 10.1136/bmjopen-2020-044289] [Medline: 33722870]
49. Deverka PA, Gilmore D, Richmond J, Smith Z, Mangrum R, Koenig BA, et al. Hopeful and concerned: public input on building a trustworthy medical information commons. J Law Med Ethics 2019 Mar 01;47(1):70-87 [FREE Full text] [doi: 10.1177/1073110519840486] [Medline: 30994071]

50. Duchange N, Darquy S, d'Audiffret D, Callies I, Lapointe AS, Loeve B, et al. Ethical management in the constitution of a European database for leukodystrophies rare diseases. Eur J Paediatr Neurol 2014 Sep;18(5):597-603 [FREE Full text] [doi: 10.1016/j.ejpn.2014.04.002] [Medline: 24786336]
51. Erikainen S, Friesen P, Rand L, Jongsma K, Dunn M, Sorbie A, et al. Public involvement in the governance of population-level biomedical research: unresolved questions and future directions. J Med Ethics 2020 Oct 06;47:522-525 [FREE Full text] [doi: 10.1136/medethics-2020-106530] [Medline: 33023977]
52. Evans EA, Delorme E, Cyr K, Goldstein DM. A qualitative study of big data and the opioid epidemic: recommendations for data governance. BMC Med Ethics 2020 Oct 21;21(1):101 [FREE Full text] [doi: 10.1186/s12910-020-00544-9] [Medline: 33087123]
53. Fernando B, King M, Sumathipala A. Advancing good governance in data sharing and biobanking - international aspects. Wellcome Open Res 2019 Nov 22;4:184 [FREE Full text] [doi: 10.12688/wellcomeopenres.15540.1] [Medline: 31950088]
54. Fleurence RL, Beal AC, Sheridan SE, Johnson LB, Selby JV. Patient-powered research networks aim to improve patient care and health research. Health Aff (Millwood) 2014 Jul;33(7):1212-1219. [doi: 10.1377/hlthaff.2014.0113] [Medline: 25006148]
55. Funnell S, Tanuseputro P, Letendre A, Bearskin LB, Walker J. "Nothing about us, without us." How community-based participatory research methods were adapted in an indigenous end-of-life study using previously collected data. Can J Aging 2020 Jun 20;39(2):145-155. [doi: 10.1017/S0714980819000291] [Medline: 31746723]
56. Gallier S, Price G, Pandya H, McCarmack G, James C, Ruane B, et al. Infrastructure and operating processes of PIONEER, the HDR-UK data hub in acute care and the workings of the data trust committee: a protocol paper. BMJ Health Care Inform 2021 Apr 13;28(1):e100294 [FREE Full text] [doi: 10.1136/bmjhci-2020-100294] [Medline: 33849921]
57. Goytia CN, Kastenbaum I, Shelley D, Horowitz CR, Kaushal R. A tale of 2 constituencies: exploring patient and clinician perspectives in the age of big data. Med Care 2018 Oct;56 Suppl 10 Suppl 1(10 Suppl 1):S64-S69 [FREE Full text] [doi: 10.1097/MLR.0000000000000786] [Medline: 30074954]
58. Henare KL, Parker KE, Wihongi H, Blenkiron C, Jansen R, Reid P, et al. Mapping a route to indigenous engagement in cancer genomic research. Lancet Oncol 2019 Jun;20(6):e327-e335. [doi: 10.1016/S1470-2045(19)30307-9] [Medline: 31162106]
59. Hudson M, Garrison NA, Sterling R, Caron NR, Fox K, Yracheta J, et al. Rights, interests and expectations: indigenous perspectives on unrestricted access to genomic data. Nat Rev Genet 2020 Jun 06;21(6):377-384. [doi: 10.1038/s41576-020-0228-x] [Medline: 32251390]
60. Hurt L, Ashfield-Watt P, Townson J, Heslop L, Copeland L, Atkinson MD, et al. Cohort profile: HealthWise Wales. a research register and population health data platform with linkage to national health service data sets in Wales. BMJ Open 2019 Dec 02;9(12):e031705 [FREE Full text] [doi: 10.1136/bmjopen-2019-031705] [Medline: 31796481]
61. Jewell A, Pritchard M, Barrett K, Green P, Markham S, McKenzie S, et al. The Maudsley Biomedical Research Centre (BRC) data linkage service user and carer advisory group: creating and sustaining a successful patient and public involvement group to guide research in a complex area. Res Involv Engagem 2019;5:20 [FREE Full text] [doi: 10.1186/s40900-019-0152-4] [Medline: 31205751]
62. Kalkman S, Mostert M, Gerlinger C, van Delden JJ, van Thiel GJ. Responsible data sharing in international health research: a systematic review of principles and norms. BMC Med Ethics 2019 Mar 28;20(1):21 [FREE Full text] [doi: 10.1186/s12910-019-0359-9] [Medline: 30922290]
63. Kirkham EJ, Crompton CJ, Iveson MH, Beange I, McIntosh AM, Fletcher-Watson S. Co-development of a best practice checklist for mental health data science: a Delphi study. Front Psychiatry 2021 Jun 10;12:643914 [FREE Full text] [doi: 10.3389/fpsyt.2021.643914] [Medline: 34177644]
64. Luna Puerta L, Kendall W, Davies B, Day S, Ward H. The reported impact of public involvement in biobanks: a scoping review. Health Expect 2020 Aug 06;23(4):759-788 [FREE Full text] [doi: 10.1111/hex.13067] [Medline: 32378306]
65. Manrique de Lara A, Peláez-Ballestas I. Big data and data processing in rheumatology: bioethical perspectives. Clin Rheumatol 2020 Apr;39(4):1007-1014. [doi: 10.1007/s10067-020-04969-w] [Medline: 32062767]
66. Milne R, Sorbie A, Dixon-Woods M. What can data trusts for health research learn from participatory governance in biobanks? J Med Ethics 2022 May 19;48(5):323-328 [FREE Full text] [doi: 10.1136/medethics-2020-107020] [Medline: 33741681]
67. Milne R, Brayne C. We need to think about data governance for dementia research in a digital era. Alzheimers Res Ther 2020 Jan 31;12(1):17 [FREE Full text] [doi: 10.1186/s13195-020-0584-y] [Medline: 32005135]
68. Mourby MJ, Doidge J, Jones KH, Aidinlis S, Smith H, Bell J, et al. Health data linkage for UK public interest research: key obstacles and solutions. Int J Popul Data Sci 2019 Apr 02;4(1):1093 [FREE Full text] [doi: 10.23889/ijpds.v4i1.1093] [Medline: 32935027]
69. Murtagh MJ, Blell MT, Butters OW, Cowley L, Dove ES, Goodman A, et al. Better governance, better access: practising responsible data sharing in the METADAC governance infrastructure. Hum Genomics 2018 Apr 26;12(1):24 [FREE Full text] [doi: 10.1186/s40246-018-0154-6] [Medline: 29695297]

70. Nelson E, Burns F. Impact through engagement: co-production of administrative data research and the approach of the administrative data research centre Northern Ireland. Int J Popul Data Sci 2020 Nov 10;5(3):1369 [FREE Full text] [doi: 10.23889/ijpds.v5i3.1369] [Medline: 34007887]
71. Nunn JS, Gwynne K, Gray S, Lacaze P. Involving people affected by a rare condition in shaping future genomic research. Res Involv Engagem 2021 Mar 15;7(1):14 [FREE Full text] [doi: 10.1186/s40900-021-00256-3] [Medline: 33722276]
72. O'Doherty KC, Burgess MM, Edwards K, Gallagher RP, Hawkins AK, Kaye J, et al. From consent to institutions: designing adaptive governance for genomic biobanks. Soc Sci Med 2011 Aug;73(3):367-374. [doi: 10.1016/j.socscimed.2011.05.046] [Medline: 21726926]
73. O'Doherty KC, Shabani M, Dove ES, Bentzen HB, Borry P, Burgess MM, et al. Toward better governance of human genomic data. Nat Genet 2021 Jan 07;53(1):2-8 [FREE Full text] [doi: 10.1038/s41588-020-00742-6] [Medline: 33414545]
74. Ohno-Machado L, Agha Z, Bell DS, Dahm L, Day ME, Doctor JN, et al. pSCANNER: patient-centered scalable national network for effectiveness research. J Am Med Inform Assoc 2014 Jul 01;21(4):621-626 [FREE Full text] [doi: 10.1136/amiajnl-2014-002751] [Medline: 24780722]
75. Omar MI, Roobol MJ, Ribal MJ, Abbott T, Agapow PM, Araujo S, et al. Introducing PIONEER: a project to harness big data in prostate cancer research. Nat Rev Urol 2020 Jun;17(6):351-362. [doi: 10.1038/s41585-020-0324-x] [Medline: 32461687]
76. Paprica PA, Sutherland E, Smith A, Brudno M, Cartagena RG, Crichlow M, et al. Essential requirements for establishing and operating data trusts: practical guidance co-developed by representatives from fifteen canadian organizations and initiatives. Int J Popul Data Sci 2020 Aug 24;5(1):1353 [FREE Full text] [doi: 10.23889/ijpds.v5i1.1353] [Medline: 33644412]
77. Patel R, Irving J, Brinn A, Broadbent M, Shetty H, Pritchard M, et al. Impact of the COVID-19 pandemic on remote mental healthcare and prescribing in psychiatry: an electronic health record study. BMJ Open 2021 Mar 30;11(3):e046365-e046363 [FREE Full text] [doi: 10.1136/bmjopen-2020-046365] [Medline: 33785494]
78. Pavlenko E, Strech D, Langhof H. Implementation of data access and use procedures in clinical data warehouses. A systematic review of literature and publicly available policies. BMC Med Inform Decis Mak 2020 Jul 11;20(1):157 [FREE Full text] [doi: 10.1186/s12911-020-01177-z] [Medline: 32652989]
79. Rowe R, Carroll SR, Healy C, Rodriguez-Lonebear D, Walker JD. The SEEDS of indigenous population health data linkage. Int J Popul Data Sci 2021 Jun 22;6(1):1417 [FREE Full text] [doi: 10.23889/ijpds.v6i1.1417] [Medline: 34212119]
80. Sleigh J, Vayena E. Public engagement with health data governance: the role of visuality. Humanit Soc Sci Commun 2021 Jun 18;8(1):149. [doi: 10.1057/S41599-021-00826-6]
81. Teng J, Bentley C, Burgess MM, O'Doherty KC, McGrail KM. Sharing linked data sets for research: results from a deliberative public engagement event in British Columbia, Canada. Int J Popul Data Sci 2019 May 07;4(1):1103 [FREE Full text] [doi: 10.23889/ijpds.v4i1.1103] [Medline: 34095532]
82. Tindana P, de Vries J, Campbell M, Littler K, Seeley J, Marshall P, et al. Community engagement strategies for genomic studies in Africa: a review of the literature. BMC Med Ethics 2015 Apr 12;16:24 [FREE Full text] [doi: 10.1186/s12910-015-0014-z] [Medline: 25889051]
83. Townson J, Davies J, Hurt L, Ashfield-Watt P, Paranjothy S. Developing and evaluating a model of public involvement and engagement embedded in a national longitudinal study: HealthWise Wales. Int J Popul Data Sci 2020 Apr 16;5(3):1356 [FREE Full text] [doi: 10.23889/ijpds.v5i3.1356] [Medline: 34007884]
84. Vayena E, Blasimme A. Biomedical big data: new models of control over access, use and governance. J Bioeth Inq 2017 Dec 5;14(4):501-513 [FREE Full text] [doi: 10.1007/s11673-017-9809-6] [Medline: 28983835]
85. Weich S, Duncan C, Bhui K, Canaway A, Crepaz-Keay D, Keown P, et al. Evaluating the effects of community treatment orders (CTOs) in England using the Mental Health Services Dataset (MHSDS): protocol for a national, population-based study. BMJ Open 2018 Oct 18;8(10):e024193 [FREE Full text] [doi: 10.1136/bmjopen-2018-024193] [Medline: 30341141]
86. Willison DJ, Trowbridge J, Greiver M, Keshavjee K, Mumford D, Sullivan F. Participatory governance over research in an academic research network: the case of Diabetes Action Canada. BMJ Open 2019 Apr 20;9(4):e026828 [FREE Full text] [doi: 10.1136/bmjopen-2018-026828] [Medline: 31005936]
87. Xafis V, Labude MK. Openness in big data and data repositories: the application of an ethics framework for big data in health and research. Asian Bioeth Rev 2019 Sep 01;11(3):255-273 [FREE Full text] [doi: 10.1007/s41649-019-00097-z] [Medline: 33717315]
88. Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. BMJ 2017 Aug 02;358:j3453 [FREE Full text] [doi: 10.1136/bmj.j3453] [Medline: 28768629]
89. PEDRI: public involvement and engagement best practice draft standards for the use of data for research and statistics. ADR UK & Economic and Social Research Council. 2023. URL: https://www.adruk.org/fileadmin/uploads/adruk/Documents/PE_reports_and_documents/PEDRI-Best-Practice-Standards.pdf [accessed 2024-04-10]
90. NIHR. National Standards for Public InvolvementNIHR announces new standards for public involvement in research. National Institutes for Health and Care Research (NIHR). 2019. URL: https://www.nihr.ac.uk/news/nihr-announces-new-standards-for-public-involvement-in-research/23830 [accessed 2024-04-29]

91. Pii KH, Schou LH, Piil K, Jarden M. Current trends in patient and public involvement in cancer research: a systematic review. Health Expect 2019 Mar;22(1):3-20 [FREE Full text] [doi: 10.1111/hex.12841] [Medline: 30378234]
92. Bailey WB, Twins B, Wilkinson-Salamea C, Raidos D, Imafidon K, McGarry N. A participatory research project: exploring the views and experiences of black and South Asian communities in the UK on patient data and its uses. ClearView Research. 2021. URL: https://understandingpatientdata.org.uk/sites/default/files/2022-04/Diverse%20voices%20on%20Data%20-%20Main%20report_0.pdf [accessed 2024-04-29]
93. Brett J, Staniszewska S, Mockford C, Herron-Marx S, Hughes J, Tysall C, et al. Mapping the impact of patient and public involvement on health and social care research: a systematic review. Health Expect 2014 Oct;17(5):637-650. [doi: 10.1111/j.1369-7625.2012.00795.x] [Medline: 22809132]

Abbreviations

GRIPP2: Guidance for Reporting Involvement of Patients and the Public
NIHR: National Institute for Health and Care Research
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

Edited by M Hudson, S Woods; submitted 23.01.24; peer-reviewed by N Natafgi, A Paprica, M McCoy; comments to author 24.03.24; revised version received 06.05.24; accepted 22.06.24; published 16.08.24.

Please cite as:
Teodorowski P, Jones E, Tahir N, Ahmed S, Rodgers SE, Frith L
Public Involvement and Engagement in Big Data Research: Scoping Review
J Particip Med 2024;16:e56673
URL: https://jopm.jmir.org/2024/1/e56673
doi:10.2196/56673
PMID:

Viewpoint

From English to “Englishes”: A Process Perspective on Enhancing the Linguistic Responsiveness of Culturally Tailored Cancer Prevention Interventions

Alexis Davis[1], MA; Joshua Martin[1], PhD; Eric Cooks[1], PhD; Melissa Vilaro[2], PhD; Danyell Wilson-Howard[3], PhD; Kevin Tang[1,4], PhD; Janice Raup Krieger[5], PhD

[1]University of Florida, Gainesville, FL, United States

[2]Department of Family, Youth and Community Sciences, Institute of Food and Agricultural Sciences, College of Agricultural and Life Sciences, University of Florida, Gainesville, FL, United States

[3]Bethune Cookman University, Daytona Beach, FL, United States

[4]Department of English Language and Linguistics, Institute of English and American Studies, Faculty of Arts and Humanities, Heinrich Heine University Düsseldorf, Düsseldorf, Germany

[5]Mayo Clinic, Jacksonville, FL, United States

Corresponding Author:
Janice Raup Krieger, PhD
Mayo Clinic
4500 San Pablo Road
Jacksonville, FL, 32224
United States
Phone: 1 614404681
Email: krieger.janice@mayo.edu

Abstract

Linguistic accommodation refers to the process of adjusting one’s language, speech, or communication style to match or adapt to that of others in a social interaction. It is known to be vital to effective health communication. Despite this evidence, there is little scientific guidance on how to design linguistically adapted health behavior interventions for diverse English-speaking populations. This study aims to document the strategies used to develop a culturally grounded cancer prevention intervention with the capabilities to linguistically accommodate to speakers of African American English (AAE). We describe the iterative process of developing a cancer prevention intervention with contributions of racially and linguistically diverse colleagues representing various community and institutional perspectives, including communication scientists, linguists, a community advisory board, professional voice talents, and institutional representatives for scientific integrity. We offer a detailed description of the successes and, in some cases, failures of strategies. Social stereotypes associated with AAE were prevalent at both institutional and community levels, resulting in unanticipated challenges and delays during intervention development. The diversity of linguistic, racial, and role identities within the message development team was integral to successfully addressing and identifying opportunities for process improvement. Language is a vital but often overlooked aspect of intervention development. Message designers should consider implicit social stereotypes that unintentionally shape linguistic choices. This study provides a novel overview of how various types of expertise and iterative message development processes contribute to successfully navigating cultural grounding when sensitive or stigmatized issues are salient.

(J Particip Med 2024;16:e57528) doi:10.2196/57528

KEYWORDS

behavior change; community-engaged research; cancer screening; colorectal cancers; communication; communication accommodation; linguistics

Introduction

Addressing cancer health inequities, particularly related to screening, is a key public health goal in the United States [1]. One such inequity is the low rates of colorectal cancer screening and the high rates of colorectal cancer mortality among African Americans in the United States [2,3]. There is widespread agreement that these efforts must be developed in partnership with the communities affected to ensure they are culturally grounded, meaning that the intervention honors and reflects salient social identities within a community [4]. Referred to as the principle of cultural grounding [5], this approach uses community engagement processes to codevelop messages that privilege how cultural identities are communicated [6].

Cancer screening messages are typically delivered using standardized forms of language, with English and Spanish being the most common in the United States. There are several reasons to question the appropriateness of defaulting to standardized forms of language in the cancer prevention context. First, the way language is used and spoken varies by region and cultural group [7]. Second, these variations indicate social group identities (or lack thereof) [8]. Third, group memberships serve as cues for status and credibility based on individual position as an ingroup or outgroup member [9]. Fourth, the ability to use language effectively positively influences health outcomes [10]. For example, African American physicians have been found to engage in “code-switching” when interacting with African American patients. This means they use a variety of English called African American English (AAE) to establish rapport and switch to Standard American English (SAE) for medical tasks such as history taking [11]. This example demonstrates that physicians naturally recognize the value of reflecting a shared social group identity through language for improving health outcomes.

The goal of this project is to explore the potential benefits and risks of reflecting these naturalistic communication accommodation patterns between African American physicians and patients in the digital intervention space. The project’s main goal was to develop an evidence-based colorectal cancer prevention intervention delivered in AAE by a virtual health care provider (VHCP) that would be perceived as culturally appropriate and authentic. This will enable future research to test whether having the option of VHCPs who can effectively use AAE could increase colorectal cancer screening among native speakers of this English language variety. To achieve this goal, the research team used the principle of cultural grounding to foster partnership and collaboration with diverse stakeholders. This manuscript describes challenges encountered while navigating perceptual biases associated with AAE and how those challenges were resolved. We hope this study serves as an impetus for wider conversation on the importance of language in developing culturally grounded behavioral interventions.

Literature Review

Communication Accommodation Theory

According to communication accommodation theory, humans navigate identity and solidarity with interlocutors through linguistic accommodation [12]. It highlights the ways in which people implicitly and explicitly identify themselves and others during social interactions by modifying various aspects of communication. A key attribute of this theory is that perceived similarity with others influences how people construct and interpret messages. If we feel connected to someone, we speak more like they do; if we feel disconnected, we dissociate our speech from theirs. This is especially true in patient–health care provider communication [13]. A communicative interaction is perceived as interpersonal if the messages exchanged are based on individual characteristics. Alternatively, it can also be experienced as intergroup, meaning that the choice of communication is influenced by salient social identities (eg, race, gender, age) rather than the unique characteristics of the individuals. Even when a patient and health care provider share salient social identities, power differentials based on social status can result in interactions being more intergroup than interpersonal in nature.[14]

When interactions are experienced as intergroup, identity negotiation becomes critically important to the success or failure of that interaction. Language plays an essential role in identity negotiation. Efforts to accommodate to a shared linguistic style—or become more linguistically similar to another person—improve communication effectiveness, understanding, and trust [15]. Both objective and perceived language similarities enhance perceptions of credibility, competence, and persuasiveness [16]. Clinicians and patients alike concur that health care providers should accommodate the linguistic style of patients, despite disagreeing about whether accommodation has occurred [17].

Perceived similarities play a crucial role in the evaluation of health care providers. Indeed, perceived dissimilarity is linked to biases, prejudices, and negative assessments of the person and their interactions [18]. However, accommodation can be challenging in interactions when a provider and patient have different racial identities and have differing levels of skill with AAE. In interactions where health care providers lack the skill to accommodate to AAE, patients may maintain or accentuate linguistic features associated with AAE for the purpose of intergroup differentiation [19]. Conversely, health care providers with the ability to speak both SAE and AAE have more flexibility to accommodate to the speech of diverse African American communities [13,20]. For the purposes of our work here, African American is defined as an individual who self-identifies as Black. Thus, both terms may be used to describe individuals in this study. Even though the use of SAE may be perceived as more common in a medical setting, a patient may find AAE more persuasive because it reflects a shared racial and linguistic identity [21-23].

Following this reasoning, we hypothesize that an African American health care provider using linguistic features drawn from AAE could be viewed as accommodating linguistic styles by African American patients whose own native dialect contains similar features. Indeed, previous research has shown that shared racial identity by visual appearance had a clear positive effect: When African American patients were paired with a virtual health care provider (VHCP) matching their racial identity, they reported higher intentions to be screened for colorectal cancer [24,25]. VHCPs are graphical representations of characters that display human-like behavior and can be effective sources of tailored health information. For interactions between humans and virtual agents, measuring the level of human communication accommodation can aid in understanding how effective virtual agents are at engaging patients in a satisfying and credible manner. VHCPs are a feasible way to experimentally examine how different communication elements influence patient outcomes. Thus, this project sought to examine whether adjusting linguistic features of the VHCP speech will have a positive, neutral, or negative effect.

Adapting the linguistic features of a cancer prevention message can be considered part of message tailoring. Tailored messages use a high level of individual customization, or accommodation, to increase relevance and are an evidence-based strategy for communicating complex health topics with the public [26]. Tailoring allows for the personalization of a message based on specific characteristics of the recipient. In doing so, the message and its content become more personally relevant and more likely to have a lasting impact on attitudes and behaviors [27]. Tailored messages have been found to specifically increase the persuasiveness of messages encouraging colorectal cancer screening, improve attitudes toward screening, and facilitate screening behaviors [28]. Tailored messaging as an intervention strategy is growing increasingly popular due to the combination of efficacy in promoting behavior change and the ability to be produced and disseminated cost-effectively using web-based applications [29].

African American English

Linguistic investigation into African American language use has increased over the last 60 years [30]. A central objective of this work is to dispel racist linguistic myths, explicate the systematic nature of the linguistic varieties of many African Americans, and dismantle the linguistic discrimination and institutional racism that has produced disparate harm for speakers in realms such as education, job procurement, and health care [31].

Researchers have identified specific pronunciations, sounds, and grammatical structures from the speech of various groups of African Americans across the United States and throughout various periods that do not appear in SAE. Together, these structures, along with other linguistic features, have traditionally been termed AAE [32]. These linguistic features are not inferior or flawed versions of SAE counterparts; they rather display the typical traits of all languages and linguistic varieties and play an important role in social interactions and identity building [33]. However, we note that AAE is not a delimiting set of structures that defines all African American speech. The speech of individual African Americans may or may not contain linguistic features of AAE alongside features of SAE and other language varieties.

The speech of individual African Americans is influenced not only by racialization but also by the intersections of various social identities, such as gender, age, education, sexuality, occupation, religion, ability status, socioeconomic class, and regional background [34]. All of these layers contribute to larger linguistic repertoires that vary by individual and may be consciously or subconsciously drawn upon as African American speakers engage in identification processes in various contexts and social situations [35].

Thus, African American speech is quite diverse. Nevertheless, African American linguists and scholars estimate that between 80% and 90% of African Americans retain and use a selection of the linguistic features of AAE at varying levels as they weave through the various interactions in their lives [36]. We find it plausible, therefore, that many of the African American participants in our research may use AAE linguistic features at some level and may find AAE linguistic accommodation provided by VHCP appealing.

Ensuring Linguistic Authenticity Using the Principle of Cultural Grounding

As stated, this project's goal was to develop an evidence-based colorectal cancer prevention intervention delivered by a VHCP that would be perceived as authentic and culturally responsive. We followed the principle of cultural grounding, which uses community-engaged processes through which communities and professionals can collaboratively ensure linguistic authenticity. We did so in 2 primary ways. First, we used a community advisory board (CAB), which brought members of the community together to provide guidance on issues such as research design and administration [37]. The CAB was comprised of 12 people from racially, ethnically, and geographically diverse communities within a largely rural area [38]. CAB members included individuals representing cancer survivors, the faith-based community, cancer prevention nonprofits, and local health care organizations. They were selected, in part, based on their ability to represent one of the priority populations of the project: individuals who identify as rural-dwelling and Black or African American. The collaboration between CAB and the research team helped to ensure the intervention was perceived as appropriate and reflected speech used in the community.

Second, we sought professional voice talent to join our research team. Given that the scripts would be tested in an experimental design, it was imperative that the different script variations be voiced by the same person. After an extensive search, the team hired 2 voice actors who were native speakers of AAE—1 man and 1 woman. The team discussed the project's goals with the voice talents, who were asked to read the same script three times, each with a different linguistic variation.

Workflow for Script Development

The idea for this project emerged when several investigators were working on a colorectal cancer prevention project for populations identifying as rural and Black or African American. To advance the dissemination of the intervention, the team began to consider how to use artificial intelligence (AI) to enable speech recognition. One of the principal investigators (PIs) was introduced to a linguist who explained that biases in AI make it difficult to respond to the natural speech of AAE speakers [39]. Given this limitation for a key population, the PI and linguist decided to jointly pursue this project to explore perceptions of linguistic accommodation in cancer prevention interventions among AAE speakers.

The script for the original intervention served as the base script for this project. When the original script was created using SAE, it was reviewed by multiple stakeholders, including CAB members, scientific advisory boards, grant reviewers, and physicians, without any mention of whether it would be appropriate to have linguistic variations of English represented. This points to the ubiquitous expectation of using SAE in cancer prevention interventions. Next, we describe the iterative process we used to create a new script for this project.

Script Adaptation

The first step for the team was to revise the base script linguistically. The goal was to create 3 scripts: in SAE, low-level African American English (L-AAE), and high-level African American English (H-AAE), with the following breakdown for inclusion of morphosyntactic (ie, grammatical) and phonological (ie, sound) features of AAE (Table 1). The process of adaptation began with the work of a linguist (linguist #1) who was an early career researcher and not a native AAE speaker. It was important that the script reflected AAE accurately without potentially causing offense through vocabulary or grammatical structure. To bolster the script's authenticity, linguist #1 referred to Green's *African American English* [33] and Rickford's *African American Vernacular English: Features, Evolution, Educational Implications* [36]. Both resources were written by African American linguists and detail the many aspects of AAE syntactic and phonological structures.

Linguist #1 began with the base SAE script that had been used in a pilot intervention the year before [24]. They used phonological features such as final consonant cluster reduction and "-ing" dropping, as well as morphosyntactic features like the absence of past tense "-s". These features were added according to the Dialect Density Measure (DDM), which quantifies the number of dialectal features of a speaker to determine "how much" of a dialect the individual speaks. Linguist #1 collected several DDMs: the lowest DDM (least number of dialectical features) came from sampling naturally occurring speech (interviews and focus group discussions with African Americans conducted for a previous project [40]); the other level (highest DDM) came from "Reactions to African American Vernacular English: Do More Phonological Features Matter?" [41]. These DDMs were used to determine how many dialectical features to include in variations of the script. They were particularly important because they provided accuracy in choosing features in the absence of insight from a native AAE speaker. Each feature added to the script was linked to a corresponding audio example contained within the Corpus of Regional African American Language (CORAAL) for further corroboration of the features' authenticity [42].

Table 1. Inclusion of 2 types of African American English linguistic features (morphosyntactic and phonological) in 3 script types (SAE, L-AAE, and H-AAE).

	SAE[a]	L-AAE[b]	H-AAE[c]
AAE[d] morphosyntactic features	No	No	Yes
AAE phonological features	No	Yes	Yes

[a] SAE: Standard American English.

[b] L-AAE: low-level African American English.

[c] H-AAE: high-level African American English.

[d] AAE: African American English.

Script Revision

After the 3 scripts were created, we provided the materials to an early career researcher, a linguist who spoke AAE natively (linguist #2 hereafter), and asked them to suggest changes and provide feedback for the L-AAE and H-AAE scripts. Linguist #2's main priority was to ensure that participants who would hear a script would be able to understand the information conveyed and feel accommodated by the language choices. Linguist #2 wrote a list of suggestions for the L-AAE and H-AAE scripts, as well as their own version of the H-AAE script, using linguist #1's script as reference (to compare the script crafted with research with one crafted with reliance on a native speaker's intuition). We provide an example of the differences between the scripts, with the underlined words and phrases indicating AAE features (Multimedia Appendix 1).

Script Recordings and Finalization

The team then held meetings with the voice actors to discuss the details of the initial recordings. Some rerecordings were made for scripts to address the accidental omission of AAE features on the part of the voice actors. These adjustments were necessary to ensure each version was distinct to avoid confounding the experimental study design. For example, if the voice actors were to use an abundance of H-AAE characteristics in the L-AAE reading, then the team would not be able to determine the effect of the randomized condition. During the rerecordings, some sentences or phrases were corrected for prosodic issues. However, the accuracy of phonological and morphosyntactic features of AAE was prioritized over suprasegmental features.

It was imperative that the voice actors understand the goals of the study, the team's aspiration for authenticity and accuracy, and the importance of feeling comfortable using "nonstandard" language. Attention was also paid to the possible reception of scripts tailored to African American populations, and several team discussions focused on preventing the potential for activating negative social stereotypes, such as "broken English," "uneducated," and "lower class."

Insights Gained

Insights From the Community Advisory Board

Before the script was finalized and the recordings created, the research team held a meeting with the CAB where several concerns, potential benefits, and recommendations were raised, as summarized below. First, the CAB agreed that health terminology in the script should not be changed or "dumbed down" (eg, the term "sugar" should not be used instead of "diabetes"). This concern may have been based on a perception of over-accommodation. That is, using nontechnical terminology could be perceived by African American users as reflecting negative social stereotypes (eg, unintelligent). This mirrors how people tend to use less complex grammatical structures, a more limited vocabulary, and more repetition, simplification, and elaboration when speaking to small children (child-directed speech), adults with limited cognitive or linguistic capacity (eg, elderspeak), and foreigners [43-45].

Second, the CAB expressed how African Americans are often judged by others (including other African Americans) for the way they speak, as either too Black or not Black enough [46]. This led to the question of whether patients would view the VHCP as less professional if it did not use SAE. The board emphasized the importance of authenticity in that the VHCP should sound like how a person would actually speak. If the voice sounded contrived or forced, this could be perceived negatively. Regarding potential benefits, the CAB agreed that linguistic variations might help some patients feel more comfortable in a medical interaction. They mentioned that patients can feel intimidated by health information and health professionals (including community health workers) and that changing linguistic style is, in fact, something community health workers already do to help patients feel more at ease [47]. Therefore, our proposed VHCP intervention is a novel way to improve health knowledge and literacy.

Overall, the CAB viewed the proposed idea as interesting. They made the following recommendations for the project. First, they noted that the study team would benefit by conducting additional research with African American patients to ensure that the developed scripts are authentic and demonstrate cultural sensitivity. Second, the CAB wanted to be involved at each stage of the intervention process. Specifically, they requested to review the recorded voices and the draft scripts to ensure cultural responsiveness. All board members indicated positively that the project could continue to move forward.

Insights From the Scientific Review Board

As part of the scientific review, an initial reviewer indicated concerns about whether AAE was appropriate for use in an intervention, necessitating 2 rounds of evaluation. Before and during the discussion with the research team, the board was concerned about the study's potential to be perceived as disrespectful of a cultural dialect or perpetuate stereotypes. Furthermore, the board expressed worry that the study has an underlying premise that all African Americans use or accept AAE.

Insights From the Linguistics Team

A key goal of this study was to engage the voices of a multidisciplinary and community-engaged research team in all aspects of the study design process. It was important that all team members approved the scripts produced for the intervention. Each team member was interviewed after the project and asked to share their thoughts on the process, their own roles, and any insights into the project.

Team Roles

Linguist #1's roles on the team extended beyond script creation. Originally, they were the point of contact for AAE research and the main creator of stimuli for the original project. That role evolved into becoming project manager, where they began organizing meetings between the researchers and voice actors, liaising with the institutional review board, working on the National Institutes of Health critical review, holding public presentations for the Clinical and Translational Science Institute and the CAB, and playing a role on the grant writing team.

Linguist #2, as the only AAE-speaking linguist on the team, felt pressure to be confident in his decisions during the script-making process and to be accountable for ensuring that the work remained accurate without being offensive. Linguist #2 was the sole AAE-speaking linguist, yet his research background consisted of an in-progress master's thesis. Thus, it was a struggle to juggle his linguistic expertise with his academic credentials.

Voice actor #1 felt prepared for their role. They had a background in the medical field as administrative support for different professionals and felt comfortable producing voice material for this project because of this previous experience. They enjoyed the ability to be frank about concerns that arose during the initial stages of working on the project. In addition, they believed that the further integration of their role into the team (not simply as a voice actor but being consulted by the linguists during the course of the script recordings and being able to follow along with study results) was professionally gratifying.

Initially, voice actor #2 had some questions about their role in the project and wanted to make sure those questions would be addressed by the team. They were curious to know "how Black" the team would want them to sound during the voice recordings. In previous works, they had been told to "sound Black" without being given further direction, and they had been left to figure out the level of AAE to use on their own. Voice actor #2 did not want the team to shy away from providing guidance on the language they would use. They appreciated that their role in the project did not remain solely as voice actors but that they were also kept up to date with the project regarding follow-ups and published results.

Opportunities and Challenges

In the uncharted territory of AAE script creation, the team faced several challenges. Voice actor #1 was initially apprehensive about speaking AAE for this project. This was not something they were used to doing, and they felt that "speaking Black" could come off as a caricature rather than as an authentic representation that would be well-received. They worked with the linguists on this concern to ensure that they could faithfully record the script and not feel uneasy.

The research team also held similar trepidations. Linguist #1, who is White, wanted to ensure that they did not offend the voice actors themselves while detailing the goals of the project and the script. They were aware that AAE could be a source of controversy, and they gave the voice actors many opportunities to share their concerns. In addition, they took suggestions from the voice actors during the script creation process. Throughout, linguist #1 acknowledged their status as a nonnative speaker of AAE. They would defer to the African American voice actors and linguist #2 (also African American) for final judgments.

Voice actor #2 was greatly appreciative of the level of communication during the project, especially regarding the voice recordings for the script. They felt comfortable with the team and appreciated the more casual atmosphere. They enjoyed the specificity of the acting direction provided, including many annotations, which enabled them to do their job well because their previous experiences had not always included such guidance.

Discussion

Perceptions of African American English

The use of developing digital health interventions using AAE use in health contexts is complicated. On the one hand, physicians naturally accommodate to AAE speakers in medical contexts, and linguistic accommodation is associated with a host of positive outcomes in health contexts (eg, increased credibility and social influence). On the other, AAE, like all language varieties, differs by region and other factors. Given the high variability within AAE, the goal is to increase perceived accommodation rather than perfect correspondence. The use of AAE is a social identity marker that is often associated with social stereotypes in the United States. These social stereotypes can make it a sensitive topic. For example, members of the CAB and the scientific review board were cautious about ensuring that the research project did not aggravate implicit bias in health care and thus harm the African American community [48]. Team composition was an important cue. These groups preferred hearing about the value of incorporating AAE in health contexts from members of the team who were native speakers of AAE.

Perceptions of Team Composition

Language is core to identity; thus, all discussions of language required careful negotiation of the identities of the participants. For example, we consider it likely that African American participants might see an African American VHCP using AAE to deliver colorectal cancer prevention messaging as more authentic and accommodating. For this reason, it was important to build a team that included an African American linguist and native AAE speaker for script development and African American voice actors for VHCP production.

Although considering source characteristics are an essential component of social influence, there were 2 instances in which the racial diversity of the study team was not effectively communicated. This, coupled with salient social stereotypes of the term “AAE,” led to concerns about the project among some stakeholders. The current project is led by a multiracial investigative team, with several investigators who self-identify as Black or African American. However, not all investigators were present at 2 key meetings, which had negative outcomes.

The first misstep was with our CAB. The study idea was presented at the first CAB meeting by linguist #1 (who is White). While CAB meetings are often good opportunities for early career researchers to learn skills regarding engaging with community members about science, the salience of perceptual biases associated with AAE made this study’s concept presentation particularly sensitive. CAB members were enthusiastic about developing an intervention customized to the Black residents of the community. They saw value in having the source be a Black VCHP; however, they initially expressed concerns that presenting health information using AAE could trigger implicit bias, specifically social stereotypes of AAE speakers as uneducated. The research team scheduled a second meeting to enable CAB members to listen to the proposed stimulus, which they determined sounded authentic to how some members of the community speak. While the term “AAE” was perceived as potentially concerning, the audible representation was perceived as authentic and appropriate.

The second instance in which team diversity was not appropriately represented was with the scientific review board, which had to approve the study. Two non-Black investigators presented the study at the initial meeting based on their expertise in linguistics and cancer screening. However, given the focus on AAE, the members of the scientific review board noted the lack of representation of Black or African American investigators. Without knowledge of the team’s true composition, the board had concerns about the propriety of non-Black scientists addressing the proposed research questions. A second meeting was scheduled when all members of the investigative team were available to share their perspectives on the importance of understanding how language concordance or discordance may alter cancer prevention outcomes for racial and ethnic minority populations. The team was also able to share the audio recordings of the stimulus, which assuaged concerns. The study was subsequently approved.

Research Challenges

One of the greater challenges during this project was conveying the meaning of “sounding Black” to members of the team, including the voice actors, the CAB, the institutional review board, and the scientific review committees. The team knew that there are certain linguistic features that listeners use to determine whether a speaker’s racial identity is African American. Despite conducting estimations of AAE density within scripts, we could not be certain what features would result in users perceiving the VHCP as an authentic AAE speaker. However, our rationale was based on the knowledge that African Americans routinely face discrimination in health care settings, and we wanted to explore if linguistic variation in VHCPs might benefit African American patient populations.

Conclusions and Key Lessons

People accommodate to the speech styles of others as a routine part of everyday life. This process of accommodation indicates liking and facilitates positive interactions. The extent to which AI-assisted interventions can and should reflect the accommodation patterns that characterize human-human interactions is currently unknown. Understanding the answers to these questions will be key to ensuring that cancer screening interventions can be delivered both ethically and efficiently in the future.

The goal of this study was to address one small piece of this larger puzzle by describing a process for designing a VHCP intervention that incorporated the ability to accommodate to the speech of users who speak AAE. While designing this intervention, key lessons were learned. An important lesson learned was the value of applied linguistics to the development and implementation of cancer prevention interventions. Language is core to cultural identity, and a specific focus on speech can ensure that efforts to engage in cultural grounding reflect both the verbal and nonverbal messages being conveyed to audience members. Another important lesson was that linguistic diversity can be a highly sensitive topic. As such, it was necessary that the linguistic diversity present within the research team be made apparent, and that all members of the research team be present when important concepts were being discussed. A third lesson came from including voice talent in the research team; this choice became a vital component of conveying the authenticity of the approach.

Future cancer screening interventions should consider linguistics as an important component of team science. For interventions with a focus on African American or Black populations, it may be helpful to ensure that there is linguistic diversity on the team. Engaging native speakers of AAE as well as experts in AAE is important, as both can provide valuable expertise on when and how to incorporate linguistic diversity. Finally, it will be important for future cancer screening interventions to explore the conditions under which accommodation to linguistic diversity improves or diminishes intervention efficacy.

Acknowledgments

This study would not have been possible without the support of the entire research team, the community advisory board, and the voice actors. We thank the audience at the 18th International Conference on Language and Social Psychology (ICLASP18:2024) and the colloquium (summer semester 2024) of the Institute of the History, Philosophy and Ethics of Medicine at Heinrich-Heine-University Düsseldorf for their feedback on earlier versions of the study. We thank Kyra Freestar and Joanna Serat for their copyediting service. Research reported in this publication was supported by the University of Florida Clinical and Translational Science Institute, which is supported in part by the NIH National Center for Advancing Translational Sciences under award number UL1 TR001427. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Authors' Contributions

KT and JRK contributed to conceptualization. AD performed data curation. KT and JRK performed formal analysis. KT and JRK handled funding acquisition. KT, AD, and JRK conducted the investigation. KT, AD, and JRK contributed to the methodology. AD contributed to project administration. KT and JRK handled the resources. KT, JRK, and AD performed supervision. KT, AD, and JRK contributed to writing (original draft). KT, AD, JRK, MV, DW-H, EC, and JM contributed to writing (review and editing).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Script samples from linguist 1 and linguist 2.
[PDF File (Adobe PDF File), 101 KB - jopm_v16i1e57528_app1.pdf]

References

1. Zavala VA, Bracci PM, Carethers JM, Carvajal-Carmona L, Coggins NB, Cruz-Correa MR, et al. Cancer health disparities in racial/ethnic minorities in the United States. Br J Cancer 2021;124(2):315-332 [FREE Full text] [doi: 10.1038/s41416-020-01038-6] [Medline: 32901135]
2. DeSantis CE, Miller KD, Goding Sauer A, Jemal A, Siegel RL. Cancer statistics for African Americans. CA Cancer J Clin 2019;69(3):211-233. [doi: 10.3322/caac.21555] [Medline: 30762872]
3. Lawrence WR, McGee-Avila JK, Vo JB, Luo Q, Chen Y, Inoue-Choi M, et al. Trends in cancer mortality among black individuals in the US from 1999 to 2019. JAMA Oncol 2022;8(8):1184-1189 [FREE Full text] [doi: 10.1001/jamaoncol.2022.1472] [Medline: 35587341]
4. Hecht ML, Krieger JLR. The principle of cultural grounding in school-based substance abuse prevention. J Lang Soc Psychol 2006;25(3):301-319. [doi: 10.1177/0261927x06289476]
5. Gordon EJ, Uriarte JJ, Anderson N, Smith JD, Caicedo JC, Shumate M. Sustainment of a complex culturally competent care intervention for hispanic living donor kidney transplantation: a longitudinal analysis of adaptations. J Clin Transl Sci 2022;6(1):e38 [FREE Full text] [doi: 10.1017/cts.2022.378] [Medline: 35574156]
6. Palmer-Wackerly AL, Krok JL, Dailey PM, Kight L, Krieger JL. Community engagement as a process and an outcome of developing culturally grounded health communication interventions: an example from the DECIDE project. Am J Community Psychol 2014;53(3-4):261-274 [FREE Full text] [doi: 10.1007/s10464-013-9615-1] [Medline: 24567052]

7. Dickerson D, Baldwin JA, Belcourt A, Belone L, Gittelsohn J, Keawe'aimoku Kaholokula J, et al. Encompassing cultural contexts within scientific research methodologies in the development of health promotion interventions. Prev Sci 2020;21(Suppl 1):33-42 [FREE Full text] [doi: 10.1007/s11121-018-0926-1] [Medline: 29959716]
8. Dixon L, Li J, Sorensen J, Thain N, Vasserman L. Measuring and mitigating unintended bias in text classification. 2018 Presented at: In: Proceedings of the 2018 AAAI/ACM Conference on AI, Ethics, and Society; 2018 December 27; New York p. 67-73. [doi: 10.1145/3278721.3278729]
9. Dragojevic M, Giles H, Beck AC, Tatum NT. The fluency principle: why foreign accent strength negatively biases language attitudes. Commun Monogr 2017;84(3):385-405. [doi: 10.1080/03637751.2017.1322213]
10. Dragojevic M, Fasoli F, Cramer J, Rakić T. Toward a century of language attitudes research: Looking back and moving forward. J Lang Soc Psychol 2020 Oct 23;40(1):60-79 [FREE Full text] [doi: 10.1177/0261927x20966714]
11. Callesano S, Carter PM. Latinx perceptions of Spanish in Miami: dialect variation, personality attributes and language use. Lang Commun 2019;67:84-98. [doi: 10.1016/j.langcom.2019.03.003]
12. Clayman ML, Manganello JA, Viswanath K, Hesse BW, Arora NK. Providing health messages to Hispanics/Latinos: understanding the importance of language, trust in health information sources, and media use. J Health Commun 2010;15 Suppl 3(Suppl 3):252-263. [doi: 10.1080/10810730.2010.522697] [Medline: 21154097]
13. Wood NI. Departing from doctor-speak: a perspective on code-switching in the medical setting. J Gen Intern Med 2019;34(3):464-466 [FREE Full text] [doi: 10.1007/s11606-018-4768-0] [Medline: 30535751]
14. Soliz J, Giles H. Relational and identity processes in communication: a contextual and meta-analytical review of communication accommodation theory. Ann Int Commun Assoc 2016;38(1):107-144. [doi: 10.1080/23808985.2014.11679160]
15. Watson B, Gallois C. Nurturing communication by health professionals toward patients: a communication accommodation theory approach. Health Commun 1998;10(4):343-355. [doi: 10.1207/s15327027hc1004_3] [Medline: 16370979]
16. Barlow M, Watson B, Jones E, Morse C, Maccallum F. The application of communication accommodation theory to understand receiver reactions in healthcare speaking up interactions. J Interprof Care 2024;38(1):42-51. [doi: 10.1080/13561820.2023.2249939] [Medline: 37702325]
17. Giles H, Taylor DM, Bourhis R. Towards a theory of interpersonal accommodation through language: some Canadian data. Lang Soc 2008;2(2):177-192. [doi: 10.1017/s0047404500000701]
18. Hornsey MJ, Imani A. Criticizing groups from the inside and the outside: an identity perspective on the intergroup sensitivity effect. Pers Soc Psychol Bull 2004;30(3):365-383. [doi: 10.1177/0146167203261295] [Medline: 15030626]
19. Aune R, Kikuchi T. Effects of language intensity similarity on perceptions of credibility relational attributions, and persuasion. J Lang Soc Psychol 1993 Sep 01;12(3):224-238 [FREE Full text] [doi: 10.1177/0261927x93123004]
20. Bourhis RY, Roth S, MacQueen G. Communication in the hospital setting: a survey of medical and everyday language use amongst patients, nurses and doctors. Soc Sci Med 1989;28(4):339-346. [doi: 10.1016/0277-9536(89)90035-x] [Medline: 2705006]
21. Giles H, Johnson P. Ethnolinguistic identity theory: A social psychological approach to language maintenance. Int J Soc Lang 1987;1987(68):68-69 [FREE Full text] [doi: 10.1515/ijsl.1987.68.69]
22. Tamasi SL. Linguistic accommodation in medical communication. 2008 Presented at: Sociolinguistic Symposium 17; April 3-5, 2008; Amsterdam, Netherlands URL: https://www.meertens.knaw.nl/ss17/contributions/abstract.php?paperID=403
23. Giles H. Accent mobility: a model and some data. Anthropol Linguist 1973;15(2):85-105 [FREE Full text]
24. Krieger JL, Neil JM, Duke KA, Zalake MS, Tavassoli F, Vilaro MJ, et al. A pilot study examining the efficacy of delivering colorectal cancer screening messages via virtual health assistants. Am J Prev Med 2021;61(2):251-255 [FREE Full text] [doi: 10.1016/j.amepre.2021.01.014] [Medline: 33888362]
25. Cooks EJ, Duke KA, Flood-Grady E, Vilaro MJ, Ghosh R, Parker N, et al. Can virtual human clinicians help close the gap in colorectal cancer screening for rural adults in the United States? The influence of rural identity on perceptions of virtual human clinicians. Prev Med Rep 2022;30:102034 [FREE Full text] [doi: 10.1016/j.pmedr.2022.102034] [Medline: 36531088]
26. Hawkins RP, Kreuter M, Resnicow K, Fishbein M, Dijkstra A. Understanding tailoring in communicating about health. Health Educ Res 2008;23(3):454-466 [FREE Full text] [doi: 10.1093/her/cyn004] [Medline: 18349033]
27. Noar SM, Harrington NG, Aldrich RS. The role of message tailoring in the development of persuasive health communication messages. Ann Int Commun Assoc 2016;33(1):73-133 [FREE Full text] [doi: 10.1080/23808985.2009.11679085]
28. Skinner CS, Halm EA, Bishop WP, Ahn C, Gupta S, Farrell D, et al. Impact of risk assessment and tailored versus nontailored risk information on colorectal cancer testing in primary care: a randomized controlled trial. Cancer Epidemiol Biomarkers Prev 2015;24(10):1523-1530. [doi: 10.1158/1055-9965.EPI-15-0122] [Medline: 26265201]
29. Lustria MLA, Noar SM, Cortese J, Van Stee SKV, Glueckauf RL, Lee J. A meta-analysis of web-delivered tailored health behavior change interventions. J Health Commun 2013;18(9):1039-1069. [doi: 10.1080/10810730.2013.768727] [Medline: 23750972]
30. Lanehart S. The Oxford Handbook of African American Language. New York, NY: Oxford University Press; 2015.
31. Baugh J. Linguistics in Pursuit of Justice. Cambridge, UK: Cambridge University Press; 2018.
32. Green LJ. African American English: A Linguistic Introduction. Cambridge, UK: Cambridge University Press; 2002.
33. Lippi-Green R. English with an Accent: Language, Ideology and Discrimination in the. London, UK: Routledge; 2011.

34. Samy Alim H, Reyes A. Introduction: complicating race: articulating race across multiple social dimensions. Discourse Soc 2011;22(4):379-384. [doi: 10.1177/0957926510395831]
35. Samy Alim H, Rickford JR, Ball AF. Raciolinguistics: How Language Shapes Our Ideas About Race. New York, NY: Oxford University Press; 2016.
36. Rickford JR. African American Vernacular English: Features, Evolution, Educational Implications. Hoboken, NJ: Blackwell Publishers; 1999.
37. Wallerstein N, Duran B, Oetzel JG, Minkler M. Community-Based Participatory Research for Health: Advancing Social and Health Equity. Hoboken, NJ: John Wiley & Sons; 2017.
38. Griffin L, Lee D, Jaisle A, Carek P, George T, Laber E, et al. Creating an mHealth app for colorectal cancer screening: user-centered design approach. JMIR Hum Factors 2019;6(2):e12700 [FREE Full text] [doi: 10.2196/12700] [Medline: 31066688]
39. Martin JL, Tang K. Understanding racial disparities in automatic speech recognition: the case of habitual "be". In: 21st Annual Conference of the International Speech Communication Association. 2020 Presented at: Interspeech 2020; October 25-29, 2020; Shanghai, China. [doi: 10.21437/interspeech.2020-2893]
40. Vilaro MJ, Wilson-Howard DS, Neil JM, Tavassoli F, Zalake MS, Lok BC, et al. A Subjective culture approach to cancer prevention: rural Black and White adults' perceptions of using virtual health assistants to promote colorectal cancer screening. Health Commun 2022;37(9):1123-1134 [FREE Full text] [doi: 10.1080/10410236.2021.1910166] [Medline: 33876658]
41. Cargile A, Rodriguez J, Rich M. Reactions to African-American vernacular English: do more phonological features matter? J Black Stud 2004;28(3):407-414 [FREE Full text]
42. Online resources for African American language. Corpus of Regional African American Language. URL: https://oraal.uoregon.edu/coraal [accessed 2024-02-12]
43. Coupland N, Giles H, Benn W. Language, communication and the blind. J Lang Soc Psychol 1986 Mar 01;5(1):53-62 [FREE Full text] [doi: 10.1177/0261927x8651005]
44. Kemper S. Elderspeak: speech accommodations to older adults. Aging Neuropsychol Cogn 2007;1(1):17-28. [doi: 10.1080/09289919408251447]
45. Margić BD. Communication courtesy or condescension? Linguistic accommodation of native to non-native speakers of English. J Engl Ling Fr 2017;6(1):29-55. [doi: 10.1515/jelf-2017-0006]
46. Carbado DW, Gulati M. Acting White?: Rethinking Race in "Post-Racial" America. New York, NY: Oxford University Press; 2015.
47. Hernandez-Salinas C, Marsiglia FF, Oh H, Campos AP, De La Rosa K. Community health workers as puentes/bridges to increase COVID-19 health equity in Latinx communities of the Southwest U.S. J Community Health 2023;48(3):398-413 [FREE Full text] [doi: 10.1007/s10900-022-01182-5] [Medline: 36536085]
48. Gopal DP, Chetty U, O'Donnell P, Gajria C, Blackadder-Weinstein J. Implicit bias in healthcare: clinical practice, research and decision making. Future Healthc J 2021;8(1):40-48 [FREE Full text] [doi: 10.7861/fhj.2020-0233] [Medline: 33791459]

Abbreviations

AAE: African American English
AI: artificial intelligence
CAB: community advisory board
CORAAL: Corpus of Regional African American Language
CTSI: Clinical and Translational Science Institute
DDM: Dialect Density Measure
H-AAE: high-level African American English
L-AAE: low-level African American English
PI: principal investigator
SAE: Standard American English
VHCP: virtual health care provider

Edited by M Hudson, T Leung; submitted 20.02.24; peer-reviewed by K Sutton, A Hassan; comments to author 24.04.24; revised version received 31.07.24; accepted 19.10.24; published 19.12.24.

Please cite as:
Davis A, Martin J, Cooks E, Vilaro M, Wilson-Howard D, Tang K, Raup Krieger J
From English to “Englishes”: A Process Perspective on Enhancing the Linguistic Responsiveness of Culturally Tailored Cancer Prevention Interventions
J Particip Med 2024;16:e57528
URL: https://jopm.jmir.org/2024/1/e57528
doi:10.2196/57528
PMID:

Original Paper

Examining the Feasibility, Acceptability, and Effectiveness of Remote Training on Community-Based Participatory Research: Single-Arm Pre-Post Pilot Study

Karen Fortuna[1], PhD, LICSW; Andrew Bohm[2], MS, PhD; Stephanie Lebby[3], MPH; Kisha Holden[4], MSCR, PhD; Branka Agic[5], MD, MHSc, PhD; Theodore D Cosco[6,7], PhD; Robert Walker[8], COAPS, MS

[1]Department of Psychiatry, Geisel School of Medicine at Dartmouth, Lebanon, NH, United States
[2]The Dartmouth Institute for Health Policy and Clinical Practice, Geisle School of Medicine, Darmouth College, Hanover, NH, United States
[3]College of Nursing and Health Sciences, The University of Vermont, Burlington, VT, United States
[4]Department of Psychiatry and Behavioral Sciences, Morehouse School of Medicine, Atlanta, GA, United States
[5]Centre for Addiction and Mental Health, University of Toronto, Toronto, ON, Canada
[6]School of Public Policy, Simon Fraser University, Vancouver, BC, Canada
[7]Oxford Institute of Population Ageing, University of Oxford, Oxford, United Kingdom
[8]Collaborative Design for Recovery and Health, Nashua, NH, United States

Corresponding Author:
Karen Fortuna, PhD, LICSW
Department of Psychiatry
Geisel School of Medicine at Dartmouth
1 Medical Center Drive
Lebanon, NH, 03756
United States
Phone: 1 603 722 5727
Email: karen.l.fortuna@dartmouth.edu

Abstract

Background: Over the past decade, a growing body of scientific evidence has demonstrated that community engagement in research leads to more relevant research, enhances the uptake of research findings, and improves clinical outcomes. Despite the increasing need for the integration of community engagement methodologies into the scientific inquiry, doctoral and master's level competencies in the field of psychiatry often lack dedicated training or coursework on community engagement methodologies.

Objective: A total of 13 service users, peer support specialists, caregivers of people with mental health challenges, and scientists (with specialties ranging from basic science to implementation science) aged 18 and older participated in remote training on community-based participatory research. Data were collected at baseline, 2 days, and 3 months.

Methods: A total of 13 service users, peer support specialists, caregivers of people with mental health challenges, and scientists (with specialties ranging from basic science to implementation science) aged 18 and older participated in remote training on community-based participatory research. Data were collected at baseline, 2 days, and 3 months.

Results: The pilot study demonstrated that a 3-month remote training on community-based participatory research ("Partnership Academy") was deemed feasible and acceptable by service users, peer support specialists, caregivers of people with mental health challenges, and scientists. Improvements were found in research engagement and the quality of partnership. A marked increase in distrust in the medical system was also found. Groups submitted 4 grant applications and published 1 peer-reviewed journal at a 3-month follow-up.

Conclusions: This pre- and postpilot study demonstrated it is possible to train groups of service users, peer support specialists, caregivers of people with mental health challenges, and scientists in community-based participatory research. These findings provide preliminary evidence that a 3-month remote training on community-based participatory research ("Partnership Academy") is feasible, acceptable, and potentially associated with improvements in research engagement as well as the quality of partnership and output, such as manuscripts and grant applications.

(J Particip Med 2024;16:e48707) doi:10.2196/48707

KEYWORDS

community-based participatory research; CBPR; peer support; health literacy; remote training; community-based; user; mental health

Introduction

Over the past decade, growing scientific evidence shows that community engagement in research produces more relevant research, increases uptake of research findings, and improves clinical outcomes [1-6]. Community engagement is defined as "a process of working collaboratively with groups of people who are affiliated by geographic proximity, special interests, or similar situations, with respect to issues affecting their well-being" [1]. Patient-centered outcomes research (PCOR) is intended to improve community engagement in research, yet it often leaves partners feeling overburdened and disenfranchised, leading to premature disengagement from PCOR [6].

Community engagement is crucial to addressing health disparities through the inclusion of historically underrepresented and disadvantaged populations in mental health research. Service users of the mental health system are primarily individuals from low-income groups who have disabilities, multiple chronic health conditions, and low health literacy. This population commonly disengages from research due to mistrust rooted in historical traumatic experiences in the mental health system, which in turn leads to the lack of representation in PCOR. As such, significant investment in the science of community engagement is needed to improve community engagement in PCOR [7].

Despite the need for the integration of community engagement methodologies into the scientific inquiry, doctoral and master's level competencies in the field of psychiatry commonly do not include dedicated training or coursework on community engagement methodologies [2]. Without appropriate training or research experience, attempts to facilitate community engagement in research are often ineffective and burdensome, leaving partners feeling disengaged [3]. The purpose of this study was to assess the feasibility, acceptability, and preliminary effectiveness of remote training on community-based participatory research—"Partnership Academy."

Methods

Procedures

The authors participated in and are members of the Early Mortality in People with a Diagnosis of a Serious Mental Illness (SMI) roundtable convened remotely on May 24 and 26, 2022. The roundtable was a diverse, interdisciplinary partnership collaborative composed of individuals with lived experience of mental health or substance misuse, peer support specialists, recovery coaches, parents and caregivers of people with SMIs, researchers and clinician-scientists with and without lived experience, policy makers, and representatives from patient-led organizations committed to addressing the health disparity in early mortality among people with SMIs through patient-centered research. To date, no such collaboration of partners exists. The roundtable aimed to advance the understanding of fundamental patterns and interactions among and between environmental, behavioral, cultural, neurobiological, psychological, and biopsychosocial mechanisms on health and health behavior relevant to early mortality in people with SMIs.

Roundtable members were selected by reviewing the published literature on early mortality and SMIs. KF and RW conducted a Google Scholar search using variations of the following search terms: "early mortality" and "serious mental illness." Next, these authors (KF and RW) emailed authors included in the identified prereviewed manuscripts. Identified members recommended additional members through a snowball sampling framework. Patient partners were identified through direct email to partners of the Collaborative Design for Recovery and Health, which is an international group of patients, clinicians, peer support specialists, caregivers, scientists with and without lived experiences, policy makers, and payer systems led by KF and RW. The Collaborative partnered with different community groups from vulnerable populations across the intersectionality of disability and race to coproduce solutions to address community-identified challenges.

Attendants of the Early Mortality in People with a Diagnosis of a Serious Mental Illness roundtable were also given the option to complete surveys before day 1, after day 2, and 3 months after the roundtable. The surveys were used to assess the impact of the training on partners. KF provided participants with a detailed description of the study protocol if they were interested, and a survey link was emailed to individuals with the digital informed consent form. Participants clicked "I agree" on the informed consent form to participate and completed the web-based baseline survey.

The roundtable convening used a remote community meeting method, adhering to the Peer and Academic Partnership model of community engagement [8]. The Peer and Academic Partnership is based on the Center for Disease Control and Prevention's principles of community engagement (2011) [9], as follows: (1) develop a clear understanding of the purpose, goal, and population involved in community change; (2) become knowledgeable about all aspects of the community; (3) interact and establish relationships with the community; (4) encourage community self-determination; (5) partner with the community; (6) respect community diversity and culture; (7) activate community assets and develop capacity; (8) maintain flexibility; and (9) commit to long-term collaboration. Although the project team initially considered convening in person, the rapid rise in remote meetings due to COVID-19 has highlighted the benefits of remote convening, especially for the early mortality community, given its international representation.

The roundtable members included people across the United States, United Kingdom, Canada, Europe, Africa, Australia, Asia, and the Netherlands. With such a geographically dispersed community, an in-person convening was not feasible for all partners and would have involved disproportionate travel expenses. To ensure a productive remote meeting, the project team offered to train members to use the virtual platform before the roundtable and planned a rehearsal to work through any last-minute challenges with the meeting platform. Further, to facilitate equitable access to engagement, members were encouraged to call in and not use video if their available technology did not allow for video.

The roundtable convened over two 5-hour days across 1 week in May 2022, structured as a summit with several remote meeting sessions. KF and RW facilitated the summit, set the tone, provided participation guidelines, and kept discussions focused and oriented to the goals of the roundtable. The roundtable used a Delphi method to achieve a consensus on the research agenda. The Delphi method is an empirically supported process used to attain consensus within an expert group [10]. Roundtable members responded to several rounds of PCOR research agenda development. After each round, their responses were aggregated and shared with the group until a consensus was achieved.

Patients made up at least 60% of meeting participants, and all verbal and written materials for the convening meeting were designed with consideration for potential cognitive and intellectual needs, following principles of design for people with SMIs (eg, information presented at fourth-grade level and single structure sentences). Further, all interactions were based on adult learning techniques designed to reduce cognitive effort and promote engagement among all members. For example, KF encouraged the roundtable to share their respective perspectives on early mortality (personal or research-related perspectives) to promote discussions (ie, experiential learning theory), and RW used a round-robin technique to encourage all members to share their ideas, built-in breaks, and energizers into sessions to keep roundtable members engaged, positive, and productive. The community engagement techniques used each day are delineated in the following sections.

Convening Meeting Day 1: Setting the Stage and Story With a Gap

The first session began with a welcome and an opportunity for introductions, followed by a session on the historical literature review of early mortality among people with SMIs. This was followed by a large group discussion intended to identify gaps in our understanding of early mortality among people with SMIs. Next, we presented a Story with a Gap to elicit gaps in the extant research. The Story with a Gap technique includes 2 contrasting pictures of "before" and "after" situations [11]. Following this technique, roundtable members identified the steps and resources needed to move from the "before" to the "after" situation. In conclusion, opportunities to lead committees to work toward tasks identified in the strategic planning process were formed. Next, each member evaluated and ranked their foci for future research, using anonymous polling videoconferencing from the first session to select the 3 highest impact areas within the bounds of financial, time, and other constraints.

Convening Meeting Day 2: Multiple Rounds of Delphi and Consensus

The first session of day 2 began with a draft PCOR research agenda based on discussions from day 1. The PCOR research agenda included, at a minimum, strategies to address gaps in research efforts. All partners commented on the PCOR research agenda and first proposed recommendations publicly in an open forum and, second, proposed additional recommendations anonymously using a Qualtrics web-based survey. This iterative process occurred until a consensus was reached. During day 2 sessions, RW implemented techniques to promote conversation. He used brainstorming, "Go Wild" prompts (ie, asking roundtable members to talk about ideas that begin with "wouldn't it be good if..."), and reverse brainstorming (ie, considering the reverse of problems) to generate creative, thoughtful, and innovative ideas regarding early mortality PCOR. Then, in the Reality Check session, RW used multivoting, ranking, and problem-solving methods to help the roundtable make decisions about which ideas were most feasible and impactful and how to overcome barriers to their implementation.

Study Design and Participants

The study used a single-arm pre- and postdesign approach to assess the impact of training partners from diverse groups designed to facilitate community-engaged research. Participants (N=13) included service users, peer support specialists, caregivers of people with mental health challenges, and scientists (basic science to implementation scientists).

Ethical Considerations

This study was approved by the Dartmouth Health institutional review board (STUDY02001532).

Instruments

Quality of Partnership

The quality of PCOR was assessed using the Quality of Patient-Centered Outcomes Research Partnerships Instrument (QPCOR) [12]. The QPCOR contains the following domains: (1) purpose, goal, and population; (2) respect (respect community diversity and culture); (3) inclusion (activate community assets); (4) colearning (develop capacity); (5) become knowledgeable about the community; (6) self-determination; (7) shared decision-making (partner with the community); (8) perceived support (interact and establish relationships with the community); (9) flexibility; and (10) sustainability (commitment to long-term collaboration). The QPCOR uses a 10-point Likert scale. Items with a score of 60 or lower indicate the need for improvement and should be addressed. Higher scores indicate higher levels of partnership.

Engagement

Engagement was measured using The Research Engagement Survey Tool (REST). The REST is a 9-item scale that evaluates the level of nonacademic partner engagement among research partners. Example items include "The focus is on problems important to the community" and "All partners assist in establishing roles and related responsibilities for the partnership."

The REST is measured on 2 Likert-type scales (for quantity and quality). The response options for the quantity scale were "never," "rarely," "sometimes," "often," "always," and "not applicable." The response options for the quality scale were "poor," "fair," "good," "very good," "excellent," and "not applicable." Responses were coded in order from 1 to 5 for both scales, with higher scores indicating higher engagement; not applicable options were coded as missing. For the REST, mean scores were calculated overall for both quality and quantity scales. The overall mean scores for both scales were created by averaging the mean scores so that each response is weighted equally regardless of the number of items.

Distrust in the Medical System

Distrust in the medical system was measured using the Health Care System Distrust Scale [13]. The Health Care System Distrust Scale contains 10 items and is measured on a Likert scale. Example prompts include "Medical experiments can be done on me without my knowing about it" and "My medical records are kept private." Scores on the Health Care System Distrust Scale range from 12 to 46 with a possible range from 10 to 50. The score is the sum of 10 questions from the Health Care System Distrust Scale after reversing 2 positively framed items. The possible range is from 10 to 50.

Effectiveness

Effectiveness was assessed by collecting data at the 3-month mark, including progress toward grant submissions, submitted manuscripts, and changes in research knowledge.

Data Analysis

Descriptive statistics were conducted to describe the demographic characteristics of the study sample. A paired-sample *t* test was conducted to assess the difference between baseline, day-2, and 3-month scores for statistical significance. Participants served as their own controls from pre- to posttest. Descriptive statistics and analyses were computed using STATA (version 13.1; StataCorp). The statistical models used to analyze the data accommodate missing data, assuming that they are missing at random.

Results

Demographically, the population of this feasibility study was predominantly female (n=8, 62%), White (n=10, 77%), and educated at or above a master's level (n=8, 62%). Study participants represented a wide range of adult age groups with the plurality being in the age category of 45-55 years, and there was a wide range of partners represented (Table 1).

For all 3 survey tools used in this study (Healthcare System Distrust Scale, REST, and Quality of Patient-Centered Outcomes Research Measurement tool), there was a marked but not statistically significant increase from pre- to posttest. The Distrust Scale and REST (5-point scales) both increased 0.03 units (*P*=.75 and *P*=.85, respectively), representing increased distrust and research engagement in the postmeeting survey. There was also a marked increase of 6.86 units in the Quality of Patient-Centered Outcomes Research Measurement tool (*P*=.20; Table 2).

When evaluating individual questions, some participants had a more significant degree of change in the postmeeting setting compared to others. In particular, a question regarding providers hiding medical mistakes showed significantly more agreement (mean 3.38, SD 1.04 vs mean 2.69, SD 1.03; *P*=.04; Hedges *g*=0.65), and participants indicated significantly more comfort in engaging with research study team members (mean 91.00, SD 15.36 vs mean 77.15, SD 27.36; *P*=.049; Hedges *g*=0.60) in the postmeeting survey. Many other questions demonstrated meaningful but not significant increases with a universal increase in survey responses for the Quality in Patient-Centered Outcomes Research Measurement tool (ie, change range per question: minimum +3.54; maximum +14.23; Hedges *g* range: 0.13-0.60).

The Health Care System Distrust Scale included some items that presented an increase on the scale and some that presented a decrease. The most notable increase in distrust was hiding medical errors, as previously mentioned. The most notable decrease (represented by increased trust in the medical system) was related to the health care system putting medical needs as a priority over all other issues during care (mean 2.85, SD 0.99 vs mean 3.31, SD 1.11; *P*=.14; Hedges *g*=–0.43). In the REST tool, there was a minimal change for most questions, with most questions exhibiting a ceiling effect and being near 5 (highest score) in both the pre- and postsetting (Table 3). There were no statistically significant differences in mean scores pre- and postintervention for any domain covered by the REST tool.

Table 1. Sociodemographic characteristics of individuals involved in the research academy. Partner categories are not mutually exclusive, and participants may be represented in multiple categories (N=13).

Characteristics	Values, n (%)
Gender	
Female	8 (62)
Male	5 (39)
Race	
Asian-Eastern	0 (0)
Asian-Indian	0 (0)
Black/African American	2 (15)
Hispanic	0 (0)
Multiple races	1 (8)
Native American	0 (0)
White	10 (77)
Age (years)	
18-24	0 (0)
25-34	1 (8)
35-44	2 (15)
45-54	4 (31)
55-64	3 (23)
65-74	3 (23)
Highest level of education	
Graduate degree or above	8 (62)
Bachelor’s degree	2 (15)
High school degree	1 (8)
Other	2 (15)
Partner role	
Caregiver of person(s) with SMI[a]	4 (31)
Service user	4 (31)
Peer support specialist	6 (45)
Scientist	6 (45)
Other	1 (8)

[a] SMI: serious mental illness.

Table 2. Pre- and postchanges on outcomes of interest.

Outcome of interest	Prechange, mean (SD)	Postchange, mean (SD)	Mean difference (SD)	*P* value	Effect size (95% CI)[a]
Health care system distrust	3.08 (0.55)	3.12 (0.50)	0.03 (0.34)	.75	0.06 (–0.69 to 0.80)
REST[b]	4.56 (0.60)	4.60 (0.58)	0.03 (0.60)	.85	0.06 (–0.69 to 0.80)
QPCOR[c]	79.01 (22.80)	85.87 (22.59)	6.86 (18.28)	.20	0.29 (–0.46 to 1.04)

[a] Hedges *g* was used to calculate effect sizes (due to the small sample size).

[b] REST: Research Engagement Survey Tool.

[c] QPCOR: Quality of Patient-Centered Outcomes Research.

Table 3. Pre- and postchanges by individual questions.

Characteristics	Prechange mean (SD)	Postchange mean (SD)	Mean difference SD	*P* value	Effect size (95% CI)[a]
Healthcare System Distrust Scale[b]					
Medical experiments can be done on me without my knowing about it.	2.23 (1.36)	2.23 (1.01)	0 (0)	1.000	0 (–0.74 to 0.74)
My medical records are kept private.	4.23 (0.83)	3.92 (0.76)	–0.31 (0.63)	0.104	–0.37 (–1.12 to 0.38)
People die every day because of mistakes by the health care system.	3.85 (1.07)	3.69 (0.85)	–0.15 (0.90)	0.55	–0.15 (–0.90 to 0.59)
When they take my blood, they do tests they don’t tell me about.	2.62 (1.19)	2.31 (0.95)	–0.31 (1.18)	0.37	–0.28 (–1.02 to 0.47)
If a mistake were made in my health care, the health care system would try to hide it from me.	2.69 (1.03)	3.38 (1.04)	0.69 (1.11)	0.040	0.65 (–0.12 to 1.41)
People can get access to my medical records without my approval.	2.54 (0.97)	2.85 (1.07)	0.31 (1.25)	0.393	0.29 (–0.45 to 1.04)
The health care system cares more about holding costs down than it does about doing what is needed for my health.	3.15 (0.99)	3.38 (1.19)	0.23 (1.30)	0.535	0.20 (–0.54 to 0.95)
I receive high-quality medical care from the health care system.	3.62 (1.12)	3.77 (0.97)	0.15 (0.99)	0.585	0.14 (–0.60 to 0.89)
The health care system puts my medical needs above all other considerations when treating my medical problems.	3.31 (1.11)	2.85 (0.99)	–0.46 (1.05)	0.139	–0.43 (–1.18 to 0.33)
Some medicines have things in them that they don't tell you about.	2.62 (1.33)	2.77 (1.17)	0.15 (1.21)	0.656	0.12 (–0.63 to 0.86)
Research Engagement Survey Tool[b]					
The focus is on problems important to the community.	4.69 (0.63)	4.76 (0.60)	0.08 (0.95)	0.776	0.12 (–0.87)
All partners assist in establishing roles and related responsibilities for the partnership.	4.53 (0.77)	4.53 (0.88)	0 (1.08)	1.000	0 (–0.74 to 0.74)
Community-engaged activities are continued until the goals (as agreed upon by all partners) are achieved.	4.38 (0.87)	4.38 (0.77)	0 (0.71)	1.000	0 (–0.74 to 0.74)
The partnership adds value to the work of all partners.	4.69 (0.48)	4.61 (0.77)	–0.08 (0.76)	0.721	–0.12 (–0.86 to 0.63)
The team builds on strengths and resources within the community or patient population.	4.62 (0.51)	4.62 (0.65)	0 (0.71)	1.000	0 (–0.74 to 0.74)
All partners’ ideas are treated with openness and respect.	4.54 (0.66)	4.69 (0.63)	0.15 (0.80)	0.502	0.23 (–0.52 to 0.98)
All partners agree on the timeline for making shared decisions about the project.	4.46 (0.78)	4.54 (0.78)	0.08 (0.49)	0.585	0.10 (–0.65 to 0.84)
The partnership’s processes support trust among all partners.	4.62 (0.65)	4.69 (0.63)	0.07 (0.95)	0.776	0.12 (–0.63 to 0.86)
Mutual respect exists among all partners.	4.54 (0.66)	4.54 (0.88)	0 (1.00)	1.000	0 (–0.74 to 0.74)
Quality of Patient-Centered Outcomes Research[c]					
I had a clear understanding of the purpose of the study.	78.6 (26.27)	82.92 (26.44)	4.31 (15.00)	0.321	0.16 (–0.59 to 0.90)
I felt listened to.	76.54 (26.98)	85.62 (28.81)	9.08 (26.90)	0.247	0.31 (–0.44 to 1.06)

Characteristics	Prechange mean (SD)	Postchange mean (SD)	Mean difference SD	*P* value	Effect size (95% CI)[a]
I felt prepared to be an equal partner in the research study.	80.77 (24.17)	84.62 (21.43)	3.85 (16.26)	0.411	0.16 (–0.58 to 0.91)
Researchers were knowledgeable about people like me or were willing to learn about people like me.	81.77 (21.60)	86.69 (20.38)	4.92 (24.28)	0.479	0.23 (–0.52 to 0.97)
I believe that I had choices in how I could be part of the research study.	80.38 (24.10)	83.93 (28.50)	3.54 (28.98)	0.668	0.13 (–0.62 to 0.87)
I feel prepared to be an equal partner in the research study.	80.92 (25.28)	84.62 (26.26)	3.69 (21.65)	0.550	0.14 (–0.60 to 0.88)
I feel accepted by all members of the research study team.	80.31 (24.30)	85.85 (26.87)	5.54 (24.65)	0.434	0.21 (–0.54 to 0.95)
Researchers used language that was consistent with my values and culture.	77.69 (27.64)	84.77 (26.31)	7.08 (24.52)	0.319	0.25 (–0.50 to 1.00)
Both community members and researchers are thinking of ways we can continue to work together in the future.	75.00 (27.49)	89.23 (18.58)	14.23 (29.62)	0.109	0.59 (–0.18 to 1.34)
I felt comfortable engaging with the members of the research study team.	77.15 (27.36)	91.00 (15.36)	13.85 (22.85)	0.049	0.60 (–0.17 to 1.36)
I felt my views were incorporated into the research study.	79.92 (27.89)	85.31 (26.07)	5.38 (18.71)	0.320	0.19 (–0.56 to 0.94)

[a] Hedges *g* was used to calculate effect size (due to the small sample size).

[b] On a 5-point Likert scale.

[c] On a 10-point scale.

Discussion

Principal Findings

The purpose of this study was to assess the feasibility, acceptability, and preliminary effectiveness of remote training on community-based participatory research. The Partnership Academy was found to be feasible and acceptable. Improvements were found in research engagement and the quality of the partnership. A marked increase in distrust in the medical system was also found. Three months after the Partnership Academy training, the trainees submitted 4 grant applications and published 1 peer reviewed research article.

Feasibility and acceptability by service users, peer support specialists, caregivers of people with mental health challenges, and scientists were demonstrated through their capacity to attend and participate in the Partnership Academy. With the geographically dispersed community of the Partnership Academy, an in-person meeting might not be feasible for all partners and could invoke disproportionate travel expenses. Remote training allowed partners from all parts of the United States to meet and work together while avoiding travel, accommodation, and facility rental expenses. Further, all aspects of the remote training were aligned with the Americans with Disability Act requirements. For example, patients with cognitive impairments may have difficulty using Zoom due to challenges related to motion sensitivity. As such, there was no requirement to use the video feature.

The Partnership Academy was found to be potentially effective in promoting research engagement. Greater alignment of partner priorities and researchers' objectives facilitates greater engagement in all parts of the research process, from study conceptualization to knowledge mobilization, ultimately increasing the likelihood of an intervention's success [14]. This shift goes beyond a paradigm where research functions as a one-way conversation, to one in which active community participation has facilitated and enabled greater integration and engagement of partners and researchers alike [15]. The model of the Partnership Academy exemplifies these concepts and practically implements their use, providing evidence for the potential effectiveness of this approach in prospective research projects. Other trainings are available, such as the Community-based Participatory Research Academy [16] and Patient-Centered Outcomes Research Institute's Research Fundamentals: Preparing You to Successfully Contribute to Research; however, they have not been designed for the unique needs of people with SMIs.

A marked increase in distrust in the medical system was also found. There are a few possible explanations for an increase in distrust in a medical system, in particular concerns for medical errors. First, it is possible that increased awareness from the conversations during the training led to further entrenchment in previously held beliefs. Second, it is possible that during the 2-day training, the roundtable participants heard not only more negative stories about the medical errors but also negative stories from fellow roundtable members who were deemed "credible" as scientists, expressing their concern with medical errors. Integrating qualitative data collection in future roundtable events may elicit new knowledge regarding perceptions of mistrust among participants.

Limitations

Due to the nature of the study and the study design, there are inherent limitations. There are additional limitations surrounding the study design and analysis of data. Due to the small sample size, we could not stratify participants by demographic characteristics or differing experiences with different SMIs. It is unknown if different participants with different diagnoses, or researchers who engaged in diagnosis-specific research had different program evaluations. Additionally, due to the Likert-scale measurements, understanding the true magnitude of the effect is limited to categorical shifts and not continuous measurement changes. Moreover, Likert questions open the study up to potential acquiescence bias due to participants' potential to overly agree with statements (in comparison to their actual feelings). Due to the sampling methodology used, those selected for participation in the roundtable were those who were actively engaged in the health care system or research, and these findings may not apply to the population with SMI. Lastly, less than 25% of the study population represents racial minorities or those with lower levels of education. Future studies should make an effort to recruit a more diverse group of participants.

Conclusions

This pre- and postpilot study demonstrated the possibility of training groups of service users, peer support specialists, caregivers of people with mental health challenges, and scientists in community-based participatory research. These findings provide preliminary evidence that a 3-month remote training on community-based participatory research ("Partnership Academy") is feasible and acceptable and potentially associated with improvements in research engagement as well as the quality of partnership and output, including coproduced grant applications and peer-reviewed manuscripts.

Addressing the multifaceted health needs as well as the mental and behavioral health needs of diverse individuals, families, and communities in the United States is a complex issue that warrants attention from clinicians, researchers, scientists, public health professionals, and policy makers. The use of a community-based participatory framework supports the notion of implementing innovative approaches to help address health and mental health disparities. Moreover, our study reinforces key tenets of values delineated through inventive collaborations and partnerships that may be promising. In particular, our engagement and training efforts suggest the significance of (1) building trust and relationships, (2) establishing a shared purpose and vision for the achievement of goals, (3) engendering transparency and effective communication, and (4) performing continuous quality improvement or process and outcome evaluation where appropriate. Advancing health equity requires multidimensional, multisectoral, and interdisciplinary approaches to adequately address the needs of ethically and culturally diverse populations.

Conflicts of Interest

KF receives funding from Social Wellness and partners with Emissary Health, Inc. The other authors declare no conflicts of interest.

References

1. Cyril S, Smith BJ, Possamai-Inesedy A, Renzaho AMN. Exploring the role of community engagement in improving the health of disadvantaged populations: a systematic review. Glob Health Action 2015 Dec 18;8(1):29842 [FREE Full text] [doi: 10.3402/gha.v8.29842] [Medline: 26689460]
2. Fortuna KL, Myers A, Brooks J, Collins-Pisano C, Marceau S, Pratt S, et al. Co-production of the quality of patient-centered outcomes research partnerships instrument for people with mental health conditions. Patient Exp J 2021 Apr 28;8(1):148-156 [FREE Full text] [doi: 10.35680/2372-0247.1533] [Medline: 35330862]
3. Holzer JK, Ellis L, Merritt MW. Why we need community engagement in medical research. J Investig Med 2023 Jan 05;62(6):851-855. [doi: 10.1097/jim.0000000000000097]
4. Kwon SC, Tandon SD, Islam N, Riley L, Trinh-Shevrin C. Applying a community-based participatory research framework to patient and family engagement in the development of patient-centered outcomes research and practice. Transl Behav Med 2018 Sep 08;8(5):683-691 [FREE Full text] [doi: 10.1093/tbm/ibx026] [Medline: 30202926]
5. MacQueen KM, Bhan A, Frohlich J, Holzer J, Sugarman J, Ethics Working Group of the HIV Prevention Trials Network. Evaluating community engagement in global health research: the need for metrics. BMC Med Ethics 2015 Jul 01;16(1):44 [FREE Full text] [doi: 10.1186/s12910-015-0033-9] [Medline: 26126899]
6. Salihu HM, Salinas-Miranda AA, Wang W, Turner D, Berry EL, Zoorob R. Community priority index: utility, applicability and validation for priority setting in community-based participatory research. J Public Health Res 2015 Jul 16;4(2):443 [FREE Full text] [doi: 10.4081/jphr.2015.443] [Medline: 26425490]
7. Woolf SH, Purnell JQ, Simon SM, Zimmerman EB, Camberos GJ, Haley A, et al. Translating evidence into population health improvement: strategies and barriers. Annu Rev Public Health 2015 Mar 18;36:463-482. [doi: 10.1146/annurev-publhealth-082214-110901] [Medline: 25581146]
8. Fortuna K, Barr P, Goldstein C, Walker R, Brewer L, Zagaria A, et al. Application of community-engaged research to inform the development and implementation of a peer-delivered mobile health intervention for adults with serious mental illness. J Particip Med 2019 Mar 19;11(1):e12380 [FREE Full text] [doi: 10.2196/12380] [Medline: 32095314]
9. Principles of community engagement second edition. Centers for Disease Control and Prevention. URL: https://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf [accessed 2024-01-18]

10. Dalkey N, Helmer O. An experimental application of the DELPHI method to the use of experts. Manag Sci 1963 Apr;9(3):458-467. [doi: 10.1287/mnsc.9.3.458]
11. Rietbergen-McCracken J, Narayan D. Participation and Social Assessment. Tools and Techniques. Washington DC, WA: World Bank Publications; 1998.
12. Fortuna KL, Myers A, Brooks J, Collins-Pisano C, Marceau S, Pratt S, et al. Co-production of the quality of patient-centered outcomes research partnerships instrument for people with mental health conditions. Patient Exp J 2021 Apr 28;8(1):148-156 [FREE Full text] [doi: 10.35680/2372-0247.1533] [Medline: 35330862]
13. Rose A, Peters N, Shea JA, Armstrong K. Development and testing of the health care system distrust scale. J Gen Intern Med 2004 Jan;19(1):57-63 [FREE Full text] [doi: 10.1111/j.1525-1497.2004.21146.x] [Medline: 14748861]
14. Wallerstein N, Duran B, Oetzel J, Minkler M. Community-Based Participatory Research for Health: Advancing Social and Health Equity, 3rd Edition. Hoboken, NJ: John Wiley & Sons; 2017.
15. Key KD, Furr-Holden D, Lewis EY, Cunningham R, Zimmerman MA, Johnson-Lawrence V, et al. The continuum of community engagement in research: a roadmap for understanding and assessing progress. Prog Community Health Partnersh 2019;13(4):427-434. [doi: 10.1353/cpr.2019.0064] [Medline: 31866597]
16. Detroit URC. URL: https://detroiturc.org/ [accessed 2024-01-18]

Abbreviations

PCOR: patient-centered outcomes research
QPCOR: Quality of Patient-Centered Outcomes Research Partnerships Instrument
REST: Research Engagement Survey Tool
SMI: serious mental illness

Edited by M Hudson; submitted 03.05.23; peer-reviewed by H Traino, A Higaki, V Girishan Prabhu; comments to author 16.06.23; revised version received 22.09.23; accepted 19.11.23; published 01.03.24.

Please cite as:
Fortuna K, Bohm A, Lebby S, Holden K, Agic B, Cosco TD, Walker R
Examining the Feasibility, Acceptability, and Effectiveness of Remote Training on Community-Based Participatory Research: Single-Arm Pre-Post Pilot Study
J Particip Med 2024;16:e48707
URL: https://jopm.jmir.org/2024/1/e48707
doi:10.2196/48707
PMID:38427414

Original Paper

Tracking the Development of Community Engagement Over Time: Realist Qualitative Study

Esther de Weger[1,2], BA, MSc, PhD; Hanneke Drewes[3], BSc, MSc, PhD; Katrien Luijkx[1], BSc, MSc, PhD; Caroline Baan[1], BSc, MSc, PhD

[1]Department of Tranzo, Tilburg School of Social and Behavioural Sciences, Tilburg University, Tilburg, Netherlands
[2]Vrije Universiteit Amsterdam, Amsterdam, Netherlands
[3]Siza, Arnhem, Netherlands

Corresponding Author:
Esther de Weger, BA, MSc, PhD
Vrije Universiteit Amsterdam
de Boelelaan 1085
Amsterdam,
Netherlands
Phone: 31 0649868829
Email: e.j.de.weger@vu.nl

Abstract

Background: A growing interest in engaging communities in the development of health care services and communities has not automatically led to progress or consensus as to how to engage communities successfully, despite the evidence base showing how to leverage enablers and alleviate barriers.

Objective: To bridge the gap between the evidence base and which community engagement (CE) approaches have actually been applied in practice over time, this study aims to investigate how CE approaches have changed over the past 4 years in 6 different regions in the Netherlands and citizens’ and professionals’ experiences underlying these changes.

Methods: For the last stage of a multiple case study following the development of CE approaches in 6 different regions in the Netherlands, a realist qualitative case study was conducted. To investigate how CE approaches had changed over the past 4 years, data from the entire 4 years of the study were used, including documents, interview transcripts, and observations. To examine citizens’ and professionals’ experiences underlying these changes, new interviews were conducted. The latest interview results were discussed with a panel to ensure the results had face validity.

Results: The regions had implemented different types of CE approaches over the past 4 years and were adapting these approaches over time. Many of the (remaining) approaches may be operating on a smaller scale. The study identified the following overarching themes along which CE had been adapted: fewer region-wide approaches and more community-focused approaches, more focus on building relationships with (already engaged) citizens and community-led initiatives, and more focus on practical and tangible health promotion and social cohesion activities and less focus on complex “abstract” programs. The study identified a further 4 overarching themes highlighting citizens’ and professionals’ experiences underlying these changes in the CE approaches: a lack of engagement environment, need for facilitative leadership from organizations, need for a clear and shared vision underscoring the importance of CE, and misalignment between citizens’ and professionals’ perspectives and motivations for CE. All participants had experienced the engagement environment as insufficient. To support CE, professionals experienced the need to develop and receive more facilitative leadership and to develop approaches better equipped to involve citizens in the decision-making process. Citizens experienced the need to better align citizens’ and professionals’ motivations and aims for CE approaches and to receive longer-term financial support for their community-led initiatives.

Conclusions: This study suggests that CE has not yet been embedded within organizational cultures. This has arguably meant that the (remaining) CE approaches are operating on a smaller scale. To enable the further development of CE approaches, an investment in the engagement environment and a shared vision is required. Only then could CE within the regions move beyond the more seemingly smaller-scale CE approaches.

(J Particip Med 2024;16:e47500) doi:10.2196/47500

KEYWORDS

community engagement; citizen involvement; health care; decentralization; realist evaluation

Introduction

Background

Over the past few decades, public sector organizations have increasingly been trying to engage citizens in shaping and improving health care services, neighborhoods, and healthy living environments [1,2]. The idea behind community engagement (CE) is that through citizens' involvement services and policies will better reflect communities' experiences and better address their needs [3-7]. The aim of CE approaches is to involve citizens in the decision-making, planning, designing, governance, or delivery of services and policies. CE approaches can range from consultation where citizens have limited power to influence decision-making to partnership and (shared) leadership, where citizens have decision-making control [1,8,9]. The approaches can take many different forms, including citizen advisory panels, citizen budgetary forums, peer service delivery, and community-led initiatives [1].

However, as Beresford [10] noted, this increasing and widespread interest in involving communities in the development and improvement of health care services and living environments does not automatically mean progress or consensus as to how to do so meaningfully and successfully for either organizations or communities. Previous literature hints at the barriers that have hindered this progress toward CE over the past few years. For example, Cook and Kothari [11] argued that many participatory processes are often undertaken uncritically based on the perceived wisdom of the overwhelming benefits of CE. However, these formulaic approaches often impose the views, objectives, and aims of organizations onto communities, resulting in benefits that primarily serve the organizations themselves, or, more commonly, fail to deliver benefits to either organizations or communities. Previous literature has described other important factors driving this lack of progress, such as power imbalances between organizations and communities, engaged citizens' limited credibility according to professionals, communities' lack of influence in decision-making processes, misaligned interests between organizations and between organizations and communities, or a lack of a clear and shared vision for CE [5,10,12-14].

Despite the wealth of previous literature identifying important barriers and enablers to the progress of CE, health and care organizations are still searching for how to implement their own successful CE approaches and largely have not yet taken the required steps to leverage these identified enablers [14] or improved the engagement environment sufficiently [14]. Moreover, previous literature has not investigated how CE has developed over time. Because of this gap between the evidence base and how the implementation process of CE approaches over time is actually experienced in practice, this study examined how CE developed during the course of 4 years in practice. To provide insight into the development of CE in the Netherlands, we conducted a 4-year multiple case study investigating how 6 different regions are developing and implementing their own CE approaches. The initial phase of the study involved conducting an international rapid realist review to identify the barriers and enablers for engaging communities. This review resulted in the development of 8 guiding principles for the successful implementation of CE [13]. Subsequently, these principles were tested in practice through various case studies, leading to the identification of a ninth guiding principle [13-16].

Objective

Building on the previous stages by using the guiding principles as program theories, this paper describes the final stage of the study. This final case study aims to investigate how CE has changed over the past 4 years in the 6 regions and to examine citizens' and professionals' experiences underlying these changes. This paper explored the following research questions:

1. What CE approaches have been applied, and how have these approaches changed over the past 4 years?
2. What are citizens' and professionals' experiences underlying the changes in CE approaches? What are the contextual factors and mechanisms explaining these experiences?

Methods

Overview

This paper presents the last stage of this multiple case study (T4). This final stage examined how CE approaches have changed over the past 4 years and what citizens' and professionals' experiences were underlying these changes. The study was informed by the realist evaluation (RE) approach. The RE approach seeks to explain the causal relationship between contexts, mechanisms, and outcomes in particular programs of interest [17]. In this way, the study sought to understand the causation behind the changes in CE approaches and to understand which (enabling and constraining) mechanisms were triggered within the (changing) contexts of the 6 regions and how these influenced citizens' and professionals' experiences of developing CE (Textbox 1 [13], [14], [18]; Multimedia Appendix 1).

Textbox 1. Community engagement–oriented definitions of realist concepts [13,14,18].

Intervention

This refers to interventions’ implemented activities, strategies, and resources [19], for example, citizen advisory panel meetings or neighborhood organized workshops.

Context

This pertains to the backdrop of an intervention and includes the preexisting organizational structures, cultural norm of the community, the nature and scope of preexisting networks, and geographic location effects [20-22].

Mechanism

This refers to what “triggers” participants to want to participate or not in an intervention. “Mechanism” does not refer to the intentional resources offered or strategies implemented within an intervention. Mechanisms usually relate to cognitive, emotional, and behavioral responses to intervention resources or strategies [20]. Mechanisms are usually hidden, sensitive to variations in context, and generate outcomes [23], for example, citizens feeling more empowered because of learning opportunities.

Outcome

Refers to intended, unintended, or expected intervention outcomes [20], for example, sustainability, quality, and integration of services (macro); citizens’ level of involvement in health and care services (eg, in designing policies; meso); and citizens’ health and well-being outcomes (micro).

Context-mechanism-outcome (CMO)

To understand how certain contextual factors shape or trigger the mechanism, causal links are expressed through “context-mechanism-outcome configurations.” Formulating and refining CMOs is largely how researchers analyze data in realist evaluation as it allows a deeper understanding of which (aspects of) interventions work, for whom, under which circumstances, and to what extent [24]. CMOs are also used to generate or refine program theories, which in turn help shape the final product of an evaluation (eg, recommendations). CMOs are also used to generate or refine program theories.

For this 4-year multiple case study, 6 different regions within the Netherlands were chosen as the research sites (Multimedia Appendix 2). The different contextual factors and the different CE approaches within the regions helped to compare and contrast citizens’ and professionals’ experiences accordingly. For the first research question regarding what CE approaches have been applied and how the approaches have changed over the past 4 years, data from the entire 4-year multiple case study were used. Data sources to answer the first research question included (strategy) documents, completed observation templates (based on stakeholders’ meetings, workshops, and activities), transcripts of (group) interviews with stakeholders, and reference panel workshop discussions [13-16]. For the second research question, which focuses on understanding the experiences of both citizens and professionals that underlie changes in CE approaches, only the most recent round of data collection (T4) was used. Data sources for this last data collection round included (new strategy) documents, (new) interviews with stakeholders, and the last reference panel workshop (T4).

Recruitment and Study Sample

The last data collection round was first based on interviews with professionals (n=7; this included policy makers, project managers, local councilors, and health care professionals) and with citizens involved in organizationally led projects and community-led initiatives (3) in the 6 different regions in the Netherlands (T4; Table 1; Multimedia Appendix 2). For this study, purposive sampling [25] was used to ensure different professionals and citizens from each of the 6 regions were included in the sample. As much as possible, the same citizen and professional participants as in the previous stages of the 4-year multiple case study were approached and interviewed, thus hoping to enable a better view of how participants’ experiences had developed over the years. Professionals and citizens were recruited through the reference panel members’ networks. Almost all approached participants agreed to take part in video or telephone interviews and had signed consent forms, except for participants in region B who only agreed to take part in the reference panel. Ultimately, a total of 10 interviews (1 dyad with a local councilor and a project manager), each lasting approximately 1.5 hours were conducted. Unfortunately owing to the COVID-19 pandemic, researchers were prevented from meeting participants face-to-face and interviews could only be conducted remotely through video or telephone calls. Interviews were conducted until the authors agreed the point of data saturation was reached or when no new themes emerged and when there was a high rate of recurrence of responses [26].

Table 1. Description of the regions and sample size [14].

Region	Region description	Sample size at this stage of the study (T4)
A	• Rural region made up of several smaller municipalities, struggling with aging population and economic decline (number of residents=106,500) • Expected average age at birth and expected average age in good health were 80.9-81.6 years and 47.9 years • Socioeconomic status variable according to different neighborhoods with pockets of deprivation and more affluent areas • Quality of life in neighborhoods varied accordingly. Region with declining and aging population	• 1 interview with policy maker • 1 interview with engaged citizen • 1 (different) policy maker involved in the reference panel
B	• Region with a mix of rural and urban areas, with significant health disparities (number of residents=270,000) • Expected age at birth and expected average age in good health 78.2 to 79.6 years and 45.2 years • Socioeconomic status variable according to different neighborhoods but included more deprived neighborhoods due to the traditional industry in the area having been closed down • Quality of life varied accordingly	• 2 patient and public involvement professionals engaged in reference panel (not interview)
C	• Rural municipality with 13 different villages with favorable unemployment and welfare support rates compared to the national average (number of residents=27,500). • Expected average age at birth and expected age in good health 82.0 to 48.7 years • Socioeconomic status higher than the national average • Quality of life higher than the national average	• 2 interviews with 2 policy makers
D	• Region with a mix of rural and urban areas, with significant health disparities and less favorable unemployment and welfare support rates compared to the national average (number of residents=27.500) • Expected average age at birth and expected average age in good health 80.5 to 84.7 years and 45.2 to 47.1 years • Socioeconomic status variable according to different neighborhoods but includes more deprived neighborhoods due to the traditional industry in the area having been closed down • Quality of life varied accordingly but has an aging population	• 1 interview with a professional • 2 citizens engaged in the reference panel
E	• Rural region made up of 4 municipalities with pockets of health disparities (number of residents=120,000). • Expected average age at birth and expected average age in good health 80.4 to 82.0 years and 48.2 years • Socioeconomic status higher than the national average but with pockets of significant deprivation (differences between the statuses) • Quality of life on average higher than the national average	• 1 dyad interview with 1 policy maker and 1 project manager
F	• Suburban municipality with favorable unemployment and welfare support rates compared to the national average (number of residents=41,000) • Expected average age at birth and expected average age in good health 81.3 years and 45.5 years • Socioeconomic status in line with national average • Quality of life in line with national average	• 1 interview with a public health professional • 1 interview with an engaged citizen • 1 interview with an engaged citizen • Same citizens engaged in the reference panel

Reference Panel

The 4-year multiple case study was conducted in collaboration with a reference panel. The panel consisted of stakeholders involved in developing CE approaches within the 6 different regions, including policy makers; involved citizens; members of patient and public involvement organizations; and experts in the field of public health, health inequalities, and citizen participation. The panel, therefore, helped to ensure that the study addressed stakeholders' questions regarding CE and addressed relevant gaps in the literature. For this data collection round (T4), the panel also helped with the sample selection and recruitment process. Furthermore, the interview findings were discussed with the reference panel to further enrich the results and to ensure that the results had face validity. Multimedia Appendix 2 highlights the participants (n=17) present during the workshop to whom the interview findings of this last study were presented.

For the final study (T4), participants were asked to draw up their own storyboards to reflect on the development of their own CE approaches during web-based or telephone interviews. Owing to the COVID-19 pandemic and to reduce the burden on participants, participants were given the option of drawing or writing on the web-based storyboard themselves or instructing the researchers how to do it for them. The storyboards aimed to enable participants to reflect in a more participative and creative way on their experiences and perceptions regarding the development of CE more broadly. The storyboards highlighted not only the broader experiences but also specifically the enablers and barriers and the support needs going forward [27-29]. Participants were asked to consider the following three questions when drawing up their storyboards: (1) which successful steps they had taken with the development of CE and which enablers they had experienced, (2) which negative results they perceived during the development of CE and barriers they experienced, (3) how these enablers and barriers have changed their CE approaches going forward.

During the second part of the interview, participants were asked to consider their storyboard and imagine they had to advise someone else to successfully develop a CE project. They were asked to note their advice down on notecards. After this, participants were asked to cluster their advice into two groups: (1) what advice they already follow themselves and (2) what advice they struggle to implement themselves. By clustering current enablers and barriers in this way, and discussing the underlying reasons, the study aimed to highlight practical advice to enable stakeholders to implement their new CE approaches [27,28,30]. The interview data were collected between February and May 2020.

After the initial analysis of the interviews and the secondary data, the anonymized results were shared and discussed during a workshop with the reference panel (Multimedia Appendix 2). This further refined and enriched the results. The workshop was held in January 2021.

Finally, to supplement and triangulate the interview data, the authors conducted a document analysis from the field notes taken over the 4 years of study and from the regions' strategy documents.

Data Analysis

To help answer the first research question (regarding the changes in CE approaches), the authors re-examined previous interview transcripts, observation templates, and documents. The authors also classified the CE approaches at "the consultation level"—whereby citizens provide information to organizations, "the communication level"—whereby citizens receive information from organizations, or "the participation level"—whereby citizens are actively engaged in dialogue with organizations and are actively involved in the planning, implementation, or decision-making—of approaches as in line with the findings of the previous studies [14]. To answer the second research question (regarding citizens' and professionals' underlying experiences), the same researchers who had been involved during the entire 4 years of this study applied an inductive and deductive analysis approach to the last round of interviews (T4). Inductively, we searched for (1) changes in CE approaches; (2) citizens' and professionals' experiences in developing and implementing CE, including enablers and barriers; and (3) required support to further develop CE. After this open coding and analysis, the researchers also deductively applied the guiding principles within the coding structure and analysis approach. These guiding principles are as follows: (1) ensure staff provide supportive and facilitative leadership to citizens; (2) foster a safe and trusting environment enabling citizens to provide input; (3) ensure citizens' early involvement; (4) share decision-making and governance control with citizens; (5) acknowledge and address citizens' experiences of power imbalances between citizens and professionals; (6) invest in citizens who feel they lack the skills and confidence to engage; (7) create quick and tangible wins; (8) consider both citizens' and organizations' motivations; and (9) develop a shared vision with clear roles for professionals and citizens, ensuring communities' diversity is reflected within the vision [13,14].

To examine how CE has been developed and changed over the past 4 years and what citizens' and professionals' experiences were underlying these changes in 6 different regions in the Netherlands, the authors constructed context-mechanism-outcome (CMO) configurations within each interview transcript to examine the contextual factors and mechanisms underlying these changes and to investigate participants' experiences. Interviews were thus coded and analyzed using CMOs, which were drafted and analyzed in MAXQDA (VERBI GmbH) by EdW, and discussed by all authors. To aid authors during the data analysis process and to ensure consistency and transparency, the authors applied the same CE-oriented definitions of "interventions," "contexts," "mechanisms," and "outcomes" (Textbox 1). The clustering followed a sequential and iterative process that has been applied in previous studies and described elsewhere [13,14]. CMOs were coded and clustered into (1) changes in CE approaches over the past 4 years, (2) participants' experiences (including enablers and barriers), and (3) required support to further develop and implement CE. The authors discussed the clusters and thematically analyzed, reviewed, and discussed them again. The final draft of the clustered CMOs was shared with all authors to confirm and refine the themes (Multimedia Appendix 3). Afterward, for the deductive analysis, the transcripts and the CMOs were coded and clustered according to the 9 guiding principles.

Ethical Considerations

The study received ethics approval from Tilburg University (reference EC-2017.96). All participants were provided with information letters concerning the study and had time to ask any questions they may have had. It was also made clear that participation was completely voluntary. Afterward, all participants signed forms stating their consent to participate. This is in accordance with Dutch national guidelines.

Results

Overview

The following section will first describe how CE approaches have changed over the past 4 years (Table 2). The study indicates that there are 3 overarching themes regarding the changes in CE approaches. Theme 1: moving away from region-wide approaches to more community-focused approaches. Theme 2: more focus on building relationships with (already-engaged) citizens and community-led initiatives. Theme 3: more focus on practical and tangible health promotion and social cohesion activities instead of on more complex “abstract” programs

Table 2. Cross-sectional summary of community engagement approaches over the past 4 years [14].

Region	Interview round 1: 2016-2017	Interview round 2: 2018-2019	Final interview round: 2020-2021
Region A	• Communication level ◦ Regional web-based community platform highlighting the projects and meetings being organized by the regional health care board. ◦ As part of the web-based community, hoped to develop "an instrument" to increase the region's self-management capacity (not developed). • Consultation level ◦ Regional web-based community platform to create propositions and test these among citizens and health and care organizations. In this way, the regional health and care board hoped to learn key issues facing health and care organizations and the residents (eg, experiences, needs, projects, or meetings). • Participation level ◦ Regional web-based community platform, supported by occasional physical meetings, to enable dialogue between residents, municipalities, health care professionals, clients, schools, and volunteer clubs (eg, sports clubs), businesses, and health and care organizations about how health and care services can become futureproof and maintain its quality and efficiency. Online community aimed at increasing social between engaged or interested residents, organizations, and other stakeholders of the regional health and care system.	• Consultation level ◦ Regional public health organization, commissioned on behalf of one of the region's municipalities, conducted interviews and focus groups with residents to discuss their perceptions and experiences of what it is like to live in that municipality (completed). ◦ Public health organization region A held informal dinner events with older residents to discuss their current and future health and care needs and the sort of local amenities they would like to have available in the municipality (completed). ◦ Regional living room: supports organizations and residents to address urgent health and care issues in the region. "Living rooms" across the province have been set up for residents to investigate such issues together (ongoing but by different organization). • Participation level ◦ Regional web-based community: online platform, which enabled all residents and professionals within the region to share and collect information regarding the region's health care system. The platform also enabled residents to share their ideas of how future health and care services should take shape in the region (disbanded).	• Participation level ◦ Municipality within the region had started a project to improve the living environment of 1 village with the aim of also contributing to the green energy transition in the municipality. The municipality together with the village council had set up the project (completed). ◦ Municipality searching for ways to include citizens (especially older citizens) in the reconfiguration of health and care services within 1 municipality. To date, it had not found a way to involve citizens on the "participation level" (ongoing).

Region	Interview round 1: 2016-2017	Interview round 2: 2018-2019	Final interview round: 2020-2021
Region B	• Communication level • Developed guidelines or how-to guide to stimulate the engagement of the >65 years age group for specific neighborhood projects and development. Guideline was developed through interviews with residents aged >65 years in the region about their engagement experiences (completed). • Participation level • Looking for ways to leverage all the separate existing citizen representative bodies (eg, village councils, client councils, and church councils) that can be leveraged to increase citizen representation on the regional governance level. Currently, these approaches all operate separately from each other and on a more local level. • A retired surgeon and a representative of a regional PPIa organization were members of the regional health care governance board (surgeon no longer involved).	• Communication level • PPI[a] organization freely distributed a magazine to all residents in the region and promoted healthy living and community engagement activities and projects (ongoing). • Participation level • "WeHelpen" web-based platform that enables residents to ask for and provide each other with informal help, from mowing each other's grass to social visits and doing groceries for the less abled (ongoing). • A local resident and a representative of a regional PPI organization were members of the regional health care governance board (resident no longer taking part, PPI representative still present).	• Communication level • PPI organization "educated" citizens on self-management and the concept of positive health, for example, workshops and conferences (ongoing). • Participation level • PPI organization advised health and care organizations on how to involve patients and citizens in their projects (ongoing). • PPI organization provided training to patients on how to be involved (ongoing).
Region C	• Communication level • Using visualizations of broader health and care concept "positive health" to discuss and develop municipal-wide policies and projects with residents and using the visualization as a financial lever for change (only projects highlighting they contribute to the positive health of residents; ongoing). • Looking to develop jargon-free language to engage residents (ongoing). • Participation level • Looking for ways to engage children, young adults, and parents to help develop municipality's youth care policies (ongoing).	• Participation level • Municipality professionals working to establish closer working relationships with residents, local sports clubs, and village council (ongoing). • Municipality was working to establish closer relationships with schools, parents, and students to engage them in the development and improvement of the municipality's youth policy (ongoing). • Involved citizens in the development of integrated local health policy (completed).	• Consultation level • Used interviews to gain insight into low-income residents' experiences and needs regarding low-income support and thus to align low-income policies more to low-income residents' needs (completed).
Region D			

Region	Interview round 1: 2016-2017	Interview round 2: 2018-2019	Final interview round: 2020-2021
	• Communication level • Looking for "tools" to increase citizens' awareness regarding positive health and to engage citizens in projects regarding positive health (completed). • Took part in health care markets to raise awareness for healthy living lifestyles (completed). • Participation level • Started their own nonmandatory client council with the idea that clients within the region can be involved in creating new projects and to share which aspects are important to their own positive health (disbanded). • Considering developing their own "Digipanel" to enable citizens to share their thoughts on policy developments (not developed).	• Consultation level • Conducted patient satisfaction surveys for general practices as part of a new quality improvement system whereby practices will be monitored as to whether they are implementing measures to improve areas highlighted in the survey (in an attempt to make general practices more accountable to the patients; completed and considering running again). • Community-led initiative kicked-off with passing around a "village diary." The volunteers went door-to-door with the diary to ask their neighbors to write something about their village, for example, what they liked about the village and what local amenities they felt were missing. Volunteers then used the diary as the foundation for the community-led initiative (completed). • Communication level • Workshops for residents with the aim of promoting "positive health" (ongoing). • With the aim of setting up better working relationships between a local municipality and the community-led initiatives, a PPI and citizen representative organization held separate workshops with the municipality and with the initiatives to gain insight into how to improve their collaboration. At the end of the learning program, the organization was hoping to have 1 joined workshop (completed). • Participation level • Primary care group's client council (disbanded). • A community-led village initiative was set up when the village's only general practitioner retired. The community-led initiative, had at the time of interviewing, set up a multidisciplinary medical center, a free library and reading nook, a shared neighborhood-allotment, social activities and evenings, and were working to expand the center's remit. • Resident village support worker who maintained close links within their own communities and ensured that the health, care, and living needs of their neighbors were being addressed (whenever possible by village residents themselves and otherwise, the village support worker ensured appropriate support from the municipality was made available; ongoing).	• Participation level • Community-led initiative continued to grow and looked to keep promoting social cohesion and social activities. They especially looked to keep this going during the COVID-19 crisis. Also looking to take on a commissioning role for certain health and care services. • Resident village support worker continued his linking pin role, especially during the COVID-19 crisis.

Region	Interview round 1: 2016-2017	Interview round 2: 2018-2019	Final interview round: 2020-2021
Region E	• Communication level ◦ Several municipalities had conducted a "health scan" with residents to investigate and discuss what key issues they were facing (completed). • Participation level ◦ The biggest insurance companies, local municipalities, and health and care providers had set up a Policyholder Cooperation to ensure policyholders could have a say in which services should be included within the insurance package and could help shape the local health care system. They wanted to provide all policyholders to be able to vote on important decisions and were looking to recruit policyholders to be on the board. ◦ Residents within some of the villages had created some groups to raise awareness for healthy living lifestyles (eg, through walking groups, setting up social meetings, and running events). Municipality is looking for ways to support these groups (ongoing).	• Communication level ◦ Annual policyholder events and workshops promoting positive health (disbanded) ◦ Local municipalities were establishing closer relationships with community-led initiatives and sports clubs with the aim of improving children's and young people's health (ongoing) ◦ A "Self-care for me" website, which enabled local residents to score their own health. The local municipalities were hoping to get local businesses involved to set up "fun challenges" improving residents' health (ongoing). • Participation level ◦ The biggest insurance companies, local municipalities, and health and care providers had set up a Policyholder Cooperation to ensure policyholders could have a say in which services should be included within the insurance package and could help shape the local health care system (disbanded).	• Communication level ◦ Looking to implement 1 contact person at municipalities for community-led initiatives.
Region F	• Participation level ◦ Project initiated by regional public health organization to support low-income families. Parents from these families are involved in the projects highlighting important priorities and activities. Parents are also involved in the implementation of activities (completed). ◦ Community-led initiative set up to promote the positive health in the community by organizing health promotion activities (eg, benches along walking paths; ongoing).	• Participation level ◦ Community-led initiative that designs and implements health promotion projects, activities, and workshops (eg, implementing benches along walking paths, workshops regarding positive health, and developing health promotion apps; nearly disbanded, but continued).	• Participation level ◦ Community-led initiative continued but with different citizens involved at the governance level. In addition, the community-led initiative was also being supported by a public health professional (ongoing).

[a] PPI: patient and public involvement.

Following on, the paper will also examine participants' underlying experiences throughout the CE process (including enabling and constraining experiences and support needs to further develop CE). The study indicated another 4 overarching themes related to these experiences:

- Theme 4: lack of investment in the engagement environment
- Theme 5: need for facilitative leadership
- Theme 6: need for a clear and shared vision underscoring the importance of CE
- Theme 7: misalignment between citizens' and professionals' perspectives and motivations for CE

Throughout this section, examples of CMOs will underpin the results, and further CMO examples can be found in Multimedia Appendix 3.

Changes in Applied CE Approaches

Overview

Within all 6 regions, there had been changes within both the organizationally led CE projects and community-led initiatives. Table 2 shows a summary of CE approaches that have been implemented over the past 4 years within the 6 regions to improve communities' health and well-being and to improve the health and care systems. This summary is not an exhaustive list, and the final column is focused on newly implemented CE approaches compared to previous years. Table 2 highlights that after 4 years, most approaches and underlying activities could still be classified at the "consultation," or "communication" level and that some "participation level" approaches within the regions had been disbanded (ie, the web-based community platform in region A, the client council in region D, and the policyholder cooperation in region E). Furthermore, although this list is not exhaustive, the results as shown in Table 2 seem to underscore that the implementation of CE in the regions is in development and that most CE initiatives are now small scale. Though some of the regions were trying to address this, for example, the patient and public involvement organization in region B had been trying to embed CE within organizational cultures through training, and the organization in region A had been trying to build relationships with engaged citizens.

Theme 1: From Regional Focus to Community Focus

Table 2 also highlights that the 6 regions have adapted their CE approaches over the past 4 years. First, some regions had shifted their CE approaches from having a more regional focus to a community-based focus. For example, the policyholder cooperation in region E had been disbanded as its focus on complicated, regional issues such as the regional economy and the viability of the hospital was seen as too far removed from "average" citizens' lived experiences. That is why, at the time of interviewing, the regional board was looking for ways to take a more community-focused approach by involving and facilitating citizens in practical health promotion activities aimed at improving the health and social cohesion of communities, thus hoping to connect more with the lived experiences of citizens and communities.

Theme 2: Building Relationships With (Already Engaged) Citizens

Second, and likely relatedly, some regions were trying to change their CE approaches to focus more on building relationships with communities and engaged citizens. For example, policy makers in region A have noticed a slow shift in mindset within municipalities. Where originally municipalities thought they knew what was best for communities, policy makers (through positive experiences of involving citizens in developing and renewing social spaces) are seeing the benefit of building relationships with (engaged) citizens and communities and involving citizens in the design phases of projects, instead of presenting finalized plans to citizens.

Theme 3: Shift to More Practical and Tangible Projects

Third, and again likely relatedly, most of the regions have started focusing more on practical, tangible CE projects with activities aimed at improving the health and social cohesion of communities (eg, placing benches in parks to encourage older residents to go for walks, walking groups, and living library events; Table 2). For example, the citizens within the community-led initiative in region F had organized many smaller-scale practical projects and events as the tangible aspects of health promotion and social cohesion activities were seen as more motivating than, for example, the development of a web-based app for individual use:

> *It's not for nothing that things [CE] start in the villages...It's got to do with the small scale that makes people want to self-organise and maybe it helps with the collaboration, it's]always easier with knowing people and after that maybe there's the right energy whereby people want to do stuff [get engaged/self-organise]. So that smaller scale, always has something to do with it.* [Region F, policy maker, male]

Citizens' and Professionals' Experiences

Underlying the nature of changes in the CE approaches, as described in the previous section, were citizens' and professionals' experiences (Multimedia Appendix 3). Overall, citizens and professionals had experienced many of the previous approaches as too far removed from citizens' lived experiences to be successful and felt that further improvements were necessary to further develop CE.

Theme 4: Lack of Engagement Environment

First, and most prominently, both citizens and professionals had experienced a lack of investment in, and a need to improve, the engagement environment. This lack of investment prevented CE from being fully embedded within organizational cultures. Both citizens and professionals experienced the need for further investments, that is, in the form of resources and funding for activities and initiatives, staff with CE skills and know-how, and space and time to build relationships with a wider range of citizens and to innovate CE approaches (Multimedia Appendix 3). The study indicated that participants experienced the need for 2 different types of investment. The first type was a "softer," more cultural type of investment. For example, in regions A and C, the organizational culture used to be that the municipalities decided everything, but because of laws such as the Participation Act (2015) and the Living Environment Act (2021), they have been forced to review the role citizens have (context). Furthermore, the newer generation of policy makers has been trained to see the value of CE and has experienced the positives of involving citizens in projects and policy making (context). Because of this, policy makers are increasingly seeing and believing the value of CE and at the same time experiencing that this belief is not supported by the wider municipality or their management (mechanism). They felt this slows down the cultural change required within organizations to enable successful CE approaches (outcome). At the same time, participants also described the more "tangible" types of investments required to enable the further development of CE approaches. For example, the community-led initiative in region F was able to organize health promotion and social cohesion activities successfully, despite the fact that organizations had not provided long-term financial support (context) and despite a drop in the number of volunteers (context). The volunteers experienced the organization of such activities as draining without support as it cost them a lot of time and energy (mechanism). This made it difficult for the community-led initiative to ensure they could keep organizing such activities in the long term (outcome). While one of the organizations in region D highlighted the need to develop CE skills and know-how. For example, one of the organizations had applied for a subsidy to involve organizations from the cultural or creative sector to develop new and innovative ways to involve citizens within the Positive Health Network (context). Because when health and care organizations think about CE, they end up involving citizens in the traditional (more limited) way (mechanism). Unfortunately, the subsidy was rejected, which meant that the search for new innovative ways to involve citizens remains (outcome):

> *I think I've been lucky in certain ways, that our conservative local councillor left and a new councillor took his place. And that new councillor said to me: "why don't you just try something." If I'd still had a councillor who kept saying: "no, that's not how we do it." Then I wouldn't have had the space to involve the citizens like that.* [Region A, policy maker, male]

> *My story, what are the blockades? I see that in the community and for the community-led initiative a lot of balloons [projects] are raised. Sometimes with a small pot of money. But when that pot of money is emptied, the balloons are popped. There's too little space for embedding things.* [Region F, citizen, female]

Theme 5: Need for Facilitative Leadership From Organizations

Second, and relatedly, both citizens and professionals had experienced a lack of, and need to provide and receive, facilitative leadership. Furthermore, both citizens and professionals were also trying to develop new leadership. For example, the community-led initiative in region F was launched 5 years ago with a local health care professional in the lead but without a clear governance or leadership structure (context). Initially, 4 board members were selected but most were health care professionals within the community as well (and were thought to have vested interests removed from "regular citizens"; context). Citizens felt these members were unapproachable and the health care professional who had launched the initiative was not motivated to take up the leadership role in the long term (mechanism). This lack of clear leadership made it difficult for the engaged citizens to know what the decision-making process was or who to turn to with their project ideas (outcome). That is why when the members of the old governance board left, the new members (all citizens) decided to be approachable and discuss and align everyone's goals clearly. An example of how professionals were experiencing CE was expressed by policy makers in region C. The negative experiences of involving citizens when the municipality had already developed the plan meant they started searching for a new approach to CE (context). The new approach is based on sharing the problem and issues the municipality is trying to address with communities with the aim of improving the collaboration between engaged citizens and organizations (context). Sharing the problem fosters commitment among engaged citizens and organizations, motivating them to consider potential solutions (mechanism). Through this new, more facilitative approach, everyone (municipality, engaged citizens, and organizations) has gained more understanding of each other (outcome):

> *I think you need leadership and guts, you have to be able to reach out to citizens and to show that you can let go [of control]. Several of our administrators find that difficult. They're used to being in charge and in control. But actually, here we say "don't be in change or in control, but ask questions. Create and connect. That's a totally different way of providing leadership."* [Region E, local councilor, male]

> *I think that you just have to talk to each other, what you want from the initiative, as professional and as volunteer. You have to create the atmosphere where such things can be talked about, and both sides have to listen...that requires that you make yourself vulnerable thus open to the ideas, suggestions and comments of others.* [Region F, citizen, male]

Theme 6: Need for a Clear and Shared Vision Underscoring the Importance of CE

Third, both citizens and professionals continued to seek and emphasize the need for the implementation of a clear and shared vision underscoring the importance of CE. Policy makers in region A highlighted that old habits of policy makers of not sharing control with citizens die hard, especially as there is not a clear or shared vision for the relevance of CE within the municipality (context). The lack of shared vision has prevented policy makers from experiencing and seeing CE as part of their "day-to-day" business (mechanism). That is why the required culture change to embed CE activities within organizations and on a regional level successfully has taken a long time (outcome). Some policy makers speculated that this lack of CE vision is because municipalities only involve citizens (through the bare minimum effort) because national policies such as the Participation Act (2015) have dictated they do so, instead of CE being part of a wider belief in how policy making should also be based on CE. This need for a shared vision was also experienced by the community-led initiative in region F. The remaining volunteers and the support worker started looking for what their next steps and new aims should be after the old governance board had left and the initiative was nearly disbanded (context). As the community-led initiative had nearly collapsed, it created a sense of urgency and commitment with the remaining volunteers to continue the initiative (mechanism). At the same time, they experienced it as difficult to rise above the failings and negative experiences (to "let go off the old ballast"; mechanism). This meant that they had not yet succeeded in developing a new vision and that they were still searching for a vision that could act as the connecting thread for the initiative (outcome):

> *It's also about the colleagues...It matters how the process is handled and by who. There's quite a big differences in that. We don't have one clear view, vision or policy of "it's in this way that we do CE or CE is always important in this phase of a project." Of course CE is not a one-size-fits-all approach, but unknown makes unloved, I think. There's so many*

> *people whereby CE is not part of the process.* [Region A, policy maker, male]

Theme 7: Misalignment Between Citizens' and Professionals' Perspectives and Motivations for CE

Fourth, and related to the lack of a shared vision, citizens and professionals had experienced a misalignment between citizens' and professionals' perspectives and motivations for CE and thus had different experiences throughout the process of CE. Citizens and professionals had experienced this lack of alignment in both organizationally led CE approaches and community-led initiatives. The citizens stated that they felt that professionals were too outcomes focused. For example, the community-led initiative in region F was in transition and was searching for which aims and activities should be continued and taken up (context). Engaged citizens and professionals had differing goals and ambitions (context). Professionals were more outcome focused, which citizens felt like made the initiative aim too high (mechanism). Citizens meanwhile were engaged because of their intrinsic motivations and because they wanted to increase their social connection within the community (mechanism). Such differences in aims should be openly discussed (outcome). Professionals in region D speculated what was underlying this misalignment. With CE approaches, everyone (citizens, professionals, and volunteers) involved has their own language, interests, and scope (context). Citizens often think and operate "on a smaller," "community-based" level (context). Professionals become irritated because, from their perspectives and aims, they feel change is not happening fast enough (mechanism). The professionals felt this showed that motivations between citizens and professionals were not aligned and that resource investments (especially time and space) should be created to discuss these differences and to address the motivations and interests of citizens more specifically (outcome). This is comparable with citizens' experiences who had also underscored the importance of creating a transparent dialogue between citizens and professionals to align the motivations:

> *Differences in interests...You have to have a shared goal.* [Region F, citizen, female]

Reference Panel Deliberations

Panel members recognized the findings and stated they had also found it easier to involve citizens with local approaches, which were more aligned with citizens' lived experiences. Furthermore, both citizens and professionals within the panel also underscored their search for new collaborative forms of working between citizens and organizations and how to best involve citizens in the decision-making process. For example, they were searching for ways to enable some citizens to be involved in the long term (mostly in governance structures) and at the same time allow other citizens to be involved in the short term (without too much investment of their time and effort). The panel also discussed important enablers to work toward these new ways of collaborative working for CE. For example, both citizens and professionals within the panel highlighted that one of the most important enablers was having leadership who can create support and garner interest for CE. The professionals particularly highlighted that such leadership would help to change the culture within organizations, for example, ensuring citizens are not involved because this has been decreed top-down (eg, through the Participation Act 2015 and Living Environment Act 2021) but because there is a sincere belief and hope within the organization to ensure services and policies are better aligned to citizens' and communities' needs and experiences. They also underscored the significant importance of a clear vision and corresponding plan for CE, for example, who should be involved, when, where, and about which topics. Finally, both citizens and professionals within the panel stated the importance of long-term investments to properly embed CE within their organizations or their neighborhoods. Citizens especially underscored their need to have organizations (health and care organizations and local and regional governments) invest financially within their initiatives in the longer term, whereas professionals stated that they needed the time and space to be able to innovate CE—not merely through financial investments but by being given more time and space to involve citizens and to experiment with new CE approaches and activities.

Discussion

Principal Findings

Using the RE approach, this multiple case study investigated how CE approaches in 6 different Dutch regions have changed over the past 4 years. It also investigated citizens' and professionals' underlying experiences impacting these changes. The results have shown that CE approaches are changing from having a region-wide focus to a more community-based focus, to building relationships with engaged citizens, and to focusing more on practical health promotion activities (rather than "abstract" topics such as the redesign of regional hospitals). The results of this study also suggest that CE (including the underlying understanding of how to develop and implement CE successfully) still has not been embedded within organizational cultures. This has arguably meant that the remaining CE approaches seem to be operating on a smaller scale (instead of using a mix of smaller scale and more regional approaches; Table 2) and that professionals and citizens required further investments in the engagement environment, the need for facilitative leadership, and the need for a shared vision on how to act upon CE based on aligned motivations.

Deductively analyzing the results showed if and how the guiding principles [13,14] (described in the *Methods* section) were being considered and applied within the 6 regions. The guiding principle that professionals were particularly concerned with was principle 1, which pertained to leadership. Professionals were aware that they needed to develop their facilitative leadership toward citizens and also required more supportive leadership from their organizations to better embed CE within projects and organizations. Broadly speaking, although many of the interviewed professionals observed and believed in the benefits of CE, they felt that their management largely did not. They felt this prevented the proper embedding of CE within organizational cultures and also hindered them from involving citizens as early as possible (principle 3) and often prevented them from sharing decision-making control with citizens (principle 4). Furthermore, citizens within this study often discussed the importance of open and transparent dialogue between citizens and professionals regarding their motivations and aims for CE approaches (principle 8). As Beresford [10] suggests, CE in health has been shaped by the political agendas of (national and local) politicians, policy makers, and professionals, and Willems [31] has shown that efficiency and effectiveness are important underlying CE aims for organizations, which has made it harder for organizations to deploy resources to improve and develop CE. Similar to previous studies, this study has shown that CE approaches (only) focused on organizational (regional and more abstract) aims largely failed to motivate citizens to become involved [11,13,14,32]. By openly discussing these aims and providing the space and leadership to communities to share their aims, CE approaches can hopefully better address citizens' aims as well.

Relatedly, an important principle that participants had recognized and experienced as an important barrier but had not yet actively invested in was principle 9 regarding the development of a shared vision for CE. This may well be related to the experienced lack of supportive leadership and dialogue (between citizens and professionals), as described above. For example, citizens highlighted the importance of articulating achievable goals and highlighted the importance of transparently discussing any differences in aims. While professionals had experienced a lack of time to formulate clear and achievable goals for CE projects—perhaps because management felt like CE has been forced upon them by national policies like the Participation Act (2015) and the Living Environment Act (2021) as some professionals within this study had theorized.

Relatedly, one of the reasons for this lack of transparent dialogue between citizens and professionals regarding a CE vision could be the fact that both citizens and professionals described a lack of investment in the engagement environment as an important barrier. Such findings are in line with previous studies, such as the study by Holley [14], which has shown that many current engagement environments are built for efficiency, rather than, for example, building relationships with not-yet engaged or harder-to-reach groups. Such an engagement environment often results in a loss of influence for citizens, especially those who are socioeconomically disadvantaged [14]. This finding is further underscored by the fact that very few of this study's participants had discussed experiences regarding the addressing of power imbalances (principle 5) or had discussed experiences regarding the need to develop safe and trusting environments for citizens to enable citizens' involvement (principle 2). This study's participants highlighted the importance of properly embedding CE, for example, by making CE a structural and routine part of projects and policy development; by providing citizens and professionals with the time and space to develop creative engagement approaches; by providing community-led initiatives with long-term financial support; and by helping professionals to develop CE skills and know-how, for example, by providing training and guidelines.

This lack of investment in the engagement environment, leadership, and shared vision (based on aligned citizens' and professionals' motivations) may well have led to organizations in the 6 regions choosing to shift from a regional approach to a community-based focus and shifting their focus from more complex regional topics to more tangible projects, instead of trying to bolster and improve the original approaches (through such investments) and at the same time also build relationships with communities and supporting more tangible projects. Arguably the different types of CE approaches (ie, regional, focused on complex issues such as the reconfiguration of health care services, community-based and focused on building relationships with communities, and focused on health promotion activities) should be applied alongside each other. Building relationships with citizens will also help to ensure CE approaches are better aligned with citizens' lived experiences and motivations. Prior literature indicates that citizens exhibit diverse interests and preferences for involvement, ranging from engaging in practical activities and providing peer support to participating in policy-making processes to ensure that policies better reflect their lived experiences [32,33]. To enhance citizens' more active participation in the development and delivery of health and care services, an investment is required to develop various types of approaches beyond the currently defined roles [16,17].

Despite the fact that this study indicates a systemic lack of investment in CE, this study also offers hopeful signs. First, Table 2 only shows the CE approaches that have been implemented and does not show potentially positive underlying (cultural) changes. For example, 1 citizen in region A described that they felt more collaboration was taking place between organizations and client councils. Furthermore, professionals within this study suggest that newer policy makers and professionals have been trained to believe in the value of CE and want to investigate new and more collaborative ways of working with communities and citizens. Not only has this newer generation been trained to believe in citizens' and communities' rights to be involved but also their CE experiences (with more local approaches) have shown them the benefits of involving citizens, for example, ensuring that policies are more aligned with citizens' own experiences and needs [15]. Furthermore, this study's findings also indicate ways to improve the engagement environment and to further develop CE. CE should be supported by a flexible system rather than bureaucratic systems and processes, which should be underpinned by a variety of creative CE approaches, sufficient resources (ie, know-how, time, and finances), and an organizational culture that maintains CE as "business as usual" for all projects. These findings suggest that a new guiding principle should be formulated regarding the different ways in which a supportive engagement environment can be implemented. More research is required to properly formulate this new guiding principle, though the results of this study show that such a principle should underline 3 different but interrelated aspects of CE. A supportive engagement environment requires (1) structural investment, including staff with CE know-how and skills, finances, and time and space to develop creative CE approaches; (2) facilitative leadership within and for communities and organizations; and (3) a clear and shared CE vision (based on alignment of citizens' and professionals' motivations). There is a circularity to the 3 aspects that makes it harder for organizations to know where to start when (further) developing their CE approaches. For example, leadership and an investment of resources may be required to create a shared vision for CE. However, a shared vision is also required to leverage sufficient resources and leadership at different levels within organizations and communities. Ultimately, this study suggests that without such investments, it will be challenging to fully integrate CE into organizational cultures and to transition CE from being perceived merely as a beneficial addition to health and care systems to being recognized as essential for enhancing transparency, accountability, equity, and person-centeredness within those systems.

Limitations

One limitation is the relatively small number of participants, especially engaged citizens, for the primary data source (T4). Unfortunately, the first COVID-19 wave may have prevented more participants, working and volunteering in the health and care system, from taking part. This limitation was mitigated by the fact that this study tracked the CE approaches being implemented for 4 years and by the reference panel's workshop discussions as this confirmed the validity and applicability of our interview findings in other contexts, thus further validating and enriching the interview findings. Another COVID-19–related limitation was the fact that interviews had to take place on the web or over the telephone; this prevented participants from fully reviewing their storyboards and areas for further development of CE.

Future Studies

This case study indicates the importance of a supportive engagement environment created by structural investments, including staff with know-how and skills, finances, and space to develop creative CE approaches; facilitative leadership within and for communities and organizations; and a clear and shared overarching vision for CE based on the alignment of citizens' and professionals' motivations. However, future studies are required to further unpack these aspects of CE and to highlight how to practically apply these aspects for the improvement of CE. For example, future studies could focus on how to create a transparent dialogue between communities and organizations to align communities' and organizations' aims for CE. Future studies could also examine different (and more practical) ways in which the engagement environment can be improved and supported by organizational management and regional and national governments.

Conclusions

This study investigated how CE approaches had changed over the past 4 years in 6 different regions in the Netherlands. It examined citizens' and professionals' experiences underlying these changes, including the barriers, enablers, and support needs. The study showed three overarching themes along which CE had been adapted: (1) moving away from regional CE approaches; (2) focusing on building relationships with already-engaged citizens and communities; and (3) focusing on practical, tangible health promotion activities (instead of more complex "abstract" programs). Furthermore, participants had experienced (1) a lack of a supportive engagement environment, (2) a lack of facilitative leadership, (3) a lack of a shared vision for CE, and (4) a misalignment in citizens' and professionals' aims. The study suggests that citizens and professionals perceive and experience CE differently and that they have different priorities for CE. To enable and support the further development of CE approaches, both citizens and professionals experienced the need for investments in the engagement environment (eg, through more structural organizational support, time, and space to innovate and improve CE approaches and to embed CE within organizational cultures), for more facilitative leadership, the need to develop a shared vision, and the alignment of citizens' and professionals' motivations. Such investments and changes to organizational cultures, structures, and processes would enable organizations to be more open and sensitive to the different ways in which different citizens want to be involved. Without such further investments and leadership, CE will remain seemingly smaller scale and piecemeal, instead of being seen as crucial to restoring accountability and person-centeredness to health and care systems.

Data Availability

All data generated and analyzed during this study are included in the published article and supplementary information files. Templates used for data extraction and analysis are available from the corresponding author on reasonable request.

Disclaimer

Consent for publication was obtained from all the study participants. Participants were provided with information letters and were also verbally informed of the fact that any information they shared would be treated completely confidentiality and anonymously (eg, without any person-identifiable information). This is in accordance with the Dutch national guidelines.

Authors' Contributions

EdW participated in conceptualization, methodology, formal analysis, investigation, writing the original draft, and reviewing and editing the final draft. HD participated in conceptualization, methodology, reviewing and editing the final draft, and supervision. KL participated in conceptualization and review and editing. CB participated in conceptualization, methodology, reviewing and editing the draft, supervision, and funding acquisition.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Realist evaluation standard reporting form.
[DOCX File , 33 KB - jopm_v16i1e47500_app1.docx]

Multimedia Appendix 2
Reference panel participants’ description.
[DOCX File , 27 KB - jopm_v16i1e47500_app2.docx]

Multimedia Appendix 3
Summary of the context-mechanism-outcomes underpinning themes.
[DOCX File , 56 KB - jopm_v16i1e47500_app3.docx]

References

1. Carman KL, Dardess P, Maurer M, Sofaer S, Adams K, Bechtel C, et al. Patient and family engagement: a framework for understanding the elements and developing interventions and policies. Health Aff (Millwood) 2013 Feb;32(2):223-231. [doi: 10.1377/hlthaff.2012.1133] [Medline: 23381514]
2. O'Mara-Eves A, Brunton G, McDaid D, Oliver S, Kavanagh J, Jamal F, et al. Community engagement to reduce inequalities in health: a systematic review, meta-analysis and economic analysis. NIHR Journals Library. 2013. URL: https://www.ncbi.nlm.nih.gov/books/NBK262817/ [accessed 2024-04-05]
3. Barnes M, Knops A, Newman J, Sullivan H. Recent research: The micro-politics of deliberation: case studies in public participation. Contemp Polit 2004 Jun;10(2):93-110. [doi: 10.1080/13569770042000278756]
4. Bruni RA, Laupacis A, Martin DK, University of Toronto Priority Setting in Health Care Research Group. Public engagement in setting priorities in health care. CMAJ 2008 Jul 01;179(1):15-18 [FREE Full text] [doi: 10.1503/cmaj.071656] [Medline: 18591516]
5. Fung A. Putting the public back into governance: the challenges of citizen participation and its future. Public Adm Rev 2015 Feb 25;75(4):513-522. [doi: 10.1111/puar.12361]
6. Glimmerveen L, Nies H, Ybema S. Citizens as active participants in integrated care: challenging the field's dominant paradigms. Int J Integr Care 2019 Mar 14;19(1):6 [FREE Full text] [doi: 10.5334/ijic.4202] [Medline: 30881264]
7. Tenbensel T. Virtual special issue introduction: public participation in health policy in high income countries--a review of why, who, what, which, and where? Soc Sci Med 2010 Nov;71(9):1537-1540. [doi: 10.1016/j.socscimed.2010.08.005] [Medline: 20869799]
8. Ocloo J, Matthews R. From tokenism to empowerment: progressing patient and public involvement in healthcare improvement. BMJ Qual Saf 2016 Aug;25(8):626-632 [FREE Full text] [doi: 10.1136/bmjqs-2015-004839] [Medline: 26993640]
9. Rowe G, Frewer LJ. A typology of public engagement mechanisms. Sci Technol Hum Val 2016 Aug 18;30(2):251-290. [doi: 10.1177/0162243904271724]
10. Beresford P. Public participation in health and social care: exploring the co-production of knowledge. Front Sociol 2019 Jan 4;3:41. [doi: 10.3389/fsoc.2018.00041]
11. Cooke B, Kothari U. Participation: The New Tyranny?. New York, NY: Bloomsbury Publishers; 2001.
12. Boivin A, Lehoux P, Burgers J, Grol R. What are the key ingredients for effective public involvement in health care improvement and policy decisions? A randomized trial process evaluation. Milbank Q 2014 Jun 03;92(2):319-350 [FREE Full text] [doi: 10.1111/1468-0009.12060] [Medline: 24890250]
13. De Weger E, Van Vooren N, Luijkx KG, Baan CA, Drewes HW. Achieving successful community engagement: a rapid realist review. BMC Health Serv Res 2018 Apr 13;18(1):285 [FREE Full text] [doi: 10.1186/s12913-018-3090-1] [Medline: 29653537]
14. De Weger E, Van Vooren NJ, Drewes HW, Luijkx KG, Baan CA. Searching for new community engagement approaches in the Netherlands: a realist qualitative study. BMC Public Health 2020 Apr 16;20(1):508 [FREE Full text] [doi: 10.1186/s12889-020-08616-6] [Medline: 32299398]
15. Holley K. The principles for equitable and inclusive civic engagement: a guide to transformative change. The Kirwan Institute for the Study of Race and Ethnicity. 2016. URL: https://kirwaninstitute.osu.edu/sites/default/files/documents/ki-civic-engagement.pdf [accessed 2024-04-05]
16. De Weger E, Drewes HW, Van Vooren NJ, Luijkx KG, Baan CA. Engaging citizens in local health policymaking. A realist explorative case-study. PLoS One 2022 Mar 24;17(3):e0265404 [FREE Full text] [doi: 10.1371/journal.pone.0265404] [Medline: 35324975]
17. de Weger E. A Work in Progress: Successfully Engaging Communities for Health and Wellbeing. A Realist Evaluation. Enschede, the Netherlands: Ipskamp Printing; 2022.
18. Wong G, Westhorp G, Manzano A, Greenhalgh J, Jagosh J, Greenhalgh T. RAMESES II reporting standards for realist evaluations. BMC Med 2016 Jun 24;14(1):96 [FREE Full text] [doi: 10.1186/s12916-016-0643-1] [Medline: 27342217]

19. Pawson R, Tilley N. Realistic Evaluation. London, UK: Sage Publications; 1997.
20. Lacouture A, Breton E, Guichard A, Ridde V. The concept of mechanism from a realist approach: a scoping review to facilitate its operationalization in public health program evaluation. Implement Sci 2015 Oct 30;10(1):153 [FREE Full text] [doi: 10.1186/s13012-015-0345-7] [Medline: 26519291]
21. Jagosh J, Macaulay AC, Pluye P, Salsberg J, Bush PL, Henderson J, et al. Uncovering the benefits of participatory research: implications of a realist review for health research and practice. Milbank Q 2012 Jun 18;90(2):311-346 [FREE Full text] [doi: 10.1111/j.1468-0009.2012.00665.x] [Medline: 22709390]
22. Macfarlane F, Greenhalgh T, Humphrey C, Hughes J, Butler C, Pawson R. A new workforce in the making? A case study of strategic human resource management in a whole-system change effort in healthcare. J Health Organ Manag 2011;25(1):55-72. [doi: 10.1108/14777261111116824] [Medline: 21542462]
23. Jagosh J, Bush PL, Salsberg J, Macaulay AC, Greenhalgh T, Wong G, et al. A realist evaluation of community-based participatory research: partnership synergy, trust building and related ripple effects. BMC Public Health 2015 Jul 30;15(1):725 [FREE Full text] [doi: 10.1186/s12889-015-1949-1] [Medline: 26223523]
24. Astbury B, Leeuw FL. Unpacking black boxes: mechanisms and theory building in evaluation. Am J Eval 2010 Sep 13;31(3):363-381. [doi: 10.1177/1098214010371972]
25. RAMESES project. URL: https://www.ramesesproject.org/ [accessed 2024-04-05]
26. Mays N, Pope C. Rigour and qualitative research. BMJ 1995 Jul 08;311(6997):109-112 [FREE Full text] [doi: 10.1136/bmj.311.6997.109] [Medline: 7613363]
27. Warwick-Booth L, Cross R. Using storyboards in participatory research. Nurse Res 2016 Jan 22;23(3):8-12. [doi: 10.7748/nr.23.3.8.s3] [Medline: 26793981]
28. Lupton D. Doing fieldwork in a pandemic (crowd-sourced document). Google Docs. URL: https://docs.google.com/document/d/1clGjGABB2h2qbduTgfqribHmog9B6P0NvMgVuiHZCl8/edit#heading=h.ze8ug1cqk5lo [accessed 2024-04-05]
29. Colucci E. "Focus groups can be fun": the use of activity-oriented questions in focus group discussions. Qual Health Res 2007 Dec 01;17(10):1422-1433. [doi: 10.1177/1049732307308129] [Medline: 18000081]
30. Giacomini MK, Cook DJ. Users' guides to the medical literature: XXIII. Qualitative research in health care A. Are the results of the study valid? Evidence-based medicine working group. JAMA 2000 Jul 19;284(3):357-362. [doi: 10.1001/jama.284.3.357] [Medline: 10891968]
31. Willems W. Countering the tragedy of the health care commons by exnovation: bringing unexpected problems and solutions into view. Sustainability 2021 Nov 26;13(23):13082. [doi: 10.3390/su132313082]
32. De Weger E, Baan C, Bos C, Luijkx K, Drewes H. 'They need to ask me first'. Community engagement with low-income citizens. A realist qualitative case-study. Health Expect 2022 Apr 15;25(2):684-696 [FREE Full text] [doi: 10.1111/hex.13415] [Medline: 35032414]
33. Schmidthuber L, Piller F, Bogers M, Hilgers D. Citizen participation in public administration: investigating open government for social innovation. R D Manag 2019 Mar 11;49(3):343-355. [doi: 10.1111/radm.12365]

Abbreviations

CE: community engagement
CMO: context-mechanism-outcome
RE: realist evaluation

Edited by M Hudson; submitted 22.03.23; peer-reviewed by AB Kennedy, N Mungoli; comments to author 07.05.23; revised version received 30.10.23; accepted 12.11.23; published 15.05.24.

Please cite as:
de Weger E, Drewes H, Luijkx K, Baan C
Tracking the Development of Community Engagement Over Time: Realist Qualitative Study
J Particip Med 2024;16:e47500
URL: https://jopm.jmir.org/2024/1/e47500
doi:10.2196/47500
PMID:38748458

Original Paper

Assessing the Quality of an Online Democratic Deliberation on COVID-19 Pandemic Triage Protocols for Access to Critical Care in an Extreme Pandemic Context: Mixed Methods Study

Claudia Lucrecia Calderon Ramirez[1], MSc, MD; Yanick Farmer[2], PhD; James Downar[3], MHSc, MD; Andrea Frolic[4], BA, MA, PhD; Lucie Opatrny[5], MSc, MHCM, MD; Diane Poirier[6], MSc, MD; Gina Bravo[7], PhD; Audrey L'Espérance[8], PhD; Nathalie Gaucher[9], MD, PhD; Antoine Payot[1], MD, PhD; Joseph Dahine[1], MSc, MD; Peter Tanuseputro[10], HBsc, MHS, MD; Louis-Martin Rousseau[11], BSc, PhD; Vincent Dumez[1], MSc; Annie Descôteaux[1], MEd; Clara Dallaire[1], MEd; Karell Laporte[1], BSN; Marie-Eve Bouthillier[1], PhD

[1]Université de Montréal, Montréal, QC, Canada
[2]Université du Québec à Montréal, Montréal, QC, Canada
[3]Division of Palliative Care, Department of Medicine, University of Ottawa, Ottawa, ON, Canada
[4]Hamilton Health Sciences, Hamilton, ON, Canada
[5]McGill University Health Centre, Montréal, QC, Canada
[6]CIUSSS du Centre-Sud-de-l‘Île-de-Montréal, Montréal, QC, Canada
[7]Université de Sherbrooke, Sherbrooke, QC, Canada
[8]École Nationale d'Administration Publique (ENAP), Montréal, QC, Canada
[9]Centre Hospitalier Universitaire Sainte-Justine, Université de Montréal, Montréal, QC, Canada
[10]Department of Family Medicine and Primary Care, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Hong Kong SAR, China
[11]Polytechnique Montréal, Montreal, QC, Canada

Corresponding Author:
Marie-Eve Bouthillier, PhD
Université de Montréal
2900 Bd Édouard-Montpetit
Montréal, QC, H3T 1J4
Canada
Phone: 1 (450) 668 1010 ext 24228
Email: marie-eve.bouthillier@umontreal.ca

Abstract

Background: Online democratic deliberation (ODD) may foster public engagement in new health strategies by providing opportunities for knowledge exchange between experts, policy makers, and the public. It can favor decision-making by generating new points of view and solutions to existing problems. Deliberation experts recommend gathering feedback from participants to optimize future implementation. However, this online modality has not been frequently evaluated.

Objective: This study aims to (1) assess the quality of an ODD held in Quebec and Ontario, Canada, on the topic of COVID-19 triage protocols for access to critical care in an extreme pandemic context and (2) determine its transformative aspect according to the perceptions of participants.

Methods: We conducted a simultaneous ODD in Quebec and Ontario on May 28 and June 4, 2022, with a diversified target audience not working in the health care system. We used a thematic analysis for the transcripts of the deliberation and the written comments of the participants related to the quality of the process. Participants responded to a postdeliberation questionnaire to assess the quality of the ODD and identify changes in their perspectives on COVID-19 pandemic triage protocols after the deliberation exercise. Descriptive statistics were used. An index was calculated to determine equality of participation.

Results: The ODD involved 47 diverse participants from the public (n=20, 43% from Quebec and n=27, 57% from Ontario). Five themes emerged: (1) process appreciation, (2) learning experience, (3) reflecting on the common good, (4) technological aspects, and (5) transformative aspects. A total of 46 participants responded to the questionnaire. Participants considered the quality of the ODD satisfactory in terms of process, information shared, reasoning, and videoconferencing. A total of 4 (80%)

of 5 participants reported at least 1 change of perspective on some of the criteria and values discussed. Most participants reported that the online modality was accessible and user-friendly. We found low polarization when calculating equal participation. Improvements identified were measures to replace participants when unable to connect and optimization of time during discussions.

Conclusions: Overall, the participants perceived the quality of ODD as satisfactory. Some participants self-reported a change of opinion after deliberation. The online modality may be an acceptable alternative for democratic deliberation but with some organizational adaptations.

(J Particip Med 2024;16:e54841) doi:10.2196/54841

KEYWORDS

quality assessment; online democratic deliberation; COVID-19 triage or prioritization; critical care; clinical ethics

Introduction

Democratic Deliberation

Democratic deliberation (DD) is a citizen participation and engagement method that is increasingly being applied across various fields of science, including health care. DD has been applied to issues of public interest related to health care, public health, and ethics [1-4]. DD involves the participation of members of the public of a given community for the purpose of collective reflection and discussion regarding a topic of public interest, emphasizing the value of their voice in the reflection. It is an interactive two-way dialogue between nonexperts and experts based on a qualitative methodology [5,6].

DD differs from other public participation methods, such as focus groups and consultations, in three key ways: (1) the provision of information relevant to the policy in question to broaden its understanding; (2) the facilitation of collective reflection and discussion with the participants in an atmosphere that fosters respect, equity, and a common good perspective; and (3) the potential use of participants' informed views to improve their health policies, especially when dealing with complex and controversial issues, such as a crisis situation [6-10]. Experts in deliberative processes recommend assessing the quality of the DD to obtain participants' feedback as a means to optimize its future application [11,12].

However, the definition of quality carries a broad spectrum of expectations. In fact, there is no consensus regarding the criteria that a quality assessment must evaluate. Some studies have combined several criteria for face-to-face DD, such as the process, acceptability, reasoning, independence, transparency, reliability, satisfaction, comprehensibility of the task, accessibility, viewpoint transformation, cost-effectiveness, and logistics [11,13-18]. Experts have underlined that there is no ideal standard according to which the quality of a face-to-face DD must be evaluated [11]. DDs have generally been conducted in person; however, during the COVID-19 pandemic, due to public health measures aimed at curbing the spread of SARS-CoV-2, some DDs were conducted online [19].

Online Democratic Deliberation

Since the 1990s, there has been an increased interest in using online DD (ODD), particularly in social science and in public policy making [20-23]. Interest in using ODD increased during the COVID-19 pandemic [24]. Despite this fact, very few quality assessments of ODD have been published. However, certain dimensions have been evaluated, such as participants' behavior throughout the process, the content of the discussions, the design (eg, synchronous or asynchronous modality and the role of online facilitators), and participants' learning and their opinion changes after deliberation [25-37]. We did not find a standardized and validated tool to evaluate the quality of online deliberation, and there seems to be no consensus on the criteria to be considered [38,39].

Although the online modality already existed before the COVID-19 pandemic, it was generally used in a mixed format [40,41]. Few studies made quality comparisons between face-to-face DD and ODD [42-47]. Such comparisons made it possible to identify some of the disadvantages and advantages associated with ODD. For instance, some disadvantages pertained to decreased participant interaction at the beginning of the discussions where more silence was noted compared to face-to-face sessions. Facilitators had to put in extra effort to engage participants in the discussion, as not all participants could be visible on the screen at the same time [42]. This modality also made it more difficult to observe and interpret participants' nonverbal communication. Translation into other languages has also been complexified with the online modality. Furthermore, technical difficulties and accessibility have been reported as issues with ODD. For instance, some studies highlighted the fact that older people lacked technical skills and lacked internet access in their care homes, which prevented them from participating in an online format [43-45]. Two studies also reported that technical glitches impacted the effectiveness of the process; however, both studies concluded that the 2 modalities ultimately produced similar results [42,44].

Conversely, some advantages have also been highlighted. For example, it has been reported that ODD allows for more time to reflect during discussions and increases participants' comfort levels. Participants tend to feel less intimidated by others, making them more comfortable in expressing their opinions freely [19]. ODD also promotes diversity and inclusion by eliminating the need for participants to travel, making it accessible to individuals with physical or financial limitations. It also accommodates older adults, who can participate from home with the assistance of caregivers [45,47]. Finally, ODD offers logistical advantages, such as greater scheduling flexibility and the ability to record sessions, which can be reviewed later if needed [46,47].

Given that little is known about the quality of ODD, we aimed to contribute to this knowledge gap by presenting the results of an empirical quality assessment of an ODD regarding triage protocols for accessing critical care in Quebec and Ontario. We prepared our assessment tool according to a validated framework for face-to-face deliberations [11]. We explored the participants' self-perceived change of opinion regarding the criteria and values that should underpin triage protocols to appreciate the transformative dimension of DD [48]. This study is one of the few ODDs conducted to obtain the public's perspectives on triage protocols in extreme pandemic contexts while involving participants in the evaluation of this type of methodology.

Methods

Design

This study used a convergent mixed methods design. Thus, it involved collecting both qualitative and quantitative data simultaneously, analyzing the 2 sets of data separately, and then merging the results of the 2 sets of data analyses for comparison purposes. The data then complemented each other, enriching our understanding of citizens' perspectives on the quality of the deliberative exercise [49]. The topic discussed during the ODD consisted of COVID-19 triage criteria for access to critical care in extreme pandemic contexts. However, the focus of this study pertains to the quality evaluation of the ODD. The findings of this quality assessment have not been reported elsewhere.

Target Population and Recruitment

The target population was the members of the public from the provinces of Ontario and Quebec.

For the recruitment of participants, we had the collaboration of the Institut du Nouveau Monde (INM), an independent, nonpartisan organization dedicated to increasing citizen participation in democratic life. INM worked in coordination with Leger Opinion, an online polling firm, which conducted participant screening in both provinces. Participants were initially reached via a call for applications posted on Leger Opinion's website, targeting a pool of 250 candidates from each province. Leger Opinion collected the application forms from April 4 to April 24, 2022. Leger Opinion subsequently conducted a random preselection of applications submitted by the public registered on its website, which resulted in 197 applications from Ontario and 202 applications from Quebec. A second semirandom selection of candidates was carried out by the INM to ensure the diversity of both groups of participants with respect to their demographic variables and region of origin. The first stage of this second selection process consisted of evaluating each application according to the inclusion criteria. The second stage consisted of selecting the 60 final candidates (n=30, 50% from each province) randomly until the composition of each group met the diversity criteria. The inclusion criteria were as follows: citizens of Ontario and Quebec aged >18 years, fluent in either English or French, and possessing basic online participation skills with access to high-speed internet. People studying or working in the field of health care and social services were excluded from this deliberation. The goal was to obtain an outside perspective from a community unrelated to the health care system.

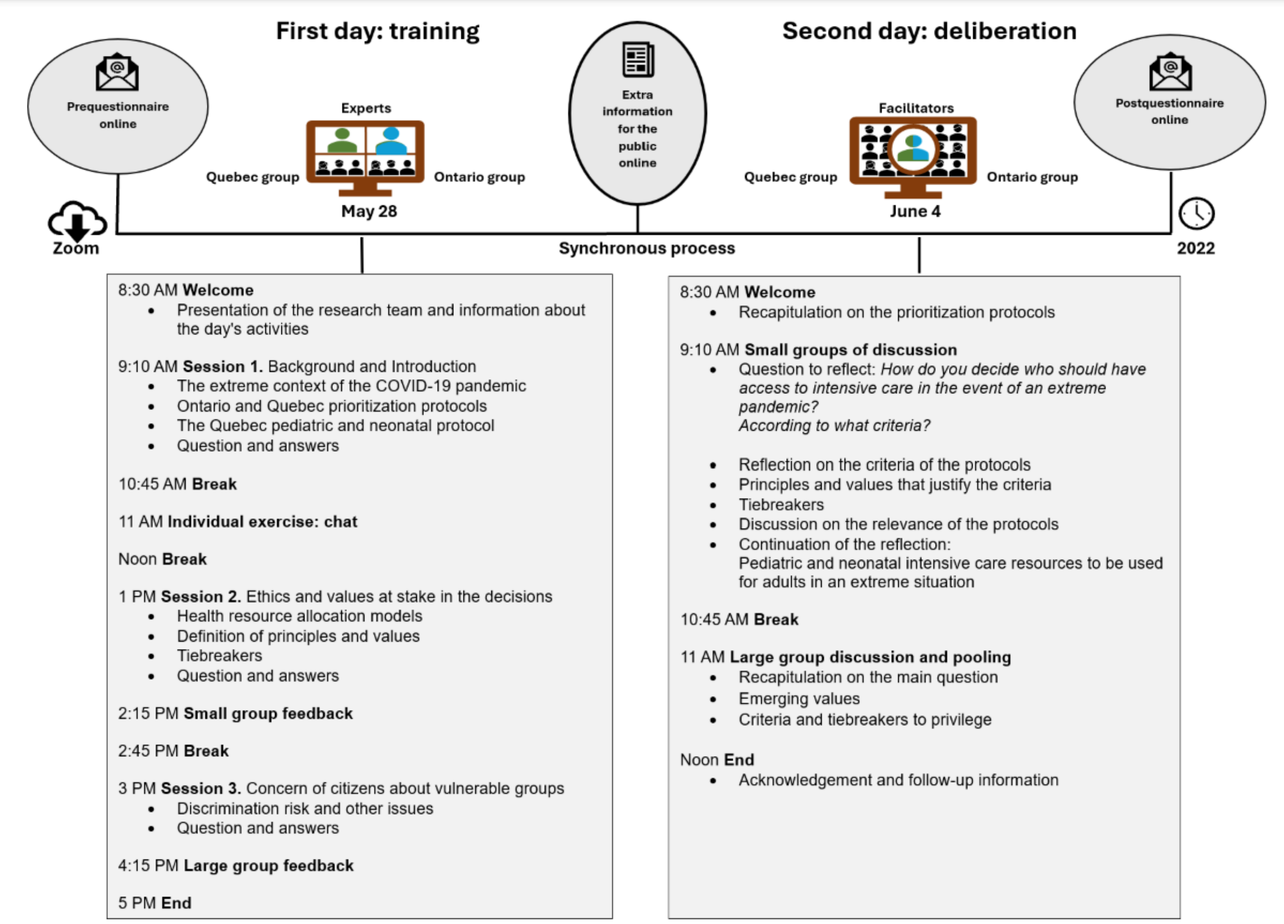
Application forms compiled by Leger Opinion were also designed to collect demographic data on the prospective candidates. INM used these data to carry out the proportional and final selection. Furthermore, these data were used to document the characteristics of the participants in this study. The research team prepared a consent form in both English and French. INM sent and collected this consent form as well as confirmed the participation of each of the candidates on May 2, 2022. Some people were contacted to be placed on a list of substitutes to participate in the event of a withdrawal.

ODD Procedure

An overview of the ODD process is presented in Figure 1. In summary, the ODD took place for 2 days on the Zoom (Zoom Video Communications) platform, simultaneously in Quebec and Ontario (Canada), on May 28 (training session) and June 4 (deliberation session), 2022. Participants received an online information document on the main concepts to facilitate understanding and encourage their participation before the deliberation.

Members of the research team and the INM carefully designed the program of presentations for the training session to equip participants for the discussion during the deliberation. Experts from various disciplines oversaw the training session. This session consisted mainly of topics related to the COVID-19 pandemic triage, its context, and its ethical issues. Experts who collaborated in the presentations were 2 intensive care physicians, 2 pediatricians, 2 ethicists, and 2 university professors in community participation and patient partnership. To ensure that all participants received the same training, the experts' presentations were identical in both English and French. The experts were instructed to present their content and then respond to questions until all inquiries had been addressed. INM facilitators oversaw the deliberation session, which included small group discussions and a plenary discussion where participants reflected and voiced out their perceptions regarding triage protocols for access to intensive care in the COVID-19 pandemic, their criteria, and ethical values to prevail. Consensus building was intended but not required. More details regarding recruitment and the overall ODD process have been reported previously [50].

Figure 1. Overview of the online democratic deliberation process.



8:30 AM **Welcome**
- Presentation of the research team and information about the day's activities

9:10 AM **Session 1.** Background and Introduction
- The extreme context of the COVID-19 pandemic
- Ontario and Quebec prioritization protocols
- The Quebec pediatric and neonatal protocol
- Question and answers

10:45 AM **Break**

11 AM **Individual exercise: chat**

Noon **Break**

1 PM **Session 2.** Ethics and values at stake in the decisions
- Health resource allocation models
- Definition of principles and values
- Tiebreakers
- Question and answers

2:15 PM **Small group feedback**

2:45 PM **Break**

3 PM **Session 3.** Concern of citizens about vulnerable groups
- Discrimination risk and other issues
- Question and answers

4:15 PM **Large group feedback**

5 PM **End**

8:30 AM **Welcome**
- Recapitulation on the prioritization protocols

9:10 AM **Small groups of discussion**
- Question to reflect: *How do you decide who should have access to intensive care in the event of an extreme pandemic?*
  According to what criteria?
- Reflection on the criteria of the protocols
- Principles and values that justify the criteria
- Tiebreakers
- Discussion on the relevance of the protocols
- Continuation of the reflection:
  Pediatric and neonatal intensive care resources to be used for adults in an extreme situation

10:45 AM **Break**

11 AM **Large group discussion and pooling**
- Recapitulation on the main question
- Emerging values
- Criteria and tiebreakers to privilege

Noon **End**
- Acknowledgement and follow-up information

Data Collection

Data collection took place in 2 ways: during the deliberation process and through a postdeliberation online questionnaire. Members of the research team stored all the data collected from this study in the University of Montreal's OneDrive (Microsoft Corp) system to ensure confidentiality.

During the Deliberation Process

We collected the participants' perceptions about the quality of the process at the end of both the training and deliberation sessions. Members of the research team and the INM recorded the entire process of the ODD on the Zoom platform. These recordings were then transcribed in both languages. A member of the team listened to the recordings on 2 occasions to compare and check the accuracy of the verbatim transcripts. These verbatim transcripts were deidentified before conducting the analysis. Observation notes were also taken throughout the deliberation session on preformatted templates; however, these notes only captured information about the topic of the deliberation (triage) and not about the quality of the process.

Postdeliberation Questionnaire to Assess the Quality of the ODD

We modified the assessment framework proposed by De Vries et al [11] to evaluate 3 important dimensions: the process, the information, and the reasoning from the point of view of the participating public. Considering the online mode of the deliberation, it was necessary to make some modifications to this evaluation in three ways: (1) by adding questions addressing the visual, sound, and usability aspects of the online modality; (2) by adding an open-ended question at the end for quality feedback; and (3) by restructuring some questions to obtain more comprehensive information from participants during the online interface, trying to keep the evaluative objective of the original framework.

We pretested the questionnaire with the help of 7 volunteers to evaluate whether the questions were intelligible, unambiguous, and unbiased. Once the pretest was undertaken, the questionnaire was re-evaluated and optimized by coresearchers with experience in qualitative and quantitative research. The questionnaire was redrafted according to the feedback provided, and then, we integrated it into the LimeSurvey software (Carsten Schmitz and LimeSurvey team) provided by the University of Montreal.

This questionnaire contained questions to assess the quality and questions related to the participants' postdeliberation perception change. The questions were primarily close-ended questions with Likert-type scales and an open-ended question at the end to allow space for feedback. Details are available in Multimedia Appendix 1.

Participants were emailed the link to the questionnaire on June 17, 2022, and were given a period of 2 weeks to complete it. Two members of the research team collected and deidentified the data from the questionnaire. Data obtained from the closed-ended questions were separated from those obtained from the open-ended questions and archived in their respective log files for management.

Tool to Assess Equality of Spoken Interventions

We applied the Herfindahl-Hirschman Index (HHI) to determine the contributions of each participant during the deliberation session. Other deliberation studies have used this index to estimate the equality of interventions among participants and to detect the presence of polarization in the group's dynamics. This index was originally used in marketing and is now also used in disciplines related to ethics [51,52].

We used the transcripts collected to calculate the HHI in both groups, determine whether some participants dominated in terms of their interventions, and detect little or no participation. One member of the team was responsible for collecting the transcripts from the participants, counting them, and entering them into the online calculator. We calculated this index using the online HHI calculator [53]. Details of the calculations are available in Multimedia Appendix 2.

Data Analysis

Qualitative Analysis

We carried out a thematic analysis using the transcriptions of the ODD sessions and the written comments (open-ended questions) from the questionnaire related to the quality. We integrated the transcripts and the participants' written comments into the NVivo software (version 14; Lumivero), released in 2023. Two independent coders reread the qualitative data to become familiar with the content. Through inductive coding, they identified the main emerging themes focusing on the quality of the deliberation process. One of the coders created a codebook to organize codes into themes and subthemes. Members of the research team reviewed the codebook on 2 occasions to ensure that the coding was a reliable representation of the data obtained regarding the quality of the ODD. They discussed coding differences until a consensus was reached. Two members of the research team calculated the percentage of agreement between the coders using NVivo, which generated a κ score of 0.8.

Quantitative Analysis

For this analysis, we included only the answers to the closed-ended questions that pertained to the quality of ODD and the self-perception of opinion changes. For the quantitative statistical analysis, we used SPSS software (version 21.0; IBM Corp). Our analysis was only descriptive, which included frequencies, percentages, means, and SDs. We calculated the response rate to the survey as a percentage. For the analysis of the quality assessment questionnaire, we adhered to the evaluative objectives of the framework proposed by De Vries et al [11]. The quality assessment survey included 15 items answered on a 5-point Likert scale (eg, 1=very easy and 5=very difficult). We analyzed the frequencies and percentages of each of the items related to process, information, reasoning, and videoconferencing. Participants' responses were rated as positive on Likert scales 1 and 2, neutral on Likert scale 3, and negative on Likert scales 4 and 5. For interpreting the mean scores, a score close to 1 indicates a positive evaluation of each aspect, while a score close to 5 indicates a negative evaluation of the assessed variables. Similarly, we analyzed frequencies and percentages of each of the items in the question on participants' self-assessment of perspective changes. This question included 4 items related to the criteria, principles, and values contained in the adult and pediatric triage protocols. These items were rated using a 4-point Likert scale score (1=totally and 4=not at all). Participants' responses were rated as having experienced a lot of, some, or little change of perspective on Likert scales 1, 2, and 3, respectively, and were rated on Likert scale 4 as having experienced no change of perspective after the deliberation exercise. For these responses, we interpreted the mean as follows: a score close to 1 indicated a positive evaluation of each of the aspects, while a score close to 4 indicated a negative evaluation of the assessed variables.

For the HHI analysis, we applied the normalized HHI^N formula to the online calculations for each group of Quebec and Ontario participants. This formula estimated the presence or absence of polarization during the deliberative session and allowed us to compare the 2 different size groups.

Our interpretation of the formula results was that normalized $HHI^N=0$ indicated complete equality of the spoken intervention, and $HHI^N=1$ indicated complete polarization of the deliberation dialogue. Details on using the normalized HHI^N formula for assessing the equality of interventions are provided in Multimedia Appendix 2.

Ethical Considerations

This study was approved by the Comité d'éthique de la recherche en sciences et en santé, de l'Université de Montréal on March 15, 2022 (no. 2022-1466), and by the Bureau d'éthique et d'intégrité de la recherche de l'Université d'Ottawa on March 28, 2022 (project H-03-22-8010). All participants provided informed consent before participating. Compensation of CAD $200 (US $130) was offered to each participant for their full participation in the process.

Results

Quality of the ODD: Thematic Analysis

A total of 47 participants (n=27, 57% from Ontario and n=20, 43% from Quebec), with a diverse demographic representation, took part in the quality assessment at the end of each session. When comparing the places of origin, the highest participation was from la Capitale Nationale, with 4 (20%) out of 20 participants, and Greater Toronto, with 12 (44%) out of 27 participants. Regarding the population groups, of the 47 participants, 2 (4%) were African American, 1 (2%) was Arab, 3 (6%) were Asian, 2 (4%) were Latin American, 2 (4%) were South Asian, and 2 (4%) belonged to First Nations. One (5%) of the 20 participants from Quebec and 2 (7%) of the 27 participants from Ontario reported belonging to a visible group and visible or multiple minority groups, respectively. In terms of work occupancy, 13 (65%) out of 20 participants from Quebec were employed, and 11 (41%) out of 27 participants from Ontario were employed. Regarding participants' educational level, the most frequent group in Quebec was professionals with preuniversity training (general and technical), with 8 (40%) out of 20 participants, and that in Ontario was participants with a bachelor's university education, with 9 (33%) out of 27 participants. Regarding annual income, in Quebec, the most frequent income bracket (CAD $ = US $1.30) was between CAD $39,999 and CAD $49,999, and the least frequent income bracket was >CAD $100,000. In Ontario, the most frequent income bracket was between CAD $49,999 and CAD $59,999, and the least frequent income bracket was <CAD $30,000. More details of the demographic characteristics of the participants are described in a previous publication [50].

Five themes emerged from our analysis: (1) process appreciation, (2) learning experience, (3) reflecting on the common good, (4) technological aspects, and (5) transformative aspects. Some quotes from participants have been stated in the subsequent sections for each of the 5 themes.

Process Appreciation

Overview

This theme emerged when coding all the transcripts and the written comments pertaining to participants' lived experiences during the exercise; for instance, feelings of satisfaction in sharing their perceptions, being listened to, being respected, and even their views on the presentations and the deliberation exercise. We classified these experiences either as positive or negative. Quotations regarding the appreciation of the ODD obtained during the deliberation processes and written comments on the questionnaire were all found positive. Two positive aspects stood out: an excellent experience and sharing with a diverse audience in a respectful atmosphere that encouraged freedom of expression.

Positive Quotes

Participants in both groups stated that they had an excellent experience during both the training session and the deliberation session:

> *I found the presentations excellent.* [Participant in Ontario 21]
>
> *Very helpful. The presenters were great. The presentations were excellent but also difficult. There was so much information that was an important part of our life.* [Participant in Ontario 3]
>
> *I just want to say that I thought the presentations were all wonderful and that I learned a lot. Everything was good. I loved it. I can't wait for next Saturday.* [Participant in Ontario 13]
>
> *Everything was great even with the long session it did not feel like it was 8 hours.* [Participant in Ontario 12]
>
> *I really enjoyed this experience, the group was great, it was rewarding, a big thank you.* [Participant in Quebec 13; translated from French]
>
> *...But overall, I have to say that the experience was rewarding...* [Participant in Quebec 17; translated from French]

Participants felt comfortable, respected, and free to express their opinions with a diverse audience:

> *I really enjoyed being a part of this and offering my opinions and accepting others and no arguments happened and everyone was engaged.* [Participant in Ontario 13]
>
> *As one of the participants remarked at the end of the first session, it was pleasantly surprising to see people from different backgrounds, with different points of view, discussing in mutual respect.* [Participant in Quebec 17; translated from French]
>
> *Excellent choice of having people from different age groups and different parts of province with the opinions and possible obstacles.* [Participant in Ontario 16]
>
> *Very good quality of conferences and debates. Good conviviality and good animation...* [Participant in Quebec 14; translated from French]
>
> *And one thing that I appreciated as well was the smaller groups, because it gives more time for each individual to give their point of view. And then once we get back to the bigger group, we can give a consensus. So, everyone can get their point across within a shorter amount of time than if we stayed in a big group and discuss everything.* [Participant in Ontario 8]

Learning Experience

Overview

This theme referred to participants' perceptions related to the overall learning experience during the exercise and the influence of this learning on their own principles and values. More specifically, this theme included comments on the acquisition of knowledge regarding triage during the COVID-19 pandemic, its implications, and the protocols presented. Participants stated that they had learned from the information session and better understood the underlying criteria and values contained in the triage protocols:

> *Before we even started the meeting, I appreciated that a questionnaire was sent to us because it got us into the mindset of what type of questions we would be asked. And also, especially the first presentation, I think it should be repackaged and broadcast to the masses to explain why we need triage. And once people understand that, then maybe more people will understand why COVID was such a serious situation and why we insisted on vaccines, masks and all that stuff...* [Participant in Ontario 8]
>
> *Totally enjoyed participating. Very well organized, speakers were amazing, and I certainly learned a lot about the behind the scenes during a pandemic.* [Participant in Ontario 22]
>
> *I felt privileged to have access to this information, and to know the scientific and other issues.* [Participant in Quebec 3; translated from French]
>
> *It allowed me to question some of my beliefs and values, I loved it.* [Participant in Quebec 13; translated from French]

Reflecting on the Common Good

Overview

This theme included participants' perceptions of their ability to reflect collectively rather than individually on the points raised during the deliberation exercise. Some participants commented that, by sharing their opinions related to the triage protocols and thinking collectively, they were engaged in a reflection for the good of the community; however, 1 participant highlighted that this was not always the case:

> *...I was surprised to see how many people bring the debate back to their personal situation, despite the explanations on the collective which must be a priority. I perceived a radical change of perception for some, following the explanations, who seemed to understand the priority of the collective, and [I was] disappointed to see that some maintained personal positions...* [Participant in Quebec 3; translated from French]
>
> *Great sense of community with the group.* [Participant in Ontario 3]
>
> *I really enjoyed being a part of this and offering my opinions and accepting others and no arguments happened and everyone was engaged.* [Participant in Ontario 13]

Technological Aspects

Overview

This theme emerged from the participants' perceptions of the ease or difficulty of participating in an online deliberation, specifically concerning the technology used. More specifically, participants were asked to comment on aspects such as the use of the Zoom platform, the use of breakout rooms for small group discussions, the plenary sessions, the videoconference, the aspects of volume, visibility, and the internet signal. This theme was subdivided into positive and negative quotes.

Positive Quotes

> *Tech aspects were handled very well. Seamless transition from plenary to breakout groups and back. Top quality presentations and content.* [Participant in Ontario 20]
>
> *I learned lots about Zooming. Unfortunately, my old machine does not support Zoom, so I had to use a pad and it was a learning experience for me, but I did manage.* [Participant in Ontario 19]
>
> *I have never been involved in video conferencing before where I needed to speak so finding out my mic didn't work was very frustrating. The team tried to help as best they could from a distance and I'm very grateful for their attempts. I made the best of it and included any of my opinions in the chat to be recorded or thumbs up on screen if my response was needed quickly.* [Participant in Ontario 3]
>
> *This is a VERY well-run study, apart from some people had technical difficulties (inevitable), I'd give 4.8 out of 5 for the whole process. Presenters are all experts in their field, presentation very informative, group discussions are well organized and purposely remixed which is beneficial.* [Participant in Ontario 7]
>
> *Nothing can replace face to face meetings; however, they did the best they could with this format.* [Participant in Ontario 21]

Negative Quotes

> *On the links that were given on the chat, I was not able to open it on my iPad, I had to copy and paste in browser.* [Participant in Quebec 20; translated from French]
>
> *Unfortunately, the sound quality from some of the presentations was lacking. I think this was due to some technical issues, but the team adapted and carried on with the seminars as best they could. At the end of the day, I was able to understand all of the information presented.* [Participant in Ontario 17]

Transformative Aspects

Overview

This theme emerged when coding the changes perceived by participants on the topics discussed, such as triage protocols in the COVID-19 pandemic and the criteria and values, considering the transformative nature of the deliberations. Participants commented on the changes they experienced with respect to their initial perspectives after the deliberation process. These expressions were divided into positive change, negative change, and no change.

Positive Change

> *I did not understand how complex this was, I feel I learned a LOT more and it helped me also respect their positions a lot more.* [Participant in Ontario 12]
>
> *I used to completely disagree with this type of protocol but now I see it as a requirement.* [Participant in Quebec 16; translated from French]
>
> *I didn't think the discussion was this advanced. I changed my perspective when I learned that non-ICU patients were not left to their own devices.* [Participant in Quebec 9; translated from French]

Negative Change

> *I thought a protocol was a good thing, but after looking at it and discussing it I feel that it is very much for the benefit of the healthcare workers. I don't feel like it serves any other purpose and is extremely cumbersome on the administrative side.* [Participant in Quebec 5; translated from French]

No Change

> *...I did not change my thinking for the tiebreaker situation, in fact I'm more convinced that lottery is much better way to handle tiebreakers...* [Participant in Ontario 7]

Written Comments on the Questionnaire

Written comments (open-ended questions) on quality were provided by 12 (60%) out of 20 participants from Quebec and 12 (44%) out of 27 participants from Ontario. The trend of responses on quality is presented in Multimedia Appendix 3. Written comments on the change of perspective were provided by 11 (55%) out of 20 participants from Quebec and 6 (22%) out of 27 participants from Ontario. The trend of responses in terms of participants' self-perceived change of opinion is presented in Multimedia Appendix 4.

Quality of the ODD: Questionnaire

Out of 47 participants, 46 answered the questionnaire (the level of participation was 98%). Most participants responded positively to each of the evaluated aspects, which included an evaluation of the process itself, the information shared with the participants, the collective reasoning experience, and the videoconference (Table 1).

Two aspects of the process stood out: the perception of equal opportunity to share opinions and feeling respected during the deliberation, both presenting 45 (98%) positive responses out of 46 responses. Positive responses were also found in other dimensions, such as commitment during the discussion, with 44 (96%) positive responses out of 46 responses, and facilitation, with 39 (85%) positive responses out of 46 responses.

Furthermore, we found positive responses with respect to the information shared with participants during the information session. A positive response rate of 100% (46/46) was obtained for both the learning experience and comprehension dimensions, indicating total satisfaction for both. In terms of the impact of the information on participants' opinions, the positive responses were 41 (89%) out of 46 responses. The use of correct information by participants was found to have 38 (83%) positive responses out of 46 responses, which suggests that they received and shared more correct than incorrect information. The lowest percentage found among the positive responses pertained to the consultation of experts, with only 20 (43%) positive responses out of 46 responses, which indicates that participants did not frequently consult the experts.

Regarding the evaluation of collective reasoning, the responses were generally positive. The reflection for a common good or societal perspective showed 46 (100%) positive responses out of 46 responses. A total of 31 (94%) positive responses out of 33 responses were reported for the justification of their opinions, and 43 (93%) positive responses out of 46 responses were reported for participants' openness to the complex and difficult issues discussed in the deliberation.

Regarding the evaluation of the videoconference, 46 (100%) positive responses out of 46 responses were found for the sound quality, 45 (98%) positive responses out of 46 responses for the video quality, and 42 (95%) positive responses out of 44 responses for the ease of using the online videoconference for deliberation.

Table 1. Assessing the quality of an online democratic deliberation on the COVID-19 pandemic triage (N=46).

Evaluated aspects and questions	Respondents, n (%)	Criteria, n (%)					Scores, mean (SD)
Process[a,b]							
Facilitation: how did you perceive your participation in the deliberation or sharing your perspectives in a videoconference?	46 (100)	Very easy, 24 (52)	Easy, 15 (33)	Neutral, 2 (4)	Difficult, 5 (11)	Very difficult, 0 (0)	1.74 (0.976)
Equal participation: how did you perceive the opportunity to share your opinions and ask questions during the process?	46 (100)	Very equal, 33 (72)	Equal, 12 (26)	Neutral, 0 (0)	Unequal, 1 (2)	Very unequal, 0 (0)	1.33 (0.598)
Respect: did you feel respected in sharing your opinions with other participants in the process?	46 (100)	Very respected, 32 (70)	Respected, 13 (28)	Neutral, 1 (2)	Little respected, 0 (0)	Not respected, 0 (0)	1.33 (0.51)
Commitment: how would you rate your engagement with the discussion group in the process?	46 (100)	Very committed, 32 (70)	Committed, 12 (26)	Neutral, 2 (4)	Little committed, 0 (0)	Uncommitted, 0 (0)	1.35 (0.56)
Information[a,b]							
Expert consultation: how often do you estimate that you have consulted experts during the deliberation to obtain clarification?	46 (100)	Very frequent, 3 (7)	Frequent, 17 (37)	Neutral, 12 (26)	Infrequent, 14 (30)	Not frequent, 0 (0)	2.80 (0.95)
Use of incorrect information: do you consider that you received or shared incorrect information during the deliberation?	46 (100)	Not at all, 27 (59)	Not really, 11 (24)	Neutral, 3 (6)	A little, 3 (7)	Totally, 2 (4)	1.74 (1.12)
Learning new information: how do you perceive your learning from the information obtained in the deliberation?	46 (100)	Very satisfied, 37 (80)	Satisfied, 9 (20)	Neutral, 0 (0)	Dissatisfied, 0 (0)	Very dissatisfied, 0 (0)	1.20 (0.40)
Understanding and applying the information: how would you rate your understanding of the information presented in the deliberation?	46 (100)	Very clear, 32 (70)	Clear, 14 (30)	Neutral, 0 (0)	Unclear, 0 (0)	Very unclear, 0 (0)	1.30 (0.46)
Impact of information on opinions: how do you perceive the impact of deliberation information on your opinions?	46 (100)	Very influential, 13 (28)	Influential, 28 (61)	Neutral, 4 (9)	Little influential, 1 (2)	Not influential, 0 (0)	1.85 (0.66)
Reasoning[a,b]							
Rationale for opinion: how would you rate your shared opinions in the deliberation? Were your opinions justified?	33 (71)	Very justified, 0 (0)	Justified, 31 (67)	Neutral, 2 (4)	Poorly justified, 0 (0)	Not justified, 0 (0)	2.06 (0.24)
Openness to complexity: how would you rate your openness to the difficult topics discussed in the deliberation?	46 (100)	Very open, 27 (59)	Open, 16 (35)	Neutral, 3 (6)	Little open, 0 (0)	Not open, 0 (0)	1.48 (0.62)
Consideration of societal perspective: how did you perceive your consideration of the collective perspective or thinking for a common good during the deliberation?	46 (100)	Very considered, 26 (57)	Considered, 20 (43)	Neutral, 0 (0)	Poorly considered, 0 (0)	Not considered, 0 (0)	1.43 (0.50)
Videoconference[c]							

Evaluated aspects and questions	Respondents, n (%)	Criteria, n (%)					Scores, mean (SD)
How would you rate the audio quality or sound quality?	46 (100)	Very satisfied, 35 (76)	Satisfied, 11 (24)	Neutral, 0 (0)	Dissatisfied, 0 (0)	Very dissatisfied, 0 (0)	1.24 (0.43)
How do you rate the video quality or image quality?	46 (100)	Very satisfied, 38 (83)	Satisfied, 7 (15)	Neutral, 1 (2)	Dissatisfied, 0 (0)	Very dissatisfied, 0 (0)	1.20 (0.45)
What is your assessment of the ease of use of videoconferencing for deliberation?	44 (95)	Very easy, 34 (74)	Easy, 8 (17)	Neutral, 2 (4)	Difficult, 0 (0)	Very difficult, 0 (0)	1.27 (0.54)

[a] Questions developed according to the framework proposed by De Vries et al [11].

[b] Modified questions.

[c] Added questions.

Changes in Perspectives Reported by Participants

Regarding the evaluation of the postdeliberation changes in participants' perspectives, based on the questionnaire (close-ended questions), we observed a similar change for all the evaluated aspects (Table 2).

In relation to the criteria contained in the triage protocols, 14 (30%) out of 46 participants reported a total change of opinion, 19 (41%) reported a partial change, and 8 (17%) reported at least 1 change. Thus, 41 (89%) out of 46 participants reported some changes in their perspective after deliberation. Results were similar for the other aspects consulted. A total of 39 (85%) out of 46 participants reported some changes of perspective regarding the principles and values of the adult protocol and the tiebreakers, and 40 (87%) out of 46 participants reported a change regarding the principles and values of the pediatric and neonatal protocol. Participants who reported experiencing no change in perspectives after deliberation consisted of the smallest group.

Table 2. Identifying the evolution of the public perspectives on the COVID-19 pandemic triage protocols after deliberation (N=46).

Question: do you consider that this democratic deliberation has generated a change in your perspectives? Please check your degree of change in perspective regarding each of the following options.	Totally, n (%)	Partially, n (%)	Somewhat, n (%)	Not at all, n (%)	Scores, mean (SD)
Clinical criteria of the adult protocol	14 (30)	19 (41)	8 (17)	5 (11)	2.09 (0.96)
Principles and values of the adult protocol	11 (24)	18 (39)	10 (22)	7 (15)	2.28 (1.00)
Pediatric and neonatal protocol principles and values	13 (28)	14 (30)	13 (28)	6 (13)	2.26 (1.02)
Tiebreaker criteria	15 (33)	15 (33)	9 (19)	7 (15)	2.17 (1.06)

Estimation of Equality of Spoken Intervention

In calculating the HHI, we were able to obtain an estimate of the spoken intervention of both groups of participants. Results indicated a low polarization in the group dynamics for both Quebec and Ontario groups (Table 3). We observed that a few participants intervened more and that a few others did not intervene, which was similar in both groups. Details are available in Multimedia Appendix 2.

Table 3. Summary of the Herfindahl‐Hirschman Index (HHI) and normalized HHI of the participants during deliberations (N=47).

Measure	Quebec group	Ontario group
Normalized HHI	0.035	0.033
HHI	688	830
Range of spoken intervention (%)	0-15	0-12
Participants, n (%)	20 (43)	27 (57)

Discussion

Principal Findings

This study found a positive appreciation regarding the ODD process in both the Quebec and Ontario groups, and minimal differences were observed regarding the equality of participation in both groups based on the HHI scores. Participants in both provinces voiced favorable perspectives in terms of the quality of the ODD. This deliberation exercise demonstrated that participants could learn specific information about triage protocols, some of whom probably had prior misconceptions about them. Despite the sensitivity of this topic, the participants showed openness in trying to understand complex ethical issues. We were aware that it would not be easy for them; however, they demonstrated their ability to grasp the shared information and to reflect on ethical dilemmas associated with the topic at hand. Similar findings were found in a study conducted with the public regarding surrogate consent for research in people with dementia. In this study, the topic was also sensitive in nature, and the participants also demonstrated an openness to the complexity of the issues involved [54].

As for reflecting on the common good, we noticed a certain difficulty at the beginning of the deliberation process for a few participants. However, during the process and especially at the end, we observed a change in the participants' perspectives. They adopted a vision that was more focused on the common good. In multicultural societies, it is common to find a diversity of values that influence people's perspectives. This heterogeneity of thoughts provides richness in terms of considering multiple angles and moral values on the subject to treat [55]. One might think that this pluralism would run counter to a common vision, but this was not the case. The breakout sessions enabled participants to delve more deeply into the subject, leading to fruitful exchanges and a sharing of diverse viewpoints. The diversity of the participants in terms of sociodemographic characteristics and the pluralism of the values discussed did not create schisms between them. Instead, participants rallied around common values and worked together to bring out what they considered to be the best possible solutions for triaging access to intensive care in the extreme context of the COVID-19 pandemic. We believe that most participants felt that they were engaged in a collective reflection, which is an important aspect to achieve during these processes [56,57].

Conducting this ODD in a COVID-19 pandemic context was a new challenge for the research team and the participants. Surprisingly, the participants felt comfortable with the online modality. Some technical problems were reported by 2 (4%) out of 47 participants, one related to the loss of sound and the other related to problems in the manipulation of the smart device, but these issues were rapidly resolved. We believe that the health measures in place during the COVID-19 pandemic also facilitated the adaptability of the participants to the new technology. The advanced age of some participants, as well as their low level of education or income, did not prove to be an obstacle to their online participation. Other studies have previously noted that older adults often have a limited ability to handle technology, which can create challenges for their participation [43-45]. An adequate internet signal is of vital importance to carry out ODD. In this study, we were affected by this type of barrier, losing some participants in the first session due to failures in their internet signal, a situation beyond the control of the research team (bad weather). We consider this to be the most problematic aspect of an online modality. The ODD was conducted in French for the Quebec group and in English for the Ontario group to provide the same content in both languages and to facilitate the participants' understanding, thus avoiding problems of linguistic interpretation [42].

Some studies mentioned "Zoom fatigue" during videoconferences [42,58]. Previous efforts to prepare participants to effectively use the Zoom platform and the screen were useful, for example, keeping their cameras on, minimizing screen sharing, using emoticons to express themselves, and asking for their turn to talk. Some participants expressed their appreciation related to the small group discussions, the chat between discussions, and the breaks during the process. We believe that the facilitators' animation made the discussions more enjoyable and reduced "Zoom fatigue." Some argue that it is more difficult to observe the faces, gestures, as well as verbal and nonverbal cues during an online meeting, which are easier to observe in person [42]. We were not able to quantify this aspect, but the facilitators did take it into account, especially during the small group discussions. The facilitators initially asked questions in a general way and, in some cases, in a direct way to each participant to encourage their participation and to prevent a passive attitude or, on the contrary, a polarization in the participation. Therefore, the role of the facilitators was essential [42,44]. Regarding the equality of spoken intervention according to the estimated HHI, both groups obtained a similar score, showing a low tendency of polarization during the group discussions on the day of the deliberation. This suggests that the facilitators tried, as much as possible, to achieve an equal distribution of participation [59].

Some participants reported having experienced at least 1 change of perspective in relation to the protocols presented. However, our objective was not to direct efforts to change the participants' perspectives on the triage protocols. We were simply interested in finding out whether these perspectives had been modulated or affected by the deliberation process. The public may be susceptible to misinformation due to a lack of complete and accurate information [60,61]. DD has proved to be an opportunity to complement and provide reliable information to the public on health strategies during the COVID-19 pandemic [62]. A deliberation conducted both in person and online found that participants' opinions and behaviors had changed. Some participants had increased their knowledge and felt more committed and encouraged to participate in deliberation online processes [29]. Others not only changed their opinions but also strengthened their sense of civic engagement [63]. In an ODD conducted in Finland about new transportation systems for the community and urban planning, the results showed that participants experienced a remarkable change of perspectives at the end of the process [64]. These results suggest that ODD can be transformational for the participants.

Some key organizational aspects are essential to achieve an effective contribution from participants, such as encouraging participation from all deliberators, adhering to the schedule, and ensuring a stable internet connection. Having backup participants in case some experience problems with their internet connection could be helpful to avoid losing participants. However, in our study, it was not possible to contact other participants to replace those experiencing technical problems, as this problem was not immediately reported. Nevertheless, the team was able to replace 1 participant in the initial hours of the training day due to an emergency. Finally, it is important to properly save the Zoom records of all the sessions (plenary and breakout sessions) because, in this study, 1 member of the team faced technical difficulty in recording 1 of the sessions on the Zoom platform.

Limitations

Regarding the limitations of this study, our participants did not constitute a representative and proportional quantitative sample of the populations studied. Therefore, our results cannot be generalized, and this should be considered when interpreting our results. Furthermore, we recognize that an online modality limited us to recruiting only people with internet access and minimal basic computer skills. However, we believe that it allowed us to foster inclusiveness of participation and citizen engagement in the deliberation process by facilitating the participation of individuals from rural regions of both provinces. It also provided an equal opportunity for a diverse range of individuals to participate. Participants provided valuable information on the topics studied: the evaluation of the quality of the deliberation process and the postdeliberation self-perceptions of changes. Among other limitations, we observed that a few participants were passive in their participation; 5 (25%) out of 20 participants from Quebec and 9 (33%) out of 27 participants from Ontario did not share their opinion during the small group activity, while some of them did intervene during the plenaries and the training day by consulting the experts. During the training session, it was not possible to count each intervention from participants, as 1 small group session was not recorded. As a result, we only calculated the HHI for the deliberation session but not for the formative session. Some observer responses were more detailed than others' responses, so the differences between their observations could not be compared.

Despite the possible biases associated with conducting an online deliberation process, we consider that it is an acceptable alternative when social distancing measures are necessary, such as during the COVID-19 pandemic. However, some unpredictable and organizational aspects must be taken into account to optimize the results. We believe that face-to-face deliberations will continue to be the first option to consider whether conditions are suitable for it.

Conclusions

Overall, participants considered the quality of the ODD to be satisfactory. Among the quality dimensions evaluated, participants attributed the highest levels of satisfaction to learning new information, understanding information on issues of triage in extreme COVID-19 pandemic contexts, and the exercise of reflecting on the common good. We found a favorable evaluation of the ODD quality on the 4 main aspects included in the questionnaire: the process, the information, the reasoning, and the participation in videoconferencing. Some participants self-reported a change of opinion after the deliberation. The results of the questionnaire were consistent with the findings of the thematic analysis from the ODD transcripts. The online modality may be an acceptable alternative for DD in a pandemic context but with some organizational adaptations. More studies are needed to determine the feasibility and effectiveness of online deliberation processes.

Acknowledgments

The authors would like to thank the Institut du Nouveau Monde for their guidance and collaboration in the development of the deliberation. The authors would like to thank all the participants for their valuable input to this study. The authors would also like to thank Vanessa Finley-Roy for rereading the manuscript. This study is funded by the Canadian Institutes of Health Research awarded to MEB (EG4179448). CLCR, a PhD candidate, received student funding from the Programme de soutien à la recherche étudiante Pôle 1–2023, Centre intégré de santé et de services sociaux de Laval, Quebec.

Data Availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization, data curation, and methodology were performed by CLCR, YF, and MEB. Formal analysis of data and investigation were conducted by CLCR. MEB and CLCR were involved in securing funding and resources. Project administration was overseen by MEB and CLCR. Software applications were developed by CLCR and KL. Supervision was provided by MEB, YF, and NG. Validation of the results was led by MEB, YF, NG, and CLCR, with the participation of JD, AF, GB, AP, LO, DP, AL, PT, LMR, VD, AD, and CD. The original draft was written by CLCR. The draft was revised by YF and MEB. The final draft was written by CLCR and revised by MEB.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Postdeliberation questionnaire.
[DOCX File , 58 KB - jopm_v16i1e54841_app1.docx]

Multimedia Appendix 2
Calculation of the Herfindahl-Hirschman Index.
[DOCX File , 218 KB - jopm_v16i1e54841_app2.docx]

Multimedia Appendix 3
NVivo coding query of participants who shared their perceptions about the quality of the online deliberation.
[DOCX File , 79 KB - jopm_v16i1e54841_app3.docx]

Multimedia Appendix 4
NVivo coding query of participants who wrote a comment on the self-perceived change of perspectives.
[DOCX File , 150 KB - jopm_v16i1e54841_app4.docx]

References

1. Abelson J, Blacksher E, Li K, Boesveld S, Goold S. Public deliberation in health policy and bioethics: mapping an emerging, interdisciplinary field. J Public Delib 2013;9(1):23. [doi: 10.16997/jdd.157]
2. Mitton C, Smith N, Peacock S, Evoy B, Abelson J. Public participation in health care priority setting: a scoping review. Health Policy 2009 Aug;91(3):219-228. [doi: 10.1016/j.healthpol.2009.01.005] [Medline: 19261347]
3. Safaei J. Deliberative democracy in health care: current challenges and future prospects. J Healthc Leadersh 2015;7:123-136 [FREE Full text] [doi: 10.2147/JHL.S70021] [Medline: 29355181]
4. Degeling C, Carter SM, Rychetnik L. Which public and why deliberate?--A scoping review of public deliberation in public health and health policy research. Soc Sci Med 2015 Apr;131:114-121 [FREE Full text] [doi: 10.1016/j.socscimed.2015.03.009] [Medline: 25770463]
5. Cavalier R. Approaching Deliberative Democracy: Theory and Practice. Pittsburgh, PA: Carnegie Mellon University Press; 2011.
6. Cooke M. Five arguments for deliberative democracy. Political Stud 2000 Dec 01;48(5):947-969. [doi: 10.1111/1467-9248.00289]
7. Pearse H. Deliberation, citizen science and COVID-19. Polit Q 2020;91(3):571-577 [FREE Full text] [doi: 10.1111/1467-923X.12869] [Medline: 32836410]
8. Abelson J. Opportunities and challenges in the use of public deliberation to inform public health policies. Am J Bioeth 2009 Nov 04;9(11):24-25. [doi: 10.1080/15265160903197721] [Medline: 19882450]
9. Fishkin JS. When the People Speak: Deliberative Democracy and Public Consultation. Oxford, UK: Oxford University Press; 2009.
10. Solomon S, Abelson J. Why and when should we use public deliberation? Hastings Cent Rep 2012;42(2):17-20 [FREE Full text] [doi: 10.1002/hast.27] [Medline: 22733325]
11. De Vries R, Stanczyk AE, Ryan KA, Kim SY. A framework for assessing the quality of democratic deliberation: enhancing deliberation as a tool for bioethics. J Empir Res Hum Res Ethics 2011 Sep 01;6(3):3-17 [FREE Full text] [doi: 10.1525/jer.2011.6.3.3] [Medline: 21931233]
12. Gauvin FP. Evaluating deliberative processes. The National Collaborating Centre for Healthy Public Policy (NCCHPP). 2010. URL: https://www.ncchpp.ca/docs/DeliberativeFS3_evaluation_EN.pdf [accessed 2024-04-29]
13. Rowe G, Marsh R, Frewer LJ. Evaluation of a deliberative conference. Sci Technol Hum Values 2004 Jan 01;29(1):88-121. [doi: 10.1177/0162243903259194]
14. Steenbergen MR, Bächtiger A, Spörndli M, Steiner J. Measuring political deliberation: a discourse quality index. Comp Eur Polit 2003 Apr 16;1(1):21-48. [doi: 10.1057/palgrave.cep.6110002]
15. Stromer-Galley J. Measuring deliberation's content: a coding scheme. J Public Delib 2007;2007(1):7. [doi: 10.16997/jdd.50]
16. Timotijevic L, Raats MM. Evaluation of two methods of deliberative participation of older people in food-policy development. Health Policy 2007 Aug;82(3):302-319. [doi: 10.1016/j.healthpol.2006.09.010] [Medline: 17067716]
17. Webler T, Tuler S, Krueger R. What is a good public participation process? Five perspectives from the public. Environ Manage 2001 Mar 1;27(3):435-450. [doi: 10.1007/s002670010160] [Medline: 11148768]
18. Edwards P, Hindmarsh R, Mercer H, Bond M, Rowland A. A three-stage evaluation of a deliberative event on climate change and transforming energy. J Public Delib 2007;4(1):12. [doi: 10.16997/jdd.65]
19. Kuylen MN, Kim SY, Ruck Keene A, Owen GS. Should age matter in COVID-19 triage? A deliberative study. J Med Ethics 2021 Mar 09;47(5):291-295 [FREE Full text] [doi: 10.1136/medethics-2020-107071] [Medline: 33687917]
20. Moss G, Coleman S. Deliberative manoeuvres in the digital darkness: e-democracy policy in the UK. Br J Polit Int Relat 2014 Feb 04;16(3):410-427. [doi: 10.1111/1467-856x.12004]

21. Santini RM, Carvalho H. The rise of participatory despotism: a systematic review of online platforms for political engagement. J Inf Commun Ethics Soc 2019 Nov 11;17(4):422-437. [doi: 10.1108/jices-02-2019-0016]
22. Bravo R, Balcells J, Padró-Solanet A. Platform politics in Europe: a model for the analysis of online citizen deliberation: Barcelona case study. Int J Commun 2019;13:25 [FREE Full text]
23. Friess D, Eilders C. A model for assessing online deliberation. Towards a more complex approach to measure and explain deliberativeness in online discussions. 2014 Presented at: The Internet, Policy & Politics Conference; September 25-26, 2014; Oxford, UK URL: https://tinyurl.com/yam6pr2k [doi: 10.1002/poi3.95]
24. Elstub S, Thompson R, Escobar O, Hollinghurst J, Grimes D, Aitken M, et al. The resilience of pandemic digital deliberation: an analysis of online synchronous forums. Javnost 2021 Oct 04;28(3):237-255. [doi: 10.1080/13183222.2021.1969616]
25. Jensen JL. Public spheres on the internet: anarchic or government ‐ sponsored – a comparison. Scand Pol Stud 2003 Nov 26;26(4):349-374. [doi: 10.1111/j.1467-9477.2003.00093.x]
26. Strandberg K. Public deliberation goes On-line?: an analysis of citizens' political discussions on the internet prior to the Finnish parliamentary elections in 2007. Javnost - The Public 2014 Nov 10;15(1):71-89. [doi: 10.1080/13183222.2008.11008965]
27. Janssen D, Kies R. Online forums and deliberative democracy. Acta Polit 2005 Aug 15;40(3):317-335. [doi: 10.1057/palgrave.ap.5500115]
28. Graham T. Beyond “political” communicative spaces: talking politics on the Wife Swap discussion forum. J Inf Technol Politics 2012 Jan;9(1):31-45. [doi: 10.1080/19331681.2012.635961]
29. Min SJ. Online vs. face-to-face deliberation: effects on civic engagement. J Comput Mediat Commun 2007;12(4):1369-1387. [doi: 10.1111/j.1083-6101.2007.00377.x]
30. Strandberg K, Berg J. Impact of temporality and identifiability in online deliberations on discussion quality: an experimental study. Javnost 2015 Jul 15;22(2):164-180. [doi: 10.1080/13183222.2015.1041230]
31. Berg J. The impact of anonymity and issue controversiality on the quality of online discussion. J Inf Technol Politics 2016 Mar 07;13(1):37-51. [doi: 10.1080/19331681.2015.1131654]
32. Spada P, Klein MA. A first step toward scaling-up deliberation: optimizing large group e-deliberation using argument maps. Research Gate. 2015. URL: https://www.researchgate.net/publication/278028114_A_First_Step_toward_Scaling-up_Deliberation_Optimizing_Large_Group_E-Deliberation_using_Argument_Maps [accessed 2024-04-29]
33. Towne WB, Herbsleb JD. Design considerations for online deliberation systems. J Inf Technol Politics 2012 Jan;9(1):97-115. [doi: 10.1080/19331681.2011.637711]
34. Stromer-Galley J, Martinson AM. Coherence in political computer-mediated communication: analyzing topic relevance and drift in chat. Discourse Commun 2009 May 12;3(2):195-216. [doi: 10.1177/1750481309102452]
35. Stromer-Galley J, Muhlberger P. Agreement and disagreement in group deliberation: effects on deliberation satisfaction, future engagement, and decision legitimacy. Polit Commun 2009 May 11;26(2):173-192. [doi: 10.1080/10584600902850775]
36. Strandberg K, Grönlund K. Online deliberation: an overview of the central aspects of a growing research field. In: Bächtiger A, Dryzek JS, Mansbridge J, Warren ME, editors. The Oxford Handbook of Deliberative Democracy. Oxford, UK: Oxford University Press; 2018:365-377.
37. Luskin RC, Fishkin JE, Iyengar S. Facilitating informed public opinion: evidence from face-to-face and online deliberative polls. Stanford Web Archive Portal. 2003. URL: https://wayback.stanford.edu/was/20180311204745mp_/http://pcl.stanford.edu/common/docs/research/iyengar/2003/facilitating.pdf [accessed 2024-10-02]
38. Jonsson M, Åström J. The challenges for online deliberation research: a literature review. Int J ePolitics 2014;1:15. [doi: 10.4018/ijep.2014010101]
39. Strandberg K, Grönlund K. Theory and practice in virtual mini-publics. In: Gr nlund K, B chtiger AD, Setälä M, editors. Deliberative Mini-Publics: Involving Citizens in the Democratic Process. New York, NY: ECPR Press; Aug 31, 2016:859-860.
40. Dryzek J. The Australian citizens’ parliament: a world first. J Public Delib 2008;5(1):68. [doi: 10.16997/jdd.73]
41. Price V. Citizens deliberating online: theory and some evidence. In: Davies T, Gangadharan SP, editors. Online Deliberation: Design, Research, and Practice. New York, NY: Center for the Study of Language and Information; 2009:37-58.
42. Lampa E, Sonnentheil B, Tökés A, Warner G. What has the COVID-19 pandemic taught us about conducting patient and public involvement remotely? Insights from a series of digital meeting observations. Res Involv Engagem 2021 Oct 11;7(1):73 [FREE Full text] [doi: 10.1186/s40900-021-00315-9] [Medline: 34635179]
43. Farrell M, Wilkinson C. A reappraisal of public engagement in Oxford during the pandemic: three case studies. Res Involv Engagem 2022 Mar 28;8(1):10 [FREE Full text] [doi: 10.1186/s40900-022-00343-z] [Medline: 35346388]
44. Grönlund K, Strandberg K, Himmelroos S. The challenge of deliberative democracy online – a comparison of face-to-face and virtual experiments in citizen deliberation. Inf Polit 2009 Dec 07;14(3):187-201. [doi: 10.3233/ip-2009-0182]
45. Schlozman KL, Verba S, Brady HE. Weapon of the strong? Participatory inequality and the internet. Persp Pol 2010 Jun 17;8(2):487-509. [doi: 10.1017/s1537592710001210]
46. Marston HR, Musselwhite C, Hadley RA. COVID 19 vs social isolation: the impact technology can have on communities, social connections and citizens. The British Society of Gerontology. 2020. URL: https://tinyurl.com/5x8m4pfj [accessed 2023-11-17]

47. Manikam L, Allaham S, Zakieh O, Bou Karim Y, Demel IC, Ali S, et al. Online community engagement in response to COVID-19 pandemic. Health Expect 2021 Apr;24(2):728-730 [FREE Full text] [doi: 10.1111/hex.13194] [Medline: 33493360]
48. Blacksher E, Diebel A, Forest PG, Goold SD, Abelson J. What is public deliberation? Hastings Cent Rep 2012 Mar 28;42(2):14-17. [doi: 10.1002/hast.26] [Medline: 22733324]
49. Creswell JW, Creswell JD. Research Design: Qualitative, Quantitative, and Mixed Methods Approaches. 5th edition. Thousand Oaks, CA: Sage Publications; 2018.
50. Calderon Ramirez C, Farmer Y, Frolic A, Bravo G, Gaucher NO, Payot A, et al. What are the views of Quebec and Ontario citizens on the tiebreaker criteria for prioritizing access to adult critical care in the extreme context of a COVID-19 pandemic? BMC Med Ethics 2024 Mar 19;25(1):31 [FREE Full text] [doi: 10.1186/s12910-024-01030-2] [Medline: 38504267]
51. Cracau D, Durán Lima J. On the normalized Herfindahl Hirschman index: a technical note. Int J Food Syst Dyn 2016;7(4):382-386. [doi: 10.22004/ag.econ.244557]
52. Goold SD, Danis M, Abelson J, Gornick M, Szymecko L, Myers CD, et al. Evaluating community deliberations about health research priorities. Health Expect 2019 Aug 28;22(4):772-784 [FREE Full text] [doi: 10.1111/hex.12931] [Medline: 31251446]
53. Knobloch KR, Gastil J, Reedy J, Cramer Walsh K. Did they deliberate? Applying an evaluative model of democratic deliberation to the Oregon citizens' initiative review. J Appl Commun Res 2013 May;41(2):105-125. [doi: 10.1080/00909882.2012.760746]
54. Kim SY, Wall IF, Stanczyk A, De Vries R. Assessing the public's views in research ethics controversies: deliberative democracy and bioethics as natural allies. J Empir Res Hum Res Ethics 2009 Dec;4(4):3-16 [FREE Full text] [doi: 10.1525/jer.2009.4.4.3] [Medline: 19919315]
55. Baker R, Mason H, McHugh N, Donaldson C. Public values and plurality in health priority setting: what to do when people disagree and why we should care about reasons as well as choices. Soc Sci Med 2021 May;277:113892 [FREE Full text] [doi: 10.1016/j.socscimed.2021.113892] [Medline: 33882440]
56. Abelson J, Forest PG, Eyles J, Smith P, Martin E, Gauvin FP. Deliberations about deliberative methods: issues in the design and evaluation of public participation processes. Soc Sci Med 2003 Jul;57(2):239-251. [doi: 10.1016/s0277-9536(02)00343-x] [Medline: 12765705]
57. Davies T, Chandler R. Online deliberation design: choices, criteria, and evidence. In: Nabatchi T, Weiksner M, Gastil J, Leighninger M, editors. In Democracy in Motion: Evaluating the Practice and Impact of Deliberative Civic Engagement, ed. Nabatchi T, Weiksner M, Gastil J, Leighninger M. (Oxford: Oxford University Press), -310. ISBN. Oxford, UK: Oxford University Press; 2011:1033-1310.
58. Fauville G, Luo M, Queiroz AC, Bailenson JN, Hancock J. Zoom exhaustion and fatigue scale. SSRN Journal. Preprint posted online February 23, 2021 2021 [FREE Full text] [doi: 10.2139/ssrn.3786329]
59. Crosby N, Nethercut D, Gastil J, Levine P. Citizens juries: creating a trustworthy voice of the people. In: Gastil J, Levine P, editors. The Deliberative Democracy Handbook: Strategies for Effective Civic Engagement in the Twenty-First Century. San Francisco, CA: Jossey-Bass; 2007.
60. Infodemic. World Health Organization (WHO). URL: https://www.who.int/health-topics/infodemic/the-covid-19-infodemic#tab=tab_1 [accessed 2024-04-22]
61. Zielinski C. Infodemics and infodemiology: a short history, a long future. Rev Panam Salud Publica 2021;45:e40 [FREE Full text] [doi: 10.26633/RPSP.2021.40] [Medline: 33995517]
62. Biddison EL, Gwon HS, Schoch-Spana M, Regenberg AC, Juliano C, Faden RR, et al. Scarce resource allocation during disasters: a mixed-method community engagement study. Chest 2018 Jan;153(1):187-195. [doi: 10.1016/j.chest.2017.08.001] [Medline: 28802695]
63. Knobloch KR, Gastil J. Civic (re)socialisation: the educative effects of deliberative participation. Politics 2014 Aug 06;35(2):183-200. [doi: 10.1111/1467-9256.12069]
64. Grönlund K, Herne K, Jäske M, Liimatainen H, Rapeli L, Värttö M, et al. Implementing a democratic innovation: online deliberation on a future transport system. Turun kaupunki. 2020. URL: https://www.turku.fi/sites/default/files/atoms/files/tutkimusraportteja_4-2020.pdf [accessed 2024-04-21]

Abbreviations

DD: democratic deliberation
HHI: Herfindahl-Hirschman Index
INM: Institut du Nouveau Monde
ODD: online democratic deliberation

Edited by T Leung; submitted 23.11.23; peer-reviewed by Y Aquino, Anonymous; comments to author 04.02.24; revised version received 30.06.24; accepted 25.09.24; published 11.11.24.

Please cite as:
Calderon Ramirez CL, Farmer Y, Downar J, Frolic A, Opatrny L, Poirier D, Bravo G, L'Espérance A, Gaucher N, Payot A, Dahine J, Tanuseputro P, Rousseau LM, Dumez V, Descôteaux A, Dallaire C, Laporte K, Bouthillier ME
Assessing the Quality of an Online Democratic Deliberation on COVID-19 Pandemic Triage Protocols for Access to Critical Care in an Extreme Pandemic Context: Mixed Methods Study
J Particip Med 2024;16:e54841
URL: https://jopm.jmir.org/2024/1/e54841
doi:10.2196/54841
PMID:

Original Paper

Self-Induced Mania Methods and Motivations Reported in Online Forums: Observational Qualitative Study

Emmanuelle CS Bostock[1,2], PhD; Adriana G Nevarez-Flores[1,3], PhD; Amanda L Neil[1,4], PhD; Halley M Pontes[5], PhD; Kenneth C Kirkby[2], MBBS

[1]Menzies Institute for Medical Research, University of Tasmania, Hobart, Australia
[2]School of Medicine, University of Tasmania, Hobart, Australia
[3]Tasmanian Centre for Mental Health Service Innovation, Tasmanian Health Service, Hobart, Australia
[4]The ALIVE National Centre for Mental Health Research Translation, University of Tasmania, Hobart, Australia
[5]School of Psychological Sciences-Birbeck, University of London, London, United Kingdom

Corresponding Author:
Emmanuelle CS Bostock, PhD
Menzies Institute for Medical Research
University of Tasmania
17 Liverpool Street
Hobart, 7000
Australia
Phone: 61 3 6226 7700
Email: ebostock@utas.edu.au

Abstract

Background: In bipolar disorder (BD), mania may be self-induced by manipulation of specific precipitants, as reported in case studies. Another potential source of information on the self-induction of mania is the online postings of users with lived experience of mania.

Objective: The primary aim of this study is to examine the range of methods used to self-induce mania or hypomania described by users of online forums with self-reported BD. Second, we summarize the motivations of users to engage in these behaviors.

Methods: We conducted an observational study of online forum posts that discussed self-induction of mania or hypomania, either in the posters themselves or observed firsthand in others. Posts were identified using Google advanced search operators, then extracted and coded for content in NVivo (version 12 for Mac; QSR International). A total of 44 online forum threads were identified discussing self-induced mania (n=25) or hypomania (n=19). These forums contained 585 posts by 405 usernames, of which 126 usernames discussed methods for self-induction across 327 posts (number of methods per username: median 2, IQR 1-4; range 1-11).

Results: In total, 36 methods were grouped by the authors. The most frequently reported were sleep reduction (n=50), caffeine (n=37), and cessation of medication (n=27). Twenty-six usernames reported their motivation to self-induce mania or hypomania; almost three-quarters (n=19) reported a desire to end a depressive episode. Almost a third of usernames (118/405) explicitly discouraged other forum users from self-inducing mania or hypomania.

Conclusions: Online forums provide an additional and valuable source of information about triggers for mania that may inform relapse prevention in BD. The online forum conversations investigated were generally responsible and included cautionary advice not to pursue these methods.

(J Particip Med 2024;16:e56970) doi:10.2196/56970

KEYWORDS
bipolar disorder; mania; hypomania; self-induced; online forums; consumer reports

Introduction

A self-induced phenomenon refers to one that is “brought about by oneself” [1]. Alternate terms used to describe symptoms, diseases, and neurocognitive and brain states “brought about by oneself” include self-precipitated, self-generated, self-stimulated, and self-regulated. The paradigmatic example of a self-induced phenomenon is self-induced seizures in patients with temporal lobe epilepsy. These seizures are achieved through repeated stimulation including behaviors such as hand waving repeatedly in front of the eyes; light-seeking, or gazing at patterns that may be accompanied by eye fluttering; and head rocking [2]. This stimulation leads to electrical excitement of a seizure focus, accompanied by changes in mood state or consciousness that may be reported as pleasurable. Patients report engaging in these forms of behavior for a variety of motivations, including a pleasant feeling, a reduction in stress or for social advantages [3], and as a treatment for depression [4].

A variety of self-induced symptoms and diseases are reported in psychiatric literature, usually under the rubric of factitious disorders or malingering, including self-induced vomiting [5], water intoxication [6], and neurodermatitis [7]. In factitious disorders, the patient intentionally acts to develop symptoms to assume the sick role, with the motivations unconscious and without external gain [8], whereas in malingering, external gains serve as the primary motivation for the self-induced disorder [8].

Limited attention has been given to self-induced presentations of other psychiatric disorders. One candidate is self-induction of an episode of mania or hypomania in bipolar disorder (BD). BD represents a group of severe and chronic mood disorders that includes bipolar I disorder, defined by the presence of mania, and bipolar II disorder, punctuated by the presence of hypomanic episodes and major depressive episodes [9]. The lifetime prevalence of the bipolar spectrum disorders is estimated at 2.4% of the population [10].

Mania has been defined as "[a] distinct period of abnormally and persistently elevated, expansive, or irritable mood and abnormally and persistently increased activity or energy, lasting at least 1 week" [11]. On the other hand, hypomania lasts at least 4 consecutive days. Contrary to mania, hypomania is less severe and does not cause marked impairment in the individual's social or occupational functioning and does not necessitate hospitalization [11]. Mania can appear independently, leading to unipolar mania [12,13]. However, it typically appears against the backdrop of preexisting depression that may or may not have received a formal diagnosis [12]. Mania is characterized by relatively rapid onset and offset making it possible to discern proximal precipitating factors for exacerbations or improvements. One consideration is that the external trigger factor may be obscured by prodromal symptoms [14]. An awareness of precipitating factors for mania provides potential avenues for the individual to modify the course of their illness.

In BD, self-induction of the often-pleasurable mood state of mania has only occasionally been reported in psychiatric literature. For example, case reports have described mania self-induced by the use of cough syrup [15] and the abuse of tricyclic antidepressants (dosulepin or clomipramine) [16]. While case reports were the predominant study type in a recent systematic review of triggers of acute mood episodes in BD (86/108 included studies) [17], only 1 study identified the purposeful triggering of manic episodes: a case report pertaining to clinically supervised sleep deprivation [18]. Rodrigues Cordeiro et al [17] identified the most studied trigger of mania in BD as pharmacotherapy, particularly antidepressant use, followed by sleep deprivation, fasting, and stressful life events. Other triggers reported in case studies include neurostimulation, energy drinks, nootropics (eg, acetyl-l-carnitine), herbal medicine (eg, St John's wort), seasonal changes, the lunar cycle, hormonal changes, and viral infection.

In an earlier narrative review of triggers of mania or hypomania in individuals with BD, Proudfoot et al [19] found a variety of precipitating factors, including goal-attainment events, antidepressant medication changes, disrupted circadian rhythms, spring or summer seasonal conditions, and more tentatively, stressful life events and high emotional expression. Self-induction of mania was not addressed. A detailed appraisal of trigger factors for mania or hypomania and depression in BD was then conducted through a survey of 198 young adults (aged 18-30 years) with BD [20]. Using their custom-made questionnaire "Triggers of mood change in young people with bipolar disorder," Proudfoot et al [20] reported a total of 21 triggers for mania or hypomania. The 6 most commonly reported triggers of mania or hypomania were falling in love, recreational stimulant use, starting a creative project, late night partying, going on vacation, and listening to loud music. Again, the self-induction of mania was not addressed.

Broad trigger factors for manic episodes were also identified in a study of 207 persons with BD [14]. Of these persons, 44% reported an external trigger, which could be either a positive or negative life event. In order of frequency, the trigger factors identified were work-related factors (eg, starting a new job), medication (including antidepressants), family-related issues, illicit drug use, sleep, and a large grouping of miscellaneous factors. The authors reported that the identification of triggers was not associated with personality traits or the number of affective episodes during a 7-year follow-up period. This study did not examine self-induction of mania or hypomania per se, rather trigger factors in general.

Notably, while both Proudfoot et al [20] and Smedler et al [14] were cited in Rodrigues Corderio et al [17], neither was included as an eligible study, potentially contributing to the noted "lack of large observational studies in the field." In their reviews of triggers, neither Proudfoot et al [20] nor Smedler et al [14] investigated self-induction as a mechanism linking triggers with the occurrence of mania or hypomania. The self-induction of mania and the methods thereof has not been comprehensively or systematically assessed, necessitating further large observational studies in the field.

People with mental disorders are reportedly eager to form connections with peers through social media, and they report benefits arising from these interactions [21]. Given these interactions, an emerging source of information regarding methods and motivations to self-induce mania or hypomania may be found in self-reported posts in online forums. Online forums are internet sites where users, also referred to as participants or members, may post messages and participate in conversations known as "threads," which are listed under an opening comment or question referred to as a "thread starter" [22]. Users will then either respond to the initial question posed or to other users' comments. Online forums can thus provide researchers with rich data sources where users report their own experiences in an open and reflective dialogue, rather than the time-constrained and predominantly closed-question format applied in a treatment setting or questionnaire administration [22].

Online forums have been analyzed in relation to various aspects of BD, including the effect of ketogenic diets on mood [23], online social support and unsolicited advice [24], and self-help [25].

Methods

Overview

An observational thematic analysis of posts published in public online forums that related to self-induction of mania or hypomania in BD was conducted. Posts were identified through an advanced Google search undertaken in the third week of September 2021. The search strategy comprised the following syntax: (intitle:induce OR intitle:induced OR intitle:inducing OR intitle:self-induce OR intitle:self-induced OR intitle:trigger OR intitle:"make yourself" OR intitle:deprive) AND (intitle:mania OR inurl:mania OR intitle:"yourself manic" OR intitle:hypomania OR intitle:hypo) AND (inurl:comments OR inurl:threads OR +"Related Questions" OR intitle:Forums OR intitle:diary). Posts that met the inclusion criteria were extracted and threads pertaining to the self-induction of mania or hypomania were downloaded with original formatting retained, and imported into NVivo (version 12; QSR International). As a deidentification procedure, each forum was allocated a study-specific unique ID code, as were posts and participants. Furthermore, no verbatim text from the posts is reported in this publication. The inclusion and exclusion criteria are presented in Textbox 1.

The text content was rated independently by 2 authors (ECSB and AGN-F), who extracted and categorized methods of and motivations for self-induction, as well as whether users were discouraging of the practice. Any disagreements were moderated by a third author (ALN). An initial list of potential triggers was identified based on Proudfoot et al [20] and expanded upon during the data extraction process. Clinical and experiential knowledge was used to classify triggers into nodes using NVivo.

Textbox 1. Inclusion and exclusion criteria for individual posts.

Inclusion criteria

- Posted on a public online forum with a thread dedicated to the subject of self-induction of mania or hypomania
- Written in English
- Accessible without registration or password requirements
- Use of forum data for research purposes was not restricted by the forum's terms and conditions

Exclusion criteria

- Defunct URLs
- Posts containing identifying information, such as email addresses
- Posts made by the username "anonymous"
- Deleted posts

Ethical Considerations

This study conformed to the Australian National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2018) guidelines. This study was granted ethics approval (H0024444) by the University of Tasmania Social Science Ethics Committee. A waiver of consent was sought as there was no way of confirming the identity of a user or of contacting them on the basis of the data recorded within the forums. Forum users were only identified by the usernames they submitted in their posts to that forum and were not linked to communication avenues such as email. Users may or may not have been still posting on a given forum when the posts were identified.

Results

The search criteria adopted identified 44 online forums with threads on self-induced mania (n=25) or hypomania (n=19). The 44 online forums contained a total of 585 posts with the number of posts per forum ranging from 1-80 (median 10.5, IQR 5.75-17). The 585 posts were attributed to 405 unique usernames (median 1, IQR 1-1; range 1-12). Of these, 126 usernames discussed 1 or more methods to self-induce mania or hypomania (number of methods per username: median 2, IQR 1-4; range 1-11).

The narratives of these 126 usernames contained 327 descriptors related to self-induction, covering a total of 36 methods as grouped by the authors (Table 1). The most widely and frequently reported individual method of self-induction was sleep reduction (forums: n=26; posts: n=50) followed by caffeine (forums: n=22; posts: n=37), then cessation of medication use (forums: n=20; posts: n=27), and antidepressant medication (forums: n=17; posts: n=27). The top 10 methods for self-inducing mania or hypomania accounted for 71.2% (230/323 posts) of all reports of methods of self-induced mania or hypomania across the usernames' posts. Seven methods (19.4%; N=36) were mentioned only once in the overall sample of posts (ie, nicotine, artificial sweeteners, green tea, playing video games, reduction or cessation of exercise, sexual encounters, and yoga).

Table 1. Methods of reported strategies to self-induce mania or hypomania in online forums.

Trigger	Forums, n	Posts, n
Sleep reduction or deprivation	26	50
Caffeine	22	37
Cessation of medication	20	27
Antidepressant medication	17	27
Alcohol	15	19
Prescription stimulants	14	20
Self-imposed psychological demands	14	13
Recreational stimulant use	10	17
Other medication	9	10
Listening to loud music	9	9
Emotion	8	10
Drugs (unspecified)	6	8
Increased exercise	6	7
Diet change	6	6
Energy drinks	6	6
Amino acids	6	5
Cannabis	5	7
Light exposure	5	4
Psychedelics	4	4
Meditation	4	4
Nootropics	4	4
Supplements	4	4
Herbal medicine	3	4
Routine change	3	3
Sugar	3	3
Flu medication	2	2
Isolation	2	2
Psychotropic medications (unspecified)	2	2
Neurostimulation	2	2
Nicotine	1	1
Artificial sweetener	1	1
Green tea	1	1
Playing videogames	1	1
Reduction or cessation of exercise	1	1
Sexual encounters	1	1
Yoga	1	1

Motivations to self-induce mania or hypomania were provided by 26 users and included to relieve a depressive episode (n=19), to validate the diagnosis of BD by inducing mania (n=2) and others (n=5) such as to increase socializing or confidence or to escape reality.

Users typically commented on particular subjects under discussion in a given thread rather than addressing triggers as a whole. In total, 118 of 405 users (29.1%) posted comments explicitly discouraging the practice of self-induction of mania or hypomania.

Discussion

Principal Findings

This study is the first to examine the methods and motivations of reported strategies to self-induce mania or hypomania in self-reported BD as posted in online forums, and is the largest sample size reported in a study on self-induced triggers of mania or hypomania in BD. In addition, as one of a growing number of analyses using online (internet) forums as a data source for academic research, this work aids in establishing the usefulness of online forums as a data source, including for lived-experience knowledge and expertise.

This study identified 36 methods for self-inducing mania or hypomania, the largest number of potential triggers of mania or hypomania reported thus far for BD. The top 10 methods for self-inducing mania or hypomania reported by online forum participants, in decreasing order, were sleep reduction, caffeine, cessation of medication, antidepressant medications, alcohol, prescription stimulants, self-imposed psychological demands, recreational stimulants, taking other medications, and listening to music. These methods accounted for 71.2% of all reports of methods of self-induced mania or hypomania across the usernames' posts.

In comparison with 3 existing studies on triggers of mania in BD (Table 2), the only trigger identified in common across all 4 was antidepressant use. Just over a third of the methods identified within this study (13/36) were explicitly identified as triggers by Proudfoot et al [20], and 2 (including 1 additional method) were explicitly identified by Smedler et al [14]. A further 13 methods identified were potentially captured by the broad classifications of triggers used in the earlier studies, such as "medication" in Smedler et al [14]. Around 15 methods were in common between this study and Rodrigues Cordeiro et al [17], including light exposure and neurostimulation, which had not been identified in either Proudfoot et al [20] or Smedler et al [14]. Newly identified in this study were several lifestyle methods, underpinning the importance of online forums as a standalone source of lived-experience knowledge. These methods were meditation, isolation, playing video games, sexual encounters, and yoga. Notably, increased exercise, meditation, isolation, light exposure, and vagus nerve stimulation were identified in multiple forums, and in turn, in multiple posts.

Differences in methods identified in this study and triggers identified in the earlier literature may reflect the different objectives of the data sources or processes of engagement. For example, forum users report that interacting online can offer personalized care through peers that cannot be provided by health care professionals [26]. Forum users may also experience the "online disinhibition effect," a phenomenon whereby individuals say and do things online that they would not typically say and do in face-to-face interactions [27], facilitated by open-ended discussion and time for reflection. In contrast, surveys are undertaken by researchers to collect data that may or may not have direct benefits to participants and are subject to time or response constraints. For example, the Proudfoot et al survey [20] mostly listed broad classifications of triggers and a single open-ended question, "We would be delighted if you could come up with any other fascinating or distinct factors which have triggered a high in you. Please tell us about them and also how often they occur." This question did not lead to the identification of any additional triggers. There may also be a difference between when a person sets out to intentionally induce mania or hypomania and when these conditions are incidentally induced, as in Proudfoot et al [20] and Smedler et al [14]. Online forums also minimize the Hawthorne effect (ie, where participants respond in accordance with perceived expectations of researchers, as they are aware that they are being studied, leading to biased results) [28].

We found sleep deprivation was a trigger for mania or hypomania, consistent with Smedler et al [14] and Rodrigues Cordeiro et al [17]. In contrast, Proudfoot et al [20] found that it was a trigger only for the onset of depression. The study by Proudfoot et al [20] was restricted to young adults (aged 18-30 years), whereas the age range of the online forum sample is not known but may be presumed to include at least older participants (all were required to be adults to participate on forums). Smedler et al [14] conducted a prospective cohort study over 7 years, with a minimum age of 17 years and a mean age of 38 years. Participants with a longer history of BD, and particularly those who have had repeated episodes of mania or hypomania, are better placed to identify methods or trigger factors. The preponderance of depressive symptoms in the average course of BD may also lead to exploration and experimentation of ways to escape depression; hence, the identification of more triggers of mania or hypomania [29].

The wide range of triggers for mania or hypomania reported in the online forums suggests a variety of proximate pathogenetic mechanisms. More than 3 decades ago, Wehr et al [18] hypothesized that diverse psychological, interpersonal, environmental, and pharmacological triggers of mania share a final common pathway of sleep deprivation. Malfunction in the circadian rhythm system has been proposed in the pathogenesis of mania [30,31]. This is supported by our finding that the most reported trigger related to sleep reduction.

While peer-to-peer interactions may involve risks, such as obtaining unreliable information resulting in unrealistic expectations, becoming online dependent, and withdrawing from social activities [21], we found that 118 users explicitly discouraged the practice of self-induction of mania or hypomania. This finding supports the positive aspects of online peer support [26]. However, there are no data available to substantiate whether exposure to discussion about triggers presented in a responsible manner results in improved insight and appropriate behavioral choices. In future research, we recommend the systematic assessment of engagement objectives and practices and an examination of the reasons to seek advice.

Table 2. Overlap of methods for self-inducing mania or hypomania reported in online forum posts and triggers for mania or hypomania identified in Proudfoot et al [20], Smedler et al [14] and Rodrigues Cordeiro et al [17].

Methods for self-induction identified in online forums	Proudfoot et al [20]	Smedler et al [14]	Rodrigues Cordeiro et al [17]
Sleep reduction or deprivation	No	Yes	Yes
Caffeine	Yes	No	No
Cessation of medication	No	Broad[a]	Yes
Antidepressant medication	Yes	Yes	Yes
Alcohol	Yes	No	No
Prescription stimulants	No	Broad	Yes
Self-imposed psychological demands	No	Broad	Broad
Recreational stimulant use	Yes	Broad	No
Other medication	No	Broad	Yes
Listening to loud music	Yes	No	No
Emotion	Yes	No	Yes
Drugs (unspecified)	No	Broad	No
Increased exercise	No	No	Yes
Diet change	Yes	No	Yes
Energy drinks	Yes	No	Yes
Amino acids	Broad	No	Yes
Cannabis	Yes	Broad	No
Light exposure	No	No	Yes
Psychedelics	Broad	Broad	No
Meditation	No	No	No
Nootropics	Broad	Broad	Yes
Supplements	Broad	Broad	No
Herbal medicine	Broad	Broad	Yes
Routine change	Yes	No	Yes
Sugar	Yes	No	No
Flu medication	Yes	No	No
Isolation	No	No	No
Psychotropic medications (unspecified)	Broad	Broad	No
Neurostimulation	No	No	Yes
Nicotine	Yes	No	No
Artificial sweeteners	Broad	No	No
Green tea	Broad	No	No
Playing video games	No	No	No
Reduction or cessation of exercise	No	No	No
Sexual encounters	No	No	No
Yoga	No	No	No

[a] "Broad" refers to broad categorizations such as "work" or "miscellaneous."

Limitations

This study is limited by several factors. A recognized issue with analyzing online forum accounts of medical conditions is that descriptions are given by the users themselves, without a confirmation of the diagnosis from a health practitioner [25]. Users may not have a formal diagnosis of BD or unipolar mania, and it is accordingly not known for certain how many of the users had a diagnosed medical condition, including BD. Furthermore, it may be the case that some users may have created additional usernames to remain anonymous in the forums they engaged with. The potential bias in people who access online forums constrains the generalizability of the study, and the frequency of these triggers in the general population cannot be assessed.

Conclusions

This study confirmed the disposition of people with self-reported BD to discuss methods of self-induction of mania or hypomania in online forums, and confirmed that these forums can provide large and wide-ranging sources of data that can lead to novel findings. This study also highlights the importance of the consumer voice in BD research, given that it is, to the best of the authors' knowledge, the first published study on methods of self-induced mania in BD. An understanding of behaviors that lead to self-induced mania may assist in improving the management and treatment of people with BD and assist in targeting relapse prevention approaches in BD.

Acknowledgments

With many thanks to the late Associate Professor Roumen Kirov and Associate Professor Michael Garry for their assistance and advice. All authors declared that they had insufficient or no funding to support open access publication of this manuscript, including from affiliated organizations or institutions, funding agencies, or other organizations. JMIR Publications provided APF support for the publication of this article.

Data Availability

The data sets generated during or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

ECSB, AGN-F, ALN, and KCK contributed to conceptualization. ECSB and AGN-F handled data curation. ECSB, AGN-F, and ALN conducted formal analysis. ECSB, AGN-F, ALN, KCK, and HMP managed investigation. ECSB, AGN-F, ALN, and KCK handled methodology. ECSB, AGN-F, and ALN managed project administration. ECSB wrote the original draft. ECSB, AGN-F, ALN, HMP, and KCK conducted the review and editing.

Conflicts of Interest

None declared.

References

1. "Self-induced". Oxford English Dictionary. URL: https://www.oed.com/dictionary/self-induced_adj?tl=true [accessed 2024-11-26]
2. Koepp MJ, Caciagli L, Pressler RM, Lehnertz K, Beniczky S. Reflex seizures, traits, and epilepsies: from physiology to pathology. Lancet Neurol 2016;15(1):92-105. [doi: 10.1016/S1474-4422(15)00219-7] [Medline: 26627365]
3. Binnie CD. Self-induction of seizures: the ultimate non-compliance. Epilepsy Res Suppl 1988;1:153-158. [Medline: 3243266]
4. Weaver DF. Self-induced "therapeutic seizures" for the treatment of depression. J Neuropsychiatry Clin Neurosci 2009;21(3):355-356. [doi: 10.1176/jnp.2009.21.3.355] [Medline: 19776330]
5. Fairburn CG. Self-induced vomiting. J Psychosom Res 1980;24(3-4):193-197. [doi: 10.1016/0022-3999(80)90041-0] [Medline: 7441587]
6. Vieweg WV, David JJ, Rowe WT, Wampler GJ, Burns WJ, Spradlin WW. Death from self-induced water intoxication among patients with schizophrenic disorders. J Nerv Ment Dis 1985;173(3):161-165. [doi: 10.1097/00005053-198503000-00005] [Medline: 3973577]
7. Torales J, Díaz NR, Barrios I, Navarro R, García O, O'Higgins M, et al. Psychodermatology of skin picking (excoriation disorder): a comprehensive review. Dermatol Ther 2020;33(4):e13661. [doi: 10.1111/dth.13661] [Medline: 32447793]
8. Mahirogullari M, Chloros GD, Cilli F, Cakmak S, Semiz UB, Kiral A. Factitious subcutaneous emphysema of an extremity. Joint Bone Spine 2008;75(1):84-86. [doi: 10.1016/j.jbspin.2007.02.007] [Medline: 17904889]
9. McIntyre RS, Berk M, Brietzke E, Goldstein BI, López-Jaramillo C, Kessing LV, et al. Bipolar disorders. Lancet 2020;396(10265):1841-1856. [doi: 10.1016/S0140-6736(20)31544-0] [Medline: 33278937]
10. Rowland TA, Marwaha S. Epidemiology and risk factors for bipolar disorder. Ther Adv Psychopharmacol 2018;8(9):251-269. [doi: 10.1177/2045125318769235] [Medline: 30181867]
11. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision. Washington, DC: American Psychiatric Association; 2022.

12. Malhi GS, Bell E, Bassett D, Boyce P, Bryant R, Hazell P, et al. The 2020 royal Australian and New Zealand college of psychiatrists clinical practice guidelines for mood disorders. Aust N Z J Psychiatry 2021;55(1):7-117. [doi: 10.1177/0004867420979353] [Medline: 33353391]
13. Angst J, Rössler W, Ajdacic-Gross V, Angst F, Wittchen HU, Lieb R, et al. Differences between unipolar mania and bipolar-I disorder: Evidence from nine epidemiological studies. Bipolar Disord 2019;21(5):437-448. [doi: 10.1111/bdi.12732] [Medline: 30475430]
14. Smedler E, Sparding T, Hattab A, Sellgren CM, Landén M. Reporting trigger factors for (hypo)manic episodes in bipolar disorder: association with personality and prognosis. Acta Psychiatr Scand 2020;141(6):534-540. [doi: 10.1111/acps.13174] [Medline: 32306385]
15. Mendez MF. Mania self-induced with cough syrup. J Clin Psychiatry 1992;53(5):173-174. [Medline: 1592847]
16. Lepping P, Menkes DB. Abuse of dosulepin to induce mania. Addiction 2007;102(7):1166-1167. [doi: 10.1111/j.1360-0443.2007.01828.x] [Medline: 17567406]
17. Rodrigues Cordeiro C, Côrte-Real BR, Saraiva R, Frey BN, Kapczinski F, de Azevedo Cardoso T. Triggers for acute mood episodes in bipolar disorder: a systematic review. J Psychiatr Res 2023;161:237-260. [doi: 10.1016/j.jpsychires.2023.03.008] [Medline: 36940629]
18. Wehr TA, Sack DA, Rosenthal NE. Sleep reduction as a final common pathway in the genesis of mania. Am J Psychiatry 1987;144(2):201-204. [doi: 10.1176/ajp.144.2.201] [Medline: 3812788]
19. Proudfoot J, Doran J, Manicavasagar V, Parker G. The precipitants of manic/hypomanic episodes in the context of bipolar disorder: a review. J Affect Disord 2011;133(3):381-387. [doi: 10.1016/j.jad.2010.10.051] [Medline: 21106249]
20. Proudfoot J, Whitton A, Parker G, Doran J, Manicavasagar V, Delmas K. Triggers of mania and depression in young adults with bipolar disorder. J Affect Disord 2012;143(1-3):196-202. [doi: 10.1016/j.jad.2012.05.052] [Medline: 22884233]
21. Naslund JA, Aschbrenner KA, Marsch LA, Bartels SJ. The future of mental health care: peer-to-peer support and social media. Epidemiol Psychiatr Sci 2016;25(2):113-122. [doi: 10.1017/S2045796015001067] [Medline: 26744309]
22. Shaw EK. The use of online discussion forums and communities for health research. Fam Pract 2020;37(4):574-577. [doi: 10.1093/fampra/cmaa008] [Medline: 32050014]
23. Campbell IH, Campbell H. Ketosis and bipolar disorder: controlled analytic study of online reports. BJPsych Open 2019;5(4):e58 [FREE Full text] [doi: 10.1192/bjo.2019.49] [Medline: 31530294]
24. Vayreda A, Antaki C. Social support and unsolicited advice in a bipolar disorder online forum. Qual Health Res 2009;19(7):931-942. [doi: 10.1177/1049732309338952] [Medline: 19556400]
25. Bauer R, Bauer M, Spiessl H, Kagerbauer T. Cyber-support: an analysis of online self-help forums (online self-help forums in bipolar disorder). Nord J Psychiatry 2013;67(3):185-190. [doi: 10.3109/08039488.2012.700734] [Medline: 22817138]
26. Brady E, Segar J, Sanders C. "You get to know the people and whether they're talking sense or not": negotiating trust on health-related forums. Soc Sci Med 2016;162:151-157. [doi: 10.1016/j.socscimed.2016.06.029] [Medline: 27359321]
27. Suler J. The online disinhibition effect. Cyberpsychol Behav 2004;7(3):321-326. [doi: 10.1089/1094931041291295] [Medline: 15257832]
28. Smith J, Bartlett J, Buck D, Honeyman M. Online support: investigating the role of public online forums in mental health. The King's Fund. 2017. URL: https://www.kingsfund.org.uk/publications/articles/online-support-public-forums-mental-health [accessed 2022-05-12]
29. Kupka RW, Altshuler LL, Nolen WA, Suppes T, Luckenbaugh DA, Leverich GS, et al. Three times more days depressed than manic or hypomanic in both bipolar I and bipolar II disorder. Bipolar Disord 2007;9(5):531-535. [doi: 10.1111/j.1399-5618.2007.00467.x] [Medline: 17680925]
30. Dallaspezia S, Benedetti F. Alteration in circadian rhythms in bipolar disorder: mechanisms and implications. In: de Quevedo JL, Carvalho AF, Vieta E, editors. Neurobiology of Bipolar Disorder: Road to Novel Therapeutics. New York, NY: Academic Press; 2021:117-128.
31. Rantala MJ, Luoto S, Borráz-León JI, Krams I. Bipolar disorder: an evolutionary psychoneuroimmunological approach. Neurosci Biobehav Rev 2021;122:28-37. [doi: 10.1016/j.neubiorev.2020.12.031] [Medline: 33421542]

Abbreviations

BD: bipolar disorder

Edited by A Powell; submitted 31.01.24; peer-reviewed by YJ Lee, P Vemavarapu; comments to author 17.05.24; revised version received 21.06.24; accepted 21.10.24; published 06.12.24.

Please cite as:
Bostock ECS, Nevarez-Flores AG, Neil AL, Pontes HM, Kirkby KC
Self-Induced Mania Methods and Motivations Reported in Online Forums: Observational Qualitative Study
J Particip Med 2024;16:e56970
URL: https://jopm.jmir.org/2024/1/e56970
doi:10.2196/56970
PMID:

Original Paper

Suicide Prevention by Peers Offering Recovery Tactics (SUPPORT) for US Veterans With Serious Mental Illness: Community Engagement Approach

Samantha A Chalker[1,2*], PhD; Jesus Serafez[1*], BA; Yuki Imai[1*], BA; Jeffrey Stinchcomb[1*], BFA; Estefany Mendez[1*]; Colin A Depp[1,2*], PhD; Elizabeth W Twamley[1,2*], PhD; Karen L Fortuna[3*], LICSW, PhD; Marianne Goodman[4,5*], MD; Matthew Chinman[6,7*], PhD

[1]Veterans Affairs San Diego Healthcare System, San Diego, CA, United States
[2]Department of Psychiatry, University of California, San Diego, San Diego, CA, United States
[3]Department of Psychiatry, Geisel School of Medicine at Dartmouth, Hanover, NH, United States
[4]James J. Peters Veterans Affairs Medical Center, Bronx, NY, United States
[5]Icahn School of Medicine at Mount Sinai, New York, NY, United States
[6]Veterans Affairs Pittsburgh Healthcare System, Pittsburgh, PA, United States
[7]RAND Corporation, Santa Monica, CA, United States
[*]all authors contributed equally

Corresponding Author:
Samantha A Chalker, PhD
Veterans Affairs San Diego Healthcare System
3350 La Jolla Village Drive
San Diego, CA, 92161
United States
Phone: 1 6199338749
Fax: 1 8585345475
Email: schalker@health.ucsd.edu

Abstract

Background: Peer specialists are hired, trained, and accredited to share their lived experience of psychiatric illness to support other similar individuals through the recovery process. There are limited data on the role of peer specialists in suicide prevention, including their role in intervention development.

Objective: To better understand peer specialists within the Veterans Health Administration (VHA), we followed partnership community engagement and a formative research approach to intervention development to (1) identify barriers, facilitators, and perceptions of VHA peer specialists delivering a suicide prevention service and (2) develop and refine an intervention curriculum based on an evidence-informed preliminary intervention framework for veterans with serious mental illness (SMI).

Methods: Following the community engagement approach, VHA local and national peer support and mental health leaders, veterans with SMI, and veteran peer specialists met to develop a preliminary intervention framework. Next, VHA peer specialist advisors (n=5) and scientific advisors (n=6) participated in respective advisory boards and met every 2-4 months for more than 18 months via videoconferencing to address study objectives. The process used was a reflexive thematic analysis after each advisory board meeting.

Results: The themes discussed included (1) the desire for suicide prevention training for peer specialists, (2) determining the role of VHA peer specialists in suicide prevention, (3) integration of recovery themes in suicide prevention, and (4) difficulties using safety plans during a crisis. There were no discrepancies in thematic content between advisory boards. Advisor input led to the development of Suicide Prevention by Peers Offering Recovery Tactics (SUPPORT). SUPPORT includes training in general suicide prevention and a peer specialist–delivered intervention for veterans with SMI at an increased suicide risk. This training aims to increase the competence and confidence of peer specialists in suicide prevention and the intervention supports veterans with SMI at an increased suicide risk through their recovery process.

Conclusions: This paper intends to document the procedures taken in suicide prevention intervention development, specifically those led by peer specialists, and to be a source for future research developing and evaluating similar interventions.

Trial Registration: ClinicalTrials.gov NCT05537376; https://classic.clinicaltrials.gov/ct2/show/NCT05537376

(J Particip Med 2024;16:e56204) doi:10.2196/56204

KEYWORDS

suicide prevention; advisor; veterans; recovery; community; peer specialist; peer support; serious mental illness; participatory design; community engagement; lived experience

Introduction

Suicide prevention is the top priority for the US Department of Veterans Affairs (VA). The 2023 National Veteran Suicide Prevention Annual Report described increases in veteran suicides between 2020 and 2021 [1]. Moreover, certain groups remain at high risk for suicide. For example, veterans with serious mental illness (SMI, eg, psychosis and bipolar disorders) have more than twice the rate of suicide and death ideation compared with nonveterans with SMI [2] and higher suicide rates compared to the general US and veteran populations [3]. Among veterans who recently used Veterans Health Administration (VHA) services, veterans with bipolar disorder had increased rates of suicide deaths from 2001 to 2021 [1], while those with schizophrenia had increased rates from 2019 to 2020 [4] but an overall decrease in suicide deaths from 2001 to 2021 [1]. All these individuals interacted with the VHA. As such, the VHA may be an ideal space to intervene and prevent future suicides.

There may be a limit to impact and usefulness of current suicide prevention standards of care for those with SMI. In a review of trials with suicide outcomes, researchers found that 61.7% of all trials and 75% of psychotherapy trials *excluded* individuals based on psychosis [5]. Relatedly, those with SMI are difficult to engage in and retain in treatment [6], experience cognitive impairments [7-11], and have limited social supports [12-15]. Therefore, veterans with SMI are an important high-risk group to target for suicide prevention interventions tailored to their unique needs.

An overarching emphasis for psychosocial treatments for SMI in the VHA is “recovery,” a process of change in which individuals strive to build a fulfilling life regardless of challenges stemming from mental health conditions [16]. A vital aspect of the recovery model is the importance of peer support, a nonmanualized form of social support in which people with similar challenges (eg, psychiatric and substance use disorders) help one another by sharing information and perspectives, helping develop problem-solving skills, and serving as successful role models [17].

Peer specialists are individuals who are certified and trained to use their own lived mental health experiences to support others through the recovery process and are paid or unpaid employees of the mental health system [18]. In VHA, peer specialists must be veterans themselves, and the ~1400 currently employed VA-wide are considered a vital part of VHA mental health recovery services [19]. VHA peer specialists are available to work with veterans once they are connected to care and provide recovery-oriented support as an adjunctive service; peer specialists may also provide outreach to veterans not enrolled in VHA. VHA peer specialists’ scope of practice includes modeling recovery and engendering hope, supporting active engagement in treatment, providing step-down recovery support, encouraging skill use, helping veterans advocate for themselves, and connecting veterans to VA and community resources [19]. Recent reviews of peer support services both in and out of VHA have documented a variety of positive outcomes for service users with SMI (eg, reduced inpatient use and improved recovery, hope, empowerment) [18,20], although some studies found little to no impact on outcomes [18,20,21]. Conclusions from these reviews highlight the need for increased methodological rigor in studies including peers.

Peer specialists are a potentially promising but untested adjunct to clinician-delivered suicide prevention. A recent review of peer specialist–based suicide prevention approaches concluded that they are feasible, including no major negative effects [22]. Peer specialists can address hopelessness, shame, burdensomeness, and social isolation, all psychosocial factors associated with suicide risk according to the interpersonal theory of suicide [23]. VHA peer specialists can screen for suicide but are not permitted to conduct comprehensive risk assessments. Furthermore, in VHA, peer specialists are already often working with individuals at high risk for suicide [24]. For example, data from a recent review of all services provided by all VHA peer specialists showed that 8% of the veterans they work with had a “high-risk suicide flag” on their medical record [25]. Qualitative data from peer specialists and clinicians working in a civilian suicide aftercare program indicate that peer specialists positively value working in suicide prevention [26]. Therefore, there is a need to improve the methodological rigor of peer support for SMI as well as systematically develop peer-delivered interventions to decrease suicide risk.

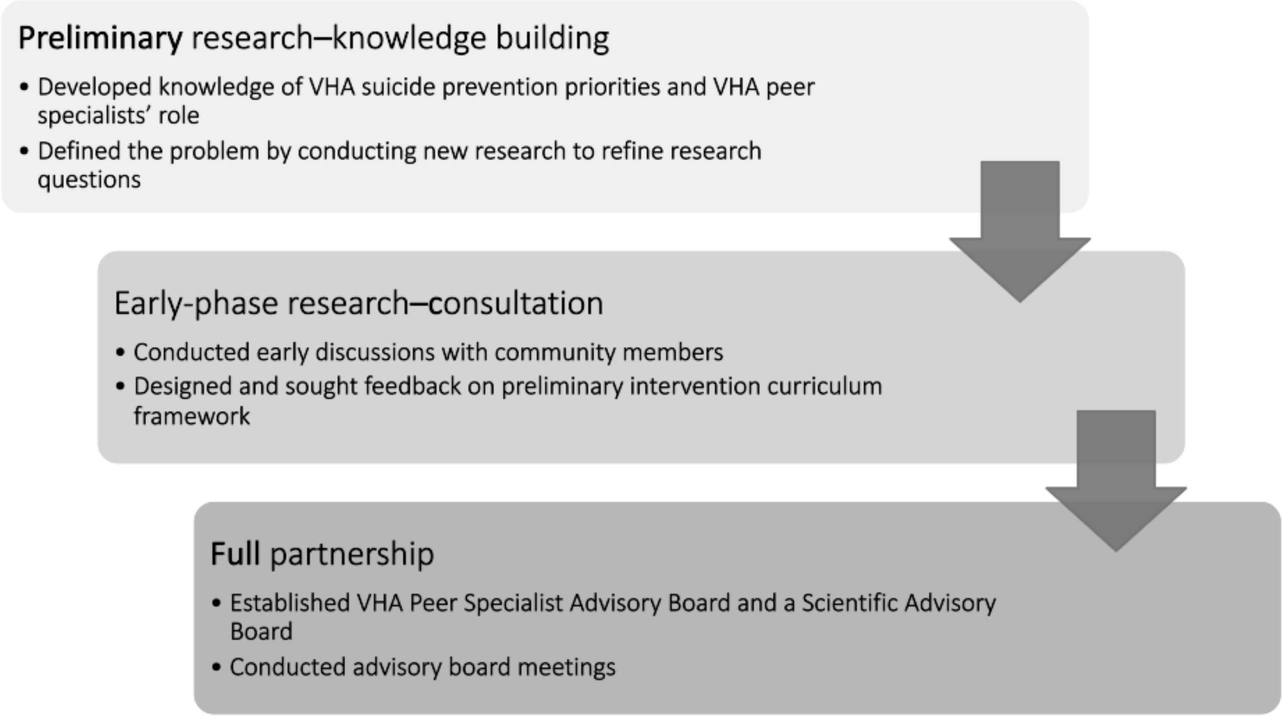
To create a peer-delivered suicide prevention intervention, we applied a formative research approach to intervention development [27]. The primary focus was including veteran peer specialists’ input to allow for equal decision-making with academic researchers in the intervention development [28,29]. We focused on potential role challenges that VHA peer specialists may experience in suicide prevention, including the recovery model of mental health and the intersection with other suicide prevention best practices. In this paper, we describe the results of a series of advisory meetings with the aims to (1) identify barriers, facilitators, and perceptions of VHA peer specialists delivering a suicide prevention service and (2) develop and refine an intervention curriculum based on an evidence-informed preliminary intervention framework.

Methods

Study Design

This overall study design is a combination intervention development approach [27] with a specific focus on a partnership through community engagement [29]. Figure 1 displays the methodological process of this study and is in chronological order unless otherwise specified as part of an iterative process.

Figure 1. Methodological process of community-engaged partnership intervention development approach. VHA: Veterans Health Administration.



Preliminary research–knowledge building

- Developed knowledge of VHA suicide prevention priorities and VHA peer specialists' role
- Defined the problem by conducting new research to refine research questions

Early-phase research–consultation

- Conducted early discussions with community members
- Designed and sought feedback on preliminary intervention curriculum framework

Full partnership

- Established VHA Peer Specialist Advisory Board and a Scientific Advisory Board
- Conducted advisory board meetings

Ethical Considerations

The VA San Diego institutional review board (IRB approval H210132) approved the larger research trial in which this paper reports on the initial phase (ClinicalTrials.gov NCT05537376). All advisors provided verbal informed consent. No monetary compensation was provided for participation.

Preliminary Research—Knowledge Building

Developed Knowledge of VHA Suicide Prevention Priorities and VHA Peers Specialists' Role

In this approach, we first identified gaps in current suicide prevention interventions and standards of care, including understanding the current state of the literature (as documented in the Introduction section), intervention development methodology among those with lived experience [30-32], and community-engaged research to inform intervention development [29,32]. Next, the principal investigator (PI, SAC) held a series of informal discussions with various VHA local and national peer support and mental health leaders, which highlighted encouraging support for VHA peer specialists to be involved in suicide prevention efforts while remaining inside their scope of practice. Simultaneously, the PI sought out and established relationships with scientific experts in suicide prevention, SMI, peer support services, and intervention design. These experts were identified as leaders in their fields by recommendations by others the PI spoke with and some were previously known to the PI. Experts in all areas echoed the same message as VHA leaders. SMI experts specifically emphasized considering cognition when tailoring interventions for individuals with SMI or anyone in an emotional or suicidal crisis. To date, compensatory cognitive strategies [33,34] have not been used to improve learning and recall in the context of suicide prevention interventions but may be crucial as cognitive impairments may limit the ability to recall and engage in preventive behaviors and intervention strategies.

Defined the Problem

Preliminary research, based on the new knowledge acquired, was then conducted. This research focused on further understanding the important role of safety planning (ie, a 6-step plan collaboratively completed with a provider and a veteran to identify when the veteran is becoming suicidal and what specifically the veteran can do next [35,36]) as a suicide prevention intervention standard of care given the calls for future research on safety planning [37] and that many trials with suicide-related outcomes exclude individuals on the basis of psychosis [5]. This preliminary research found that increased social support is needed during a suicidal crisis [38,39], that veterans welcome the use of peers in suicide prevention care [40,41], and that improved ability to remember and use one's safety plan is needed [42-44]. Further conversations were needed to determine whether peers could enhance safety planning.

Early Phase Research—Consultation

Discussions With Community Members

Valuing veteran peer specialists' perspectives on their potential role in suicide prevention, the PI first met with a group of 5 veteran peer specialists across the country interested in providing input as identified by a community liaison expert. Then, the PI joined the monthly meeting of the 9 local VHA peer specialists via invitation from the local recovery coordinator. Across meetings, a major discussion point was “recovery planning,” the prime example being the Wellness Recovery Action Plan (WRAP) [45]. WRAP is a peer-delivered, evidence-based intervention for those with SMI. WRAP centers on identifying broad warning signs of mental illness, developing wellness or coping tools for functional independence, planning for day-to-day effective living within one’s community, and building a crisis and postcrisis plan. WRAP focuses broadly on mental health and shares aspects with suicide safety planning. Although no formal protocols have been tested to adapt recovery planning for suicidal crises, veteran peer specialists informally shared that they have successfully used WRAP with individuals who are suicidal. Given the added benefit of interventions that directly target suicidal ideation and behaviors [46,47], a suicide-focused, WRAP-inspired plan delivered by peer specialists would allow for a recovery-oriented approach to enhance safety planning for veterans with SMI.

Designed and Sought Feedback on Preliminary Intervention Curriculum Framework

Following these conversations, a preliminary intervention curriculum framework was designed. Core concepts included valuing recovery, using wellness tools broadly and when suicidal, setting recovery goals, daily planning development, and learning (ie, cognitive training) strategy identification. This first iteration was reviewed by a VHA peer specialist, and, with verbal consent, the VHA peer specialist then explored the core concepts with 3 veterans with SMI. Both the VHA peer specialist and the veterans with SMI shared that the core concepts were relevant and acceptable to discuss in a peer support appointment. Notably, the VHA peer specialist expressed increased comfort, competence, and confidence in suicide prevention care following review of this intervention framework. Local and national VHA leadership provided feedback on the intervention framework and study design in one-on-one meetings over the study planning period. Leadership feedback remained centered on keeping the service within a VHA peer specialist’s scope of practice.

Full Partnership

Established VHA Peer Specialist Advisory Board and a Scientific Advisory Board

Five of the 9 locally employed peer specialists approached agreed to formally participate on a peer specialist advisory board. These advisors were provided with an informational sheet and provided verbal consent for their participation. All advisors on this board were peer specialists employed by the VHA and provided peer support services in mental health–related clinics and outreach teams. Peer specialist advisors attended eight, 30- to 60-minute meetings via videoconferencing to discuss the 3 themes in aim 1.

Of the scientific experts who provided input in the knowledge development phase, 6 scientific advisors were approached based on the sustained relationship with the PI and the unique area of expertise they championed. They all agreed to participate on the scientific advisory board. The scientific advisors included experts in suicide prevention, SMI, VHA peer support services and implementation, and intervention design and development. The scientific advisors attended one-on-one meetings with the PI and met regularly in small breakout groups every 3-4 months via videoconferencing. Each meeting focused on questions pertaining to the scientific advisors’ expertise area to best use that expertise to enhance the intervention and subsequent implementation.

Advisory Board Meetings

The PI moderated all advisory board meetings. Before each meeting, advisory board members reviewed the current intervention material. They could provide written feedback in addition to providing their verbal feedback during the meeting. Discussion questions were posed in the following predetermined key areas in each meeting: (1) scope of practice (eg, how would this intervention change or enhance a peer specialist’s duties?); (2) content (eg, what do you think about a person thinking about suicide setting long-term recovery goals?); (3) intervention design (eg, how many appointments should be provided to cover the material?); (4) suicide prevention interventions (eg, what role should safety planning play in the intervention?); (5) training (eg, how much background suicide prevention information should be provided?); and (6) study design (eg, what role do the peer specialists delivering the intervention play in relation to the research team?). Meetings were audio-recorded with verbal consent. Advisors were not given compensation due to the nature of funding available.

Reflexive Thematic Analysis Process

Observational notes were collected in real time by 2 research staff members who were in attendance and directly after the meetings by the PI. Audio recordings of the meeting discussions were transcribed. A reflexive thematic analysis process was used after each meeting [48,49]. One research staff member and the PI read a transcript to familiarize themselves with the data. Then initial codes of the first meeting’s transcripts for each advisory board were generated noting these codes using Word’s (Microsoft Corp) comment function. Discrepancies were addressed and then codes were collaboratively determined for the remaining meetings. Codes were added into Excel (Microsoft Corp) and organized by potential theme. Themes were then finalized. Intervention material revisions by the research staff included all feedback and were provided to advisors to review 1 month prior to the next meeting. This process was iterative and discussed with the full research team. The process for each subsequent meeting was repeated.

Results

VHA Peer Specialist Advisory Board Contributions

Overview

VHA Peer Specialist Advisory Board themes included (1) the desire for suicide prevention training for peer specialists, (2) determining the role of VHA peer specialists in suicide prevention, (3) integration of recovery themes in suicide prevention, and (4) difficulties using a suicide safety plan during a crisis.

Desire for Suicide Prevention Training for Peer Specialists

Peer specialist advisors were unclear what they are “allowed” to do when working with an individual at high risk for suicide, specifically when that individual was already known to be at a higher risk; they desired training to address these uncertainties. The peer specialist advisors believed that they did not have the confidence and competence to work with someone who is at a high risk for suicide (eg, “I’m worried I won’t know what to do or say [when someone says they are suicidal].”).

Determining the Role of VHA Peer Specialists in Suicide Prevention

The peer specialist advisors were unclear of the role of their direct clinical supervisor when a veteran is already identified to be at an increased risk of suicide (compared with whether the risk was newly identified by the peer specialist, eg, “I’ve been told to just bring my supervisor in at any mention of suicide.”). At the same time, peer specialist advisors indicated that they felt that they could do more for a veteran at an increased risk for suicide instead of immediately bringing in a licensed provider (eg, their clinical supervisor) to address the risk (eg, via a comprehensive suicide risk assessment [48]) if they had the necessary training (eg, “I feel like I can do more for suicidal veterans, but I’m not sure what I am allowed to do.”). Peer specialist advisors believed that they should have more autonomy when it comes to working with veterans at risk for suicide (eg, “We can adapt to what is needed in the moment … that’s what we’re best at.”). These advisors expressed interest in continued participation in future phases of study, including providing informed consent to deliver the intervention and to share their experiences.

Integration of Recovery Themes in Suicide Prevention

Unique skills peer specialists bring to a suicidal crisis are discussions of recovery and recovery planning (eg, “…I’ve been there and, even if I don’t have the exact same experience, I can still share my story to show that recovery is possible…”). A suicide-focused recovery plan was welcomed by advisors (paired with the appropriate suicide prevention training) as it (1) is within their scope of practice to complete a recovery plan with a veteran and (2) would provide them an intervention that is focused on suicide when they encounter a veteran at an increased suicide risk. Advisors agreed that this type of plan would be useful for veterans before and after a suicidal crisis, suggesting that this intervention could be for veterans at varying risk levels. Establishing rapport at the beginning of the interaction with veterans, focusing on strengths (eg, “specifically, reasons for living”), and modeling effective communication of suicidal thoughts were desired components to include in this intervention.

Relatedly, in developing the design of this intervention, advisors made a series of requests based on the recovery model. First, they asked for the intervention to follow a similar order as other recovery-oriented interventions they deliver in VHA, such as Whole Health. They stated that the general format should start with psychoeducation, move into inspiring hope, and then focus on recovery goals and social connection through daily action planning. Advisors noted that they liked “the option to have multiple versions” of certain materials. For example, the veteran could choose what format they prefer to use for their learning strategies (eg, post-it notes and mobile phone calendar). Finally, the advisors recommended a “triage approach” of what intervention material to focus on first (ie, asking about suicide) and then a hierarchy of recovery topics to target next in each appointment.

Difficulties Using a Suicide Safety Plan During a Crisis

In discussing the current standards of care for suicide prevention, the advisors reported potential difficulties with using suicide safety plans during a crisis based on their own lived experience of using a safety plan. Advisors expressed needing something shorter (eg, “a reminder of just my main reason for living and whom I am going to call”), instead of a 1-page or longer document when in a crisis. Advisors also suggested that this shorter plan should be recovery- and strengths-focused as well as “pocket-sized.” Wallet-sized hard copies and digital phone backgrounds with the pertinent information were discussed to have options to meet the needs of varying veteran preferences. Advisors expressed that while veteran patient treatment manuals are helpful for some, the option of translating any curriculum to memorable subelements may be beneficial especially when in a suicidal crisis. Relatedly, they suggested strategies for reminding a veteran to engage with their plan (eg, “Have you ever thought about the use of cell phones or alarms to help people with their daily goals? It’s something I try to use because I’m really good at getting lost in my mind.”). Ultimately, they requested to not have safety planning play a direct role in the intervention except for reviewing the veteran’s safety plan with them if they indicated that they were at higher suicide risk following VHA mandates.

Scientific Advisory Board Contributions

The scientific advisors’ recommendations were consistent in many respects to the VHA Peer Specialist Advisory Board’s contributions. They echoed the desire for peer specialists to play a valued role in suicide prevention and supported suicide prevention and intervention training for peer specialists within VHA (ie, theme 1). The scientific advisors focused on the peer specialists’ scope of practice within suicide prevention (ie, theme 2), which shaped the overall study design and outcomes as well as the intervention curriculum. There were no discrepancies between the advisory board’s feedback on the intervention.

In determining the role of peer specialists within suicide prevention (ie, theme 2), scientific advisors discussed the boundaries of VHA peer specialists’ scope of practice to address suicide risk (eg, promoting hope but not providing comprehensive suicide evaluations) and concerns from national advisors regarding the protection of peer specialists in this work. Possible iatrogenic effects to the peer specialists were considered paramount. Scientific advisors suggested peer specialists already hired at VHA as part of the Mental Health Care Line to serve as the peer specialists delivering the intervention in the study. The basis of this suggestion was made on funding availability as well as to further illuminate VHA peer specialists’ roles on site, clinic feasibility, and future broader implementation needs. However, including peer specialists as participants in the study was an ongoing point of debate. Some scientific advisors believed that peer specialists should be treated as any other member of the research team—and therefore not participants in the study. Other advisors as well as the local IRB requested peer specialists delivering the intervention to be considered participants (ie, provide informed consent and data) to better learn about potential iatrogenic effects of peer specialists delivering a suicide prevention intervention. To settle this, both sides of the argument were presented to the VHA Peer Specialist Advisory Board, and it was agreed that peer specialists already hired within VHA will be consented participants as part of the study design and documentation of their roles will be pertinent outcomes to the overall study.

In terms of intervention materials and navigating challenges of current standards of care in suicide prevention (ie, themes 3 and 4), scientific advisors focused primarily on the need for compensatory cognitive strategies to increase salience and recall of intervention materials. Similarly, they provided formatting recommendations for the veteran workbook.

Preliminary Curriculum

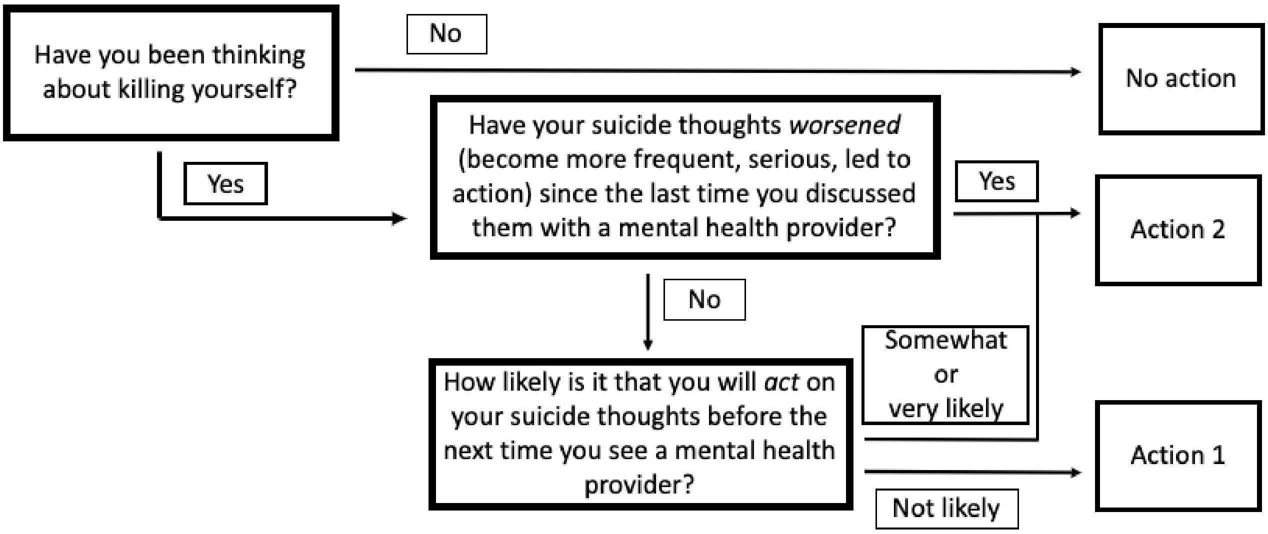
Overview

Based on the input from both advisory boards, we developed Suicide Prevention by Peers Offering Recovery Tactics (SUPPORT). The aims of SUPPORT are two-fold: (1) increase competence and confidence of peer specialists in suicide prevention and (2) assist veterans with SMI at increased suicide risk through the recovery process.

Training

The request for suicide prevention training by advisors led to the development of a training manual tailored to VHA peer specialists including two main sections: (1) a general suicide prevention training that can be a stand-alone training for any peer and (2) a training for VHA peer specialists in how to deliver a recovery-oriented, evidence-informed intervention for veterans with SMI at an increased suicide risk (Multimedia Appendix 1). The complete SUPPORT training includes two 4-hour training days. Adapting from other suicide prevention models for peer specialists [49], Figure 2 demonstrates the procedure in which peer specialists can ask directly about suicidal thoughts and an algorithm for when to incorporate intervention by a licensed provider.

Figure 2. Peer specialist protocol for directly asking about suicidal thoughts and what to do next. PI: principal investigator.



No action = continue with the appointment.
Action 1 = review Veteran's suicide safety plan with them, ensure they have contact information for their local regular mental health provider, the Veterans Crisis Line (988 press 1), and PI. Continue with the appointment. Inform PI after the appointment concludes.
Action 2 = alert on-call clinician (eg, PI) for further assessment with the person still present. You can complete Action 1 while waiting for on-call clinician.

Supervision and Consultation

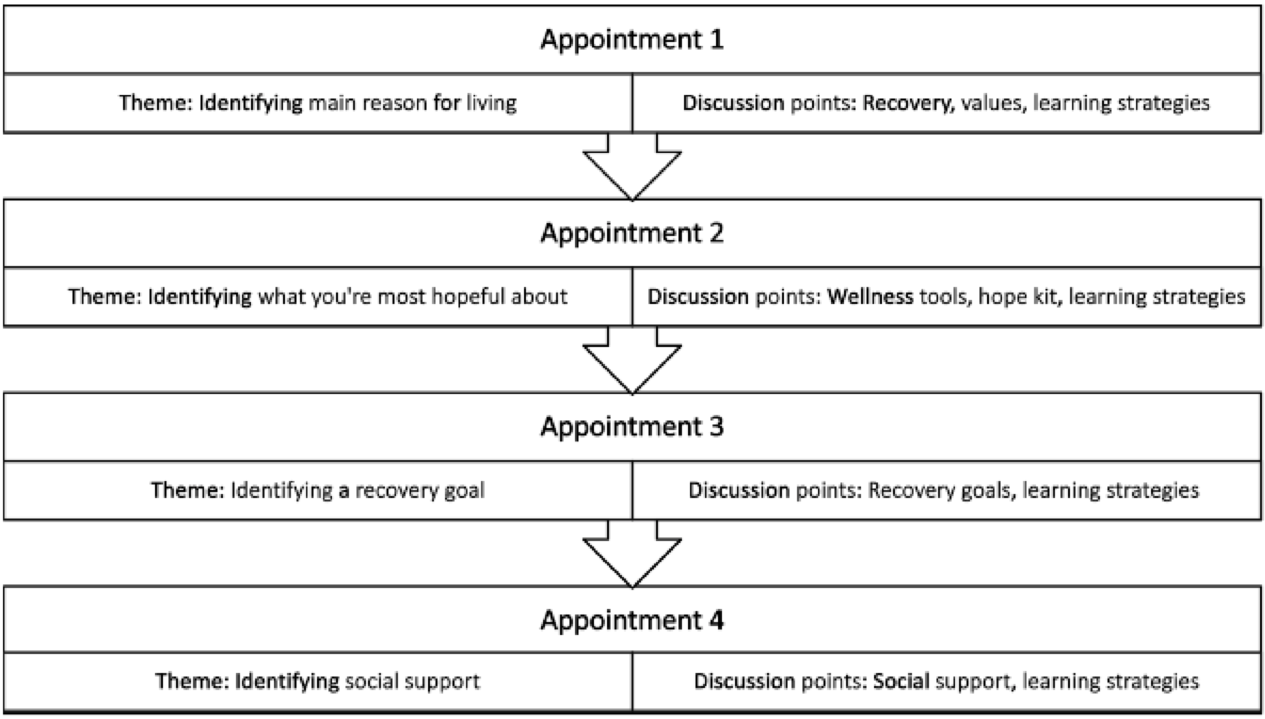
As part of ongoing training, a study consultation group is also provided biweekly (timing based on the peer specialists' request) after the complete SUPPORT training. The consultation group, comprising the peer specialists delivering SUPPORT, research staff, and a licensed clinical psychologist, serves as a dedicated time to discuss immediate concerns; receive feedback on SUPPORT appointments; discuss and process general concerns, fears, and questions; and discuss implementation or other administrative topics.

Intervention Content

The SUPPORT intervention is designed to promote enhanced personal recovery, quality of life, and connectedness to foster effective management of veterans' suicidal thoughts and behaviors (Figure 3). As is typical with other peer support services, the SUPPORT intervention augments and complements ongoing care (eg, case management, individual therapy, and psychiatric medication appointments).

After completing a comprehensive mental health evaluation with a licensed VHA provider, the veteran will meet with their peer specialist for approximately four 50-minute appointments to discuss and mutually share elements of value-based living, recovery and action planning, and compensatory cognitive (ie, learning) strategies. Including learning strategies as part of the SUPPORT intervention may improve learning of concepts, memory for intervention elements, prospective memory for symptom self-evaluations, review of intervention material, and promote general functional and social recovery. The final result is pocket-sized hard copy or digital set of 4 reminders for living (ie, the veteran's main reason for living, what the veteran is most hopeful about, the veteran's recovery goal, and who the veteran is going to call in a suicidal crisis).

Figure 3. Suicide Prevention by Peers Offering Recovery Tactics intervention preliminary intervention curriculum.



Discussion

Principal Findings

Over 18 months, the research team built trust and relationships with peer specialists and scientific advisors across the United States to design a suicide prevention intervention for veterans with SMI using the recovery model. Partnership engagement consisted of contacting potential partners via email to determine interest, building relationships with potential partners, creating 2 separate advisory boards, and meeting separately with both advisory boards to include their input and equal decision-making in the intervention development process. A peer specialist–delivered suicide prevention intervention and a suicide prevention training for VHA peer specialists were developed. This work adds to the literature of lived experience–driven intervention design and development in suicide prevention [30,31]. The steps reported here are intended to document the procedures taken in suicide prevention intervention development, specifically those led by peer specialists, and to be a source for future research developing and evaluating similar interventions.

Lessons Learned

This research paper depicts lessons learned, but 3 additional lessons are worthy of discussion. The first focuses on staffing. Peer specialists, clinical supervisors, and leadership changes are necessary considerations in VHA training and intervention development work. This study saw turnover of local leadership, leading to delays in the community engagement process due to the uncertain structure of local peer support services. This process will continue to be carefully documented to support related work throughout the remainder of the study. Second, the research funding for this project precludes compensation of VHA employees for study activities. That is, peer specialists employed by VHA—the target population of advisors and deliverers of the intervention—were not eligible for study compensation. Other than monetary compensation, such as time off, should be considered. Third, limited models for advisor engagement exist [50], especially in suicide prevention intervention development [30,51]. Although there are relevant models to draw from in other areas [28,32,52], some of which focus on important diverse and underserved populations [53], and there is a need for clear documentation of partnership engagement in this intersection.

Limitations

While this study adds to the community engagement literature in suicide prevention intervention development studies, it has limitations. The advisory boards included a small number of individuals who were self-selected and, therefore, may differ from the larger population the study aims to serve. Due to IRB constraints, the advisory board excluded veterans who were not peer specialists. To rectify this, veterans recruited as participants in the implementation phase will participate in qualitative interviews to include their perspectives in refining the intervention. Moreover, while initial advisors included veteran peer specialists outside of VHA, the final advisory board is made up of only VHA-employed peer specialists. Therefore, these findings may not generalize to other community or clinical settings where peer specialists are less common or may have different roles and levels of interaction with patients.

Conclusions

As Watling et al [30] suggested, a combined methodology is presented here. To further refine these materials, a 2-phase study design that continues to involve these advisory boards is underway. In the remaining portion of phase 1, the research team will train VHA peer specialists via an open pilot trial and continue to monitor the role of the peer specialists as research team members and study participants. Individual semistructured qualitative interviews of the peer specialist and veteran participants will be conducted, and materials will be revised based on these interviews and ongoing input from both advisory boards. The open pilot trial of phase 1 is actively recruiting as of August 2023. This partnership approach to intervention development champions the crucial elements of including voices with lived experience of suicidal thoughts and behaviors in research design, testing, and implementation.

Acknowledgments

This work was supported in part by an award (IK2RX004239-01) from VA Rehabilitation Research and Development awarded to SAC. EWT gratefully acknowledges the support of a VA Rehabilitation Research and Development Research Career Scientist Award. The contents do not represent the views of the US Department of Veterans Affairs or the United States Government.

Conflicts of Interest

SAC discloses financial support from CAMS-care, LLC (a clinical training/consulting company), and from the Zero Suicide Institute. KLF discloses financial support from Social Wellness, LLC, and Emissary Health. MG discloses financial support from Boehringer Ingleheim Pharmaceuticals. There are no other conflicts of interest to disclose.

Multimedia Appendix 1
SUPPORT training manual preliminary curriculum for veteran certified peer specialists.
[DOCX File , 29 KB - jopm_v16i1e56204_app1.docx]

References

1. 2023 National Veteran Suicide Prevention annual report. Office of Mental Health and Suicide Prevention. 2023. URL: https://www.mentalhealth.va.gov/docs/data-sheets/2023/2023-National-Veteran-Suicide-Prevention-Annual-Report-FINAL-508.pdf [accessed 2024-04-17]
2. Jahn DR, Muralidharan A, Drapalski AL, Brown CH, Fang LJ, Lucksted A. Differences in suicide and death ideation among veterans and nonveterans with serious mental illness. Psychol Serv 2018;15(1):31-39 [FREE Full text] [doi: 10.1037/ser0000127] [Medline: 28287770]
3. Aslan M, Radhakrishnan K, Rajeevan N, Sueiro M, Goulet JL, Li Y, et al. Suicidal ideation, behavior, and mortality in male and female US Veterans with severe mental illness. J Affect Disord 2020;267:144-152. [doi: 10.1016/j.jad.2020.02.022] [Medline: 32063566]
4. 2022 National Veteran Suicide Prevention annual report. Office of Mental Health and Suicide Prevention. 2022. URL: https://www.mentalhealth.va.gov/suicide_prevention/data.asp [accessed 2022-09-25]
5. Villa J, Ehret BC, Depp CA. Systematic review of the inclusion of people with psychosis in suicide-specific clinical trials. Crisis 2020;41(3):233-236. [doi: 10.1027/0227-5910/a000628] [Medline: 31657642]
6. Dixon LB, Holoshitz Y, Nossel I. Treatment engagement of individuals experiencing mental illness: review and update. World Psychiatry 2016;15(1):13-20 [FREE Full text] [doi: 10.1002/wps.20306] [Medline: 26833597]
7. Stergiopoulos V, Cusi A, Bekele T, Skosireva A, Latimer E, Schütz C, et al. Neurocognitive impairment in a large sample of homeless adults with mental illness. Acta Psychiatr Scand 2015;131(4):256-268. [doi: 10.1111/acps.12391] [Medline: 25604122]
8. Velligan DI, Mahurin RK, Diamond PL, Hazleton BC, Eckert SL, Miller AL. The functional significance of symptomatology and cognitive function in schizophrenia. Schizophr Res 1997;25(1):21-31. [doi: 10.1016/S0920-9964(97)00010-8] [Medline: 9176924]
9. Twamley EW, Doshi RR, Nayak GV, Palmer BW, Golshan S, Heaton RK, et al. Generalized cognitive impairments, ability to perform everyday tasks, and level of independence in community living situations of older patients with psychosis. Am J Psychiatry 2002;159(12):2013-2020 [FREE Full text] [doi: 10.1176/appi.ajp.159.12.2013] [Medline: 12450950]
10. Green MF, Kern RS, Heaton RK. Longitudinal studies of cognition and functional outcome in schizophrenia: implications for MATRICS. Schizophr Res 2004;72(1):41-51. [doi: 10.1016/j.schres.2004.09.009] [Medline: 15531406]

11. Green MF. What are the functional consequences of neurocognitive deficits in schizophrenia? Am J Psychiatry 1996;153(3):321-330. [doi: 10.1176/ajp.153.3.321] [Medline: 8610818]
12. Kilbourne AM, McCarthy JF, Post EP, Welsh D, Blow FC. Social support among veterans with serious mental illness. Soc Psychiatry Psychiatr Epidemiol 2007;42(8):639-646. [doi: 10.1007/s00127-007-0212-1] [Medline: 17520160]
13. Chronister J, Chou CC, Kwan KLK, Lawton M, Silver K. The meaning of social support for persons with serious mental illness. Rehabil Psychol 2015;60(3):232-245 [FREE Full text] [doi: 10.1037/rep0000038] [Medline: 26009778]
14. Hendryx M, Green CA, Perrin NA. Social support, activities, and recovery from serious mental illness: STARS study findings. J Behav Health Serv Res 2009;36(3):320-329 [FREE Full text] [doi: 10.1007/s11414-008-9151-1] [Medline: 19011972]
15. Corrigan PW, Phelan SM. Social support and recovery in people with serious mental illnesses. Community Ment Health J 2004;40(6):513-523. [doi: 10.1007/s10597-004-6125-5] [Medline: 15672690]
16. SAMHSA's working definition of recovery. Substance Abuse and Mental Health Services Administration. 2012. URL: https://store.samhsa.gov/sites/default/files/pep12-recdef.pdf [accessed 2021-10-13]
17. Solomon P. Peer support/peer provided services underlying processes, benefits, and critical ingredients. Psychiatr Rehabil J 2004;27(4):392-401. [doi: 10.2975/27.2004.392.401] [Medline: 15222150]
18. Chinman M, George P, Dougherty RH, Daniels AS, Ghose SS, Swift A, et al. Peer support services for individuals with serious mental illnesses: assessing the evidence. Psychiatr Serv 2014;65(4):429-441 [FREE Full text] [doi: 10.1176/appi.ps.201300244] [Medline: 24549400]
19. VHA directive 1163: psychosocial rehabilitation and recovery services. Department of Veterans Affairs, Veterans Health Administration. 2019. URL: https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=8438 [accessed 2024-04-17]
20. Lloyd-Evans B, Mayo-Wilson E, Harrison B, Istead H, Brown E, Pilling S, et al. A systematic review and meta-analysis of randomised controlled trials of peer support for people with severe mental illness. BMC Psychiatry 2014;14:39 [FREE Full text] [doi: 10.1186/1471-244X-14-39] [Medline: 24528545]
21. Chien WT, Clifton AV, Zhao S, Lui S. Peer support for people with schizophrenia or other serious mental illness. Cochrane Database Syst Rev 2019;4(4):CD010880 [FREE Full text] [doi: 10.1002/14651858.CD010880.pub2] [Medline: 30946482]
22. Bowersox NW, Jagusch J, Garlick J, Chen JI, Pfeiffer PN. Peer-based interventions targeting suicide prevention: a scoping review. Am J Community Psychol 2021;68(1-2):232-248 [FREE Full text] [doi: 10.1002/ajcp.12510] [Medline: 33720444]
23. Joiner TE, Van Orden KA, Witte TK, Selby EA, Ribeiro JD, Lewis R, et al. Main predictions of the interpersonal-psychological theory of suicidal behavior: empirical tests in two samples of young adults. J Abnorm Psychol 2009;118(3):634-646 [FREE Full text] [doi: 10.1037/a0016500] [Medline: 19685959]
24. Cook JA, Copeland ME, Jonikas JA, Hamilton MM, Razzano LA, Grey DD, et al. Results of a randomized controlled trial of mental illness self-management using wellness recovery action planning. Schizophr Bull 2012;38(4):881-891 [FREE Full text] [doi: 10.1093/schbul/sbr012] [Medline: 21402724]
25. Bowersox NW. Peer providers in the Veterans Health Administration: summary of providers, care, and veterans served, FY2015-FY2018Q2. Department of Veterans Affairs. 2019. URL: https://www.veteranshealthlibrary.va.gov/142,41684_VA [accessed 2024-04-17]
26. Van Zanden B, Bliokas V. Taking the next step: a qualitative study examining processes of change in a suicide prevention program incorporating peer-workers. Psychol Serv 2022;19(3):508-518. [doi: 10.1037/ser0000445] [Medline: 34138619]
27. O'Cathain A, Croot L, Sworn K, Duncan E, Rousseau N, Turner K, et al. Taxonomy of approaches to developing interventions to improve health: a systematic methods overview. Pilot Feasibility Stud 2019;5:41 [FREE Full text] [doi: 10.1186/s40814-019-0425-6] [Medline: 30923626]
28. Fleurence R, Selby JV, Odom-Walker K, Hunt G, Meltzer D, Slutsky JR, et al. How the Patient-Centered Outcomes Research Institute is engaging patients and others in shaping its research agenda. Health Aff (Millwood) 2013;32(2):393-400. [doi: 10.1377/hlthaff.2012.1176] [Medline: 23381533]
29. Principles of community engagement (2nd ed), NIH publication no. 11-7782. Agency for Toxic Substances and Disease Registry. URL: https://www.atsdr.cdc.gov/communityengagement/ [accessed 2023-09-06]
30. Watling D, Preece M, Hawgood J, Bloomfield S, Kõlves K. Developing an intervention for suicide prevention: a rapid review of lived experience involvement. Arch Suicide Res 2022;26(2):465-480. [doi: 10.1080/13811118.2020.1833799] [Medline: 33073734]
31. Schlichthorst M, Ozols I, Reifels L, Morgan A. Lived experience peer support programs for suicide prevention: a systematic scoping review. Int J Ment Health Syst 2020;14:65 [FREE Full text] [doi: 10.1186/s13033-020-00396-1] [Medline: 32817757]
32. Fortuna K, Barr P, Goldstein C, Walker R, Brewer L, Zagaria A, et al. Application of community-engaged research to inform the development and implementation of a peer-delivered mobile health intervention for adults with serious mental illness. J Particip Med 2019;11(1):e12380 [FREE Full text] [doi: 10.2196/12380] [Medline: 32095314]
33. Twamley EW, Vella L, Burton CZ, Heaton RK, Jeste DV. Compensatory cognitive training for psychosis: effects in a randomized controlled trial. J Clin Psychiatry 2012;73(9):1212-1219 [FREE Full text] [doi: 10.4088/JCP.12m07686] [Medline: 22939029]

34. Twamley EW, Thomas KR, Burton CZ, Vella L, Jeste DV, Heaton RK, et al. Compensatory cognitive training for people with severe mental illnesses in supported employment: a randomized controlled trial. Schizophr Res 2019;203:41-48 [FREE Full text] [doi: 10.1016/j.schres.2017.08.005] [Medline: 28823720]
35. Stanley B, Brown GK, Karlin BE, Kemp JE, Vonbergen HA. Safety plan treatment manual to reduce suicide risk: veteran version. United States Department of Veterans Affairs. 2008. URL: https://www.mentalhealth.va.gov/docs/VA_Safety_planning_manual.doc [accessed 2024-04-17]
36. Stanley B, Brown GK, Brenner LA, Galfalvy HC, Currier GW, Knox KL, et al. Comparison of the safety planning intervention with follow-up vs usual care of suicidal patients treated in the emergency department. JAMA Psychiatry 2018;75(9):894-900 [FREE Full text] [doi: 10.1001/jamapsychiatry.2018.1776] [Medline: 29998307]
37. VA/DoD clinical practice guideline for the assessment and management of patients at risk for suicide. Department of Veterans Affairs and Department of Defense. 2019. URL: https://www.healthquality.va.gov/guidelines/MH/srb/VADoDSuicideRiskFullCPGFinal5088212019.pdf [accessed 2024-04-17]
38. Chalker SA, Parrish EM, Ceren CSM, Depp CA, Goodman M, Doran N. Predictive importance of social contacts on U.S. veteran suicide safety plans. Psychiatr Serv 2023;74(3):244-249 [FREE Full text] [doi: 10.1176/appi.ps.202100699] [Medline: 36039556]
39. Chalker SA, Parrish EM, Ceren CSM, Depp CA, Ilgen MA, Goodman M, et al. Crisis service utilization following completion of a suicide safety plan for veterans with and without affective and nonaffective psychosis. J Psychiatr Res 2022;154:219-223. [doi: 10.1016/j.jpsychires.2022.07.034] [Medline: 35961177]
40. Chalker SA. U.S. Veteran interest in peer specialists' help to enhance suicide safety plans: understanding Veteran perspectives on safety plan engagement. In: Association of Cognitive and Behavioral Therapies. Seattle, WA; 202 Presented at: Association of Cognitive and Behavioral Therapies; April 17, 2023; Seattle, WA URL: https://www.abct.org/
41. Wilson MP, Waliski A, Thompson RG. Feasibility of peer-delivered suicide safety planning in the emergency department: results from a pilot trial. Psychiatr Serv 2022;73(10):1087-1093 [FREE Full text] [doi: 10.1176/appi.ps.202100561] [Medline: 35502515]
42. Parrish EM, Quynh A, Scott V, Chalker SA, Chang C, Kamarsu S, et al. Suicide safety plan self-knowledge in serious mental illness: psychiatric symptom correlates and effects of brief intervention. Community Ment Health J 2023;59(8):1639-1646. [doi: 10.1007/s10597-023-01155-5] [Medline: 37340170]
43. Kayman DJ, Goldstein MF, Dixon L, Goodman M. Perspectives of suicidal veterans on safety planning: findings from a pilot study. Crisis 2015;36(5):371-383. [doi: 10.1027/0227-5910/a000348] [Medline: 26502788]
44. Matthieu MM, Morissette SB, Clafferty S, Degutis L, Oliver CM, Adkins DA, et al. Veteran experiences with suicide ideation, suicide attempt, and social support in safety planning within the Department of Veterans Affairs. Mil Med 2023;188(11-12):e3289-e3294 [FREE Full text] [doi: 10.1093/milmed/usad144] [Medline: 37201198]
45. Canacott L, Moghaddam N, Tickle A. Is the Wellness Recovery Action Plan (WRAP) efficacious for improving personal and clinical recovery outcomes? A systematic review and meta-analysis. Psychiatr Rehabil J 2019;42(4):372-381. [doi: 10.1037/prj0000368] [Medline: 31135173]
46. Calati R, Courtet P. Is psychotherapy effective for reducing suicide attempt and non-suicidal self-injury rates? Meta-analysis and meta-regression of literature data. J Psychiatr Res 2016;79:8-20. [doi: 10.1016/j.jpsychires.2016.04.003] [Medline: 27128172]
47. Meerwijk EL, Parekh A, Oquendo MA, Allen IE, Franck LS, Lee KA. Direct versus indirect psychosocial and behavioural interventions to prevent suicide and suicide attempts: a systematic review and meta-analysis. Lancet Psychiatry 2016;3(6):544-554. [doi: 10.1016/S2215-0366(16)00064-X] [Medline: 27017086]
48. King D. OPERATION S.A.V.E.: suicide prevention training for front-line employees in the U.S. Department of Veterans Health Affairs. In: Lavigne JE, editor. Frontiers in Suicide Risk. New York: Nova Science Publishers, Inc; 2012:185-193.
49. Pfeiffer PN, King C, Ilgen M, Ganoczy D, Clive R, Garlick J, et al. Development and pilot study of a suicide prevention intervention delivered by peer support specialists. Psychol Serv 2019;16(3):360-371 [FREE Full text] [doi: 10.1037/ser0000257] [Medline: 30382743]
50. Kujala J, Sachs S, Leinonen H, Heikkinen A, Laude D. Stakeholder engagement: past, present, and future. Bus Soc 2022;61(5):1136-1196 [FREE Full text] [doi: 10.1177/00076503211066595]
51. Bornheimer LA, Li Verdugo J, Holzworth J, Im V, Smith FN, Sliwa H, et al. Modifying a cognitive behavioral suicide prevention treatment for adults with schizophrenia spectrum disorders in community mental health. Psychiatry Res 2022;311:114505 [FREE Full text] [doi: 10.1016/j.psychres.2022.114505] [Medline: 35290884]
52. Shelef DQ, Rand C, Streisand R, Horn IB, Yadav K, Stewart L, et al. Using stakeholder engagement to develop a patient-centered pediatric asthma intervention. J Allergy Clin Immunol 2016;138(6):1512-1517 [FREE Full text] [doi: 10.1016/j.jaci.2016.10.001] [Medline: 27744029]
53. Vastine A, Gittelsohn J, Ethelbah B, Anliker J, Caballero B. Formative research and stakeholder participation in intervention development. Am J Health Behav 2005;29(1):57-69. [doi: 10.5993/ajhb.29.1.5] [Medline: 15604050]

Abbreviations

IRB: institutional review board
PI: principal investigator
SMI: serious mental illness
SUPPORT: Suicide Prevention by Peers Offering Recovery Tactics
VA: Veterans Affairs
VHA: Veterans Health Administration
WRAP: Wellness Recovery Action Plan

Edited by S Woods; submitted 09.01.24; peer-reviewed by J LaCroix, A Peeples; comments to author 22.02.24; revised version received 11.03.24; accepted 15.03.24; published 23.05.24.

Please cite as:
Chalker SA, Serafez J, Imai Y, Stinchcomb J, Mendez E, Depp CA, Twamley EW, Fortuna KL, Goodman M, Chinman M
Suicide Prevention by Peers Offering Recovery Tactics (SUPPORT) for US Veterans With Serious Mental Illness: Community Engagement Approach
J Particip Med 2024;16:e56204
URL: https://jopm.jmir.org/2024/1/e56204
doi:10.2196/56204
PMID:38781010

Original Paper

Shifting Grounds—Facilitating Self-Care in Testing for Sexually Transmitted Infections Through the Use of Self-Test Technology: Qualitative Study

Bettina Trettin[1,2,3], PhD; Mette Maria Skjøth[1], PhD; Nadja Trier Munk[1], MNS; Tine Vestergaard[1,2], PhD; Charlotte Nielsen[2,4,5], PhD

[1]Department of Dermatology and Allergy Centre, Odense University Hospital, Odense, Denmark
[2]Clinical Institute, Health Sciences, University of Southern Denmark, Odense, Denmark
[3]Centre for Innovative Medical Technology, Odense University Hospital, Odense, Denmark
[4]Department of Plastic Surgery, Odense University Hospital, Odense, Denmark
[5]Department of Oral and Maxillofacial Surgery, Odense University Hospital, Odense, Denmark

Corresponding Author:
Bettina Trettin, PhD
Department of Dermatology and Allergy Centre
Odense University Hospital
J. B. Winsløws Vej 4
Odense, 5000
Denmark
Phone: 45 60494279
Email: bettina.trettin@rsyd.dk

Abstract

Background: Chlamydia remains prevalent worldwide and is considered a global public health problem. However, testing rates among young sexually active people remain low. Effective clinical management relies on screening asymptomatic patients. However, attending face-to-face consultations of testing for sexually transmitted infections is associated with stigmatization and anxiety. Self-testing technology (STT) allows patients to test themselves for chlamydia and gonorrhea without the presence of health care professionals. This may result in wider access to testing and increase testing uptake. Therefore, the sexual health clinic at Odense University Hospital has designed and developed a technology that allows patients to get tested at the clinic through self-collected sampling without a face-to-face consultation.

Objective: This study aimed to (1) pilot-test STT used in clinical practice and (2) investigate the experiences of patients who have completed a self-test for chlamydia and gonorrhea.

Methods: The study was conducted as a qualitative study inspired by the methodology of participatory design. Ethnographic methods were applied in the feasibility study and the data analyzed were inspired by the action research spiral in iterative processes using steps, such as plan, act, observe, and reflect. The qualitative evaluation study used semistructured interviews and data were analyzed using a qualitative 3-level analytical model.

Results: The findings from the feasibility study, such as lack of signposting and adequate information, led to the final modifications of the self-test technology and made it possible to implement it in clinical practice. The qualitative evaluation study found that self-testing was seen as more appealing than testing at a face-to-face consultation because it was an easy solution that both saved time and allowed for the freedom to plan the visit independently. Security was experienced when the instructions balanced between being detail-oriented while also being simple and illustrative. The anonymity and discretion contributed to preserving privacy and removed the fear of an awkward conversation or being judged by health care professionals thus leading to the reduction of intrusive feelings.

Conclusions: Accessible health care services are crucial in preventing and reducing the impact of sexually transmitted infections and STT may have the potential to increase testing uptake as it takes into account some of the barriers that exist. The pilot test and evaluation have resulted in a fully functioning implementation of STT in clinical practice.

(J Particip Med 2024;16:e55705) doi:10.2196/55705

KEYWORDS

chlamydia; sexually transmitted diseases; participatory design; self-test; qualitative; Chlamydia trachomatis; lymphogranuloma venereum; participatory; STD; STDs; sexually transmitted; sexually transmitted illness; sexually transmitted illnesses; STI; STIs; participatory; participation; self-testing; screening; health screening; asymptomatic screening; testing uptake

Introduction

Background

Chlamydia remains prevalent worldwide and is considered a global public health problem. However, testing rates among young sexually active people remain low. The majority of infected individuals are asymptomatic and potentially constitute a significant reservoir for transmission. In Denmark, far fewer men are tested than women despite men having the highest positivity rate in all age groups [1]. From 2018 to 2021, there was an increase in the positivity rate, and the largest increase was observed in 15- to 19-year-olds, where the positivity rate in 2021 was 36% for men and 26% for women. Remarkably, considerably fewer individuals were tested in 2020; however, the positivity rate was significantly higher than in 2019 [1]. This progression is worth taking seriously because untreated chlamydia can lead to complications, such as pelvic inflammatory disease and, in the worst-case scenario, ectopic pregnancies and infertility [2,3]. Thus, there is an urgent need to develop new ways to increase the testing uptake. In Denmark, general practitioners offer free testing and perform the majority of testing. Furthermore, 6 sexual health clinics in the country perform testing and screening for sexually transmitted infections (STIs). All of these testing options require that patients book an appointment and attend a face-to-face consultation, which may be a barrier for some patients because feelings of embarrassment and stigma are well-known deterrents to STI testing [4,5]. Young people, in particular, demand an alternative way of testing, with no explanation needed and minimal contact with health care professionals (HCPs) [6]. In Denmark, some municipalities offer home testing kits that can be ordered on the internet. Home tests are particularly popular among young people as they are perceived as easy and anonymous. However, the turnaround time for these tests is 10 days, plus delivery time, which is a challenge, as short waiting times are considered essential among young people who desire quick access to testing that can be integrated with school or work routines. Drop-in clinics are therefore popular and effective for detecting STIs at an early stage [7]. This knowledge has to be considered when developing new ways to increase testing uptake. In Denmark, testing uptake did not increase significantly despite national educational campaigns and programs by the Danish Health Authority. Thus, new innovative approaches are needed to reach the target group, and digital technologies may have the potential to support testing accessibility and meet challenges such as a lack of staff and emotional barriers linked to testing [8]. Therefore, we have designed and developed a self-testing technology (STT) that allows patients to be tested at a sexual health clinic through self-collected sampling without a face-to-face consultation, with no need to schedule an appointment. Instead, patients can use drop-in and visit sexual health clinics whenever they prefer.

Objective

This study aimed to (1) pilot-test STT used in clinical practice and (2) investigate the experiences of patients who have completed a self-test for chlamydia and gonorrhea.

Methods

Study Design

The research was conducted as a qualitative study inspired by participatory design (PD) methodology. In health science, PD is often conducted in three phases, which include (1) identification of needs, (2) design and development, and (3) test and evaluation [9]. Genuine participation is considered essential, and the co-design in PD has the potential to design and develop future technologies based on users' needs and adaptable to clinical practice. PD is characterized as a democratic research methodology in which mutual understanding emerges when all end users are involved in the change process [10]. Everyone affected by the technology gets a democratic voice and has a say and is therefore involved in its design. In this study, phase 1 consisted of literature studies, and the STT was designed based on research findings from several studies [6,11-14] that identified barriers in testing for STIs. Thus, the design and development of the STT was based on identified needs in the literature. In phase 2, a feasibility study was conducted to ensure the STT was feasible for clinical practice. It was considered an important step in the process because end users did not design the actual STT directly. However, the participant observations and structured interviews used to explore the patients' experiences of using the STT were based on one of PDs core values: having a say and thus, giving them a voice to affect the outcome. In that way, the STT was co-designed, adjusted, and adapted based on end users' experiences through the use of ethnographic methods. The further design and development phase was an iterative process that included end users and made necessary changes before implementation in clinical practice. In phase 3, a qualitative evaluation study was conducted to explore the users' experiences of using the STT.

While PD inspired the overall study, 2 separate studies were conducted and analyzed: 1 feasibility study and 1 qualitative evaluation study, which were closely related. This paper will present the studies separately, although within the same methodological frame inspired by PD.

Four research group members were employed at the outpatient clinic; they consisted of nurses and 1 medical doctor. One was employed at another department. All members were experienced researchers; 4 have a PhD and 1 has an a masters in nursing science.

Current Clinical Setting

The study was carried out at an outpatient clinic at a university hospital in Denmark, where patients can get free testing for STIs. A test requires a phone call to a secretary, who then will book the patient for a face-to-face consultation at the clinic within a day or two. During the consultation, HCPs obtain a medical record and ask questions about sexual (risk) behavior and symptoms. Patients will then be tested. To receive the test result, patients need to call a nurse trained in venereology.

The Self-Testing Technology

During the COVID-19 pandemic, the university hospital placed several STTs on their property. HCPs used them for their mandatory COVID-19 throat swabs at the time. After the pandemic, the STTs were removed and no longer used. At the Department of Dermatology and Allergy Centre at the university hospital, the majority of patients tested for chlamydia and gonorrhea were young people with no symptoms who just wanted a check to be on the safe side. Having been introduced to the STTs, HCPs suggested using this technology to test and screen patients for STIs. Thus, an STT was rebuilt (Figure 1), and software was developed in close collaboration with the IT consultants that made its use possible for patients in clinical practice. The STT was placed at the outpatient clinic in a relatively quiet and undisturbed place. HCPs already trained in the field of venereology were introduced to the STT and the new workflow. The STT solution ensures anonymity and privacy in the way that users no longer need face-to-face consultation to test for chlamydia and gonorrhea. Instead, patients can use the drop-in facility and visit the sexual health clinic whenever they prefer. They will have to perform the test themselves using written instructions or video information.

Under the new system, patients who wanted to get tested for chlamydia and gonorrhea would call a nurse trained in the field of venereology, who would conduct a short interview for the patient's medical records. The nurse would then set up the process in the electronic medical record that would give patients access to the STT using their personal identification number. Men were informed about having to self-collect a urine sample, and women about having to self-collect a vaginal swab. How to collect those samples was not elaborated because this information would be provided when patients used the STT. Patients were informed that they had 14 days to take the test within the opening hours of the outpatient drop-in clinic. Furthermore, they were informed about the location of the STT and that in case of a positive test result, they would receive an electronic letter in their secure personal digital mailbox. In case of a negative test, they would not be contacted but would have to check their test result on the Danish national portal for patient communication, a secure digital platform that contains all medical information linked to patients' personal identification numbers. The unique personal identification numbers of all Danish citizens allow us to link medical information in different IT systems in a secure way. When entering the STT system the users will use their unique personal identification numbers and the system will recognize the user as a legitimate user of the system.

Figure 1. The self-testing technology.

Recruitment

For the feasibility study, asymptomatic patients who attended a face-to-face consultation were asked if they were willing to use the STT instead. If patients agreed and gave their oral consent, they were asked to fill out a written consent.

For the qualitative evaluation study, patients were recruited at the STT, where written consent forms were available. Patients who had filled out the consent forms were contacted by phone to schedule an interview. Patients were included using a purposive sampling strategy for both approaches to achieve diversity in sex, age, and geographical distance. All participants were older than 18 years, heterosexual, and were Danish-speaking.

Data Collection

The Feasibility Study

Participant observation and informal interviews were carried out for the feasibility study. The participant observation aimed to gain insight into patient experience while following the instructions on how to find and use the STT. The participant observations were conducted based on American anthropologist James Spradley's approach and thus concerned with a social situation [15]. An observational guide was developed based on Spradley's 9 dimensions (Table 1) of a social situation to ensure that data were collected systematically and to provide structure to the observations in order not to miss important data. The social situation observed was patients using the STT for the first time. According to Spradley, a social situation concerns three elements, that are (1) a place, (2) actors, and (3) activities, and in order to understand this social situation, it first has to be described. Thus, making inferences makes it possible to discover meaning [15]. Therefore, in this study, inferences were made in relation to what the participants did (cultural behavior), the things they used (cultural artifacts), and what they said (cultural knowledge). The degree of participation can vary; however, passive participation was chosen in this study because the researchers might have influenced the outcome too much otherwise. Participants were asked to enter the front door, find their way to the STT, and take the test at the STT. Field notes were collected in a descriptive way to gain insight into possible obstacles and challenges while using the STT. After each session of participant observation, informal interviews with participants were conducted. Data were collected by the authors NTM and BT who are experienced in qualitative research. A structured interview guide was developed to obtain knowledge about the participants' experiences using the STT. Participants were asked about the challenges, the information provided, suggestions for improvement, and their sense of security in using the STT. In total, 13 patients, 6 men and 7 women aged between 21 and 46 years were invited, and none declined to participate. During the participant observations, field notes were written, and informal interviews were recorded. All data were transcribed verbatim. Participants were recruited at the outpatient clinic and consisted of patients who had scheduled an appointment for a face-to-face consultation.

Table 1. Spradley's 9 dimensions of a social situation.

Number	Dimensions	Place, actors, and activities
1	Space	The physical setting–location of the STT
2	Actor	Patients involved in the study–participants
3	Activity	Activities conducted by patients–using the STT
4	Object	Physical elements used by patients–the STT
5	Act	Individual actions taken by patients
6	Events	Context of the act–using the STT
7	Time	A sequence of events from beginning to end
8	Goal	What patients seek to accomplish–taking a self-test
9	Feeling	Emotions expressed by patients during the test

The Qualitative Evaluation

In total, 10 semistructured interviews were conducted with patients who had used the STT for the first time to explore their experiences and perceptions of the STT and, thereby, to gain insight into their experiences of having used it [16]. The interviews were carried out from October 2022 to January 2023 and were conducted at the location preferred by patients. An interview guide was developed to explore patients' experiences, impressions, and acceptance of the STT. The interview guide was developed to ensure that participants could share their experiences and perceptions on using the STT, how they experienced the information provided, what, in their opinion, could be improved and why, how they experienced the access to STI testing in general, and wishes or requests they had for STI testing in the future. In total, 21 patients filled out a consent form, and 14 were contacted to schedule an interview. Of the 14 patients contacted, 1 did not show up for the interview, and 3 did not respond to our contact. In total, 10 patients aged between 18 and 32 years were included (6 females and 4 males). See Table 2 for participant characteristics. The interviews were conducted according to each participant's preference, either at the sexual health clinic (n=2) or by phone (n=8). After conducting these interviews, the authors agreed that data saturation was reached and no further interviews needed to be conducted. The semistructured interviews were conducted by NTM, who is highly experienced in qualitative research. All transcripts were recorded and transcribed verbatim.

Table 2. Qualitative evaluation study.

Participant characteristics	Values
Median age (range), years	25 (18-32)
Sex, n	
Male	4
Female	6
Employment status, n	
Employed	2
Student	8
Relationship, n	
Single	8
With partner	2
Previously tested, n	
Sexual health clinic	7
General practitioner	3
Checkpoint	2
No	1

Ethical Considerations

The study was approved by the Danish Data Protection Agency (journal number 22/30101), following the principles of the Declaration of Helsinki [17]. All patients received verbal and written information about the studies and signed an informed consent form before data collection. For the qualitative evaluation study, participants received information about confidentiality and that only the person performing the interview would know their identity. They were ensured anonymity in both data analysis and reporting of the results. In order to respect the privacy of the potential participants for the qualitative study, patients themselves initiated the recruitment process. The authors fully acknowledged that participants during the interviews would elaborate on sensitive topics, therefore we chose not to recruit patients face-to-face while they were getting tested at the STT, thus, prioritizing patients' interest and participating on a voluntary basis. Because patients were recruited during face-to-face consultations for the feasibility study, we did not collect other characteristics about the participants. Ethically, this seemed wrong since patients did not have time to think through whether they wanted to share more sensitive information with the researchers.

Data Analysis

The Feasibility Study

The analysis of the feasibility study was inspired by the action research spiral in iterative processes [18] using the steps, that are plan, act, and reflect. The participant observation was conducted as a cyclical approach, where the reflected findings were shared with the research team before the next participant observation. Data analysis thus acted to adapt and modify the STT. Thus, each new activity and modification was based on shared reflections on the previous activity. These iterations were conducted until no further adjustments were required.

The Qualitative Evaluation

The semistructured interviews, which aimed to explore experiences of the use of the STT, were analyzed inspired by Ricoeur's theory of narrative and interpretation [19]. This is a 3-level analytical model that allows for interpretation of data collected through qualitative research methods such as semistructured interviews in order to gain insight into what patients experience [20]. This was carried out as a dialectical movement among three levels, which are (1) a naïve reading, (2) structural analysis, and (3) critical interpretation and discussion. First, all transcripts were gathered as one coherent text. Next, the transcripts were read and reread several times to get an initial impression of the text. This initial impression was the naïve reading and was written down. This step was performed by NTM. Then, a structural analysis was carried out where units of meaning (what the text said) and units of significance (what the text speaks about) were identified. Units of meaning were quotations from the data. Through a dialectical movement between understanding and explanation, by alternately distancing oneself from and coming closer to the text, a critical interpretation was possible and led to "units of significance." This step was performed in collaboration through reflections and discussions to ensure saturation, agreement, and following the research objective and finally led to the identification of patterns, 1 main theme, and 3 subthemes. (Figure 2). All themes were subsequently interpreted and discussed in relation to theory and previous research results as part of the critical interpretation to gain an even deeper understanding. An example of the analysis is provided in Figure 3. The Consolidated Criteria for Reporting Qualitative Studies (COREQ) guided the reporting [21].

Figure 2. Results, main theme, and subthemes.

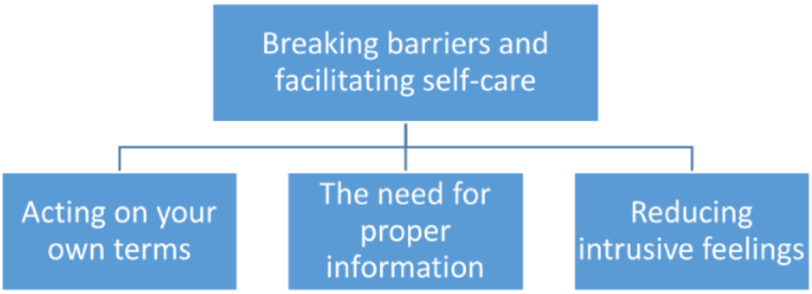
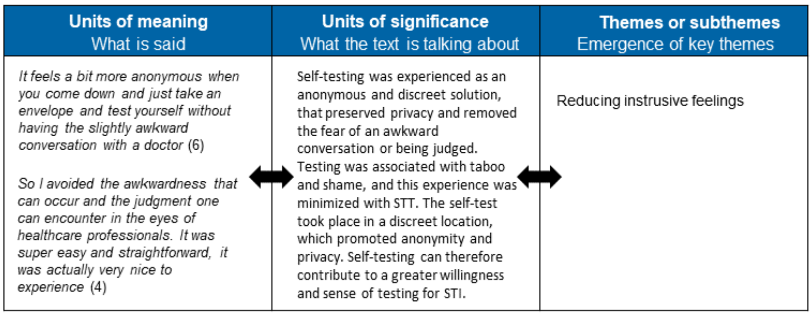


Figure 3. Example of the structural analysis.



Units of meaning What is said	**Units of significance** What the text is talking about	**Themes or subthemes** Emergence of key themes
It feels a bit more anonymous when you come down and just take an envelope and test yourself without having the slightly awkward conversation with a doctor (6) *So I avoided the awkwardness that can occur and the judgment one can encounter in the eyes of healthcare professionals. It was super easy and straightforward, it was actually very nice to experience* (4)	Self-testing was experienced as an anonymous and discreet solution, that preserved privacy and removed the fear of an awkward conversation or being judged. Testing was associated with taboo and shame, and this experience was minimized with STT. The self-test took place in a discreet location, which promoted anonymity and privacy. Self-testing can therefore contribute to a greater willingness and sense of testing for STI.	Reducing instrusive feelings

Results

Findings From the Feasibility Study

Patients had difficulties in finding the STT despite the signposting. Some had difficulties locating the STT because they had to enter through a door with a missing signpost. Others, following the blue arrows on the floor, entered the door but went straight into the toilet without looking up. Thus, the blue arrows on the floor were modified to point more directly at the STT. Furthermore, a signpost was added on the door patients had to enter. Patients had no problems scanning their social security cards; however, 2 patients could not print a requisition because of technical problems, and the HCPs had to print them. The reason for being unable to print the requisitions was technological, and the IT consultants analyzed these data and made the necessary changes at the STT. During the actual test, several problems occurred. Patients were insecure about which bar code to place on the sample, as the requisition had 2. Furthermore, they were not provided with sufficient information on correctly placing the bar code. Some patients were unsure whether the liquid inside the tests should be poured out. After the test, some patients did not know what to do with their used requisition. Thus, the written information for patients was adjusted and made extremely explicit (Figure 4). It was added to the written information that (1) the liquid should stay in the sample bottle; (2) an arrow along with text that clearly showed what bar code to place on the sample; and (3) a picture of how to place the bar code along with text. These findings led to the final modifications of the STT and made it possible to implement it in clinical practice. Thus, the users were directly involved in the design process based on participant observations and structured interviews. These user experiences collected through ethnographic methods facilitated co-design and made the STT adaptable to clinical practice.

Figure 4. Example of revised instructions for male patients.

Instructions for men - urine test for chlamydia & gonorrhea

For patients

patienten først OUH

Unpack the sample set. Remove the lid from the sample bottle and place it in the container on the wall. The liquid should stay in the sample bottle.

Fill a cup with first-catch urine (1/4 full) and use the disposable pipette to transfer urine into the sample bottle.

Fill the bottle to the point where urine is visible between the two black lines.

Screw the lid onto the bottle, as tightly as possible.

Dispose of the trash in the garbage bin.

Wash your hands and clean the shelf.

Check your name and social security number on the requisition form.

Place the barcode vertically on the glass (the bottom barcode by the arrow).

Drop the sample bottle in the marked area on the stand. Dispose of the requisition slip in the shredder bin, which is located on the stand.

Findings From the Qualitative Evaluation

The naïve reading revealed that security was a central aspect for patients taking a test at the STT. Furthermore, it seemed that providing patients with the opportunity to take a test without having to face an HCP was experienced as a positive aspect.

Breaking Barriers and Facilitating Self-Care

Breaking barriers were experienced on both a psychological and organizational level, creating feelings of security. This feeling of security was the central advantage in performing self-tests for STIs and was thus included in all 3 subthemes. Feelings of security facilitated self-care.

Acting on One’s Own Terms

The flexibility and convenience of acting on one’s own terms were highlighted as significant factors in self-testing.

> *Convenience means something to many people. It’s incredibly easy to just make a phone call and order a test. It also matters that you don’t have a specific appointment time, but rather 2 weeks to get it done. I believe many people see this as an advantage. It makes it easy and manageable, so you get it done* [9]

Being able to take the test when it “fits in” and on one’s own terms could overcome barriers and give a sense of security and feelings of being independent of the system. For some, it made them more willing to get tested.

> *That was the easiest–I didn’t have to make an appointment with my own doctor. I could just decide for myself when I had a gap in my schedule to get it done* [8]

Self-testing was seen as more appealing than face-to-face testing because it was an easy solution that both saved time and allowed for the freedom to plan the visit independently. It was perceived as orderly and meaningful for its purpose, which could create motivation to self-care by getting tested, which increased the possibility of taking responsibility for one’s sexual health. On the other hand, the experience of hassle and meaninglessness of a standard face-to-face appointment could lead to hesitant behavior.

The Need for Proper Information

The individual and illustrative instructions created a sense of security in performing the test correctly.

> *I found it to be very detailed and that it was very easy to follow the instructions and figure out what to do and in what order* [9]

Being taken by the hand and guided throughout the test was perceived as important. Some individuals experienced insecurity about the procedure, especially if they had never tested themselves before.

> *It was probably a bit overwhelming, maybe because it was the first time. I just had to think about how to do it... not because it was difficult; I just had to figure it out* [7]

Thus, security was experienced when the instructions were balanced between being detail-oriented while also being simple and illustrative.

For some, a phone conversation with an HCP before the self-test created a sense of security because they could ask questions and receive information that “prepared them” for taking the test. However, anonymity was challenged for others due to the phone call with an HCP.

Reducing Intrusive Feelings

Self-testing was experienced as an anonymous and discreet solution.

> *If you reduce the fear one may have, I believe it will make a difference. I easily believe that self-testing will encourage more people to get tested* [7]

The anonymity and discretion contributed to preserving privacy and removed the fear of an awkward conversation or being judged by HCPs, thus reducing intrusive feelings.

Testing for STIs is associated with taboo and shame, and this experience was minimized when the test could be taken anonymously.

> *So I avoided the awkwardness that can occur and the judgment one can encounter in the eyes of healthcare professionals. It was super easy and straightforward; it was actually very nice to experience* [4]

Many preferred using the self-test rather than going to their general practitioner because they only saw their doctor for other medical issues. This may be explained by the fear of being judged for their sexual behavior or irresponsibility in relation to unsafe sex.

For some, it took courage to get tested for an STI, and this courage was empowered when the test could be done anonymously. The fact that the self-test took place in a discreet and less crowded location promoted anonymity and a sense of privacy.

> *It feels a bit more anonymous when you come down and just take an envelope and test yourself without having a slightly awkward conversation with a doctor* [6]

Discussing one’s sexual behavior was experienced as invasive and judgmental, which could lead to hesitation in getting tested. However, using the STT reduced these barriers, enhanced feelings of security, and, in that way, supported patient self-care.

Discussion

Principal Findings

The development of new technology will inevitably lead to changes elsewhere in the health care organization [22]. The co-design process that led to the development and implantation of the STT ensured that the solution was integrated into existing clinical workflows and that HCPs and patients supported it. These critical aspects must be addressed to ensure the adoption and implementation of new technologies for STI testing [23]. Khumalo et al [23] stated that if new technologies are implemented correctly, patients will be provided with autonomy and be empowered to take control of their sexual health because barriers toward testing, such as stigma, can be reduced. This is consistent with the findings of our study, where being tested for STIs was associated with taboo and shame. However, taking an anonymous test minimized this experience, enhancing feelings of security.

Self-testing was seen as more appealing than a face-to-face consultation because it was an easy solution that both saved time and allowed for freedom and flexibility to plan the visit independently. These aspects highlight the improvements in offering testing using the STT compared with existing home test kits. The STT gives patients the opportunity to be tested quickly and enables them to get a test result within 1 to 2 days, which is considered an important aspect of STI testing. [7]. Aicken et al [24] found similar findings in their study of a newly established e-Sexual health clinic. The participants in their study described that they chose to use the eHealth intervention because it was convenient and fit into their busy lifestyle, and it was considered both easy and discreet to use. Likewise, helpline contact was considered important and created a sense of security for the majority of patients; however, like in our study, anonymity was challenged for some due to a phone call with an HCP. This highlights the extent to which STI testing is connected to feelings of shame and stigma and, therefore, the need to constantly improve and develop the services for this group using co-design approaches in order to facilitate patient self-care.

Orem defines self-care as activities an individual initiates and performs on their own behalf to maintain life, health, and well-being [25]. This involves adaptions to health-related behavior and the ability to perform self-care activities, referred to as self-care agencies. Thus, nursing has to support or enhance the individual’s self-care agency in order to promote independence [26]. We found that using the STT was perceived as orderly and meaningful for its purpose, which could create motivation for self-care by getting tested, which enhanced the possibility of taking responsibility for one’s own sexual health. This highlights a certain paradox: the ability to perform self-care depends not solely on the individual but also on a health care system that has to adapt to users. The routines in clinical practice, such as only providing face-to-face consultations despite the well-documented barriers this creates, can lead to self-care deficits, not caused by the individual but by the system. Thus, providing patients with the appropriate intervention to address self-care deficits is not only the responsibility of individual patients and HCPs but also the responsibility of the health care system. This study found that the STT solution provided patients with feelings of anonymity and allowed them to take the test on their own terms. This empowered patients because it gave them control and the ability to make choices, enhancing their confidence and feelings of self-determination. Furthermore, it underlines the possible impact technologies can have, such as enabling self-care for patients who may not be regarded as having self-care deficits. In that way, technology plays a crucial role in empowering patients in STI testing by providing them with tools and resources to take control of their health and well-being. By leveraging technology in these ways, health care systems can empower patients to be more proactive, engaged, and informed in managing their health and well-being. This, in turn, contributes to improved patient outcomes and a more patient-centered approach to health care, ultimately contributing to the prevention and early detection of STIs.

The STT described here is the first and only one of its kind used in STI testing in Denmark, and with the health care system under pressure, there is a need to explore new paths and seek innovative solutions. Furthermore, by addressing one of the significant threats to the health care system, the workforce shortage, this solution has increased patient satisfaction. It is important to have a range of different options and solutions to meet patients' needs, and the use of technology and self-testing can seamlessly coexist as an offering alongside more traditional consultation, as demonstrated by this study. While some patients easily adapt to new solutions, such as self-testing, others may need assistance. It is important that support, such as informational videos and helpline numbers, is integrated to ensure accessibility and understanding.

Considering the digital divide and health equality, it is important to ensure accessibility of the STT for diverse populations, including those with limited access to technology or low eHealth literacy. This has been an important focus area in the process of designing the STT and the STT provides the possibility to support a more traditional way of providing information and health care more flexibly. For instance, the solutions allow to provide information in different ways (videos, text, and personal information), to make sure that all needs are met. It has been an important focus area to make sure that a health care professional can be contacted for any need of support with respect to the STT and to allow patients to be tested without using the STT, but instead attending a face-to-face consultation if preferred.

Limitations

A limitation of this study is that it was single-centered and included only 13 patients in the feasibility study and 10 patients in the qualitative interview, which is a rather small sample size. However, this was a design and development process and an evaluation of technology to explore the experiences and perceptions of patients and the technology's adaptability in clinical practice. This favors a qualitative approach, and thus, the sample size seems adequate since qualitative research is concerned with deepening the understanding of a phenomenon rather than numerical representability [27]. The qualitative approach was used to obtain an in-depth insight suitable to the aim and considered a main strength of this study. In addition, we aimed for maximum variation during recruitment, which is considered a strength [28]. In the qualitative evaluation study, we recruited heterosexual patients only and did not collect data about other risk factors; this could have an impact on the transferability of the findings. However, heterosexual patients comprise the main target group of those being tested at the sexual health clinic and, thus, contribute to a representative group. We acknowledge that STI testing intersects with various cultural beliefs and practices related to sexual health, influenced by social norms, religious teaching, sexual preferences, and stigma. In some cultures, discussing sexual health openly is considered taboo, leading to reluctance in being tested. In addition, barriers such as privacy concerns, fear of judgment, and accessibility may be some obstacles. The STT gives individuals the opportunity to get tested more anonymously, thus, circumventing potential barriers. However, the inclusion criteria for this study were heterosexual Danish-speaking participants, therefore the cultural aspects and how the STT accommodates diverse beliefs and practices related to sexual health needs to be investigated further.

In the feasibility study, we included patients who attended a face-to-face consultation and asked them if they would use the STT instead and that data would be collected through participant observation and a subsequent interview. We deliberately omitted to gather demographic data because the time to think over to agree to participate was sparse. This information may have strengthened the generalizability of the study; however, we chose to uphold research ethics [29]. Another limitation is that the perceptions and experiences of HCPs were not elaborated on, although the STT created a significant change in clinical practice. However, the STT was implemented quickly into clinical practice at the request of HCPs, which indicated that the STT was a demanded solution.

Future Perspectives

It would be interesting to evaluate the use of the STT over a longer time period, monitoring the number of users, their sex and age, whether they had used the STT before, as well as the number of positive samples. Our clinic has plans to further automate the STT. This will eliminate the need for a telephone conversation with an HCP and enhance users' anonymity. In addition, the STT should be expanded to users with a higher risk of STI infection, for example, pre-exposure prophylaxis users who are routinely tested for STIs regularly.

Conclusions

Based on PD, we have designed and developed an STT that allows patients to be tested at a sexual health clinic through self-collected sampling without a face-to-face consultation. Using the STT minimized feelings of shame and awkwardness, which is a well-known barrier to STI testing and can contribute to a greater willingness to live with STIs. Thus, accessible health care services are crucial in preventing and reducing the impact of STIs, and the SST may increase testing uptake as it takes into account some of the barriers that exist. More simplified and accessible chlamydia testing by the STT proved feasible. The feasibility study and qualitative evaluation have resulted in a fully functioning implementation of the STT in clinical practice.

Acknowledgments

We thank all participants in the study, the patients for testing the STT and sharing their experiences, and the IT consultants for their engagement and commitment during the study.

Conflicts of Interest

None declared.

References

1. Statens Serum Institut. Klamydia - opgørelse over sygdomsforekomst 2019-2021. 2022. URL: https://www.ssi.dk/sygdomme-beredskab-og-forskning/sygdomsovervaagning/k/klamydia---opgoerelse-over-sygdomsforekomst-2019-2021 [accessed 2024-06-06]
2. Hoenderboom BM, van Oeffelen AAM, van Benthem BHB, van Bergen JEAM, Dukers-Muijrers NHTM, Götz HM, et al. The Netherlands Chlamydia Cohort Study (NECCST) protocol to assess the risk of late complications following chlamydia trachomatis infection in women. BMC Infect Dis 2017;17(1):264 [FREE Full text] [doi: 10.1186/s12879-017-2376-y] [Medline: 28399813]
3. Davies B, Turner KME, Frølund M, Ward H, May MT, Rasmussen S, et al. Risk of reproductive complications following chlamydia testing: a population-based retrospective cohort study in Denmark. Lancet Infect Dis 2016;16(9):1057-1064. [doi: 10.1016/s1473-3099(16)30092-5] [Medline: 27289389]
4. Balfe M, Brugha R. Disclosure of STI testing activities by young adults: the influence of emotions and social networks. Sociol Health Illn 2010;32(7):1041-1058 [FREE Full text] [doi: 10.1111/j.1467-9566.2010.01281.x] [Medline: 20937054]
5. Gilbert M, Thomson K, Salway T, Haag D, Grennan T, Fairley CK, et al. Differences in experiences of barriers to STI testing between clients of the internet-based diagnostic testing service GetCheckedOnline.com and an STI clinic in Vancouver, Canada. Sex Transm Infect 2018 Feb 07;95(2):151-156. [doi: 10.1136/sextrans-2017-053325] [Medline: 29437984]
6. Trettin B, Vestergaard T, Stensgaard A. Understanding young people’s barriers to sexually transmitted disease screening and meeting their needs: A focus group study. JNEP 2015 Apr 10;5(6):81-86. [doi: 10.5430/jnep.v5n6p81]
7. Handy P, Pattman RS, Richards J. 'I'm OK?' Evaluation of a new walk-in quick-check clinic. Int J STD AIDS 2006;17(10):677-680. [doi: 10.1258/095646206780071027] [Medline: 17059637]
8. Grandahl M, Larsson M, Herrmann B. 'To be on the safe side': a qualitative study regarding users' beliefs and experiences of internet-based self-sampling for Chlamydia trachomatis and Neisseria gonorrhoeae testing. BMJ Open 2020;10(12):e041340 [FREE Full text] [doi: 10.1136/bmjopen-2020-041340] [Medline: 33376171]
9. Clemensen J, Rothmann MJ, Smith AC, Caffery LJ, Danbjorg DB. Participatory design methods in telemedicine research. J Telemed Telecare 2017;23(9):780-785. [doi: 10.1177/1357633X16686747] [Medline: 28027678]
10. Simonsen J, Robertson T. In: NA NA, editor. Routledge International Handbook of Participatory Design. London: Routledge; 2012:1136266259.
11. Theunissen KATM, Bos AER, Hoebe CJPA, Kok G, Vluggen S, Crutzen R, et al. Chlamydia trachomatis testing among young people: what is the role of stigma? BMC Public Health 2015;15:651 [FREE Full text] [doi: 10.1186/s12889-015-2020-y] [Medline: 26169173]
12. McDonagh LK, Saunders JM, Cassell J, Curtis T, Bastaki H, Hartney T, et al. Application of the COM-B model to barriers and facilitators to chlamydia testing in general practice for young people and primary care practitioners: a systematic review. Implement Sci 2018;13(1):130 [FREE Full text] [doi: 10.1186/s13012-018-0821-y] [Medline: 30348165]
13. Lee AS, Cody SL. The stigma of sexually transmitted infections. Nurs Clin North Am 2020;55(3):295-305. [doi: 10.1016/j.cnur.2020.05.002] [Medline: 32762851]
14. Balfe M, Brugha R, O'Donovan D, O'Connell E, Vaughan D. Young women's decisions to accept chlamydia screening: influences of stigma and doctor-patient interactions. BMC Public Health 2010;10(1):425. [doi: 10.1186/1471-2458-10-425] [Medline: 20642845]
15. Spradley J. In: NA NA, editor. Participant Observation. Long Grove, Illinois: Waveland Press; 2016:1478633247.
16. Kvale S, Brinkmann S. In: NA NA, editor. Learning the Craft of Qualitative Research Interviewing. London, United Kingdom: Sage Publications; 2009:0761925422.
17. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA 2013;310(20):2191-2194. [doi: 10.1001/jama.2013.281053] [Medline: 24141714]
18. Moltu C, Stefansen J, Svisdahl M, Veseth M. Negotiating the coresearcher mandate - service users' experiences of doing collaborative research on mental health. Disabil Rehabil 2012;34(19):1608-1616. [doi: 10.3109/09638288.2012.656792] [Medline: 22489612]

19. Ricoeur P. Interpretation Theory: Discourse and the Surplus of Meaning. Fort Worth, TX: Texas Christian University Press; 1976:0912646594.
20. Simonÿ C, Specht K, Andersen IC, Johansen KK, Nielsen C, Agerskov H. A Ricoeur-inspired approach to interpret participant observations and interviews. Glob Qual Nurs Res 2018;5:2333393618807395 [FREE Full text] [doi: 10.1177/2333393618807395] [Medline: 30397637]
21. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007;19(6):349-357. [doi: 10.1093/intqhc/mzm042] [Medline: 17872937]
22. Leavitt H. Applied Organizational Change in Industry: Structural, Technological and Humanistic Approaches. London, UK: Routledge; 2013:1144-1170.
23. Khumalo F, Passmore J, Manhanzva M, Meyer B, Duyver M, Lurie M, et al. Shifting the power: scale-up of access to point-of-care and self-testing for sexually transmitted infections in low-income and middle-income settings. Curr Opin Infect Dis 2023;36(1):49-56. [doi: 10.1097/QCO.0000000000000895] [Medline: 36753705]
24. Aicken CRH, Sutcliffe LJ, Gibbs J, Tickle LJ, Hone K, Harding-Esch EM, et al. Using the eSexual health clinic to access chlamydia treatment and care via the internet: a qualitative interview study. Sex Transm Infect 2018;94(4):241-247 [FREE Full text] [doi: 10.1136/sextrans-2017-053227] [Medline: 28988193]
25. Denyes MJ, Orem DE, Bekel G. Self-care: a foundational science. Nurs Sci Q 2001;14(1):48-54. [doi: 10.1177/089431840101400113] [Medline: 11873354]
26. Orem DE, Calnan ME, Renpenning KM. Nursing: Concepts of Practice. St. Louis, MO: Mosby; 1995.
27. Queirós A, Faria D, Almeida F. Strengths and limitations of qualitative and quantitative research methods. European Journal of Education Studies 2017:00.
28. Polit D, Beck C. Essentials of Nursing Research: Appraising Evidence for Nursing Practice. Philadelphia, PA: Lippincott Williams & Wilkins; 2010.
29. Damianakis T, Woodford MR. Qualitative research with small connected communities: generating new knowledge while upholding research ethics. Qual Health Res 2012;22(5):708-718. [doi: 10.1177/1049732311431444] [Medline: 22232294]

Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Studies
HCP: health care professional
PD: participatory design
STI: sexually transmitted infection
STT: self-testing technology

Edited by D van Leeuwen; submitted 21.12.23; peer-reviewed by S Mitra, A Hassan; comments to author 09.04.24; revised version received 18.04.24; accepted 22.05.24; published 14.08.24.

Please cite as:
Trettin B, Skjøth MM, Munk NT, Vestergaard T, Nielsen C
Shifting Grounds—Facilitating Self-Care in Testing for Sexually Transmitted Infections Through the Use of Self-Test Technology: Qualitative Study
J Particip Med 2024;16:e55705
URL: https://jopm.jmir.org/2024/1/e55705
doi:10.2196/55705
PMID:

Original Paper

Implementing a Patient Portal for the Remote Follow-Up of Self-Isolating Patients With COVID-19 Infection Through Patient and Stakeholder Engagement (the Opal-COVID Study): Mixed Methods Pilot Study

Yuanchao Ma[1,2,3,4], MScA; David Lessard[1,2,3], PhD; Serge Vicente[1,2,5,6], PhD; Kim Engler[1,2], PhD; Adriana Rodriguez Cruz[3], PhD; Moustafa Laymouna[1,2,6], MD; Opal-COVID Patient Expert Committee[7]; Tarek Hijal[8], MD, MSc, CM; Lina Del Balso[3]; Guillaume Thériault[3]; Nathalie Paisible[3], BSc; Nadine Kronfli[1,2,3,9], MD; Marie-Pascale Pomey[10,11,12], MD, PhD; Hansi Peiris[1], BSc; Sapha Barkati[2,9], MD, MSc; Marie-Josée Brouillette[1,3,13], MD; Marina Klein[1,2,3,9], MD, MSc; Joseph Cox[1,3,14], MD, MSc; Alexandra de Pokomandy[1,2,3,6], MD, MSc; Jamil Asselah[15], MD; Susan J Bartlett[1,9], MD, PhD; Bertrand Lebouché[1,2,3,6], MD, PhD

[1]Center of Outcomes Research and Evaluation, Research Institute of the McGill University Health Centre, Montreal, QC, Canada
[2]Infectious Diseases and Immunity in Global Health Program, Research Institute of McGill University Health Centre, Montreal, QC, Canada
[3]Chronic Viral Illness Service, McGill University Health Centre, Montreal, QC, Canada
[4]Department of Biomedical Engineering, Polytechnique Montréal, Montreal, QC, Canada
[5]Department of Mathematics and Statistics, University of Montreal, Montreal, QC, Canada
[6]Department of Family Medicine, Faculty of Medicine and Health Sciences, McGill University, Montreal, QC, Canada
[7]See Acknowledgments
[8]Department of Radiation Oncology, McGill University Health Centre, Montreal, QC, Canada
[9]Department of Medicine, Faculty of Medicine and Health Sciences, McGill University, Montreal, QC, Canada
[10]Research Centre of the University of Montreal Hospital Centre, Montreal, QC, Canada
[11]Centre of Excellence on Partnership with Patients and the Public, Montreal, QC, Canada
[12]Department of Health Policy, Management and Evaluation, School of Public Health, University of Montreal, Montreal, QC, Canada
[13]Department of Psychiatry, Faculty of Medicine and Health Sciences, McGill University, Montreal, QC, Canada
[14]Department of Epidemiology, Biostatistics and Occupational Health, Faculty of Medicine and Health Sciences, McGill University, Montreal, QC, Canada
[15]Department of Medicine, Division of Medical Oncology, McGill University Health Centre, Montreal, QC, Canada

Corresponding Author:
Bertrand Lebouché, MD, PhD
Chronic Viral Illness Service
McGill University Health Centre
D02.4110 – Glen Site
1001 Decarie Blvd
Montreal, QC, H4A 3J1
Canada
Phone: 1 514 843 2090
Email: bertrand.lebouche@mcgill.ca

Abstract

Background: The COVID-19 pandemic was an unprecedent challenge to public health systems, with 95% of cases in Quebec sent home for self-isolation. To ensure continuous care, we implemented an intervention supported by a patient portal (Opal) to remotely monitor at-home patients with COVID-19 via daily self-reports of symptoms, vital signs, and mental health that were reviewed by health care professionals.

Objective: We describe the intervention's implementation, focusing on the (1) process; (2) outcomes, including feasibility, fidelity, acceptability, usability, and perceived response burden; and (3) barriers and facilitators encountered by stakeholders.

Methods: The implementation followed a co-design approach operationalized through patient and stakeholder engagement. The intervention included a 14-day follow-up for each patient. In the mixed methods study at the McGill University Health Centre in Montreal, Quebec, participants completed questionnaires on implementation outcomes on days 1, 7, and 14. All scores were examined against predefined success thresholds. Linear mixed models and generalized estimating equations were used to assess changes in scores over time and whether they differed by sex, age, and race. Semistructured interviews were conducted with expert patients, health care professionals, and coordinators for the qualitative analysis and submitted to thematic analysis guided by the Consolidated Framework for Implementation Research.

Results: In total, 51 participants were enrolled between December 2020 and March 2021; 49 (96%) were included in the quantitative analysis. Observed recruitment and retention rates (51/52, 98% and 49/51, 96%) met the 75% feasibility success threshold. Over 80% of the participants found it “quite easy/very easy” to complete the daily self-report, with a completion rate (fidelity) of >75% and a nonsignificant decreasing trend over time (from 100%, 49/49 to 82%, 40/49; *P*=.21). Mean acceptability and usability scores at all time points exceeded the threshold of 4 out of 5. Acceptability scores increased significantly between at least 2 time points (days 1, 7, and 14: mean 4.06, SD 0.57; mean 4.26, SD 0.59; and mean 4.25, SD 0.57; *P*=.04). Participants aged >50 years reported significantly lower mean ease of use (usability) scores than younger participants (days 1, 7, and 14: mean 4.29, SD 0.91 vs mean 4.67, SD 0.45; mean 4.13, SD 0.89 vs mean 4.77, SD 0.35; and mean 4.24, SD 0.71 vs mean 4.72, SD 0.71; *P*=.004). In total, 28 stakeholders were interviewed between June and September 2021. Facilitators included a structured implementation process, a focus on stakeholders’ recommendations, the adjustability of the intervention, and the team’s emphasis on safety. However, Opal’s thorough privacy protection measures and limited acute follow-up capacities were identified as barriers, along with implementation delays due to data security–related institutional barriers.

Conclusions: The intervention attained targets across all studied implementation outcomes. Qualitative findings highlighted the importance of stakeholder engagement. Telehealth tools have potential for the remote follow-up of acute health conditions.

International Registered Report Identifier (IRRID): RR2-10.2196/35760

(J Particip Med 2024;16:e48194) doi:10.2196/48194

KEYWORDS

SARS-CoV-2; coronavirus; infectious disease; implementation science; Canada; patient portal; telehealth; telemedicine; app; health information technology; remote monitoring; mobile phone

Introduction

Background

COVID-19 is a major public health concern. At the beginning of the pandemic in 2020, the large number of patients attending clinics for screening and treatment posed unprecedented challenges for hospital management [1,2]. To allow hospitals to focus on patients considered vulnerable and seriously ill, 95% of those with COVID-19 infection in Quebec were sent home for self-isolation and self-care. During this period, the clinical features of people with COVID-19 infection were well known: most presented mild or no symptoms during the first week, but some deteriorated rapidly within hours to days in the second week [3,4]. When a patient’s condition worsened, delays in identification and treatment could lead to poor patient outcomes, including death. Self-isolation was thus a source of anxiety and distress, especially for people at risk of deterioration, such as older adults and those living alone or with chronic conditions [5,6].

To ensure continuous care and to address some of the psychological implications of self-isolation [7], it became crucial to help self-isolating patients with COVID-19 infection monitor their health condition and maintain contact with health care professionals. Telehealth, which uses telecommunication technologies to deliver care and health services, can address some of these challenges, empower its users, and efficiently support self-management of care by enabling patients to collect and remotely share health information with health care professionals [8,9].

For this purpose, Opal was a promising telehealth tool. Currently used by >5000 patients, it is an award-winning patient portal first implemented in the radiation-oncology department of the McGill University Health Centre (MUHC) in 2018 [10]. A patient portal is a connected platform (eg, website, software, and app) that gives patients access to a portion of their electronic medical records, such as their appointment calendar, laboratory results, and health care provider’s clinical notes. Co-designed by expert patients [11], IT developers, and health care professionals, Opal also provides, through a smartphone app available in English and French, educational materials and patient-reported outcome measures (PROMs) for completion [12]. Physicians use Opal to remotely administer these through a desktop dashboard.

Objectives

When COVID-19 was declared a global pandemic, our team was working on implementing Opal in HIV clinical care. We redirected these efforts to support self-isolating patients with COVID-19 infection, while helping them avoid face-to-face interactions with health care professionals [13]. This paper aims to describe the intervention’s implementation, focusing on the (1) process; (2) outcomes, including feasibility, fidelity, acceptability, usability, and perceived response burden; and (3) barriers and facilitators from the perspective of stakeholders. The assessed clinical outcomes will be presented in another manuscript.

Methods

Implementation Strategy

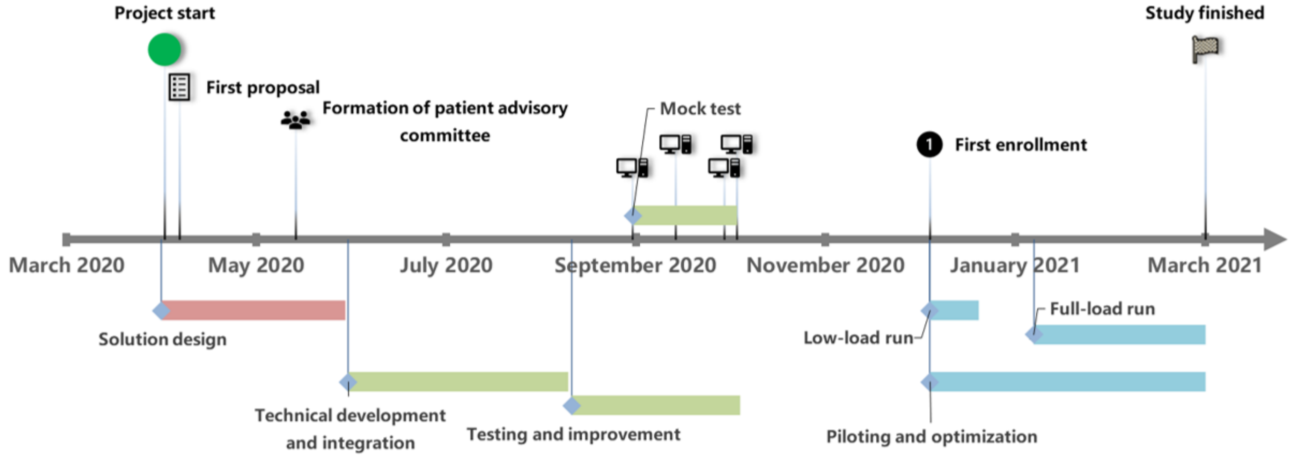
Overview

This study followed the principles of co-design, which refers to creative cooperative processes involving diverse experts and potential end users during the planning and development stages of products, projects, or interventions [14,15]. Collaboration in defining expectations and solutions can optimize the implementation and outcomes of a telehealth-based intervention [13].

We operationalized co-design through patient and stakeholder engagement (PSE), that is, the meaningful involvement of stakeholders affected by a given health condition and its associated care, such as patients, health care professionals, and researchers, in potentially all steps of a given project. PSE seeks the coconstruction of knowledge [16-19] by emphasizing deliberation in health-related decision-making [20,21], patient autonomy [22], sensitive listening and accountability, and partnerships [23]. PSE has been critical in the context of the COVID-19 pandemic to ensure that research effectively and rapidly translated into social and medical benefits [24]. Our researcher-driven PSE framework [18,25,26] represents activities ranging from (1) information (informing patients and stakeholders) and (2) consultation (obtaining and accounting for patients' and stakeholders' perspectives) to (3) collaboration (partnering with patients and stakeholders in decision-making) [27-30].

In this project, PSE included three phases (Figure 1): (1) solution design; (2) technical integration and testing; and (3) a pilot study phase, including a low-load and a full-load run, which are defined in the Study Design and Recruitment subsection.

Figure 1. Opal-COVID solution configuration and implementation timeline.



Solution Design (April-May 2020)

The initial research team included 6 members: BL (MD, PhD, principal investigator [PI], and clinician-scientist), a COVID-19 frontline physician; KE (PhD in public health) and Kedar KV Mate (PhD in neurophysiotherapy), both experts in PROM development; DL (PhD in anthropology), an expert in PSE; ARC (PhD in immunology), the research coordinator; and YM (MSc in engineering), the technical coordinator.

The research team recognized the possibility of using Opal to follow patients with COVID-19 infection and secured funding from the McGill Interdisciplinary Initiative in Infection and Immunity Emergency COVID-19 Research Funding (ECRF-R2-44) on April 20, 2020. BL and YM confirmed their intention to implement Opal for the clinical follow-up of self-isolating patients with COVID-19 infection with its IT developers led by TH and John Kildea. BL, YM, KE, and Kedar KV Mate then conducted a week-long first set of meetings to broadly identify the target population for the intervention, the proposed follow-up, and its overall mechanisms.

Subsequently, BL, DL, and YM organized a series of meetings with the Opal–COVID-19 expert patient committee consisting of 3 patients who had recovered from COVID-19 infection, as well as nurses (LDB and GT) and physicians, including infectious disease and public health specialists (NK, SB, JC, and MK) and a psychiatrist (MJB). During these meetings, stakeholders made recommendations for the intervention, the selection of PROMs, and other data collection instruments.

Researchers and stakeholders consensually decided that patients would use Opal to self-report symptoms, vital signs, and mental health daily using validated instruments (Multimedia Appendix 1). Responses to certain questions could trigger symptom management counseling that provided guidance to patients; for example, if a patient lost their sense of smell/taste, they would be advised to avoid using inhaled or oral corticosteroids for treatment and to contact the nurse for more information. Nurses would review the results remotely and send appropriate feedback based on their observations. Nurses could, for example, confirm that a patient's health status was stable or offer a teleconsultation with a physician. The intervention lasted a minimum of 14 days and could be extended if the patient's condition required further follow-up (eg, persistent symptoms). Medical devices (ie, pulse oximeters and thermometers) were sent to patients who did not have them, and educational materials (eg, government guidelines and instructional videos for medical devices) were prepared and integrated into Opal.

In the meantime, KE and Kedar KV Mate collaborated to prepare a pilot study protocol for this project.

Technical Integration and Testing (June-November 2020)

YM initiated ongoing exchanges with Opal developers through email and videoconferencing to discuss the project requirements and the technical aspects of configuring Opal for managing patients with COVID-19 infection. They followed the Agile framework [31] for project management and software development, which was used during the initial development of Opal for managing patients with cancer [12]. The Agile framework consists of an iterative approach interspersing episodes of technical work on specific aspects of software with testing and debriefing with stakeholders and testers for feedback.

First, the IT developers adapted the clinical dashboard to make it easier for nurses to access and track patients' self-reports. They also created and integrated electronic versions of the selected PROMs and data collection tools into Opal, along with educational materials. They configured standardized feedback messages to patients, based on their daily self-report results, and relevant appointment information.

Four prototype tests of functionality and usability were then conducted over a 2-month period. Before each test, YM provided a videoconference training session to health care professionals and expert patient committee members, introducing them to the latest improvements in Opal. The expert patients tested Opal on their personal device for 4 days and provided feedback (eg, reporting bugs and suggesting improvements), while health care professionals made recommendations concerning the dashboard. On the basis of stakeholder feedback, developers adjusted Opal after each test; for example, we integrated a color code (red and green) to encourage patient completion of essential aspects of the self-report. In addition, YM developed guidelines for health care professionals participating in the pilot study with the input received during testing.

Piloting and Optimization (December 2020-March 2021)

This phase encompasses the pilot study conducted at the MUHC (Glen site) in Montreal, Quebec. This study was registered in ClinicalTrials.gov (NCT04978233). This study and its results are described in the sections that follow. Three frontline nurses (GT, NP, and LDB), a technical coordinator (YM), and a research coordinator (ARC) ensured that the pilot testing was conducted effectively, and an on-call physician was available for consultation if necessary. Each nurse monitored and followed up to 6 patient participants simultaneously.

Throughout the pilot study, feedback from users, including patient participants and health care professionals, was recorded in a coordinator logbook. Accordingly, the intervention and implementation were optimized, promoting adaptability. The adjustments included (1) modifying the self-report by changing some questions from mandatory to optional and adding a "none of the above" option to certain multiple-choice questions, (2) implementing additional daily self-reports for participants with symptoms that required further observation, (3) proactively contacting participants who did not respond for 3 consecutive days, and (4) applying hotfixes for bugs encountered during the use of the registration system and clinical monitoring dashboard (eg, nonfunctional registration code system and incorrect last check time for the questionnaire).

Study Design and Recruitment

This pilot study used mixed quantitative and qualitative methods to report implementation strategies and evaluate outcomes. The previously published protocol [32] contains additional methodological details on the study and its intervention. We reported our findings by following the guidance provided by the CONSORT (Consolidated Standards of Reporting Trials) statement for pilot and feasibility studies (Multimedia Appendix 2) [33,34] and the StaRI (Standards for Reporting Implementation Studies; Multimedia Appendix 3) [35].

Participants were selected using convenience sampling [36]. Participant inclusion criteria were as follows: aged ≥18 years, fluent in French or English, testing positive for COVID-19 infection at the MUHC and being instructed to self-isolate, enrollment in Quebec's provincial health insurance plan, comfortable with using health-related apps via a smart device (eg, a smartphone) or having someone close by who is, and possessing an internet connection. Exclusion criteria were being hospitalized, concurrent enrollment in another COVID-19 clinical trial, or having a cognitive impairment that prevented participation.

When delivering a positive SARS-CoV-2 infection test result, the MUHC test center staff briefly explained the study to the patient and asked whether they were interested in participating. The study coordinator then contacted interested individuals either on the same day or the following day to schedule a videoconference appointment to obtain consent. After consent, the technical coordinator helped participants register on the Opal app and offered training. Recruitment began with a "low-load" run of 5 participants recruited from early to mid-December 2020. Recruitment for the "full-load" run began in January 2021 to include the remainder of the quantitative study sample.

One month after all patient follow-up ended with Opal, we used purposive expert sampling [25] to propose to expert patients, health care professionals, and the coordinators of the study (ie, IT developers and study staff) involved in any of the 3 phases of the implementation to participate in a qualitative interview. A research coordinator sent an email to these stakeholders with an invitation to schedule a qualitative interview. All agreed to be interviewed.

Quantitative Data

Data Collection

The pilot study participants completed a 1-time sociodemographic questionnaire on day 1 and a research questionnaire each week (ie, on days 1, 7, and 14 of the intervention) on implementation outcomes, namely acceptability, usability, and perceived response burden. To supplement the assessment of usability, participants were asked in the daily self-report whether they had help to complete the self-report. Recruitment data and completion records of the daily self-reports were recorded in the coordinator logbook to assess feasibility and fidelity. Success thresholds, outlined in the following paragraphs, were set for each outcome.

To assess feasibility, that is, how successfully an intervention can be used in a given setting [37], we examined the recruitment rate (ie, the proportion of eligible contacts enrolled in the study), and the retention rate (ie, the proportion of participants who remained enrolled for the whole duration of the intervention), both with a target of at least 75% [38].

We evaluated fidelity, the degree to which the intervention was implemented as intended [37], by measuring the proportion of participants who filled out the daily self-reports (completion rate) every day for the duration of the intervention, also with a minimum target of 75%.

To evaluate acceptability, which reflects how agreeable, palatable, or satisfactory an intervention is perceived to be [37], we adapted the Acceptability of Intervention Measure (Multimedia Appendix 4) [39]. This scale consists of 6 items rated on a 5-point Likert scale, with scores averaged to produce a summary score ranging from 1 to 5. In accordance with the recommendations of the scale developers, a minimum average score of 4 was considered indicative of high acceptability.

To assess usability, the extent to which using a product can achieve specific goals [40], we used the Health Information Technology Usability Evaluation Scale (Multimedia Appendix 4) [41]. This scale is customizable and specifically designed to evaluate telehealth technology. We selected subscales concerned with perceived impact (3 items), usefulness (9 items), and ease of use (5 items). The items were rated on a 5-point scale of agreement and averaged to generate subscale scores ranging from 1 to 5. Consistent with the previous threshold, the target was a mean score of at least 4 on each subscale.

Finally, we evaluated perceived response burden, represented by the effort required to answer the daily self-reports on Opal, by adapting a single question with a 5-point response scale from an existing survey, with scores ranging from 1 to 5 (Multimedia Appendix 4) [42]. We considered ≥80% of the participants rating the perceived response burden as “quite easy” or “very easy” as a success.

Statistical Analysis

The sample’s sociodemographic characteristics were described using frequency counts and proportions. These factors are deemed important because patient portal use varies by sociodemographic factors [9,43,44]. Indeed, capturing sex, age, and racial group is essential in portal research to assess generalizability [45]. Hence, the implementation outcomes were summarized with descriptive statistics and stratified by the selected sociodemographic variables (sex, age, and racial group) at days 1, 7 and 14. Acceptability and usability, treated as continuous outcomes, were summarized using the minimum, the maximum, and mean (SD). Feasibility, fidelity, and perceived response burden, treated as ordinal outcomes, were summarized using frequency counts and proportions.

We used linear mixed models to evaluate whether mean acceptability and usability scores changed significantly over time. The dependent variable for each model was the implementation outcome considered, and the independent variable was time (days 1, 7, and 14). If, at each time point, the outcome’s mean score was greater than or equal to the predefined success threshold, we considered that the target was met. If not, we used a 1-tailed *t* test to test the null hypothesis of threshold nonattainment.

The evaluation of perceived response burden was similar to that of acceptability and usability but with parameters estimated using generalized estimating equations for ordinal data. To test the null hypothesis of threshold nonattainment when the observed proportion fell below the predefined success threshold, we used a 1-tailed *z* test.

To evaluate whether fidelity changed significantly over time, we used a generalized estimating equations model for binary data. The dependent variable was the completion rate, and the independent variable was time (days 1 to 14). To test the null hypothesis of threshold nonattainment when the observed completion rate fell below the predefined success threshold, we used a 1-tailed *z* test.

Finally, the analysis was repeated with the selected sociodemographic variables added separately as independent variables to determine whether there were significant differences in the associated implementation outcomes between the groups represented over time.

For all hypothesis tests, the significance level was set at 5%.

Qualitative Data

Data Collection

To better understand stakeholder experiences of the implementation process, we conducted qualitative interviews with the stakeholders via videoconferencing, using either Zoom (Zoom Video Communications, Inc) or Skype (Microsoft Corp). Each interview lasted 30 to 45 minutes and was recorded. Trained and experienced researchers conducted them in French or English following a semistructured guide (Multimedia Appendix 5) on the following themes: experiences with COVID-19 or providing COVID-19–related care, role in the intervention’s implementation, perspective on the intervention, and recommendations for improvement. The interview guide included follow-up questions on each main theme.

Analysis

The interview recordings were transcribed verbatim and deidentified, after which they were reviewed by DL. DL and ML conducted an inductive-deductive thematic analysis [46] using NVivo 12 (Lumivero). They used the Consolidated Framework for Implementation Research (CFIR) [47], a commonly used implementation science framework, to identify influences on implementation. Using the CFIR’s 5 broad domains and 39 constructs, DL and ML deductively coded and categorized interview content on the stakeholders’ experiences of the intervention and its implementation. They used these categories to identify themes associated with CFIR domains. Illustrative quotes in French presented in this manuscript have been translated into English. To ensure reliability, the results were repeatedly discussed with coauthors.

Ethics Approval

This study was approved by the MUHC Research Ethics Board (2021-6763).

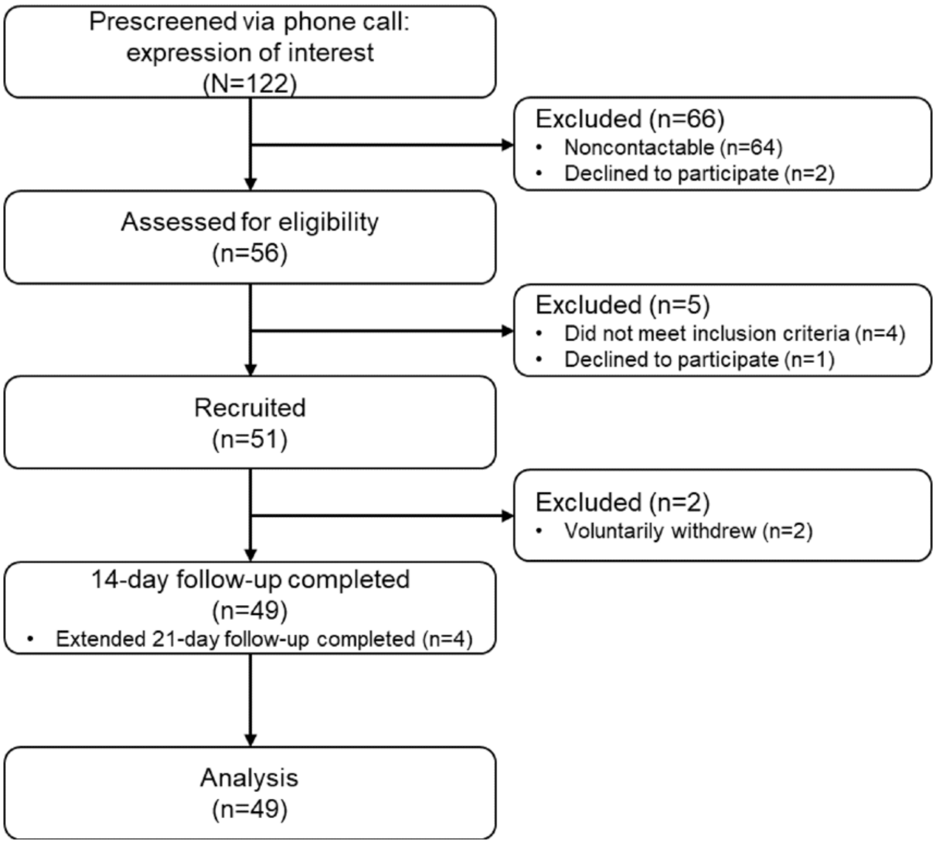
Results

Quantitative Results

Sociodemographic Characteristics

Figure 2 shows the flow of participants through the pilot study. From December 8, 2020, to February 23, 2021, a total of 51 patients were enrolled in the study. Of these 51 patients, 2 (4%) withdrew voluntarily before day 14, while 45 (88%) completed the 14-day follow-up, and 4 (8%) had their follow-up extended to 21 days because they were still symptomatic at day 14. All participants who completed at least 14 days of follow-up (49/51, 96%) were included in the analysis.

Figure 2. Opal-COVID study participant flowchart.



The sociodemographic characteristics of the study sample are described in Multimedia Appendix 6. As more than half of the participants (25/49, 51%) chose not to disclose their income, this variable was not reported. Table 1 displays the selected sociodemographic variables considered for further statistical analysis. As 3 (6%) of the 49 participants did not provide sociodemographic information, the sample size for analysis with these variables was 46.

Table 1. Descriptive statistics of the sociodemographic variables considered for statistical analysis (n=46).

Characteristics	Participants, n (%)
Sex	
Female	23 (50)
Male	23 (50)
Age group (years)	
18-50	37 (80)
51-70	9 (20)
Racial group	
White	22 (48)
People of color	24 (52)

Feasibility, Fidelity, and Usability

In terms of feasibility, the observed recruitment rate was 98% (51/52) and the retention rate was 96% (49/51), both of which were above the predetermined success threshold of 75%.

Concerning fidelity, Figure 3A shows the self-report completion rates of participants (n=49) over time, which ranged from 78% (38/49; day 1) to 100% (49/49 day 3) during the 14-day follow-up. The target threshold of 75% was met at each time point. The completion rates exhibited a slight tendency to decrease over time, but these results were not statistically significant (*P*=.21).

Figure 3. Self-report completion rates of participants (A) over time (n=49) and stratified by (B) sex (n=46), (C) age group (n=46), and (D) racial group (n=46).

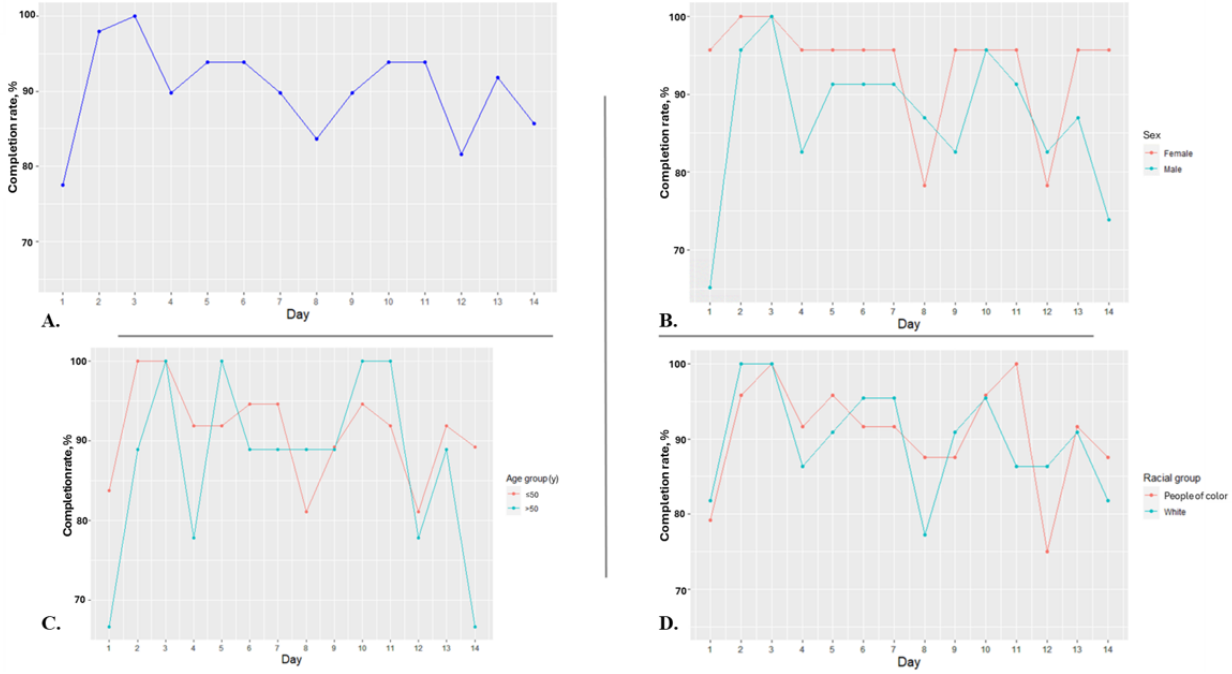


Figure 3B shows the completion rates over time, stratified by sex (n=46). For female participants (23/46, 50%), they ranged from 78% (18/23; day 8) to 100% (23/23; days 2 and 3). For male participants (23/46, 50%), they ranged from 65% (15/23; day 1) to 100% (23/23; day 3). Overall, female participants had a significantly higher fidelity rate over time than male participants (*P*=.004).

Completion rates by age group over time (n=46) are shown in Figure 3C. They ranged from 81% (30/37; days 8 and 12) to 100% (37/37; days 2 and 3) for participants aged 50 years (37/46, 80%). Among participants aged >50 years (9/46, 20%), completion rates ranged from 67% (6/9; days 1 and 14) to 100% (9/9; days 3, 5, 10, and 11). No significant difference was found in fidelity between the 2 age groups over time (*P*=.19).

Figure 3D shows completion rates over time stratified by racial group (n=46). For participants of color (24/46, 52%), they ranged from 75% (18/24; day 12) to 100% (24/24; days 3 and 11). For White participants (22/46, 48%), they ranged from 77% (17/22; day 8) to 100% (22/22; days 2 and 3). There was no significant difference in fidelity between the 2 racial groups over time (*P*=.72).

Table 2 displays the descriptive statistics for acceptability and usability at each time point for the overall sample, as well as for the sample stratified by sex, age, and racial group. For the overall sample, the *P* values correspond to the null hypothesis of no mean difference between time points (day 1, day 7, and day 14 of follow-up). For the sociodemographic group comparisons, the *P* values correspond to the null hypothesis of no mean difference between groups.

Table 2. Descriptive statistics for the intervention's acceptability and usability scores at each time point for the overall sample (n=49) and stratified by the sociodemographic variables (n=46).

Sociodemographic variables	Total (n=49)	Sex		Age group (years)		Racial group	
		Female (n=23)	Male (n=23)	18-50 (n=37)	51-70 (n=9)	People of color (n=24)	White (n=22)
Acceptability (Acceptability of Intervention Measure)							
Day 1, mean (SD; min-max)	4.06 (0.57; 1.75-5.00)	4.00 (0.65; 1.75-5.00)	4.14 (0.49; 3.00-5.00)	4.02 (0.57; 1.75-5.00)	4.22 (0.58; 3.25-5.00)	4.08 (0.70; 1.75-5.00)	4.05 (0.41; 3.00-5.00)
Day 7, mean (SD; min-max)	4.26 (0.59; 2.75-5.00)	4.32 (0.61; 2.75-5.00)	4.25 (0.49; 3.25-5.00)	4.29 (0.55; 2.75-5.00)	4.28 (0.60; 3.25-5.00)	4.33 (0.59; 2.75-5.00)	4.24 (0.52; 3.25-5.00)
Day 14, mean (SD; min-max)	4.23 (0.57; 2.75-5.00)	4.32 (0.71; 2.75-5.00)	4.21 (0.43; 3.25-5.00)	4.28 (0.59; 2.75-5.00)	4.19 (0.61; 3.25-5.00)	4.26 (0.60; 2.75-5.00)	4.26 (0.57; 3.00-5.00)
P value	.04[a]	.99[b]	.99[b]	.90[b]	.90[b]	.88[b]	.88[b]
Usability							
Perceived impact							
Day 1, mean (SD; min-max)	4.34 (0.71; 2.67-5.00)	4.25 (0.73; 2.67-5.00)	4.41 (0.71; 3.00-5.00)	4.32 (0.64; 2.67-5.00)	4.33 (1.00; 3.00-5.00)	4.44 (0.68; 3.00-5.00)	4.21 (0.75; 2.67-5.00)
Day 7, mean (SD; min-max)	4.49 (0.66; 2.67-5.00)	4.48 (0.74; 2.67-5.00)	4.46 (0.60; 3.33-5.00)	4.45 (0.66; 2.67-5.00)	4.54 (0.75; 3.33-5.00)	4.56 (0.65; 2.67-5.00)	4.38 (0.69; 2.67-5.00)
Day 14, mean (SD; min-max)	4.40 (0.82; 1.00-5.00)	4.44 (0.90; 1.00-5.00)	4.30 (0.78; 2.33-5.00)	4.50 (0.76; 1.00-5.00)	3.85 (0.96; 2.33-5.00)	4.25 (0.92; 1.00-5.00)	4.50 (0.74; 2.33-5.00)
P value	.80[a]	.72[b]	.72[b]	.27[b]	.27[b]	.68[b]	.68[b]
Usefulness							
Day 1, mean (SD; min-max)	4.66 (0.47; 3.00-5.00)	4.66 (0.45; 3.67-5.00)	4.65 (0.51; 3.00-5.00)	4.69 (0.40; 3.67-5.00)	4.53 (0.72; 3.00-5.00)	4.63 (0.56; 3.00-5.00)	4.68 (0.38; 3.67-5.00)
Day 7, mean (SD; min-max)	4.68 (0.39; 3.56-5.00)	4.70 (0.40; 3.56-5.00)	4.66 (0.41; 3.78-5.00)	4.71 (0.36; 3.56-5.00)	4.53 (0.54; 3.78-5.00)	4.68 (0.42; 3.78-5.00)	4.68 (0.39; 3.56-5.00)
Day 14, mean (SD; min-max)	4.60 (0.68; 1.00-5.00)	4.57 (0.90; 1.00-5.00)	4.62 (0.46; 3.67-5.00)	4.65 (0.72; 1.00-5.00)	4.37 (0.61; 3.67-5.00)	4.47 (0.90; 1.00-5.00)	4.73 (0.36; 3.89-5.00)
P value	.50[a]	.76[b]	.76[b]	.13[b]	.13[b]	.82[b]	.82[b]
Ease of use							
Day 1, mean (SD; min-max)	4.60 (0.57; 3.00-5.00)	4.61 (0.51; 3.60-5.00)	4.58 (0.65; 3.00-5.00)	4.67 (0.45; 3.60-5.00)	4.29 (0.91; 3.00-5.00)	4.49 (0.64; 3.00-5.00)	4.71 (0.49; 3.20-5.00)
Day 7, mean (SD; min-max)	4.67 (0.53; 2.60-5.00)	4.76 (0.37; 4.00-5.00)	4.53 (0.67; 2.60-5.00)	4.77 (0.35; 4.00-5.00)	4.13 (0.89; 2.60-5.00)	4.59 (0.61; 2.60-5.00)	4.71 (0.47; 3.20-5.00)
Day 14, mean (SD; min-max)	4.64 (0.71; 1.00-5.00)	4.64 (0.88; 1.00-5.00)	4.61 (0.56; 3.20-5.00)	4.72 (0.71; 1.00-5.00)	4.24 (0.71; 3.20-5.00)	4.52 (0.94; 1.00-5.00)	4.73 (0.41; 3.80-5.00)
P value	.79[a]	.69[b]	.69[b]	.004[b]	.004[b]	.30[b]	.30[b]

[a] *P* value corresponds to the null hypothesis of no mean difference between time points (days 1, 7, and 14 of follow-up).

[b] *P* value corresponds to the null hypothesis of no mean difference between groups.

The mean values of acceptability and usability were above the set minimum of 4 at each time point. Their means increased between day 1 and day 7 and stabilized or slightly decreased between day 7 and day 14. Mean acceptability scores differed significantly over time (*P*=.04); they increased from day 1 to day 7 (*P*=.04) and from day 1 to day 14 (*P*=.07). No significant differences were found in mean usability scores between time points.

Mean acceptability scores surpassed the required minimum of 4 at each time point for all sociodemographic groups. No significant differences were found in mean acceptability scores between groups, for each variable considered, independent of time point.

Mean usability scores were above the minimum threshold of 4 at each time point and for each sociodemographic variable. No significant differences in mean usability scores were found between groups, independent of time point, except for ease of use. In this case, participants aged >50 years reported significantly lower mean ease of use scores than younger participants (*P*=.004).

In addition, among the 49 patients who completed the 14-day follow-up, 3 (6%) were not able to complete the daily self-report by themselves and needed help from someone to complete it for at least 1 day.

Perceived Response Burden

Table 3 displays the descriptive statistics for the perceived response burden of completing the daily self-reports at each time point for the overall sample and stratified by sex, age, and racial group. For the overall sample, the *P* value corresponds to the null hypothesis of no effect of time on the odds of being at a lower burden level, while for the sociodemographic group comparisons, the *P* values refer to the null hypothesis of no difference between groups in the odds of being at a lower response burden level.

Table 3. Descriptive statistics for intervention-related response burden at each time point for the overall sample (n=49) and stratified by the sociodemographic variables (n=46).

Day and response [a]	Total (n=49), n (%)	Sex		Age group (years)		Racial group	
		Female (n=23), n (%)	Male (n=23), n (%)	18-50 (n=37), n (%)	51-70 (n=9), n (%)	People of color (n=24), n (%)	White (n=22); n (%)
Day 1							
1	22 (45)	10 (43)	11 (48)	17 (46)	4 (44)	10 (42)	11 (50)
2	20 (41)	11 (48)	9 (39)	17 (46)	3 (33)	11 (46)	9 (41)
3	3 (6)	2 (9)	1 (4)	2 (5)	1 (11)	1 (4)	2 (9)
4	1 (2)	0 (0)	1 (4)	0 (0)	1 (11)	1 (4)	0 (0)
5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	3 (6)	0 (0)	1 (4)	1 (3)	0 (0)	1 (4)	0 (0)
Day 7							
1	31 (63)	16 (70)	13 (57)	25 (68)	4 (44)	11 (46)	18 (82)
2	16 (33)	7 (30)	8 (35)	11 (30)	4 (44)	11 (46)	4 (18)
3	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	2 (4)	0 (0)	2 (9)	1 (3)	1 (11)	2 (8)	0 (0)
Day 14							
1	32 (65)	17 (74)	12 (52)	24 (65)	5 (56)	15 (63)	14 (64)
2	13 (27)	4 (17)	9 (39)	11 (30)	2 (22)	7 (29)	6 (27)
3	3 (6)	1 (4)	2 (9)	1 (3)	2 (22)	1 (4)	2 (9)
4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
5	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	1 (2)	1 (4)	0 (0)	1 (3)	0 (0)	1 (4)	0 (0)
P value[c]	.21[b]	.67[c]	.67[c]	.49[c]	.49[c]	.23[c]	.23[c]

[a] 1=“very easy,” 2=“quite easy,” 3=“neither easy nor burdensome,” 4=“quite burdensome,” and 5=“very burdensome.” “Missing” corresponds to the missing value at each time point.

[b] *P* value corresponds to the null hypothesis of no effect of time on the odds of being at a lower burden level.

[c] *P* values refer to the null hypothesis of no difference between groups in the odds of being at a lower response burden level.

Surpassing our target, >80% of the participants at each time point—86% (42/49) at day 1, 96% (47/49) at day 7, and 92% (45/49) at day 14—rated completing the daily self-reports (response burden) as “quite easy” to “very easy,” with no significant differences found between time points (*P*=.21).

Approximately 80% of the participants in each sociodemographic group found it “very easy” or “quite easy” to complete the daily self-reports, with no significant difference between groups, independent of time point.

Qualitative Results

A total of 13 individuals participated in the interviews from June to September 2021, including engaged expert patients (n=3, 23% women who had recovered from COVID-19 infection), health care professionals (n=6, 46%, including the PI of the study; n=3, 50% research nurses; and n=2, 33% physicians), and the coordinators (n=4, 31%, including n=1, 25% clinical study coordinator; n=1, 25% digital coordinator; n=1, 25% laboratory coordinator; and n=1, 25% Opal manager).

The thematic analysis identified 8 themes of factors that influenced the implementation process related to 10 constructs across the 5 domains of the CFIR.

Implementation Process

Planning: Structured Process

For the interviewed stakeholders, meetings held during the “solution design” phase (Figure 1) enhanced feasibility by providing guidance and structure in the intervention’s preparation, mainly by turning this process into a series of manageable collective decisions about its key components, as mentioned by a participant:

> *Meetings were quite structured. We had Zoom meetings to discuss the questionnaire, and the questions to include, details that we had to review...I think these steps were well placed and framed, so the project could be launched and useful for people.* [Expert patient 1]

Planning: Focus on Stakeholder Recommendations

Stakeholders highlighted the presence of different experts at these meetings, including expert patients, physicians, nurses, a psychiatrist, and IT developers, and how the integration of their perspectives improved quality and patient centeredness. The same expert patient stated as follows:

> *We were several people revising documents. We made other revisions. Then we applied it and tested it physically. And we gave feedback during Zoom meetings with the two nurses, and I was there as a “patient.” We could look at it, and answer questions, and then [IT developers] would do their thing making sure that it is “user-friendly.”* [Expert patient 1]

Engaging: Emphasis on Stakeholder Knowledge

Stakeholders described their involvement as a learning process and an opportunity to share experience and expertise related to COVID-19 infection, medical follow-up, and IT. The implementation process led to a series of mutual training that benefited stakeholders and facilitated feasibility:

> *Since I am part of the team, they [health care professionals] provided me with the overview, the importance, and the significance of the study, which is very interesting.* [Coordinator; laboratory coordinator]

> *The principal investigator is a physician with whom we work, in the same clinic. We are three research nurses, linked to an outpatient clinic. We see patients in other research projects from the clinic, so we know about this kind of research and could share our experience. As other stakeholders, he approached us, and it made a motivated team for the implementation. It included the patient committee, which helped a lot, because they could test the app.* [Health care professional; nurse 3]

Intervention

Security: Burdensome Privacy Protection Measures

Stakeholders who interacted with patient participants in the pilot study mentioned that many had felt that these measures were cumbersome or time consuming; for instance, a stakeholder stated as follows:

> *What patients disliked the most were the security measures. They really disliked having to use such a complex password with low and upper case, with special characters.* [Coordinator; clinical research coordinator]

This aspect was identified as a barrier to usability, especially ease of use.

Relative Advantage: Emphasis on Providing Safe Care for All

Several stakeholders commented on how patient safety was set as a priority throughout the implementation process, and this aspect was identified as enhancing acceptability. They highlighted the importance of both patients and health care professionals feeling secure with the technology and the intervention throughout the follow-up. Indeed, a stakeholder presented the whole project as having emerged from a concern for the safety of self-isolating patients with COVID-19 infection:

> *[We had an initial meeting] to discuss basically the algorithm and what steps should be taken to provide safe and good care in the event that a patient decompensates, who should be notified, should they just be informed to go to the emergency.* [Health care professional; physician 1]

In this vein, a stakeholder, a patient expert who was also a health care professional, discussed the intervention as reassuring from both the patient and professional perspectives:

> *For me, as a nurse, I found it reassuring to touch base every day with these patients, because they could deteriorate very, very quickly. Often, we wait for them to call, or for their next appointment, it can be a long time and there can be changes. These questionnaires ask relevant questions on the condition itself. The nurse can see it: “They’re deteriorating. I want to talk with them. I want to understand what is going on...” As a patient, I find reassuring that my health care team knows what is happening to me, and I do not have to wait to become very sick to go to the emergency room. And if I’m worried, I can leave a message.* [Expert patient 2]

Relative Advantage: Reduced Stress

Stakeholders commented that the intervention was instrumental in providing patient participants with emotional support and reducing stress associated with their health status. This aspect, identified as facilitating usefulness, was attributed to the access acquired via the intervention to health care professionals and to reliable information on COVID-19:

> *I think that [the information on COVID-19 within Opal] is a big addition for patients because they are*

> *at home, with COVID-19. They have many worries, with everything they hear in the media. So, it could reassure them. And to have somebody on the phone to answer questions, I think it's really something good that could calm them and ease their preoccupations.* [Health care professional; nurse 3]

Adaptability: Certain Functionalities Require Further Tailoring for Acute Follow-Up

Stakeholders explained that Opal was not perfectly adapted to closely monitor acute conditions such as COVID-19 infection (eg, administration and collection of daily surveys) probably because it had been conceived for the clinical follow-up of chronic conditions (eg, no integrated automated reminder system). They consequently took measures to encourage patient participants to adhere to the intervention to optimize fidelity. Mainly, study coordinators and health care professionals often sent in-app text message reminders to patient participants for them to complete daily self-reports, resulting in increased workloads:

> *Before this project, Opal was used mainly by cancer patients...As I said, even if the system allows to distribute surveys, it's not very easy because it's not conceived to use questionnaires to monitor patients, at least [not] every day. It's better for chronic conditions with one consultation once every second or third week.* [Coordinator; digital coordinator]

Adaptability: Adjustable Intervention to Meet Emerging Needs

Stakeholders appreciated that the intervention could be adjusted to individual patient needs, which enhanced usability; for instance, the duration of participation was extended for certain participants based on perceived risks (eg, when they were infected with an emerging COVID-19 variant); some participants were invited to answer >1 self-report on certain days to better monitor their state (eg, if they showed risks of rapid deterioration); 2 (4%) of the 49 participants applied questions about symptoms, vital signs, and mental health to other household members (eg, their children) with COVID-19 infection—without transmitting them to health care professionals—who could not participate in the study to enable monitoring; and patient participants and health care professionals used telephone consultations more often than expected and for unanticipated purposes (eg, to discuss a chronic health condition, learn how to use the oximeter, and discuss remote work conditions in the context of self-isolation):

> *Flexibility, this is what people enjoyed the most. Most of all when patients were sicker. Even if the protocol planned for a 14-day follow-up, we extended this follow-up with three patients. One woman was very worried about her son, but the son was excluded because he was not an adult. But being in Opal, she felt reassured as she could use the questions used in Opal, and also employed the oximeter on her son.* [Coordinator; clinical research coordinator]
>
> *Patient participants reappropriated the study. We hadn't planned that they would call the nurses all the time. It was not planned at all. And there were contacts outside of the application. This is what is interesting, they wanted to talk to the nurse, and have Zoom consultations.* [Health care professional; PI]

Inner and Outer Settings

Networks and Communication: Delays Due to Institutional Barriers

For stakeholders, an important barrier to feasibility was the institutional approval process for Opal's protection measures to ensure patient privacy and data security. A coordinator noted as follows:

> *We were delayed by the ethics committee because of concerns about the safety of patient data. The committees were very worried, and they put a lot of conditions.* [Coordinator; digital coordinator]

Another stakeholder provided the following comment:

> *We were completely blocked by the security department, an internal MUHC institution responsible for validating all "IT tools." I think they blocked us for about four months. We could not submit the project to Ethics, we could not finish it. We only received ethics approval in December, and the approval from this institution within the MUHC, and this is why we started in December to include patients. Otherwise, we could have started before.* [Health care professional; PI]

These measures delayed the institutional approval for the implementation of the intervention, as well as the recruitment of patient participants.

Discussion

Principal Findings

This paper reports on the implementation of a patient portal (Opal) configured to support the follow-up of self-isolating patients with COVID-19 infection. A mixed methods pilot study was conducted to test and evaluate the intervention's implementation with 49 patient participants who used Opal for at least 14 days. Quantitatively, the implementation was evaluated with research questionnaires administered to patients on the intervention's acceptability, usability (including perceived impact, usefulness, and ease of use), and perceived response burden, as well as through descriptive statistics on feasibility and fidelity. Qualitatively, semistructured interviews on implementation barriers and facilitators were held with 13 stakeholders of the intervention, including expert patients, health care professionals, and coordinators.

The COVID-19 pandemic has led to the development of numerous remote monitoring programs to support patients as well as health care systems. Initially focused on discharge follow-up of admitted patients [48-50], the technology was expanded to direct remote monitoring of patients in home isolation who had tested positive for COVID-19 infection and those who were suspected of having been infected with COVID-19 [51-58]. Multiple studies have shown that such interventions can help patients better manage their symptoms at home and reduce patient hospitalization or rehospitalization rates [48-50,53,54,56,57]. Patients could also be identified and admitted in a timelier manner after their condition worsened, reflecting the fact that remote monitoring programs are a good way to ease the management of hospital beds and reduce the burden on the health care system during a pandemic [52,55-58]. However, 2 systematic reviews on COVID-19 remote home monitoring programs noted the lack of implementation research on these technologies and attention to stakeholder perspectives [59,60]. Our study fills this gap by describing PSE throughout the implementation process and by analyzing stakeholder experiences, providing evidence for co-design through PSE.

Health information technologies have the potential to increase access to health care, but digital divides related to limited access to technology or technological literacy may alienate certain groups, such as women, older people, or certain ethnic or racialized groups [61,62]. The literature highlights the need to consider equity when implementing telehealth interventions and reduce these divides [63,64]. In this regard, the sociodemographic profiles of the pilot study participants were relatively diverse: nearly half (23/49, 47%) were female, close to half (24/49, 49%) were people of color, and almost a fifth (9/49, 18%) were aged >50 years. Nevertheless, we achieved the minimum success thresholds set for all included implementation outcomes (ie, fidelity, feasibility, acceptability, usability, and perceived response burden), at all time points and across all sociodemographic groups considered. Hence, we can conclude that the intervention was feasible in the context of implementation.

The positive feasibility and fidelity results support the intervention's viability. The 98% (51/52) recruitment rate indicates that self-isolating patients wanted to stay connected to the health system, which the Opal patient portal's smartphone app allowed. Given the delays caused by institutional barriers in both solution deployment and patient recruitment, we started the study only during the second wave of COVID-19 in Quebec, and participants were often enrolled on or after the third day of a positive test confirmation. The team was concerned that the 14-day routine follow-up, initially chosen according to official guidelines, was too long. Research suggests that half of those who download mobile health apps stop using them because of loss of interest, high data entry burden, or hidden costs [65]. While we observed a slight decrease in fidelity over time, this change was not significant. It was also found that female participants had significantly higher fidelity over time than male participants (*P*=.004). This is consistent with research that suggests that women are usually more concerned about health issues and more likely to report their health care problems than men [66]. In sum, the 96% (49/51) retention rate and >80% response rate to the self-reports exceeded researchers' expectations. The Opal intervention for COVID-19 seems to have responded well to the needs of the target population, and patient and stakeholder involvement throughout the configuration and implementation process likely contributed to the positive feasibility and fidelity results.

One explanation for the high retention rate may lie in the participants' high acceptability ratings of the intervention, which, in turn, may have been fostered by the co-design approach taken in the planning phase. This allowed the intervention to be refined based on suggestions from a range of perspectives and areas of expertise. Previous studies have underscored the ability of PSE to improve the acceptability of studies [60,67], and our results suggest its utility for telehealth intervention–based studies. Furthermore, in situations where participants are self-isolating and have little knowledge of COVID-19, it is important to design interventions with their safety as a primary concern. In this case, the intervention contributed to ensure safety, which also contributed to its acceptability. Similarly, it is worth noting the significant increase in the acceptability score observed between day 1 and day 7 (from mean 4.06, SD 0.57 to mean 4.26, SD 0.59). This increase resonates with models of acceptance of health IT that imply that the use of the technology contributes to acceptance [68]. In other words, acceptability tends to increase over time as users learn to use a technology and if they are satisfied by its quality and the services it provides [69].

The usability of Opal for COVID-19 remote follow-up was also demonstrated. Our results indicate that it was impactful, useful, and easy to use. We only noted a significant difference on this outcome for 1 sociodemographic variable: age. People aged >50 years showed significantly lower mean ratings of ease of use than younger participants. While the sample size of this age group was very small (9/46, 20%), the qualitative results suggest that the rigorous privacy protection mechanisms were an implementation barrier. Opal has a complex password combination requirement, which can be challenging for older users. Moreover, Opal automatically logs users out of their accounts if they are inactive for >5 minutes. This can result in users having to log in repeatedly to complete self-reports if they are interrupted. The balance between usability and security could be further considered in the future [70].

By contrast, our qualitative results, particularly the themes identified for the "adaptability" construct, suggest that usability was contingent on the reactiveness of stakeholders; for example, health care professionals offered more teleconsultations than expected and, in some cases, provided support to patients' family members who also had contracted COVID-19 infection. Furthermore, the technical team sent more reminders than expected to patients to fill out their daily self-reports. Indeed, timely feedback and support to users is important to ensure the usability of telehealth technologies [71]. Similar to a previous study [72], this may increase stakeholder workload, especially when there is still room for improvement in the technology. However, our qualitative results suggest that these adaptations were not seen as a burden to stakeholders. The literature on the impacts of such tools on workload suggests that any extra effort by service providers may be compensated by an increased ability to identify information that would otherwise have been missed and intervene early to avoid worse outcomes [73,74]. What may have occurred instead was a reprioritization of work time [73,74]. Such benefits were also seen by stakeholders as part of the ultimate purpose of this project, which was to increase access to care, promote safety, and reduce mental stress for homebound, self-isolating patients with COVID-19 infection. Nonetheless, on the technical front, future implementation will require more advanced automation of such features as reminders.

Further assessment of the costs associated with potential large-scale implementation of this intervention, including workforce requirements, is also recommended. Future studies could analyze its cost-effectiveness and, to facilitate more efficient staffing, document the reorientation of human interactions necessitated when using a patient portal.

It is finally worth noting that >80% of the patient participants found it “quite easy” or “very easy” to answer the self-reports via Opal. Overall, 94% (46/49) of the patient participants were able to complete daily self-reports by themselves. Both results illustrate the feasibility of sharing information with the health care team through the patient portal by answering electronically administrated PROMs in mild COVID-19 infection conditions, further supporting the usability of the intervention.

Limitations

We acknowledge several limitations of this study. First, the sample size of this pilot study was small. Furthermore, participants were recruited through convenience sampling, potentially contributing to sampling bias; for instance, participants may have been more willing to participate and to rate the intervention favorably. Patient participants were also screened at a single institution in Montreal. Therefore, the generalizability of our findings to other geographic areas is limited. Future similar studies should consider increasing their sample size, adding a control group (eg, a control group that only receives daily telehealth check-ins from health care providers), and including multiple study sites to enhance the reliability of their findings.

Second, for technical reasons related to participant identification, enrollment in Quebec’s provincial health insurance plan was necessary for inclusion in the study, which led us to exclude 4 potential patient participants who were members of populations considered vulnerable during the COVID-19 pandemic (eg, international students and resettled refugees) [75,76]. As such, the intervention may have contributed to health care inequity. Future improvements to the identification system could help alleviate this issue.

Finally, the qualitative interviews with stakeholders were conducted 1 month after completing quantitative data collection, which may have introduced recall bias.

Conclusions

This work illustrates how PSE can enable co-design, including the development and implementation of a telehealth intervention for remote follow-up of an emerging acute condition (ie, COVID-19 infection), in this case, by making configurational changes to a patient portal used for chronic disease management. The mixed methods pilot study design provided a detailed understanding of the positive implementation outcomes of the intervention and identified some barriers. Thresholds were attained or surpassed for the feasibility, fidelity, usability, acceptability, and perceived response burden of the intervention, and the qualitative findings highlighted the importance of PSE in the configuration and implementation processes. These data also further demonstrate the significant potential of such telehealth tools for managing acute but stable illnesses or medical conditions that require remote follow-up. Future work can be devoted to further tailoring such interventions, improving the balance of usability and security measures, and assessing the cost of large-scale implementation.

Acknowledgments

This study secured funding from the McGill Interdisciplinary Initiative in Infection and Immunity Emergency COVID-19 Research Funding (ECRF-R2-44; principal investigator [PI]: BL) and from the Canadian Institutes of Health Research (CIHR) Strategy for Patient-Oriented Research Québec Support Unit–Methodological Developments (M006; PI: BL). MPP and BL received a CIHR Operating Grant (VR4-172769) under COVID-19 Rapid Research Funding Opportunity–Clinical Management & Health System Interventions for the project titled “Real time evaluation of the deployment of connected technologies and of the partnership of services and care during the COVID-19 sanitary crisis—the Techno-COVID-Partnership program” (2020-2021) to support the evaluation of this study.

YM is supported by the postgraduate scholarship–doctoral program from the Natural Sciences and Engineering Research Council and a doctoral research award from the Fonds de recherche du Québec–Nature et technologies. NK is supported by a career award from the Fonds de recherche du Québec–Santé (Junior 1). MPP is supported by a senior career award financed by the Fonds de recherche du Québec–Santé, the Centre de Recherche du Centre Hospitalier de l’Université de Montréal, and the Québec Ministry of Health and Social Services. BL is supported by 2 career awards—a senior salary award from Fonds de recherche du Québec–Santé (311200) and the LE 250 from the Québec Ministry of Health and Social Services for researchers in family medicine—and holds a CIHR Strategy for Patient-Oriented Research Mentorship Chair in Innovative Clinical Trials for HIV Care. MK is supported by a Tier 1 Canada Research Chair. The funding sources had no role in the design of this study and were not involved in the interpretation of the results or the decision to submit them for publication.

The authors acknowledge the development and operation of Opal as an in-kind support provided by the Opal Health Informatics Group at the Research Institute of the McGill University Health Centre (MUHC). Opal’s development and operation at the MUHC was facilitated by a MEDTEQ+ Fonds de soutien à l’innovation en santé et en services sociaux grant (PI: John Kildea) as well as by the generous support of the Montreal General Hospital Foundation, the Cedars Cancer Foundation, the MUHC Foundation, and the Montreal Children’s Hospital Foundation. The authors also acknowledge helpful conversations with John Kildea during the configuration of Opal and the preparation of the McGill Interdisciplinary Initiative in Infection and Immunity grant application.

The authors thank the Chronic Viral Illness Service research team, particularly the nurses of the clinical monitoring team, LDB, GT, and NP. The authors also thank the laboratory research personnel responsible for shipping the medical equipment to the study participants. Finally, the authors thank Kedar KV Mate for his help and advice during the initial phase of the study.

The names of the members of the Opal–COVID-19 patient expert committee cannot be provided because they are patients, and their names must remain confidential.

Data Availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

YM, DL, KE, ARC, NK, MPP, SB, MK, SJB, BL, and the Opal–COVID-19 patient expert committee helped design the study, the intervention, and the data collection tools. YM, TH, and JA configured the Opal app for the COVID-19 follow-up. LDB, GT, NP, NK, SB, MJB, JC, AdP, and BL participated in the remote monitoring and teleconsultations with the study participants. YM, DL, and ARC contributed to data collection. YM and SV completed the statistical analysis. DL and ML completed the qualitative analysis. YM, DL, SV, and BL wrote the manuscript. All authors critically reviewed the manuscript and approved the final version.

Conflicts of Interest

BL has received research support, consulting fees, and speaker fees from ViiV Healthcare, Merck, and Gilead Sciences. NK reports research funding from Gilead Sciences; advisory fees from Gilead Sciences, ViiV Healthcare, Merck, and AbbVie; and speaker fees from Gilead Sciences and Merck (all outside of the submitted work). MK received research support and consulting fees from ViiV Healthcare, AbbVie, and Gilead Sciences. All other authors declare no conflicts of interest.

Multimedia Appendix 1
Opal-COVID study daily self-report.
[DOC File , 74 KB - jopm_v16i1e48194_app1.doc]

Multimedia Appendix 2
CONSORT (Consolidated Standards of Reporting Trials) feasibility guidelines.
[PDF File (Adobe PDF File), 112 KB - jopm_v16i1e48194_app2.pdf]

Multimedia Appendix 3
StaRI (Standards for Reporting Implementation Studies) guidelines.
[PDF File (Adobe PDF File), 221 KB - jopm_v16i1e48194_app3.pdf]

Multimedia Appendix 4
Study questionnaire (adapted Acceptability of Intervention Measure, Health Information Technology Usability Evaluation Scale, and questionnaire for perceived response burden).
[DOC File , 62 KB - jopm_v16i1e48194_app4.doc]

Multimedia Appendix 5
Qualitative interview guide.
[DOC File , 40 KB - jopm_v16i1e48194_app5.doc]

Multimedia Appendix 6
Sociodemographic characteristics of the study sample.
[PDF File (Adobe PDF File), 16 KB - jopm_v16i1e48194_app6.pdf]

References

1. Armocida B, Formenti B, Ussai S, Palestra F, Missoni E. The Italian health system and the COVID-19 challenge. Lancet Public Health 2020 May;5(5):e253 [FREE Full text] [doi: 10.1016/S2468-2667(20)30074-8] [Medline: 32220653]
2. Legido-Quigley H, Mateos-García JT, Campos VR, Gea-Sánchez M, Muntaner C, McKee M. The resilience of the Spanish health system against the COVID-19 pandemic. Lancet Public Health 2020 May;5(5):e251-e252 [FREE Full text] [doi: 10.1016/S2468-2667(20)30060-8] [Medline: 32199083]

3. COVID-19 Investigation Team. Clinical and virologic characteristics of the first 12 patients with coronavirus disease 2019 (COVID-19) in the United States. Nat Med 2020 Jul;26(6):861-868. [doi: 10.1038/s41591-020-0877-5] [Medline: 32327757]
4. Zhou F, Yu T, Du R, Fan G, Liu Y, Liu Z, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. Lancet 2020 Mar 28;395(10229):1054-1062 [FREE Full text] [doi: 10.1016/S0140-6736(20)30566-3] [Medline: 32171076]
5. Richardson S, Hirsch JS, Narasimhan M, Crawford JM, McGinn T, Davidson KW, the Northwell COVID-19 Research Consortium, et al. Presenting characteristics, comorbidities, and outcomes among 5700 patients hospitalized with COVID-19 in the New York City area. JAMA 2020 May 26;323(20):2052-2059 [FREE Full text] [doi: 10.1001/jama.2020.6775] [Medline: 32320003]
6. Wu C, Chen X, Cai Y, Xia J, Zhou X, Xu S, et al. Risk factors associated with acute respiratory distress syndrome and death in patients with coronavirus disease 2019 pneumonia in Wuhan, China. JAMA Intern Med 2020 Jul 01;180(7):934-943 [FREE Full text] [doi: 10.1001/jamainternmed.2020.0994] [Medline: 32167524]
7. Brooks SK, Smith LE, Webster RK, Weston D, Woodland L, Hall I, et al. The impact of unplanned school closure on children's social contact: rapid evidence review. Euro Surveill 2020 Apr;25(13):2000188 [FREE Full text] [doi: 10.2807/1560-7917.ES.2020.25.13.2000188] [Medline: 32265006]
8. James J, Hibbard J, Agres T, Lott R, Dentzer S. Health policy brief: patient engagement. Health Aff 2013;33(6):1-6.
9. Irizarry T, DeVito Dabbs A, Curran CR. Patient portals and patient engagement: a state of the science review. J Med Internet Res 2015 Jun 23;17(6):e148 [FREE Full text] [doi: 10.2196/jmir.4255] [Medline: 26104044]
10. Opal homepage. Opal. URL: https://www.opalmedapps.com/ [accessed 2024-10-25]
11. Cordier JF. The expert patient: towards a novel definition. Eur Respir J 2014 Oct;44(4):853-857 [FREE Full text] [doi: 10.1183/09031936.00027414] [Medline: 25271227]
12. Kildea J, Battista J, Cabral B, Hendren L, Herrera D, Hijal T, et al. Design and development of a person-centered patient portal using participatory stakeholder co-design. J Med Internet Res 2019 Feb 11;21(2):e11371 [FREE Full text] [doi: 10.2196/11371] [Medline: 30741643]
13. Alhomod AS, Alzahrani S. Patient empowerment via mobile personal health records and mobile health applications: a review of the current use. In: Proceedings of the Portland International Conference on Management of Engineering and Technology. 2019 Presented at: PICMET 2019; August 25-29, 2019; Portland, OR. [doi: 10.23919/picmet.2019.8893847]
14. Slattery P, Saeri AK, Bragge P. Research co-design in health: a rapid overview of reviews. Health Res Policy Syst 2020 Feb 11;18(1):17 [FREE Full text] [doi: 10.1186/s12961-020-0528-9] [Medline: 32046728]
15. Steen M, Manschot MA, de Koning N. Benefits of co-design in service design projects. Int J Des 2011 Aug;5(2) [FREE Full text]
16. Carman KL, Dardess P, Maurer M, Sofaer S, Adams K, Bechtel C, et al. Patient and family engagement: a framework for understanding the elements and developing interventions and policies. Health Aff (Millwood) 2013 Feb;32(2):223-231. [doi: 10.1377/hlthaff.2012.1133] [Medline: 23381514]
17. Domecq JP, Prutsky G, Elraiyah T, Wang Z, Nabhan M, Shippee N, et al. Patient engagement in research: a systematic review. BMC Health Serv Res 2014 Feb 26;14(1):89 [FREE Full text] [doi: 10.1186/1472-6963-14-89] [Medline: 24568690]
18. Pomey MP, Flora L, Karazivan P, Dumez V, Lebel P, Vanier MC, et al. The “Montreal model”: issues of the relational partnership between patients and health professionals. Public Health 2015:41-50. [doi: 10.3917/spub.150.0041]
19. Shippee ND, Domecq Garces JP, Prutsky Lopez GJ, Wang Z, Elraiyah TA, Nabhan M, et al. Patient and service user engagement in research: a systematic review and synthesized framework. Health Expect 2015 Oct;18(5):1151-1166 [FREE Full text] [doi: 10.1111/hex.12090] [Medline: 23731468]
20. Bruni RA, Laupacis A, Levinson W, Martin DK. Public involvement in the priority setting activities of a wait time management initiative: a qualitative case study. BMC Health Serv Res 2007 Nov 16;7:186 [FREE Full text] [doi: 10.1186/1472-6963-7-186] [Medline: 18021393]
21. Díaz Del Campo P, Gracia J, Blasco JA, Andradas E. A strategy for patient involvement in clinical practice guidelines: methodological approaches. BMJ Qual Saf 2011 Sep 02;20(9):779-784. [doi: 10.1136/bmjqs.2010.049031] [Medline: 21460393]
22. Grande SW, Faber MJ, Durand MA, Thompson R, Elwyn G. A classification model of patient engagement methods and assessment of their feasibility in real-world settings. Patient Educ Couns 2014 May;95(2):281-287. [doi: 10.1016/j.pec.2014.01.016] [Medline: 24582473]
23. Forbat L, Hubbard G, Kearney N. Patient and public involvement: models and muddles. J Clin Nurs 2009 Sep;18(18):2547-2554. [doi: 10.1111/j.1365-2702.2008.02519.x] [Medline: 19207798]
24. Shah SK, Miller FG, Darton TC, Duenas D, Emerson C, Lynch HF, et al. Ethics of controlled human infection to address COVID-19. Science 2020 May 22;368(6493):832-834 [FREE Full text] [doi: 10.1126/science.abc1076] [Medline: 32381590]
25. Briefing notes for researchers - public involvement in NHS, health and social care research. National Institute for Health and Care Excellence. 2021 Apr 5. URL: https://www.nihr.ac.uk/briefing-notes-researchers-public-involvement-nhs-health-and-social-care-research [accessed 2024-10-25]
26. Kirwan JR, de Wit M, Frank L, Haywood KL, Salek S, Brace-McDonnell S, et al. Emerging guidelines for patient engagement in research. Value Health 2017 Mar;20(3):481-486 [FREE Full text] [doi: 10.1016/j.jval.2016.10.003] [Medline: 28292494]

27. A resource toolkit for engaging patient and families at the planning table. The Center of Excellence on Partnership with Patients and the Public. URL: https://ceppp.ca/en/evaluation-toolkit/a-resource-toolkit-for-engaging-patient-and-families-at-the-planning-table/ [accessed 2024-10-25]
28. Nelimarkka M, Nonnecke B, Krishnan S, Aitumurto T, Catterson D, Crittenden C, et al. Comparing three online civic engagement platforms using the spectrum of public participation. Center for Information Technology Research in the Interest of Society (CITRIS). 2014. URL: https://escholarship.org/uc/item/0bz755bj [accessed 2024-10-25]
29. Bellows M, Kovacs Burns K, Jackson K, Surgeoner B, Gallivan J. Meaningful and effective patient engagement: what matters most to stakeholders. Patient Exp J 2015 Apr 29;2(1):18-28. [doi: 10.35680/2372-0247.1069]
30. Pomey M, Lebel P. Patient engagement: the Quebec path. HealthcarePapers 2016 Oct;16(2):80-85. [doi: 10.12927/hcpap.2017.24998]
31. Beck K, Beedle M, van Bennekum A, Cockburn A, Cunningham W, Fowler M, et al. Manifesto for agile software development. Ward Cunningham. 2001. URL: https://agilemanifesto.org/ [accessed 2024-10-25]
32. Lessard D, Engler K, Ma Y, Rodriguez Cruz A, Vicente S, Opal-COVID-19 Patient Expert Committee, et al. Remote follow-up of self-isolating patients with COVID-19 using a patient portal: protocol for a mixed methods pilot study (Opal-COVID study). JMIR Res Protoc 2022 Aug 18;11(8):e35760 [FREE Full text] [doi: 10.2196/35760] [Medline: 35820054]
33. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. Pilot Feasibility Stud 2016;2:64 [FREE Full text] [doi: 10.1186/s40814-016-0105-8] [Medline: 27965879]
34. Thabane L, Hopewell S, Lancaster GA, Bond CM, Coleman CL, Campbell MJ, et al. Methods and processes for development of a CONSORT extension for reporting pilot randomized controlled trials. Pilot Feasibility Stud 2016;2:25 [FREE Full text] [doi: 10.1186/s40814-016-0065-z] [Medline: 27965844]
35. Pinnock H, Barwick M, Carpenter CR, Eldridge S, Grandes G, Griffiths CJ, et al. Standards for Reporting Implementation Studies (StaRI) statement. BMJ 2017 Mar 06;356:i6795 [FREE Full text] [doi: 10.1136/bmj.i6795] [Medline: 28264797]
36. Etikan I, Musa SA, Alkassim RS. Comparison of convenience sampling and purposive sampling. Am J Theor Appl Stat 2016;5(1):1. [doi: 10.11648/j.ajtas.20160501.11]
37. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health 2011 Mar;38(2):65-76 [FREE Full text] [doi: 10.1007/s10488-010-0319-7] [Medline: 20957426]
38. Smith BE, Hendrick P, Bateman M, Moffatt F, Rathleff MS, Selfe J, et al. A loaded self-managed exercise programme for patellofemoral pain: a mixed methods feasibility study. BMC Musculoskelet Disord 2019 Mar 27;20(1):129 [FREE Full text] [doi: 10.1186/s12891-019-2516-1] [Medline: 30917806]
39. Weiner BJ, Lewis CC, Stanick C, Powell BJ, Dorsey CN, Clary AS, et al. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci 2017 Aug 29;12(1):108 [FREE Full text] [doi: 10.1186/s13012-017-0635-3] [Medline: 28851459]
40. Ergonomics of human-system interaction: part 11: usability: definitions and concepts. International Organization for Standardization. 2018. URL: https://www.iso.org/standard/63500.html [accessed 2024-10-25]
41. Schnall R, Cho H, Liu J. Health information technology usability evaluation scale (Health-ITUES) for usability assessment of mobile health technology: validation study. JMIR Mhealth Uhealth 2018 Jan 05;6(1):e4 [FREE Full text] [doi: 10.2196/mhealth.8851] [Medline: 29305343]
42. Hedlin D, Dale T, Haraldsen G, Jones J. Developing methods for assessing perceived response burden. Statistics Sweden, Statistics Norway, Office for National Statistics. 2005 Feb. URL: https://ec.europa.eu/eurostat/documents/64157/4374310/10-DEVELOPING-METHODS-FOR-ASSESSING-PERCEIVED-RESPONSE-BURDEN.pdf/1900efc8-1a07-4482-b3c9-be88ee71df3b [accessed 2024-10-22]
43. Goldzweig CL, Orshansky G, Paige NM, Towfigh AA, Haggstrom DA, Miake-Lye I, et al. Electronic patient portals: evidence on health outcomes, satisfaction, efficiency, and attitudes: a systematic review. Ann Intern Med 2013 Nov 19;159(10):677-687. [doi: 10.7326/0003-4819-159-10-201311190-00006] [Medline: 24247673]
44. Antonio MG, Petrovskaya O, Lau F. The state of evidence in patient portals: umbrella review. J Med Internet Res 2020 Nov 11;22(11):e23851 [FREE Full text] [doi: 10.2196/23851] [Medline: 33174851]
45. Grossman LV, Masterson Creber RM, Benda NC, Wright D, Vawdrey DK, Ancker JS. Interventions to increase patient portal use in vulnerable populations: a systematic review. J Am Med Inform Assoc 2019 Aug 01;26(8-9):855-870 [FREE Full text] [doi: 10.1093/jamia/ocz023] [Medline: 30958532]
46. Joffe H, Yardley L. Content and thematic analysis. In: Marks DF, Yardley L, editors. Research Methods for Clinical and Health Psychology. Thousand Oaks, CA: SAGE Publications; 2003.
47. Kirk MA, Kelley C, Yankey N, Birken SA, Abadie B, Damschroder L. A systematic review of the use of the consolidated framework for implementation research. Implement Sci 2016 May 17;11:72 [FREE Full text] [doi: 10.1186/s13012-016-0437-z] [Medline: 27189233]

48. Gordon WJ, Henderson D, DeSharone A, Fisher HN, Judge J, Levine DM, et al. Remote patient monitoring program for hospital discharged COVID-19 patients. Appl Clin Inform 2020 Oct;11(5):792-801 [FREE Full text] [doi: 10.1055/s-0040-1721039] [Medline: 33241547]
49. Bartczak KT, Milkowska-Dymanowska J, Piotrowski WJ, Bialas AJ. The utility of telemedicine in managing patients after COVID-19. Sci Rep 2022 Dec 10;12(1):21392 [FREE Full text] [doi: 10.1038/s41598-022-25348-2] [Medline: 36496499]
50. Marquez-Algaba E, Sanchez M, Baladas M, España C, Dallo HS, Requena M, et al. COVID-19 follow-app. Mobile app-based monitoring of COVID-19 patients after hospital discharge: a single-center, open-label, randomized clinical trial. J Pers Med 2022 Jan 01;12(1):24 [FREE Full text] [doi: 10.3390/jpm12010024] [Medline: 35055339]
51. Yordanov Y, Dechartres A, Lescure X, Apra C, Villie P, Marchand-Arvier J, et al. Covidom, a telesurveillance solution for home monitoring patients with COVID-19. J Med Internet Res 2020 Oct 22;22(10):e20748 [FREE Full text] [doi: 10.2196/20748] [Medline: 33006938]
52. Agarwal P, Mukerji G, Laur C, Chandra S, Pimlott N, Heisey R, et al. Adoption, feasibility and safety of a family medicine-led remote monitoring program for patients with COVID-19: a descriptive study. CMAJ Open 2021 Apr 01;9(2):E324-E330 [FREE Full text] [doi: 10.9778/cmajo.20200174] [Medline: 33795222]
53. Coffey JD, Christopherson LA, Glasgow AE, Pearson KK, Brown JK, Gathje SR, et al. Implementation of a multisite, interdisciplinary remote patient monitoring program for ambulatory management of patients with COVID-19. NPJ Digit Med 2021 Aug 13;4(1):123 [FREE Full text] [doi: 10.1038/s41746-021-00490-9] [Medline: 34389787]
54. Steinberg R, Anderson B, Hu Z, Johnson TM, O'Keefe JB, Plantinga LC, et al. Associations between remote patient monitoring programme responsiveness and clinical outcomes for patients with COVID-19. BMJ Open Qual 2021 Sep;10(3):e001496 [FREE Full text] [doi: 10.1136/bmjoq-2021-001496] [Medline: 34518302]
55. Wurzer D, Spielhagen P, Siegmann A, Gercekcioglu A, Gorgass J, Henze S, et al. Remote monitoring of COVID-19 positive high-risk patients in domestic isolation: a feasibility study. PLoS One 2021 Sep 24;16(9):e0257095 [FREE Full text] [doi: 10.1371/journal.pone.0257095] [Medline: 34559832]
56. Crotty BH, Dong Y, Laud P, Hanson RJ, Gershkowitz B, Penlesky AC, et al. Hospitalization outcomes among patients with COVID-19 undergoing remote monitoring. JAMA Netw Open 2022 Jul 01;5(7):e2221050 [FREE Full text] [doi: 10.1001/jamanetworkopen.2022.21050] [Medline: 35797044]
57. Haddad TC, Coffey JD, Deng Y, Glasgow AE, Christopherson LA, Sangaralingham LR, et al. Impact of a high-risk, ambulatory COVID-19 remote patient monitoring program on utilization, cost, and mortality. Mayo Clin Proc 2022 Dec;97(12):2215-2225 [FREE Full text] [doi: 10.1016/j.mayocp.2022.08.015] [Medline: 36464463]
58. Laur C, Agarwal P, Thai K, Kishimoto V, Kelly S, Liang K, et al. Implementation and evaluation of COVIDCare@Home, a family medicine-led remote monitoring program for patients with COVID-19: multimethod cross-sectional study. JMIR Hum Factors 2022 Jun 28;9(2):e35091 [FREE Full text] [doi: 10.2196/35091] [Medline: 35499974]
59. Vindrola-Padros C, Singh KE, Sidhu MS, Georghiou T, Sherlaw-Johnson C, Tomini SM, et al. Remote home monitoring (virtual wards) for confirmed or suspected COVID-19 patients: a rapid systematic review. EClinicalMedicine 2021 Jul;37:100965 [FREE Full text] [doi: 10.1016/j.eclinm.2021.100965] [Medline: 34179736]
60. Lara B, Kottler J, Olsen A, Best A, Conkright J, Larimer K. Home monitoring programs for patients testing positive for SARS-CoV-2: an integrative literature review. Appl Clin Inform 2022 Jan;13(1):203-217 [FREE Full text] [doi: 10.1055/s-0042-1742370] [Medline: 35172373]
61. Senteio C, Murdock PJ. The efficacy of health information technology in supporting health equity for black and hispanic patients with chronic diseases: systematic review. J Med Internet Res 2022 Apr 04;24(4):e22124 [FREE Full text] [doi: 10.2196/22124] [Medline: 35377331]
62. Pérez-Stable EJ, Jean-Francois B, Aklin CF. Leveraging advances in technology to promote health equity. Med Care 2019 Jun;57 Suppl 6 Suppl 2:S101-S103. [doi: 10.1097/MLR.0000000000001112] [Medline: 31095045]
63. Konnoth C. Health information equity. Univ Penn Law Rev 2017;165:1317-1376.
64. Craig S, McPeak KE, Madu C, Dalembert G. Health information technology and equity: applying history's lessons to tomorrow's innovations. Curr Probl Pediatr Adolesc Health Care 2022 Jan;52(1):101110. [doi: 10.1016/j.cppeds.2021.101110] [Medline: 34974991]
65. Krebs P, Duncan DT. Health app use among US mobile phone owners: a national survey. JMIR Mhealth Uhealth 2015 Nov 04;3(4):e101 [FREE Full text] [doi: 10.2196/mhealth.4924] [Medline: 26537656]
66. Gil‐Lacruz M, Gil‐Lacruz AI. Health perception and health care access: sex differences in behaviors and attitudes. Am J Econ Sociol 2010 Mar 22;69(2):783-801. [doi: 10.1111/j.1536-7150.2010.00723.x]
67. Maurer M, Mangrum R, Hilliard-Boone T, Amolegbe A, Carman KL, Forsythe L, et al. Understanding the influence and impact of stakeholder engagement in patient-centered outcomes research: a qualitative study. J Gen Intern Med 2022 Apr;37(Suppl 1):6-13 [FREE Full text] [doi: 10.1007/s11606-021-07104-w] [Medline: 35349017]
68. Tao D, Shao F, Wang H, Yan M, Qu X. Integrating usability and social cognitive theories with the technology acceptance model to understand young users' acceptance of a health information portal. Health Informatics J 2020 Jun;26(2):1347-1362 [FREE Full text] [doi: 10.1177/1460458219879337] [Medline: 31603378]
69. Sebetci Ö. Enhancing end-user satisfaction through technology compatibility: an assessment on health information system. Health Policy Technol 2018 Sep;7(3):265-274. [doi: 10.1016/j.hlpt.2018.06.001]

70. Bhana B, Flowerday SV. Usability of the login authentication process: passphrases and passwords. Inf Comput Secur 2021 Nov 30;30(2):280-305. [doi: 10.1108/ics-07-2021-0093]
71. Foster MV, Sethares KA. Facilitators and barriers to the adoption of telehealth in older adults: an integrative review. Comput Inform Nurs 2014 Nov;32(11):523-33; quiz 534. [doi: 10.1097/CIN.0000000000000105] [Medline: 25251862]
72. Annis T, Pleasants S, Hultman G, Lindemann E, Thompson JA, Billecke S, et al. Rapid implementation of a COVID-19 remote patient monitoring program. J Am Med Inform Assoc 2020 Aug 01;27(8):1326-1330 [FREE Full text] [doi: 10.1093/jamia/ocaa097] [Medline: 32392280]
73. Sharma U, Clarke M. Nurses' and community support workers' experience of telehealth: a longitudinal case study. BMC Health Serv Res 2014 Apr 10;14(1):164 [FREE Full text] [doi: 10.1186/1472-6963-14-164] [Medline: 24721599]
74. Fredericksen RJ, Short D, Fitzsimmons E, McReynolds J, Karras S, Lober W, et al. PROgress implementation toolkit: integrating patient-reported outcomes (PROs) assessments into routine HIV care. ViiV Healthcare. 2020 Nov. URL: https://progresshivcare.org/assets/PROgress%20Implementation%20Toolkit-FINAL-Nov2020.pdf [accessed 2024-10-22]
75. Firang D. The impact of COVID-19 pandemic on international students in Canada. Int Soc Work 2020 Jul 14;63(6):820-824. [doi: 10.1177/0020872820940030]
76. Edmonds J, Flahault A. Refugees in Canada during the first wave of the COVID-19 pandemic. Int J Environ Res Public Health 2021 Jan 22;18(3):947 [FREE Full text] [doi: 10.3390/ijerph18030947] [Medline: 33499071]

Abbreviations

CFIR: Consolidated Framework for Implementation Research
CONSORT: Consolidated Standards of Reporting Trials
MUHC: McGill University Health Centre
PI: principal investigator
PROM: patient-reported outcome measure
PSE: patient and stakeholder engagement
StaRI: Standards for Reporting Implementation Studies

Edited by T Leung; submitted 16.04.23; peer-reviewed by M Gasmi , T Aslanidis, B Wang, I Raikov; comments to author 30.04.24; revised version received 16.05.24; accepted 07.10.24; published 04.12.24.

Please cite as:
Ma Y, Lessard D, Vicente S, Engler K, Rodriguez Cruz A, Laymouna M, Opal-COVID Patient Expert Committee, Hijal T, Del Balso L, Thériault G, Paisible N, Kronfli N, Pomey MP, Peiris H, Barkati S, Brouillette MJ, Klein M, Cox J, de Pokomandy A, Asselah J, Bartlett SJ, Lebouché B
Implementing a Patient Portal for the Remote Follow-Up of Self-Isolating Patients With COVID-19 Infection Through Patient and Stakeholder Engagement (the Opal-COVID Study): Mixed Methods Pilot Study
J Particip Med 2024;16:e48194
URL: https://jopm.jmir.org/2024/1/e48194
doi:10.2196/48194
PMID:

Original Paper

Developing a Digital Tool to Calculate Protein Quality in Plant-Based Meals of Older Adults: User Engagement Design Approach With End Users

Lotte van Dam[1*], MSc; Sine Højlund Christensen[2*], MSc; Inge Tetens[2], Prof Dr; William Riley III[3], PhD; Mariëlle Timmer[3], PhD; George Suciu Jr[4], PhD; Iuliana Marin[5], PhD; Lisette De Groot[1], Prof Dr; Pol Grootswagers[1], PhD

[1]Division of Human Nutrition and Health, Wageningen University, Wageningen, Netherlands
[2]Department of Nutrition, Exercise and Sports, University of Copenhagen, Copenhagen, Denmark
[3]Wageningen Food and Biobased Research, Wageningen University & Research, Wageningen, Netherlands
[4]Research & Development Department, BEIA, Bucharest, Romania
[5]Faculty of Engineering in Foreign Languages, University Politehnica of Bucharest, Bucharest, Romania
[*]these authors contributed equally

Corresponding Author:
Pol Grootswagers, PhD
Division of Human Nutrition and Health
Wageningen University
Stippeneng 4
Wageningen, 6708 WE
Netherlands
Phone: 31 644032097
Email: pol.grootswagers@wur.nl

Abstract

Background: The global shift toward plant-based diets has been increasing, with more people making the transition for various reasons. In vulnerable subgroups such as older adults, the transition to plant-based diets deserves attention due to the potentially detrimental consequences of lower protein quantity and quality.

Objective: We aimed to develop a digital tool that ensures adequate protein quality in plant-based meals for older adults experiencing low protein intake through an interdisciplinary collaboration and user engagement with potential end users.

Methods: Three focus group interviews of Dutch and Danish dietitians and older adults as potential end users were conducted to identify their needs, preferences, and deal-breakers. Focus group interviews were based on a user-task-environment analysis, the Walt Disney method, the brainwriting method, and a cognitive walkthrough. The interview transcripts were analyzed with a thematic analysis. The front end and backend development of a potential tool took place in parallel and was well-synced to the focus group interviews.

Results: Both dietitians and older adults from Dutch and Danish sites expressed high interest in a tool that provides feedback and background information on protein quality, sustainability, and nutrients or micronutrients. The user-task-environment analysis delivered input among others that dietitians and older adults are good potential users, the tool should be functional as an app as well as a website and the tool should provide preprogrammed meals or recipes. The Walt Disney method delivered usable and realistic solutions to the 4 challenges presented. Thirty-two percent of the solutions on all themes presented with the brainwriting method appeared to be highly feasible and relevant, having the potential to be implemented in a tool. The cognitive walkthrough identified certain screens as unclear, necessitating revisions for improved understandability, for example, the need for explanation in selecting food item filters is shown in screenshot 2, with an overall usability score of 59%.

Conclusions: Our user engagement design approach resulted in a prototype that ensured end users' wishes and needs, with a finetuned output tested in focus groups. We conclude that our user engagement design approach was a suitable and meaningful stepwise approach to ensure the relevance of the tool and identify potential barriers. The focus group results indicate that dietitians have a clear understanding and need for a tool to aid in meal planning for enhanced protein quality, highlighting its absence in their current resources despite increasing demands arising from the protein transition. Conversely, for older adults, the introduction of a digital tool appears less appropriate; instead, there is a necessity for foundational education on protein quality before such a tool can be effectively used. Future studies are needed to further implement the prototype into practice.

(J Particip Med 2024;16:e48323) doi:10.2196/48323

KEYWORDS

digital tool; protein quality; user engagement design approach; plant-based diets; healthy ageing; mobile phone

Introduction

Societal trends and governmental pressures steer populations toward more plant-based diets due to their environmental benefits and positive health outcomes, such as reduced risk of heart disease and certain cancers [1-4]. These diets are gaining popularity due to growing awareness of their benefits, alongside policy initiatives aimed at promoting sustainable eating habits. However, the transition to plant-based diets must consider the specific nutritional needs of different population groups, because plant-based food items have a lower essential amino acids (EAA) content compared to animal-based foods [5-7]. A successful protein transition should also benefit the growing population of older adults (ie, 65 years and above). Currently, 106 million older adults in Europe comprise 21% of the total population, a proportion expected to rise to 30%, or 150 million, over the next 3 decades [8]. Older adults who consume traditional diets but who have less appetite than earlier are already at risk of insufficient protein, vitamin D, and vitamin B12, nutrients, all of which are typically derived from animal sources [9-11]. As vitamin D can also be synthesized through sun exposure, limited time outdoors can exacerbate deficiencies, especially in older adults with restricted mobility or those living in northern climates. Thus, transitioning to plant-based diets in this age group must be carried out with care to avoid nutritional deficiencies that can lead to declines in muscle mass, bone health, cognitive functioning, and loss of independence [12].

Health authorities in the Netherlands recommend a 20% to 30% increase in protein intake for vegetarian and vegan diets to compensate for lower protein quality [13]. However, this strategy seems unsuitable for some older adults due to prevalent decreases in appetite [14,15] and the lower protein densities and higher fiber content of plant-based foods [16]. Moreover, increasing protein consumption to compensate for lower quality is counterintuitive considering the environmental goals of the protein transition. A more feasible strategy is careful meal planning, in which complementary protein sources are combined, to optimize the EAA composition. Yet, consumers often lack access to detailed information on amino acid content, digestibility, and recommendations, making meal planning complex.

While identifying complementary plant-based protein sources is challenging for consumers, digital tools can streamline this process. Using databases that contain information on EAA content, algorithms can be set up to identify optimal food combinations to meet nutrient requirements. Such tools can aid those seeking to eat more sustainably and concurrently, prevent nutritional deficiencies. Existing nutritional assessment tools such as Optimeal [17] and Fortifull [18] provide general guidance but do not incorporate amino acid data crucial for evaluating protein quality.

To develop a useful and effective tool, 7 aspects should be addressed. First, the tool should rely on scientifically sound databases that have complete and accurate data on the amino acid composition and the digestibility of protein-containing foods. Second, the time window in which multiple foods can complement each other's amino acid profiles needs to be defined. Third, personalized amino acid requirements per such a window should be developed [7]. Fourth, the tool must be trustworthy, ensuring that users can rely on its recommendations and data accuracy. Fifth, the tool should be functional and user-friendly, providing an intuitive and seamless experience. Sixth, it should be visually appealing and engaging to encourage regular use. Seventh, the development process should be user-centered, incorporating feedback and preferences from potential users to ensure it meets their needs and expectations.

In collaboration with nutrition scientists and food informatics experts, we aim to address these aspects of a digital tool. This paper describes the user engagement design approach with older adults and dietitians in Denmark and the Netherlands, investigating the wishes and needs for a tool ensuring adequate protein quality in plant-based meals for older adults experiencing low protein intake.

Methods

Methodological Approach

Overview

Given the exploratory nature of this study's objective, a user engagement approach was chosen. Focus group interviews were applied to facilitate group interaction and enable the development of ideas through mutual elaboration [19]. This study is reported per the standards for reporting qualitative research [20].

Study Setting

This study was conducted in 2022 in parallel at the University of Wageningen and the University of Copenhagen. This study population consisted of older adults (>60 y of age) and dietitians who work with older people. The participant sampling was a purposive sampling.

Recruitment

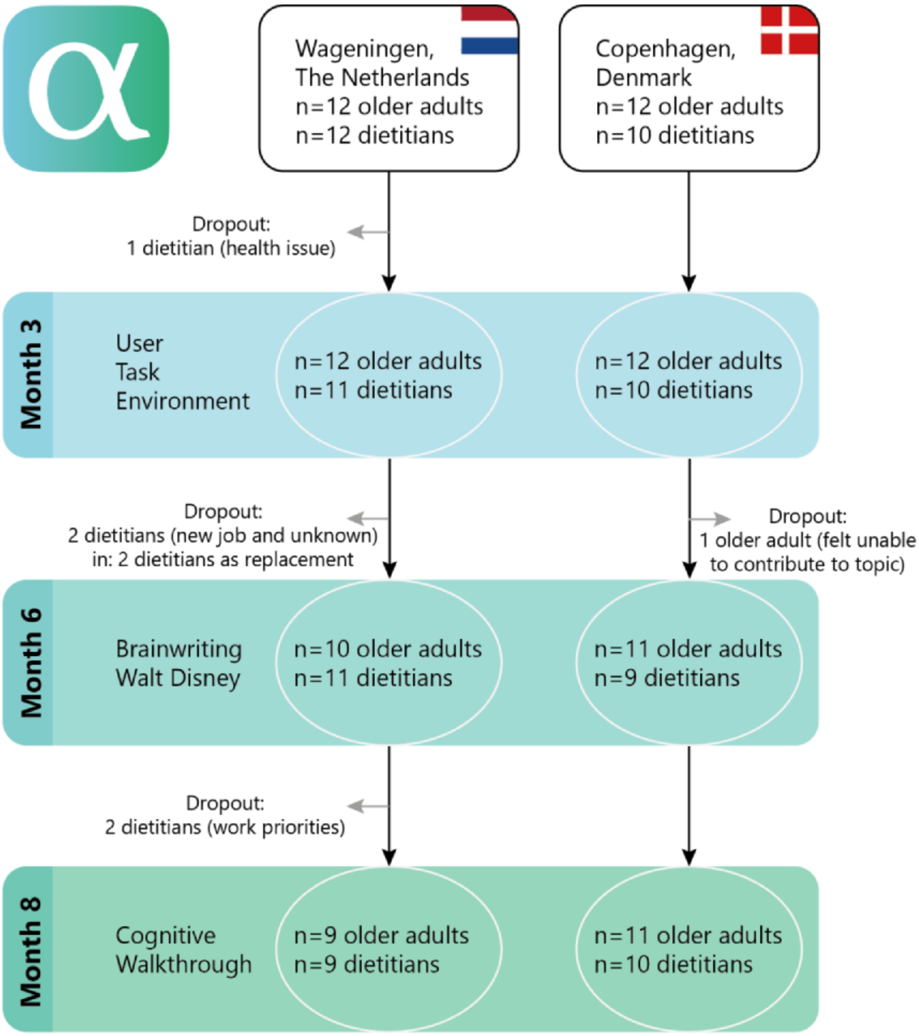
The participants were recruited in both countries by reaching out through existing networks, social media, and mailing lists. In both countries, the dietitians were recruited throughout the whole country from multiple hospitals, private clinics, and municipalities. Older adults in both countries were recruited through established user panels and volunteer databases.

Participants were eligible if they fulfilled the following inclusion criteria: older adults: ≥60 years of age, interested in plant-based diets or protein quality, familiar with smartphones or tablets, providing informed consent; and dietitians: working directly or indirectly and have experience with clients aged ≥60 years of age, providing informed consent.

Sampling Strategy

The goal was to reach a total of at least 20 older adults and 20 dietitians. In total, 22 dietitians and 24 older adults participated in this study (Figure 1). Focus group meetings were held with 4 to 7 participants per group. The participants were invited to attend all 3 focus group interviews. Except for 2 married couples in the Netherlands and 1 in Denmark, none of the participants knew each other beforehand. The composition of the 3 focus groups' meetings differed throughout the 3 sessions due to the participants' availability.

Figure 1. Flowchart of participants. In the Netherlands, two dietitians were not present due to work priorities during the cognitive walkthrough, two older adults were not present during the second focus group, one due to vacation and one due to surgery. During the third and final focus group, three older adults were not present due to other priorities, and one due to health issues. In Denmark, one dietitian missed the second focus group due to illness.



Ethical Considerations

This study was approved by the local university Research Ethics Committees in both countries (Denmark: Ethical Committee of SCIENCE and SUND, University of Copenhagen: 504-0325/22-5000, Netherlands: Social Sciences Ethical Committee: 2022-50-Grootswagers).

Description of the Methods

Overview

Focus group interviews were held during three phases: (1) understanding (need assessment), (2) conceptualizing (development and refinement to meet specific wishes), and (3) testing, with all participants going through all 3 phases. The focus group structure was standardized across the two countries by using the same script, questions, and agenda, all developed in English. The sessions were facilitated by trained researchers from each country, serving as moderators. These moderators tried to allow every participant to share their opinions in discussions, asked for further elaborations, and tried to create an open and safe space to speak their minds. The focus groups' sessions with the dietitians had a duration of 2 hours per session, while the focus groups with older adults had a duration of 3 hours per session. These durations were chosen to account for an estimated higher need for explanations and more elaborate answers with older adults.

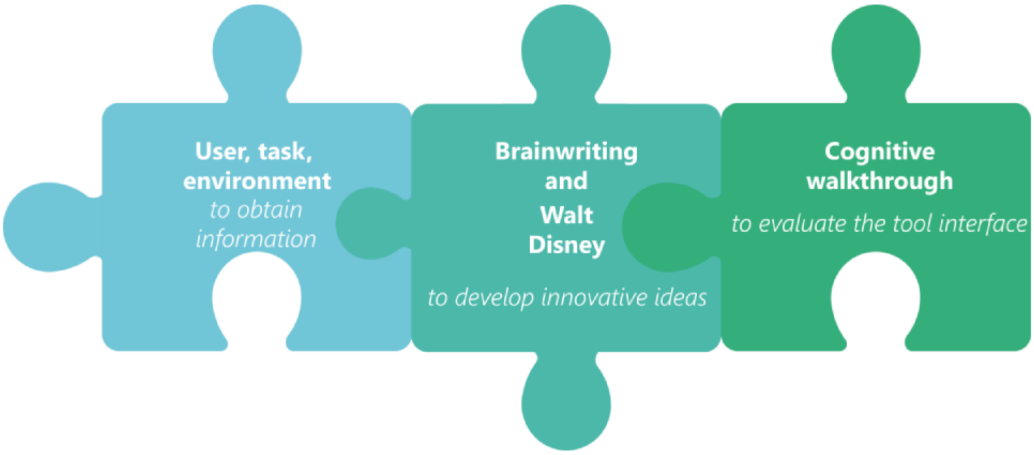
All focus group interviews were held in June, September, and November 2022, all scheduled in the afternoon. The 3 phases for the focus group interviews were constructed in Figure 2.

A user-task-environment analysis [16] was conducted during the first interview session to understand the needs of end users. In this session, data were gathered on the user (user), the relevant functionalities of the tool (task), and the intended usage environment (environment). Questions about these 3 topics were combined into a script (Multimedia Appendix 1). During the focus groups, the script was used as a guideline, while participants were free to talk, and questions were asked to elaborate further on what was said. Sound recordings were made of all focus groups in duplicate, using either mobile phones or an audio recorder (Philips Voice Tracker DVT6110). These sound recordings were used for further analysis.

In the conceptualizing phase, the second interview session used 7 specific questions, applying the Walt Disney (WD) method [21] and the brainwriting method to develop innovative ideas [22]. In the WD method, 4 specific questions or problems were presented, and the participants were divided into 3 different roles to generate ideas and state barriers: dreamers, realists, and critics as described by Dilts et al [23] and Dilts [21]. Sound recordings during the WD method were made for further analysis. In the brainwriting method, which is a validated method for high-quality idea generation [22], 3 specific questions or problems were presented to the participants. Every participant wrote down 3 suggestions for solving the question or problem (3-6 min). The forms were then passed on to the next participant who refined or amended the suggested ideas until everyone had their original form back. These forms were used for further analysis. For both the WD method and the brainwriting method the minimum required outcome was the provision of at least one idea or suggestion for each question presented.

In the testing phase, the third interview session was conducted as a cognitive walkthrough (CW). Here, the participants were shown 8 static screenshots of the future tool and asked for feedback [24]. The screenshots were shown without additional explanation, except for necessary translations into the native language. The three specific questions that were asked about the screenshots were the following: (1) Do you know how to navigate on this screen? (2) Do you understand everything on this page? (3) Do you find the function relevant? Participants answered “yes” or “no,” and in the case of a “no,” a brief discussion was held about the answers. After every screenshot, a short discussion was held about their written answers. The written forms, including all the answers and the notes made during the discussions afterward, were used for further analysis.

Figure 2. The goals of each of the three phases in the development of a digital tool that can ensure sufficient protein for older adults.



Development of the Databases and Algorithms

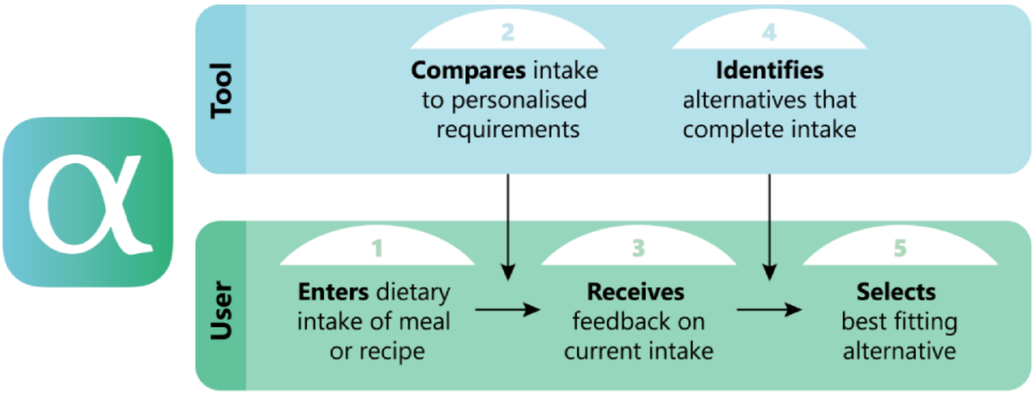
The database used for the first development steps of the tool was based on the NEVO (Dutch nutritional database, Nederlands Voedingsstoffenbestand)–table, which is the Dutch national food database that contains unique codes for ~2500 food items and information on nutrient composition. In a separate project by the Division of Human Nutrition of Wageningen University, a database was built that linked digestibility factors and amino acid contents to NEVO codes. The full description of the methodology can be found elsewhere [25]. In short, digestibility factors were added by averaging known protein digestibility corrected amino acid score values of foods within a food group to a joint correction factor, weighted by the relative frequency in which food items within a category are consumed. Amino acid contents were added to all foods containing ≥1 EN% protein. Amino acid data were used from the national food databases of Denmark, the United States, the United Kingdom, and Japan, in that order of priority based on data availability and cultural similarity. If products did not have a similar direct equivalent, 4 different solutions were considered: (1) the amino acid data of the source protein was used if the proteins in the food item mainly originated from 1 source, (2) amino acid data of highly comparable products were used, or (3) a recipe was built based upon the relative content of different protein sources with known amino acid contents. In the case of database differences in total protein content, (4) amino acid data were scaled to the protein content reported in NEVO.

For step 2 in the workflow (Figure 3), personalized requirements for EAAs needed to be developed. The detailed overview of the development and validation of these requirements is beyond the scope of this paper. In short, for the 3 main meals of a day threshold values for all EAAs were established, from the perspective of optimal muscle protein synthesis in older adults. The extent to which the current meal contributed to the threshold values for the EAAs was expressed as a Meal Protein Quality Score (MPQS) and fed back to the user (step 3). MPQS ranges from 0 to 100, where 0 means that 1 EAA is completely absent in the meal and 100 means that all EAAs are consumed above the threshold values. In step 4, alternatives, such as a change or an addition to the meal, are identified.

We considered 3 different algorithms designed by experts in nutrition and food informatics:

- Gram-by-gram alternative: for a specific protein-containing item in the meal, a simulation is performed in which the exact consumed amount of this food item (in grams) is replaced by a similar food item, but all other food items in the meal are kept fixed (ie, no alternatives are proposed for them). Food item similarity is based on taste, food category, and empirical evidence for frequent coconsumption with the other meal items. For every potential replacement with the alternative, a new MPQS is calculated for the meal (keeping the other food items fixed), and the alternatives that lead to the largest improvement in MPQS are presented as optional alternatives.
- Missing-piece alternative: the difference in the required amino acid profile and consumed amino acid profile is used to find any NEVO item that will increase the MPQS to 100 once added to the meal. The alternatives are sorted in ascending order by the amount of grams that would need to be consumed of the item.
- Proportion-adjustment: by linear programming, the influence on MPQS of adjusting the proportions of food items within the meal is determined, and the best ratio is presented as an alternative. The constraints are that the total weight of the meal cannot be adjusted and that the adjusted intake of the food items stays within 50% to 200% of the current intake.

Figure 3. Flow of the proposed solution.



Data Analysis

For the analysis of the data from the first focus group (user-task-environment analysis) and the analysis of the data from the WD method in the second focus group, sound recordings were transcribed manually, in their native language. A thematic analysis was used [19]. An English coding book was made based on the script. This was used for coding the transcription in both sites (for the full coding book, see Multimedia Appendix 2). Examples of codes used were crucial functions, interesting thoughts, doubts, and deal-breakers. Additional codes that were made during analysis were added to the coding book, so the codes were consistently used in both sites. Coding of the transcriptions was carried out using the program NVivo (QSR International, release 1.6.1 {1137} and release 1.7 {1533} in both sites, using English codes. A cross-check was performed by the two researchers performing the coding, with a short part (~10%) of both transcriptions translated into English to keep consistency. Where differences occurred, the codes were discussed until full agreement was reached. After coding, selected quotes were sorted, translated into English, and then combined from both sites. Duplicates were removed, with a note behind it, showing that multiple participants agreed upon it (both within and between sites with a separate notation). The combined results were presented to the tool development team.

For the analysis of the brainwriting method of the second focus group, results were translated, sorted, combined, and scored to develop a selection list and were scored based on 3 factors: developmental feasibility, scientific feasibility, and scientific relevance, including nutrition, health, and sustainability. The 3 factors were scored individually by 2 professionals recruited within the project team with expertise in the respective areas. One could score a 1 when not feasible or not relevant, and a 3 if easily feasible or very relevant. The end score was determined by the lowest score. If needed, comments were added to the scoring list. Based on this scoring list, important changes to the tool were identified and presented to the tool development team.

The results of the third focus group (CW) of the participants' understanding of the screenshots were quantified. The CW consisted of 3 questions for each of the screenshots, related to (1) navigating, (2) understanding, and (3) relevance. The frequency of "yes" ("yes I do know how to navigate/understand/see the relevance") and "no" was counted and percentages were calculated. When both a "yes" and "no" were encircled, this was scored as a half yes or no, and when nothing was encircled, this was considered as missing data. Suggestions and further explanations from the participants were all sorted, translated, and combined from both sites. The frequency of how often the same suggestions were given by the participants was counted and these suggestions were placed above, in a ranking order. This ranking order was presented to the tool development team.

Results

Overview

In this study, we recruited 22 dietitians and 24 older adults.

Baseline Characteristics

Of the total of 22 dieticians, all were female in both countries, whereas with the older adults (n=24), a total of 50% (n=6) were male in the Netherlands and 25% (n=3) were male in Denmark (Table 1). The age range of the dietitians was 26-60 years in Denmark and 26-64 years in the Netherlands, and the age range of the older adults was 68-79 and 62-89 years, respectively, in Denmark and the Netherlands. With regards to the workplace of dietitians, in both countries, various parts of the country were represented (data not shown). In both countries, most of the older adults were used to cooking for themselves. All older adults participating in the focus groups were interested in eating plant-based diets.

Table 1. Characteristics of the focus group participants.

	Netherlands	Denmark
Dietitians[a]		
Sex (male/female), n/n	0/12	0/10
Age (y), median (range)	32 (26-64)	37 (26-60)
Working place (hospital/municipality/private), n/n/n	2/4/6	6/4/0
Work experience (years), mean (SD)	17.8 (15.6)	12.9 (14.4)
Older adults[b]		
Sex (male/female), n/n	6/6	3/9
Age (y), median (range)	67 (62-89)	75 (68-79)
Education (high/intermediate/low), n/n/n	5/7/0	11/1/0
Living situation (cohabiting/alone), n/n	10/2	4/8
Cooking habits (never/sometimes/always), n/n/n	2/3/7	0/0/12
Dietary habits (omnivore/flexitarian/vegetarian), n/n/n	5/6/1	12/0/0

[a] Netherlands: n=12 and Denmark: n=10.

[b] Netherlands: n=12 and Denmark: n=12.

Understanding

Identifying User Needs With the User-Task-Environment Analysis

According to all participants, the tool might be interesting for diverse target populations. Examples were young families, pregnant women, patients undergoing surgery, athletes, older adults, health care practitioners, and people interested in eating vegan or vegetarian food.

Visual Aspects and Format

Big fonts and good contrast were important for all participants. Pictures were highly valued in both target groups, for example, images of products or alternatives and the use of icons that are already familiar.

Dietitians and older adults wanted either a smartphone app or a website, with a preference for a website for dietitians, and a preference for a smartphone app for older adults. For both target groups at both sites, security was important or necessary. A possibility should be present to use the tool without the login step.

Nutritional Input and Feedback

Dietitians wanted to fill in the nutritional intake during consultations, together with the client. Both target groups wanted the possibility to fill in personal information (such as age, sex, protein requirement, allergies, and food preferences). With entering the dietary intake, dietitians wanted to be able to enter the basic ingredients. When their clients have to enter the data, the possibility to work with pictures of food would be valued, which was in agreement with the preferences of the older adults. For both target groups, it was important that the dietary assessment be easy and quick. The tool should be able to remember input history, should be flexible in the amount of the product (user can choose between spoon size, portion size, or amount in grams), and should be short (just for 1 meal).

Both target groups wanted to receive feedback per meal moment and an overall conclusion of the intake over the whole day. Both target groups wanted feedback on protein quality (amino acids), micro- and macronutrients, and sustainability. Visually, it should be immediately clear if the intake does not meet requirements. Dietitians wanted the feedback to be clear and rather harsh, while the older adults wanted to receive feedback in a positive manner.

Dietitians wanted to obtain between 3 and 5 alternatives presented by the tool, while older adults prefer to receive between 3 and 10 alternatives. Both target groups wanted to have the alternatives shown in a ranking with the best alternative shown at the top, including information on the reasoning behind the alternatives, and the amounts of the alternative products that should be consumed. Alternatives should be presented based on personal preference, culture, season, location of origin, and price.

In general, the tool should provide background information. “Motivation often comes from knowledge” according to one of the dietitians. Therefore, both target groups wanted short texts and short videos. Background information should contain information on the general idea of the application, amino acids, muscle mass, recipes, the difference between plant-based and animal-based protein, and sustainability.

Crucial Functions, Interesting Thoughts, Doubts, and Deal-Breakers

According to all participants, the tool should trigger the user’s interest and should function easily and quickly, with the fewer clicks the better. Both target groups preferred integrations or API (application program interface)–connections with other dietary intake tools. Feedback should be savable to allow for retrieval at a later stage and for the dietitians exportable in PDF format for communicative and administrative purposes. The tool should be updated regularly to include the newest food item data. Dietitians wanted to be able to change the protein requirements for their clients themselves.

Other additional thoughts from both target groups at both sites were that the tool provides preprogrammed meals or recipes. For older adults, it might be motivational if there was a community of users with whom experiences and recipes can be shared. Both target groups request the possibility to give feedback to the software developers.

Dietitians had some doubts about the tool, especially about the number of plant-based products necessary to consume to reach amino acid requirements in case of decreased appetite. Other doubts of dietitians at both sites were that clients lack motivation due to a lack of knowledge and that clients are digitally incapable of using such a tool. Older adults had some doubts about the tool, especially about the time and energy needed to fill in nutritional information, and about the suitability of the tool for older users.

For both target groups, deal-breakers were the lack of speed of the tool, too much time investment needed, unsuitable alternatives presented, and complexity of the tool. A deal-breaker specifically for dietitians was missing products in the database. A deal-breaker for older adults was the price of the tool.

Environment

The environment in which the tool might be used according to the older adults at both sites is especially at home, and some also wanted to bring the tool to the supermarket. Dietitians wanted to use the tool together with their client during consultations, being able to immediately show the feedback to the client.

At this step, 1 target group had to be identified to tailor the development of the back end and the front end. The consortium agreed to focus on dietitians for the first development. This was due to the complexity of the topic. Additionally, it was seen as an advantage to have experts in nutrition as the first target group in the development of the tool, as that will likely result in receiving more valuable feedback on how to improve the tool and reduce the risk of misinterpreted information.

Conceptualizing

Developing Solutions With the WD Method

The themes discussed in the WD method were the following: (1) What to do with consumed food items that are not present in official nutritional databases in the Netherlands and Denmark (NEVO and Frida)? (2) How can we explain the relevance of receiving feedback and further background information? (3) How do we keep data entry exciting? (4) Which results are essential to export? (dietitians only).

According to both target groups at both sites, the best solution when food items are not present in the databases was to fill in a tick-box indicating that this is feedback for the software development team. In this way, the missing product information is fed back and can be added with an update. Another solution was to have other comparable products presented immediately. Other solutions were that the users search for a comparable product or that the user would upload a picture of the food item so the tool could come up with comparable products.

Several solutions were brought up by dietitians on how to explain the relevance of the tool, such as information icons to click on, knowledge clips, the possibility to click through for further information, newsletters, and a community of users involved in development. The older adults suggested knowledge clips, informative cartoons, famous ambassadors, and providing information in speech.

Dietitians provided solutions for how to keep data entry exciting, such as suggesting previously consumed products and meals, and the ability to ignore small typographical errors. Older adults looked at the data entry from a different perspective and came up with solutions, such as data entry in the form of a game, using sounds, and traffic lights. Suggesting previously consumed products and meals was also stated by the older adults in both countries.

Lastly, for the fourth question, dietitians at both sites reported that it is essential for the results to include the original intake of all amino acids relative to the requirements. They also wanted the possibility to choose other nutrients (macro and micro) on which they could receive feedback.

Developing Solutions With Brainwriting Method

Categories discussed with the brainwriting method were: How should feedback look like for (1) protein quality, (2) other nutrients, and (3) sustainability? (4) Which criteria would you desire to filter alternatives? (5) What do you want to obtain from the tool?

Suggestions were scored on 3 criteria: development feasibility, scientific feasibility, and scientific relevance from 1 to 3, where 3 indicates high feasibility or relevance (Multimedia Appendix 3). The total score was based on the lowest score.

For all categories, suggestions with high feasibility and relevance were provided. Of all the suggestions obtained 23 of 72 suggestions had a total score of 3, which is 32% of the total amount (52% scored a 2 [37/72], and 17% scored a 1 [12/72]).

Of the feasible and relevant suggestions, 39% (9/23) were about protein quality. Of the suggestions that were scored as 1 a total of 92% (11/12) were due to lack of scientific feasibility. It was judged that the data was not available at the moment (October 2022). This might change in the future. Find a detailed distribution of suggestions in Multimedia Appendix 3.

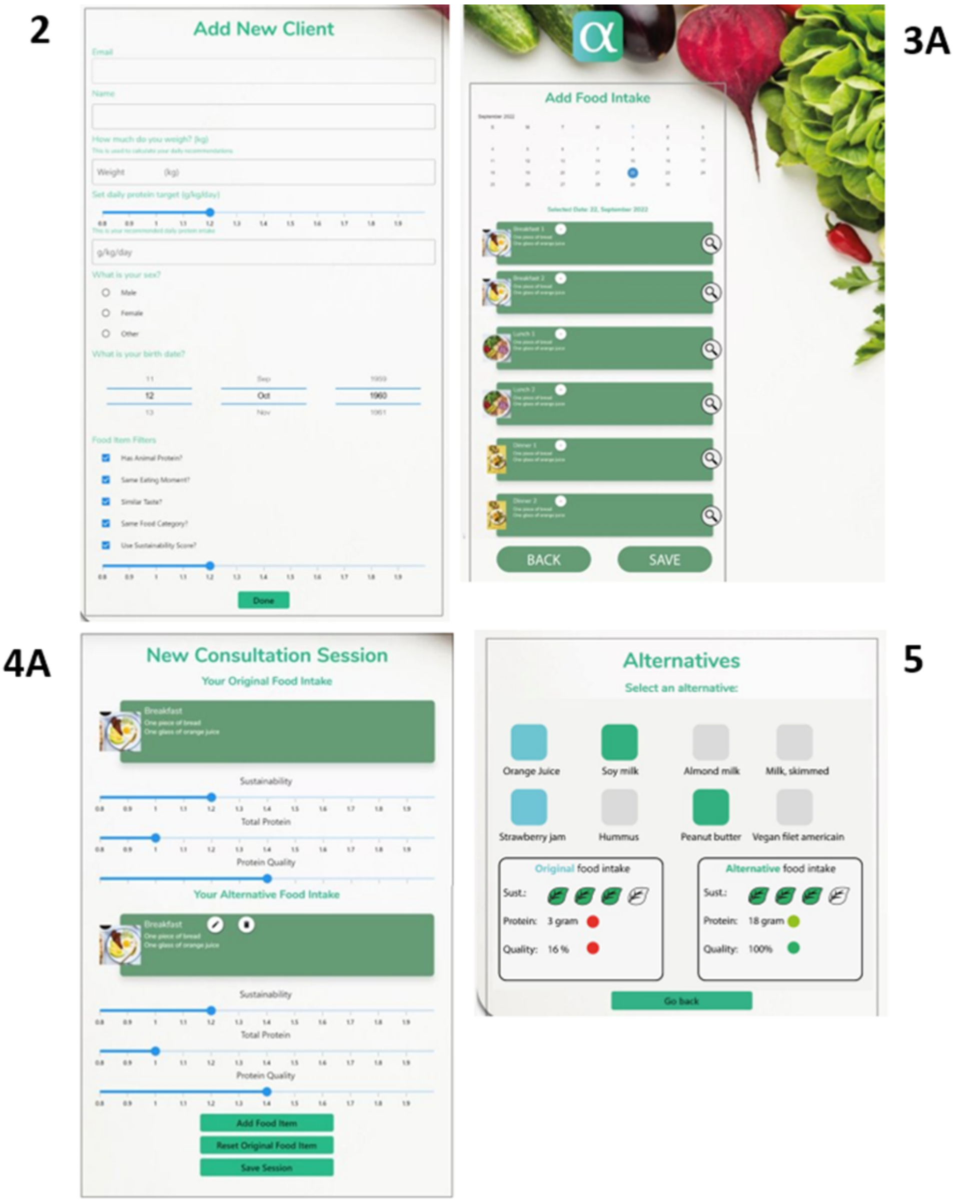
Among the highly feasible and relevant suggestions were the following: protein quality: Radar chart of EAAs with circles indicating 100%, and then details can be seen when the "cursor" is placed upon it; other nutrients: Use of household measures; and sustainability: a suggestion for more information with a click on an I-icon. Regarding filters allergens, lactose, and animal proteins were among the suggestions that are feasible and relevant among all the assessment categories. Essentials of the tool sources to optimize protein quality with the highest content first, was a suggestion, which was found feasible for all 3 categories. The suggestions, which had a total score of 3 were used as direction for further development of the tool.

Testing

Assessing Usability Using CW

In the CW screenshots were assessed by the user panel. Based on the average of the 3 questions asked per screenshot, the 4 most challenging screenshots were the same among the two target groups. The most challenging screenshots were screen 2: add new client, 3A: add food intake, 4A: new consultation session, and 5: alternatives, compare Figure 4 and Multimedia Appendix 4.

Figure 4. Screenshot 2: add new client, 3A: add food intake, 4A: new consultation session, and 5: alternatives; all used in the cognitive walkthrough. Screenshot 2 shows how to add a new client with client details; screenshot 3A shows how to add a new product separated by meal moments; screenshot 4A shows the feedback that is given on the original and alternative food intake on sustainability, protein intake, and protein quality; screenshot 5 is the screenshot where alternatives (green) can be chosen for the original products (blue).



Screenshot 2: Add New Client

Screenshot 2 has an overall usability score of 59% among the dietitians, driven by understanding (4/19, 21%), relevance (14/19, 74%), and navigation (15.5/19, 82%; Figure 3). The understanding was lacking at both sites due to a need for an explanation of the specific food item filters, and no meaning of the unit of the sustainability bar.

Screenshot 2 had a usability score of 66% among older adults (Figure 3). The result showed that understanding had the lowest percentage (3.5/20, 19%), whereas relevance (14.5/18, 83%) and navigation scored higher (19/20, 95%). Both user panels suggested moving the filters to a later screen. As for dietitians, the challenge with understanding was due to food item filters (what do the different filters mean, and how many can a user choose?).

Screenshot 3A: Add Food Intake

The dietitians found it difficult to use screenshot 3A (46%), where the issues were mainly related to understanding and navigation (understanding: 1.5/19, 8%; navigation: 9/19, 47%; relevance: 15/19, 83%; Figure 3). The biggest challenges were related to the confusion about the calendar (why and the visual aspect of it) and the eating moments (how, where, and what to fill in). In addition, the meaning of the magnifying glass was not clear.

For the older adults, the screenshot that scored the lowest was 3A (60%) distributed among understanding (5/20, 28%), which was the lowest-scored category, followed by navigation (14.5/20, 74%) and relevance (15.5/20, 79%; Figure 3). As for the dietitians, the lack of understanding was due to confusion about the main meal headings regarding not knowing where to place drinks, snacks, and food eaten outside of main meals. Moreover, the meaning of the magnifier glass was unpredictable.

Screenshot 4A: New Consultation Session

Among all the screenshots, dietitians were mostly challenged by the usability of screenshot 4A (42%), both due to understanding (0.5/19, 3%) and navigation (9/19, 47%) of the screen (relevance: 14/18, 76%, compare Figure 3). The challenges with understanding were pointed out to be that it was not intuitive that the triangles would show more information, a lack of understanding of how the alternative food intake box functioned, and a lack of details. The challenges with navigation were pointed out to be not clear enough about what to do, and the heading was more misleading than guidance (Figure 3).

For older adults, the overall usability of screenshot 4A was 74%, with understanding as the lowest percentage (10/19, 51%), followed by relevance (14/17, 83%) and navigation (17/19, 89%; Figure 3). As for dietitians, the lack of understanding was due to not knowing the purpose of the triangles.

Screenshot 5: Alternatives

For screenshot 5 (57%), the dietitians scored understanding the lowest (6/19, 31%), followed by navigation (9.5/19, 50%) and relevance (16.5/18, 92%; Figure 3). The navigation was challenged by uncertainty about the meaning of the colors, and whether the alternative can be changed, whereas the lack of understanding was disturbed by ambiguity about whether the user has to choose something or not. Moreover, uncertainty about meal moments, the quantities of the alternatives, and whether the box shows the original food intake was present.

Screenshot 5 scored 64% for overall usability among older adults. Understanding had the lowest score (6/19, 36%), followed by navigation (12/19, 65%) and relevance (15/17, 90%; Figure 3). The understanding was disturbed by not understanding the color pattern and not knowing if the text on the screen was linked horizontally or vertically. Moreover, they expressed insecurity about how many food items the user can choose from this screen.

Similarities and Differences

The screenshots with the highest usability based on the average were the same among older adults and dietitians, in the same order of usability (the least difficult screen was 1 followed by 3C and 3B).

The biggest difference between older adults and dietitians regarding usability calculated by the average percentage of the 3 questions per screen was screenshot 4A with a 32% (74% versus 32%) difference and screenshot 3B with an 18% (87% versus 69%) difference, where the older adults had the highest score in both cases.

In general, the CW showed a need for higher consistency through screens, primarily due to visual aspects (colors or symbols), but also text (eg, save buttons).

Discussion

Principal Findings

In this study, we successfully used a user-centered design approach to assess the needs of a group of older adults and dieticians as potential end users for the digital tool under development. This study's findings show that (1) the need for a tool was present among both target groups; (2) suggestions on how to handle nonpresent food items, how to explain the relevance of the feedback, and suggestions on how to keep the data entry interesting were all identified. For the dietitians suggestions for exporting data were also identified. (3) Feasible and relevant suggestions for the tool feedback were successfully identified per (a) protein quality, (b) other nutrients, (c) sustainability, (d) criteria for filtering suggested alternatives, and (e) desired benefit of use. (4) By testing the tools' interface, challenging functions in the tool were identified. This approach allowed us to both develop and refine various solutions for the tool. However, during the development and refinement phase, differences in the desired solutions between the two groups became apparent. Due to resource constraints, we decided to focus on developing the prototype for 1 target group only, ultimately choosing dietitians for three reasons: (1) the physiological and nutritional understanding that is needed to successfully operate the tool is present in dietitians but would have to be trained in older adults; (2) to avoid the risk of misconception, the tool can deliver raw feedback, which the dietitian hands over to older adults in relevant context; and (3) dietitians are skilled in data entry and will be better able to find food-item alternatives in the occasions where products are missing in the dataset because of their professional experience and knowledge. The dietitians involved in this research have presented their support and interest in the tool until the end of data collection, and many dietitians have expressed their interest in being involved in its further development, indicating that the tool does fill an existing demand among dietitians.

During the development phase of the digital tool, the main landmarks that were achieved were: (1) the development of databases with data on nutritional content, amino acids, digestibility, and sustainability and (2) the development of algorithms that fetch nutritional data from the database and that calculate MPQSs. The development of the algorithms that identify alternatives has been commenced and needs further development. Moreover, the assumptions underlying the calculations of MPQS need validation, and the functionality of the feedback-providing algorithms should be tested on real-life data. These tests ideally comprise quantitative testing, where improvements in MPQSs over time are visible after the implementation of presented alternatives, and qualitative testing, where presented alternatives are scored on cultural, culinary, and nutritional relevance. Moreover, the tool has been developed based on the Dutch NEVO food database. To ultimately implement the tool worldwide, more food databases should be supplemented with data on amino acids and digestibility, and algorithms should be easily convertible to other food databases.

Comparison With Prior Work

In this study, we had a 3-phase user-centered design approach. This 3-phase approach allows us to understand the user's needs per different functionalities. Maramba et al [26], evaluated the use of usability of a testing phase in 133 eHealth tools (including nutritional tools) in a scoping review and found that less than 1/3 of the tools did undergo usability testing and that the use of "think-aloud" resulted in at least 1 further relevant iteration. Further iteration supports the relevance of approaching the development using methods that allow end users to have high involvement in the idea-generation process.

Other recent studies have used a similar approach compared to this study, with a high focus on end users and usability testing in the development of health-related tools [27,28], some of which are nutritional tools [27,28]. The development of the tool Dieta Dash (Alebg) had the purpose of giving the best food choices for preventing and evaluating hypertension [27]. The target audience sample (primary care physicians and nutritionists) was asked questions on how the prototype of the tool could be improved. They found that quick access to information, use of images, offline mode, and free access were some of the needs the end users had [27]. These needs are very similar to our results and strengthen the idea that this is a universal need for end users when they use eHealth tools. Kavanagh et al [28] developed a web-based health app (PortFolioDiet) for cardiovascular risk reduction. Here they used a 2-phase usability testing, including the acceptability of the tool. They found that a user guide on how to navigate the tool could be useful. This result was also seen in our study, and this strengthens the likelihood that it is a crucial function to include in a tool.

Loureiro et al [29] used focus group interviews in the development of a web-based tobacco tracker tool. The purpose of the focus groups was to explore ideas for the tracker prototypes' content and design and also how to motivate people to use the tool, by using a thematic analysis of the data based on an a priori codebook and the development of new codes during the process. Although it is a completely different type of tool, the results were quite similar regarding user needs, where they found that positive reinforcement, gamification, and ease of use, for example, in the form of dropdown menus, are all relevant aspects [29].

Keniston et al [30] developed a tool for discharge planning. They also used a user-centered design strategy with several meetings with end users. According to the evaluation team, this approach, in close collaboration with end users, enabled the successful implementation of the tool in the hospitals. These findings support the probability that a tool that is developed in close collaboration with end users would be well-accepted.

The prototype of this tool had to be further developed, but based on the findings, we believe that the core functionalities have the potential to contribute positively to the target groups' everyday lives by being a very practical and easy-to-use tool to raise awareness of protein quality and allow for the optimization of the individual's diet concerning protein quality where relevant.

Methodological Considerations

A strength of this study was the selection of participants. Specific inclusion and exclusion criteria ensured representative groups at both research sites, yielding targeted results. Consistent focus group interviews engaged participants deeply in the tool development, ensuring contextual understanding and relevant contributions. Recruited dietitians of diverse profiles, ages, and geographic backgrounds with experience in older adult nutrition enhanced suggestion validity. However, a limitation is potential selection bias. Dietitians who participated in this study might have been dietitians interested and supportive of protein transition. Thus, the findings may not be representative of all dietitians. The unequal gender representation in both focus groups could be seen as a limit, especially in the target group of older adults where the number of men is not representative of the gender distribution.

A further strength of this study is its use of focus group interviews. Contrary to individual interviews, a facilitated group discussion allows ideation through group interaction. This interaction ensured the ideas were created, discussed, and evaluated collectively, which has been seen to be a successful data collection process, also in the target group of older adults [31]. Moreover, such a discussion gives the individual a space to explore and rethink their point of view when meeting other perspectives. A risk of focus group interviews is that one participant might be dominant during a discussion compared to others. However, the moderators were aware of this risk and invited every participant to the discussion when relevant to reduce dominant respondent bias from the perspective of the moderators. Another strength of this study was the format and facilitation of the focus groups. Each focus group interview had a maximum of 7 participants which enabled everyone to become actively involved in the sessions [32]. Focus group interviews had a maximum duration of 3 hours for the older adults and 2 hours for the dietitians. While some older adults had difficulty focusing at the end of the session, we tried to maintain focus by holding breaks in between. This seemed to increase the focus and enable a more productive focus group.

During the first focus group interview, a short introduction round was held for participants to introduce themselves and their motivation for participation. Moderators asked follow-up questions to ensure participants felt heard. These initiatives may have increased the chance that participants felt safe to share their opinions openly. Moreover, in the first phase, moderators used open-ended questions and emphasized that there were no right or wrong answers. In addition, by asking follow-up questions, the moderators validated the statements of the participants when needed, which helped the moderators understand the statements, and thereby increased the validity of the data. Both moderators were neutral during the first focus group by not disrupting the discussion or leading it in a specific direction to reduce the risk of moderator bias.

Focus group interviews were conducted using a script and coding book. These steps increased consistency in data collection and data analysis across sites. Both research sites worked closely together in preparing, holding, and analyzing the focus groups. In the end, they compared the results and combined them. To avoid differences in coding between the two researchers at both sites cross-checks were performed by both researchers to check if coding was performed the same way. This also increased the reliability of the analysis.

By using the brainwriting and WD methods within the focus group interviews, we used a method of triangulation. This method combination increases the data quality by expanding and qualifying the understanding of the user's perspectives and most important needs. The WD method not only made room for innovative ideas but also put the ideas into evaluation carried out by the role of critics. The critics contributed to an in-depth evaluation of the strengths and weaknesses of the ideas. The choice of the brainwriting method ensured concrete suggestions, increasing the chance that the implementation was aligned with the user´s needs. Brainwriting is used in similar research with success to include stakeholders in developing new patient programs, for example, in the contraception navigator program [33].

The stepwise increase in user involvement from the first until the last focus group interviews contributed to ensuring that a potential tool is developed in a way that fits the user's needs. To have high user involvement when developing tools is used with success elsewhere [34].

A final limitation of the current approach is that by using a CW in the third phase as a way of testing usability we obtain quantitative results on the usability. These are difficult to compare with other usability studies. A way of improving this could have been by using the validated System Usability Scale as they give a comparable quantification of the results [35].

Conclusion

Our user engagement design approach resulted in a prototype digital tool that ensured end users' wishes and needs, with a finetuned output tested in focus groups. Our user engagement design approach appeared to be a suitable and meaningful stepwise approach to ensure the relevance of the tool and identify potential barriers. The prototype resulted in a finetuned output tested in the focus group sessions. The focus group results indicate that dietitians have a clear understanding and need for a tool to aid in meal planning for enhanced protein quality, highlighting its absence in their current resources despite increasing demands arising from the protein transition. Conversely, for older adults, the introduction of a digital tool appears less appropriate. Instead, before introducing such a tool, there is a necessity for foundational education on protein quality before such a tool can be effectively used. Future studies are needed to further implement the prototype into practice.

Acknowledgments

We would like to thank MSc students Rikke Sand Andersen, Aimée van 't Hoff, and Josephine van der Wel for assisting with the preparation, performing, and transcribing of the focus groups. We would like to thank Nicolo Ferretti, MSc, and Gorkem Simsek-Senel, MSc, who helped with the building of the back end of the tool, and we would like to thank our colleagues from BEIA who started the design of the front end of the tool. This study was jointly supported by the European Union, ZonMW, Innovation Fund Denmark (1117-00025B), and UEFISCDI (the executive agency for higher education, research, development, and innovation funding) using an Active Assisted Living Program Small Collaborative Project grant (aal-2021-8-202-SCP).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Script user-task-environment analysis.
[DOCX File , 18 KB - jopm_v16i1e48323_app1.docx]

Multimedia Appendix 2
Coding book.

[DOCX File , 16 KB - jopm_v16i1e48323_app2.docx]

Multimedia Appendix 3
Brainwriting method results table.
[DOCX File , 32 KB - jopm_v16i1e48323_app3.docx]

Multimedia Appendix 4
Cognitive walkthrough results.
[DOCX File , 3020 KB - jopm_v16i1e48323_app4.docx]

References

1. Willett W, Rockström J, Loken B, Springmann M, Lang T, Vermeulen S, et al. Food in the anthropocene: the EAT-Lancet commission on healthy diets from sustainable food systems. Lancet 2019;393(10170):447-492. [doi: 10.1016/S0140-6736(18)31788-4] [Medline: 30660336]
2. Melina V, Craig W, Levin S. Position of the academy of nutrition and dietetics: vegetarian diets. J Acad Nutr Diet 2016;116(12):1970-1980. [doi: 10.1016/j.jand.2016.09.025] [Medline: 27886704]
3. Katharina C W. Vegan diet in sports and exercise – health benefits and advantages to athletes and physically active people: a narrative review. Int J Sports Exerc Med 2020;6(3):1-32. [doi: 10.23937/2469-5718/1510165]
4. Schmidt P. Promoting healthy sustainable diets in the EU. European Economic and Social Comitteection for Agriculture, Rural Development and the Environment. 2018. URL: https://www.eesc.europa.eu/en/our-work/opinions-information-reports/opinions/promoting-healthy-and-sustainable-diets-eu-own-initiative-opinion [accessed 2024-12-04]
5. Gorissen SHM, Crombag JJR, Senden JMG, Waterval WAH, Bierau J, Verdijk LB, et al. Protein content and amino acid composition of commercially available plant-based protein isolates. Amino Acids 2018;50(12):1685-1695 [FREE Full text] [doi: 10.1007/s00726-018-2640-5] [Medline: 30167963]
6. Pinckaers PJ, Domić J, Petrick HL, Holwerda AM, Trommelen J, Hendriks FK, et al. Higher muscle protein synthesis rates following ingestion of an omnivorous meal compared with an isocaloric and isonitrogenous vegan meal in healthy, older adults. J Nutr 2024;154(7):2120-2132 [FREE Full text] [doi: 10.1016/j.tjnut.2023.11.004] [Medline: 37972895]
7. Grootswagers P, Højlund Christensen S, Timmer M, Riley W, de Groot L, Tetens I. Meal protein quality score: a novel tool to evaluate protein quantity and quality of meals. Curr Dev Nutr 2024;8(9):104439 [FREE Full text] [doi: 10.1016/j.cdnut.2024.104439] [Medline: 39290315]
8. Department of Economic and Social Affairs Population Division. World Population Prospects: The 2017 Revision, Methodology of the United Nations Population Estimates and Projections. Working Paper No. ESA/P/WP. 250. New York: United Nations; 2017:1-48.
9. Grootswagers P, de Groot LCPGM. Nutritional concerns later in life. Proc Nutr Soc 2021;80(3):339-343. [doi: 10.1017/S0029665121001932] [Medline: 33971996]
10. Vaes AMM, Brouwer-Brolsma EM, van der Zwaluw NL, van Wijngaarden JP, Berendsen AAM, van Schoor N, et al. Food sources of vitamin D and their association with 25-hydroxyvitamin D status in Dutch older adults. J Steroid Biochem Mol Biol 2017;173:228-234. [doi: 10.1016/j.jsbmb.2016.10.004] [Medline: 27777183]
11. Heaney RP, Recker RR, Grote J, Horst RL, Armas LAG. Vitamin D(3) is more potent than vitamin D(2) in humans. J Clin Endocrinol Metab 2011;96(3):E447-E452. [doi: 10.1210/jc.2010-2230] [Medline: 21177785]
12. Domić J, Grootswagers P, van Loon LJC, de Groot LCPGM. Perspective: vegan diets for older adults? A perspective on the potential impact on muscle mass and strength. Adv Nutr 2022;13(3):712-725 [FREE Full text] [doi: 10.1093/advances/nmac009] [Medline: 35108354]
13. Gezondheidsraad. Gezonde eiwittransitie. Den Haag; 2023. Contract No.: 2023/13. URL: https://www.gezondheidsraad.nl/onderwerpen/voeding/alle-adviezen-over-voeding/gezonde-eiwittransitie [accessed 2024-12-04]
14. Malafarina V, Uriz-Otano F, Gil-Guerrero L, Iniesta R. The anorexia of ageing: physiopathology, prevalence, associated comorbidity and mortality. A systematic review. Maturitas 2013;74(4):293-302. [doi: 10.1016/j.maturitas.2013.01.016] [Medline: 23415063]
15. Pilgrim AL, Robinson SM, Sayer AA, Roberts HC. An overview of appetite decline in older people. Nurs Older People 2015;27(5):29-35 [FREE Full text] [doi: 10.7748/nop.27.5.29.e697] [Medline: 26018489]
16. Spinhof L, Calvi L. User and task analysis in a home care environment. 2006 Presented at: 20th international symposium on human factors in telecommunication; 2006 March 20; Sophia Antipolis, France.
17. Sustainable diets. NZO. URL: https://www.nzo.nl/en/nutrition/sustainable-diets/ [accessed 2024-11-30]
18. Besselink J, Bruins M. When it comes to plant-based-products, nutrition matters. 2021. URL: https://www.dsm.com/food-beverage/en_US/insights/insights/savory/dsm-fortifull-nutrition-guide.html [accessed 2024-11-30]
19. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006;3(2):77-101. [doi: 10.1191/1478088706qp063oa]

20. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med 2014;89(9):1245-1251 [FREE Full text] [doi: 10.1097/ACM.0000000000000388] [Medline: 24979285]
21. Dilts R. Strategies of Genius: Aristotle, Sherlock Holmes, Walt Disney, Wolfgang Amadeus Mozart. Redwood City, California: Meta Publications; 1994.
22. Gilmartin H, Lawrence E, Leonard C, McCreight M, Kelley L, Lippmann B, et al. Brainwriting premortem: a novel focus group method to engage stakeholders and identify preimplementation barriers. J Nurs Care Qual 2019;34(2):94-100 [FREE Full text] [doi: 10.1097/NCQ.0000000000000360] [Medline: 30148746]
23. Dilts RB, Epstein T, Dilts RW. Know-how für Träumer: Strategien der Kreativität, NLP & modelling, Struktur der Innovation. St Peters, MO, USA: Junfermann; 1994.
24. Mahatody T, Sagar M, Kolski C. State of the art on the cognitive walkthrough method, its variants and evolutions. Int J Hum-Comput Interact 2010;26(8):741-785. [doi: 10.1080/10447311003781409]
25. Heerschop SN, Kanellopoulos A, Biesbroek S, van 't Veer P. Shifting towards optimized healthy and sustainable Dutch diets: impact on protein quality. Eur J Nutr 2023;62(5):2115-2128 [FREE Full text] [doi: 10.1007/s00394-023-03135-7] [Medline: 36949232]
26. Maramba I, Chatterjee A, Newman C. Methods of usability testing in the development of eHealth applications: a scoping review. Int J Med Inform 2019;126:95-104. [doi: 10.1016/j.ijmedinf.2019.03.018] [Medline: 31029270]
27. Gadenz SD, Harzheim E, Amaral HG, Drehmer M. Development and assessment of a mobile nutritional counseling tool for primary care physicians. Telemed e-Health 2020;26(6):805-811. [doi: 10.1089/tmj.2019.0070] [Medline: 31556810]
28. Kavanagh ME, Chiavaroli L, Glenn AJ, Heijmans G, Grant SM, Chow C, et al. A web-based health application to translate nutrition therapy for cardiovascular risk reduction in primary care (PortfolioDiet.app): quality improvement and usability testing study. JMIR Hum Factors 2022;9(2):e34704 [FREE Full text] [doi: 10.2196/34704] [Medline: 35451981]
29. Loureiro SF, Pulvers K, Gosdin MM, Clift K, Rice M, Tong EK. The development of a web-based tobacco tracker tool to crowdsource campus environmental reports for smoke and tobacco-free college policies: mixed methods study. J Med Internet Res 2021;23(10):e26280 [FREE Full text] [doi: 10.2196/26280] [Medline: 34714248]
30. Keniston A, McBeth L, Pell J, Bowden K, Ball S, Stoebner K, et al. Development and implementation of a multidisciplinary electronic discharge readiness tool: user-centered design approach. JMIR Hum Factors 2021;8(2):e24038 [FREE Full text] [doi: 10.2196/24038] [Medline: 33890860]
31. Reichstadt J, Depp CA, Palinkas LA, Folsom DP, Jeste DV. Building blocks of successful aging: a focus group study of older adults' perceived contributors to successful aging. Am J Geriatr Psychiatry 2007;15(3):194-201. [doi: 10.1097/JGP.0b013e318030255f] [Medline: 17322132]
32. Tausch AP, Menold N. Methodological aspects of focus groups in health research: results of qualitative interviews with focus group moderators. Glob Qual Nurs Res 2016;3:2333393616630466 [FREE Full text] [doi: 10.1177/2333393616630466] [Medline: 28462326]
33. Wilkinson TA, Hawryluk B, Moore C, Peipert JF, Carroll AE, Wiehe S, et al. Developing a youth contraception navigator program: a human-centered design approach. J Adolesc Health 2022;71(2):217-225 [FREE Full text] [doi: 10.1016/j.jadohealth.2022.03.005] [Medline: 35562301]
34. Epstein DA, Lee NB, Kang JH, Agapie E, Schroeder J, Pina LR, et al. Examining menstrual tracking to inform the design of personal informatics tools. 2017 Presented at: Proceedings of the 2017 CHI Conference on Human Factors in Computing Systems; 2017 May 02; Colorado, Denver, USA p. 6876-6888 URL: https://europepmc.org/abstract/MED/28516176 [doi: 10.1145/3025453.3025635]
35. Peres SC, Pham T, Phillips R. Validation of the system usability scale (SUS). Proc Hum Factors Ergon Soc Annu Meet 2013;57(1):192-196. [doi: 10.1177/1541931213571043]

Abbreviations

API: application program interface
CW: cognitive walkthrough
EAA: essential amino acid
MPQS: Meal Protein Quality Score
NEVO: Dutch nutritional database, Nederlands Voedingsstoffenbestand
WD: Walt Disney

Edited by S Woods, T Leung; submitted 21.04.23; peer-reviewed by M Gasmi , KC Wirnitzer; comments to author 06.06.24; revised version received 21.08.24; accepted 19.10.24; published 19.12.24.

Please cite as:
van Dam L, Christensen SH, Tetens I, Riley III W, Timmer M, Suciu Jr G, Marin I, De Groot L, Grootswagers P
Developing a Digital Tool to Calculate Protein Quality in Plant-Based Meals of Older Adults: User Engagement Design Approach With End Users
J Particip Med 2024;16:e48323
URL: https://jopm.jmir.org/2024/1/e48323
doi:10.2196/48323
PMID:

Original Paper

Implementation of a Recovery College Embedded in a Swedish Psychiatry Organization: Qualitative Case Study

Lina Al-Adili[1*], PhD; Moa Malmqvist[1*], MA; Maria Reinius[1], PhD; Inka Helispää Rodriguez[1]; Terese Stenfors[1], PhD; Mats Brommels[1], PhD

[1] Medical Management Centre, Department of Learning, Informatics, Management and Ethics, Karolinska Institute, Stockholm, Sweden

[*] these authors contributed equally

Corresponding Author:
Lina Al-Adili, PhD
Medical Management Centre
Department of Learning, Informatics, Management and Ethics
Karolinska Institute
Tomtebodavägen 18 a
Stockholm, 17177
Sweden
Phone: 46 0707799245
Email: lina.aladili@ki.se

Abstract

Background: Recovery colleges are service user–led educational interventions aiming at empowering people with mental health issues and promoting recovery through peer learning. Despite the increasing interest in recovery colleges in recent years and the demonstrated beneficial effects for users, there is limited research addressing aspects that influence their implementation. This knowledge is necessary for the successful integration of such interventions in various contexts.

Objective: This study aims to explore factors that influence the implementation of a recovery college embedded within a Swedish psychiatry organization.

Methods: A qualitative case study of a recovery college based on semistructured interviews with 8 course participants, 4 course leaders, and 4 clinical staff was conducted. The transcripts were scrutinized with conventional content analysis, and the interpretation of results was guided by the Consolidated Framework for Implementation Research.

Results: The findings highlight key areas that either hinder or promote the successful implementation of the recovery college. These areas included recruitment, resources, staff attitudes, and ways of organizing courses. Each area has elements that appear both as facilitators and barriers, demonstrating the duality of conditions.

Conclusions: Allocating dedicated resources, engaging individuals with service user experience as organizers who are willing to share their personal experience, having an open-door policy, creating an open space for participants to share their experiences, and offering practical advice and written material are useful to create favorable conditions for a recovery college to reach its goals of empowering psychiatry service users.

(J Particip Med 2024;16:e55882) doi:10.2196/55882

KEYWORDS

mental health; educational intervention; recovery college; implementation research approach; qualitative research; coproduction

Introduction

Background

Many mental health service users have engaged in self-care with the aim of taking control over their lives despite diseases as well as turning to peer support. This started in the United States as a mental health consumer movement in the 1970s. In an *emerging issues* paper, Davidson [1] discussed how this movement has been supported by changes in US legislation from the 1990s onward. He referred to longitudinal studies of patients with schizophrenia performed in the 1970s and 1980s that changed the previously pessimistic view on psychiatric disorders. This was well in line with the personal experience of people that they were, despite a psychiatric diagnosis, able to lead meaningful and productive lives. He also claimed that those studies showed that the capacity of patients to recover fully or learn to manage their condition, in many instances developed outside formal treatment settings.

Perkins et al [2] differentiated this patient-driven self-management activity from professional psychiatric care by referring to those approaches as *educational* versus *therapeutic approaches*. Instead of focusing on problems and dysfunctions and labeling all activities as therapies, the recovery movement supports people to identify and develop their talents and skills, explore their possibilities, and focus on achieving ambitions and goals. It has, consequently, also been defined as an *assets-based* approach, aiming at developing the *recovery capital* of patients, defined as “the array of social, psychological and cultural networks beyond professional inputs” [3].

“Recovery colleges” are such educational activities that have proliferated in the United Kingdom. A network titled *Implementing Recovery through Organisational Change* coordinates about 40 recovery colleges that engage over 500 peer workers, promoting learning and self-management as core practices among patients with mental health conditions [4]. Recovery colleges are typically led by persons with lived experience as service users and they focus on sharing experience, support for coping, and skills training.

The interest in recovery colleges has increased over the years, more colleges have been established, and the number of reports on their outcomes keep growing. A recent systematic review concluded that “Recovery college attendance was associated with high satisfaction among participants, attainment of recovery goals, changes in service providers’ practice, and reductions in service use and cost” [5]. Attending a recovery college was described by participants as being useful in supporting recovery, leading to a decrease in service use [6]. Another study reported that well-being and personal resources were strengthened, and user satisfaction increased as the service provided was perceived as accepting and enabling. In addition, participants felt a greater sense of hope, confidence, and higher aspirations [7]. In focus group interviews, recovery college participants expressed that they had experienced a positive impact on their lives and had seen benefits brought by the college to the organization [8].

A systematic literature review analyzed outcomes of recovery college activities on mental health staff, mental health services, and the society at large [9]. Mental health clinical staff who participated in recovery colleges valued collaboration with service users and, as a result, gained a different perception of those service users and felt more passion and higher job motivation. Within mental health organizations, recovery college activities provided staff with a learning environment to practice coproduction with users. Recovery colleges involve agencies in the community and their staff in collaboration with service users, which has a positive effect on staff attitudes and public opinion [9].

Some impact studies have included process evaluations with information on program content and resources used. Those tend to focus on improvement opportunities, such as standardizing course processes and planning for longer courses [10]. Hall et al [11] represented 1 group of a few researchers addressing the implementation of a recovery college. They found “delays in the development of some key policies and procedures, including the enrollment and attendance information, standardization of evaluation measures and course standardization” [11]. The reasons for these delays were lack of resources, funding, and staffing; staff turnover; and less defined staff roles. Some staff felt uncertain about coproducing with persons with lived experience and the quality of external expert input. Slade et al [12] found similar attitudinal problems among staff, characterizing those as “abuses of recovery colleges.” Staff might feel that recovery colleges are a fad, that those would not benefit their patients, and that psychiatry services would be sufficient to address their problems.

In summary, these studies on the outcomes of recovery college activities show high satisfaction among participants, experiencing a greater sense of hope, confidence, strengthened personal resources, and a positive impact on their lives in general. Finally, participants had reduced their use of formal services. Mental health professionals with experience in recovery colleges valued collaboration with service users and reported, as a result, feeling more passion and higher job motivation. The collaboration between recovery colleges and agencies in the community had a positive effect on the staff of those agencies and public opinion. However, some challenges were also reported. Lack of resources, funding, and staff attitudes would delay the launch of a recovery college. Some staff members felt that the activity would not benefit their patients beyond that of formal psychiatry services.

When setting up a recovery college, prospects for success would be enhanced by a clear conceptualization of the college, an integration between the college and the host organization, and attention paid to the power imbalance between providers and patients [13]. These observations refer mostly to the design of the educational activity, whereas information on the way in which plans have been carried out and adjusted to fit local conditions and contexts is lacking. Such approach is referred to as *implementation*, which preferably should be studied with an *implementation research approach* [14]. Hence, implementation includes not only the introduction of an intervention but also the continuous adaptation and optimization of it within the organizational context.

This Study

Given the scant literature and the importance of understanding the context, we set out to specifically study the *implementation* of a recovery college that is embedded in a psychiatry organization. Elsewhere, recovery colleges are typically freestanding centers. We took advantage of the fact that we had access to 1 recovery college at a psychiatry clinic, called *Patient School*, in Region Stockholm, Sweden. We have recently analyzed the value of this Patient School, as described elsewhere [15]. Hence, the aim of this study was to explore factors that influence the implementation of the Patient School within this psychiatry organization.

Methods

Study Design

This is a qualitative inductive study based on semistructured interviews conducted using a coproduced approach [16,17]. The research team included persons with formal experience of research (health care professionals and other academically trained individuals), those with lived experience of being a patient in a mental health care facility, and those presently working in the psychiatry organization. The team of authors cocreated all different aspects of the research process, including reflexive discussions on how team members' different perspectives have affected the research process. The COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines have been followed to support the transparency and quality of this research [18]. To strengthen the focus on the implementation process, the analysis and the interpretation of the data were guided by the updated Consolidated Framework for Implementation Research framework, as proposed by Damschroder et al [19].

Context

The psychiatry organization provides both inpatient and outpatient services to the Region Stockholm population and is part of its public health care. It has consistently led efforts in fostering user participation and organizing user-centric initiatives within the mental health sector of this region. Since 2007, the psychiatry organization has appointed dedicated *user-involvement coordinators* on a full-time basis. By 2016, the organization expanded its approach by incorporating peer-support workers, known as *staff with user experience*, who serve as mentors for patients in psychiatry units. User-involvement coordinators conduct regular surveys among users to gather insights and relay this information to the psychiatry organization's management. In addition, a user-involvement coordinator holds a position in the organization's Patient Safety Group and presides over the User Council, which includes members from patient organizations and the management team. The founders of the Patient School were working within the organization as user-involvement coordinators or staff with user experience. The Patient School was established in 2018 by the user-involvement coordinators and offered initially to outpatient users. The clinical manager, who the lead user-involvement coordinator reported to, endorsed the plan and anchored it with the full senior management team of the organization. The Patient School gatherings take place in psychiatry care facilities with the support of the management and with professional staff contributing.

As guiding principles for the Patient School, they agreed upon (1) promoting recovery; (2) placing the activity in facilities within the psychiatry organization with the support of its leadership; (3) choosing employed user-involvement coordinators and staff with user experience as coordinators; and (4) while encouraging sharing of personal experience, avoiding suggesting those as generalizable recommendations.

Before launching the first Patient School program, the course leaders had visited recovery colleges in England, acquiring inspiration from that experience. They then formed a working group to ensure they all had the same vision for the program. All leaders were present at every meeting during the first round of Patient School so that they would all teach the course the same way. After that, the work was divided, and leaders were assigned sessions with specific themes so that not all leaders had to be present every time.

As previously described by Reinius et al [15], the Patient School was founded in 2018 for both inpatient and outpatient units. However, information about the Patient School was originally circulated at outpatient departments (ambulatory mental health centers). All participants so far have been recruited this way.

In total, 12 courses were offered, with close to 70 course participants. The Patient School consists of a series of five workshops offered over 5 weeks covering the following themes: (1) psychiatry: how does it work? (2) recovery: what is helpful? (3) other resources in society, (4) relations and disclosure, and (5) personal tools. The course leaders invited, to each workshop, health care personnel from the psychiatry organization or researchers to act as coleaders and substance matter experts.

The study is part of the *Patients in the driver's seat* partnership research program, situated at Karolinska Institute exploring patient-driven innovations to promote self-care and cocare [20].

The choice of themes to include in the course curriculum was based on views expressed by psychiatry service users in *Patient forums*, organized by the user-involvement coordinators planning the Patient School. Some of those were related to *patient competence*, that is, knowledge about the health care system and laws and regulations needed to be able to *navigate the system*. Patient School participants (service users) were asked for feedback, both orally and in surveys, and the content was adjusted accordingly. Participants in previous courses were engaged to be mentors to new participants and participated alongside them. These mentors shared their observations and gave useful feedback.

Participant Recruitment

The data used for this study were gathered as part of a larger research project as described in the study by Reinius et al [15]. In total, 45 participants in the Patient School who had provided contact information during or after completing the school were invited by MR to participate. In total, 7 clinical staff who acted as experts as well as 6 course leaders (user-involvement coordinators and staff with user experience) were also sent invitations. Apart from one who is a coauthor with user experience (IHR), no previous relationships with IHR were established before the commencement of the study. MR was introduced as a researcher interested in exploring participants' views about the Patient School. The timeline of respondent recruitment is presented in Multimedia Appendix 1.

Ethical Considerations

Ethics approval was granted by the Regional Ethical Review Board of Stockholm (Dnr 2019-03849 with amendment Dnr 2020-04604). All procedures followed were in accordance with the ethical standards of the responsible committee for human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study. The data are anonymized, and no compensations were provided to participants in this study.

Data Collection

A researcher trained in qualitative methodology and interview technique was responsible for developing a semistructured interview guide, and it was discussed, revised, and received approval from the entire team. The interviews were conducted over the telephone by the same researcher MR from her office. The interviews were recorded and transcribed verbatim. The respondents had received written information in advance and were able to ask questions before the interview started. An interview guide was designed in discussions within the research team, including members who had been involved as course organizers. Their experience was important in identifying different items of the implementation process that could be used in follow-up questions. However, the interviews started with open-ended questions, such as “according to you, what is needed for the Patient School to be carried out? and probes such as can you tell me more about that?” The data collection stopped when no more aspects connected to the study aims were identified, that is, when data saturation was reached.

Data Analysis

The transcripts were subjected to conventional content analysis using an inductive approach [21]. For this manuscript, interview data were analyzed with particular focus on aspects of implementing the Patient School. First, MR read through all transcripts several times to reach immersion and formulated meaning units to cover all sections of the text that responded to the aim and defined 2 main themes (ie, barriers and facilitators). Barriers refer to obstacles and difficulties when organizing courses, and facilitators refer to conditions that make implementation easier or promote perceived successes. MB read 5 transcripts to verify the preliminary categorization.

The selected meaning units were checked against the original transcript, labeled, grouped, and posted on a Miro dashboard by MM. MB, MMC, TS, and IHR participated in 4 analysis workshops that started with all participants reading the meaning units in silence and making notes on their first impressions, thoughts, and initial analysis. The preliminary labeling and categorization were discussed in the full team, and agreement was reached on defining subcategories. All authors reviewed initial findings and suggested revisions until a consensus was reached. MMC then returned to the full data related to the selected meaning units to select representative citations. To validate those, LA read all the transcripts and confirmed the preliminary analysis. In this way, data analysis was performed by all team members participating while also protecting the integrity of the interviewees. As it was felt that member checking would have run the equal risk of individual interviewees being identified, the procedure was not performed.

LA was responsible for manuscript writing and composition. She drafted and revised the manuscript based on critical input from the other authors. Of crucial importance were user-involvement coordinator members’ comments, which guided the contextual interpretation. All authors approved the final manuscript.

Results

Overview

In total, 16 individual interviews were conducted from March to May 2021 (lasting between 25 min and 75 min) with 8 (50%) course participants, 4 (25%) course leaders, and 4 (25%) clinical staff who had participated in the Patient School as invited experts.

The findings highlight key areas that either hinder (barriers) or promote (facilitate) the successful implementation of the Patient School within the psychiatry organization. These areas encompassed *recruitment*, *resources*, *staff attitudes*, and *ways of organizing courses.* The findings are structured around these distinctive subthemes. Each subtheme appears both as a facilitator and a barrier, demonstrating opposite conditions. Our comprehensive summary of the findings is described in Textbox 1.

Textbox 1. Summary of barriers and facilitators for the implementation of the Patient School based on interviews with course leaders, participants, and staff and course documents.

Barriers

- Recruitment
  - Lack of contact with fellow service users
  - Lack of knowledge and understanding of the Patient School and its benefits among clinical staff
- Resources
  - Patient School not included in the reimbursement system
  - Focus on service production and less time for staff to support Patient School
  - Lack of a dedicated venue
- Negative attitude among staff
  - Negative stance toward staff with user experience and patient involvement
  - Change resistance—fear of heavier workload
  - *Wrong to teach a person to be a patient*
- Ways of organizing course
  - Course leaders spending too much time describing their own experience left little space for participants
  - Some participants dominated too much
  - Some experts not appreciated by participants

Facilitators

- Recruitment
  - Everybody can join the Patient School
  - Active information to patients from staff
- Resources
  - User-involvement coordinators and staff with user experience as course leaders
- Positive attitude among staff
  - Patient satisfaction and perceived value of Patient School increases staff motivation to support Patient School
- Ways of organizing course
  - Course leaders sharing their own experience encouraged participants
  - Moderator giving everybody space
  - Participant feedback paid attention to
  - *Open door policy* (everybody is welcome)
  - Appreciated course material

Recruitment

Recruitment barriers for the Patient School were primarily attributed to limited contact between patients and staff with user experience as well as user-involvement coordinators and inadequate information dissemination by staff. The staff were described to have an essential role in recruiting patients and conveying the value of the Patient School. Participants acknowledged that not all patients had the opportunity to meet with staff with user experience and user-involvement coordinators directly, highlighting the importance of regular staff interactions with patients to disseminate information about Patient School and assist in recruitment efforts:

> *[In order for the patient school to be implemented, it is necessary] that [staff] want to participate, of course. Participate both with us and to help get information out so that people will be interested in it. So a collaboration is required.* [Interviewee #10]

Ensuring that information about Patient School was available in wards and outpatient departments was described to be essential for successful recruitment. Although written materials were accessible in the clinics, participants viewed verbal reminders by staff as a necessary complement. However, the lack of active information about Patient School to patients from staff was described as a barrier by several participants. One staff interviewee explained that, although reminding patients about Patient School would be helpful, it was easily forgotten about.

Some participants highlighted a lack of knowledge and understanding about Patient School among other staff. Interviewed staff described uncertainty about its structure and a lack of adequate information about how to provide patients with information about Patient School. Consequently, this led to feelings of insecurity when discussing the Patient School with patients.

The lack of an information channel about the Patient School was believed to contribute to a low understanding of Patient School among staff. Course leaders believed that it was difficult to spread information about Patient School to staff and that it would have been valuable if information of Patient School benefits would have been shared with them. They expressed concern that patients who did not have the opportunity to meet with a user-involvement coordinator or staff with user experience might miss out on being informed about Patient School:

> *What can be an obstacle, then, is...that they, patients, have not met us, and are not informed by staff, i.e. their contacts at outpatient care, that the Patient School exists.* [Interviewee #3]

Recruitment was facilitated by adopting an inclusive approach, wherein all outpatients at the clinic who were willing and capable of participating in structured group events were welcomed to participate. It was also seen as a future enabling factor to further spread the Patient School across all clinics in the region. That was desired by both staff and course leaders and could help both increase the size of groups that were felt to be too small and minimize frequency of waiting lists, which sometimes occurred. It was also believed that if patients from other clinics were recruited, it would help spread the word about Patient School. However, some interviewed staff raised concerns about mixing participants from different stages of recovery in the same sessions. They believed that there was a risk that people who had progressed on their path to recovery might have a flashback. This was confirmed by 1 staff member:

> *Those who leads it [the Patient School] should have knowledge about whether there's a participant there who if something comes up that makes them feel bad, or triggers a flashback...that they can handle it. I think that whoever it was that was leading it, was very receptive to how people were feeling and how they reacted to what was said. It's important to have the right person leading it.* [Interviewee #12]

Some participants made suggestions for the future improvement of the Patient School and expressed appreciation for the attentiveness of the course leaders to their feedback. For instance, a proposal was made to link participants' care plans with the course program, which could create added value. Another proposal was to involve former participants to visit the Patient School, share their experiences, and aid course leaders. Those alumni would shadow a course leader for some time to learn the dynamics of the Patient School and afterward contribute as assistants to a course leader.

Resources

The success of Patient School was described as relying on essential resources, including the availability of user-involvement coordinators and staff with user experience, time, suitable venues, and funding. The integration of Patient School in the regional health care reimbursement system was seen as the most important promoting factor, and if it was not, Patient School would not be able to evolve, let alone survive. The absence of Patient School from the reimbursement system was thus highlighted as a significant barrier to its implementation:

> *But I think the priority would probably be to try to approach the clients or those who manage that part, and see if there is any order, some type of compensation we can get as a business, to hold the Patient School. Because I think it's more essential for us to survive.* [Interviewee #7]

Participating course leaders described that with earmarked funding, more course leaders could be hired, which would increase the number of sessions, lecturers with care provision commitments could be recruited, and a spread of Patient School across clinics would be possible. Another improvement would be to include Patient School education as a service to be reimbursed, in parallel with clinical services. The lack of these preconditions contributed to an undersupply and a long waiting list for participants to join Patient School at the clinic.

Participating course leaders emphasized that, at present, Patient School is held in the clinic's facilities and the venue must be booked in competition with other activities. Course leaders stressed the need for improved access to clinic facilities, of which some could be specifically dedicated to Patient School. When requesting the venue, course leaders were sometimes met with resistance, which was seen as a direct effect of Patient School not being a part of the reimbursement system. Patient School competes with other initiatives that generate income for the clinic, which often were given first access.

Course leaders explained that they needed more time allocated to Patient School and to planning Patient School workshops. Some described that a dedicated budget for hiring expert lecturers would ease the burden on course leaders. Other course leaders stated that almost all clinics have used user-involvement coordinators and highlighted that to expand Patient School to additional sites would require either allocation of more staff or more active collaboration between user-involvement coordinators.

Staff Attitudes

Several barriers connected to staff and managers' attitudes were highlighted by course leaders. Some described a noticeable reluctance among staff toward including staff with user experience in health care in general. As the Patient School was initiated by user-involvement coordinators and staff with user experience, this affected staff attitude toward Patient School. A drastic example of the consequence of a negative attitude was told by course leaders. On some occasions, staff falsely claimed to have reserved the facility where Patient School was to be held. This behavior was perceived by some course leaders as an indirect expression of staff's doubts about the value of the Patient School. Course leaders felt that some managers also were critical of the Patient School and misunderstood its purpose:

> *Then there have been some attitudes...obstacles too. There have been certain...Some managers, who have thought that no, should you really teach people to be patients?* [Interviewee #7]

A viewpoint expressed by some course leaders was that managers appeared to prioritize financial considerations over quality aspects. They suggested that managers perceived Patient School as less significant, as it does not generate income for the provider.

According to course leaders, there existed a degree of reluctance among staff toward Patient School among some staff. They had experienced that staff had actively singled out aspects of Patient School to criticize. This attitude was felt to mirror the fear of an increased workload triggering change resistance. One staff interviewee stated that during Patient School sessions, patients were encouraged to actively engage in care planning and participate in their care, such as by reading their medical records:

> *There are people who believe it's, unnecessary, to remind that one can read one's medical record, I heard from a colleague once, since the patient had expressed concerns (about a note and its content). I believe it's evident that patients should be able to read their medical record, and at the same time, also to use it as a tool, as I do. However, not everyone likes it...So, of course, it's true that some find it worrying that...patients, are well-informed and also that they have demands.* [Interviewee #10]

In contrast, facilitators included the perceived value of the Patient School, which not only influenced the general staff attitude toward Patient School but was also said to impact their willingness to recruit patients to participate. Patient satisfaction with the Patient School was described as a motivating factor leading to the dissemination of information about the program. For example, 1 staff interviewee took the initiative to frequently remind colleagues to inform patients about Patient School. In addition, 1 course leader suggested that staff on some occasions should accompany their patients to Patient School workshops, allowing them to gain firsthand experience of the Patient School and realize its value.

Ways of Organizing the Course

The role of course leaders and the collaboration between them and participants were widely acknowledged as a cornerstone of a successful Patient School. Among the challenges encountered was the issue of equal participation during discussions. Some participants recognized their tendency to dominate discussions, hence limiting contributions from more quiet peers. The role of course leaders was thus emphasized as vital to directing the discussion, introducing clear topics, and helping participants to maintain focus. One staff interviewee highlighted the importance of the course leaders' competence in directing the conversation:

> *I believe they were very competent at leading...you need the right person to lead it, someone with knowledge who is responsive and can evaluate how the information is being received by participants...And could interfere if a participant started to talk too much...and quickly redirect the conversation.* [Interviewee #10]

Participants expressed their appreciation of the skills of course leaders as moderators and mentioned that they had high trust in them. Course leaders highlighted that they made sure that everyone had a chance to speak and that all topics were covered. By sharing their own experiences, course leaders encouraged patients to speak up. Those features were seen as facilitating the successful implementation of the Patient School. Conversely, the role and behavior of course leaders were sometimes described as a barrier. Initially, course leaders at times focused too much on sharing their own experiences. This trap was avoided by creating clear agendas for sessions. Furthermore, course leaders described that to enhance coherence and promote improved group dynamics the following policy was implemented: if a participant missed the 2 first meetings, they had to quit the course.

As employees of the psychiatry organization, course leaders knew what psychiatry has to offer. Having user experience, they also succeeded in presenting a balanced view of life. In addition, by countering negative stories with positive examples, they wished to provide a nuanced perspective on the life situation of a user, contributing to the perceived value of Patient School:

> *Course leaders try to balance each other with examples we take from our own lives. That if someone has a very negative experience of a single event...maybe someone else has a more positive picture. And then we sort of try to balance that with the fact that it can look different.* [Interviewee #7]

Participants shared various additional observations of a positive experience related to the Patient School. Participants expressed their satisfaction with the course material and believed that the 5 meetings, which had different foci fit well together and progressed in a logical order. They also valued the fact that course leaders were in the position to contact clinical staff and facilitate medical interventions when needed. The practice of course leaders working in pairs was also appreciated, as it enables the leader to have a private encounter with a participant when needed without disrupting discussions within the rest of the group. Furthermore, a guest lecturer providing expert insights was something described as beneficial. In contrast, on 1 specific occasion, a guest lecturer was critical of psychiatric care, which was considered less constructive.

The Lens of an Implementation Research Framework

Overview

To further highlight the primary focus of the study, the implementation of the Patient School program, the Patient School was analyzed using the additional information provided in the context in relation to the five dimensions of the

Consolidated Framework for Implementation Research [19]: (1) intervention characteristics as defined by the *content* of the Patient School, (2) its outer setting, (3) inner setting, (4) individuals, and the (5) implementation process.

Patient School Content

The aim of the Patient School was to promote recovery and to reach out to service users by placing itself in facilities within the psychiatry organization and to charge user-involvement coordinators and staff with user experience to organize and lead the school workshops.

Each school course consisted of five workshops offered over 5 weeks, titled (1) psychiatry: how does it work? (2) recovery: what is helpful? (3) other resources in society, (4) relations and disclosure, and (5) personal tools. Health care staff from the psychiatry organization and researchers were invited as either coleaders or subject matter experts.

Outer Context

The outer setting of the Patient School was the Region Stockholm, Sweden, a comprehensive psychiatry organization, covering in-hospital care as well as outpatient services. The commitment of the organization to use patient-centered practices and ensure user influence and involvement was shown by the employment of persons with user experience as part of the permanent staff.

Inner Setting

The inner setting was the outpatient departments offering facilities for inpatients and outpatients to join the Patient School, organized by the salaried staff with user experience. The school was backed by supporting clinical staff, informing them about the Patient School, and participating in the active recruitment of participants. A barrier was the lack of earmarked funding and dedicated venues.

Individuals

The individuals involved were high-level managers having instituted the functions of user-involvement coordinators and staff with user experience and supporting their various initiatives. The school organizers benefited from their own user experience as well as being salaried staff of the organization. Clinical staff that had positive attitudes to user involvement participated in recruiting participants as well as contributed with information and expert advice. Finally, service users were active participants, sharing their experiences, and supporting the continuous improvement of school activities by giving regular feedback.

Implementation Process

The implementation process was characterized by the school content, covering practical information on services and support available, as well as skills training, and the creation of a safe environment for sharing experience by the example of the course leaders. Success factors facilitating the implementation process were an *open door policy* psychiatry staff actively informing service users of the Patient School, the lived experience of the course leaders, positive attitudes among some professional staff, and course leaders' attention to participant feedback. Barriers to successful implementation were a lack of dedicated resources, negative attitudes among some staff who had doubts about the benefits of the Patient School, and instances where course leaders or participants dwelled too much on sharing personal experiences, thus impeding an open discussion and reflection process.

Discussion

Principal Findings

In our study, focusing on the implementation of a recovery college–like Patient School organized by persons with user experience within a psychiatry organization, we identified activities and attitudes that had both positive and negative impacts, that is, that could be both hindering and promoting factors. In terms of *recruitment*, the lack of both knowledge about the Patient School among staff and contacts with user-involvement coordinators and staff with user experience were barriers, whereas staff actively informing potential participants, the information provided during other user-activating courses, and the open-door policy created opportunities to reach out to potential participants more broadly. As to *resources*, educational activities such as the Patient School were not included in the reimbursement scheme for the psychiatry organization and were consequently felt to compete with service provision generating income, thus reducing the possibility for staff to contribute and salaried staff with user experience to take on organizer duties. In contrast, dedicated funds for the Patient School would remove those barriers and make it possible to pay honorariums to external experts. A dedicated venue would also be helpful to course organizers. Negative *attitudes among staff* were demonstrated as a negative attitude toward employees with user experience and suspicions about the value of the Patient School, change resistance, and negative views on patient involvement and empowerment in general. Staff who saw evidence of the value of the Patient School had a positive attitude and recommended patients to join the school. The *ways of organizing* the school had negative as well as positive consequences. When course leaders spent too much time on their own experiences and let a single participant dominate the discussions, other participants felt uneasy. In contrast, those course leaders who shared their own experiences encouraged participants to express their own concerns. Course leaders who gave everybody space and paid attention to participant feedback were appreciated. However, some expert contributions being out of touch with Patient School principles were seen as disturbing, whereas the course material was assessed as proper and useful. In summary, course leaders, participants, and staff identified the following facilitators of successful implementation: active recruitment of participants at wards and outpatient departments, information freely available in the same locations, a dedicated budget and venue for course activities, active moderation of discussions during courses, responding to participant needs, adjusting the group dynamics, and paying attention to the feedback by course participants.

The Patient School was favorably assessed by participants, staff, and organizers as shown in a previous report by Reinius et al [15]. The perceived value was enhanced by the willingness of peer organizers to share their own experiences, thus creating a sense of belonging and a forum for sharing experiences with like-minded people. In that environment, new knowledge, practical skills, roles, and attitudes were acquired. These experiences felt empowering, and they decreased stigma and reassured participants that one's identity is not defined by mental health issues.

The thick description of the Patient School based on the comprehensive data reported enables an attempt to present a tentative explanation for these positive outcomes. One way of conceptualizing such a *program theory* is to build on the analysis performed by using the Consolidated Framework for Implementation Research framework [19].

The regional psychiatry organization offered a favorable *outer setting* as demonstrated by its long-term commitment to patient-centered practices and ensuring user influence and involvement. An equally favorable *inner setting* was the outpatient departments providing facilities for the Patient School and allowing their salaried staff with user experience to organize the school, although the lack of dedicated funding and venues was seen as impeding school activities. *Individuals* contributing to the Patient School's success were the user-involvement coordinators and staff with user experience as course organizers, clinical staff with positive attitudes to user involvement who helped to recruit participants and provide those with information and expert advice, and, finally, service users actively participating and sharing their personal experience. The *implementation process* was guided by the school content, providing practical information on services and support available as well as skills training. The willingness of the course leaders to share their experiences as service users was instrumental to creating a safe environment for participants, enabling them to openly discuss and reflect.

As emphasized in the *Introduction* section, although there are a number of evaluation studies reporting the benefits of recovery colleges and educational activities, implementation processes and experiences are rarely described. However, we find some support for our tentative explanatory model. The *enabling environment* of a recovery college has been said to be a key driver of positive experiences among users and families. Challenges are delays in course standardization and enrollment and attendance procedures. Such barriers can be overcome with a supporting outer setting as well as an inner setting with dedicated staff with user experience and supportive clinical staff [13].

On a more overarching level, the importance of certain characteristics of outer and inner settings has been reported. When assessing several recovery programs, Whitley et al [22] found 4 cross-site themes with an impact on success or failure. They were leadership, organizational culture, training, staff, and supervision. Moreover, they have implications for the implementation process. Other authors highlight the importance of values. Program aims and policies but also practices such as recruitment, staffing, and documentation should be *recovery compatible* [23].

A more practical approach, as used by Smith-Merry et al [24] in Scottish recovery activities, gives useful hints on implementation processes as well. They recommend the application of 4 recovery technologies: recovery narratives (as practiced in the Patient School), the *Scottish Recovery Indicator*, which measures the extent to which services are implementing a recovery-oriented practice model, a structured tool for service users to manage their own recovery, and peer support. While we did not explore the direct influence of the Patient School on the clinical practice, findings indicate that those elements might be found in the Patient School implementation program. The Patient School provided, for example, participants with tools and practices to cope with their challenges and those were assessed in discussions during the sessions. Exchange of lived experience and peer support was a central part of the program.

Finally, not surprisingly, issues on planning and resources are also raised in the literature. Burhouse et al [25] emphasized that when organizing a recovery activity as a continuous improvement, project time for planning is warranted, and *sustainability planning needs resources from the start*. The authors also emphasize the importance of finding a robust measure of the long-term cost-benefit to ensure support from decision makers.

Strengths and Limitations

This study has strengths as well as weaknesses. It describes a case from 1 psychiatry organization in Sweden and is based on a limited group of interviewees. Attempts to transfer the findings to other contexts must be done with caution [26]. However, this study is focused on the context and processes of implementation, which is an angle seldom chosen in studies evaluating recovery colleges and other educational interventions in psychiatric care. Despite being, in essence, a case study, it adopts a framework, widely used in implementation research, enabling us to present a tentative explanatory model for a recovery college, experienced as being valuable by participants. It shows what features in the context might contribute to the positive impact, as well as the importance of individuals such as organizers with user experience, preconditions in terms of resources, and specifics of the implementation process, the most important being an *open door policy* and *giving everybody space*. Other sites and organizations would be well-advised to pay attention to these features when organizing recovery colleges aiming at strengthening psychiatry service users' self-management skills and reducing their sense of stigma. Future studies performed in other contexts and comparing different sites would develop and deepen the understanding of the successful implementation of recovery colleges.

Conclusions

Conditions that will support recovery colleges to reach their goals of empowering psychiatry service users include, first, allocating dedicated resources and engaging, as organizers, individuals with user experience who are willing to share their personal experience. An additional benefit is provided by these organizers working in-house as salaried employees. It is equally important to have an open-door policy, create an open space for participants to share, and offer practical advice and written material that are felt to be useful. Future studies comparing various sites would enhance and broaden our comprehension of the effective implementation of recovery colleges across different contexts.

Data Availability

The data sets generated during and analyzed during this study are not publicly available due (due to the nature of this research, interviewees of this study did not agree for their data to be shared publicly) but are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Timeline of respondent recruitment.
[DOCX File , 14 KB - jopm_v16i1e55882_app1.docx]

References

1. Davidson L. The recovery movement: implications for mental health care and enabling people to participate fully in life. Health Aff (Millwood) 2016 Jun 01;35(6):1091-1097 [FREE Full text] [doi: 10.1377/hlthaff.2016.0153] [Medline: 27269027]
2. Perkins R, Repper J, Rinaldi M, Brown H. Implementing recovery through organisational change. Centre for Mental Health, NHS Confederation Mental Health Network. 2012. URL: https://www.researchgate.net/publication/360522982_Recovery_Colleges_-_Implementing_Recovery_through_Organisational_Change [accessed 2024-08-13]
3. Burns H. Health in Scotland 2010: Assets for Health. Annual Report of the Chief Medical Officer 2010;Edinburgh:A [FREE Full text]
4. By inspiring hope, empowering change, and transforming practices, Imroc is dedicated to creating a world where we all have the opportunity to live well and feel included. Imroc. URL: https://www.imroc.org/ [accessed 2024-04-29]
5. Thériault J, Lord MM, Briand C, Piat M, Meddings S. Recovery colleges after a decade of research: a literature review. Psychiatr Serv 2020 Sep 01;71(9):928-940. [doi: 10.1176/appi.ps.201900352] [Medline: 32460684]
6. Meddings S, McGregor J, Roeg W, Shepherd G. Recovery colleges: quality and outcomes. Ment Health Soc Incl 2015;19(4):212-221 [FREE Full text] [doi: 10.1108/MHSI-08-2015-0035]
7. Ebrahim S, Glascott A, Mayer H, Gair E. Recovery colleges; how effective are they? J Ment Health Train Educ Pract 2018;13(4):209-218. [doi: 10.1108/jmhtep-09-2017-0056]
8. Zabel E, Donegan G, Lawrence K, French P. Exploring the impact of the recovery academy: a qualitative study of recovery college experiences. J Ment Health Train Educ Pract 2016;11:162-171.
9. Crowther A, Taylor A, Toney R, Meddings S, Whale T, Jennings H, et al. The impact of recovery colleges on mental health staff, services and society. Epidemiol Psychiatr Sci 2018 Oct 23;28(5):481-488. [doi: 10.1017/s204579601800063x]
10. Wilson RC, Shenhav A, Straccia M, Cohen JD. The Eighty Five Percent Rule for optimal learning. Nat Commun 2019 Nov 05;10(1):4646 [FREE Full text] [doi: 10.1038/s41467-019-12552-4] [Medline: 31690723]
11. Hall T, Jordan H, Reifels L, Belmore S, Hardy D, Thompson H, et al. A process and intermediate outcomes evaluation of an Australian recovery college. J Recovery Ment Health 2018;1(3):7-20 [FREE Full text]
12. Slade M, Amering M, Farkas M, Hamilton B, O'Hagan M, Panther G, et al. Uses and abuses of recovery: implementing recovery-oriented practices in mental health systems. World Psychiatry 2014 Feb;13(1):12-20 [FREE Full text] [doi: 10.1002/wps.20084] [Medline: 24497237]
13. Ali I, Benkwitz A, McDonald P. Setting up a recovery college: exploring the experiences of mental health service-users, staff, carers and volunteers. J Psychosocial Rehab Ment Health 2022 Aug 22;10(2):157-166 [FREE Full text] [doi: 10.1007/s40737-022-00295-3]
14. Peters DH, Adam T, Alonge O, Agyepong IA, Tran N. Implementation research: what it is and how to do it. BMJ 2013 Nov 20;347:f6753. [doi: 10.1136/bmj.f6753] [Medline: 24259324]
15. Reinius M, Al-Adili L, Rodriguez IH, Stenfors T, Brommels M. Assessing the perceived value of a user-led educational intervention to support recovery in a Swedish psychiatric organization: a qualitative case study. Health Expect 2024 Jun;27(3):e14064 [FREE Full text] [doi: 10.1111/hex.14064] [Medline: 38695287]
16. Flick U. The SAGE Handbook of Qualitative Data Collection. Thousand Oaks, CA: SAGE Publications; 2017.
17. Lin E, Harris H, Black G, Bellissimo G, Di Giandomenico A, Rodak T, et al. Evaluating recovery colleges: a co-created scoping review. J Ment Health 2023 Aug;32(4):813-834. [doi: 10.1080/09638237.2022.2140788] [Medline: 36345859]
18. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007 Dec;19(6):349-357 [FREE Full text] [doi: 10.1093/intqhc/mzm042] [Medline: 17872937]

19. Damschroder LJ, Reardon CM, Widerquist MA, Lowery J. The updated Consolidated Framework for Implementation Research based on user feedback. Implement Sci 2022 Oct 29;17(1):75 [FREE Full text] [doi: 10.1186/s13012-022-01245-0] [Medline: 36309746]
20. Patients in the driver's seat! A multimethod partnership program on patient-driven innovations. Karolinska Institutet. URL: https://ki.se/en/lime/research-groups-and-units-at-lime/medical-management-centre-mmc/patients-in-the-drivers-seat-a-multimethod-partnership-program-on-patient-driven-innovations [accessed 2024-08-13]
21. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res 2005 Nov;15(9):1277-1288 [FREE Full text] [doi: 10.1177/1049732305276687] [Medline: 16204405]
22. Whitley R, Gingerich S, Lutz WJ, Mueser KT. Implementing the illness management and recovery program in community mental health settings: facilitators and barriers. Psychiatr Serv 2009 Feb;60(2):202-209. [doi: 10.1176/ps.2009.60.2.202] [Medline: 19176414]
23. Farkas M, Gagne C, Anthony W, Chamberlin J. Implementing recovery oriented evidence based programs: identifying the critical dimensions. Community Ment Health J 2005 Apr;41(2):141-158 [FREE Full text] [doi: 10.1007/s10597-005-2649-6] [Medline: 15974495]
24. Smith-Merry J, Freeman R, Sturdy S. Implementing recovery: an analysis of the key technologies in Scotland. Int J Ment Health Syst 2011 May 15;5(1):11 [FREE Full text] [doi: 10.1186/1752-4458-5-11] [Medline: 21569633]
25. Burhouse A, Rowland M, Marie Niman H, Abraham D, Collins E, Matthews H, et al. Coaching for recovery: a quality improvement project in mental healthcare. BMJ Qual Improv Rep 2015;4(1):u206576.w2641 [FREE Full text] [doi: 10.1136/bmjquality.u206576.w2641] [Medline: 26734387]
26. Stenfors T, Kajamaa A, Bennett D. How to … assess the quality of qualitative research. Clin Teach 2020 Dec;17(6):596-599. [doi: 10.1111/tct.13242] [Medline: 32790137]

Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research

Edited by M Hudson, K Fortuna; submitted 28.12.23; peer-reviewed by S Soklaridis, A Nordin; comments to author 01.02.24; revised version received 01.03.24; accepted 09.07.24; published 12.09.24.

Please cite as:
Al-Adili L, Malmqvist M, Reinius M, Helispää Rodriguez I, Stenfors T, Brommels M
Implementation of a Recovery College Embedded in a Swedish Psychiatry Organization: Qualitative Case Study
J Particip Med 2024;16:e55882
URL: https://jopm.jmir.org/2024/1/e55882
doi:10.2196/55882
PMID:

Original Paper

Examining the Spillover Economic Impacts of Caregiving Among Families of Children With Medical Complexity to Inform Inclusive Economic Models: Qualitative Study

Jessica Keim-Malpass[1], RN, CPNP-AC, PhD; K Jane Muir[2], FNP-BC, PhD; Lisa C Letzkus[3], RN, CPNP-AC, PhD; Eleanore Scheer[4], BS; Rupa S Valdez[4,5], PhD

[1]Division of Pediatric Hematology-Oncology, Department of Pediatrics, University of Virginia School of Medicine, Charlottesville, VA, United States
[2]School of Nursing, University of Pennsylvania, Philadelphia, PA, United States
[3]Division of Developmental Medicine, Department of Pediatrics, University of Virginia School of Medicine, Charlottesville, VA, United States
[4]Department of Systems and Information Engineering, University of Virginia School of Engineering, Charlottesville, VA, United States
[5]Department of Public Health Sciences, University of Virginia School of Medicine, Charlottesville, VA, United States

Corresponding Author:
Jessica Keim-Malpass, RN, CPNP-AC, PhD
Division of Pediatric Hematology-Oncology
Department of Pediatrics
University of Virginia School of Medicine
P.O. Box 800386
1215 Lee Street
Charlottesville, VA, 22908
United States
Phone: 1 4349240000
Email: jlk2t@virginia.edu

Abstract

Background: Children with medical complexity represent a heterogeneous group of children with multiple chronic health care conditions. Caregivers of children with medical complexity experience a high intensity of caregiving that is often variable, extends across several networks of care, and often lasts for the entirety of the child’s life. The spillover, or indirect, economic impacts of caregiving are understudied in the context the family units of children with medical complexity. There have been recognized limitations to the sole use of quantitative methods when developing economic models of disease, because they lack direct caregiver voice and context of caregiving activities, and existing methods have been noted to be ableist.

Objective: This study aimed to explore the economic spillover impacts of caregiving among families of children with medical complexity using their own words and perspectives, with the intent of expanding caregiver-centered perspectives when developing economic models.

Methods: This study was a secondary analysis of a qualitative study that was conducted to examine family management practices among caregivers of children with medical complexity and their social networks. Caregivers of children with medical complexity were recruited through a pediatric complex care clinic at an academic medical center in the mid-Atlantic region, United States. This study used inductive qualitative descriptive methods and a template to define features of the person impacted and to define the economic construct as either a direct or indirect (spillover) cost.

Results: A total of 20 caregivers were included in this study. Perspectives from the caregivers of children with medical complexity revealed several key themes: (1) time lost from employment, impacting the primary caregivers; (2) physical and mental health impacts, impacting the child themselves, siblings, and the primary caregivers; (3) impacts to leisure activities and self-care, impacting the child themselves, siblings, and the primary caregivers; and (4) impacts to the social network or social capital.

Conclusions: The themes described can be operationalized into inclusive family-centered models that represent the impacts of caregiving in the context of the family units of children with medical complexity. The use of qualitative methods to expand our development of quantitative economic models can be adapted to other populations where caregivers are involved in care. Caregivers can and should have an active voice in preference-based assessments that are operationalized in economic contexts to make them more inclusive.

International Registered Report Identifier (IRRID): RR2-10.2196/14810

(J Particip Med 2024;16:e60666) doi:10.2196/60666

KEYWORDS

caregiving; children with medical complexity; social network; qualitative; self-management; care coordination; economic evaluation; spillover; economic model; care; mobile phone

Introduction

Efforts to improve the value of health care services for patients, families, and payers have increasingly incorporated health economic evaluations that measure the costs and outcomes of health care services and interventions through causal methods, cost-effectiveness, cost-utility, or decision analyses [1,2]. Often underrepresented in these approaches are the inclusion of spillover effects, or the unintended economic externalities of studied disease states, interventions, or care models to relational entities beyond associated health outcomes or direct costs of health care services, such as the health impacts to family members and caregivers [3,4]. As such, the measurement of spillover effects captures a more comprehensive depiction of the cost outcomes and health impacts of affected groups and the potential impact on society [5].

Spillover effects are unintended, can be positive or negative, and can impact an entity beyond the initial person of interest. Studies evaluating spillover effects have advanced evidence on, for example, the spillovers of nurse burnout to emergency department patient outcomes, mental health burdens for caregivers of children with autism, the health impacts of caregiving, and parents' health insurance status on a child's school absenteeism [6-9]. Despite multifaceted approaches to evaluating spillover effects, their inclusion in health economic models is sparse and largely absent in literature involving children [10,11].

Economic models using a cost-effectiveness framework are often used in medical decision-making contexts to represent both present and future costs and benefits in evaluating novel therapeutics or health technologies [12]. A defining outcome of most cost-effective studies is the concept of the quality-adjusted life-year (QALY), which is the evaluation of perfectly healthy life-years after accounting for adverse effects of the condition and associated treatment. QALYs have been widely criticized for not equally valuing intervention benefits for those patients who are disabled compared with a nondisabled population [13]. This inherent perspective in quantitative valuation methods favoring nondisabled people likely contributes to societal structural ableism [14]. QALYs also only capture a small subset of potential benefits and ignore other more holistic elements of value, such as the value of equity, the value of hope, reduction in uncertainty, scientific spillovers, and so on [12]. Within this framework, economic spillover impacts on caregivers are rarely considered as elements of benefits and costs, and impacts on other members of the family and social network unit, like siblings, grandparents, and close friends, have not been widely reported in the economic literature. This lack of inclusion in economic decision-making models reduces the ability to make decisions that include the family context.

Children with medical complexity represent a heterogeneous group of children with multiple, chronic health care conditions that frequently use the health care system [15,16]. Children with medical complexity often require technology at home through the use of home-based mechanical ventilation, feeding interventions through gastrostomy tubes, and home-based intravenous infusions [17,18]. Because of the intensity of care, the unpredictable nature of their disease course, and complex multimorbidity, much of the actual care of children with medical complexity occurs in the home and community-based settings [19]. Furthermore, many of the interventions of care require ongoing family management and communication across members of the caregiving network (family, friends, home-based nursing staff members, and members of the child's specialist providers and health care teams) [20].

There is substantial evidence documenting the economic impacts of caregiving, with most of the evidence focused on caregivers of older adults [4,9,21] and fewer focused on caregivers of children with medical complexity [11,22,23]. Economic effects among caregivers have been predominantly conceptualized as the direct valuing of caregiver time and, thus, underestimate opportunity costs, impacts on physical and mental health, impacts on employment, and impacts on other members of the household [21]. In general, studies demonstrate that unpaid caregivers are less likely to be used, are more likely to cut back on education, take more unpaid time off of work, work fewer hours, and are more likely to quit a job [21].

Surprisingly, caregiving costs are frequently not included in pediatric economic models despite the central nature of direct caregiving activities to children's health [10,11]. A 2023 systematic review assessing the inclusion of family spillover impacts in pediatric cost-utility analysis found that out of 878 pediatric cost-utility analyses, only 35 included any family spillover effects within the model development [11]. Including family or caregiver spillover impacts is critical in properly assessing the impact of a novel health intervention on the entire family unit, or when assessing the overall burden of disease. Further complicating this lack of economic evaluation of caregiving as it relates to children with medical complexity is that caregiving activities are often negotiated among parents or guardians as primary caregivers, but also extend into diverse informal caregiving networks, including extended family members and friends in the community [20,24]. Because of the broad expanse of caregiving activity, broadly classified as family management of children with medical complexity, the spillover economic impacts are likely more diffuse and should include impacts to other children or siblings living in the house. Second, caregivers may perform caregiving activities throughout the entire life of children with medical complexities, as the child may still require significant caregiving support into adulthood.

There have been recognized limitations to the sole use of quantitative methods for economic evaluations, and there is emerging epistemological diversity in support of qualitative methods that can underpin a holistic approach to family- and caregiver-centered perspectives [3,25-28]. Expanding traditionally quantitative economic modeling frameworks to explicate family and caregiver benefits and costs of caregiving are necessary to make equitable individual, system, and societal decisions. By engaging with communities directly and understanding the experiences of caregiving through their own words and perspectives, we can include the spillover impacts they describe as important within economic models. Herein, we conducted a secondary analysis of a qualitative study assessing the negotiation of self-management tasks among caregivers of children with medical complexity and their social networks, to develop a broader understanding of the economic spillover impacts of caregiving for children with medical complexity using their own words and perspectives [20,24].

Methods

Design and Participants

Details of the primary qualitative study design and involvement of members of the social network can be found elsewhere [20,24,29]. Caregivers were recruited in a mid-Atlantic pediatric complex care clinic through purposive sampling. Caregivers could be included if they were primary caregivers (either parent or legal guardian), were younger than 18 years of age, were English speakers, and lived in the same household as the children with medical complexity. Children with medical complexity classification was defined using the Center of Excellence on Quality of Care Measures for Children with Complex Needs, because the complex care clinic that we recruited from uses this definition for referral patterns. By this definition, we identified children with medical complexity as those younger than 21 years with chronic conditions impacting 2 or more body systems, requiring resources beyond what is typical for most children, and relying on ongoing care management [30].

Primary caregivers were the focus of this secondary analysis. Clinical and demographic characteristics of the participants were collected so that the investigators could sample to ensure diversity in the types of children with medical complexity (body systems impacted, age, and technology dependence). Clinical characteristics were self-described by the caregivers themselves. Health literacy was assessed through a validated 3-question screen [31]. The interview guide was developed based on a theoretically-driven perspective to highlight the self-management experiences across families of children with medical complexity within diverse social networks and contextual environments [24]. The interviews were conducted from October 2019 through March 2021, which required flexibility in study conduct due to the evolution of the COVID-19 pandemic. Interviews were conducted over the phone, either in one more extended session or multiple shorter sessions throughout the week, based on the preference of the primary caregiver. While the interviews were conducted in a cross-sectional manner, either representing a singular day or week in time as a caregiver, the team used approaches from the interview guide to elicit longitudinal perspectives, both historically from the child's birth and thinking to the future care, on implications of the children with medical complexity. Interviews were transcribed verbatim and were approximately 40-75 minutes in length.

Analysis

Analysis was guided by qualitative description and thematic analysis, in which inductive approaches were applied to the entire dataset of primary caregiver interviews [32,33]. The first phase of analysis involved reading the transcripts and jotting memos of relevant contextual information related to the interview. The initial coding strategy was open based on elements of direct and indirect economic consequences and applied to the entire dataset. An a priori analytic template that identified direct versus indirect economic impacts guided the analysis informed by economic spillover literature [5,34]. The next phase involved transforming open codes into categories that may encompass several codes. In the final stage, a thematic analysis used underlying economic constructs, which aligned a final theme with the descriptive elements of the template analysis. This process allowed for themes conceptualized as model inputs in future economic models, outlining the people impacted and direct versus indirect or spillover costs. Attention to rigor and trustworthiness were handled through documentation of key analytic decisions, reflexivity practices including reflection on assumptions and positionality across roles (eg, researcher, clinician, and family member), epistemological perspectives of economic models, and review of the final themes by all members of the study team [35].

Ethical Considerations

The University of Virginia Institutional Review Board for Social and Behavioral Sciences approved this study (SBS 2182). Informed consent for each study participant was obtained verbally. Participants were given a US $40 gift card following the conclusion of the interviews to compensate for their time and energy. Privacy was maintained by deidentifying interviews and linking by participant ID code.

Results

Participant Characteristics

A total of 20 primary caregivers of children with medical complexity were included in this analysis. Across the sample of 20 caregivers of children with medical complexity, the participants were on average 34.9 (SD 7.9) years of age; they were mostly female (18/20, 90%), White (17/20, 85%), and with at least some college education or more (14/20, 70%; Table 1). The most common medical conditions that parents reported of their children (not mutually exclusive) were cerebral palsy (8/20, 40%), congenital anomaly or genetic syndrome (7/20, 35%), and behavioral or mental health (7/20, 35%). Half (10/20, 50%) of the sample had adequate health literacy, and the majority (16/20, 80%) of the sample had home and phone access to the internet.

The thematic analysis of the participant interviews resulted following themes: (1) time lost from employment, impacting the primary caregivers; (2) physical and mental health impacts, impacting the child themselves, siblings, and the primary caregivers; (3) impacts to leisure activities and self-care, impacting the child themselves, and the primary caregivers; (4) impacts to the social network or social capital. The themes described can be operationalized into inclusive family-centered models that represent the impacts of caregiving in the context of the family units of children with medical complexity (Figure 1). We also developed a hypothetical case exemplar to demonstrate how spillover impacts of caregiving can be included in economic models.

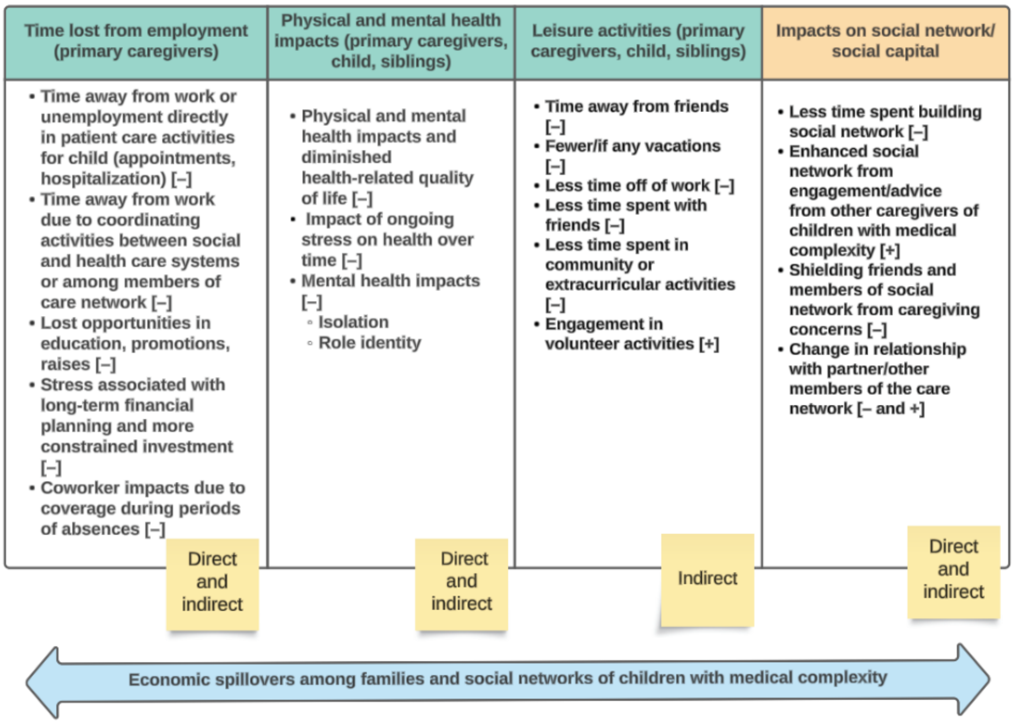
Table 1. Participant and child characteristics.

Participant characteristics (N=20)	Values
Age (years), mean (SD)	34.9 (7.9)
Missing, n (%)	2 (10)
Gender identity, n (%)	
Female	18 (90)
Male	2 (10)
Own cell phone, n (%)	
Yes	18 (90)
No	0 (0)
Missing	2 (10)
Own smartphone, n (%)	
Yes	17 (85)
No	1 (5)
Missing	2 (10)
Highest level of education, n (%)	
Less than high school	1 (5)
High school graduate or GED[a]	3 (15)
Some college	9(45)
2-year college degree	1 (5)
4-year college degree	4 (20)
Missing	2 (10)
Race, n (%)	
White	17 (85)
Black	2 (10)
Missing	1 (5)
Health literacy, n (%)	
Adequate	10 (50)
Marginal or limited	8 (40)
Missing	2 (10)
Access internet, n (%)	
Home and phone	16 (80)
Phone only	2 (10)
Missing	2 (10)
Medical conditions of the child (not mutually exclusive), n (%)	
Prematurity	5 (25)
Chronic lung disease	5 (25)
Cerebral palsy	8 (40)
Epilepsy	6 (30)
Brain tumor	1 (5)
Congenital heart disease	3 (15)
Feeding difficulty or poor weight gain	3 (15)
Congenital anomaly or genetic syndrome	7 (35)
Behavioral or mental health	7 (35)

Participant characteristics (N=20)	Values
Endocrine	1 (5)
Technology dependence of child (not mutually exclusive), n (%)	
Home oxygen requirement	3 (15)
Gastrostomy tube	3 (15)

[a]GED: General education diploma.

Figure 1. Representation of direct and indirect spillover economic impacts of children with medical complexity on caregiver and family units.



Time lost from employment (primary caregivers)

- Time away from work or unemployment directly in patient care activities for child (appointments, hospitalization) [–]
- Time away from work due to coordinating activities between social and health care systems or among members of care network [–]
- Lost opportunities in education, promotions, raises [–]
- Stress associated with long-term financial planning and more constrained investment [–]
- Coworker impacts due to coverage during periods of absences [–]

Physical and mental health impacts (primary caregivers, child, siblings)

- Physical and mental health impacts and diminished health-related quality of life [–]
- Impact of ongoing stress on health over time [–]
- Mental health impacts [–]
    - Isolation
    - Role identity

Leisure activities (primary caregivers, child, siblings)

- Time away from friends [–]
- Fewer/if any vacations [–]
- Less time off of work [–]
- Less time spent with friends [–]
- Less time spent in community or extracurricular activities [–]
- Engagement in volunteer activities [+]

Impacts on social network/ social capital

- Less time spent building social network [–]
- Enhanced social network from engagement/advice from other caregivers of children with medical complexity [+]
- Shielding friends and members of social network from caregiving concerns [–]
- Change in relationship with partner/other members of the care network [– and +]

Theme 1: Time Lost From Employment

The first theme representing time investment in caregiving (Textbox 1 includes qualitative exemplars), encompasses several categories including time involved in the coordination of direct care, energy in financial navigation (reimbursement and insurance coverage), time required for information seeking, and the requirement for future financial planning (requiring both time and emotional energy). This theme also includes both direct and indirect or spillover economic implications. The direct financial impacts are elements such as time away from work due directly to patient care activities, coordination of care, financial and disease navigation, and so on. In addition, there may be interruptions to employment, loss of employment, opportunity costs from loss of promotion, raises, and so on. One caregiver describes as follows:

> *Well, I had a job before he came home, and then once he was home, I didn't go back.* [Participant 8]

Another caregiver said the following:

> *I don't work outside the house. My plan was to go back to work after she was born, but once we realized all of the doctor's appointments and therapy appointments, it was just gonna be too difficult. I needed to be home to be her caregiver.* [Participant 9]

Participants describe the mental energy and countless hours spent in the context of information seeking and communication between medical teams and members of the social network. Numerous participants also discussed the time spent on future financial and long-term planning to ensure care coverage of their child for both the near and distant future. There are indirect economic implications to this theme as well. One example is the stress associated with short and long-term financial planning, which impacts mental and physical health and constrains investment opportunities. Finally, there are indirect impacts on the socio-organizational work environment surrounding caregivers, who are able to remain in the workforce but may experience interruptions within their workday or unexpected days off of work. Coworkers may have to cover more duties or feel resentful of the caregiver, which could negatively impact the work team.

Textbox 1. Qualitative exemplars: time investment (time away from employment for direct caretaking).

Theme

- Time lost from employment

Categories

- Coordination of direct care
- Energy in navigation of reimbursement, insurance, and coverage
- Information seeking
- Future financial planning (time)

Exemplars

- *[We have to take turns with appointments because of work] Between therapies and doctor appointments, yup. There's like ten every month [rotates with partner and mother].* [Participant 1]
- *They offer support when they're visiting. They offer emotional support to my wife and I on phone calls or if we go to visit them, but big-picture plan is just us.* [Participant 5]
- *I call them because no one knows. Yeah. There's no making sense of it. There've been times where I have called between the office billing for a service and our primary insurance and then Medicaid 6 or eight times and gotten a different story every single time. Then suddenly magically, something resolved and no one knows why. I pretty much resigned myself to a couple full days on the phone and try not to cry.* [Participant 6]
- *The insurance especially when he [child with medical complexity] was first—when he first came out of the hospital, part of the reason why I didn't go back to work as soon as I—we had gotten to a point where we were ready for me to go back to work, but I took an extra—I took a lot of extra time because I was dealing with all of the insurance and everything else and trying to get him on Medicaid and all of the other things that went about with. Right now, a little bit of that has calmed down because we're—he's enrolled in Medicaid. A lot of that is set up now. In the beginning, it was figuring all that out, figuring out what he could be eligible for, fighting the insurance companies on things until we were on Medicaid and everything else that had to happen, made it so that I lost a lot of—I'm an hourly employee, so it made it so that I lost a lot of hours at work and days at work and income.*[Participant 7]
- *There were coworkers [that helped]. There's the employers who gave me some flexibility. There's the coworkers who stepped in to cover us in certain ways. There was the support of friends and family and community who came to the hospital to give us support, or family who came and stayed with us to help us immediately post-op.* [Participant 7]
- *Hours and hours of phone calls and pressure and talking to people and different organizations. There was some help from care coordinators through early intervention and social services and some—yeah. We reached out and got a little bit of help from a number of people, but it's—I don't know if some of it was just because of the unique situations of his condition, but it also—we felt like we were very lucky that both of us were able to take time off work and were able to invest the time in making the phone calls, doing the research, getting him evaluated by social services, getting him evaluated by early intervention, all of these programs, which I don't know that—we were able to do all of that because we were very motivated, and we were taking the initiative. I didn't feel like the support system that's out there was really very aggressive at finding ways to help us necessarily*. [Participant 7]
- *Well, I had a job before he came home, and then once he was home, I didn't go back.* [Participant 8]
- *I don't work outside the house. My plan was to go back to work after she was born, but once we realized all the doctor's appointments and therapy appointments, that thing, it just was gonna be too difficult. I needed to be able to be home to be her caregiver.* [Participant 9]
- *We are constantly planning for the future in terms of financially, trying to prepare for the day that my husband and I no longer can take care of her.* [Participant 9]
- *Financially, yes, we are always preparing for the future. In terms of a plan while I'm still living, and I'm still capable of taking care of her, that's the plan. Even in five short years, we have learned that this life of raising a child with medical complexity, the only consistent thing about it is its inconsistency. Things change constantly. It doesn't really matter how we plan. A lotta times it typically doesn't go to plan. That's not necessarily to say that it changes in a bad way. Sometimes we get surprised, and we get blessed with something that we didn't see coming, something as simple as a new waiver that we qualify for.* [Participant 9]

Theme 2: Physical and Mental Health Impacts

The next theme broadly encompasses the physical and mental health impacts of chronic care and uncertainty on the health-related quality of life of children with medical complexity, siblings, and primary caregivers (Textbox 2 includes qualitative exemplars). The direct physical and mental health impacts can be represented in health economic models. One qualitative exemplar highlights this in the following way:

> *I have Crohn's disease that whenever I get too stressed it starts to flare up. So it's pretty much a circle. If she's sick, I get sick because I get too stressed.* [Participant 1]

Feeding much of these experiences are the chronic and uncertain nature of the illness trajectory, the changes in role identity both within and outside of the family, and the mental health impacts of the isolation caused by chronic caregiving. As described by 1 participant:

> *It's stressful. It's difficult. It's exhausting. It's nonstop. There are days that are significantly better, there are time periods that are better, but those are still stressful and still tiring and everything.* [Participant 7]

There are several indirect or spillover impacts especially as it relates to the chronic nature of physical and mental health impacts such as the ability to participate in school, attend work, or engage in the community.

Textbox 2. Qualitative exemplars: physical and mental health impacts.

Theme

- Physical and mental health impacts

Categories

- Chronic illness as caregivers
- Mental health: isolation
- Mental health: role identity
- Mental health: emotional energy future planning

Exemplars

- *[I have] Crohn's disease that whenever I get too stressed it starts to flare up. So it's pretty much a circle. If she's sick, I get sick because I get too stressed.* [Participant 1]
- *I think, I mean, I have people who are in my social network who are helpful with the kids and that's wonderful. I think having people that aren't necessarily helping with the kids, that are just good with the kids, that enjoy them and enjoy being around, that's a pretty huge thing. Because it's very easy to feel isolated when you're a caregiver*. [Participant 6]
- *Because that reminds me that I'm not just [child with medical complexity]'s mom and I'm not just the caregiver. There has to be balance.* [Participant 6]
- *It's stressful, difficult, exhausting, and nonstop. There are days that are significantly better, and there are time periods that are better, but those are still stressful and still tiring and everything. They're just less so than the bad days.* [Participant 7]
- *I don't know. We just don't know where [child with medical complexity]'s gonna be when he's an adult. We have issues with him learning. One day he can do certain things, and it's another day he doesn't know any of what—he doesn't retain what he's learned. We have already made arrangements if something happened to myself and my husband that our older son—if something were to happen to us by the time they're 21, he would take over that care. It's just a what if.* [Participant 18]

Theme 3: Impacts on Leisure Activities and Self-Care

Many participants described the challenges of relaxing with friends, taking time for themselves, and planning activities for leisure, such as vacations (Textbox 3 includes qualitative exemplars). The economic implications of this are predominantly in the indirect or spillover context, as the lack of time to be by themselves, engage in leisure activities, and lack of time or resources for self-care directly contribute to the physical and mental health impacts of care and can certainly contribute to overall well-being at work and school. One participant described as follows:

> *All her [child with medical complexity] medication was not working well because she needed an adjustment on her medication plus the machine that we take down there broke on me when we were down there so it was a lot of stuff together and it completely ruined our vacation…since then we never take a vacation again.* [Participant 1]

Uniformly, none of the participants described any leisure activities, hobbies, or self-care activities that they were able to participate in.

Textbox 3. Qualitative exemplars: impacts on leisure activity.

Theme

- Impacts on leisure activities and self-care

Categories

- Primary caregivers, child, and sibling impacts

Exemplars

- *All her [child with medical complexity] medication wasn't working well because she needed an adjustment on her medication plus the machine that we took down there broke on me when we were down there, so it was a lot of stuff together and it completely ruined our vacation so yeah. That was the first thing that I can think about. Since then, we never take a vacation again just because we don't want none of that to happen again.* [Participant 1]
- *The other thing we notice is that if there's—let's go with a family picnic or something—other parents will kind of hang out around the table, having a drink, eating food, chatting with each other, things like that, while their kids run around and play and do all sorts of stuff. We miss out on that social interaction because we can't just sit back and let him go. We have to be sometimes physically helping him, other times just watching him in a way that other parents don't need to.* [Participant 7]

Theme 4: Social Network and Social Capital

Participants described significant changes in their social networks from both a direct and indirect or spillover perspective. Often social networks have narrowed from the people who were in their lives before the birth of children with medical complexity. One participant describes the nature of changed relationships within their own household:

> *Specifically it has changed the dynamic of our relationship. I rely on him for a lot more than I used to. I was always a very independent person. The toll that raising [child's name] put on me and me being her full-time caregiver changed me into not such an independent person and really needing to lean on him. That was a big change for both of us that we had to adapt to. Yeah, I'd say my relationship with my husband is the one that's changed the most.* [Participant 9]

Many of the participants were very self-aware of the reliance on the network and did not want them to be overburdened. The same participant describes it as follows:

> *We try to be as cognizant as possible-with our friends and families-not to wear anybody down too much with our issues.* [Participant 9]

Of note, these experiences were not uniformly negative in relation to members of the social network that were engaged after the birth of their children with medical complexity. In fact, there were several positive examples of how social networks have expanded in unexpected ways through connection with other families of children with medical complexity, and how they view the health care team as a social network and social capital expansion (Textbox 4).

Textbox 4. Qualitative exemplars: impacts on social network or social capital.

Theme

- Social network and social capital

Exemplars [participant]

- *[My social network] has narrowed. We have less contact with people who we used to have more contact with. We have less time to maintain relationships with people. Even when we get to see people within our social networks, our interactions with them are typically a little bit shallower because a certain portion of our attention is always devoted to [child with medical complexity].* [Participant 7]
- *[My social network] has gotten smaller*. [Participant 8]
- *We try to be as cognizant as possible about—with our friends and families, not to wear anybody down too much with our issues.* [Participant 9]
- *[Positive impact] I've been really fortunate. I know a lot of people, theirs [social network] have changed significantly. Mine really haven't other than growing. I've added people to them just through meeting people who have kids with special needs. Obviously, we have a lot more doctors and therapists and teachers and stuff or through us seeking out new activities for her [child with medical complexity] to participate in. We meet other people through those kinds of things. It's grown. I've been fortunate that it hasn't shrunk.* [Participant 9]
- *Yeah, I'd say my relationship with my husband is the one that's changed the most.* [Participant 9]

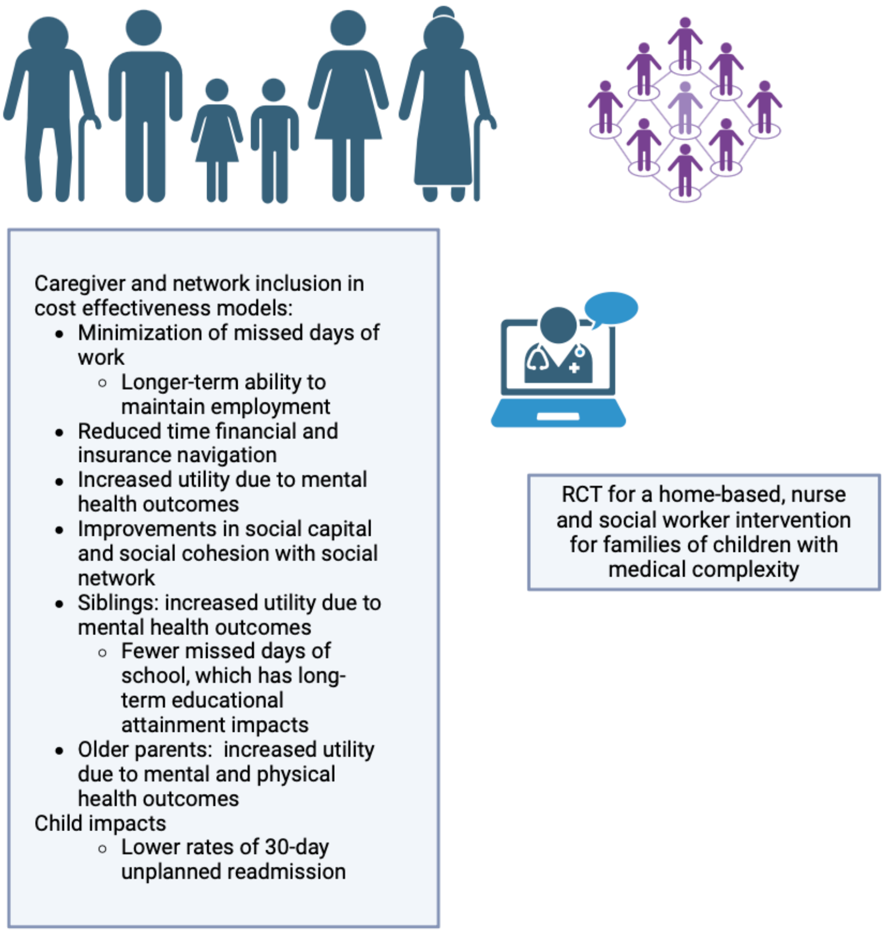
Hypothetical Case Exemplar of Using the Findings to Inform an Economic Model

A new randomized controlled trial (RCT) was recently published that demonstrated the efficacy of a family-centered, home-based dual nursing and social work model for children with medical complexity during the transition from the hospital to the home. The family-centered, home-based dual nursing and social work model included physical and mental health assessments for the children with medical complexity, caregivers, siblings, and caregivers’ older parents in the house, along with navigation services if referrals to additional medical providers were needed. The embedded social worker aided with completing the appropriate documentation for short- and long-term disability from caregivers’ places of employment. The social worker also provided resources for financial or insurance navigation services. Finally, they both provided connections for monthly in-person and virtual support groups for caregivers of children with medical complexity and another support group specifically for siblings of children with medical complexity. The RCT assessed the outcomes of the children with medical complexity, the caregivers, and the siblings. The study demonstrated that the children with medical complexity in the intervention arm had greater adherence to medication and therapies and lower rates of 30-day unplanned readmission. The caregivers in the intervention arm demonstrated improvement in mental health outcomes, had fewer days missed from work, had a lower proportion of caregivers having to leave work over 2 years, and spent less time on the phone with insurance companies. They also reported improvements in social cohesion and social capital because of the connection to other children with medical complexity families. Siblings in the household in the intervention arm demonstrated improvement in mental health outcomes and fewer days missed of school. The older parents in the household also reported improved physical and mental health outcomes.

The dual, embedded, home-based, nurse and social work model was costly given the amount of time in the home and the long travel for home-based visits. An economist wishes to demonstrate the cost-effectiveness of this intervention to assist health systems and payers in determining the economic value of this intervention.

Figure 2 highlights the ways in which the outcomes of the RCT can be included in a cost-effectiveness analysis, which includes the children with medical complexity, caregivers, as well as older parents and siblings in the household (Figure 2).

Figure 2. Broad view of economic impacts that can be included in a cost-effectiveness analysis based on the case exemplar. RCT: randomized controlled trial.



Caregiver and network inclusion in cost effectiveness models:
- Minimization of missed days of work
  - Longer-term ability to maintain employment
- Reduced time financial and insurance navigation
- Increased utility due to mental health outcomes
- Improvements in social capital and social cohesion with social network
- Siblings: increased utility due to mental health outcomes
  - Fewer missed days of school, which has long-term educational attainment impacts
- Older parents: increased utility due to mental and physical health outcomes

Child impacts
  - Lower rates of 30-day unplanned readmission

RCT for a home-based, nurse and social worker intervention for families of children with medical complexity

Discussion

Principal Findings

This novel approach uses qualitative data elicited from direct caregivers and allows health economists and health services researchers to expand their modeling perspectives to include broader caregiver, sibling, child, and social network spillover impacts. This study provides guidance for exploring caregiver-centered perspectives on elements of caregiving that impact their health-related quality of life, ability to engage in work or education activities with implications for community cohesion, and changes to social networks. While direct economic caregiver impacts of families with children with medical complexity have been explored [36-39], there have been very few economic models eliciting the overall burden of disease in the form of indirect or spillover impacts. There has been much less attention paid to how to translate these impacts into quantitative economic models, such as cost-effectiveness models, that include model parameters beyond the child themselves or direct caregiving impacts.

Caregiving time constraints directly impact numerous aspects of life, including time away from employment, loss or reduction of employment, interruptions to education, and opportunity costs in relation to loss of career advancement or other related opportunities [5,21,23,40]. Physical and mental health impacts can be quantified through the assessment of disutility through QALYs, potentially leading to an ableist assessment that can be discriminatory [13,41,42]. Methods have been developed to offset the ableist lens of the QALY such as a measure of the health years in total [43] and the equal-value life-year [44]. Despite the expanded methodological approaches to offset ableist epistemological underpinnings, only direct costs and benefits related to the patients themselves tend to be included in these modeling approaches. Spillover impacts, as reported here, are rarely fully considered nor included in economic modeling efforts [3].

Our thematic findings coincide with conceptual definitions of family spillover effects that have been previously published [11]. A 2023 systematic review found that conceptual definitions of family spillover impacts include the health and nonhealth effects experienced by family members due to a child's illness, disability, and treatment, encompassing physical and psychological health, emotional well-being, and quality of life [11]. They acknowledge that these impacts can not only be a result of direct caregiving tasks but also the result bearing witness to the enduring, decline, or death of their child [11]. Our findings extend previous definitions by also including social network members who engage in direct caregiving within these frameworks. Within this paradigm, family spillover impacts can be conceptualized as community spillover impacts.

Qualitative methods can extend traditional preference-based utility assessment to incorporate the lived experiences of those who are actively represented by these groups and expand our understanding of trade-offs of caregiving through the embedded context. They also can expand epistemological diversity by centering the perspectives of families caring for a child with medical complexity. As noted with the findings associated with the benefits of caregiving, caregivers of children with medical complexity often experience an expansion of a network of families in similar health situations and an expansion of a health care team that they generally trust to assist them with family management of their children with medical complexity. Positive aspects of caregiving are rarely considered with traditional economic perspectives, and there is immense opportunity to further assess the impact of network dynamics on economic outcomes and the effectiveness of health interventions. Even though our study did not demonstrate positive associations of caregiving on physical or mental health, there are certainly reported positive impacts of caregiving on stress and well-being [45]. This is one such example where reductionist utility assessments do not capture the full value of caregiving.

This work supports future methodological expansions of economic assessments to include a mixed methods perspective. Future research should work with caregivers to better understand their perception of the value of caregiving and then embed those perspectives into quantitative stated or revealed preference methods (such as discrete choice experience) to elicit utility values. Finally, qualitative methods can be used at the end of an economic modeling study again to present findings to caregiver stakeholders and get feedback on the quantitative model.

There are limitations to this analysis that we wish to acknowledge. While we used purposive sampling criteria based on child condition, the sample was still homogeneous with mostly White, female caregivers, with the majority having at least some access to at least some college education. The participants had levels of limited or marginal health literacy, which mimicked other real-world samples [46]. In addition, our study sample only included English speakers, which does not represent all families of children with medical complexity [47-49]. This study also was conducted in a single geographic region where state-based policies for children with medical complexity and home- and community-based care could impact the caregiving experience in various ways in terms of Medicaid coverage, access to durable medical equipment through Medicaid, and 1915/1115 home- and community-based waiver coverage. In addition, the sample was recruited from a comprehensive complex care clinic at an academic medical center, which connotes a high level of care coordination that likely takes place within the health system for children with medical complexity and their families. While we attempted to use approaches to garner longitudinal perspectives, interviews were still cross-sectional, taking place in either a single day or the course of a week. COVID-19 occurred in the middle of sample recruitment. Fortunately, the pandemic did not alter our study procedures, but it is unclear what impact the pandemic had on our recruitment or families' abilities to participate or the narratives shared with us. Finally, we relied on several demographic characteristics from the interviews themselves, several items were not reported on in a way that allowed for harmonized reporting.

Conclusion

Our work demonstrates that qualitative methods can provide an expanded perspective of traditionally quantitative economic models that relate to either assessing the effectiveness of health interventions directed toward children with medical complexity or the overall burden of disease for children with medical complexity and their families. Qualitative findings can be operationalized to help modelers build more inclusive and less ableist modeling perspectives. This method can and should be replicated in other populations where caregivers and social networks are involved in care. Caregivers can and should have an active voice in preference-based assessments that are operationalized in economic contexts. There is a defined need for interventions focused on caregivers of children with medical complexity focused on their own physical and mental health impacts, along with mitigation of financial toxicity. As demonstrated within this work, family spillover impacts can be conceptualized as community spillover impacts, given that members of the social network are also impacted. Finally, there is a critical need for this work to interface with those who are a part of the disability community, emphasizing the importance of understanding the intersection of other identities with disability in this context.

Conflicts of Interest

None declared.

References

1. Neumann PJ, Ganiats TG, Russell LB, Sanders GD, Siegel JE. In: Neumann PJ, Ganiats TG, Russell LB, Sanders GD, Siegel JE, editors. Cost-Effectiveness in HealthMedicine. Oxford, United Kingdom: Oxford University Press; 2016.
2. Sanders GD, Neumann PJ, Basu A, Brock DW, Feeny D, Krahn M, et al. Recommendations for conduct, methodological practices, and reporting of cost-effectiveness analyses: second panel on cost-effectiveness in health and medicine. JAMA 2016;316(10):1093-1093. [doi: 10.1001/jama.2016.12195] [Medline: 27623463]
3. Muir KJ, Keim-Malpass J. Analyzing the concept of spillover effects for expanded inclusion in health economics research. J Comp Eff Res 2020;9(11):755-766 [FREE Full text] [doi: 10.2217/cer-2020-0051] [Medline: 32543221]
4. Wittenberg E, James LP, Prosser LA. Spillover effects on caregivers' and family members' utility: a systematic review of the literature. Pharmacoeconomics 2019;37(4):475-499. [doi: 10.1007/s40273-019-00768-7] [Medline: 30887469]
5. Grosse SD, Pike J, Soelaeman R, Tilford JM. Quantifying family spillover effects in economic evaluations: measurement and valuation of informal care time. Pharmacoeconomics 2019;37(4):461-473 [FREE Full text] [doi: 10.1007/s40273-019-00782-9] [Medline: 30953263]
6. Basu A, Meltzer D. Implications of spillover effects within the family for medical cost-effectiveness analysis. J Health Econ 2005;24(4):751-773. [doi: 10.1016/j.jhealeco.2004.12.002] [Medline: 15960995]
7. Timmermans S, Orrico LA, Smith J. Spillover effects of an uninsured population. J Health Soc Behav 2014;55(3):360-374. [doi: 10.1177/0022146514543523] [Medline: 25138202]
8. Muir KJ, Wanchek TN, Lobo JM, Keim-Malpass J. Evaluating the costs of nurse burnout-attributed turnover: a markov modeling approach. J Patient Saf 2022;18(4):351-357. [doi: 10.1097/PTS.0000000000000920] [Medline: 35617593]
9. Lin P, D'Cruz B, Leech AA, Neumann PJ, Sanon Aigbogun M, Oberdhan D, et al. Family and caregiver spillover effects in cost-utility analyses of alzheimer's disease interventions. Pharmacoeconomics 2019;37(4):597-608. [doi: 10.1007/s40273-019-00788-3] [Medline: 30903567]
10. Lavelle TA, D'Cruz BN, Mohit B, Ungar WJ, Prosser LA, Tsiplova K, et al. Family spillover effects in pediatric cost-utility analyses. Appl Health Econ Health Policy 2019;17(2):163-174. [doi: 10.1007/s40258-018-0436-0] [Medline: 30350218]
11. Lamsal R, Yeh EA, Pullenayegum E, Ungar WJ. A systematic review of methods used by pediatric cost-utility analyses to include family spillover effects. Pharmacoeconomics 2024;42(2):199-217 [FREE Full text] [doi: 10.1007/s40273-023-01331-1] [Medline: 37945777]
12. Lakdawalla DN, Doshi JA, Garrison LP, Phelps CE, Basu A, Danzon PM. Defining elements of value in health care-a health economics approach: an ISPOR special task force report [3]. Value Health 2018;21(2):131-139 [FREE Full text] [doi: 10.1016/j.jval.2017.12.007] [Medline: 29477390]
13. Schneider P. The QALY is ableist: on the unethical implications of health states worse than dead. Qual Life Res 2022;31(5):1545-1552 [FREE Full text] [doi: 10.1007/s11136-021-03052-4] [Medline: 34882282]
14. Valdez RS, Swenor BK. Structural ableism - essential steps for abolishing disability injustice. N Engl J Med 2023;388(20):1827-1829. [doi: 10.1056/NEJMp2302561] [Medline: 37183982]
15. Cohen E, Kuo DZ, Agrawal R, Berry JG, Bhagat SKM, Simon TD, et al. Children with medical complexity: an emerging population for clinical and research initiatives. Pediatrics 2011;127(3):529-538 [FREE Full text] [doi: 10.1542/peds.2010-0910] [Medline: 21339266]
16. Berry JG, Hall M, Neff J, Goodman D, Cohen E, Agrawal R, et al. Children with medical complexity and medicaid: spending and cost savings. Health Aff (Millwood) 2014;33(12):2199-2206 [FREE Full text] [doi: 10.1377/hlthaff.2014.0828] [Medline: 25489039]
17. Trowbridge K, Mische-Lawson L. Families with children with medical complexity and self-management of care: a systematic review of the literature. Soc Work Health Care 2014;53(7):640-658. [doi: 10.1080/00981389.2014.916776] [Medline: 25133298]
18. Feudtner C, Feinstein JA, Zhong W, Hall M, Dai D. Pediatric complex chronic conditions classification system version 2: updated for ICD-10 and complex medical technology dependence and transplantation. BMC Pediatr 2014;14:199 [FREE Full text] [doi: 10.1186/1471-2431-14-199] [Medline: 25102958]

19. Keim-Malpass J, Constantoulakis L, Letzkus LC. Variability in states' coverage Of children with medical complexity through home and community-based services waivers. Health Aff (Millwood) 2019;38(9):1484-1490. [doi: 10.1377/hlthaff.2018.05413] [Medline: 31479354]
20. Keim-Malpass J, Lunsford C, Letzkus LC, Scheer E, Valdez RS. Establishing the need for anticipatory symptom guidance and networked models of disease in adaptive family management among children with medical complexity: qualitative study. JMIR Form Res 2023;7:e52454 [FREE Full text] [doi: 10.2196/52454] [Medline: 37801346]
21. Jacobs JC, van Houtven CH, Tanielian T, Ramchand R. Economic spillover effects of intensive unpaid caregiving. Pharmacoeconomics 2019;37(4):553-562. [doi: 10.1007/s40273-019-00784-7] [Medline: 30864064]
22. Arora S, Goodall S, Viney R, Einfeld S. Using discrete-choice experiment methods to estimate the value of informal care: the case of children with intellectual disability. Pharmacoeconomics 2019;37(4):501-511. [doi: 10.1007/s40273-018-0637-2] [Medline: 29512032]
23. Holdford D, Vendetti N, Sop DM, Johnson S, Smith WR. Indirect economic burden of sickle cell disease. Value Health 2021;24(8):1095-1101 [FREE Full text] [doi: 10.1016/j.jval.2021.02.014] [Medline: 34372974]
24. Valdez RS, Lunsford C, Bae J, Letzkus LC, Keim-Malpass J. Self-management characterization for families of children with medical complexity and their social networks: Protocol for a qualitative assessment. JMIR Res Protoc 2020;9(1):e14810 [FREE Full text] [doi: 10.2196/14810] [Medline: 32012094]
25. Stevens K, Palfreyman S. The use of qualitative methods in developing the descriptive systems of preference-based measures of health-related quality of life for use in economic evaluation. Value Health 2012;15(8):991-998 [FREE Full text] [doi: 10.1016/j.jval.2012.08.2204] [Medline: 23244799]
26. Dopp AR, Mundey P, Beasley LO, Silovsky JF, Eisenberg D. Mixed-method approaches to strengthen economic evaluations in implementation research. Implement Sci 2019;14(1):2 [FREE Full text] [doi: 10.1186/s13012-018-0850-6] [Medline: 30635001]
27. Niessen LW, Bridges J, Lau BD, Wilson RF, Sharma R, Walker DG, et al. Assessing the impact of economic evidence on policymakers in health care. A Systematic Review 2012;12(13):133. [Medline: 23236642]
28. Coast J, McDonald R, Baker R. Issues arising from the use of qualitative methods in health economics. J Health Serv Res Policy 2004;9(3):171-176. [doi: 10.1258/1355819041403286] [Medline: 15272976]
29. Scheer ER, Werner NE, Coller RJ, Nacht CL, Petty L, Tang M, et al. Designing for caregiving networks: a case study of primary caregivers of children with medical complexity. J Am Med Inform Assoc 2024;31(5):1151-1162. [doi: 10.1093/jamia/ocae026] [Medline: 38427845]
30. Simon TD, Cawthon ML, Popalisky J, Mangione-Smith R, Center of Excellence on Quality of Care Measures for Children with Complex Needs (COE4CCN). Development and validation of the pediatric medical complexity algorithm (PMCA) version 2.0. Hosp Pediatr 2017;7(7):373-377 [FREE Full text] [doi: 10.1542/hpeds.2016-0173] [Medline: 28634166]
31. Sarkar U, Schillinger D, López A, Sudore R. Validation of self-reported health literacy questions among diverse english and spanish-speaking populations. J Gen Intern Med 2011;26(3):265-271 [FREE Full text] [doi: 10.1007/s11606-010-1552-1] [Medline: 21057882]
32. Sandelowski M. Telling stories: narrative approaches in qualitative research. Image J Nurs Sch 1991;23(3):161-166. [doi: 10.1111/j.1547-5069.1991.tb00662.x] [Medline: 1916857]
33. Sandelowski M. Focus on research methods-whatever happened to qualitative description. Res Nurs Health 2000;23(4):334-340. [doi: 10.1002/1098-240x(200008)23:4<334::aid-nur9>3.0.co;2-g] [Medline: 10940958]
34. Wu Y, Al-Janabi H, Mallett A, Quinlan C, Scheffer IE, Howell KB, et al. Parental health spillover effects of paediatric rare genetic conditions. Qual Life Res 2020;29(9):2445-2454. [doi: 10.1007/s11136-020-02497-3] [Medline: 32266555]
35. Lincoln YS, Guba EG. Naturalistic Inquiry. Thousand Oaks, CA: SAGE Publications Inc; 1985 Apr. URL: https://us.sagepub.com/en-us/nam/naturalistic-inquiry/book842 [accessed 2020-11-28]
36. Romley JA, Shah AK, Chung PJ, Elliott MN, Vestal KD, Schuster MA. Family-provided health care for children with special health care needs. Pediatrics 2017;139(1):e20161287. [doi: 10.1542/peds.2016-1287] [Medline: 28028202]
37. ??Lindley; K. The Association between poverty and family financial challenges of caring for medically complex children. Nursing Economic 2019;34(4).
38. Guertin JR, Gilbert-Ouimet M, Dugas M, Carnovale V, Jalbert L, Svyntozelska O, et al. Methods used to account for caregivers' sex and gender within studies examining the financial burden of caregivers of children and adolescents : results from a scoping review. Clinicoecon Outcomes Res 2024;16:35-53 [FREE Full text] [doi: 10.2147/CEOR.S443077] [Medline: 38298908]
39. Allshouse C, Comeau M, Rodgers R, Wells N. Families of children with medical complexity: a view from the front lines. Pediatrics 2018;141(Suppl 3):S195-S201. [doi: 10.1542/peds.2017-1284D] [Medline: 29496970]
40. Mudrazija S. Work-related opportunity costs of providing unpaid family care In 2013 And 2050. Health Aff (Millwood) 2019;38(6):1003-1010. [doi: 10.1377/hlthaff.2019.00008] [Medline: 31158030]
41. Griebsch I, Coast J, Brown J. Quality-adjusted life-years lack quality in pediatric care: a critical review of published cost-utility studies in child health. Pediatrics 2005;115(5):e600-e614. [doi: 10.1542/peds.2004-2127] [Medline: 15867026]
42. Andrade G. Ethical shortcomings of QALY: discrimination against minorities in public health. Camb Q Healthc Ethics 2024:1-8. [doi: 10.1017/S0963180123000580] [Medline: 38221736]

43. Basu A, Carlson J, Veenstra D. Health years in total: a new health objective function for cost-effectiveness analysis. Value Health 2020;23(1):96-103 [FREE Full text] [doi: 10.1016/j.jval.2019.10.014] [Medline: 31952678]
44. Campbell JD, Whittington MD, Pearson SD. An alternative measure of health for value assessment: the equal value life-year. Pharmacoeconomics 2023;41(10):1175-1182. [doi: 10.1007/s40273-023-01302-6] [Medline: 37458912]
45. Amtmann D, Bamer AM, Salem R, Gammaitoni AR, Galer BS, Jensen MP. Translation and cultural validation of the university of Washington caregiver stress and benefit scales. J Patient Rep Outcomes 2021;5(1):113 [FREE Full text] [doi: 10.1186/s41687-021-00394-y] [Medline: 34718901]
46. Paasche-Orlow MK, Parker RM, Gazmararian JA, Nielsen-Bohlman LT, Rudd RR. The prevalence of limited health literacy. J Gen Intern Med 2005;20(2):175-184 [FREE Full text] [doi: 10.1111/j.1525-1497.2005.40245.x] [Medline: 15836552]
47. Edelstein H, Schippke J, Sheffe S, Kingsnorth S. Children with medical complexity: a scoping review of interventions to support caregiver stress. Child Care Health Dev 2017;43(3):323-333. [doi: 10.1111/cch.12430] [Medline: 27896838]
48. Odgis JA, Gallagher KM, Suckiel SA, Donohue KE, Ramos MA, Kelly NR, et al. The NYCKidSeq project: study protocol for a randomized controlled trial incorporating genomics into the clinical care of diverse New York City children. Trials 2021;22(1):56 [FREE Full text] [doi: 10.1186/s13063-020-04953-4] [Medline: 33446240]
49. Pilarz MS, Bleed E, Rodriguez VA, Daniels LA, Jackson KL, Sanchez-Pinto LN, et al. Medical complexity, language use, and outcomes in the pediatric ICU. Pediatrics 2024;153(6):e2023063359. [doi: 10.1542/peds.2023-063359] [Medline: 38747049]

Abbreviations

QALY: quality-adjusted life-year
RCT: randomized controlled trial

Edited by J Wald; submitted 17.05.24; peer-reviewed by R Coller, C Foster; comments to author 22.06.24; revised version received 30.09.24; accepted 01.11.24; published 30.12.24.

Please cite as:
Keim-Malpass J, Muir KJ, Letzkus LC, Scheer E, Valdez RS
Examining the Spillover Economic Impacts of Caregiving Among Families of Children With Medical Complexity to Inform Inclusive Economic Models: Qualitative Study
J Particip Med 2024;16:e60666
URL: https://jopm.jmir.org/2024/1/e60666
doi:10.2196/60666
PMID:38758728

Original Paper

The Effect of Using a Client-Accessible Health Record on Perceived Quality of Care: Interview Study Among Parents and Adolescents

Janine Benjamins[1,2,3], MD, PhD; Emely de Vet[1,4], PhD; Chloe A de Mortier[5,6,7], MSc; Annemien Haveman-Nies[1,8], PhD

[1]Chairgroup Consumption and Healthy Lifestyles, Wageningen University & Research, Wageningen, Netherlands

[2]Icare JGZ, Meppel, Netherlands

[3]Stichting Jeugd Noord Veluwe, Nunspeet, Netherlands

[4]University Collega Tilburg, Tilburg University, Tilburg, Netherlands

[5]Department of Health Services Research, Care and Public Health Research Institute, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, Netherlands

[6]School of Health Professions Education, Faculty of Health Medicine and Life Sciences, Maastricht University, Maastricht, Netherlands

[7]Knowledge Institute of Medical Specialists, Utrecht, Netherlands

[8]GGD Noord-en Oost Gelderland, Warnsveld, Netherlands

Corresponding Author:
Janine Benjamins, MD, PhD
Stichting Jeugd Noord Veluwe
Stationsplein 18E
Nunspeet, 8071 CH
Netherlands
Phone: 31 612329494
Email: j.benjamins@cjgnoordveluwe.nl

Abstract

Background: Patient-accessible electronic health records (PAEHRs) are assumed to enhance the quality of care, expressed in terms of safety, effectiveness, timeliness, person centeredness, efficiency, and equity. However, research on the impact of PAEHRs on the perceived quality of care among parents, children, and adolescents is largely lacking. In the Netherlands, a PAEHR (Iuvenelis) was developed for preventive child health care and youth care. Parents and adolescents had access to its full content, could manage appointments, ask questions, and comment on written reports.

Objective: This study aims to assess whether and how using this PAEHR contributes to perceived quality of care from a client's perspective.

Methods: We chose a qualitative design with a phenomenological approach to explore how parents and adolescents perceived the impact of using a PAEHR on quality of care. In-depth interviews that simultaneously included 1 to 3 people were conducted in 2021. In total, 20 participants were included in the study, representing parents and adolescents, both sexes, different educational levels, different native countries, and all participating municipalities. Within this group, 7 of 13 (54%) parents had not previously been informed about the existence of a client portal. Their expectations of using the client portal, in relation to quality of care, were discussed after a demonstration of the portal.

Results: Parents and adolescents perceived that using Iuvenelis contributed to the quality of care because they felt better informed and more involved in the care process than before the introduction of Iuvenelis. Moreover, they experienced more control over their health data, faster and simpler access to their health information, and found it easier to manage appointments or ask questions at their convenience. Parents from a migratory background, among whom 6 of 7 (86%) had not previously been informed about the portal, expected that portal access would enhance their understanding of and control over their care processes. The parents expressed concerns about equity because parents from a migratory background might have less access to the service. Nevertheless, portal usability was regarded as high. Furthermore, both parents and adolescents saw room for improvement in the broader interdisciplinary use of Iuvenelis and the quality of reporting.

Conclusions: Using Iuvenelis can contribute to the client-experienced quality of care, more specifically to perceived person centeredness, timeliness, safety, efficiency, and integration of care. However, some quality aspects, such as equity, still need addressing. In general, client information about the portal needs to be improved, specifically focusing on people in vulnerable circumstances, such as those from migratory backgrounds. In addition, to maximize the potential benefit of using Iuvenelis, stimulating a person-centered attitude among professionals is important. Considering the small number of adolescent participants (n=7), adding quantitative data from a structured survey could strengthen the available evidence.

(J Particip Med 2024;16:e50092) doi:10.2196/50092

KEYWORDS

electronic health record; EHR; personal health record; child health services; child health; child welfare; adolescent health services; pediatrics; parent; care quality; perceived quality of care; patient experience; client perception; quality of care; parent; adolescent; patient portal; client portal; qualitative study

Introduction

Background

In the implementation and optimization of health care services, assessing the quality of care is an important topic. Quality of care is a broad concept, and it encompasses various aspects of health care. Most commonly used is the Institute of Medicine's definition of quality of care, which distinguishes 6 different domains: safety, effectiveness, timeliness, patient centeredness, efficiency, and equity [1]. Patient safety refers to the notion that provided care should prevent patients from harm [1]. Effectiveness reflects the use of appropriate interventions and treatments [1]. Timeliness refers to delivering health care services on time [1]. Patient centeredness is about tailoring care to the unique patient's needs and preferences and engaging them and their proxies in decision-making [1,2]. Efficiency deals with how well resources are used and about avoiding waste [1]. Equity ensures everyone has equal access to the best possible care, independent of personal characteristics or geographic location [1]. Traditionally, quality of care has been approached from a professional's perspective, aiming to increase the likelihood of desired health outcomes. In 2015, the World Health Organization (WHO) reformulated the term patient centeredness into person centeredness, emphasizing that patients are more than just their health condition and proposing a broadened scope for health and well-being [3]. With this pivot shift from conventional biomedical health care models to a more holistic approach, patient experiences have become an important health care quality outcome, and patient-reported experiences have evolved into important indicators for quality of care [4,5].

Patient-accessible electronic health records (PAEHRs) are assumed to enhance the quality of care because they provide users with information about their health and health care [6-8]. Information can be provided in a one-way manner, by sharing health data in a patient portal or interactively when the system supports messaging between patient and care provider [9-12]. Either way, providing patients with their health data promotes empowerment and enhances people's engagement in their care plans [6,7,13]. Consequently, health consciousness (ie, the inclination to take health actions), therapy adherence, and self-management of health improve, all of which contribute to better health outcomes [8,9,13-16]. Moreover, transparency of PAEHRs is reported to enhance patient safety, for instance, because patients can identify errors in their health records and have them corrected [12,17,18].

PAEHRs in Adolescent Health Care

The growing body of literature reporting the effect of using PAEHRs on quality of care predominantly stems from adult health care. Research on the impact of using PAEHRs on the quality of care among children, adolescents, and their parents is limited because the development of PAEHRs for these target groups is delayed by age-specific challenges regarding autonomy and confidentiality [19,20]. Meeting these challenges during the development of PAEHRs is important because research shows that adolescents only share information with professionals who assure their confidentiality [21-23].

The protection of confidentiality and access to health information differs depending on the country or state. While there are different legal measures in place to safeguard confidentiality, all health care systems face the challenge of transferring access rights from parents to adolescents [20,24,25]. Initially, parents have the right to their child's health information, but as children grow into adolescence, and therefore in capacity and autonomy, these rights are transferred to the adolescent [26,27]. This transfer, varying across and within countries, can be gradual, with both parents and adolescents having access, or occur at a specific age [20,24,25]. Solutions for the emerging autonomy and confidentiality issues aim to balance adolescent autonomy and confidentiality with parental involvement [26-28]. In the United States, laws explicitly safeguard parents' rights to access their children's health information [25,29]. Contrastingly, countries such as Canada, the United Kingdom, the Netherlands, and most Scandinavian nations more strongly emphasize the rights of adolescents, depending on their capacity and maturity [24,30]. Restrictions on access to health information for both parents and adolescents vary globally, from shared access during a specified period to no access at all during adolescence [20,24]. The age at which adolescents can access their health information differs from any age in Finland and Estonia to 18 years in Austria and New Zealand [20,24]. Consent from either the adolescent or the parent may be necessary, with certain jurisdictions permitting adolescents to restrict parental access [20,25].

Objectives

In the Netherlands, a PAEHR named Iuvenelis has been developed for children, adolescents, and their parents. Iuvenelis is used in an interdisciplinary manner in preventive child health care and youth care. It is accessible to adolescents aged ≥12 years and to parents of children aged from 0 to 16 years. Investigating the impact of using Iuvenelis on perceived quality of care among adolescents and parents will contribute to knowledge about using PAEHRs in an age group that is evolving toward autonomous adulthood. This study aimed to investigate how Dutch parents and adolescents visiting preventive health care and youth care perceived the impact of using a client-accessible interdisciplinary health record on quality of care, exploring both the experiences of active users and the expectations or first impressions of nonusers.

Methods

Research Design

A qualitative design with a phenomenological approach was chosen to explore how parents and adolescents perceived the impact of using Iuvenelis on the quality of care [31]. A total of 12 in-depth interviews with 1 to 3 people simultaneously were conducted between October 11 and November 25, 2021. We reported our qualitative study according to the COREQ (Consolidated Criteria for Reporting Qualitative Studies) [32]. Multimedia Appendix 1 contains the completed COREQ checklist for this study.

Study Setting

The Dutch North Veluwe region consists of 6 municipalities. These municipalities commissioned 2 organizations providing preventive child health care to children aged 0 to 3 years and children aged 4 to 18 years and 1 organization providing youth care to integrate their services in the Centre for Youth and Family (CJG). The CJG is a network organization that houses professionals from the 3 parent organizations involved. Since 2015, the CJG has provided preventive health care to all 38,000 children aged from 0 to 18 years in the region and provided additional youth care for children and families with behavioral or sociopsychological problems [33]. Both preventive child health care and youth care refer to parents, children, and adolescents as clients rather than as patients. Using a participatory approach, the CJG in 2016 developed a quality standard for their services, following the European "Quality 4 Children" protocol [34]. In dialogue sessions with parents and adolescents, they jointly wrote a document that defined quality of care from a client's perspective [35]. The document establishes 3 core values for quality—"child-centredness," "partnership between family and professionals," and "families in charge when decisions are made"—and describes the corresponding supportive professional behavior for each value [35]. Supporting the integration of services, the electronic health record "Iuvenelis" was built, to which all CJG professionals report. Furthermore, to support client autonomy and collaboration between professionals and families, Iuvenelis includes a tethered client portal in which parents and adolescents can read everything professionals report, such as visit notes, measurements, test results, and referrals. They can manage appointments, send secure messages to professionals, ask questions, comment on written reports, and request corrections of errors. Compliant with Dutch legislation, adolescents receive automatic access to the portal at the age of 12 years [36]. At the same moment, the portal closes for parents, who have a legal right to access Iuvenelis until their child is 16 years of age. However, this right can only be effectuated when their child personally grants permission. When parents are granted access to their child's record between 12 and 16 years of age, their child can still have single visit reports shielded from them. Iuvenelis was introduced in September 2019.

Study Population and Inclusion

The study included the parents of children aged 0 to 16 years and adolescents aged ≥12 years, living in the North Veluwe region, further referred to as clients. Clients who visited the CJG in September 2021 were invited personally by CJG professionals, and some general characteristics were reported, such as sex, age, educational level, and native country. Clients who expressed interest in participating were contacted by email or phone to explain the nature and purpose of the interview and to make an appointment. Where feasible, clients were invited to join focus group interviews at a CJG location. Those unable to attend a group session were offered an individual or dual interview live at the location of their choice or on the web. Purposive sampling ensured a varied group representing both sexes, parents and adolescents, various educational levels, active users of Iuvenelis and nonusers, both visitors of preventive health care and youth care, and inhabitants from all participating municipalities. We included parents from native Dutch and migratory backgrounds. In this paper, we use the term migratory background for immigrants who moved to the Netherlands, regardless of their command of the Dutch language. In total, 12 interviews were conducted with 20 participants. Apart from 7 (58%) individual interviews, 2 (17%) double and 3 (25%) triple interviews were conducted. Except for 1 (8%) triple interview with a mother and her 2 teenage children, group interviews consisted of only parents or only adolescents, and respondents did not know each other.

Data Collection

To create an interview topic guide (Multimedia Appendix 2), a working session was convened with an interdisciplinary expert panel of 8 professionals. On the basis of the CJG quality standard and the overarching Institute of Medicine framework [1], they explored what aspects of client-perceived quality of care could be influenced by using Iuvenelis. Textbox 1 presents the main topics from the semistructured interview guide.

Textbox 1. Client interview main topics, with sample questions from the interview guide.

General

- Are participants acquainted with Iuvenelis?
- How have their experiences been in general?
- If they were not acquainted, what are their first impressions?

Safety

- How do participants feel about security of their data?
- How do participants feel about detecting errors?
- How do participants value the view log?

Effectiveness

- How do participants experience completeness and understandability of reports in Iuvenelis?
- How do participants value professional expertise?

Timeliness

- How do participants experience the possibility of 24/7 access to their health data?
- How do participants experience the possibility to manage their own appointments?
- How do participants experience the possibility to ask questions at their convenience?

Person centeredness

- To what extent do participants perceive an influence of using Iuvenelis on client-professional collaboration or communication?
- To what extent do participants perceive an influence of using Iuvenelis on equal relationship?
- To what extent do participants perceive an influence of using Iuvenelis on sense of ownership?

Efficiency

- How do participants experience collaboration between disciplines through Iuvenelis?
- How do participants experience the use of interdisciplinary shared care plans?

Equity

- How do participants experience ease of access and ease of use?
- How do participants experience comprehensibility of record content?
- Were participants informed about the existence of Iuvenelis?

All participants were interviewed once by an experienced female interviewer (JB). For the first 6 of the 12 (50%) interviews, a female research assistant (CAdM) assisted as an observer and note-taker. Individual interviews lasted 30 to 60 minutes, and double and triple interviews lasted 90 minutes. When the participants were not acquainted with the client portal, the first part of the interview was used to demonstrate its functionalities in real time, followed by the main interview, which then focused on expectations and first impressions instead of experiences. Every interview was audio recorded, supplemented by note-taking, and by video recorded for web-based interviews.

Data Analysis

The interviewers transcribed all interviews verbatim for analysis. A member check was conducted with all participants to affirm transcript accuracy. Data were analyzed in ATLAS.ti (version 9; ATLAS.ti Scientific Software Development GmbH). On the basis of the topic list with the 6 domains of quality of care as a framework, a preliminary codebook was written. In accordance with best practices, data collection and analysis were conducted in an iterative, cyclical process, checking for data saturation. The interviewing authors (JB and CAdM) conducted a thematic analysis, rereading and coding all transcripts independently [37,38]. After coding a full transcript, the 2 researchers discussed discrepancies in coding until consensus was reached. Simultaneously, in a continuous process, additional codes were added to the codebook, coding definitions were refined, and transcripts were recoded when necessary. Saturation was discussed during analysis and was reached after 12 interviews. Subsequently, JB and CAdM grouped all codes into major themes and discussed the interpretation of themes with all authors.

Research Team and Reflexivity

The interviews were conducted by a researcher working as a policy advisor at the CJG and a research assistant, both trained in qualitative research. Although 1 interviewer worked in the CJG, no working relationship had been established with any of the participants before the study. Every interview started with an introduction of the interviewers and an explanation of the study goal. Combining an experienced researcher with inside knowledge of the CJG and Iuvenelis (JB) with a young researcher from outside the CJG (CAdM) had 2 advantages: first, when present during the interviews with adolescents, the younger researcher could identify easily with the participants and vice versa; second, during analysis, comparing observations and discussing interpretations from both inside and outside perspectives enriched the process of interpretation and limited the risk of bias.

Ethical Considerations

The study was carried out following relevant guidelines and regulations, complying with the Netherlands Code of Conduct for Scientific Practice. On these grounds, the research protocol was approved by the Social Sciences Ethics Committee of Wageningen University (2018-24-Benjamins). All participants received an invitation beforehand with information about the study and gave explicit verbal consent at the beginning of the interview. Each interview was recorded and transcribed verbatim, including verbal consent.

Results

General Characteristics

Of the 20 participants, 13 (65%) parents and 7 (35%) adolescents were interviewed individually (n=7, 35%), in pairs (n=4, 20%) or in triplets (n=9, 45%). Initially, 23 participants were included, of whom 3 (13%) dropped out due to agenda mismatches. The participants represented both sexes, parents, and adolescents from different educational levels, from native Dutch and migratory backgrounds, and from all involved municipalities and also represented those making use of preventive child health care and youth care services. All adolescents were making use of youth care services. (Table 1).

A total of 35% (7/20) of the participants were not acquainted with the client portal before the interview, and 85% (6/7) of them were from a migratory background. Of the participants who were acquainted with the client portal, 46% (6/13) had received information from a CJG professional and, 54% (7/13) had discovered the portal through a questionnaire about Iuvenelis. In total, 30% (6/20) of the participants came to the CJG office, 50% (10/20) of them were interviewed in their own homes, and 20% (4/20) of the participants had web-based interviews.

Table 1. Characteristics of participants in the client interviews.

	Parents (n=13), n (%)	Adolescents (n=7), n (%)	Total (N=20), n (%)
Sex			
Male	2 (15)	2 (29)	4 (20)
Female	11 (85)	5 (71)	16 (80)
Educational level			
High	3 (23)	2 (29)	5 (25)
Middle	4 (31)	3 (43)	7 (35)
Low	6 (46)	2 (29)	8 (40)
Native country			
Netherlands	6 (46)	7 (100)	13 (65)
Kosovo	1 (8)	0 (0)	1 (5)
Syria	1 (8)	0 (0)	1 (5)
Afghanistan	2 (15)	0 (0)	2 (10)
Thailand	2 (15)	0 (0)	2 (10)
Sudan	1 (8)	0 (0)	1 (5)
Municipality			
Oldebroek	1 (8)	1 (14)	2 (10)
Elburg	1 (8)	0 (0)	1 (5)
Nunspeet	2 (15)	1 (14)	3 (15)
Harderwijk	5 (38)	3 (43)	8 (40)
Ermelo	3 (23)	2 (29)	5 (25)
Putten	1 (8)	0 (0)	1 (5)
Visiting preventive child health care or youth care			
Preventive child health care	10 (77)	0 (0)	10 (50)
Youth care	3 (23)	7 (100)	10 (50)
Acquainted with the portal			
Yes	6 (46)	7 (100)	13 (65)
No	7 (54)	0 (0)	7 (35)

Interview Outcomes

A code tree (Multimedia Appendix 3) was created with branches for all 6 aspects of quality of care: safety, effectiveness, timeliness, person centeredness, efficiency, and equity [1]. One additional theme emerged, related to professional attitude and behavior. Because this theme is linked with person centeredness, we divided the theme of person centeredness into 2 subthemes: client perspective and professional attitude. Most expressions from the participants could be coded in the domain of person centeredness (668/1749, 38.19%), followed by safety (382/1749, 21.84%), equity (337/1749, 19.27%), timeliness (158/1749, 9.03%), and efficiency (135/1749, 7.72%), whereas effectiveness was mentioned the least (69/1749, 3.95%). When experiences across quality-of-care domains were compared, it appeared that positive experiences were expressed for person centeredness, safety, and timeliness, whereas the domains equity and effectiveness evoked predominantly expressions of concerns. The participants expressed mixed feelings about the domain efficiency. In the following paragraph, more in-depth analyses of the participants’ reflections on individual dimensions of quality of care will be presented, starting with the domain that generated the highest number of codes.

Person Centeredness

Subtheme A: Client Perspective

Both parents and adolescents reported that rereading information in the client portal contributed to person centeredness because it helped them to *recollect* what had been discussed during a visit, to *get an overview* over a longer period, and to *prepare* for the next visit:

> *Sometimes it is so crowded in my head. Then I start thinking: what was it all about?* [Mother, 2 children, respondent 7.2]

> *It’s more like when I am struggling with something that we have discussed earlier that I think: Hey, wait a minute. Didn’t we already talk about this once?*

> *And I can reread our conversation.* [Female adolescent, aged 17 years, respondent 10]

Using the client portal to get an overview was even more important for the parents with a migratory background, although only 1 of them had been using the portal before the interview. However, after watching the portal demonstration and accessing their own child's health record, all parents from a migratory background considered access to the client portal to be very valuable. They expected that both rereading and reading with others would be vital. Rereading, and using a web-based translation tool when they did not comprehend the Dutch text, would help them to get a *better understanding* of what was discussed during a previous visit. A total of 50% (3/6) of the mothers with a migratory background had partners who understood Dutch better than they did. Rereading together after a mother's visit to the CJG would *provide* the father with all relevant *information* and would help the mother *recollect* what was discussed or provide her with information that she had not grasped yet during the visit:

> *This one (client portal), this is good! My husband always asks: "How big was his head, how tall was he and how many kilos." And then I go: "Oh my goodness, I forgot! Do I need to memorize that?" Now I can say: "Hey, you can log in and see for yourself what has happened."* [Mother, 1 child, respondent 2.1]

Involving relatives in one's care was an aspect of person centeredness that not only the parents with a migratory background reported as a benefit from access to the client portal. Most parents valued that a partner who had not been present at the physician's visit could read the notes afterward. For adolescents, it felt easier to have parents read a visit report than to recall the whole conversation themselves, although they also valued the possibility of actively withholding information from their parents if they wanted to. Finally, rereading with relatives or friends was reported as helpful as well, when *preparing* for a next visit, or when *decisions* had to be made about the care process:

> *I have a Syrian friend who does not speak Dutch. Her daughter has a growth problem. I helped her and we took the information from the growth chart in this portal, bringing it with us to the hospital.* [Mother, 3 children, respondent 11]

Being able to reread information, the parents and the adolescents felt *well informed* and *engaged* in their care plan. They also valued being part of the reporting process, discussing beforehand what should be reported and how. The combination of reporting together and rereading information enhanced their sense of *ownership* and contributed to *equal client-professional collaboration*:

> *Now I know, because I can check myself, when my children need vaccinations* [Father, 5 children, respondent 3.2]

> *You construct the report together, so to speak, and you can both navigate the plan a little.* [Mother, 2 children, respondent 7.3]

Both parents and adolescents would like to have *more ownership* than was facilitated by the client portal. Some parents expressed the need to *add* more *information* to Iuvenelis to create a full overview of all health and welfare issues concerning their child. Adolescents wanted to be more in control of who accessed their health records; they wanted to *actively give access* to professionals or at least be able to see beforehand who had access to their record instead of reading afterward in their view log who had accessed their health information:

> *At least I want to see beforehand which professional is authorized to access my health record, instead of seeing who has accessed my record afterwards.* [Male adolescent, aged 17 years, respondent 5.1]

Subtheme B: Professional Attitude

Numerous participants emphasized that a *professional attitude* was an important underlying condition to deliver person-centered care and to experience the possible benefits of using Iuvenelis. The transparency of Iuvenelis contributed to a sense of *trust*, but only if professionals reported respectfully, showing that they did take clients seriously. Being able to see in a view log who accessed your health record was considered reassuring and enhanced trust. A mother stated the following:

> *You should consider very carefully how you report, because you are inviting me: "Go ahead, read it." You are giving full access to the health record.* [Mother, 2 children, respondent 7.3]

On the other hand, trust could be damaged if professionals did not report respectfully or did not respect a client's privacy. After experiencing numerous instances where professionals were speaking about her, 1 parent chose not to access the client portal, to protect herself from losing trust in her current care provider:

> *I have decided that I trust "X" completely. Why should I read my health record when I do not need to and take the risk to read something that might harm that trust?* [Mother, 2 children, Respondent 9]

Safety

Both parents and adolescents were satisfied with the *security* of their *health data* and the way professional authorization was organized. They generally valued the possibility to see in their view log who accessed their health record. Adolescents all valued their *right to decide* about access for their parents. Knowing how safety was warranted was an important factor contributing to their *trust* in the system:

> *This afternoon I saw that someone had accessed my daughter's record. But I remembered I approved that person. It's nice to know that my approval is needed beforehand.* [Mother, 4 children, respondent 7.1]

> *I had problems with my parents, and I don't know if that's still in all those documents. Then it is nice indeed that you can decide, what they can and can't see.* [Male adolescent, 17 years, respondent 5.1]

However, half of the portal-using participants were well informed about the privacy and data security measures, and knew where to find the view log. For 1 adolescent, the view log was a reminder that professionals were discussing her situation without her being present, which she did not appreciate:

> *Although I like seeing who has accessed my health information, it also gives me stress. Because once they discussed my condition in a meeting with several people and I was not there. They were talking about me without me, so to speak, and that's not okay. When I check the view log that situation comes back in mind.* [Female adolescent, aged 18 years, respondent 5.2]

> *Can other people [outside the CJG] see my child's record? How do I know that you don't give it to other people? Because everything is web-based.* [Mother, 1 child, respondent 2.1]

Correcting errors is generally considered a part of the element "safety" [12]. Throughout the interviews, 2 adolescents and 3 parents encountered registration errors or missed appointments without follow-up when checking their portal. They said identifying errors did not upset them. Quite the reverse; they appreciated the possibility to detect errors, report them, and have them corrected. Moreover, being able to correct mistakes increased their sense of ownership over their care process. The parents said it was important to correct found errors, whereas adolescents said they would not ask for correction:

> *Sometimes things go wrong. For example, E had missed a vaccination. So now we can check the record ourselves and see which vaccination he needs.* [Father, 5 children, respondent 3.2]

Equity

Independent of their native country and educational level, participants thought very positively of the client portal's *usability*. The portal was experienced as easy-to-use and intuitive. The parents and the adolescents could log on to the system easily using digital ID, because people had familiarized themselves with this verification procedure during the COVID-19 pandemic. Usability on mobile phones was also considered good:

> *Logging in with DigiD makes things easier actually, solving the whole hassle of passwords.* [Mother, 4 children, respondent 7.1]

> *For me, it must be well-organised and then it's good. The way it is constructed right now, it's clear, uncluttered and you can read everything. I think I will look more often.* [Mother, 2 children, respondent 7.3]

The parents and the adolescents also considered most recorded content *comprehensible*. However, some portal features, for example, vaccination overview and planning appointments, required explanation, and the parents and the adolescents sometimes encountered jargon or incomprehensible abbreviations:

> *I understood most things I read. But I thought about some information from when I was a little kid, some expressions: that must be only for doctors.* [Female adolescent, aged 18 years, respondent 12]

The most serious concern expressed by parents was that not all clients were informed *equally* about the existence of Iuvenelis. A total of 7 (35%) out of 20 participants had not received any information about Iuvenelis before the interview, and 86% (6/7) of them were from a migratory background. One parent from a migratory background did use the client portal to manage appointments but was not aware that she could also reread visit reports:

> *If I had not been here, I would not have known anything about it at all, and that's a shame.* [Mother, 1 child, respondent 2.3]

The parents presented many options for improving communication. Emphasizing the importance of providing more equal information to all population groups, 1 parent offered to participate in information meetings with mothers from migratory backgrounds:

> *Some mothers (with a migratory background) are unsure about their language proficiency. For them, it is easier to do it through the internet.* [Mother, 3 children, respondent 11]

Timeliness

The client portal's 24/7 accessibility did not contribute to *faster* access to care. However, it did provide parents and adolescents with the opportunity to ask questions or schedule appointments easily and at their *convenience*. Especially, parents valued this opportunity as *time saving*, including the immediate access to their health information without the interference of a CJG professional:

> *Suppose I get very anxious during the weekend about certain behaviour I observed. I would prefer to search for information right then and there, instead of sending an email and waiting several days until someone responds. I think it's a plus that I can check the client portal and ask my questions immediately.* [Mother, 2 children, Respondent 7.3]

> *I rescheduled my appointment once through the portal. Very convenient and timesaving!* [Mother, 2 children, respondent 7.2]

Efficiency

In Iuvenelis, all CJG professionals had access to all relevant information stored in the same place, which was considered an advantage contributing to efficiency. Consequently, the parents and the adolescents did not have to repeat their stories when visiting a new professional in the CJG:

> *I think it is very convenient when you visit several people in the same period that all information is in one place. So, they can make use of each other's information.* [Female adolescent, 15 years, respondent 6]

However, both parents and adolescents saw room for improvement in expanding Iuvenelis toward other care providers and in a more active role for themselves in uploading information from other care providers in their client portal. They felt that if all their health data were stored in one place and accessible to all their care providers, it would be easier for both care providers and clients themselves to create a clear overview and manage their care:

> *I hope lines between all professionals will be shorter. Eventually, I hope my children will have all their health data in this record, that this will be their complete and only health record.* [Mother, 2 children, respondent 8.3]

Effectiveness

Parents and adolescents did not associate using Iuvenelis with effectiveness. Although a fully accessible health record allows clients to engage in the management of their care process, none of the participants commented on the actual care process and whether the right choices had been made.

Parents and adolescents did comment on the process and quality of reporting: they felt that reporting quality could be improved. Some reports contained mistakes, and some were incomplete or missing. One parent expressed the concern that reports were sometimes prejudiced, elaborating on risk factors and neglecting protective factors:

> *They only report what is wrong. Do you know what could really help? If you would read in your child's record what is going well if someone would write down what a lovely little boy he is.* [Mother, 2 children, respondent 9]

Discussion

Principal Findings

With this study, we explored how parents and adolescents visiting preventive health care and social care perceived the quality of care when using Iuvenelis. Both the experiences of active users and the expectations or first impressions of nonusers were included. The results suggest that using Iuvenelis contributed to some, but not all, aspects of quality of care. On the positive side, parents and adolescents felt better informed and expressed more engagement in the care process than before introduction of Iuvenelis. They felt more in control of their health data, reported having faster and simpler access to their health information, and found it easier to manage appointments or ask questions at their convenience. Portal usability and data safety were regarded as high, and interdisciplinary collaboration in Iuvenelis was considered to enhance efficiency. The parents from a migratory background expected that portal access would give them a better understanding of and more control over their care processes.

However, parents expressed concerns about possible unequal access due to a lack of information for the parents from a migratory background. Furthermore, both parents and adolescents saw room for improvement in the broader interdisciplinary use of Iuvenelis. Finally, they felt that effectiveness could be improved by more complete reporting regarding protective factors as well as risk factors.

Comparison With Prior Work

Overall Contribution to Quality of Care

Previous research investigating quality of care in relation to using PAEHRs predominantly focused on adult health care. These studies reported largely the same outcomes as our study, although described from a care provider's perspective. Using a PAEHR was reported to contribute to person centeredness [7,39,40], safety, and efficiency [16,39,40]. Contrary to this study, prior studies also show a positive impact of using a PAEHR on effectiveness [16,39,40]. Some studies report that patient portals enhance timeliness through messaging functionalities or quicker access to results [41-45].

Person Centeredness and Professional Perspective

Some participants emphasized the importance of a person-centered professional attitude, which they considered fundamental for Iuvenelis' contribution to quality of care. When professionals reported respectfully in Iuvenelis, this enhanced the client's trust in their care providers, whereas earlier experiences with professionals not respecting a client's privacy damaged that trust. An extensive review by Scholl et al [46] generated a patient-centered care model that places a professional's attitude central in the delivery of person-centered care. In this model, delivering patient-centered care relies on professionals embracing a person-centered attitude characterized by respecting a patient's unique preferences and needs, building a professional-patient relationship based on equality, and viewing a patient's health from a biopsychosocial perspective [46]. Leeuwis and Aarts [47] stated that complex interventions, such as technological innovations, usually require change on different levels. These changes, on a technological, organizational, and professional level, are considered interdependent [47]. In this case, implementing a PAEHR to enhance person centeredness is not only about introducing the technological tool; the implementation needs to address professional attitude and behavior as well. In turn, changes in professional behavior and attitude require adjustments at the organizational or institutional level. These interdependencies should be anticipated when organizations start implementing a PAEHR, and the necessary changes on an organizational and professional level should be planned and facilitated in addition to the development and implementation of the tool itself.

Equity

Equity emerged in this study as an issue of concern because most participants with a migratory background appeared to be unaware of the existence of a client portal, as opposed to 1 participant with a native background. Diving a bit deeper into this, anecdotal evidence may suggest that professionals hesitated to inform clients about the existence of the client portal when they noticed that a client's knowledge of Dutch was limited. Unawareness of the existence of a patient portal has been reported as a main barrier for using a patient portal [48,49] and could be resolved by provider encouragement, which is an important contributor to portal use [50-52]. However, when providers selectively encourage certain groups of people to use a patient portal and neglect others, they could enhance disparity. Previous research shows that persons living in vulnerable circumstances, such as lower-educated people or persons from a migratory background, make less use of patient portals than average [17,42,53-58]. The literature on the digital divide reports that social exclusion can lead to digital exclusion and that the introduction of new technology then might unintentionally reinforce already existing health disparities [59-61]. In total, 2 studies investigating a provider's role in patient portal use reported that professionals play a role in this reinforcement: higher-educated and White patients were more likely to report being encouraged by health care providers to use a client portal than lower-educated patients and patients from migratory backgrounds [50,51]. Antonio et al [62] stated in a review that "healthcare providers' prejudgments may further exclude populations that are already underserved."

This is an important issue to address because research shows that people, especially those living in vulnerable circumstances, experience benefits from using a PAEHR [42,43,63,64]. In our study, parents from migratory backgrounds reported that rereading their health information and sharing it with family members or friends would provide them with a better understanding of the care process and would increase their engagement in care. We concluded that ensuring that all clients are equally informed about the existence of a client portal is not only necessary to prevent further disparities but could even diminish existing disparities [65]. This may require adapted measures for specific population groups, for example, using informal meetings with the parents from migrant backgrounds to inform them in their language about Iuvenelis. In addition, professionals need to be made aware of the risk of the digital divide and of their crucial role in conquering this phenomenon.

Confidentiality

On the basis of the known bottlenecks to developing PAEHRs for adolescents [26,27], we expected data safety, confidentiality, and privacy to be an issue of concern for at least some of our participants. However, surprisingly, participants did not express concerns about their data safety. Adolescents did value highly how their confidentiality was protected and reported that this contributed to their trust in their care provider. Comparably, recent studies investigating adolescent use of PAEHRs suggest that adolescents are not concerned about their confidentiality when using a PAEHR [8,13,18,23]. A recent review investigated the experiences of parents and adolescents using a PAEHR in hospital, primary, and mental health care settings versus the expectations of parents and adolescents without access to a PAEHR. In this review, the authors found that parents and adolescents without access to a PAEHR anticipated confidentiality issues when using a PAEHR, whereas parents and adolescents using a PAEHR did not experience these issues [66]. In a similar vein, research that compared professionals' general concerns about using PAEHRs beforehand with experiences after a period of using a PAEHR shows that anticipated worries were not always justified. For example, an expected increase in workload and excessively anxious patients did not occur after introducing PAEHRs [67-69]. Confidentiality issues could have been one of the expected problems that did not evolve. Another explanation of the contrast between expected bottlenecks and real experiences may be that the explicit focus in the literature on confidentiality issues has initiated specific awareness for this topic during the development of Iuvenelis and has led to the implementation of successful solutions.

Integrated Care

The participants considered the interdisciplinary use of Iuvenelis a contribution to efficiency and even expressed a need to expand the use of Iuvenelis to other disciplines outside the CJG. This would allow them to view all their health data in one place. Parents and adolescents stated that, in their opinion, this would contribute to efficiency. However, with their remarks, participants draw upon an additional aspect of quality of care, integrated care, that the WHO has added recently [1,70]. The WHO defines integrated care as "providing care that is coordinated across levels and providers and makes available the full range of health services throughout the life course." The parents and the adolescents even challenged the CJG organizations to extend opportunities for interdisciplinary collaboration within Iuvenelis, facilitating them to gather all their health information here. With that challenge, the parents and the adolescents confirmed the value of the Dutch aim for integrated care in child health care and youth care [71]. This aim is also reflected in the recently established Healthy and Active Living Agreement between the Dutch government, municipalities, and public health associations [72], although it is not yet common practice throughout the country.

Differences Between Parents' and Adolescents' Experiences

Although parents' and adolescents' perceptions were similar in many aspects, differences were reported as well. Parents considered it more important to correct errors than adolescents and valued the web-based option to ask questions and manage appointments more highly than adolescents. Comparably, recent studies among adolescent patients show that adolescents are less likely to speak up about mistakes in their records than their parents [73,74], and are more reluctant to send direct messages in the PAEHR to their caregivers than adults [13,23]. Both parents and adolescents liked to share record content with their close ones, but adolescents also valued the opportunity to shield specific content from their parents when needed. Adolescents considered deciding who had access to their health information vital to exercising ownership over their health information. In line with this, a recent review reports that teens believe they should have control over what remains confidential in their medical records and what their parents can access through proxy portal accounts [23].

Strengths and Limitations

Recruiting a well-balanced group of participants in this qualitative study was a strength of this study, compared to our previous studies on Iuvenelis, where adolescents were represented in small numbers and participants with migratory backgrounds could not be included [75,76]. The inclusion of the most important characteristics in this study enabled us to explore different client perspectives. Choosing a qualitative research design made it possible to collect rich, in-depth information about the client's expectations of and actual experiences with using Iuvenelis.

Due to the COVID-19 pandemic, organizing focus groups proved to be difficult. Although some triple interviews could be organized, most participants were interviewed individually or in couples. Consequently, our study lacked some of the interaction that is usually generated in larger groups, which could be considered a limitation [77]. We partly managed to overcome this limitation because we collected and analyzed data in a continuously iterative process. This meant that topics that were brought up in the first interview could be explored further in the following interviews.

As JB had a role as a policy advisor in the CJG, she was able to introduce the participants to Iuvenelis who were not yet acquainted with the client portal, which allowed us to include more parents with a migratory background and to add valuable information to our data. However, combining a portal demonstration with an interview about how clients perceived the quality of care using this portal might have created a respondent bias: the interviewer's positive attitude toward the client portal could have evoked socially desirable answers. To enhance trustworthiness, the interviewers followed the interview guide as closely as possible, allowing some adaptation to the conversational flow. A member check was conducted, transcripts were coanalyzed with a researcher with no connections with Iuvenelis or the CJG, and reporting followed the COREQ checklist [32,78].

Conclusions

Using Iuvenelis is expected to contribute to experienced quality of care from the perspectives of both parents and adolescents, specifically to the aspects of person centeredness, timeliness, and safety. Parents and adolescents feel better informed, experience a greater sense of ownership, and are satisfied with data security and portal usability. Clients also report that using Iuvenelis contributes to integrated care. Some quality aspects, however, such as equity in portal access, still need addressing. In general, client information about the portal needs to be improved, specifically focusing on people in vulnerable circumstances, such as those from migratory backgrounds. In addition, to maximize the potential benefit of using Iuvenelis, stimulating a person-centered attitude among professionals is important. With our study, we have investigated parents' and adolescents' perspectives regarding all domains of quality of care. However, considering the small number of adolescent participants, adding quantitative data from a structured survey could strengthen the available evidence.

Data Availability

As interview transcripts contain sensitive information, these will not be published in a separate data set.

Authors' Contributions

JB, EdV, and AH-N conceived and designed the study. JB and CAdM collected and analyzed the data. JB drafted the manuscript as first author. All authors provided critical feedback, helped shape the analysis and manuscript, and have read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Completed COREQ (Consolidated Criteria for Reporting Qualitative Studies) checklist.
[DOCX File , 29 KB - jopm_v16i1e50092_app1.docx]

Multimedia Appendix 2
Interview topic list.
[DOCX File , 18 KB - jopm_v16i1e50092_app2.docx]

Multimedia Appendix 3
Codetree, displaying all applied codes, grouped in colours around every single aspect of quality ofcare.
[PDF File (Adobe PDF File), 652 KB - jopm_v16i1e50092_app3.pdf]

References

1. Committee on Quality of Health Care in America, Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. New York, NY: The National Academies Press; 2001.
2. WHO global strategy on people-centred and integrated health services: interim report. World Health Organization. 2015. URL: https://www.afro.who.int/sites/default/files/2017-07/who-global-strategy-on-pcihs-main-document_final.pdf [accessed 2024-04-05]
3. People-centred and integrated health services: an overview of the evidence. World Health Organization. 2015. URL: https://apps.who.int/iris/bitstream/handle/10665/155004/WHO_HIS_SDS_2015.7_eng.pdf?sequence=1 [accessed 2024-04-05]

4. Price D, Edwards M, Davies F, Cooper A, McFadzean J, Carson-Stevens A, et al. Patients' experiences of attending emergency departments where primary care services are located: qualitative findings from patient and clinician interviews from a realist evaluation. BMC Emerg Med 2022 Jan 22;22(1):12 [FREE Full text] [doi: 10.1186/s12873-021-00562-9] [Medline: 35065616]
5. Baumhauer JF, Bozic KJ. Value-based healthcare: patient-reported outcomes in clinical decision making. Clin Orthop Relat Res 2016 Jun;474(6):1375-1378 [FREE Full text] [doi: 10.1007/s11999-016-4813-4] [Medline: 27052020]
6. Davis Giardina T, Menon S, Parrish DE, Sittig DF, Singh H. Patient access to medical records and healthcare outcomes: a systematic review. J Am Med Inform Assoc 2014;21(4):737-741 [FREE Full text] [doi: 10.1136/amiajnl-2013-002239] [Medline: 24154835]
7. Benjamins J, Haveman-Nies A, Gunnink M, Goudkuil A, de Vet E. How the use of a patient-accessible health record contributes to patient-centered care: scoping review. J Med Internet Res 2021 Jan 11;23(1):e17655 [FREE Full text] [doi: 10.2196/17655] [Medline: 33427683]
8. Dohil I, Cruz R, Sweet H, Huang JS. Sharing notes with adolescents and young adults admitted to an inpatient psychiatry unit. J Am Acad Child Adolesc Psychiatry 2021 Mar;60(3):317-320. [doi: 10.1016/j.jaac.2020.09.016] [Medline: 33035620]
9. Earnest MA, Ross SE, Wittevrongel L, Moore LA, Lin CT. Use of a patient-accessible electronic medical record in a practice for congestive heart failure: patient and physician experiences. J Am Med Inform Assoc 2004 Sep 01;11(5):410-417. [doi: 10.1197/jamia.m1479]
10. Cimino JJ, Patel VL, Kushniruk AW. The patient clinical information system (PatCIS): technical solutions for and experience with giving patients access to their electronic medical records. Int J Med Inform 2002 Dec 18;68(1-3):113-127. [doi: 10.1016/s1386-5056(02)00070-9] [Medline: 12467796]
11. Honeyman A, Cox B, Fisher B. Potential impacts of patient access to their electronic care records. Inform Prim Care 2005;13(1):55-60 [FREE Full text] [doi: 10.14236/jhi.v13i1.579] [Medline: 15949176]
12. Mold F, de Lusignan S, Sheikh A, Majeed A, Wyatt JC, Quinn T, et al. Patients' online access to their electronic health records and linked online services: a systematic review in primary care. Br J Gen Pract 2015 Mar;65(632):e141-e151 [FREE Full text] [doi: 10.3399/bjgp15X683941] [Medline: 25733435]
13. Hong MK, Wilcox L, Feustel C, Wasileski-Masker K, Olson TA, Simoneaux SF. Adolescent and caregiver use of a tethered personal health record system. AMIA Annu Symp Proc 2016;2016:628-637 [FREE Full text] [Medline: 28269859]
14. Bao C, Bardhan IR, Singh H, Meyer BA, Kirksey K. Patient–provider engagement and its impact on health outcomes: a longitudinal study of patient portal use. MIS Q 2020 Jun 1;44(2):699-723. [doi: 10.25300/misq/2020/14180]
15. Kruse CS, Bolton K, Freriks G. The effect of patient portals on quality outcomes and its implications to meaningful use: a systematic review. J Med Internet Res 2015 Feb 10;17(2):e44 [FREE Full text] [doi: 10.2196/jmir.3171] [Medline: 25669240]
16. Carini E, Villani L, Pezzullo AM, Gentili A, Barbara A, Ricciardi W, et al. The impact of digital patient portals on health outcomes, system efficiency, and patient attitudes: updated systematic literature review. J Med Internet Res 2021 Sep 08;23(9):e26189 [FREE Full text] [doi: 10.2196/26189] [Medline: 34494966]
17. de Lusignan S, Mold F, Sheikh A, Majeed A, Wyatt JC, Quinn T, et al. Patients' online access to their electronic health records and linked online services: a systematic interpretative review. BMJ Open 2014 Sep 08;4(9):e006021 [FREE Full text] [doi: 10.1136/bmjopen-2014-006021] [Medline: 25200561]
18. Huang JS, Yueh R, Ma S, Cruz R, Bauman L, Choi LJ. Adolescents' and young adults' satisfaction with and understanding of medical notes from a pediatric gastroenterology practice: a cross-sectional cohort study. J Pediatr 2019 Dec;215:264-266. [doi: 10.1016/j.jpeds.2019.06.052] [Medline: 31377044]
19. Sarabu C, Pageler N, Bourgeois F. OpenNotes: toward a participatory pediatric health system. Pediatrics 2018 Oct 18;142(4):e20180601. [doi: 10.1542/peds.2018-0601] [Medline: 30228169]
20. Hagström J, Scandurra I, Moll J, Blease C, Haage B, Hörhammer I, et al. Minor and parental access to electronic health records: differences across four countries. Stud Health Technol Inform 2022 May 25;294:495-499. [doi: 10.3233/SHTI220508] [Medline: 35612129]
21. Bergman DA, Brown NL, Wilson S. Teen use of a patient portal: a qualitative study of parent and teen attitudes. Perspect Health Inf Manag 2008;5(13):13 [FREE Full text] [Medline: 18923702]
22. Klein JD, McNulty M, Flatau CN. Adolescents' access to care: teenagers' self-reported use of services and perceived access to confidential care. Arch Pediatr Adolesc Med 1998 Jul;152(7):676-682. [doi: 10.1001/archpedi.152.7.676] [Medline: 9667540]
23. Sethness JL, Golub S, Evans YN. Adolescent patient portals and concerns about confidentiality. Curr Opin Pediatr 2023 Aug 01;35(4):430-435. [doi: 10.1097/MOP.0000000000001252] [Medline: 37036289]
24. Essén A, Scandurra I, Gerrits R, Humphrey G, Johansen MA, Kierkegaard P, et al. Patient access to electronic health records: differences across ten countries. Health Policy Technol 2018 Mar;7(1):44-56. [doi: 10.1016/j.hlpt.2017.11.003]
25. Sharko M, Wilcox L, Hong MK, Ancker JS. Variability in adolescent portal privacy features: how the unique privacy needs of the adolescent patient create a complex decision-making process. J Am Med Inform Assoc 2018 Aug 01;25(8):1008-1017 [FREE Full text] [doi: 10.1093/jamia/ocy042] [Medline: 29788423]

26. Bayer R, Santelli J, Klitzman R. New challenges for electronic health records: confidentiality and access to sensitive health information about parents and adolescents. JAMA 2015 Jan 06;313(1):29-30. [doi: 10.1001/jama.2014.15391] [Medline: 25562260]
27. Bourgeois FC, DesRoches CM, Bell SK. Ethical challenges raised by OpenNotes for pediatric and adolescent patients. Pediatrics 2018 Jun 18;141(6):e20172745. [doi: 10.1542/peds.2017-2745] [Medline: 29776979]
28. Calman N, Pfister HR, Lesnewski R, Hauser D, Shroff N. Electronic access to adolescents' health records: legal, policy, and practice implications. Fam Pract Manag 2015;22(2):11-14 [FREE Full text] [Medline: 25884967]
29. Does the HIPAA privacy rule allow parents the right to see their children’s medical records? US Department of Health and Human Services. URL: https://www.hhs.gov/hipaa/for-professionals/faq/227/can-i-access-medical-record-if-i-have-power-of-attorney/index.html [accessed 2024-04-05]
30. Nehel A. Privacy of a child’s healthcare: do parents have a right to access a child’s healthcare records? Procido LLP. URL: https://procido.com/2023/09/20/privacy-of-a-childs-healthcare-do-parents-have-a-right-to-access-a-childs-healthcare-records/ [accessed 2024-04-05]
31. Moustakas C. Phenomenological Research Methods. Thousand Oaks, CA: Sage Publications; 1999.
32. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007 Dec;19(6):349-357. [doi: 10.1093/intqhc/mzm042] [Medline: 17872937]
33. Transformatieplan samenwerking noord veluwe 2018-2021. Regio Noord Veluwe. 2017. URL: https://vng.nl/files/vng/noord_veluwe.pdf [accessed 2024-03-04]
34. van Beek F, Rutjes L. Beschrijving van de Kwaliteitsstandaarden Jeugdzorg Q4C. In: van Beek F, Rutjes L, editors. Kwaliteitsstandaarden Jeugdzorg Q4C: Wat Kinderen en Jongeren Belangrijk Vinden als ze Niet Thuis Wonen. Houten, the Netherlands: Bohn Stafleu van Loghum; 2009:29-85.
35. Kwaliteitswaarden CJG. Centrum voor Jeugd en Gezin, Noord Veluwe. URL: https://www.cjgoldebroek.nl/documents/230/20161202_CJG_Kwaliteitswaarden_def_sQO5BpM.pdf [accessed 2024-03-04]
36. Wet geneeskundige behandel overeenkomst (WGBO). Dutch Ministry of Justice and Security. 2006. URL: https://wetten.overheid.nl/BWBR0005290/2020-07-01/ [accessed 2024-03-04]
37. Braun V, Clarke V. What can "thematic analysis" offer health and wellbeing researchers? Int J Qual Stud Health Well-being 2014 Oct 16;9:26152 [FREE Full text] [doi: 10.3402/qhw.v9.26152] [Medline: 25326092]
38. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
39. Neves AL, Freise L, Laranjo L, Carter AW, Darzi A, Mayer E. Impact of providing patients access to electronic health records on quality and safety of care: a systematic review and meta-analysis. BMJ Qual Saf 2020 Dec 12;29(12):1019-1032 [FREE Full text] [doi: 10.1136/bmjqs-2019-010581] [Medline: 32532814]
40. Lear R, Freise L, Kybert M, Darzi A, Neves AL, Mayer EK. Perceptions of quality of care among users of a web-based patient portal: cross-sectional survey analysis. J Med Internet Res 2022 Nov 17;24(11):e39973 [FREE Full text] [doi: 10.2196/39973] [Medline: 36394922]
41. Hefner JL, MacEwan SR, Biltz A, Sieck CJ. Patient portal messaging for care coordination: a qualitative study of perspectives of experienced users with chronic conditions. BMC Fam Pract 2019 May 03;20(1):57 [FREE Full text] [doi: 10.1186/s12875-019-0948-1] [Medline: 31053063]
42. Gerard M, Fossa A, Folcarelli PH, Walker J, Bell SK. What patients value about reading visit notes: a qualitative inquiry of patient experiences with their health information. J Med Internet Res 2017 Jul 14;19(7):e237 [FREE Full text] [doi: 10.2196/jmir.7212] [Medline: 28710055]
43. Jackson SL, Mejilla R, Darer JD, Oster NV, Ralston JD, Leveille SG, et al. Patients who share transparent visit notes with others: characteristics, risks, and benefits. J Med Internet Res 2014 Nov 12;16(11):e247 [FREE Full text] [doi: 10.2196/jmir.3363] [Medline: 25405911]
44. Rief JJ, Hamm ME, Zickmund SL, Nikolajski C, Lesky D, Hess R, et al. Using health information technology to foster engagement: patients' experiences with an active patient health record. Health Commun 2017 Mar;32(3):310-319 [FREE Full text] [doi: 10.1080/10410236.2016.1138378] [Medline: 27223684]
45. Rexhepi H, Åhlfeldt RM, Cajander Å, Huvila I. Cancer patients' attitudes and experiences of online access to their electronic medical records: a qualitative study. Health Informatics J 2018 Jun;24(2):115-124 [FREE Full text] [doi: 10.1177/1460458216658778] [Medline: 27440056]
46. Scholl I, Zill JM, Härter M, Dirmaier J. An integrative model of patient-centeredness - a systematic review and concept analysis. PLoS One 2014 Sep 17;9(9):e107828 [FREE Full text] [doi: 10.1371/journal.pone.0107828] [Medline: 25229640]
47. Leeuwis C, Aarts N. Rethinking communication in innovation processes: creating space for change in complex systems. J Agric Educ Ext 2011 Feb;17(1):21-36. [doi: 10.1080/1389224x.2011.536344]
48. Mishuris RG, Stewart M, Fix GM, Marcello T, McInnes DK, Hogan TP, et al. Barriers to patient portal access among veterans receiving home-based primary care: a qualitative study. Health Expect 2015 Dec 12;18(6):2296-2305 [FREE Full text] [doi: 10.1111/hex.12199] [Medline: 24816246]

49. Ronda MC, Dijkhorst-Oei LT, Rutten GE. Reasons and barriers for using a patient portal: survey among patients with diabetes mellitus. J Med Internet Res 2014 Nov 25;16(11):e263 [FREE Full text] [doi: 10.2196/jmir.3457] [Medline: 25424228]
50. Mukhopadhyay S, Basak R, Khairat S, Carney TJ. Revisiting provider role in patient use of online medical records. Appl Clin Inform 2021 Oct 15;12(5):1110-1119 [FREE Full text] [doi: 10.1055/s-0041-1740189] [Medline: 34911125]
51. Shimoga SV, Lu YZ. Role of provider encouragement on patient engagement via online portals. J Am Med Inform Assoc 2019 Oct 01;26(10):968-976 [FREE Full text] [doi: 10.1093/jamia/ocz026] [Medline: 30925585]
52. Patel V, Johnson C. Individuals' use of online medical records and technology for health needs. ONC Data Brief. URL: http://resource.nlm.nih.gov/9918332985706676 [accessed 2024-03-04]
53. Yamin CK, Emani S, Williams DH, Lipsitz SR, Karson AS, Wald JS, et al. The digital divide in adoption and use of a personal health record. Arch Intern Med 2011 Mar 28;171(6):568-574. [doi: 10.1001/archinternmed.2011.34] [Medline: 21444847]
54. Aljabri D, Dumitrascu A, Burton MC, White L, Khan M, Xirasagar S, et al. Patient portal adoption and use by hospitalized cancer patients: a retrospective study of its impact on adverse events, utilization, and patient satisfaction. BMC Med Inform Decis Mak 2018 Jul 27;18(1):70 [FREE Full text] [doi: 10.1186/s12911-018-0644-4] [Medline: 30053809]
55. Cromer R, Denneson LM, Pisciotta M, Williams H, Woods S, Dobscha SK. Trust in mental health clinicians among patients who access clinical notes online. Psychiatr Serv 2017 May 01;68(5):520-523 [FREE Full text] [doi: 10.1176/appi.ps.201600168] [Medline: 28142383]
56. Crouch PB, Rose CD, Johnson M, Janson SL. A pilot study to evaluate the magnitude of association of the use of electronic personal health records with patient activation and empowerment in HIV-infected veterans. PeerJ 2015;3:e852 [FREE Full text] [doi: 10.7717/peerj.852] [Medline: 25802815]
57. Fossa AJ, Bell SK, DesRoches C. OpenNotes and shared decision making: a growing practice in clinical transparency and how it can support patient-centered care. J Am Med Inform Assoc 2018 Sep 01;25(9):1153-1159 [FREE Full text] [doi: 10.1093/jamia/ocy083] [Medline: 29982659]
58. Grossman LV, Masterson Creber RM, Benda NC, Wright D, Vawdrey DK, Ancker JS. Interventions to increase patient portal use in vulnerable populations: a systematic review. J Am Med Inform Assoc 2019 Aug 01;26(8-9):855-870 [FREE Full text] [doi: 10.1093/jamia/ocz023] [Medline: 30958532]
59. Goedhart NS, Zuiderent-Jerak T, Woudstra J, Broerse JE, Betten AW, Dedding C. Persistent inequitable design and implementation of patient portals for users at the margins. J Am Med Inform Assoc 2021 Feb 15;28(2):276-283 [FREE Full text] [doi: 10.1093/jamia/ocaa273] [Medline: 33463691]
60. Helsper EJ. A corresponding fields model for the links between social and digital exclusion. Commun Theor 2012 Oct 15;22(4):403-426. [doi: 10.1111/j.1468-2885.2012.01416.x]
61. Latulippe K, Hamel C, Giroux D. Social health inequalities and eHealth: a literature review with qualitative synthesis of theoretical and empirical studies. J Med Internet Res 2017 Apr 27;19(4):e136 [FREE Full text] [doi: 10.2196/jmir.6731] [Medline: 28450271]
62. Antonio MG, Petrovskaya O, Lau F. Is research on patient portals attuned to health equity? A scoping review. J Am Med Inform Assoc 2019 Aug 01;26(8-9):871-883 [FREE Full text] [doi: 10.1093/jamia/ocz054] [Medline: 31066893]
63. Bell SK, Mejilla R, Anselmo M, Darer JD, Elmore JG, Leveille S, et al. When doctors share visit notes with patients: a study of patient and doctor perceptions of documentation errors, safety opportunities and the patient-doctor relationship. BMJ Qual Saf 2017 Apr;26(4):262-270 [FREE Full text] [doi: 10.1136/bmjqs-2015-004697] [Medline: 27193032]
64. Gerard M, Chimowitz H, Fossa A, Bourgeois F, Fernandez L, Bell SK. The importance of visit notes on patient portals for engaging less educated or nonwhite patients: survey study. J Med Internet Res 2018 May 24;20(5):e191 [FREE Full text] [doi: 10.2196/jmir.9196] [Medline: 29793900]
65. Helsper EJ, van Deursen AJ. Do the rich get digitally richer? Quantity and quality of support for digital engagement. Inf Commun Soc 2016 Jun 29;20(5):700-714. [doi: 10.1080/1369118x.2016.1203454]
66. Hagström J, Blease C, Haage B, Scandurra I, Hansson S, Hägglund M. Views, use, and experiences of web-based access to pediatric electronic health records for children, adolescents, and parents: scoping review. J Med Internet Res 2022 Nov 22;24(11):e40328 [FREE Full text] [doi: 10.2196/40328] [Medline: 36413382]
67. Delbanco T, Walker J, Bell SK, Darer JD, Elmore JG, Farag N, et al. Inviting patients to read their doctors' notes: a quasi-experimental study and a look ahead. Ann Intern Med 2012 Oct 02;157(7):461-470 [FREE Full text] [doi: 10.7326/0003-4819-157-7-201210020-00002] [Medline: 23027317]
68. Pell JM, Mancuso M, Limon S, Oman K, Lin CT. Patient access to electronic health records during hospitalization. JAMA Intern Med 2015 May;175(5):856-858. [doi: 10.1001/jamainternmed.2015.121] [Medline: 25751393]
69. Petersson L, Erlingsdóttir G. Open notes in swedish psychiatric care (part 2): survey among psychiatric care professionals. JMIR Ment Health 2018 Jun 21;5(2):e10521 [FREE Full text] [doi: 10.2196/10521] [Medline: 29929946]
70. Delivering quality health services: a global imperative for universal health coverage. World Health Organization, Organisation for Economic Co-operation and Development, and The World Bank. URL: https://www.worldbank.org/en/topic/universalhealthcoverage/publication/delivering-quality-health-services-a-global-imperative-for-universal-health-coverage [accessed 2024-03-04]

71. Beleidskader transformatie jeugdzorg noord-veluwe, 'in een keer goed', 2015-2018. De raad der gemeente Elburg. 2015. URL: https://lokaleregelgeving.overheid.nl/CVDR340352/1 [accessed 2024-03-04]
72. GALA - gezond en actief leven akkoord. Dutch Ministry of Public Health, Welfare and Sports. 2023. URL: https://open.overheid.nl/documenten/ronl-e8e739b2e77bf92b7bfed78d4569ae4ecbce8dac/pdf [accessed 2024-03-04]
73. Lam BD, Bourgeois F, DesRoches CM, Dong Z, Bell SK. Attitudes, experiences, and safety behaviours of adolescents and young adults who read visit notes: opportunities to engage patients early in their care. Future Healthc J 2021 Nov 29;8(3):e585-e592 [FREE Full text] [doi: 10.7861/fhj.2021-0118] [Medline: 34888446]
74. Hagström J, Blease C, Kharko A, Scandurra I, Hägglund M. Adolescents identifying errors and omissions in their electronic health records: a national survey. Stud Health Technol Inform 2023 May 18;302:242-246. [doi: 10.3233/SHTI230111] [Medline: 37203655]
75. Benjamins J, de Vet E, Jordaan G, Haveman-Nies A. Effect of using client-accessible youth health records on experienced autonomy among parents and adolescents in preventive child healthcare and youth care: a mixed methods intervention study. J Child Health Care 2023 May 25:13674935231177782 [FREE Full text] [doi: 10.1177/13674935231177782] [Medline: 37227030]
76. Benjamins J, Duinkerken JG, den Hamer-Jordaan G, Canfijn R, Koster R, de Vet E, et al. Implementation of EPR-youth, a client-accessible and multidisciplinary health record; a mixed-methods process evaluation. Int J Integr Care 2023;23(2):26 [FREE Full text] [doi: 10.5334/ijic.6905] [Medline: 37333776]
77. Kitzinger J. Focus groups. In: Pope C, Mays N, editors. Qualitative Research in Health Care. 3rd edition. Williston, VT: BMJ Books; 2006:21-31.
78. Korstjens I, Moser A. Series: practical guidance to qualitative research. Part 4: trustworthiness and publishing. Eur J Gen Pract 2018 Dec 05;24(1):120-124 [FREE Full text] [doi: 10.1080/13814788.2017.1375092] [Medline: 29202616]

Abbreviations

CJG: Centre for Youth and Family
COREQ: Consolidated Criteria for Reporting Qualitative Studies
PAEHR: patient-accessible electronic health record
WHO: World Health Organization

Edited by S Woods; submitted 10.07.23; peer-reviewed by J Hagström, Y Chu; comments to author 30.08.23; revised version received 11.12.23; accepted 20.03.24; published 23.04.24.

Please cite as:
Benjamins J, de Vet E, de Mortier CA, Haveman-Nies A
The Effect of Using a Client-Accessible Health Record on Perceived Quality of Care: Interview Study Among Parents and Adolescents
J Particip Med 2024;16:e50092
URL: https://jopm.jmir.org/2024/1/e50092
doi:10.2196/50092
PMID:38652532

Original Paper

Getting to Know Your Patient: Content Analysis of Patients' Answers to a Questionnaire for Promoting Person-Centered Care

Juno HK Bergers[1], BSc; Hester Wessels-Wynia[2], PhD; Tatjana Seute[3], MD, PhD; Astrid Janssens[1], PhD; Johannes JM van Delden[1], MD, PhD

[1]Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Utrecht, Netherlands
[2]Marketing and Communication, Concern Staff, University Medical Center Utrecht, Utrecht, Netherlands
[3]Department of Neuro-oncology, University Medical Center Utrecht, Utrecht, Netherlands

Corresponding Author:
Johannes JM van Delden, MD, PhD
Julius Center for Health Sciences and Primary Care
University Medical Center Utrecht
Universiteitsweg 100
Utrecht, 3584 CX
Netherlands
Phone: 31 88 75 681 81
Email: j.j.m.vandelden@umcutrecht.nl

Abstract

Background: Person-centered care (PCC) encourages patients to actively participate in health care, thus facilitating care that fits the life of the patient. Therefore, health care professionals (HCPs) need to know the patient. As part of a broad policy for improving PCC, a digital questionnaire ("We would like to know you") consisting of 5 questions has previously been developed to help HCPs to get to know the patient with the help of patient and staff involvement.

Objective: The purpose of this study was to provide insight into the content and aims of the questionnaire to understand its potential and usability.

Methods: We conducted a qualitative, retrospective content analysis of patients' answers using NVivo Pro (QSR International). The questionnaire was used in the outpatient neuro-oncology department of a Dutch academic hospital.

Results: Of 374 invited patients, 78 (20.9%) completed the questionnaire. We selected a sample of 42 (54%) of the 78 patients. Patients used a median of 16 (IQR 7-27) words per question, and most answers were easily interpretable. When asked about important activities, social activities, sports, or maintaining a normal life were most frequently mentioned. Patients wrote about fear of the disease, its possible influence on life, or fear of the future in general. Patients wanted HCPs to know about their care and communication preferences or shared personal information. They formulated expectations about effective treatment, communication, and the care process.

Conclusions: The questionnaire seems usable because patients provide interpretable answers that take little time to read, which HCPs can use to personalize care. Our study shows the potential of the questionnaire to help deliver PCC.

(J Particip Med 2024;16:e48573) doi:10.2196/48573

KEYWORDS

person-centered care; shared decision-making; patient engagement; positive health

Introduction

Background

Person-centered care (PCC) is a model of care in which the active participation of patients in their own health care is encouraged. PCC is about providing holistic care to patients and not only about focusing on the patient's disease to facilitate high-quality health care. A holistic view, taking the socioeconomic environment and psychological status into consideration, is important to obtain an overall understanding of the patient's illness and is necessary for high-quality care [1].

Several definitions of PCC have been presented in the literature. Morgan and Yoder [2] defined PCC as follows: "PCC is a holistic (bio-psychosocial-spiritual) approach to delivering care that is respectful and individualized, allowing negotiation of care, and offering choice through a therapeutic relationship where persons are empowered to be involved in health decisions at whatever level is desired by that individual who is receiving the care.” Street [3] defines PCC using the combination of four domains: “(1) biopsychosocial approach to medical care, (2) patient as person/sharing power and responsibilities, (3) therapeutic alliance, and (4) coordinated care.” Listening to patients’ needs, values, and important topics is essential in health care. In the oath that new physicians take, they pledge to acknowledge patients’ values and needs and, in the Dutch oath especially, to listen to their patients [4,5].

Therefore, it is essential for a health care professional (HCP) to get to know the patient and to enhance communication with the patient to improve the mutual understanding of health care options and preferences. The acknowledged communication model to incorporate patients’ perspectives is shared decision-making (SDM). However, using SDM does not always mean that care is person centered. Generally, in SDM, discussing the patients’ preferences occurs after the HCP explains the available options and discusses the pros and cons [6]. SDM can result in a conversation where the HCP simply offers information and choices and cannot see the available options from the patient’s perspective [7]. Previously conducted studies have shown that health care interventions based on the patient narrative and getting to know the patient can be used to stimulate PCC in health care [8-10]. In addition, we have reason to believe that it is important to start the medical encounter by identifying what matters to the patient [11], so that the patient and the HCP together can decide which option is best in the patient’s context [7,12,13]. Barry and Edgman-Levitan [12] state that it is about teaching HCPs how to be effective partners in care. They specifically mention the potential of health care technologies that focus on better understanding patients’ experiences and eliciting patients’ needs and preferences.

In a large, Dutch academic hospital, as part of standard care in neuro-oncology, a technological initiative was introduced to facilitate PCC in daily health care. On the basis of the needs and preferences of stakeholders, patients, and HCPs of the hospital, a new, digital patient questionnaire “We would like to know you” was implemented, consisting of 5 questions. The aim of this initiative was to gather the health care preferences and needs of patients in a manner that would enable HCPs to seamlessly incorporate these needs and perspectives into medical consultations. It also aimed to provide patients the opportunity to express what they considered important for them. The initiative focused on enabling HCPs to use this information to make the consultation more receptive to patients’ contexts, needs, and preferences. Multimedia Appendix 1 shows the format of the questionnaire administered to the patients.

Objective

An evaluation is needed to obtain information about the usefulness of this PCC tool in health care. Insight into the content of the patients’ written answers and its possible relevance for getting to know the patient is currently lacking. It is unknown whether respondents are able to answer the questions and whether these answers are interpretable. This study filled this knowledge gap by evaluating patients’ answers to the questionnaire “We would like to know you.”

Methods

We conducted a retrospective content analysis using a qualitative, narrative research method to explore in depth the content of the questionnaire “We would like to know you” (hereafter, referred to as “the questionnaire”).

Context

The questionnaire was developed at a large university medical center in the Netherlands. It was introduced in December 2020 as part of standard care in the outpatient neuro-oncology clinic. This department specializes in oncological diagnostics and treatment of the central nervous system.

The questionnaire was developed before commencing this study as part of a broad policy of the academic hospital to improve and facilitate PCC in daily health care practice. An internal assessment was conducted using personal interviews and a patient participation network meeting from December 2020 to April 2021. The personal interviews focused on what patients thought was important personal information to share with their HCPs. They were also asked how they wanted to share this information. HCPs answered questions about how they wanted to receive patient narratives. Overall, 21 individuals were interviewed: 10 (48%) patients and 11 (52%) HCPs. The questionnaire was further developed at a network meeting for patient participation. At this meeting, 22 members were present: 6 (27%) patients; 10 (45%) hospital employees, including HCPs; 4 (18%) students; and 2 (9%) members of the hospital’s client council. In addition, input from a neuro-oncology patient panel (n=10) was collected. Overall, 7 (70%) patients, 2 (20%) HCPs, and 1 (10%) researcher were present. All members of this panel were patients currently in treatment at that time or patients who had been treated for a neuro-oncological disease. A selection of 4 possible PCC interventions was discussed. The group decided to use the questionnaire and further discussed whether the topics of the questions and the additional information buttons were suitable for the context of the neuro-oncology.

This input was used to develop the questionnaire. No alterations to the questions were made based on the discussion.

The Research Instrument

In this study, the questionnaire was further developed in the neuro-oncology patient panel (n=11). Overall, 8 (73%) patients or former patients, 2 (18%) HCPs, and 1 (9%) researcher participated. Again, the content of the questions and the information buttons were discussed. In addition, the format was further discussed. No alterations regarding the questions and information buttons were made. During the meeting, special attention was given to optimize the questionnaire so that it could easily be used by the patients in the clinical context and was embedded in the existing health care pathway.

This study’s questionnaire consists of 5 questions and an information button for each question. These information buttons were added to help patients answer the questions when they needed guidance. The 5 questions of the questionnaire and the content of the information buttons are presented in Table 1.

Table 1. Questions of the "We would like to know you" questionnaire.

Questions	Information buttons
1—What are important activities, now or in the future?	You can think of work, hobbies, or other ways you like to spend your time (traveling, sports, family and friends).
2—Which people are important in your life, and why are they important?	You can think of your partner, children, family, neighbors, friends, or people from your community, health care center, city, or other organizations.
3—What are you worried about concerning your health?	You can think of symptoms, fatigue, fear of pain, or concerns about specific things you might not be able to do in the future.
4—What do you think is important that your health care professionals know about you?	You can think of everything in relation to your care or treatment, like: do you want your doctor to address you with sir/madam or do you prefer an informal way of communication? Do you want your doctor to show pictures to explain something? Do you always want to bring a certain person to the consultation?
5—What do you expect from your treatment at the [large academic hospital]?	You can think of the results of your treatment, a regular contact person that you can always call or ask a question via e-consultations or anything else.

An internal assessment was conducted between December 2020 and April 2021. Overall, 2 HCPs of the neuro-oncology ward personally selected patients for the questionnaire based on the presumed diagnosis of a primary brain tumor and similarity of health care pathways, which included consultations with a nurse specialist, a neuro-oncologist, and a neurosurgeon. Selected patients received an invitation to answer the questionnaire together with a general introduction e-mail from the outpatient clinic before their first appointment at the hospital. From May 2021, patients were automatically selected through an electronic health record labeling system (diagnosis-treatment combination) that used the label of primary brain tumors.

The selected patients received an invitation through the hospital's electronic personal patient portal. Patients could answer the questions on a voluntary basis, either individually or with the help of relatives, before the first hospital visit and during the entire treatment process. It was possible to answer the questions multiple times. After submission of the patient's answers, the content of the questionnaire was accessible to HCPs involved in the patient's care through the personal electronic health record. During internal staff meetings, the HCPs were instructed to read the patients' answers before the consultation and were expected to address the relevant topics derived from the patients' answers during the consultation.

Data Collection

The data consisted of patients' written responses to the questionnaire submitted in the period between December 2020 and August 2021. In September 2021, an HCP involved in the treatment of patients at the neuro-oncology department received a list of patients' hospital identification numbers provided by the hospital's IT department, which automatically registered the names of the patients who completed the questionnaire. The list consisted of patients who had started to fill in or completed the questionnaire. Because of the HCP's involvement in treatment of the patients, the HCP had access to the electronic health records of the listed patients.

Patients' written answers to the questionnaire were included using a sampling strategy that was based on choosing every second questionnaire on the list provided by the IT department during 3 sessions. The HCP accessed the written patient answers through the electronic health record and extracted data by pseudoanonymizing them into plain text fragments. To protect privacy, the treating HCP (TS) provided the researchers with anonymized patients' answers, excluding information such as names, locations, and work specifications. Patients' characteristics were collected by the treating HCP and were also presented to the researcher (JHKB).

The questionnaires were included based on their number and eligibility. They were eligible when the patients' written answers were submitted between December 2020 and August 2021 and if the patients were still under treatment at the neuro-oncology department. The HCP did not extract written patient answers if the main treating physician was not from the neuro-oncology department. If written patient answers were not eligible, the HCP used the patient's identification number next on the list and assessed whether the written patient answer to the questionnaire was eligible.

Data Analysis

The aim of the analysis was to understand how patients interpreted the questions and whether their answers would help HCPs to get to know their patients Therefore, we used a content analysis approach to study the answers provided by patients [14]. We decided that the level of analysis was themes and predefined a set of categories based on the 5 questions in the survey. A researcher (JHKB) with qualitative research experience collated the answers of patients by survey question and read the answers carefully. The aim was to identify how the patients used the categories (survey questions), which would allow us to decide the usefulness and interpretability of the survey questions. Therefore, the collated answers were coded, and themes were identified. A coding tree was developed using NVivo Pro (QSR International), allowing for both deductive (predefined categories based on survey questions) and inductive codes. The inductive codes were added to reflect themes the respondents frequently addressed; they were added throughout the coding process. Practically, the first author conducted most of the work but did so in collaboration with the other authors (HWW, JJMvD, and AJ). Another researcher (HWW), skilled in narrative research, coded half of the patients' answers independently to allow for coder triangulation. Double-coded text and the resulting coding trees were discussed, and a final tree was agreed upon. In the next step, the codes were grouped: codes were merged into existing higher-level codes, or new higher-lever codes were created to group lower-level codes. Saturation was achieved at the level of main themes. The preliminary results were also discussed with the patient panel.

The quotations used in this paper were translated into English; the original quotes were in Dutch.

Ethical Considerations

Owing to the anonymized and retrospective nature of the study, ethics approval from the REC was not necessary according to Dutch law.

Results

Description of the Sample

According to the IT register, 374 patients received an invitation to complete the questionnaire between December 2020 and August 2021. Overall, 20.9% (78/374) of the patients completed the questionnaire and saved their written answers. Between December 2020 and April 2021, when patients were personally selected by HCPs for the questionnaire, 41, (41/374, 10.9%) patients received the questionnaire, 54% (22/41) answered the questions, and none (0/41, 0%) completed the questionnaire more than once.

From May 2021 to August 2021, a total of 333 (333/374, 89%) individuals were automatically provided access to the questionnaire based on a financial label of the diagnosis-treatment combination in their electronic health record. Of this group, 16.8% (56/333) of the patients completed it.

A sample of 42 (54%) written answers was selected from 78 completed questionnaires. Of this sample of 42 patients, 1 (2%) had not completed a single question, 3 (7%) answered 4 questions, and 1 (2%) answered only question 1. All 5 questions were answered by 88% (37/42) of the patients. All patients (42/42, 100%) completed the questionnaire for the first time, and none of them (0/42, 0%) completed the questionnaire more than once. The characteristics of the 42 patients are presented in Table 2. Log data were not registered by the hospital. Therefore, information about patients’ duration for completing the questionnaire, how often and for how long the information button was used, and how often and for how long an HCP looked at the questionnaire could not be collected.

Table 2. Patient characteristics (n=42).

Characteristics	Values, n (%)
Sex	
Male	20 (48)
Female	22 (52)
Age group (y)	
<40	8 (19)
40-50	4 (10)
51-60	16 (38)
>60	14 (33)
Type of disease	
Meningioma	8 (19)
Glioma	26 (62)
Glioblastoma	19 (45)
Brain metastases	5 (12)
Other	2 (5)
Unknown	1 (2)
Recurrence of the disease	8 (19)

General Impression About the Written Answers

The average use of words was quite similar for all 5 questions, but there was a spread in the number of words that patients used. The numbers are presented in Table 3. Almost all patients were able to answer the questions and provided personal information.

Most patients’ answers were intelligible and interpretable. In some cases, the interpretation was more difficult. For example, a person did not use punctuation, and another person seemed distrustful, possibly as a consequence of their neurological condition.

Table 3. Word count.

Questions	Average length of answers (words)[a]	Number of words used, median (IQR)	Spread of words[b], range
1—What are important activities, now or in the future?	25	12 (7-29)	1-298
2—Which people are important in your life, and why are they important?	25	15 (6-24)	0-218
3—What are you worried about concerning your health?	27	17 (8-25)	0-220
4—What do you think is important that your health care professionals know about you?	33	16 (9-38)	0-280
5—What do you expect from your treatment at the [large academic hospital]?	20	17 (7-24)	0-90

[a] Values are rounded to the nearest whole number.

[b] Variation between the number of words used in the written answers.

Nearly all patients stayed close to the topic of the questions. Only in a few cases, a part of the answers entailed a topic that did not directly relate to the question and included extra, personal information. Overall, 4 (10%) of the 42 answers were elaborate, consisting of >200 words.

Most patients described things that were specific to their situation. They provided additional information, such as the name and age of their children, specific activities, personal concerns, or information about their individual situation. Some patients wrote more concisely, using general language.

Question 1: What Are Important Activities, Now or In the Future?

When answering the first question, many people wrote about leisure activities and other social activities. Sports and family activities were mentioned most frequently. Slightly less than half of the respondents wrote about their job as an important activity. Some described driving a car or doing housework independently. A part of the respondents wrote about activities they wanted to do or keep doing in the future:

> *Being able to keep doing the daily housework chores including buying groceries. Exercise and cycling and going for a walk. Going on a trip with the camper (I do not drive myself). Maintaining social relationships and participating in the [organization].* [Participant 18]

Some patients did not mention a specific activity but wrote about ”maintaining normal activities” or “being independent.”

Question 2: Which People Are Important in Your Life, and Why Are They Important?

The people considered to be most important were the partner, children, family, and friends. Other people mentioned were colleagues, neighbors, and other acquaintances.

More than half of the patients provided a reason why particular people were important. Respondents noted different reasons, varying from “loving the person,” “being physically and/or mentally supported by them,” or “having fun together”:

> *My (grand)children ([number of] sons, [number of] daughters in law, [number of] grandchildren, [number] on its way). They are my everything, I am incredibly proud of them. [They give me] support and care with lots of things, vice versa.* [Participant 14]

Question 3: What Are You Worried About Concerning Your Health?

The most frequently expressed worries were about the possible influence of the disease on the patient’s life. Some patients were concerned about their health declining in general. People were worried about the development of specific physical complaints, such as brain damage, decrease in energy level, or neurological deficits. Some explicitly mentioned that they were worried about how treatment would affect their lives; others mentioned the possible influence of the disease on their loved ones. In addition, some wrote about the fear of cognitive impairment, fear of “not being themselves anymore,” or being scared to “lose control of their minds.” In addition, the influence of the disease on undertaking activities was mentioned. People worried about whether they would still be able to do their job, live independently, or stay mobile:

> *My disease and the uncertainty it brings. Will I be able to do my job the way I used to do it? How will the process [of working again] go? Will I be my old self regarding my energy level and will I be a nice partner for my girlfriend and a good father for my son?* [Participant 7]

Some worried about the disease itself. They felt that the tumor was a “thing” that was not supposed to be there and used language that referred to their disease as an entity on its own.

Some answers were about “getting better.” People were worried about whether the disease was curable and whether “everything would be alright” or that they may not have “enough time.” Furthermore, a general fear about what the future has in store was seen.

A few of the patients shared that they had no concerns, and a person explicitly did not answer the question because they wanted to stay positive. Some patients wrote the worries that they prioritized:

> *Physical [issues] do not bother me too much at the moment, I can cope with anything as long as I can be myself and my brain keeps working properly. Another great worry is that soon I won’t be able to function*

> *anymore and so as a freelancer I won't have a job, income or insurance.* [Participant 31]

Question 4: What Do You Think Is Important That Your HCPs Know About You?

Preferences regarding health care were frequently mentioned. An important topic was communication preferences. Respondents wrote about "clear or transparent communication" and "explaining medical information," sometimes with pictures. Some noted that they wanted "to be addressed casually." A number of patients wanted to take someone with them to the consultation:

> *I want to be addressed informally[.] I like it when people use humor and make jokes, also about my disease and treatment[.]...I want people to be honest with me and my partner about the treatment and prognosis[.] Openness and honesty is important to me.* [Participant 10]

In addition to discussing communication preferences, patients provided insight into their needs from and attitude toward treatment and overall health care. Some wrote that they would do anything to stay as healthy as possible, whereas a patient described the importance of having a choice:

> *I do not want to get every treatment, I want to think about the treatment and I want to have a choice...* [Participant 3]

In addition to preferences, some provided HCPs with personal information. They described how they felt, for instance, being nervous or feeling shocked by the test results. Patients also wrote about their social situation, personal characteristics, previous diseases, or current physical situation.

Question 5: What Do You Expect From Your Treatment?

Approximately half of the patients wrote about expectations regarding their treatment goals. Some wrote about "the removal of the tumor" and the hope for "curing the disease", or they wanted "the treatment to be effective". A few were afraid of possible side effects:

> *First of all the removal of the [disease]. And that the treatment does not cause long-term harmful side effects. I don't want to suffer from nasty side effects of a treatment like I did [number] years ago.* [Participant 13]

Some mentioned that they hoped to "go back to their normal lives" or wanted to "maintain quality of life." Wishes regarding the end of life were also written. Some wanted their HCP to be professional or wanted their close ones to be involved in their care. A few specifically expected guidance from HCPs throughout the care process.

Communication was mentioned as an important topic in the answers to both questions 4 and 5. Some patients expressed their desire for "clear, transparent" communication or wrote about a regular point of contact:

> *It is nice to talk to the same person every time, but I am aware that this is not always possible. I always want to know what is going on with me, openness and clarity. Even if you cannot give me an answer yet, otherwise I cannot deal with it, let alone accept "it." And yes, I want to be able to contact you for when I am having questions, it doesn't really matter how.* [Participant 14]

Information Button

Some written answers used the same words or suggested the same topics as those in the text of the information button (Table 1). For question 4, approximately one-third of the patients specifically mentioned their wish to bring someone to the consultation. Others wrote that they wanted to be addressed informally or wanted an HCP to show pictures while explaining the medical information.

Slightly less than half of the respondents wrote about the result of the treatment while answering question 5, and a few patients mentioned a regular contact person. A person seemed to directly react to the information button:

> *I already have a regular contact person, very nice. Pull out all the stops to get better.* [Participant 9]

Discussion

Principal Findings

This study showed that patients addressed a variety of topics related to their care. Frequently mentioned topics for important activities were leisure activities, such as social activities or sports. Some mentioned their job, and others wrote more generally about maintaining normal activities. Many respondents said that their partner, children, other family members, and friends were important people. If patients provided a reason why these people were important to them, they often wrote about loving the person or feeling supported by them. The possible influence of the disease on their health was a concern expressed most frequently by the patients. The written answers contained concerns about the effect of the disease on their physical and mental health or the effect on undertaking activities. Getting better in general was also an issue that was mentioned. For some, the tumor itself, being a thing that does not belong in someone's head or body, made them anxious. Others wrote about fear of the future in general. The respondents wanted their HCP to know about their health care preferences, such as their treatment goals or communication preferences. Others shared information about their personal life, such as their social situation, personal characteristics, or physical situation. Expectations regarding effective treatment and the care process, including HCPs' attitudes, the involvement of close ones, and decision-making, were emphasized.

This content appears to be relevant for health care, even if it is not always surprising. The addressed topics show similarity with the important factors regarding patients' perception about high-quality communication [15-18]. The questionnaire provides an opportunity for patients to think about what they consider important for their health care. Moreover, it can help HCPs to follow up on these topics during the consultation. The questionnaire can be a starting point for HCPs to explore patients' wishes, needs, and preferences relevant for a person-centered approach to care, allowing for a phenomenological approach to illness, to supplement the traditional, naturalistic medical approach.

Our results show similarities to the results of the study by Zwakman et al [19]. Zwakman et al [19] conducted a content analysis of a preference form as part of advance care planning for patients with advanced stage cancer. The preference form has questions that are comparable with questions 1, 3, 4, and 5 of this study. Both in the study by Zwakman et al [19] and in this study, maintaining a normal life and doing everyday activities were important topics. Moreover, patients valued spending time with family and friends. In both studies, patient populations expressed concerns about the effect of the treatment and the disease's progression. Furthermore, staying independent and clear communication were important topics. However, in our study, respondents wrote less about end-of-life arrangements and alternative treatment options, possibly owing to the difference in treatment phase. Patients expressed a more precise expectation regarding their care in our study, perhaps because the question was asked more directly.

Overall, approximately 20.9% (78/374) of patients completed the questionnaire. Between December 2020 and April 2021, the percentage of completed questionnaires was higher, namely 54% (22/41). In this first phase, an internal assessment was conducted, in which the questionnaire was actively promoted. The low response percentage after April 2021 suggests that HCPs' awareness is important and can stimulate patients to complete the questionnaire, making the questionnaire potentially more usable. Other reasons that could have influenced the response percentage were unawareness of the patient portal, difficulties in finding the questionnaire, or not wanting to answer the questions.

The selected sample showed an average word count of approximately 26 words per question, and the median number of words used was between 12 and 17. Time constraints for HCPs are a known barrier to the implementation of PCC interventions [20,21]. In this sample, patients mostly used a limited number of words, making it easy to read quickly for HCPs. Most patients were able to respond to the 5 questions and wrote an interpretable answer. Most stayed close to the topics of the questions, and some patients wrote additional information.

The information button was developed to provide guidance to patients. Our results suggest that the information buttons might influence the patients' answers. The respondents sometimes write about particular topics mentioned in the information button, such as bringing a person to the consultation, explaining medical information with pictures, talking about a regular contact person, or having expectations about the result of treatment. Altering the text of the information button could improve the relevance of the information the questionnaire yields regarding daily health care. An example could be adjusting the information button's text for question 4 by adding treatment preferences as a suggested topic.

Strengths and Limitations

The strength of this study lies in the data and the thoroughness of the content analysis. Apart from the anonymized parts of the text, we used the patients' exact words and punctuation as the treating HCP would read it. Moreover, we assessed the answers to the questionnaire regarding concise versus detailed writing and digression from and elaboration about the topic and estimated the ease of interpretation.

This study also had some limitations. First, this patient population is specific. Patients with neuro-oncological conditions have a very serious, often life-limiting disease that requires high-intensity care. It is possible that other topics found in this study may be different for other patient populations. Second, patients included in this study were affected by different histological diagnoses with therefore different prognoses and treatments for their diseases. In this study, this was not analyzed specifically. Third, our sample size of 42 patients is limited. Nevertheless, it still provides useful insights and can help to elucidate the questionnaire's ability to improve PCC in daily health care.

Conclusions

This questionnaire helps to stimulate patients to write about things that they consider important. By reading the patient's answers before the consultation, HCPs can start the medical encounter with more insight into what matters to the patient. This is a major component of what determines the quality of care according to patients [22] and thus may facilitate care to become truly person centered.

This study can help the further development and implementation of the questionnaire, for instance, by adjusting the information buttons. For future studies, it may be important to repeat the questionnaire later in the care process to evaluate the possible changes in patients' answers. The questionnaire could benefit from future studies that focus on the experiences of patients and HCPs with the questionnaire, its possible effect on the medical consultation, and the evaluation of facilitators of and barriers to its implementation in daily health care practice.

Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Authors' Contributions

JHKB contributed to the design of the study, collected the data, analyzed and interpreted the data, drafted the paper, and approved the final paper as submitted. HWW contributed to the design of the study, analyzed and interpreted the data, critically reviewed and revised the paper, and approved the final paper as submitted. TS contributed to the collection of the data, critically reviewed and revised the paper, and approved the final paper as submitted. AJ drafted and edited the paper with a special focus on methodology and approved the final paper as submitted. JJMvD contributed to the design of the study, interpreted the data, drafted and edited the paper, and approved the final paper as submitted.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Format of the “We would like to know you” questionnaire administered to patients.
[DOC File , 81 KB - jopm_v16i1e48573_app1.doc]

References

1. Håkansson Eklund J, Holmström IK, Kumlin T, Kaminsky E, Skoglund K, Höglander J, et al. "Same same or different?" a review of reviews of person-centered and patient-centered care. Patient Educ Couns 2019 Jan;102(1):3-11. [doi: 10.1016/j.pec.2018.08.029] [Medline: 30201221]
2. Morgan S, Yoder LH. A concept analysis of person-centered care. J Holist Nurs 2012 Mar 19;30(1):6-15. [doi: 10.1177/0898010111412189] [Medline: 21772048]
3. Street RLJ. Mapping diverse measures of patient-centered communication onto the conceptual domains of patient-centered care. Patient Educ Couns 2019 Jul;102(7):1225-1227. [doi: 10.1016/j.pec.2019.05.011] [Medline: 31155039]
4. Dossabhoy SS, Feng J, Desai MS. The use and relevance of the Hippocratic oath in 2015-a survey of US medical schools. J Anesth Hist 2018 Apr;4(2):139-146. [doi: 10.1016/j.janh.2017.09.005] [Medline: 29960679]
5. Biesma DH, Legemaate J, Houwaart ES, van Dijk G, Briët JW, van der Kooi AL, et al. Nederlandse artseneed. Nederlandse Federatie van Universitair medische Centra (NFU). 2020. URL: https://www.nfu.nl/sites/default/files/2020-08/Artseneed2009.pdf [accessed 2021-10-20]
6. Stiggelbout AM, Pieterse AH, De Haes JC. Shared decision making: concepts, evidence, and practice. Patient Educ Couns 2015 Oct;98(10):1172-1179. [doi: 10.1016/j.pec.2015.06.022] [Medline: 26215573]
7. Hargraves I, LeBlanc A, Shah ND, Montori VM. Shared decision making: the need for patient-clinician conversation, not just information. Health Aff (Millwood) 2016 Apr;35(4):627-629. [doi: 10.1377/hlthaff.2015.1354] [Medline: 27044962]
8. Clarke A, Hanson EJ, Ross H. Seeing the person behind the patient: enhancing the care of older people using a biographical approach. J Clin Nurs 2003 Sep;12(5):697-706. [doi: 10.1046/j.1365-2702.2003.00784.x] [Medline: 12919216]
9. Fors A, Ekman I, Taft C, Björkelund C, Frid K, Larsson ME, et al. Person-centred care after acute coronary syndrome, from hospital to primary care - a randomised controlled trial. Int J Cardiol 2015 May;187:693-699. [doi: 10.1016/j.ijcard.2015.03.336] [Medline: 25919754]
10. Banfi P, Cappuccio A, Latella ME, Reale L, Muscianisi E, Marini MG. Narrative medicine to improve the management and quality of life of patients with COPD: the first experience applying parallel chart in Italy. Int J Chronic Obstr Pulm Dis 2018 Jan;Volume 13:287-297. [doi: 10.2147/copd.s148685]
11. Verberne WR, Stiggelbout AM, Bos WJ, van Delden JJ. Asking the right questions: towards a person-centered conception of shared decision-making regarding treatment of advanced chronic kidney disease in older patients. BMC Med Ethics 2022 Apr 27;23(1):47 [FREE Full text] [doi: 10.1186/s12910-022-00784-x] [Medline: 35477488]
12. Barry MJ, Edgman-Levitan S. Shared decision making — the pinnacle of patient-centered care. N Engl J Med 2012 Mar;366(9):780-781. [doi: 10.1056/nejmp1109283]
13. Duggan PS, Geller G, Cooper LA, Beach MC. The moral nature of patient-centeredness: is it "just the right thing to do"? Patient Educ Couns 2006 Aug;62(2):271-276. [doi: 10.1016/j.pec.2005.08.001] [Medline: 16356677]
14. White MD, Marsh EE. Content analysis: a flexible methodology. Libr Trends 2006 Jun;55(1):22-45 [FREE Full text] [doi: 10.1353/lib.2006.0053]
15. Bensing J, Rimondini M, Visser A. What patients want. Patient Educ Couns 2013 Mar;90(3):287-290. [doi: 10.1016/j.pec.2013.01.005] [Medline: 23395286]
16. Kenny DT. Determinants of patient satisfaction with the medical consultation. Psychol Health 1995 Sep;10(5):427-437. [doi: 10.1080/08870449508401961]
17. Alessy SA, Alhajji M, Rawlinson J, Baker M, Davies EA. Factors influencing cancer patients' experiences of care in the USA, United Kingdom, and Canada: a systematic review. EClinicalMedicine 2022 May;47:101405 [FREE Full text] [doi: 10.1016/j.eclinm.2022.101405] [Medline: 35497061]
18. Deledda G, Moretti F, Rimondini M, Zimmermann C. How patients want their doctor to communicate. a literature review on primary care patients' perspective. Patient Educ Couns 2013 Mar;90(3):297-306. [doi: 10.1016/j.pec.2012.05.005] [Medline: 22709720]
19. Zwakman M, van Delden JJ, Caswell G, Deliens L, Ingravallo F, Jabbarian LJ, et al. Content analysis of Advance Directives completed by patients with advanced cancer as part of an Advance Care Planning intervention: insights gained from the ACTION trial. Support Care Cancer 2020 Mar 5;28(3):1513-1522 [FREE Full text] [doi: 10.1007/s00520-019-04956-1] [Medline: 31278462]

20. McMillan SS, Kendall E, Sav A, King MA, Whitty JA, Kelly F, et al. Patient-centered approaches to health care: a systematic review of randomized controlled trials. Med Care Res Rev 2013 Jul 26;70(6):567-596. [doi: 10.1177/1077558713496318]
21. Moore L, Britten N, Lydahl D, Naldemirci Ö, Elam M, Wolf A. Barriers and facilitators to the implementation of person-centred care in different healthcare contexts. Scand J Caring Sci 2017 Dec 08;31(4):662-673 [FREE Full text] [doi: 10.1111/scs.12376] [Medline: 27859459]
22. Entwistle V, Firnigl D, Ryan M, Francis J, Kinghorn P. Which experiences of health care delivery matter to service users and why? a critical interpretive synthesis and conceptual map. J Health Serv Res Policy 2012 Apr 01;17(2):70-78 [FREE Full text] [doi: 10.1258/jhsrp.2011.011029] [Medline: 21967821]

Abbreviations

HCP: health care professional
PCC: person-centered care
SDM: shared decision-making

Edited by J Wald; submitted 01.05.23; peer-reviewed by A Oostdyk, M Wright, R Marshall; comments to author 30.06.23; revised version received 08.11.23; accepted 03.01.24; published 04.03.24.

Please cite as:
Bergers JHK, Wessels-Wynia H, Seute T, Janssens A, van Delden JJM
Getting to Know Your Patient: Content Analysis of Patients' Answers to a Questionnaire for Promoting Person-Centered Care
J Particip Med 2024;16:e48573
URL: https://jopm.jmir.org/2024/1/e48573
doi:10.2196/48573
PMID:38437017

Original Paper

Investigating Patient Satisfaction Through Web-Based Reviews of Norwegian Dentists: Quantitative Study Using the Meaning Extraction Method

Maria Larsen[1]; Gro Eirin Holde[1,2], PhD; Jan-Are Kolset Johnsen[1], PhD

[1]Department of Clinical Dentistry, Faculty of Health Sciences, UiT The Arctic University of Norway, Tromsø, Norway
[2]The Public Dental Health Service Competence Centre of Northern Norway, Tromsø, Norway

Corresponding Author:
Jan-Are Kolset Johnsen, PhD
Department of Clinical Dentistry
Faculty of Health Sciences
UiT The Arctic University of Norway
Hansine Hansens veg 86
Tromsø, 9019
Norway
Phone: 47 77 64 67 51
Email: jan.a.johnsen@uit.no

Abstract

Background: Challenging encounters in health care professions, including in dentistry, are relatively common. Challenging encounters can be defined as stressful or emotional situations involving patients that could impact both treatment outcomes and patients' experiences. Through written web-based reviews, patients can share their experiences with health care providers, and these posts can be a useful source for investigating patient satisfaction and their experiences of challenging encounters.

Objective: This study aims to identify dominant themes from patient-written, web-based reviews of dentists and investigate how these themes are related to patient satisfaction with dental treatment.

Methods: The study data consisted of 11,764 reviews written by dental patients, which included 1- to 5-star ratings on overall satisfaction and free-text comments. The free-text comments were analyzed using Linguistic Inquiry and Word Count software, and the meaning extraction method was used to group words into thematic categories. These themes were used as variables in a multilevel logistic regression analysis to predict patient satisfaction.

Results: Eight themes emerged from the analyses, of which 6 (75%)—*explanation* (odds ratio [OR] 2.56, 95% CI 2.16-3.04; $P<.001$), *assurance* (OR 3.61, 95% CI 2.57-5.06; $P<.001$), *performance assessment* (OR 2.17, 95% CI 1.84-2.55; $P<.001$), *professional advice* (OR 1.81, 95% CI 1.55-2.13; $P<.001$), *facilities* (OR 1.78, 95% CI 1.08-2.91; $P=.02$), and *recommendation* (OR 1.31, 95% CI 1.12-1.53; $P<.001$)—increased the odds of high patient satisfaction. The remaining themes (2/8, 25%)—*consequences of treatment need* (OR 0.24, 95% CI 0.20-0.29; $P<.001$) and *patient-centered care* (OR 0.62, 95% CI 0.52-0.74; $P<.001$)—reduced the odds of high patient satisfaction.

Conclusions: The meaning extraction method is an interesting approach to explore patients' written accounts of encounters with dental health professionals. The experiences described by patients provide insight into key elements related to patient satisfaction that can be used in the education of dental health professionals and to improve the provision of dental health services.

(J Particip Med 2024;16:e49262) doi:10.2196/49262

KEYWORDS

internet use; Linguistic Inquiry and Word Count; LIWC; patient satisfaction; patient preference; challenging encounters; preventive dentistry; population surveillance

Introduction

Challenging Encounters and Patient Satisfaction

Challenging encounters in health care are not uncommon [1,2] and can be defined in various ways by individual health care providers [3]. Situations such as dealing with violent patients, “breaking bad news,” and managing demanding family members are examples of challenging situations mentioned by health care providers [4,5]. Health care providers have also referred to patients they perceive as challenging as the source of conflict, and anxious or angry patients are most often mentioned as challenging [4,6]. Studies have also defined challenging encounters as situations where patients are “causing negative feelings in physicians” [7], and challenging encounters between health care providers and patients have been linked to increased burnout and stress among health care providers [2,8]. This issue is also highly relevant in dentistry, and dentists have reported that up to 25% of their daily encounters are perceived as challenging [6]. While studies have addressed how health care providers define and experience challenging encounters, the patient experience has been explored to a lesser extent. Whether a patient has experienced a challenging encounter could be researched through use of patient satisfaction measures.

Patient satisfaction has been defined in many different ways in research through the years. In a recent literature review [9], three main definitions of patient satisfaction were identified: (1) the patients’ experience based on their expectations of a health care service and how the service met their expectations, (2) patient satisfaction defined as feedback forming the basis for the improvement of health care services, and (3) patient satisfaction defined as the patients’ perception of health care providers’ ability to provide proper care and the quality of the interpersonal relationship. Research investigating patient satisfaction has revealed inconsistent results regarding the establishment of important determinants [10]. This might be due to differing definitions of the concept of patient satisfaction among studies [9,10]. In addition, in most studies, patient satisfaction is generally reported as high; however, this could be an overstatement due to limitations in the data collection instruments, and it has been suggested that including measurements of patient dissatisfaction in the instruments may help produce a more correct picture [10]. Arguably, there is a need to include issues relevant to patients that are not predefined by health care personnel or researchers [9]. A recent literature review has criticized current methods for evaluating patient satisfaction in health care, arguing that they seem to have been adopted from consumer satisfaction models and could therefore be inappropriate in health care settings [9]. Research has shown that the most important predictor of patient satisfaction is high-quality patient communication [11]. In addition, what seems most important to patients when indicating satisfaction is the relationship between the patient and the health care personnel, as well as the perceived social abilities of the health care personnel [12]. Furthermore, a link has been found between patient satisfaction and the performance of dental health professionals [13]. Other issues, such as the availability of services (including short waiting times, access to local hospitals, and ample parking) and the technical performance of the health care personnel, seem to matter less while still remaining important determinants of patient satisfaction [12].

Internet Research and Health Care Services

The internet provides almost unlimited user-generated content available for research, and for health researchers, it presents the opportunity to investigate the general public’s opinions and knowledge on a myriad of topics, including those related to health [14,15]. These data also enable research on social interactions (eg, the interactions between caregivers and users in web-based treatment procedures [15] through the use of natural language processing [NLP] [16]). NLP refers to the use of computational models on natural text materials to study associations between language and other variables, including the prediction of behavior or other outcomes. It is used widely in several disciplines (eg, opinion mining in sales and marketing services [14] as well as research on user-written reviews of experiences and products [17]). The methods within the field of NLP can also be used to investigate interesting health-related aspects, such as the detection of signs of clinical depression [18] and social anxiety [19]. In the broader context of health care, topics such as users’ opinions, experiences, and health literacy and competence are relevant to investigate with NLP [15]. In addition, patient-written reviews of health care services could present a major source of information relevant to health care workers.

There are currently many websites that provide patients with the opportunity to rate and write about their experiences with health care providers. While the use of social media as a platform for health communication is generally considered a powerful tool for both patient and health care providers [20], web-based reviews of health care services and health care providers might provide unique insight into the experiences of patients and their evaluations of the quality of health services [20]; for example, in recent research investigating the web-based reviews of an obstetric care clinic, it was found that patients’ experiences of the quality of the facilities and the perception of staff as comforting and providing high-quality care were associated with increased patient satisfaction [21]. Compared to other means of providing feedback to health care professionals, web-based reviews have benefits such as perceived anonymity and freedom from potentially negative consequences of evaluating figures of authority. Further benefits can be related to the social dimension of disseminating one’s views, experiences, and opinions to peers [20]. However, some challenges are also apparent, such as the subjectivity and contextual nature of web-based reviews [22] as has been found for other web-based evaluations related to health care [23].

Web-Based Evaluations of Dentists

While numerous studies have examined web-based ratings of physicians [9], few have examined web-based ratings of dentists. In a study of web-based evaluations of dentists in Germany, it was found that rating scores were largely positive and that younger or female dentists provided the most positive ratings [24]. In addition, differences in ratings emerged among clinical specialties, with pediatric dentists receiving better ratings than orthodontists [24]. Furthermore, a study published in the United States showed that younger or female dentists received the best web-based reviews, as did dentists where patients experienced shorter waiting times [25]. Studies also point to specific topics that seem to influence evaluations, such as experiences of discomfort perceptions of a lack of professional ethics [25], and topics that might be specifically related to challenging encounters or negative evaluations of dentists on the web [26]. Interestingly, negative web-based reviews about dentists, while uncommon [24,26], are perceived as more trustworthy than positive reviews [27].

Considering these findings and challenges, this study aims to investigate how the content of web-based reviews of dentists in Norway can be used to predict patient satisfaction and challenging encounters, indicated by high and low rating scores, respectively, through the following steps: (1) identify dominant themes discussed by patients in their reviews and (2) investigate the dominant themes and their relationship with patient satisfaction and challenging encounters as rated by the patients.

Methods

Overview

The data were extracted from a Norwegian website that helps patients connect with health care professionals by the administrators of the website and made available to us as a downloadable data dump [28]. On this website, there is an option for patients to write about their experiences regarding receiving health care from dentists, general practitioners, physical therapists, and other health care professionals. A total of 11,764 patient reviews of dentists posted during the period from February 2013 to June 2020 were included in the data set. The patients rated their overall experience using 1 to 5 stars (1=*very unsatisfied* and 5=*very satisfied*) in addition to providing written comments. Patients could also rate other aspects of treatment, such as service, price, and treatment comfort. In addition, information about the date of the post and self-reported visiting frequencies was included. However, in this study, only the written comments and overall rating scores were used in the analysis.

Language Analysis and Theme Extraction

The language analysis tool Linguistic Inquiry and Word Count (LIWC; version 2022) [29] was used to analyze the text data. The LIWC is designed to measure psychometric properties in language. As noted by Boyd [30], LIWC analysis typically works best with texts exceeding 50 words (shorter texts with a minimum of 10 words may still yield some insights, but the results may be less accurate). This is because LIWC dictionaries work by calculating the relative percentage of a word’s occurrence in a body of text. In our analysis, the Norwegian LIWC 2007 dictionary was used [31]. By applying the meaning extraction method (MEM) through the LIWC's built-in meaning extraction helper, we could determine the dominant word categories used in the reviews. A detailed description of the principles behind the MEM can be found elsewhere [30]; however, in the following subsections, we will describe the process in detail as it relates to this data set.

Analysis Inclusion Criteria: Text Length and Word Frequencies

The free text of the comments section of the 11,764 reviews was run through the meaning extraction helper. Each review consisted of a header and a main comment. In the analysis, all words with raw frequency of >2% were retained. The decision to use 2% instead of 5%, as recommended by Boyd [30], was due to the large number of small texts in our data set. Specifically, we found that a large number of words would appear in <5% of the material because each comment was analyzed as a single text. Hence, a 5% cutoff would exclude too many words, whereas the cutoff value of 2% provided sufficient removal of uncommon words. Each comment posted on the aforementioned Norwegian website needed to be at least 100 characters long, including punctuations and spaces. Even so, to avoid including text that would not provide any meaningful information to the content analysis (eg, exclamatory remarks such as “Great dentist!” with no further information other than signs or emojis), the inclusion criterion for the length of reviews included in the analysis was set to >5 words. To ensure meaningful results, the header was removed from further analysis because it often duplicated words used in the main comment. This could have created a false emphasis on certain commonly used phrases.

Lemmatization List and Stop List

The MEM relies on the process of lemmatization, which requires a lemmatization list and a stop list. These were created following the recommendations from previous research [30,32,33]. The lemmatization list converts commonly used words to their word stem to count words correctly (Multimedia Appendix 1). The stop list omits words from further analysis, and the words chosen to be omitted would typically be words that were of no interest to the research question, such as the names of geographic locations, the word “dentist” (as we would expect it to be present in almost all comments), or numerical words. In addition, some function words, such as selected personal pronouns, conjunctions, and prepositions, were omitted ahead of analysis because they appeared often and could therefore dilute important content words. Examples of function words and other words omitted can be found in the stop list (Multimedia Appendix 2). Words included in the analysis were verbs, adjectives, adverbs, nouns, and all function words that were not included in the stop list. Care was taken not to omit too many words to preserve the rawness of the data. In addition, because internet-based language often adopts an informal, conversational style, resembling speech [34], we needed some function words to be retained, although some recommend that they be removed completely [30].

Exploratory Factor Analysis

The results provided from the MEM were used to perform an exploratory factor analysis [35] using SPSS (version 28.0; IBM Corp). The MEM analysis provided a binary matrix for all reviews, which included a value of 1 if the words appeared in the review and 0 if not. The Bartlett test of sphericity and the Kaiser-Meyer-Olkin test of sampling adequacy were performed to test whether the MEM results were suitable for factor analysis. Varimax rotation was used to extract uncorrelated factor items with a factor loading threshold set to >0.2 based on the recommendations made by Markowitz [33]. Determining the number of factors to extract was based partly on an inspection of the scree plot (ie, the identification of the elbow of the plot) and eigenvalues (>1), as well as on the proposed factors' interpretability. Words that had cross-loadings of >0.2 were omitted.

The words contained within the factors were then added to the Norwegian LIWC dictionary [31] as separate word categories. The complete data set was run through the LIWC analysis using the modified dictionary. The LIWC gives information for each review in terms of the percentage of words that matches the dictionary word categories.

Multilevel Logistic Regression Analysis

To determine how the retrieved factors could predict patient satisfaction, a 2-level (dentist and review) random intercept logistic regression model was built, with *high patient satisfaction* as the outcome. *Patient satisfaction* was the overall rating variable recoded to a binary variable, whereby ratings of either 4 or 5 stars signified *high patient satisfaction*, and ratings of 1, 2, or 3 stars signified *low patient satisfaction*. The 8 factors (the aforementioned 8 themes) were entered as covariates recoded into binary variables—*frequent use* versus *infrequent use* or *use* versus *no use*—with the median as cutoff value (with median=0 being recoded as *no use*). A multilevel analysis was chosen as the reviews were not statistically independent variables because they could be commenting on the same dentist. The multilevel logistic regression analysis was performed in MLwiN (Centre for Multilevel Modelling, University of Bristol) [36]. The results are reported as regression coefficients, odds ratios (ORs), and respective 95% CIs. The variance partition coefficient (VPC) was also reported. The VPC estimates the proportion of the total variance in positive versus challenging encounters attributable to differences among dentists. The VPC is given as $\sigma^2_{\upsilon0}/(\sigma^2_{\upsilon0}+\Pi^2/3)$ [37].

Ethical Considerations

All reviews were posted on the Norwegian website [28] voluntarily, and the data set provided by the website administrators contained only anonymous data. The study was approved by the Norwegian Centre for Research Data (468642).

Results

Overview of the Data

A description of the demographics of the data set can be viewed in Table 1. The mean word count of each review was 48.9 (SD 39). More than nine-tenths of the reviews (10,977/11,764, 93.31%) had a high rating score (4-5 stars), whereas the remaining reviews (687/11,764, 5.84%) had a low rating score (1-2 stars). A total of 2950 dentists had received a rating in our data set, and the mean number of reviews per dentist was 3.9.

Table 1. Age and sex distribution of dentists and patients.

	Dentists (n=2950), n (%)	Patients (n=11,764), n (%)
Age (y)		
<20	0 (0)	64 (0.54)
20-30	74 (2.51)	2017 (17.15)
31-40	710 (24.07)	1947 (16.55)
41-50	823 (27.90)	1417 (12.05)
51-60	591 (20.03)	1098 (9.33)
>60	751 (25.46)	755 (6.42)
Missing	1 (0.03)	4466 (37.96)
Sex		
Male	1597 (54.14)	3407 (28.96)
Female	1328 (45.02)	4235 (36)
Missing	25 (0.85)	4122 (35.04)

Exploratory Factor Analysis

The exploratory factor analysis identified 8 factors (Textbox 1) that will be described in the following subsection. The Bartlett test of sphericity was significant ($P<.001$), and the Kaiser-Meyer-Olkin measure of sampling adequacy was 0.66.

The factors extracted together explained 13.2% of the sample variation, and they were thematically labeled based on a theoretical understanding of the words they contained: *consequences of treatment need*, *explanation*, *assurance*, *facilities*, *recommendation*, *patient-centered care*, *professional advice*, and *performance assessment*.

Textbox 1. Factors and factor loading (%) for words from the exploratory factor analysis.

Consequences of treatment need (eigenvalue: 3.205)

- Receive: 0.479
- Tooth: 0.478
- Must: 0.421
- Become: 0.421
- Come: 0.356
- Go: 0.350
- Caries: 0.314
- Sat: 0.296
- Because of: 0.283
- Back: 0.274
- Bad: 0.273
- Same: 0.261
- Ache: 0.258
- New: 0.254
- Wanted: 0.249
- Day: 0.244
- Pain: 0.242
- Anesthetics: 0.241
- Where: 0.239
- Enough: 0.225

Explanation (eigenvalue: 2.087)

- To do: 0.632
- Explain: 0.571
- Why: 0.386
- Good: 0.258
- Tell: 0.249
- Thorough: 0.205

Assurance (eigenvalue: 1.863)

- Feel: 0.881
- Safe: 0.676
- Take care of: 0.613
- Hands: 0.369

Recommendation (eigenvalue: 1.777)

- Recommend: 0.787
- Strongly: 0.484
- Warm: 0.466
- Could: 0.375
- Absolutely: 0.230
- Really: 0.226
- Unbelievable: 0.201

Facilities (eigenvalue: 1.671)

- Modern: 0.774
- Equipment: 0.751
- Premises: 0.507

Patient-centered care (eigenvalue: 1.571)

- Take: 0.789
- Consideration: 0.453
- Care: 0.433
- Patient: 0.263

Professional advice (eigenvalue: 1.511)

- Give: 0.505
- Advice: 0.403
- Information: 0.337
- Treatment: 0.325
- Very: 0.263
- Profoundly: 0.223
- Pleased: 0.217
- Amazing: −0.230
- Professional: 0.200

Performance assessment (eigenvalue: 1.456)

- Quick: 0.495
- Efficient: 0.428
- Nice: 0.348
- Wisdom tooth: 0.260
- Job: 0.241
- Forthcoming: 0.234

Dominant Themes Identified by the Analysis

Consequences of Treatment Need

The theme *consequences of treatment need* seemed to contain words related to the patients' need for treatment, with mentions of dental health issues such as dental caries ("tooth" and "caries"). In addition, other words associated with this theme seemed to express the urgent need to obtain an appointment ("must," "receive," "new," "come," and "go"), as well as words that might be related to an explanation of what happened ("back," "because of," "same," and "where"). The word "must" could be related to the feeling of a lack of self-agency and self-determination in the situation, for example, in this quote, where the patient might have felt that they had no control of the situation:

> *When I first got there, she seemed friendly, but that was before the treatment started. During treatment she had no consideration and continued even though I was crying in the chair.* [Example 1]

In this theme, many words were action related (verbs), in the sense that something happened or certain actions were performed ("go," "receive," and "become"); for instance, patients would sometimes explain the turn of events resulting in a dentist appointment or their reasons for either seeking dental treatment or writing about the dental encounter. Arguably, it could also be the case that these words were related to the feeling of unmet expectations ("wanted" and "enough"). Typically, patients would often describe themselves as experiencing dental anxiety, which contributed to an uncomfortable treatment situation:

> *He got annoyed and asked very rudely what my problem was. Well yeah mister I have dental phobia! DO YOU EVEN KNOW SOME PEOPLE SUFFER FROM THIS? I stopped the treatment and paid 450 NOK for him to be rude to me. Still on the lookout for a good dentist who can deal with people like me. Don't go to him if you have this phobia!* [Example 2]

Explanation

The theme *explanation* contained words such as “explain,” “tell,” and “why.” From the other prevalent words in this theme (“thorough,” “good,” and “to do”), it could be argued that patients used these words to describe instances where the dentist thoroughly explained the treatment or other topics, as exemplified by this quote:

> *[Name] adapts the treatment, stops and gives you small breaks during treatment, check that you feel okay, she is very good at explaining what is going to happen and what she does during treatment.* [Example 3]

Assurance

The theme *assurance* contained words related to safety and care (“safe,” “take care of,” “hands,” and “feel”) as experienced in relation to the encounter between patient and dentist:

> *You feel like you are in good hands. A cheerful and pleasant lady! Your dental fear disappears when you sit down and she begins to talk.* [Example 4]

Facilities

The theme *facilities* contained the words “modern,” “equipment,” and “premises,” which indicates that patients specifically noticed the environment of the dental clinic:

> *Shows and explains to you using modern equipment. I strongly recommend him.* [Example 5]
>
> *Got no information about cost and got yelled at for not using them last time (dental emergency office—I have a regular dentist) bragged about the expensive equipment, where I had to pay 900 NOK for a picture I didn’t need.* [Example 6]

Recommendation

The theme *recommendation* contained words related to the need to disseminate the patients’ views of the dentist to others, with words such as “recommend” and “strongly”:

> *I recommend him to everyone I know with toothache.* [Example 7]
>
> *I strongly recommend this dentist!* [Example 8]

Patient-Centered Care

The theme *patient-centered care* contained words related to patient-centered care or the experience of empathetic behavior from the dentist (“take,” “care,” “patient,” and “consideration”). It would be tempting to think that this theme would be linked to *high patient satisfaction*, but the words could also be used to express how the patient would have liked to be treated; for instance, in the following quote, we see how the words related to patient-centered care were used when the patient expressed experiencing a lack of patient centeredness:

> *It is distressing that there are dentists that have so little consideration for their patients. When you are in a vulnerable situation beforehand, then this is the last thing you need. It is not just teeth they are working with, but humans!* [Example 9]

In any case, we noted that patients often wrote about patient centeredness and found it important to experience that the staff and dentist were comforting.

Performance Assessment

The theme *performance assessment* contained words describing the perceived performance of the dentist, an inference to how they performed and the quality of the performance. Here, we find words such as “nice,” “quick,” “efficient,” and “wisdom tooth.” Patients writing the reviews seemed to value their time, and efficient dentists (those completing procedures quickly) were viewed more favorably than dentists perceived to be inefficient at managing their time:

> *Removed all 4 of my wisdom teeth in a total of 31 (!!!) minutes. 18 minutes the first time and 13 minutes the second time. Do I have to say more? Great experience!* [Example 10]
>
> *I was not impressed when I went to [name]. I think he spends too much time treating relatively simple issues. Had some complications with a dental restoration that he did which never really got better.* [Example 11]

Interestingly, dentists who were perceived as careless or too quick may risk increasing the likelihood of posttreatment issues for patients:

> *Rushed through the appointment, did not wait long enough to let the anesthetics kick in and drilled right into the nerve, so my head exploded. My dental anxiety that [name; in the same building] had cured came back.* [Example 12]

Patients value high-quality work and might feel more pleased with treatment if the dentist acts professionally, is competent, and achieves efficiency without compromising the quality of the treatment.

Professional Advice

The theme *professional advice* consisted of words related to providing information and clinical advice to patients, such as “give,” “advice,” and “information.” It also contained quality assessments of how the advice was perceived or provided, as we can infer from the words “amazing,” “professional,” “pleased,” “very,” and “profoundly.” Patients clearly appreciate professional advice on how to take care of their oral health and their treatment options:

> *Experience this dentist as skilled, thorough and detail oriented. Gives good information about follow up treatment and what to do at home.* [Example 13]
>
> *[Name]’s ability to inform about how to treat the post-treatment complications was bad, and the recommended measures had no effect.* [Example 14]
>
> *Professional, nice and efficient. Good at explaining and I felt safe and taken care of. I got sufficient information ahead of treatment on recommended procedures. Was happy with their follow up on me during treatment and afterwards as well, and how efficient and professional the work was done.* [Example 15]

In addition, patients would sometimes express concerns about professionalism, for instance, when they perceived that the personal beliefs of dentists were indistinguishable from professional medical advice:

> *She tried to push life-threatening antivaccination propaganda on me, without me even bringing up the subject, and what in God's grace does a dentist know about vaccines? And be careful with the double standards all the time she offers Botox treatment (Botox is a nerve toxin).* [Example 16]

Predicting Patient Satisfaction

To predict patient satisfaction based on the dominant themes, a multilevel logistic regression analysis was performed (Table 2; Figure 1). Of the total explained variance, 28% was attributable to the differences among dentists (VPC=0.28).

The regression analysis showed that when the patients used words related to *explanation*, the OR for a high satisfaction score (4 or 5 stars) was 2.56 (95% CI 2.16-3.04; *P*<.001). In addition, if words related to *assurance* were used, the OR was even higher (3.61, 95% CI 2.57-5.06; *P*<.001) for a high satisfaction rating. The odds of a high satisfaction rating also increased with the frequent use of words related to *facilities*, *professional advice*, and *performance assessment* by a factor of 1.77 (95% CI 1.08-2.91; *P*=.02), 1.81 (95% CI 1.55-2.13; *P*<.001) and 2.16 (95% CI 1.84-2.55; *P*<.001), respectively, compared to infrequent use of the respective word categories. This was also the case if patients used words connected to the theme *recommendation*, which increased the odds of the patient being satisfied with dental treatment by 31% compared to when no words related to *recommendation* were used (*P*<.001). By contrast, when patients used words related to the *patient-centered care* theme, the odds of a high satisfaction rating were reduced by 38% (*P*<.001). Similarly, for the theme *consequences of treatment need*, the frequent use of words connected to this theme reduced the odds of a high satisfaction rating by 76% (*P*<.001).

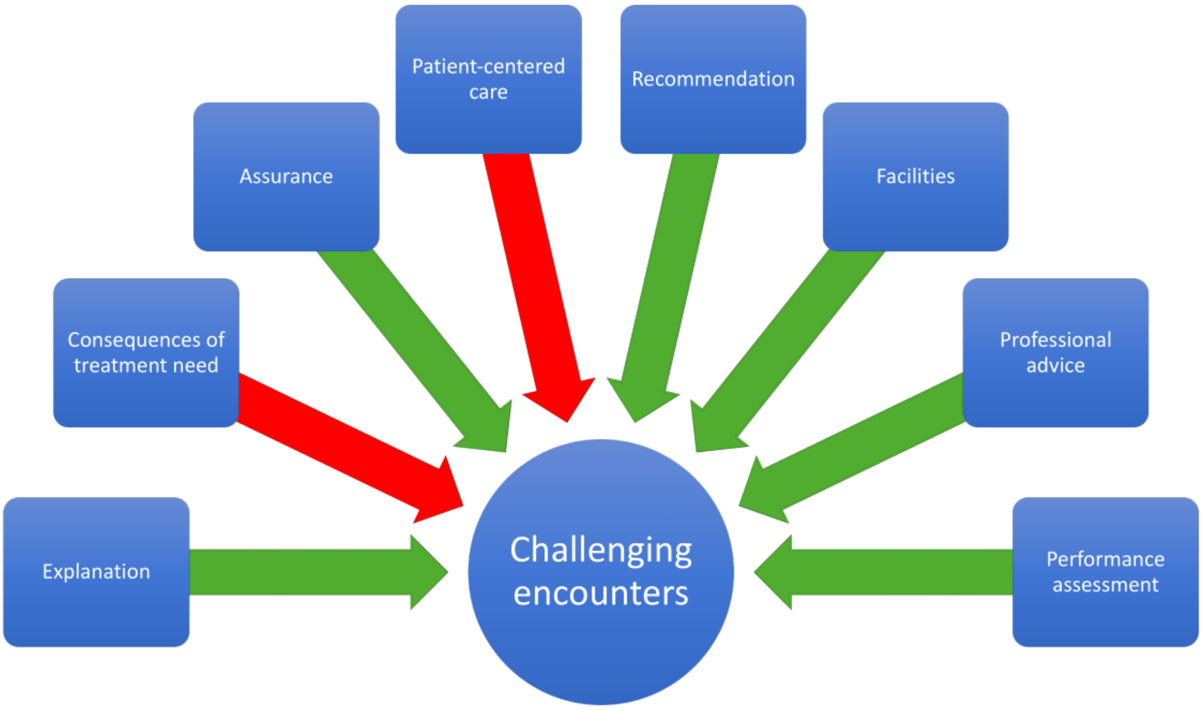
Table 2. A multilevel logistic regression analysis predicting patient satisfaction from dominant themes.

	B (SE)	Odds ratio[a] (95% CI)	*P* value
Fixed effects			
Intercept, β_{0j}	2.47 (0.11)	N/A[b]	N/A
Themes			
Consequences of treatment need (frequently used vs infrequently used)	−1.43 (0.09)	0.24 (0.20-0.29)	<.001
Explanation (frequently used vs infrequently used)	0.94 (0.09)	2.56 (2.16-3.04)	<.001
Assurance (used vs not used)	1.28 (0.17)	3.61 (2.57-5.06)	<.001
Recommendation (used vs not used)	0.27 (0.08)	1.31 (1.12-1.53)	<.001
Facilities (used vs not used)	0.57 (0.25)	1.78 (1.08-2.91)	.02
Patient-centered care (used vs not used)	−0.48 (0.09)	0.62 (0.52-0.74)	<.001
Professional advice (frequently used vs infrequently used)	0.60 (0.08)	1.81 (1.55-2.13)	<.001
Performance assessment (use vs no use)	0.77 (0.08)	2.17 (1.84-2.55)	<.001
Random effects			
Dentist-level variance	1.13 (0.13)	N/A	N/A
Variance partition coefficient	0.28	N/A	N/A

[a] Odds ratio for the patient experiencing a positive encounter when words from the themes are present in the review.

[b] N/A: not applicable.

Figure 1. The dominant themes identified and their relation to the challenging encounter. The green arrows indicate that the factor decreases the likelihood of a challenging encounter, while the red arrows indicate that the factor increases the likelihood of a challenging encounter.



Discussion

Eight themes were identified related to patient reviews of encounters with dental health professionals: 6 (75%) were linked to higher patient satisfaction scores and the experience of a positive dental encounter, while 2 (25%) were linked to lower patient satisfaction scores and the experience of a challenging dental encounter.

Principal Findings

If words related to the themes *explanation*, *assurance*, *recommendation*, *performance assessment*, *facilities*, and *professional advice* were present, patients were more likely to rate their experience as satisfying. Conversely, the use of words from the themes *consequences of treatment need* and *patient-centered care* reduced the likelihood of patients rating their experience as satisfying. In the following subsections, we will discuss the results and their implications.

Challenging encounters have been defined earlier in this paper as situations resulting in aversive feelings for dental health professionals [7] and as encounters involving conflicts between the perspectives of dental health professionals and those of the dental patient. In this study, we were interested in the challenging encounter from the dental patients' perspectives, and it was assumed that when patients provided low satisfaction ratings, it indicated the experience of a challenging encounter. Conversely, high satisfaction ratings, it was assumed, indicated the absence of a challenging encounter.

Consequences of Treatment Need

The theme *consequences of treatment need* contained words that could be interpreted as a reflection of unmet expectations, and we found that this theme was associated with an increased probability of experiencing a challenging encounter. Previous research suggests that some patients might have unrealistic expectations of dental treatment outcomes [38], and it is likely that a disjunction between treatment expectations and perceived treatment outcomes could influence the satisfaction with dental treatment, as indicated by a previous study [19]. However, Yao et al [38] suggest that the studies investigating dental treatment expectations in relation to patient satisfaction do not properly define the term "expectations" and that the results from the studies are diverse and difficult to interpret. This is supported by a recent literature review, which found it difficult to propose a link between patient satisfaction and expectations and suggested that this could be because "expectations" as a concept is not consistently defined in the literature and furthermore that it might be only indirectly associated with patient satisfaction [9].

On the basis of the words used in the *consequences of treatment need* theme, we found that the patients discussed reasons to seek dental health care (eg, "pain" and "caries"), as well as challenges that might have developed (eg, complications and disappointment regarding the outcome). In addition, the patients sometimes expressed feelings that could indicate a lack of self-agency (eg, words and expressions such as "had to," "because," and "caries"), which would indicate that the patients felt that they *had* to see the dentist because of a dental issue or some external cause. Motivations for seeking dental treatment could play a major role in how patients experience the dental treatment. One could envision that the dental encounter would be experienced differently based on the source of the patient's motivation (eg, based on the motivational locus: internal vs external). This closely resembles key features of a problem-oriented visiting pattern, which refers to patients only seeking dental help when faced with acute circumstances (eg, pain or fractured teeth). This type of attendance has been associated with increased risk of tooth loss [39] and reduced oral health–related quality of life [40] compared to regular attendance. A Finnish study investigating dental patients' perception of their dentist's explanation during treatment found that patients with a problem-oriented visiting pattern and that perceived their economic situation as difficult were more likely to feel dissatisfied with their dentist's explanation skills [41]. It has also been found that individuals with a fear of dental treatment tend to delay treatment and more often report poor oral health [42,43], implying that these patients could often have a problem-oriented visiting pattern. Therefore, it is not very surprising that this theme increases the risk of experiencing a challenging encounter. This could have been avoided if the patients had visited their dentist more often. Different intervention strategies have been used aimed at motivating patients to visit their dentist regularly (eg, community-based dental campaigns and a reduction in expenses) [44]. A recent literature review found that regular attendance could be increased if patients had the opportunity to visit a dental anxiety clinic and receive dental check-ups for free [44]. Such interventions could prove valuable to reduce challenging encounters in the clinic from the patient's perspective.

Patient-Centered Care

The theme *patient-centered care* was related to lower satisfaction with the dental encounter. Initially, this might seem odd because we would expect patient centeredness in dental health care to be a positive element. However, in this case, we would argue that the patients would primarily use words related to this theme when they discuss the lack of patient centeredness, which could again be similar to the notion of unmet expectations. In any case, it is clear that the patients in this study are concerned with patient centeredness in a dental context, which is in support of other findings suggesting that dentists need to improve their communication skills and be empathetic when cooperating with patients [45]. Furthermore, research has shown that dental students' self-reported empathy may diminish with increased patient interaction [46]. Even so, a study investigating a patient-centered training program and its effects on dental students' self-reported empathy has revealed promising results to halt this concerning trend [47]. Other research implementing communication training programs in dentistry show that applying active training methods, such as role play and patient treatment experience, as well as acquiring behavioral or psychological knowledge alongside attending more traditional didactic lectures, was most effective in improving dental students' communication skills [48].

Assurance and Explanation

The theme *assurance* was associated with higher patient satisfaction, supporting results from other studies that have proposed a link between higher patient satisfaction and the perception of caring or comforting staff behavior [21]. This supports the idea that in dental encounters, patients might be in need of assurance and comforting behaviors because they might perceive that they have little control over the situation. The establishment of trust between the dentist and the patient has long been regarded as an essential part of treatment, with a corresponding impact on treatment outcomes [49]. Therefore, behaviors associated with *assurance* could help prevent a challenging encounter. It has been found too that when patients perceive their dentists' *explanation* skills as good, they indicate greater satisfaction with treatment [50,51]. The relationship among the dental health professionals involved in the treatment seems to influence patient satisfaction [52], as well as the dental assistant's knowledge of the patient's needs [51]. Investing time in careful explanations before and during treatment could be a useful way to prevent challenging encounters and increase patient satisfaction.

Professional Advice

Dentists have a professional responsibility to teach patients how to take care of their oral health. The theme *professional advice* could be interpreted as the patients' perception of this teaching practice. It could also be viewed as proof that patients welcome professional advice regarding how to take care of their oral health. Oral health literacy is the individual's ability to obtain, understand, and use oral health information [53,54]. According to a recent literature review, it consists of three important aspects: (1) the individual's capacity to access health information through basic information acquisition skills (eg, the ability to read, an understanding of numbers, and the capability to interpret facial expressions), (2) the individual's ability to use the information (eg, informed decision-making), and (3) oral health maintenance abilities (eg, self-regulation and goal achievement) [55]. The patient's perception of the dentist's ability to communicate and provide useful information about the patient's oral health is therefore dependent not only upon the skills of the dentist but also on the patient's oral health literacy. Dentists should consider that health information can be difficult to access and that information should be individually adapted according to patients' abilities.

Recommendation, Performance Assessment, and Facilities

Not surprisingly, the patients who wrote about positive dental encounters used more words related to *recommendation*, which suggests a need to disseminate their view of the dentist to peers on the web. Other research has supported the existence of this need, where web-based review sites are used to disseminate experiences and views to peers [20]. This sharing of experiences is believed to have a more profound meaning to users than can sometimes be suspected because shared experiences can function as a gateway to feeling connected to others and feeling empowered as a user of health care services [56]. In addition, *performance assessment* was associated with a higher satisfaction rating. This is supported by previous research findings linking patients' perception of high-quality performance to increased patient satisfaction [21,57]. Dental health professionals could benefit from continuous training in clinical skills and striving to update their knowledge according to medical advances. The theme *facilities* was linked to a small increase in odds that the patient was satisfied, which extends the prior finding that patients seemed to write about clinical facilities in both positive encounters and challenging encounters [26] and that this theme was seemingly independent of the satisfaction rating. However, high-quality facilities have been linked to higher patient satisfaction in previous studies [21,58]. As some of these studies were conducted with inpatients at hospitals, it could be the case that patients needing to stay longer at the clinic found high-quality facilities to be more important for overall satisfaction.

Strengths and Limitations

A LIWC analysis is best performed when the word count in each sample text exceeds 50 [30]. As previously stated, LIWC dictionaries work by calculating the relative percentage of a word's occurrence in a body of text. In samples with small text sizes, for example 5 to 10 words, the relative percentage of each word tends to be very high; for example, in the sentence "I was at Molly's birthday," we see that the word "birthday" accounts for 20% of the word use. To counteract this effect, Boyd [30] suggests that one could have a sample size that is very large. For dental patients' reviews to be accepted on the previously mentioned Norwegian website, they need to be at least 100 characters long [59]. We would argue that, in this case, since the mean word count is close to 50 (mean 48.9, SD 39) and the sample size is large (n=11,764), our findings will be less affected by this bias. However, it could prove valuable to repeat this study using larger sample sizes. As a language analysis tool, the LIWC has proven to be reliable in research [29], with examples available from a wide range of research to underscore its usefulness [60,61].

In general, it would be expected that only a limited number of patients would write a web-based review after a visit to the dentist. A true estimate of the response rate is not possible because we do not know the exact number of patients who have chosen not to respond or whether a patient has provided ratings for several dentists. Given the low review volume relative to the dentist-to-patient ratio (1:1250 [62]) and a mean of 3.9 reviews per dentist, only a small percentage of patients likely write online reviews. However, this should not significantly impact our ability to investigate themes related to high versus low patient satisfaction, which was our study objective. Because most of the reviews were positive (10,977/11,764, 93.31% have a rating of 4-5 stars), this could mean that the findings in our study are more representative of positive reviews. To counteract this bias, one could consider splitting the data set into 2 parts before analysis: the reviews with a low satisfaction rating (1-2 stars) versus the reviews with a high satisfaction rating (4-5 stars). This approach would enable a separate word analysis for each data set to compare the satisfied patients versus the unsatisfied patients and their word use. However, the number of reviews representing a low satisfaction rating was considered to be insufficient to provide reliable results in a bottom-up text analysis using the MEM, which usually depends on a large amount of text data to provide reliable results.

In the exploratory factor analysis performed using SPSS software, the words within each word category were extracted from the body of text based on how often they appeared together in a phrase. The interpretation and labeling of the themes were based on a theoretical understanding of the meaning of the factors. Other researchers intending to perform similar analyses could arrive at different theme labels based on their particular theoretical understanding; for instance, the theme *consequences of treatment need* was a broad category containing a greater number of words than the other themes, and we found it difficult to interpret and to agree on the final label because it seemed to be a theme with multiple layers. By contrast, other themes containing fewer words were more easily interpretable (eg, the themes *facilities* or *assurance*). This is a limitation related to the use of factor analysis often mentioned in the literature [63]. Despite these challenges, previous research has arrived at themes that are similar in their content with regard to patient satisfaction [21,57], indicating that our findings could be applicable in other contexts.

Implications for Future Research

Websites provide large amounts of text data that will enable researchers to perform large-scale analyses (eg, using text analysis programs that build upon machine learning methods, such as BERT [64]). Even so, machine learning methods could encounter difficulties related to "poor language" in short internet texts, elucidating the need to develop these methods further [65]. The findings from this study and similar studies could help clinicians develop a better understanding of their patients' perspectives and needs in light of challenging treatment situations. Hopefully, some of these findings could also help guide future research on increasing patient satisfaction, while limiting challenging encounters in the dental clinic. In addition, there is a need to establish effective interventions to motivate patients to visit their dentist regularly.

Conclusions

The findings of this study demonstrate the value of web-based patient reviews as a gateway to patient experiences, and we would argue that implementing the themes or elements from the themes expressed in these reviews could help improve patient satisfaction. While dissatisfaction with dental treatment seems to be associated with negative consequences and (a lack of) patient centeredness, high satisfaction seems to hinge on patients' experiences of being acknowledged by the dentist. Investigations of web-based reviews could produce valuable insights into what patients experience and value in dental treatment settings.

Acknowledgments

The authors would like to acknowledge Legelisten.no AS for their contribution of data to this study. The authors would also like to express their gratitude to the administrators of Språksamlingane (The Norwegian Language Collections) at the University of Bergen for providing a complete Norwegian dictionary in which we could find words for our customization of the Linguistic Inquiry and Word Count 2007 Norwegian dictionary. This project was funded as part of the Student Research Program at the Department of Clinical Dentistry, UiT The Arctic University of Norway.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Lemmatization list.
[TXT File , 25 KB - jopm_v16i1e49262_app1.txt]

Multimedia Appendix 2
Stop list.
[TXT File , 1 KB - jopm_v16i1e49262_app2.txt]

References

1. Mota P, Selby K, Gouveia A, Tzartzas K, Staeger P, Marion-Veyron R, et al. Difficult patient-doctor encounters in a Swiss university outpatient clinic: cross-sectional study. BMJ Open 2019 Jan 25;9(1):e025569 [FREE Full text] [doi: 10.1136/bmjopen-2018-025569] [Medline: 30782753]
2. Cannarella Lorenzetti R, Jacques CH, Donovan C, Cottrell S, Buck J. Managing difficult encounters: understanding physician, patient, and situational factors. Am Fam Physician 2013 Mar 15;87(6):419-425 [FREE Full text] [Medline: 23547575]
3. Breen KJ, Greenberg PB. Difficult physician-patient encounters. Intern Med J 2010 Oct 19;40(10):682-688. [doi: 10.1111/j.1445-5994.2010.02311.x] [Medline: 20646098]
4. Collins K, Hopkins A, Shilkofski NA, Levine RB, Hernandez RG. Difficult patient encounters: assessing pediatric residents' communication skills training needs. Cureus 2018 Sep 21;10(9):e3340 [FREE Full text] [doi: 10.7759/cureus.3340] [Medline: 30473973]
5. Tölli S, Partanen P, Kontio R, Häggman-Laitila A. A quantitative systematic review of the effects of training interventions on enhancing the competence of nursing staff in managing challenging patient behaviour. J Adv Nurs 2017 Dec 07;73(12):2817-2831. [doi: 10.1111/jan.13351] [Medline: 28556934]
6. Goetz K, Schuldei R, Steinhäuser J. Working conditions, job satisfaction and challenging encounters in dentistry: a cross-sectional study. Int Dent J 2019 Feb;69(1):44-49 [FREE Full text] [doi: 10.1111/idj.12414] [Medline: 30028019]
7. Shikino K, Mito T, Ohira Y, Yokokawa D, Katsuyama Y, Ota T, et al. Frequency of difficult patient encounters in a Japanese university hospital and community hospitals: a cross-sectional study. Intern Med 2023 Feb 15;62(4):533-537 [FREE Full text] [doi: 10.2169/internalmedicine.0085-22] [Medline: 35793958]
8. Fosnot L, Jones CD, Keniston A, Burden M, Indovina KA, Patel H. Hospitalists' perspectives on challenging patient encounters and physician well-being: a qualitative study. Patient Educ Couns 2022 May;105(5):1209-1215. [doi: 10.1016/j.pec.2021.08.023] [Medline: 34511284]
9. Afrashtehfar KI, Assery MK, Bryant SR. Patient satisfaction in medicine and dentistry. Int J Dent 2020;2020:6621848 [FREE Full text] [doi: 10.1155/2020/6621848] [Medline: 33456467]
10. Batbaatar E, Dorjdagva J, Luvsannyam A, Savino MM, Amenta P. Determinants of patient satisfaction: a systematic review. Perspect Public Health 2017 Mar 20;137(2):89-101. [doi: 10.1177/1757913916634136] [Medline: 27004489]
11. Shirley ED, Sanders JO. Patient satisfaction: implications and predictors of success. J Bone Joint Surg Am 2013 May 15;95(10):e69. [doi: 10.2106/JBJS.L.01048] [Medline: 23677370]
12. Chow A, Mayer EK, Darzi AW, Athanasiou T. Patient-reported outcome measures: the importance of patient satisfaction in surgery. Surgery 2009 Sep;146(3):435-443. [doi: 10.1016/j.surg.2009.03.019] [Medline: 19715800]
13. Chen JH, Huang HL, Lin YC, Chou TM, Ebinger J, Lee HE. Dentist-patient communication and denture quality associated with complete denture satisfaction among Taiwanese elderly wearers. Int J Prosthodont 2015 Sep;28(5):531-537. [doi: 10.11607/ijp.4223] [Medline: 26340016]
14. Sun S, Luo C, Chen J. A review of natural language processing techniques for opinion mining systems. Inf Fusion 2017 Jul;36:10-25. [doi: 10.1016/j.inffus.2016.10.004]
15. Cano-Marin E, Mora-Cantallops M, Sanchez-Alonso S. The power of big data analytics over fake news: a scientometric review of Twitter as a predictive system in healthcare. Technol Forecast Soc Change 2023 May;190:122386. [doi: 10.1016/j.techfore.2023.122386]
16. Funk B, Sadeh-Sharvit S, Fitzsimmons-Craft EE, Trockel MT, Monterubio GE, Goel NJ, et al. A framework for applying natural language processing in digital health interventions. J Med Internet Res 2020 Feb 19;22(2):e13855 [FREE Full text] [doi: 10.2196/13855] [Medline: 32130118]
17. Wakefield LT, Wakefield RL. Anxiety and ephemeral social media use in negative eWOM creation. J Interact Mark 2018 Feb;41:44-59. [doi: 10.1016/j.intmar.2017.09.005]
18. Karmen C, Hsiung RC, Wetter T. Screening internet forum participants for depression symptoms by assembling and enhancing multiple NLP methods. Comput Methods Programs Biomed 2015 Jun;120(1):27-36. [doi: 10.1016/j.cmpb.2015.03.008] [Medline: 25891366]

19. Hoogendoorn M, Berger T, Schulz A, Stolz T, Szolovits P. Predicting social anxiety treatment outcome based on therapeutic email conversations. IEEE J Biomed Health Inform 2017 Sep;21(5):1449-1459 [FREE Full text] [doi: 10.1109/JBHI.2016.2601123] [Medline: 27542187]
20. Moorhead SA, Hazlett DE, Harrison L, Carroll JK, Irwin A, Hoving C. A new dimension of health care: systematic review of the uses, benefits, and limitations of social media for health communication. J Med Internet Res 2013 Apr 23;15(4):e85 [FREE Full text] [doi: 10.2196/jmir.1933] [Medline: 23615206]
21. Seltzer EK, Guntuku SC, Lanza AL, Tufts C, Srinivas SK, Klinger EV, et al. Patient experience and satisfaction in online reviews of obstetric care: observational study. JMIR Form Res 2022 Mar 31;6(3):e28379 [FREE Full text] [doi: 10.2196/28379] [Medline: 35357310]
22. Mulgund P, Sharman R, Anand P, Shekhar S, Karadi P. Data quality issues with physician-rating websites: systematic review. J Med Internet Res 2020 Sep 28;22(9):e15916 [FREE Full text] [doi: 10.2196/15916] [Medline: 32986000]
23. Sun Y, Zhang Y, Gwizdka J, Trace CB. Consumer evaluation of the quality of online health information: systematic literature review of relevant criteria and indicators. J Med Internet Res 2019 May 02;21(5):e12522 [FREE Full text] [doi: 10.2196/12522] [Medline: 31045507]
24. Emmert M, Halling F, Meier F. Evaluations of dentists on a German physician rating website: an analysis of the ratings. J Med Internet Res 2015 Jan 12;17(1):e15 [FREE Full text] [doi: 10.2196/jmir.3830] [Medline: 25582914]
25. Lin Y, Hong YA, Henson BS, Stevenson RD, Hong S, Lyu T, et al. Assessing patient experience and healthcare quality of dental care using patient online reviews in the United States: mixed methods study. J Med Internet Res 2020 Jul 07;22(7):e18652 [FREE Full text] [doi: 10.2196/18652] [Medline: 32673240]
26. Larsen M, Holde GE, Johnsen JA. Challenging encounters in clinical dentistry: a qualitative study investigating online reviews of patient satisfaction with Norwegian dentists. Acta Odontol Scand 2022 Jul 07;80(5):328-337. [doi: 10.1080/00016357.2021.2009909] [Medline: 34875189]
27. Khasawneh A, Ponathil A, Firat Ozkan NF, Chalil Madathil KC. How should I choose my dentist? A preliminary study investigating the effectiveness of decision aids on healthcare online review portals. Proc Hum Factors Ergon Soc Annu Meet 2018 Sep 27;62(1):1694-1698. [doi: 10.1177/1541931218621383]
28. Om oss. Legelisten.no. 2012. URL: https://www.legelisten.no/om-oss [accessed 2024-04-05]
29. Boyd RL, Ashokkumar A, Seraj S, Pennebaker JW. The development and psychometric properties of LIWC-22. University of Texas at Austin. URL: https://www.liwc.app/static/documents/LIWC-22%20Manual%20-%20Development%20and%20Psychometrics.pdf [accessed 2024-04-05]
30. Boyd RL. Psychological text analysis in the digital humanities. In: Hai-Jew S, editor. Data Analytics in Digital Humanities. Cham, Switzerland: Springer; 2017:161-189.
31. LIWC dictionary repository: Norwegian LIWC2007 dictionary. Linguistic Inquiry and Word Count. 2007. URL: https://www.liwc.app/dictionaries [accessed 2024-04-15]
32. Meaning extraction. Linguistic Inquiry and Word Count. 2022. URL: https://www.liwc.app/help/mem [accessed 2024-08-02]
33. Markowitz DM. The meaning extraction method: an approach to evaluate content patterns from large-scale language data. Front Commun 2021 Feb 23;6:1-8. [doi: 10.3389/fcomm.2021.588823]
34. Barton D, Lee C. Language Online: Investigating Digital Texts and Practices. London, UK: Routledge; 2013.
35. Williams B, Onsman A, Brown T. Exploratory factor analysis: a five-step guide for novices. Australas J Paramed 2010 Jan 01;8:1-13. [doi: 10.33151/ajp.8.3.93]
36. Charlton C, Rasbash J, Browne WJ, Healy M, Cameron B. A user’s guide to MLwiN. Version 3.05. University of Bristol. 2020. URL: https://www.bristol.ac.uk/cmm/media/software/mlwin/downloads/manuals/3-05/manual-print.pdf [accessed 2024-04-05]
37. Snijders TA, Bosker RJ. Multilevel Analysis: An Introduction to Basic and Advanced Multilevel Modeling. Thousand Oaks, CA: SAGE Publications; 1999.
38. Yao J, Tang H, Gao XL, McGrath C, Mattheos N. Patients' expectations to dental implant: a systematic review of the literature. Health Qual Life Outcomes 2014 Oct 29;12(1):153 [FREE Full text] [doi: 10.1186/s12955-014-0153-9] [Medline: 25358599]
39. Yoshino K, Ito K, Kuroda M, Sugihara N. Tooth loss in problem-oriented, irregular, and regular attenders at dental offices. Bull Tokyo Dent Coll 2016;57(1):11-19 [FREE Full text] [doi: 10.2209/tdcpublication.57.11] [Medline: 26961332]
40. Gaewkhiew P, Bernabé E, Gallagher JE, Klass C, Delgado-Angulo EK. Oral impacts on quality of life and problem-oriented attendance among South East London adults. Health Qual Life Outcomes 2017 Apr 26;15(1):82 [FREE Full text] [doi: 10.1186/s12955-017-0663-3] [Medline: 28446237]
41. Raittio E, Lahti S, Suominen AL. Adult Finns' perceptions about communication with the dentist during their latest visit. Community Dent Oral Epidemiol 2019 Apr 29;47(2):112-118 [FREE Full text] [doi: 10.1111/cdoe.12431] [Medline: 30370968]
42. Meng X, Heft MW, Bradley MM, Lang PJ. Effect of fear on dental utilization behaviors and oral health outcome. Community Dent Oral Epidemiol 2007 Aug 04;35(4):292-301. [doi: 10.1111/j.1600-0528.2007.00315.x] [Medline: 17615016]

43. Steinvik LM, Svartdal F, Johnsen JA. Delay of dental care: an exploratory study of procrastination, dental attendance, and self-reported oral health. Dent J (Basel) 2023 Feb 20;11(2):56 [FREE Full text] [doi: 10.3390/dj11020056] [Medline: 36826201]
44. Currie CC, Araujo-Soares V, Stone SJ, Beyer F, Durham J. Promoting regular dental attendance in problem-orientated dental attenders: a systematic review of potential interventions. J Oral Rehabil 2021 Oct;48(10):1183-1191 [FREE Full text] [doi: 10.1111/joor.13244] [Medline: 34398460]
45. Jones LM, Huggins TJ. Empathy in the dentist-patient relationship: review and application. N Z Dent J 2014 Sep;110(3):98-104. [Medline: 25265748]
46. Narang R, Mittal L, Saha S, Aggarwal VP, Sood P, Mehra S. Empathy among dental students: a systematic review of literature. J Indian Soc Pedod Prev Dent 2019;37(4):316. [doi: 10.4103/jisppd.jisppd_72_19]
47. Rosenzweig J, Blaizot A, Cougot N, Pegon-Machat E, Hamel O, Apelian N, et al. Effect of a person ‐ centered course on the empathic ability of dental students. J Dent Educ 2016 Nov;80(11):1337-1348. [doi: 10.1002/j.0022-0337.2016.80.11.tb06219.x]
48. Khalifah AM, Celenza A. Teaching and assessment of dentist ‐ patient communication skills: a systematic review to identify best ‐ evidence methods. J Dent Educ 2019 Jan;83(1):16-31. [doi: 10.21815/jde.019.003]
49. Song Y, Luzzi L, Brennan DS. Trust in dentist-patient relationships: mapping the relevant concepts. Eur J Oral Sci 2020 Apr 10;128(2):110-119. [doi: 10.1111/eos.12686] [Medline: 32154607]
50. Hamasaki T, Soh I, Takehara T, Hagihara A. Applicability of both dentist and patient perceptions of dentists' explanations to the evaluation of dentist-patient communication. Community Dent Health 2011;28(4):274-279. [doi: 10.1922/CDH_2589Hagihara06]
51. Dewi FD, Sudjana G, Oesman YM. Patient satisfaction analysis on service quality of dental health care based on empathy and responsiveness. Dent Res J (Isfahan) 2011 Oct;8(4):172-177 [FREE Full text] [doi: 10.4103/1735-3327.86032] [Medline: 22135687]
52. Hamasaki T, Kato H, Kumagai T, Hagihara A. Association between dentist-dental hygienist communication and dental treatment outcomes. Health Commun 2017 Mar 25;32(3):288-297. [doi: 10.1080/10410236.2016.1138376] [Medline: 27223581]
53. Firmino RT, Ferreira FM, Paiva SM, Granville-Garcia AF, Fraiz FC, Martins CC. Oral health literacy and associated oral conditions: a systematic review. J Am Dent Assoc 2017 Aug;148(8):604-613. [doi: 10.1016/j.adaj.2017.04.012] [Medline: 28477838]
54. Kaur N, Kandelman D, Nimmon L, Potvin L. Oral health literacy: findings of a scoping review. Dent Sci 2015;2:293-306.
55. Tian Z, Wang Y, Li Y, Lu J, Song L, Ding L, et al. Defining the connotations of oral health literacy using the conceptual composition method. Int J Environ Res Public Health 2023 Feb 16;20(4):3518 [FREE Full text] [doi: 10.3390/ijerph20043518] [Medline: 36834212]
56. Ziebland S, Powell J, Briggs P, Jenkinson C, Wyke S, Sillence E, et al. Examining the role of patients’ experiences as a resource for choice and decision-making in health care: a creative, interdisciplinary mixed-method study in digital health. Programme Grants Appl Res 2016 Nov;4(17):1-214. [doi: 10.3310/pgfar04170] [Medline: 27929620]
57. Ali DA. Patient satisfaction in dental healthcare centers. Eur J Dent 2019 Sep 24;10(03):309-314. [doi: 10.4103/1305-7456.184147]
58. Liang H, Xue Y, Zhang ZR. Patient satisfaction in China: a national survey of inpatients and outpatients. BMJ Open 2021 Sep 07;11(9):e049570 [FREE Full text] [doi: 10.1136/bmjopen-2021-049570] [Medline: 34493518]
59. Generelle vilkår og betingelser. Legelisten.no. 2012. URL: https://www.legelisten.no/vilkar [accessed 2023-11-18]
60. Holtzman NS, Tackman AM, Carey AL, Brucks MS, Küfner AC, Deters FG, et al. Linguistic markers of grandiose narcissism: a LIWC analysis of 15 samples. J Lang Soc Psychol 2019 Sep 11;38(5-6):773-786. [doi: 10.1177/0261927x19871084]
61. Hasan MK, Sen T, Yang Y, Baten RA, Haut KG, Hoque ME. LIWC into the eyes: using facial features to contextualize linguistic analysis in multimodal communication. In: Proceedings of the 8th International Conference on Affective Computing and Intelligent Interaction. 2019 Presented at: ACII '19; September 3-6, 2019; Cambridge, UK p. 1-7 URL: https://ieeexplore.ieee.org/document/8925467 [doi: 10.1109/acii.2019.8925467]
62. Tannlegeårsverk per 10 000 innbygger. Helsedirektoratet. 2018. URL: https://www.helsedirektoratet.no/statistikk/kvalitetsindikatorer/tannhelse/Antall%20tannlege%C3%A5rsverk%20per%2010%20000%20innbyggere [accessed 2023-11-12]
63. Yong AG, Pearce S. A beginner’s guide to factor analysis: focusing on exploratory factor analysis. Tutor Quant Methods Psychol 2013 Oct 01;9(2):79-94. [doi: 10.20982/tqmp.09.2.p079]
64. Biggiogera J, Boateng G, Hilpert P, Vowels M, Bodenmann G, Neysari M. BERT meets LIWC: exploring state-of-the-art language models for predicting communication behavior in couples’ conflict interactions. In: Proceedings of the Companion Publication of the 2021 International Conference on Multimodal Interaction. 2021 Presented at: ICMI '21; October 18-22, 2021; Montreal, QC p. 385-389. [doi: 10.1145/3461615.3485423]
65. Eisenstein J. What to do about bad language on the internet. In: Proceedings of the 2013 Conference of the North American Chapter of the Association for Computational Linguistics: Human Language Technologies. 2013 Presented at: NAACL '13; June 9-14, 2013; Atlanta, Georgia p. 359-369 URL: https://aclanthology.org/N13-1037.pdf

Abbreviations

LIWC: Linguistic Inquiry and Word Count
MEM: meaning extraction method
NLP: natural language processing
OR: odds ratio
VPC: variance partition coefficient

Edited by S Woods; submitted 24.05.23; peer-reviewed by M Elbattah, M Pang, Y Freire, M Sarhan; comments to author 11.10.23; revised version received 15.11.23; accepted 22.03.24; published 03.05.24.

Please cite as:
Larsen M, Holde GE, Johnsen JAK
Investigating Patient Satisfaction Through Web-Based Reviews of Norwegian Dentists: Quantitative Study Using the Meaning Extraction Method
J Particip Med 2024;16:e49262
URL: https://jopm.jmir.org/2024/1/e49262
doi:10.2196/49262
PMID:38700933

Original Paper

Understanding the Values, Qualities, and Preferences of Patients in Their Relationships With Obstetrics and Gynecology Providers: Cross-Sectional Survey With a Mixed Methods Approach

Ann Blair Kennedy[1,2], DrPH; Anna Tarasidis Harb[3,4], MD; Chloe Schockling[3,5], MD; Lauren Jackson Ray[3,6], MD; Jennifer Palomo[3], MD; Rebecca Russ-Sellers[1], PhD

[1]Department of Biomedical Sciences, School of Medicine Greenville, University of South Carolina, Greenville, SC, United States
[2]Family Medicine Department, Prisma Health, Greenville, SC, United States
[3]School of Medicine, University of South Carolina, Greenville, SC, United States
[4]Obstetrics and Gynecology, The University of Tennessee Graduate School of Medicine, Knoxville, TN, United States
[5]Department of Pediatrics, University of Pittsburgh School of Medicine, Pittsburgh, PA, United States
[6]Department of Pathology, Massachusetts General Hospital, Boston, MA, United States

Corresponding Author:
Ann Blair Kennedy, DrPH
Department of Biomedical Sciences
School of Medicine Greenville
University of South Carolina
701 Grove Road
Health Science Administration Building
Greenville, SC, 29605
United States
Phone: 1 18647662028
Email: kenneda5@greenvillemed.sc.edu

Abstract

Background: The patient-provider relationship in obstetrics and gynecology (OBGYN) is uniquely complex due to the sensitive nature of examinations and topics. Patients often prefer health care providers who share similar racial, ethnic, gender, or linguistic backgrounds, particularly in sensitive health care situations, to improve communication and comfort, though historically, specific gender preferences for OBGYNs have not been evident.

Objective: This study aims to describe the values, qualities, and preferences of patients in their relationships with OBGYN providers.

Methods: This cross-sectional survey, conducted from October 2019 to December 2019, involved 1039 US OBGYN patients and used a mixed methods approach, integrating quantitative responses and qualitative insights from open-ended questions. Recruitment was facilitated through targeted social media campaigns, and the survey aimed to capture detailed patient preferences and barriers to care by assessing responses on provider traits, patient experiences, and demographic factors. The study's rigorous data collection and analysis were designed to fill gaps identified in previous research on patient-provider relationships in OBGYN care.

Results: The findings underscore the paramount importance of trust and comfort, with listening skills identified as crucial. A notable finding is the marked preference for same-gender providers, observed in 80.7% (545/675) of participants. Primary barriers to seeking care reported included daily commitments, highlighting the need for accessible and flexible care options.

Conclusions: The study highlights a significant shift from previous scientific findings in patient preferences toward gender concordance and trust in OBGYN settings, diverging from previous research. These results emphasize the need for patient-centered care and tailored communication strategies to enhance patient experiences and outcomes. Future research should focus on diverse populations to broaden the findings' applicability and explore the impact of recent shifts in health care policies.

(J Particip Med 2024;16:e58096) doi:10.2196/58096

KEYWORDS
communication; obstetrics; gynecology; trust; barriers to care; patient-provider relationships

Introduction

The patient-provider relationship in obstetrics and gynecology (OBGYN) presents unique complexities due to the sensitive nature of examinations and discussions. The patient provider relationship is further shaped by increasing emphasis on patient-centered care, which highlights the importance of patient needs, perspectives, beliefs, and values [1,2]. While not always explicitly stated, a closer examination of the existing research reveals potential gaps in the comprehensively evaluating the multifaceted aspects of patient-provider relationships, diverse barriers to care, and evolving patient preferences within the OBGYN context [3-8].

The concept of patient-physician concordance, which emphasizes shared identities such as race, ethnicity, gender, or language, has gained significant attention in health care research. Numerous studies indicate that patients often prefer providers who share similar backgrounds, positing that such shared identities enhance understanding and communication, thereby potentially improving the quality of care [3,5,6,9]. This preference is particularly pronounced in scenarios involving sensitive health matters, where patients may feel more at ease discussing intimate issues with providers who share their cultural background or language [3,6,9-11]. Historically, however, desired traits of OBGYNs expressed by patients did not indicate a gender preference [1-16].

Furthermore, despite strong patient preferences for concordance, conclusive evidence linking patient-provider concordance directly to improved health outcomes remains elusive [5,8,10,17]. This gap highlights a critical need for further research, especially within OBGYN, to elucidate how patient preferences for concordance translate into tangible health outcomes. This inquiry is increasingly relevant given the dynamic shifts in health care delivery, such as the rising number of women in medical professions and the expanding role of nurse practitioners and primary care physicians in providing gynecological care [3,13,18]. This study aims to describe the values, qualities, and preferences of patients in their relationships with OBGYN providers. By documenting these preferences, the research seeks to establish a foundation for future investigations into how these factors might influence patient satisfaction and health outcomes in OBGYN care.

Methods

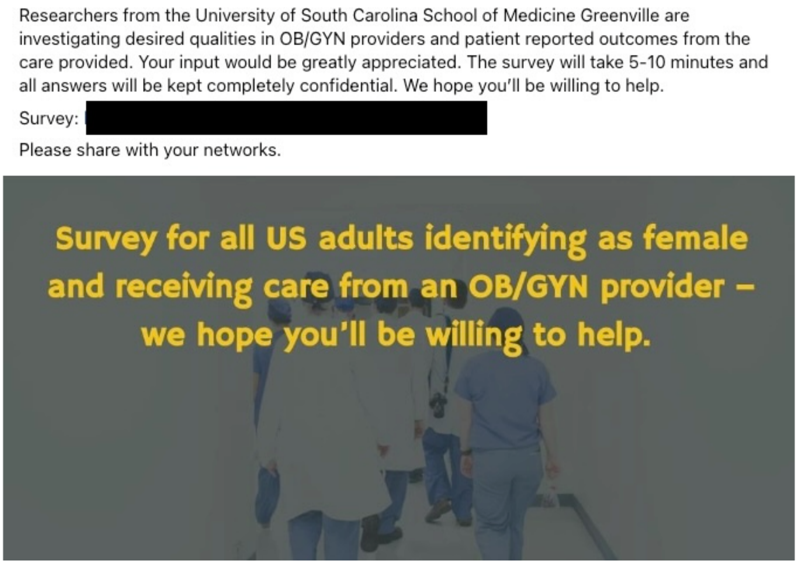
Study Design

This cross-sectional survey, which collected both quantitative and qualitative data, used qualitative insights from open-ended questions for data transformation and validation [19] to investigate factors impacting patient-OBGYN provider relationships in the United States (Multimedia Appendix 1).

Setting and Participant Recruitment

To reduce social desirability bias and elicit truthful responses, an invitation to participate in an anonymous survey was disseminated through social media outlets [20]. Between October 2019 and December 2019, the research team shared posts on the social media platforms such as Facebook, Twitter, Instagram, and LinkedIn through their individual networks and within potential interested groups on Facebook (Figure 1). The recruitment posts asked those who were female and receiving care from an OBGYN provider to complete a confidential 5- to 10-minute survey through a link to a self-administered questionnaire through REDCap (Research Electronic Data Capture; Vanderbilt University) survey software [21]. The posts also asked for others to share the survey within their own networks.

Figure 1. Social media post for recruitment. OB/GYN: Obstetrics and gynecology.



Researchers from the University of South Carolina School of Medicine Greenville are investigating desired qualities in OB/GYN providers and patient reported outcomes from the care provided. Your input would be greatly appreciated. The survey will take 5-10 minutes and all answers will be kept completely confidential. We hope you'll be willing to help.

Survey: [redacted]

Please share with your networks.

Participants were included in this study if they were aged 18 years or older, consented to participate, had current or previous interactions with an OBGYN provider, and agreed to discuss personal health-related topics. Confidentiality of all responses was ensured to encourage open and honest communication. Though confidentiality was ensured, the survey offered an opportunity for respondents to receive survey analysis results by providing an email address.

Survey Development

The survey was developed by reviewing existing surveys on OBGYN patient-physician relationships to align the content with current research gaps [1-16]. These key studies highlighted factors influencing the selection of OBGYN providers, such as physician gender, experience, and bedside manner [1-16]. These studies guided the inclusion of questions to assess participants' preferences and beliefs regarding OBGYN provider characteristics [1-16]. In addition, research on stereotyped beliefs about male and female OBGYNs and patient satisfaction informed the incorporation of items addressing participants' satisfaction and perceived empathy based on their provider's gender [16]. In addition, the survey included participant and practice demographics and barriers to care (Multimedia Appendix 1). By integrating these elements, our survey aims to capture a comprehensive understanding of patient preferences and experiences in the context of OBGYN services, addressing gaps identified in previous research.

The specific questions chosen were based on their relevance and proven effectiveness in capturing critical aspects of patient-provider relationships. The studies reviewed provided a robust foundation for identifying key variables and developing a comprehensive survey. By systematically integrating these insights, the final survey instrument was designed to fill identified research gaps and provide valuable data on patient preferences and experiences in OBGYN services.

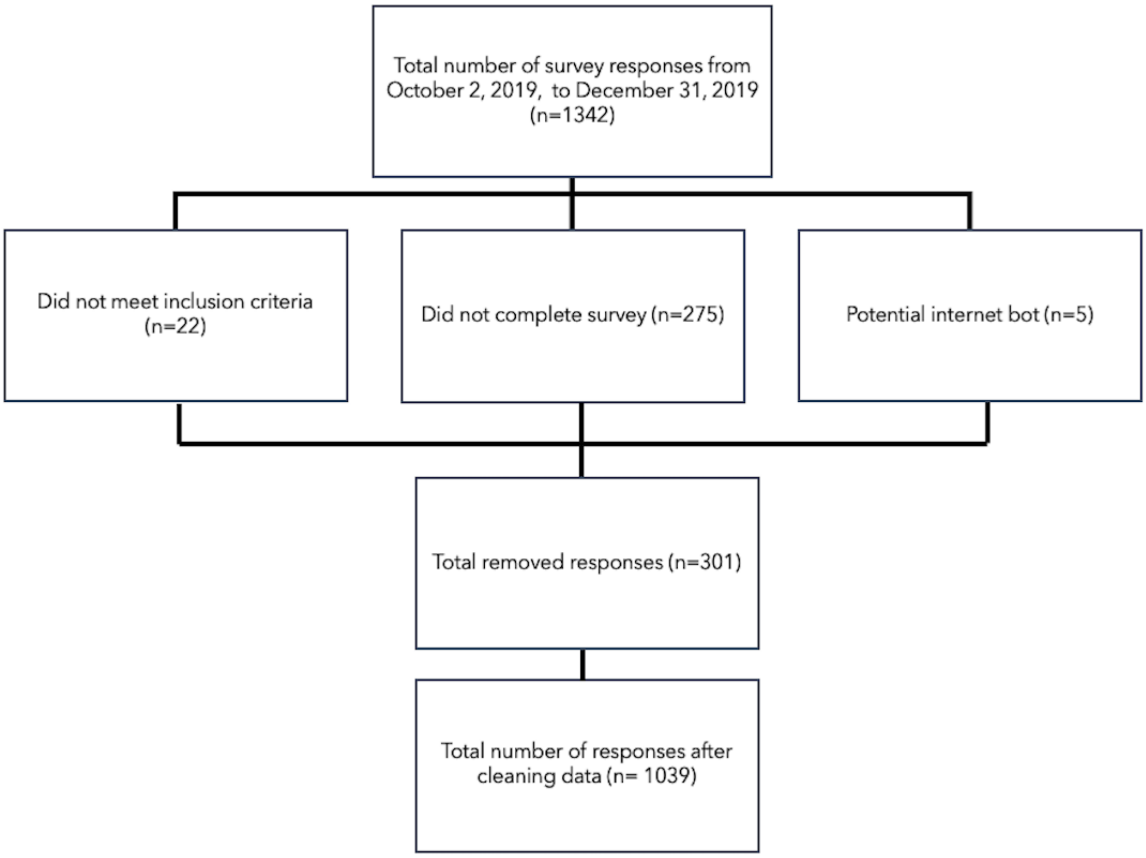
Patient and Public Involvement and Engagement

To enhance the survey's validity and to assist with recruitment procedures, a patient and public engagement group trained in research methodology and communication with researchers assisted the research team. This group of individuals is trusted to critically review research projects and act as coinvestigators throughout the life of the study. As a part of the learning academic health center's research infrastructure, this group was established in 2016 specifically for the purpose of providing patient and community partner input to co-develop and co-design research. This group included 3 scientists (experienced in health service research, comparative effectiveness research, and social health research), 4 physician representatives, a representative from the patient experience team, and 8-12 patient partners (experts). The patient experts come from diverse backgrounds and have participated in training on team building, research methods, and communication [22]. Specific demographics for the group participants are not provided due to group policy of being collaborators and not study participants. Feedback from the group was used to revise our survey for language clarity, to be culturally sensitive, and appropriate. The group also helped to revise the language in the recruitment materials.

Data Collection

Recruitment on social media for survey participation was initially posted on October 22, 2019, and was reshared 2 times (once in each of the following months) until responses were cut off at 11:59 PM on December 31, 2019. A total of 1342 responses were counted at the end of this 2-month period. Data were screened, filtered, and cleaned before statistical analysis (Figure 2). Incomplete survey responses, those that did not meet the inclusion criteria, and those that were determined to potentially be an internet response bot (eg, random letter strings in open-ended questions) were removed. The remaining 1039 responses were used for analysis.

Figure 2. Study inclusion flow diagram including data cleaning of survey participants' responses.



Data Analysis

Quantitative data were analyzed using IBM SPSS Statistics for Windows (version 26) to create descriptive statistics including means, SDs, and frequencies.

Qualitative data from open-ended survey questions were reviewed for data transformation (eg, provide additional categories or combine responses based upon themes from open-ended "describe other" responses for check all that apply answers) and data validation (eg, explore open-ended questions for emergent themes to provide context and explanation of quantitative results) purposes [19]. Responses were reviewed to determine any commonalities that could be pooled into an existing or new category. Specifically, many of the free response options from the open-ended questions asking participants to describe the "other" response they had selected. This allowed for new response categories to be created for analysis. These original responses and revised responses are listed in Table 1. Data were further transformed as some participants' selections were revised if open-ended answers could be synthesized into a current response option. For example, in the question investigating barriers to care, if a participant did not select "daily commitments" but did select "other" and the open-ended response was work, time, life, and so on, then the "daily commitments" was selected as a valid response and the "other" response was removed.

Table 1. Revised response options based upon themes in open-ended text options.

Original response options	Revised response options
How did you hear about your OBGYN provider?	
- Friends or family - Social media - Covered by my insurance plan - From my primary care provider - Other	- Internet (social media, internet search, online reviews, referral resource) - In insurance network - Other health care provider or practice - Work or school - Other
What factors will keep you from visiting your OBGYN provider?	
- Lack of insurance coverage - Cost - Transportation - Daily commitments - Fear of diagnosis - No factor would keep me from visiting - Other	- Lack of insurance coverage - Cost - Transportation - Daily commitments - Fear of diagnosis - No factor would keep me from visiting - Lack of access (distance to provider) - Lack of access (availability or scheduling issues in clinic) - Mistreatment by office staff - Mistreatment or dismissal by provider - Trauma related to visits - Lack of therapeutic relationship - Frustration with doctor or treatment (including disliking exam) - Delaying care (wait for problems to resolve, procrastination, or worried they were overreacting) - Other
Which of the following would allow you to feel that your OBGYN provider can relate to you?	
- Same race - Same geographical background - Same social class - Same religious background - Same sex - Same sexual orientation - Same educational level - None of these are necessary for relatability - Other	- Same race - Same geographical background - Same social class - Same religious background - Same gender identity - Same sexual orientation - Same educational level - None of these are necessary for relatability - Provides culturally competent care - Same socio-political beliefs - Same age - Same life experiences - Provides evidence-based care - Provides compassionate care - Other

In total, 2 new variables were also calculated. To determine if participants faced multiple barriers to care, a new variable was created by summing the total number of responses that were checked including the new response options. To determine if women experienced a pregnancy loss, the categorical variables responses were given a value (0=0, 1=1,…4+=5), then the number of children was subtracted from the number of times pregnant. While the exact number of pregnancy losses could not be determined, any number 1 or greater is assumed to be a pregnancy loss.

Ethical Considerations

This project was reviewed and approved by the University of South Carolina institutional review board (Pro00092199). Informed consent was provided through an opt-in question on the first page of the survey. Through this, participants were given a description of the survey, and their willingness to participate was confirmed before continuing. No incentives were provided for participating in the study.

Results

Participant Demographics

The majority of respondents were highly educated (568/1039, 54.7%) had higher than a bachelor’s degree), had 1 or more children (597/1039, 57.4%), and had a mean age of 36.53 (SD 12.21) years (Table 2). Participants were given the option of selecting multiple responses for their racial or ethnic identity and a majority (901/1086, 83%) of the sample selected white. A small percentage of the sample (41/1086, 4.1%) identified as multiracial (ie, selecting more than 1 race or ethnicity). Nearly 3 in 10 (290/1086, 26.6%) of the participants experienced a pregnancy loss.

Table 2. Demographics of survey respondents.

Variable	Statistical values (N=1039)
Age (years), mean (SD)	36.5 (12.2)
Gender identity, n (%)	
Woman	1034 (99.5)
Nonbinary	3 (0.3)
Other	2 (0.2)
Race or Ethnicity[a] (n=1086), n (%)	
American Indian or Alaskan native	8 (0.7)
Asian	38 (3.5)
Black or African American	94 (8.7)
Hispanic or Latino/a	31 (2.9)
Native Hawaiian or Pacific islander	2 (0.2)
White	901 (83)
Other	8 (0.7)
Choose not to answer	4 (0.4)
Marital Status, n (%)	
Divorced	51 (4.9)
Married	673 (64.8)
Separated	6 (0.6)
Single	304 (29.3)
Widowed	5 (0.5)
Sexual activity, n (%)	
Abstinent	69 (6.6)
Asexual	8 (0.8)
Sex with men	907 (87.3)
Sex with women	23 (2.2)
Sex with both men and women	32 (3.1)
Number of pregnancies, n (%)	
0	394 (37.9)
1	188 (18.1)
2	220 (21.2)
3	129 (12.4)
4+	108 (10.4)
Number of children, n (%)	
No response	7 (0.7)
0	435 (41.9)
1	235 (22.6)
2	271 (26.1)
3	73 (7)
4+	18 (1.7)
Highest level of education	
No formal education	2 (0.2)
High school diploma	52 (5)

Variable	Statistical values (N=1039)
Vocational training	32 (3.1)
Bachelor’s degree	385 (37.1)
Master’s degree	243 (23.4)
Doctoral or professional degree (JD, MD, PhD, DrPH, etc)	325 (31.3)

[a] Race or ethnicity: Race or ethnicity offers multiple response options (check all that apply).

Relationship With Provider

Participants were asked a series of questions about their OBGYN provider. The respondents report seeing their provider for an average of 6.01 (SD 6.78) years. A total of 62% (648/1039) have seen their provider at least once per year, while 184 (17.7%) and 107 (19.9%) participants reported seeing their provider less than once per year or more than once per year, respectively. Nearly 90% either see the same provider with each visit (672/1039, 64.7%) or see an OBGYN within the same practice (253/1039, 24.4%). Approximately 15.2% (158/1039) of the reported providers are underrepresented in medicine (Black, Mexican American, American Indian, Alaska Native, and Native Hawaiian). The top 3 ways participants found their OBGYN provider were through either friends or family (495/1039, 47.6%), their insurance network (226/1039, 21.8%), or another health care provider or practice (164/1039, 15.8%). A majority of the participants (562/1039, 54.1%) stated that they will wait a few days before reaching out to their provider if they have an OBGYN-related health concern, and 14.7% (153/1039) will tough it out; yet, 1 in 4 (261/1039, 25.1%) will reach out immediately. Most participants (615/1039, 59.2%) are not afraid to share personal details with their provider; however, 27.2% (283/1039) of them do experience fear some of the time when discussing sensitive topics. A total of 863/1039 (83.0%) participants always or most of the time have a strong level of trust in their provider, and nearly all (1008/1039, 97%) reported that their provider remains professional during their appointments.

Characteristics, Traits, and Relatability

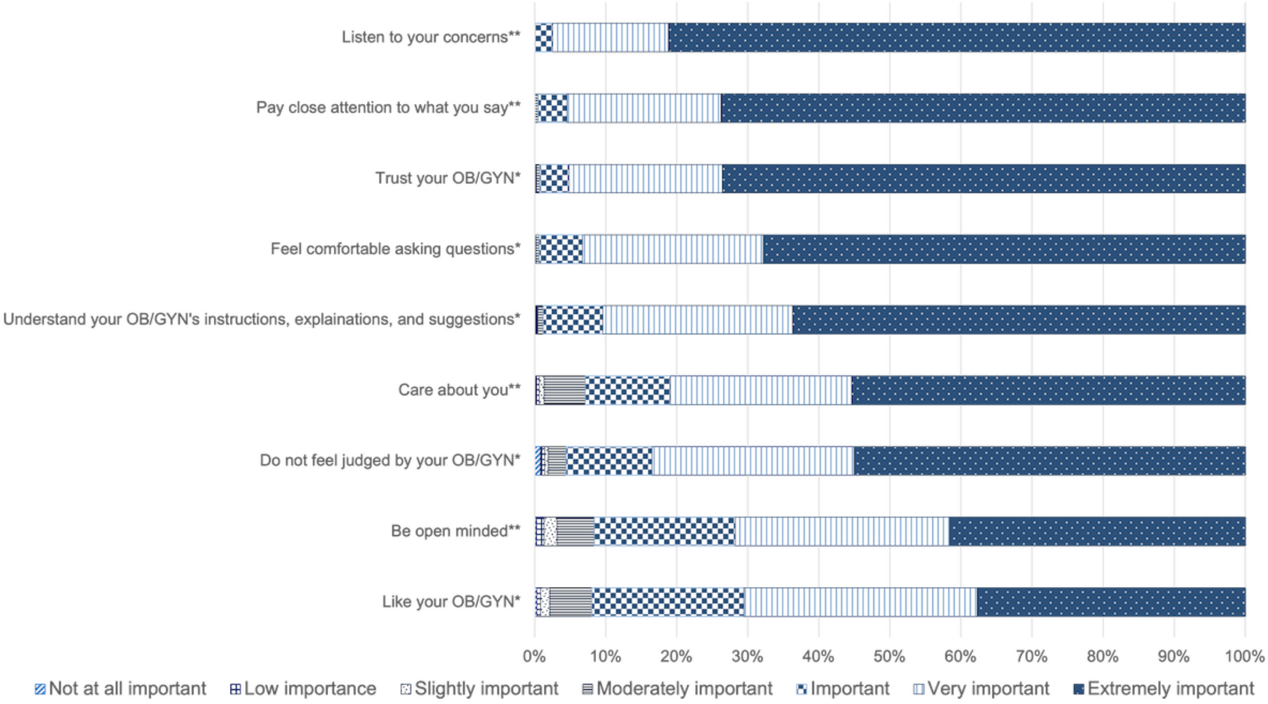
In total, 57.4% (596/1039) of the participants indicated that it is very important or necessary that their OBGYN provider can relate to them, while only 9.2% (95/1039) of them indicated that it is of little or no importance. A total of 35% (346/1039) of the participants found none of the characteristics or traits necessary for relatability; however, the rest of the participants (675/1039, 65%) identified between 1 and 7 different traits or characteristics that could increase relatability. The most often cited characteristics (Table 3) for a provider to have that would impact relatability were same gender identity (545/675, 80.7%) followed by same race (122/675, 18.1%) and same education level (107/675, 15.9%). These results of the importance of gender identity are supported by several responses in the final open-ended questions. A word count was performed on the question inquiring about internet search terms that could be used to find the ideal OBGYN provider. The most frequent responses (n=348/3067, 7.95%) had to do with the provider’s gender (eg, woman or female OBGYN).

Table 3. Descriptive statistics from multiple response survey data.

Attributes	Frequency, n (%)	Percentage of cases, %
Relatable characteristics (number of participants responding n=675, number of responses n=1160)		
Provides culturally competent care	9 (0.8)	1.3
Other	9 (0.8)	1.3
Provides compassionate care	32 (2.9)	5.0
Provides evidence-based care	10 (0.9)	1.5
Same age	15 (1.3)	2.2
Same educational level	107 (9.2)	15.9
Same gender	545 (47)	80.7
Same geographical background	59 (5.1)	8.7
Same life experiences	12 (1)	1.8
Same race	122 (10.5)	18.1
Same religious background	64 (5.5)	9.5
Same sexual orientation	91 (7.8)	13.5
Same social class	74 (6.4)	11.0
Same sociopolitical views	9 (0.8)	1.3
Barriers to care (number of participants responding n=738, number of responses n=1117)		
Access (availability or scheduling)	26 (2.3)	3.5
Access (distance)	5 (0.4)	0.7
Cost	245 (21.9)	33.2
Daily commitments	485 (43.4)	65.7
Delaying care	10 (0.9)	1.4
Fear of diagnosis	128 (11.5)	17.3
Frustration with doctor, treatment, or dislike examination	15 (1.3)	2.0
Lack of insurance coverage	110 (9.8)	14.9
Lack of therapeutic relationship	8 (0.7)	1.1
Mistreatment or dismissal by provider	35 (3.1)	4.7
Mistreated by office staff	2 (0.2)	0.3
Other	5 (0.4)	0.7
Transportation	38 (3.4)	5.1
Trauma	5 (0.4)	0.7

Figure 3 provides the levels of importance for each of the factors within the therapeutic alliance scale. Participants indicate that their provider listening to them is the most important part of the alliance while liking their provider is the least important factor.

Figure 3. Levels of importance for factors within a therapeutic alliance between patient and provider. *: answers to question "how important is it for you to"; **: answers question "how important is it for your care provider to.". OB/GYN: obstetrics and gynecology.



Barriers to Seeking Care

While 29.0% (301/1039) of participants report no barriers to seeking care, the rest of the participants (n=738) report between 1 and 5 total barriers to care. Table 3 indicates the percentage of respondents who cited each type of barrier. The most often cited barrier (485/735, 67.5%) to seeking care were daily commitments.

Discussion

Principal Findings

This study sheds new light on the preferences and values that OBGYN patients hold regarding their providers, emphasizing the critical role of relatability and trust in patient-provider relationships. Our findings underscore the paramount importance of listening skills, with patients ranking the ability to listen as more crucial than provider likeability or the delivery of medical advice. This aligns with existing literature which emphasizes empathy and listening as foundational to building trust and improving patient outcomes [1,5,23,24].

Participants in this study represent a demographic that is commonly analyzed in OBGYN research, predominantly white, cisgender women, a focus that has limited the diversity of perspectives traditionally captured in the literature [7,15,25,26]. Unlike previous studies, our findings reveal a notable preference for same-gender providers, an area where past research has shown mixed results [3,12-14,25,27]. Though evidence suggests that most patients still prioritize provider competence and communication, the role of gender concordance in specific medical specialties like obstetrics and gynecology hints at a potential shift in patient priorities within those fields [1,3,26].

Patients highly value trust, comfort, and respectful, personalized care from their providers, impacting their willingness to share personal details [1,2,5,10,23,25,28]. Our study reveals that 83% (863/1039) of participants prioritize trust, aligning with the intimacy and sensitivity inherent in OBGYN care. This focus on trust supports broader health care trends where empathy and listening skills are increasingly recognized as essential to effective patient care [6,9,23,26,28,29]. In addition, more than a quarter of our participants expressed concerns about disclosing personal information, indicating a need for providers to foster nonjudgmental and supportive environments. This aspect is particularly critical given the recent shifts toward more diverse health care teams, including the increase in female trainees and the expanding roles of nurse practitioners and primary care physicians in gynecological care, which may influence patient comfort and trust levels [3,9,12,18,30,31].

Patients highly prioritize professionalism and courtesy when selecting their OBGYN provider, aligning with the emphasis on listening skills found in this study. While studies show patients prioritize physician qualities such as experience, knowledge, and ability above all else [3], patients also consistently rank professionalism as a top factor when choosing an OBGYN provider [13,32]. Professionalism in this context encompasses traits such as courtesy, respect, and a positive bedside manner, which are closely tied to effective listening skills [1,13,32]. This study's focus on the importance of listening skills in OBGYN care aligns with existing research highlighting the essential role of these skills in establishing trust and effective patient-clinician relationships [1,2,5,23]. By emphasizing listening as a crucial element within professionalism and courtesy, this study underscores the evolving patient expectations regarding patient-centered care, particularly in the context of increased advocacy for this approach [1,5,23].

Barriers to OBGYN care have been well documented in the scientific literature, including costs, language differences, reluctance to disclose information, inadequate insurance, transportation, discrimination, and lack of access due to geography or other structural barriers [28,33-39] While the most often discussed barriers in the literature focus on cost and access to care, our results differ indicating the greatest barrier to care is daily commitments. However, barriers of cost and insurance combined to prevent nearly half of respondents from seeking care. With a greater understanding for patient barriers, it is important to note that results of this study primarily represent the demographic of well-educated women. For this group of patients, it is expected that work or school commitments could pose difficulties in setting aside time for OBGYN appointments. By understanding a common barrier patients may face, stronger patient-physician interactions will likely be built.

Clinical Implications

The study's findings align with the principles of patient-centered care, suggesting avenues for educational initiatives and quality improvement efforts to enhance patient experiences and outcomes in the OBGYN setting.

The emphasis on factors such as trust, communication, and relatability aligns seamlessly with the tenants of patient-centered care and highlights that patient-provider relationships are pivotal in fostering an environment where patients feel valued and empowered in their health care journey. These findings support the scientific literature which emphasizes the significance of trust and communication in patient-provider relationships which can lead to better patient satisfaction and health outcomes [23,24,40]. The need for a high level of trust with their provider highlights the importance of strong therapeutic relationships and may be especially important for future male OBGYN providers. As a majority of participants indicated that gender concordance impacts relatability with their provider, male OBGYNs will not have the same gender advantage as their female counterparts and instead will need to focus on other desired categories such as communication and enhancing trust.

This study's findings present opportunities for educational initiatives targeting both health care providers and patients. Providing education opportunities for OBGYN providers in effective communication skills, cultural competency, and enhancing trust could enhance their abilities to establish strong patient-provider relationships and reduce barriers to care [23,28,33,38-40]. Furthermore, providing patient education about the importance of communication, trust, and their own role in health care decision-making could encourage more active engagement in their care for patients [4-43].

Finally, the results of this study can guide quality improvement efforts within OBGYN practices through provider diversity and reducing barriers. Recognizing the importance of relatability, health care institutions can strive to diversify their provider pool to better mirror their patient populations. In addition, addressing practical barriers to care, as highlighted by the study, can be a quality improvement priority. Offering extended office hours, advanced telehealth options, and streamlining appointment processes can enhance patient access.

Limitations and Future Directions

It was noted through a literature review that the majority of previous study participants in similar studies to this, investigating provider traits, were White heterosexual females [13,15,25,32,44]. Our study has a similar demographic majority of white females; therefore, it may be difficult to generalize patient preferences of OBGYN providers in a more diverse population. With this potential lack of generalizability to other populations, it is important to continue these studies and attempt to create a more diverse participant population. This study also suggests a strong preference for patients to have a same-sex OB-GYN provider. This may call for more research into the reasoning behind this response, as well as an investigation into patient-identified traits and suggestions to male providers.

In addition, the survey was distributed solely in English, which could exclude non–English speaking participants and limit the diversity of responses. The reliance on self-reported data introduces potential biases, including social desirability bias, where participants may respond in a manner they perceive as favorable rather than providing genuine answers. This is particularly pertinent in sensitive topics such as personal health care experiences.

Furthermore, as a cross-sectional study, the timing of the survey could influence the results. Changes in public opinion, health care policies, or societal norms that occur before or after the survey period might not be reflected in the data, affecting the study's relevance over time. Cross-sectional designs also restrict the ability to infer causality from the associations observed, limiting the conclusions that can be drawn regarding the effects of patient preferences on health care outcomes.

Future research should incorporate expanded analyses, including detailed subgroup analyses, to explore how different demographic variables, such as age, race, and socioeconomic status, influence patient preferences and perceptions. This approach will help to address the current study's limitations in generalizability and provide a deeper understanding of the complex factors that shape patient-provider interactions in diverse populations. In addition, amid shifting federal and state policies on pregnancy and abortion care, future research should explore how these legal changes influence patient preferences and access to OBGYN care. Investigating variations in patient attitudes across different policy environments, through longitudinal and qualitative studies, will help understand the evolving dynamics of patient-provider relationships. This research could also highlight disparities and inform interventions to enhance health care access and quality, particularly for demographics most affected by legislative changes.

Conclusions

The relationship between an OBGYN provider and patients is one of the most intimate within medicine. Whether the interactions involve a physical examination or sensitive topic conversations, medical care in this field requires more trust and comfort than typical patient-physician relationships. The major findings of this study indicate that listening skills and building trust are valued most by patients. The data provide convincing evidence demonstrating a shift from previous research that patients can have a clear preference for OBGYN providers who share the same gender. As social climates fluctuate, women receiving reproductive health care deserve to be listened to and cared for by providers with whom they can build a strong relationship that may be influenced by pieces of one's worn identity.

Acknowledgments

We would like to thank the amazing patient experts in the University of South Carolina Patient Engagement Studio for their review and suggestions for this project.

Conflicts of Interest

ABK serves as the Director of the USC Patient Engagement Studio, which contributed to the project review from a patient and community perspective. No financial or other conflicts relevant to the study are declared.

Multimedia Appendix 1
Survey instrument.
[PDF File (Adobe PDF File), 56 KB - jopm_v16i1e58096_app1.pdf]

References

1. Srivastava A, Avan BI, Rajbangshi P, Bhattacharyya S. Determinants of women's satisfaction with maternal health care: a review of literature from developing countries. BMC Pregnancy Childbirth 2015;15:97 [FREE Full text] [doi: 10.1186/s12884-015-0525-0] [Medline: 25928085]
2. Dale HE, Polivka BJ, Chaudry RV, Simmonds GC. What young African American women want in a health care provider. Qual Health Res 2010;20(11):1484-1490 [FREE Full text] [doi: 10.1177/1049732310374043] [Medline: 20562249]
3. Nguyen BT, Streeter LH, Reddy RA, Douglas CR. Gender bias in the medical education of obstetrician-gynaecologists in the United States: a systematic review. Aust N Z J Obstet Gynaecol 2022;62(3):349-357 [FREE Full text] [doi: 10.1111/ajo.13511] [Medline: 35293613]
4. Alspach JG. Because women's lives matter, we need to eliminate gender bias. Crit Care Nurse 2017;37(2):10-18. [doi: 10.4037/ccn2017326] [Medline: 28365646]
5. Bogdan-Lovis E, Zhuang J, Goldbort J, Shareef S, Bresnahan M, Kelly-Blake K, et al. Do black birthing persons prefer a black health care provider during birth? Race concordance in birth. Birth 2023;50(2):310-318. [doi: 10.1111/birt.12657] [Medline: 35635034]
6. Zhao C, Dowzicky P, Colbert L, Roberts S, Kelz RR. Race, gender, and language concordance in the care of surgical patients: a systematic review. Surgery 2019;166(5):785-792. [doi: 10.1016/j.surg.2019.06.012] [Medline: 31375322]
7. Peterson CE, Silva A, Goben AH, Ongtengco NP, Hu EZ, Khanna D, et al. Stigma and cervical cancer prevention: a scoping review of the U.S. literature. Prev Med 2021;153:106849. [doi: 10.1016/j.ypmed.2021.106849] [Medline: 34662598]
8. Miller AN, Duvuuri VNS, Vishanagra K, Damarla A, Hsiao D, Todd A, et al. The relationship of race/ethnicity concordance to physician-patient communication: a mixed-methods systematic review. Health Commun 2024;39(8):1543-1557. [doi: 10.1080/10410236.2023.2223402] [Medline: 37338139]
9. Lauwers EDL, Vandecasteele R, McMahon M, De Maesschalck S, Willems S. The patient perspective on diversity-sensitive care: a systematic review. Int J Equity Health 2024;23(1):117 [FREE Full text] [doi: 10.1186/s12939-024-02189-1] [Medline: 38840119]
10. Rand LZG, Berger Z. Disentangling evidence and preference in patient-clinician concordance discussions. AMA J Ethics 2019;21(6):E505-E512 [FREE Full text] [doi: 10.1001/amajethics.2019.505] [Medline: 31204991]
11. Mendoza-Grey S, Ramos-Muniz J, Armbrister AN, Abraído-Lanza AF. Mammography screening among Latinas: does gender and ethnic patient-physician concordance matter? J Immigr Minor Health 2021;23(5):986-992. [doi: 10.1007/s10903-021-01170-2] [Medline: 33660103]
12. Mavis B, Vasilenko P, Schnuth R, Marshall J, Jeffs MC. Female patients' preferences related to interpersonal communications, clinical competence, and gender when selecting a physician. Acad Med 2005;80(12):1159-1165. [doi: 10.1097/00001888-200512000-00022] [Medline: 16306294]
13. Johnson AM, Schnatz PF, Kelsey AM, Ohannessian CM. Do women prefer care from female or male obstetrician-gynecologists? A study of patient gender preference. J Am Osteopath Assoc 2005;105(8):369-379. [Medline: 16166391]
14. Zuckerman M, Navizedeh N, Feldman J, McCalla S, Minkoff H. Determinants of women's choice of obstetrician/gynecologist. J Womens Health Gend Based Med 2002;11(2):175-180. [doi: 10.1089/152460902753645317] [Medline: 11975865]
15. Plunkett BA, Kohli P, Milad MP. The importance of physician gender in the selection of an obstetrician or a gynecologist. Am J Obstet Gynecol 2002;186(5):926-928. [doi: 10.1067/mob.2002.123401] [Medline: 12015516]

16. Buck KS, Littleton HL. Stereotyped beliefs about male and female OB-GYNS: relationship to provider choice and patient satisfaction. J Psychosom Obstet Gynaecol 2014;35(1):1-7. [doi: 10.3109/0167482X.2013.866646] [Medline: 24320840]
17. Otte SV. Improved patient experience and outcomes: is patient-provider concordance the key? J Patient Exp 2022;9:23743735221103033 [FREE Full text] [doi: 10.1177/23743735221103033] [Medline: 35664933]
18. Smith GH, Hampton C, Brandon WP. Physicians, physician extenders and health outcomes: race, gender and patient-health provider concordance in North Carolina medicaid. J Health Care Poor Underserved 2018;29(1):530-555. [doi: 10.1353/hpu.2018.0035] [Medline: 29503316]
19. Creswell JW, Plano CVL. Designing and Conducting Mixed Methods Research. Thousand Oaks, California: SAGE Publications; 2017.
20. Davies W. Insights into rare diseases from social media surveys. Orphanet J Rare Dis 2016;11(1):151 [FREE Full text] [doi: 10.1186/s13023-016-0532-x] [Medline: 27829465]
21. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research Electronic Data Capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42(2):377-381 [FREE Full text] [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
22. Fleming PR, Swygert MM, Hasenkamp C, Sterling J, Cartee G, Russ-Sellers R, et al. Patient engagement in fertility research: bench research, ethics, and social justice. Res Involv Engagem 2021;7(1):29 [FREE Full text] [doi: 10.1186/s40900-021-00278-x] [Medline: 33980313]
23. Müller E, Zill JM, Dirmaier J, Härter M, Scholl I. Assessment of trust in physician: a systematic review of measures. PLoS One 2014;9(9):e106844 [FREE Full text] [doi: 10.1371/journal.pone.0106844] [Medline: 25208074]
24. Wassenaar A, van den Boogaard M, van der Hooft T, Pickkers P, Schoonhoven L. 'Providing good and comfortable care by building a bond of trust': nurses views regarding their role in patients' perception of safety in the intensive care unit. J Clin Nurs 2015;24(21-22):3233-3244. [doi: 10.1111/jocn.12995] [Medline: 26374345]
25. Makam A, Mallappa Saroja CS, Edwards G. Do women seeking care from obstetrician-gynaecologists prefer to see a female or a male doctor? Arch Gynecol Obstet 2010;281(3):443-447. [doi: 10.1007/s00404-009-1199-5] [Medline: 19669776]
26. Evans S, Myers EM, Vilasagar S. Patient perceptions of same-day discharge after minimally invasive gynecologic and pelvic reconstructive surgery. Am J Obstet Gynecol 2019;221(6):621.e1-621.e7. [doi: 10.1016/j.ajog.2019.06.046] [Medline: 31254524]
27. Janssen SM, Lagro-Janssen ALM. Physician's gender, communication style, patient preferences and patient satisfaction in gynecology and obstetrics: a systematic review. Patient Educ Couns 2012;89(2):221-226. [doi: 10.1016/j.pec.2012.06.034] [Medline: 22819711]
28. Logan RG, Daley EM, Vamos CA, Louis-Jacques A, Marhefka SL. "When Is Health Care Actually Going to Be Care?" The lived experience of family planning care among young black women. Qual Health Res 2021;31(6):1169-1182 [FREE Full text] [doi: 10.1177/1049732321993094] [Medline: 33622078]
29. Harik L, Yamamoto K, Kimura T, Rong LQ, Vogel B, Mehran R, et al. Patient-physician sex concordance and outcomes in cardiovascular disease: a systematic review. Eur Heart J 2024;45(17):1505-1511. [doi: 10.1093/eurheartj/ehae121] [Medline: 38551446]
30. Meghani SH, Brooks JM, Gipson-Jones T, Waite R, Whitfield-Harris L, Deatrick JA. Patient-provider race-concordance: does it matter in improving minority patients' health outcomes? Ethn Health 2009;14(1):107-130 [FREE Full text] [doi: 10.1080/13557850802227031] [Medline: 19012091]
31. Chan KS, Bird CE, Weiss R, Duan N, Meredith LS, Sherbourne CD. Does patient-provider gender concordance affect mental health care received by primary care patients with major depression? Womens Health Issues 2006;16(3):122-132. [doi: 10.1016/j.whi.2006.03.003] [Medline: 16765288]
32. Piper I, Shvarts S, Lurie S. Women's preferences for their gynecologist or obstetrician. Patient Educ Couns 2008;72(1):109-114. [doi: 10.1016/j.pec.2008.02.004] [Medline: 18387774]
33. Adler A, Biggs MA, Kaller S, Schroeder R, Ralph L. Changes in the frequency and type of barriers to reproductive health care between 2017 and 2021. JAMA Netw Open 2023;6(4):e237461 [FREE Full text] [doi: 10.1001/jamanetworkopen.2023.7461] [Medline: 37036704]
34. McKenney KM, Martinez NG, Yee LM. Patient navigation across the spectrum of women's health care in the United States. Am J Obstet Gynecol 2018;218(3):280-286 [FREE Full text] [doi: 10.1016/j.ajog.2017.08.009] [Medline: 28844825]
35. Mendiola M, Chu J, Haviland MJ, Meservey M, Hacker MR, Gomez-Carrion Y. Barriers to care and reproductive considerations for transmasculine gender affirming surgery. Am J Obstet Gynecol 2020;222(1):90-92 [FREE Full text] [doi: 10.1016/j.ajog.2019.09.043] [Medline: 31586603]
36. Ranji U, Salganicoff A, Rousseau D, Kaiser Family Foundation. Barriers to care experienced by women in the United States. JAMA 2019;321(22):2154. [doi: 10.1001/jama.2019.5271] [Medline: 31184724]
37. Institute of Medicine (US) Committee to Study Outreach for Prenatal Care. Prenatal care: reaching mothers, reaching infants. In: Brown SS, editor. Women's Perceptions of Barriers to Care. Washington DC: National Academies Press; 1988.
38. Okoro ON, Hillman LA, Cernasev A. "We get double slammed!": Healthcare experiences of perceived discrimination among low-income African-American women. Womens Health (Lond) 2020;16:1745506520953348 [FREE Full text] [doi: 10.1177/1745506520953348] [Medline: 32856564]

39. Kingsberg SA, Schaffir J, Faught BM, Pinkerton JV, Parish SJ, Iglesia CB, et al. Female sexual health: barriers to optimal outcomes and a roadmap for improved patient-clinician communications. J Womens Health (Larchmt) 2019;28(4):432-443 [FREE Full text] [doi: 10.1089/jwh.2018.7352] [Medline: 30714849]
40. Merenstein Z, Shuemaker JC, Phillips RL. Measuring trust in primary care. Milbank Q 2023;101(3):841-880. [doi: 10.1111/1468-0009.12654] [Medline: 37167452]
41. McCarus SD, Wiercinski K, Heidrich N. Shared decision-making to improve patient engagement in minimally invasive hysterectomy. Surg Technol Int 2019;34:265-268. [Medline: 30472723]
42. Légaré F, Adekpedjou R, Stacey D, Turcotte S, Kryworuchko J, Graham ID, et al. Interventions for increasing the use of shared decision making by healthcare professionals. Cochrane Database Syst Rev 2018;7(7):CD006732 [FREE Full text] [doi: 10.1002/14651858.CD006732.pub4] [Medline: 30025154]
43. Stabile C, Goldfarb S, Baser RE, Goldfrank DJ, Abu-Rustum NR, Barakat RR, et al. Sexual health needs and educational intervention preferences for women with cancer. Breast Cancer Res Treat 2017;165(1):77-84 [FREE Full text] [doi: 10.1007/s10549-017-4305-6] [Medline: 28547655]
44. Schnatz PF, Murphy JL, O'Sullivan DM, Sorosky JI. Patient choice: comparing criteria for selecting an obstetrician-gynecologist based on image, gender, and professional attributes. Am J Obstet Gynecol 2007;197(5):548.e1-548.e7. [doi: 10.1016/j.ajog.2007.07.025] [Medline: 17980206]

Abbreviations

OBGYN: obstetrics and gynecology
REDCap: Research Electronic Data Capture

Edited by M Hudson; submitted 05.03.24; peer-reviewed by N Schwartz, S Woods; comments to author 27.06.24; revised version received 12.08.24; accepted 13.08.24; published 16.10.24.

Please cite as:
Kennedy AB, Harb AT, Schockling C, Ray LJ, Palomo J, Russ-Sellers R
Understanding the Values, Qualities, and Preferences of Patients in Their Relationships With Obstetrics and Gynecology Providers: Cross-Sectional Survey With a Mixed Methods Approach
J Particip Med 2024;16:e58096
URL: https://jopm.jmir.org/2024/1/e58096
doi:10.2196/58096
PMID:39412870

Original Paper

Patients’ Perspectives on Plans Generated During Primary Care Visits and Self-Reported Adherence at 3 Months: Data From a Randomized Trial

Cheryl D Stults[1], PhD; Kathleen M Mazor[2], EdD; Michael Cheung[3], BA; Bernice Ruo[4], MD, MAS; Martina Li[1], MPH; Amanda Walker[5], MS; Cassandra Saphirak[2], MA; Florin Vaida[3], PhD; Sonal Singh[2], MPH, MD; Kimberly A Fisher[2], MSc, MD; Rebecca Rosen[5], MD; Robert Yood[6], MD; Lawrence Garber[6], MD; Christopher Longhurst[7], MS, MD; Gene Kallenberg[5], MD; Edward Yu[8], MD; Albert Chan[1,9,10], MS, MD; Marlene Millen[4], MD; Ming Tai-Seale[5,7], MPH, PhD

[1]Palo Alto Medical Foundation Research Institute, Center for Health Systems Research, Sutter Health, Palo Alto, CA, United States
[2]Department of Medicine, UMass Chan Medical School, Worcester, MA, United States
[3]Herbert Wertheim School of Public Health and Human Longevity Science, University of California San Diego, La Jolla, CA, United States
[4]Department of Medicine, University of California San Diego, La Jolla, CA, United States
[5]Department of Family Medicine, University of California San Diego, La Jolla, CA, United States
[6]Research Department, Reliant Medical Group, Worcester, MA, United States
[7]Division of Biomedical Informatics, Department of Medicine, University of California San Diego, La Jolla, CA, United States
[8]Department of Family Medicine, Palo Alto Medical Foundation, Sutter Health, Mountain View, CA, United States
[9]Digital Team, Sutter Health, Sacramento, CA, United States
[10]Department of Medicine, Division of Biomedical Informatics Research, Stanford University, Stanford, CA, United States

Corresponding Author:
Cheryl D Stults, PhD
Palo Alto Medical Foundation Research Institute
Center for Health Systems Research
Sutter Health
795 El Camino Real
Ames Building
Palo Alto, CA, 94301
United States
Phone: 1 650 853 2346
Email: cheryl.stults@sutterhealth.org

Abstract

Background: Effective primary care necessitates follow-up actions by the patient beyond the visit. Prior research suggests room for improvement in patient adherence.

Objective: This study sought to understand patients’ views on their primary care visits, the plans generated therein, and their self-reported adherence after 3 months.

Methods: As part of a large multisite cluster randomized pragmatic trial in 3 health care organizations, patients completed 2 surveys—the first within 7 days after the index primary care visit and another 3 months later. For this analysis of secondary outcomes, we combined the results across all study participants to understand patient adherence to care plans. We recorded patient characteristics and survey responses. Cross-tabulation and chi-square statistics were used to examine bivariate associations, adjusting for multiple comparisons when appropriate. We used multivariable logistic regression to assess how patients’ intention to follow, agreement, and understanding of their plans impacted their plan adherence, allowing for differences in individual characteristics. Qualitative content analysis was conducted to characterize the patient’s self-reported plans and reasons for adhering (or not) to the plan 3 months later.

Results: Of 2555 patients, most selected the top box option (9=definitely agree) that they felt they had a clear plan (n=2011, 78%), agreed with the plan (n=2049, 80%), and intended to follow the plan (n=2108, 83%) discussed with their provider at the primary care visit. The most common elements of the plans reported included reference to exercise (n=359, 14.1%), testing (laboratory, imaging, etc; n=328, 12.8%), diet (n=296, 11.6%), and initiation or adjustment of medications; (n=284, 11.1%). Patients who strongly agreed that they had a clear plan, agreed with the plan, and intended to follow the plan were all more likely to report plan completion 3 months later (*P*<.001) than those providing less positive ratings. Patients who reported plans related to following up with the primary care provider (*P*=.008) to initiate or adjust medications (*P*≤.001) and to have a specialist visit were more likely to report that they had completely followed the plan (*P*=.003). Adjusting for demographic variables, patients who indicated intent to follow their plan were more likely to follow-through 3 months later (*P*<.001). Patients' reasons for completely following the plan were mainly that the plan was clear (n=1114, 69.5%), consistent with what mattered (n=1060, 66.1%), and they were determined to carry through with the plan (n=887, 53.3%). The most common reasons for *not* following the plan were lack of time (n=217, 22.8%), having decided to try a different approach (n=105, 11%), and the COVID-19 pandemic impacted the plan (n=105, 11%).

Conclusions: Patients' initial assessment of their plan as clear, their agreement with the plan, and their initial willingness to follow the plan were all strongly related to their self-reported completion of the plan 3 months later. Patients whose plans involved lifestyle changes were less likely to report that they had "completely" followed their plan.

Trial Registration: ClinicalTrials.gov NCT03385512; https://clinicaltrials.gov/study/NCT03385512

International Registered Report Identifier (IRRID): RR2-10.2196/30431

(J Particip Med 2024;16:e50242) doi:10.2196/50242

KEYWORDS

primary care; survey; patient adherence; adherence; self-reported; surveys; content analysis; RCT; randomized; controlled trial; controlled trials; plan; plans; willingness; experience; experiences; attitude; attitudes; opinion; opinion; perception; perceptions; perspective; perspectives

Introduction

Primary care is an essential component of health care in the United States, where primary care providers (PCPs) provide comprehensive and longitudinal care to patients [1]. The role of the PCP has expanded over time, with PCPs providing more diagnoses, more treatments, and more preventive services in recent years [2]. In 2015, about 25% of PCP visits were for preventive care, about 30% care for chronic conditions, and just under 40% for acute care [3]. In many instances, primary care visits generate a plan for follow-up actions that extend beyond the encounter, as care often involves tasks that the patient (and sometimes the PCP) will do in the subsequent days and weeks. Ideally, the patient and the PCP jointly decide upon and agree to a plan [4], which might involve initiating or adjusting medications, monitoring symptoms, scheduling tests, implementing lifestyle modifications, or a multitude of other steps. Adherence to plans is affected by a broad range of factors including the provider-patient relationship [5]. One meta-analysis reported a 19% greater risk of nonadherence among patients who reported their physician communicated poorly during the visit [6].

While there is a substantial body of research on patient adherence, much of it is focused on adherence in the context of specific diseases, such as diabetes [7], coronary heart disease [8], asthma [9], and depression [10]. Medication adherence has been particularly well studied; 1 meta-analysis of 50 years of adherence research found that 63% of the studies focused on medication adherence, with many fewer studies examining adherence to recommendations for changes in diet (4.8%) and exercise (2.5%) [11]. In general, overall adherence rates have been estimated to range between 50% and 75%, suggesting substantial room for improvement [11,12]. Understanding patients' perspectives on the plan that they have (or have not) understood and agreed to and their reasons for following or not following the plan could provide insights that would help PCPs promote better adherence. To our knowledge, there have been no large, multisite studies in the United States describing patients' perceptions of the plans that result from their primary care visits, the extent to which patients follow these plans, and their reasons for following or not.

The purpose of this study was to describe patients' perceptions of the plans generated during primary care visits and characterize these plans. We also sought to describe patients' reports of whether they adhered to the plan, the extent to which follow-through was related to their initial perceptions of the plan, and their reasons for adherence (or lack of adherence) to the plan.

Methods

Overview

The data for this analysis were collected in the context of a large multisite cluster randomized controlled trial (ClinicalTrials.gov NCT123456) evaluating the impact of 3 approaches to facilitating communication and shared decision-making in primary care encounters. The 3 approaches were 1. in-person coaching for clinicians along with patients receiving a pre-visit questionnaire in advance of their visit regarding what they wanted to talk about and a video about how to prepare for their visit; 2. Mobile app coaching for clinicians and the same 2 components for patients (pre-visit questionnaire and video), and 3. Poster in exam room to encourage shared decision making. The primary study outcomes were patient-reported perceptions of communication and decision making during the appointment. While not one of the primary outcomes, this analysis was of secondary outcomes that were a part of the original research questions to examine patient plans and how patients were then able to carry them out. A detailed description of the methods and the findings of the trial are available elsewhere [13]; we briefly summarize the relevant methods here. Because the main analysis did not detect a statistically significant difference between the 3 study arms, we do not present the findings about plans by study arm. Additionally, when coding the data, we did not see any major differences across the arms and so we are examining data across all study participants.

English-speaking adult patients with a web-based patient portal account were invited to participate in the study at least 3 days in advance of scheduled appointments with participating PCPs at each site. We selected English-speaking primary care patients as that was the group studied in the initial pilot [14]. We also selected patients with a web-based patient portal account because 2 key components of the intervention (the single-item previsit questionnaire and video) were delivered via the portal. Details about the recruitment processes, which include patient portal and email invitations, have been described elsewhere [15]. Patients who provided informed consent and completed a web-based postvisit survey within 7 days of the visit were sent a follow-up survey approximately 3 months later (also on the web). Nonrespondents to the follow-up survey were sent 2 reminder emails. Patients received a US $20 incentive for completing each survey. Survey data were collected and managed using REDCap (Research electronic data capture; Vanderbilt University) tools [16,17]. Data collection occurred from September 2019 through November 2021.

The analytic sample for the study reported here includes all patients who completed the initial postvisit survey within 7 days of the visit and also completed a 3-month survey. We focus specifically on the questions related to development and adherence to plans generated during the visit. In the initial postvisit survey, patients' perceptions of the plan discussed during their medical appointment were assessed with 3 statements, each rated on a 10-point scale (from 0 to 9, with 0 as "strongly disagree" and 9 as "strongly agree"): (1) My doctor and I have a clear plan for what to do next about my health issues; (2) I agree with the plan my doctor and I have for taking care of my health issues; and (3) I will follow the plan my doctor and I made for taking care of my health issues. Patients were asked to enter a free-text response to the open-ended question: "Thinking about the plan that you and your doctor made, what is the most important thing that you will do over the next three months?"

In the 3-month survey, patients' descriptions of their plan from the postvisit survey (ie, response to "the most important thing you will do") were populated into the survey to remind patients of what they had written originally. Patients were then asked: "To what extent have you carried out the plan?" with response options of "Completely," "Somewhat," "Not At All," and "This Doesn't Apply To Me/I Didn't Have a Plan." Patients who responded "Somewhat" or "Not At All" were asked to select from a list of reasons for not carrying out the plan and those who responded "Completely" were asked to select what helped them adhere to the plan. Patients were able to select multiple reason options or write in a text response.

Ethical Considerations

The study was conducted at 3 health care organizations in 2 states (California and Massachusetts). The overall study, including these secondary outcomes, was reviewed and approved by institutional review boards at Sutter Health (2017.094EXP), the University of California San Diego (#180310), and the UMass Chan Medical School (H0001310).

Analysis

We computed means and frequencies to describe the patient characteristics and responses to the survey questions described above. We dichotomized patients' responses to each of the 3 questions about communication into the "top box," indicating whether the patient gave the highest score possible, that is, 9 or less than top box. This approach is often used operationally [14]. Cross-tabulation and chi-square statistics were used to examine the bivariate associations between patients' initial postvisit ratings of their plan and reported plan adherence approximately 3 months later. We also examined the association between the type of plan and plan adherence. We also examined the association between the type of plan and plan adherence. Significance values were adjusted by the Bonferroni corrections for multiple comparisons for the various types of plans. The binary outcome of carrying out the plan was analyzed using a multipredictor logistic regression, including the 3 questionnaire responses mentioned above and adjusted for the demographic factors to demonstrate how the patients' understanding or agreement or intention to follow the plan impacts the adherence to the plan, allowing for differences due to various characteristics. We used qualitative content analysis to categorize responses to the open-ended questions "Thinking about the plan that you and your doctor made, what is the most important thing that you will do over the next three months?" in the postvisit survey and the free-text responses to other reasons for not adhering to a plan and adhering to a plan in the 3-month survey.

We developed a codebook for the content analysis using an iterative process. Investigators and staff at each site first reviewed the free-text responses for their site to create inductive codes capturing the content evident in the responses. We then compared the codes generated at each site to determine common codes and established a formal codebook that coders at each site applied to their data. Coders flagged any text that was difficult to code and brought these responses to the full coding team, which discussed the text and determined whether modifications to the coding scheme were needed. The full coding team also adjudicated final code assignments for any difficult or questionable responses.

Results

We present the results combining all 3 sites as we found that they were very similar during the qualitative analysis. The analytic sample for this study included 2555 patients who completed both the postvisit and 3-month surveys (3847 total completed surveys, 66.4%). Patient participants were on average 52 (SD 16.4) years old. The majority were female (n=1662, 65%), White (n=2097, 82%), non-Hispanic (n=2304, 90%), and had a 4-year college degree or higher (n=1151, 72%). Many (n=1547, 60.5%) had their visit during the COVID-19 pandemic (eg, after March 16, 2020; Table 1).

Overall, a large majority of patients selected the top box option (9=definitely agree) to indicate that they felt they had a clear plan (n=2011, 78%), agreed with the plan (n=2049, 80%), and intended to follow the plan (n=2108, 83%) discussed with their PCP.

The types of plans patients reported are summarized in Table 1. Patients could report more than 1 type of plan or a plan that included multiple components. The most common elements of the plans reported included reference to exercise (n=359, 14.1%), testing (laboratory, imaging, etc; n=328, 12.8%), diet (n=296, 11.6%), and initiation or adjustment of medications (n=284, 11.1%). The correspondence between patients' views of their plan as reported soon after the visit and their report of whether they had followed the plan 3 months later is presented in Table 2. Patients who reported that they had a clear plan, agreed with the plan, and intended to follow the plan were all more likely to report completion of the plan 3 months later compared to those who provided less positive ratings on these items initially (*P*<.001). Table 2 also shows the percentage of patients who reported they had "Completely" followed through 3 months later for each type of plan. Patient plans related to following up with the PCP, initiating or adjusting medications, and having a specialist visit were more likely to indicate that they had completely followed the plan (*P*=.008, *P*≤.001, and *P*=.003, respectively). Patients whose plans involved lifestyle changes such as weight loss, diet, and exercise were less likely to report that they had "Completely" followed their plan than those whose plans did not involve lifestyle changes (*P*<.001).

For the multivariable logistic regression, compared to those who responded other than "definitely agree," those patients who indicated "definitely agree" that they would follow the plan were more likely to report 3 months later that they completely followed the plan (adjusted odds ratio 1.95, 95% CI 1.48-2.58; Table 3).

Patients were able to report more than 1 reason for following or not following the plan. Patients' reasons for completely following the plan included that the plan was clear (n=1114, 69.5%), consistent with what mattered (n=1060, 66.1%), they were determined to carry through with the plan (n=887, 53.3%), and had the support needed to carry through the plan (n=570, 33.7%; Table 4). The most common reasons for *not* following the plan were lack of time (n=217, 22.8%), decided to try a different approach (n=105, 11%), the COVID-19 pandemic impacted the plan (n=105, 11%), the plan did not fit the lifestyle (n=93, 9.7%), and the plan was no longer needed or relevant (n=90, 9.5%; Table 4).

Table 1. Sample characteristics (N=2555).

Characteristic	Overall sample
Age (years)	
Median (IQR)	54.0 (39.0-66.0)
mean (SD)	52.6 (16.4)
Gender, n (%)	
Female	1662 (65)
Male	838 (32.8)
Other or missing	55 (2.15)
Race, n (%)	
American Indian or Alaska Native	12 (0.5)
Asian	266 (10.4)
Black or African American	50 (2)
Native Hawaiian or other Pacific Islander	11 (0.4)
White	2097 (82.1)
More than 1 race	68 (2.7)
Missing	51 (2)
Ethnicity, n (%)	
Hispanic	231 (9)
Non-Hispanic	2304 (90.2)
Missing	20 (0.8)
Education, n (%)	
High school graduate or general educational diploma or less	161 (6.3)
Some college or 2-year degree	548 (21.4)
4-year college graduate	695 (27.2)
More than a 4-year college degree	1151 (45)
Index visit on or after March 16, 2020 (COVID-19 pandemic), n (%)	
No	986 (38.6)
Yes	1547 (60.5)
Missing	22 (0.9)
Health system, n (%)	
A	1240 (48.5)
B	857 (33.5)
C	458 (17.9)
How confident are you in filling out forms by yourself?, n (%)	
Extremely	2309 (90.4)
Quite a bit or somewhat or a little bit	237 (9.3)
Not at all	7 (0.3)
Missing	2 (0.1)
Type of plan, n (%)[a]	
Exercise	359 (14.1)
Testing (laboratory, imaging, etc)	328 (12.8)
Diet	296 (11.6)
Medication management	284 (11.1)

Characteristic	Overall sample
Specialist referral	246 (9.6)
Monitor or control condition	218 (8.5)
Follow-up with PCP[b]	181 (7.1)
Lose weight	96 (3.8)
Other strategies not specified above[c]	230 (9)
Other preventive behaviors not specified above[d]	168 (6.6)
Did not have a plan	17 (0.7)
My doctor and I have a clear plan for what to do next about my health issues, n (%)	
Definitely agree (“top box”)	2011 (78.7)
Less than definitely agree	544 (21.3)
I agree with the plan my doctor and I have for taking care of my health issues, n (%)	
Definitely agree (“top box”)	2049 (80.2)
Less than definitely agree	506 (19.8)
I will follow the plan my doctor and I made for taking care of my health issues, n (%)	
Definitely agree (“top box”)	2108 (82.5)
Less than definitely agree	447 (17.5)
To what extent have you carried out the plan?, n (%)	
Completely	1603 (62.7)
Not at all or somewhat	952 (37.3)

[a] Plans could include more than 1 component; categories are not mutually exclusive.

[b] PCP: primary care provider.

[c] Other strategies included physical therapist, occupational therapist, health educator, mental health therapy, herbal supplements, managing stress, and independent learning.

[d] Smoking cessation, vaccination, reducing alcohol consumption, and general comments about healthy lifestyle.

Table 2. Extent of the followed plan by intention and types of plan.

Characteristics	To what extent have you carried out the plan?		Odds ratio (95% CI)	Overall *P* value
	Completely (n=1603, 62.7%), n (%)	Less than completely (n=952, 37.3%), n (%)		
My doctor and I have a clear plan for what to do next about my health issues				<.001
Definitely agree (“top box”)	1323 (65.8)	688 (34.2)	1.81 (1.5-2.2)	
Less than definitely agree	280 (51.5)	264 (48.5)	N/A[a]	
I agree with the plan my doctor and I have for taking care of my health issues				<.001
Definitely agree (“top box”)	1350 (65.9)	699 (34.1)	1.93 (1.59-2.35)	
Less than definitely agree	253 (50)	253 (50)	N/A	
I will follow the plan my doctor and I made for taking care of my health issues				<.001
Definitely agree (“top box”)	1398 (66.3)	710 (33.7)	2.32 (1.89-2.86)	
Less than definitely agree	205 (45.9)	242 (54.1)	N/A	
Types of plan				
Exercise	174 (48.5)	185 (51.5)	0.51 (0.37-0.7)[b]	<.001[c]
Testing (laboratory, imaging, etc)	222 (67.7)	106 (32.3)	1.28 (0.9-1.84)[b]	.54[c]
Diet	149 (50.3)	147 (49.7)	0.56 (0.4-0.8)[b]	<.001[c]
Medication management	209 (73.6)	75 (26.4)	1.75 (1.19-2.63)[b]	<.001[c]
Specialist referral	181 (73.6)	65 (26.4)	1.73 (1.15-2.68)[b]	.003[c]
Monitor or control condition	152 (69.7)	66 (30.3)	1.4 (0.92-2.19)[b]	.31[c]
Follow-up with primary care provider	135 (74.6)	46 (25.4)	1.81 (1.12-3.02)[b]	.008[c]
Lose weight	41 (42.7)	55 (57.3)	0.43 (0.23-0.77)[b]	<.001[c]
Other strategies not specified above	127 (55.2)	103 (44.8)	0.71 (0.48-1.05)[b]	.16[c]
Other preventive behaviors not specified above	100 (59.5)	68 (40.5)	0.86 (0.55-1.38)[b]	≥.99[c]

[a] N/A: not available.

[b] Bonferroni-corrected 99.5% CI.

[c] Bonferroni-corrected *P* value.

Table 3. Adjusted logistic regression of extent followed plan.

Explanatory variable	Odds ratio (95% CI)	Overall *P* value
My doctor and I have a clear plan for what to do next about my health issues: Definitely agree ("top box"; Reference: Less than definitely agree)	1.16 (0.85-1.57)	.35
I agree with the plan my doctor and I have for taking care of my health issues: Definitely agree ("top box"; Reference: Less than definitely agree)	1.15 (0.82-1.60)	.42
I will follow the plan my doctor and I made for taking care of my health issues: Definitely Agree ("top box"; Reference: Less than definitely agree)	1.95 (1.48-2.58)	<.001
Age	1.0 (1.0-1.0)	.80
Gender: non-female or missing (Reference: Female)	1.03 (0.87-1.23)	.71
Race: non-White (Reference: White)	1.10 (0.87-1.39)	.43
Education: less than a 4-year college degree (Reference: 4-year college graduate)	0.92 (0.76-1.11)	.39
Index visit on or after March 16, 2020: Yes (Reference: No)	1.05 (0.88-1.25)	.60
Health system (Reference: A)		
B	0.93 (0.77-1.13)	.46
C	0.81 (0.64-1.02)	.07

Table 4. Reasons for following the plan.

	Values, n (%)
Patients who reported "Completely" followed the plan (n=1603)	
What helped you to carry out the plan? (Select ALL that apply)	
The plan was clear to me	1114 (69.5)
The plan was consistent with what mattered most to me	1060 (66.1)
I was determined to carry it through	887 (55.3)
I had the support needed to carry it through	540 (33.7)
Other	19 (1)
Patients who reported "Not at All" or "Somewhat" followed plan (n=952)	
There are many reasons why people do not carry out a plan exactly. Please select ALL reasons that apply to you	
5 most frequently selected responses	
Lack of time	217 (22.8)
Try a different approach	105 (11)
Did not fit with my lifestyle	93 (10)
Plan was no longer needed or relevant	90 (9)
Plan was not working	39 (4)
5 most frequently written in as "Other"	
Impact from COVID-19	105 (11)
Plan in progress	77 (8)
Life events or activities of daily living impact	44 (5)
Not motivated to complete the plan	40 (4.2)
Other health issues	33 (3)

Discussion

Principal Findings and Comparison With Prior Work

In this multisite study of primary care visits, we found that the majority (roughly 80%, n=2049 and 2108, respectively) of patient participants felt that they agreed with and would follow the plan that resulted from their primary care visit. These views gathered soon after their PCP visit were statistically significantly associated with the likelihood of completely following their plan after controlling for other factors. Patients who did not feel clear about the plan or who were not in agreement with the plan were much less likely to follow the plan. This is consistent with the finding reported in 1 meta-analysis, which found that the odds of patient adherence are 2.16 times higher if a physician communicates effectively [6]. This suggests that future studies could evaluate whether providers could improve treatment adherence through "teach-back," where they confirm patients understand and are in agreement with the plan before the end of the visit [18].

We found that many patients reported that they did not completely follow plans related to weight loss, diet improvement, and increased exercise. These findings are consistent with other studies that found patients tended to be more adherent to circumscribed treatment regimens (eg, medication use) as compared to complex health behavior change efforts such as diet [11]. Given these challenges and limited insights provided through research, patients and providers may need to be proactive and anticipate difficulties in these areas. The evidence suggests that "knowledge alone is not sufficient to enhance adherence in recommendations involving complex behavior change" [19] like modifying diet and exercise. Providers should consider simplifying proposed regimen changes to better "match patients' activities of daily living" [19]. Motivational interviewing could be used to better help the patient identify and set their own goals and identify both potential barriers and ways to overcome them [20]. Some other potential ways to improve provider communication include additional training on how to provide empathy [21] as empathy has been shown to improve both adherence and patient satisfaction [22,23] and training on agenda setting can help the flow of the visit and improve the overall interaction [24].

Many patients in our study identified lack of time as the reason for not fully adhering to their plan, which is also consistent with previous research [25]. Patients in our study were further impacted by the COVID-19 pandemic, which caused nonessential medical appointments to be canceled, affecting patients' plans to follow up with their PCPs or specialists, or to complete laboratory testing. Gyms were closed, which impacted some patients' plans to exercise. Other researchers have documented the impact of COVID-19 on exercise in the general population; for instance, a survey conducted in November 2020 found that over 25% of respondents said that they still did not go out to walk, hike, or exercise even after the initial pandemic lockdown restrictions were lifted [26].

Limitations

A major limitation of our study is our reliance on patient self-report. Participating patients may have only reported limited descriptions of their plans, whereas there may have been more in-depth discussions with their PCP about the plans and next steps during the actual conversations. We also did not provide an opportunity for patients to identify elements of their physician's recommendations, and future research should consider potentially incorporating this aspect. We did not capture the PCP's perspective on the encounter or the plan, and doing so would have allowed us to examine the correspondence between the patient's understanding of the plan and the PCP's understanding of what had been agreed to (or what was most important). Our analysis assumed that all patient plans carried equal clinical importance and we did not evaluate for complexity of the plan. These are 2 factors that could potentially impact plan adherence. Additionally, our population was predominately White and nearly half have more than a 4-year college degree; their ability to understand instructions and reasoning to carry out the plan may not be representative of what might be found in a general population. Finally, our study evaluated plan adherence after 3 months so that may be insufficient time to expect resolution of some more complex medical issues.

Conclusions

In this multisite study of patients' views on their primary care visits and the plans generated during these visits, we found that overall, patients' initial assessment of their plan as clear, their agreement with the plan, and their initial willingness to follow the plan were all strongly related to their self-reported completion of the plan 3 months later.

Acknowledgments

The research reported in this paper was funded through a Patient-Centered Outcomes Research Institute (PCORI) award (contract IHS-1608-35689-IC). The views in this paper are solely the responsibility of the authors and do not necessarily represent the views of the PCORI, its Board of Governors, or the Methodology Committee.

Conflicts of Interest

None declared.

References

1. Levine DM, Landon BE, Linder JA. Quality and experience of outpatient care in the United States for adults with or without primary care. JAMA Intern Med 2019;179(3):363-372 [FREE Full text] [doi: 10.1001/jamainternmed.2018.6716] [Medline: 30688977]
2. Rao A, Shi Z, Ray KN, Mehrotra A, Ganguli I. National trends in primary care visit use and practice capabilities, 2008-2015. Ann Fam Med 2019;17(6):538-544 [FREE Full text] [doi: 10.1370/afm.2474] [Medline: 31712292]
3. Bensken WP, Dong W, Gullett H, Etz RS, Stange KC. Changing reasons for visiting primary care over a 35-year period. J Am Board Fam Med 2021;34(2):442-448 [FREE Full text] [doi: 10.3122/jabfm.2021.02.200145] [Medline: 33833017]
4. Elwyn G, Edwards A, Kinnersley P. Shared decision-making in primary care: the neglected second half of the consultation. Br J Gen Pract 1999;49(443):477-482 [FREE Full text] [Medline: 10562751]
5. Adherence to long-term therapies: evidence for action. World Health Organization. 2003. URL: https://iris.who.int/handle/10665/42682 [accessed 2024-01-04]
6. Zolnierek KBH, Dimatteo MR. Physician communication and patient adherence to treatment: a meta-analysis. Med Care 2009;47(8):826-834 [FREE Full text] [doi: 10.1097/MLR.0b013e31819a5acc] [Medline: 19584762]
7. García-Pérez LE, Alvarez M, Dilla T, Gil-Guillén V, Orozco-Beltrán D. Adherence to therapies in patients with type 2 diabetes. Diabetes Ther 2013;4(2):175-194 [FREE Full text] [doi: 10.1007/s13300-013-0034-y] [Medline: 23990497]
8. Alm-Roijer C, Stagmo M, Udén G, Erhardt L. Better knowledge improves adherence to lifestyle changes and medication in patients with coronary heart disease. Eur J Cardiovasc Nurs 2004;3(4):321-330 [FREE Full text] [doi: 10.1016/j.ejcnurse.2004.05.002] [Medline: 15572021]
9. Özdemir KC, Jacobsen R, Dahl M, Landt E. Factors associated with medication adherence among adults with asthma. J Asthma 2023;60(6):1202-1209. [doi: 10.1080/02770903.2022.2139717] [Medline: 36278848]
10. Grenard JL, Munjas BA, Adams JL, Suttorp M, Maglione M, McGlynn EA, et al. Depression and medication adherence in the treatment of chronic diseases in the United States: a meta-analysis. J Gen Intern Med 2011;26(10):1175-1182 [FREE Full text] [doi: 10.1007/s11606-011-1704-y] [Medline: 21533823]
11. DiMatteo MR. Variations in patients' adherence to medical recommendations: a quantitative review of 50 years of research. Med Care 2004;42(3):200-209. [doi: 10.1097/01.mlr.0000114908.90348.f9] [Medline: 15076819]
12. Vermeire E, Hearnshaw H, Van Royen P, Denekens J. Patient adherence to treatment: three decades of research. A comprehensive review. J Clin Pharm Ther 2001;26(5):331-342 [FREE Full text] [doi: 10.1046/j.1365-2710.2001.00363.x] [Medline: 11679023]
13. Comparing Ways to Support Communication between Patients and Their Primary Care Providers. Patient-Centered Outcomes Research Institute. 2024. URL: https://www.pcori.org/research-results/2016/comparing-ways-support-communication-between-patients-and-their-primary-care-providers#section_professional_abstract [accessed 2024-03-11]
14. Tai-Seale M, Elwyn G, Wilson CJ, Stults C, Dillon EC, Li M, et al. Enhancing shared decision making through carefully designed interventions that target patient and provider behavior. Health Aff (Millwood) 2016;35(4):605-612 [FREE Full text] [doi: 10.1377/hlthaff.2015.1398] [Medline: 27044959]
15. Tai-Seale M, Rosen R, Ruo B, Hogarth M, Longhurst CA, Lander L, et al. Implementation of patient engagement tools in electronic health records to enhance patient-centered communication: protocol for feasibility evaluation and preliminary results. JMIR Res Protoc 2021;10(8):e30431 [FREE Full text] [doi: 10.2196/30431] [Medline: 34435960]
16. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research Electronic Data Capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42(2):377-381 [FREE Full text] [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
17. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, et al. The REDCap consortium: building an international community of software platform partners. J Biomed Inform 2019;95:103208 [FREE Full text] [doi: 10.1016/j.jbi.2019.103208] [Medline: 31078660]
18. Bodenheimer T. Teach-back: a simple technique to enhance patients' understanding. Fam Pract Manag 2018;25(4):20-22 [FREE Full text] [Medline: 29989780]
19. Atreja A, Bellam N, Levy SR. Strategies to enhance patient adherence: making it simple. MedGenMed 2005;7(1):4 [FREE Full text] [Medline: 16369309]
20. Anstiss T. Motivational interviewing in primary care. J Clin Psychol Med Settings 2009;16(1):87-93. [doi: 10.1007/s10880-009-9155-x] [Medline: 19253016]
21. Riess H, Kelley JM, Bailey RW, Dunn EJ, Phillips M. Empathy training for resident physicians: a randomized controlled trial of a neuroscience-informed curriculum. J Gen Intern Med 2012;27(10):1280-1286 [FREE Full text] [doi: 10.1007/s11606-012-2063-z] [Medline: 22549298]
22. Kim SS, Kaplowitz S, Johnston MV. The effects of physician empathy on patient satisfaction and compliance. Eval Health Prof 2004;27(3):237-251. [doi: 10.1177/0163278704267037] [Medline: 15312283]
23. Kelm Z, Womer J, Walter JK, Feudtner C. Interventions to cultivate physician empathy: a systematic review. BMC Med Educ 2014;14:219 [FREE Full text] [doi: 10.1186/1472-6920-14-219] [Medline: 25315848]
24. Rodriguez HP, Anastario MP, Frankel RM, Odigie EG, Rogers WH, von Glahn T, et al. Can teaching agenda-setting skills to physicians improve clinical interaction quality? A controlled intervention. BMC Med Educ 2008;8:3 [FREE Full text] [doi: 10.1186/1472-6920-8-3] [Medline: 18194559]

25. Forrest CB, Shadmi E, Nutting PA, Starfield B. Specialty referral completion among primary care patients: results from the ASPN referral study. Ann Fam Med 2007;5(4):361-367 [FREE Full text] [doi: 10.1370/afm.703] [Medline: 17664503]
26. Crane MA, Shermock KM, Omer SB, Romley JA. Change in reported adherence to nonpharmaceutical interventions during the COVID-19 pandemic, April-November 2020. JAMA 2021;325(9):883-885 [FREE Full text] [doi: 10.1001/jama.2021.0286] [Medline: 33480971]

Abbreviations

PCP: primary care provider
REDCap: Research Electronic Data Capture

Edited by M Hudson; submitted 15.08.23; peer-reviewed by W Bensken, M Ma; comments to author 08.09.23; revised version received 02.11.23; accepted 12.11.23; published 14.03.24.

Please cite as:
Stults CD, Mazor KM, Cheung M, Ruo B, Li M, Walker A, Saphirak C, Vaida F, Singh S, Fisher KA, Rosen R, Yood R, Garber L, Longhurst C, Kallenberg G, Yu E, Chan A, Millen M, Tai-Seale M
Patients' Perspectives on Plans Generated During Primary Care Visits and Self-Reported Adherence at 3 Months: Data From a Randomized Trial
J Particip Med 2024;16:e50242
URL: https://jopm.jmir.org/2024/1/e50242
doi:10.2196/50242
PMID:38483458

A Practical Guide to Participatory Design Sessions for the Development of Information Visualizations: Tutorial

Adriana Arcia[1], PhD, RN; Samantha Stonbraker[2], MPH, PhD, RN; Sabrina Mangal[3], PhD, RN; Maichou Lor[4], PhD, RN

[1]Hahn School of Nursing and Health Science, University of San Diego, 5998 Alcalá Park, San Diego, CA, United States
[2]College of Nursing, Anschutz Medical Campus, University of Colorado, Aurora, CO, United States
[3]School of Nursing, University of Washington, Seattle, WA, United States
[4]School of Nursing, University of Wisconsin-Madison, Madison, WI, United States

Corresponding Author:
Adriana Arcia, PhD, RN
Hahn School of Nursing and Health Science, University of San Diego, 5998 Alcalá Park, San Diego, CA, United States

Abstract

Participatory design is an increasingly common informatics method to engage intended audiences in the development of health-related resources. Participatory design is particularly helpful for developing information visualizations that aim to improve health outcomes by means of improved comprehension, communication or engagement, and subsequent behavior changes. Existing literature on participatory design lacks the practical details that influence the success of the method and does not address emergent issues, such as strategies to enhance internet-based data collection. In this tutorial, our objective is to provide practical guidance on how to prepare for, conduct, and analyze participatory design sessions for information visualization. The primary audience for this tutorial is research teams, but this guide is relevant for organizations and other health professionals looking to design visualizations for their patient populations, as they can use this guide as a procedural manual. This start-to-finish guide provides information on how to prepare for design sessions by setting objectives and applying theoretical foundations, planning design sessions to match project goals, conducting design sessions in different formats with varying populations, and carrying out effective analysis. We also address how the methods in this guide can be implemented in the context of resource constraints. This tutorial contains a glossary of relevant terms, pros and cons of variations in the type of design session, an informed consent template, a preparation checklist, a sample design session guide and selection of useful design session prompts, and examples of how surveys can supplement the design process.

(J Particip Med 2024;16:e64508) doi:10.2196/64508

KEYWORDS

audiovisual aids; cultural competency; health communication; patient participation; participatory design; information visualization; health literacy; user-centered design; human-computer interaction

Background and Significance

Overview

Research from diverse fields (health, education, computer science, human-computer interaction, etc) has incorporated participatory design methods to ensure the products of research are acceptable to and effective among intended audiences [1-7]. Similarly, increasing interest in developing patient- and public-facing health visualizations has led to the uptake of participatory design methods within health informatics [8-11]. Furthermore, there is an existing and growing body of evidence indicating that well-designed visualizations can lead to better communication, heightened understanding of intended concepts, and other improvements in health outcomes, such as medication adherence when used in the health care space [12-14].

There are existing guidelines and recommendations on how to conduct participatory design sessions (the study by Spinuzzi [15] will be of greatest interest to readers) [1,15-17]. Some include its history and epistemological foundations [15]. However, we have learned that the efficiency, ease, and rigor of participatory design depend heavily on procedural details and practical considerations not addressed in existing guides, such as how to conduct internet-based sessions or track image iterations [1,15,18]. Therefore, this tutorial is in response to an acute need for a procedural and training manual specific to participatory design for information visualizations. We draw from our team's collective experience designing health-related information visualizations through participatory design sessions with lay audiences and the current literature to provide detailed, practical guidance on conducting participatory design sessions.

Definitions

Participatory design is a method for engaging members of the intended audience to develop a creative product, such as an information visualization [19]. It can ensure final products are culturally acceptable, visually appealing, and meaningful to intended audiences [7,20,21]. Within the larger sphere of user- or human-centered design methods, participatory design is one method that actively involves the intended audience [17]. If the intended audience consists of domain or visualization experts themselves, the activity may be more accurately described as a peer critique session and might best be served by different approaches (refer to the study by Semouchkina [22]). While both participatory design and focus groups gather feedback representing the group's collective opinion [23], participatory design actively engages and works collaboratively with intended audiences in shaping how a visualization should look or function, whereas focus groups focus on exploring participants' opinions or reactions to a topic without direct involvement in the design process. Textbox 1 presents a glossary of terms relevant to participatory design as used for the purposes of this guide.

Textbox 1. Glossary of terms.

- Participatory design: a method for collaborating with members of the intended audience to drive the development of a creative product, such as an information visualization. Often, it is an iterative process with changes made to the visualization between design sessions.
- Information visualization: a visual product, typically combining text and images, that has a communicative intent. Contrast with data visualizations, which are intended primarily for analysis and discovery.
- Design brief: a document defining the objectives, audience, content, and key requirements of a planned visualization.
- Graphical element: an image component, such as an icon or pictogram, of a larger visualization.
- Prototype design: a visualization that is still under development.
- Stimulus or stimuli: An umbrella term that includes graphical elements, prototype designs, and any other material presented to participants.
- Expert design phase: a collaboration during which the design team ideates and creates the initial graphical elements or prototype designs that will be presented in participatory design sessions. Design teams can include researchers, content experts, graphic designers, and illustrators.
- Graphic designer: a professional who uses text, typography, color, and images to create layouts, such as posters, pamphlets, etc.
- Illustrator: a professional who creates images via drawing, sketching, painting, etc.
- Generic infographic: an information visualization that has the same appearance for every viewer.
- Tailored infographic: an information visualization that varies in appearance because it incorporates data or information from or about the intended viewer.
- Design saturation: the point in the participatory design process at which participants express satisfaction with the stimuli and their feedback no longer leads to substantive design changes pertinent to the primary visualization objective. Put another way, the research team comes to consensus that they have arrived at the point of diminishing returns and concur that additional data will not further contribute to the accomplishment of the previously established visualization objectives.

In this paper, we draw on our collective experience and current best practices in the literature to provide clear and detailed guidance on how to conduct participatory design sessions to create information visualizations. Multimedia Appendix 1 gives an overview of our team's expertise and a table of case studies that summarize real-life scenarios of how 4 different studies implemented the recommendations offered in this guide, focusing on various populations and health issues. It is noteworthy that participatory design sessions are just one part of the broader visualization design process, as shown in Figure 1. Participatory design sessions are preceded by *formative work* (eg, literature review, interviews, and focus groups) that informs the *design brief*: a document defining the objectives, audience, content, and key requirements of the planned visualization [24,25]. We then engage a graphic designer or illustrator in the *expert design phase* to iteratively develop the prototype designs (stimuli) that kick off the *design sessions*. We find that offering participants some initial stimuli to respond to is more effective for actively engaging them in the design process than presenting them with a blank slate. We have previously described our process as a *hybrid* iterative participatory process to acknowledge the inclusion of the expert design phase in the process. We are discontinuing our use of the term *hybrid* to avoid potential confusion with meetings that involve both in-person and virtual participation.

Figure 1. Design sessions are just one part of the larger visualization design process. This comic depicts an idealized design process to illustrate key concepts from this guide.

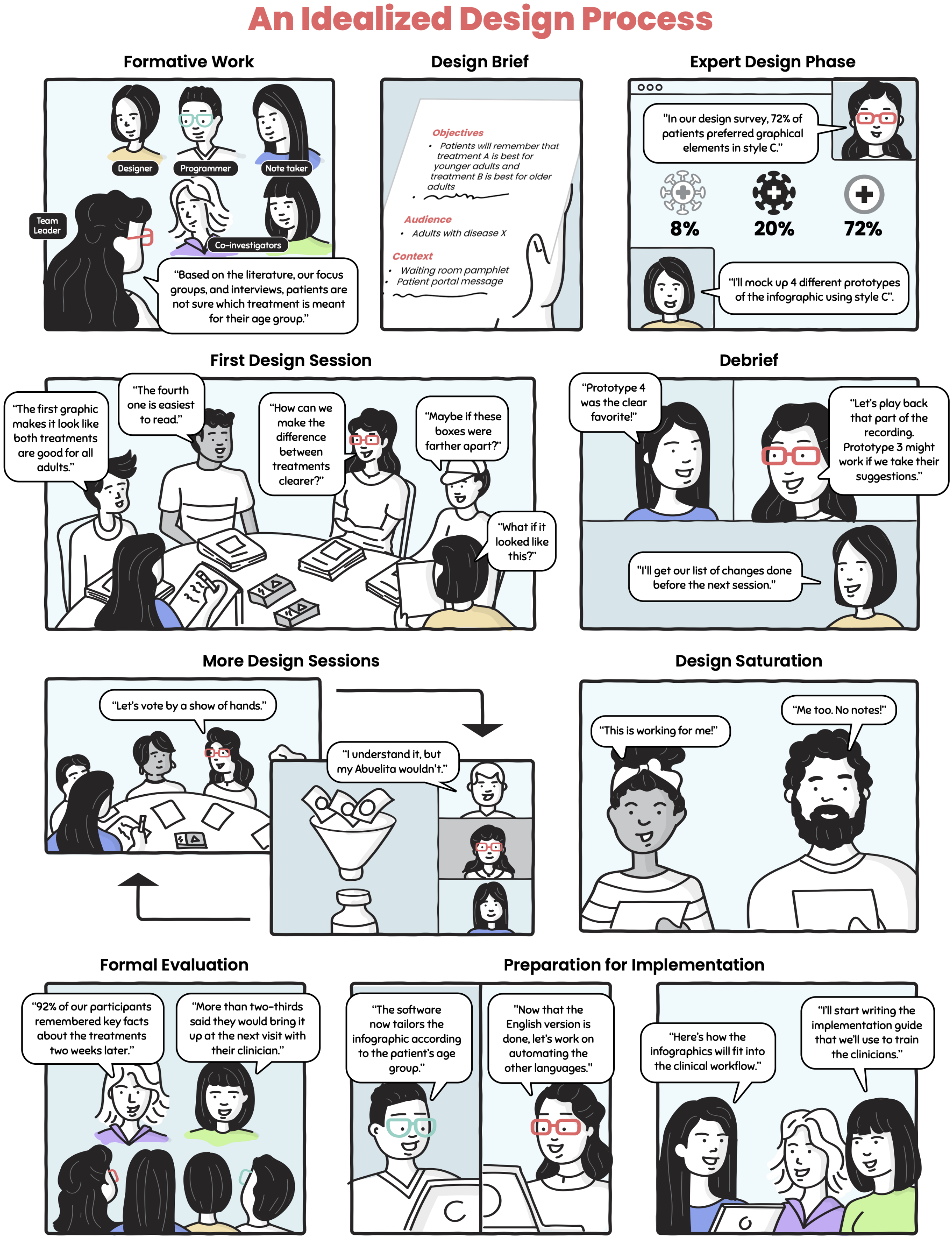


Illustration by A. de la Cruz

Our methods were created and refined over time [26], align with best practices in participatory design (eg, meaningful iterative engagement with intended audiences), and are distinct from co-design approaches that incorporate participants from the earliest ideation phases and thus omit a phase that only involves experts [27,28]. Design sessions, carried out until reaching *design saturation*, can provide preliminary evidence that visualizations are meeting their objectives. However, *formal* *evaluations* (eg, comprehension testing, usability, and assessing behavioral intention or change) are essential for ensuring rigor and preparing for the later stages of the implementation phase, where their impact on health outcomes can be thoroughly evaluated. As one example, SS conducted a longitudinal assessment of the impact of an educational program using infographics for patients with HIV. The study found statistically significant improvements in HIV-related knowledge (proximal), self-efficacy to manage HIV (intermediate), and viral load (distal) outcomes [10,12]. In addition, Arcia et al [29] have formally evaluated infographic comprehensibility using the International Organization for Standardization (ISO) 9186 comprehension testing method, modified for interview-based (rather than written) administration [29]. *Preparation for implementation* includes activities such as software development [30], documentation, and training those who will deploy the visualization.

The Structure of This Guide

We first discuss the importance of *setting visualization objectives* to define when visualizations are successful. Next, we address the importance of leveraging *theoretical foundations* for both the content domain and design decisions. We then summarize some of the variations we have applied to the *design session format* alongside their pros and cons. Then, the section on *preparation* covers practical concerns for preparing to conduct iterative participatory design sessions, such as ethical considerations, group composition, guidance on developing a robust design session guide, preparing stimuli for use in a session, and suggestions for preparing to track multiple iterations. Following that, there is a section on *conducting sessions*, where we discuss team roles, in-session tasks and prompts, navigating group dynamics, and procedures for concurrent data analysis and debriefing. The subsequent section focuses on what occurs *after sessions*, namely transcription, translation, and post hoc analysis. Next, we make suggestions about *working within resource constraints*, including highlighting options that can reduce costs. We close with a *discussion* of the value and limitations of participatory design and a brief *conclusion*. Readers are encouraged to refer to the Multimedia Appendix 1 for an overview of our expertise and case studies of 4 studies that used the methods in this guide, Multimedia Appendix 2 for an informed consent template, Multimedia Appendix 3 for a sample design session guide, Multimedia Appendix 4 for suggestions for supplementing design sessions with surveys, and Multimedia Appendix 5 for a preparation checklist that includes suggestions for the consent process, participant instructions, stimulus tracking, staffing, and supplies.

Setting Visualization Objectives

We consider visualizations successful when they are culturally acceptable, visually appealing to the intended audience, and help the viewer achieve specific a priori objectives. Comprehension of personal health information has been the primary objective for much of our work based on the premise that comprehension is a necessary (although potentially not sufficient) precondition for impact on health outcomes. However, visualizations can serve other objectives, such as supporting clinical communication or emotional engagement [31,32]. For comprehension, the main discussion prompt might be “What do you think we are trying to tell you with this image?” whereas for engagement it might be “How does this image make you feel?” Consequently, it is important to have clarity and specificity about visualization objectives at the outset. Adar and Lee [33] provide excellent guidance on using the taxonomy proposed by Bloom to set visual learning objectives that are granular enough to be useful. For example, “understand the key differences between COVID-19 tests” is not as useful for supporting design decisions as “recognize that diagnostic tests detect current infection whereas antibody tests detect past infection.”

Theoretical Foundations

Overview

We use multiple theories to guide our work. Typically, one theory will be specific to the topic domain, and another will support design decisions. A deeper discussion of how specific theories can influence individual design decisions is beyond the scope of this guide but can be found in the study by Arcia et al [34].

Content Domain

Theory selection should be based on the visualization objective and topic domain of the content. For example, if the objective is to encourage the viewer to take preventive health action, then the Health Belief Model suggests the included content should specifically address perceived susceptibility, severity, benefits, and barriers [35]. By contrast, if the objective is the promotion of physical activity, the choice of content could be informed by social cognitive theory and thus address questions of goal setting, self-monitoring, and feedback reinforcement [36,37].

Design Decisions

To facilitate design decisions about how content should be visualized, we frequently rely on the Data-Frame Theory of Sensemaking proposed by Klein et al [38], and on the Conceptual Metaphor Theory proposed by Lakoff and Johnson [39,40]. The Data-Frame Theory of Sensemaking by Klein et al [38] suggests that people make sense of incoming data and stimuli by comparing them to the frames (schemas) that they have developed from prior lived experience. Consequently, sensemaking can be eased by using images and text that reference a frame that the viewer is likely to already have, such as stoplight colors to convey value judgments.

Conceptual Metaphor Theory treads similar territory in that it proposes that humans learn about new ideas (target domains) by drawing metaphorical comparisons to ideas that have become familiar through embodied experience (source domains). The logical consequences of the comparison are called entailments. For example, if ARTERIES (target) are like PLUMBING (source), they can become clogged but also cleared. Parsons [40] points out that many graphical conventions feel intuitive not just because they are familiar but also because they use apt conceptual metaphors. For instance, in most charts, values increase upward along the y-axis rather than downward because our lived experience is that MORE IS UP. Applying this theory effectively means making design choices that deliberately evoke conceptual metaphors that have robust and accurate entailments. Design sessions are an opportunity to evaluate the extent to which design choices are functioning as intended and that unhelpful frames or conceptual metaphors are not being evoked unintentionally.

Design Session Format Variations

Our initial design session format was to meet in person with a group of participants who had not previously seen any of the prototype visualizations. We have since varied aspects of the format as needed to accommodate the unique needs of each project, including budget and external circumstances (eg, virtual sessions due to pandemic lockdown). Within practical constraints, we choose a format—especially participant tasks—according to the likelihood that it will foster a successful design session by yielding actionable data. In Tables 1 and 2, we describe format variations and summarize their pros and cons.

Table . Variations on participatory design session format and activities.

Variation	Good for	Cautions and caveats
Number of participants per session		
Individual: one participant takes part in the design session.	Eliciting granular feedback Stimuli with large amounts of content (eg, multipage documents) Design sessions held by videoconference	Generally requires more staff time per participant More difficult to discern when feedback is based on personal idiosyncrasy More sessions may be needed to reach design saturation than the group session format
Group: two or more participants take part in the design session.	Establishing consensus Stimulating discussion Efficient use of staff’s time Encouraging ideas or brainstorming	Comprehension assessment may not be robust because the first person to speak can influence others’ comments Can be hard to schedule, especially when grouping participants by shared characteristics. Need to manage group dynamics, such as one person dominating the discussion
Venue		
In-person: participants and research staff are physically present in the same room.	Observing body language, facial expressions, and other nonverbal cues Observing what areas of the page a participant is looking at (gaze following) Inclusion of people who lack devices, have a poor internet connection, and/or are not adept with technology Holding participants’ attention	Participants who are caregivers must arrange care for children or older people or be able to bring the care recipient with them Privacy and difficulty discussing sensitive topics
Virtual: a session is held via videoconference.	Minimizing travel time and geographic sampling restrictions Inclusion of people who are homebound, caregiving, or facing transportation difficulties Avoiding communicable disease transmission	Not recommended for groups because discussion is stilted and video and audio recordings may be of poor quality Technical problems, such as loss of internet connection, are common All parties must have a strong internet connection and be able to minimize background noise or distractions Participants must have comfort with the technology being used Harder for participants to sketch or indicate suggested changes during sessions Ability to evaluate body language may be limited
Participant tasks		
Elicit meaning: participants are asked to describe their interpretation of the stimulus.	Assessing comprehension and first impressions Exploring cultural associations	Individuals can only participate once because each must be naive to the stimuli being presented
Choose the best option: participants are told what the intended concept is (eg, depression) and asked to choose from among ≥2 stimuli (eg, graphical elements) the one that best represents that concept.	Narrowing down a pool of graphical elements Establishing consensus quickly	Not robust for assessing comprehension Researchers may need a second way to validate participants’ choices (eg, “explain your answer”), especially if participants are permitted to choose >1 option. Could limit participants’ creativity
Feedback: participants are asked for suggestions to improve the stimulus. They may also be asked to vote for their favorite(s) from among ≥2 stimulus options.	Generating actionable design changes Winnowing down a pool of prototype designs	Participants may make suggestions that violate basic design principles or are personal idiosyncrasies (eg, “I just don’t like the color blue”) Although directly contradictory feedback is possible, it is very rare

Variation	Good for	Cautions and caveats
Generate new ideas: participants are encouraged to suggest design ideas beyond those already presented.	• Expanding the scope of design concepts • Exploring the mental models of participants	• Participants may make suggestions that violate basic design principles; often they have no suggestions at all • Lack of consensus on designs due to increased variety of ideas • Many participants are not familiar with this type of task
Design surveys: printed or digital surveys can be used to collect data asynchronously for any of the above participant tasks.	• Boosting the total number of participants and reaching consensus, especially when resources are limited • Rapidly tallying preferences • Informing design decisions before conducting design sessions	• Survey data are not as rich and informative as data from design sessions • Written responses are often terse and may not be interpretable; this limitation can be mitigated by allowing participants to audio-record their responses, but these must then be transcribed

Table . Variations on stimulus presentation and documentation.

Variation	Good for	Cautions and caveats
Stimulus preview		
No: participants do not see stimuli in advance of design sessions.	• Assessing comprehension and first impressions (including nonverbal behaviors and interactions with the stimulus)	• Must allow time for participants to read and review the stimuli; participants may be bored waiting for others
Yes: participants see the stimuli in advance of the design session. Options include sending printed material by mail or sharing files via email or SMS.	• Stimuli with large amounts of content • Thoughtful and considered feedback	• May be logistically challenging to arrange • In the interim, participants may forget some of the thoughts they intended to share • Research staff relinquish control of the stimuli, which may be shared with others before designs are finalized • Instructions in the stimulus must be very clear for participants to follow • Participants might review the stimulus in a cursory manner or not at all
Recording type		
Audio only: only audio is recorded.	• Easy and inexpensive documentation	• It is advisable to use ≥2 recorders for adequate coverage if participants are seated far apart • Recorders may run out of batteries or memory • Transcribers must be able to distinguish between participants' voices • Participation is limited to those who consent to being recorded
Audio and video: both audio and video are recorded.	• Design sessions held by videoconference • Documenting nonverbal behaviors • Matching the speaker to the voice	• In-person design sessions may require multiple cameras and angles, including overhead, to provide useful levels of detail. • Participants may be uncomfortable being video recorded • Greater loss of confidentiality if unauthorized persons access recordings • Participation is limited to those who consent to being recorded
Note-taking		
In a real-life situation: research staff take notes (free-form or in a template) during the design session.	• Supporting rapid decision-making, identifying probing questions during a session, and facilitating analysis • Supplementing transcripts and recordings	• The notetaker may not be able to keep up with a fast-paced discussion or numerous participants
From a recording: research staff make notes (free-form or in a template) based on the review of a recording.	• Thoughtful and thorough notes • Reviewing moments of fast-paced discussion or when participants did not express themselves clearly • Useful in the absence of a notetaker	• Some initial observations and first impressions may be lost, especially if working only from an audio recording • Can be time consuming

Preparation

Ethical Considerations

When used for research, participatory design requires institutional review board approval and an informed consent process. Multimedia Appendix 2 is a template that can be used for an informed consent form or for an information sheet if approval is obtained for waiving written documentation of consent. In most cases, the research will be considered minimal risk and will qualify for expedited approval.

Group Composition

Participants must be grouped for sessions by language preference, including dialect (eg, Spanish speakers for Spanish-language visualizations). They may also be grouped by relevant characteristics, such as age, gender, or level of expertise (eg, newly diagnosed patient vs expert patient). Thoughtful groupings can be critical for some topics (eg, age and gender when discussing HIV) and of little importance for less sensitive ones. Occasionally, there is a benefit to deliberately mixing participants according to key characteristics. For example, while working with Hmong participants, ML has conducted sessions with mixed-gender groups, particularly including both husbands and wives who prefer to participate together. This gender composition aligns with the participants' cultural values and fosters engagement. In practice, logistical constraints, such as recruiting on short notice, can limit the ability to maintain these groupings [41]. In these instances, it may be advisable to alert participants to potential discomforts (eg, a mixed-gender group) and remind them that participation is voluntary. Participants often benefit from multiple reminders (eg, date, time, and location) leading up to the session and should be reminded to bring their glasses, if applicable.

Occasionally, researchers have the luxury of selecting participants from a known cohort, such as individuals who have previously participated in studies with the same research team. In that case, the recruiter has the advantage of bypassing participants whose previous contributions were minimal in favor of those who not only articulate their opinion effectively but also reflect on how a stimulus influences their thoughts and emotions. Some participants struggle with this, especially if they have experienced few situations, such as higher education, in which they are regularly asked to engage in metacognition.

It is often important that participants be naive to the stimuli, particularly if the researchers wish to assess comprehension. If so, new participants must be recruited for each session. Otherwise, people may be invited to participate more than once.

Design Session Duration, Size, and Number

In our experience, design sessions typically last 60 to 90 minutes, including consent and other paperwork (eg, demographic survey); sessions >120 minutes are inadvisable due to participant fatigue (people will just get bored and either leave or stop engaging). Previous research suggests piloting interviews to gauge the length of time that would be appropriate based on the intended audience [42]. We find a group size of 4 to 8 people to work well for most tasks, though we have run sessions with as few as 1 and as many as 15. Smaller groups (eg, 1 - 3 people) are best if very granular feedback is needed so people do not get bored waiting to contribute. In addition, groups of >8 people can be difficult to manage, as it is rare for this many participants to wait for their turn to speak. The number of participants and whether individual or group sessions are needed will also depend on the team's objectives or participant availability (eg, larger samples are harder to obtain with difficult-to-reach populations). In addition to providing more granular feedback, individual or smaller sessions are helpful for providing feedback on stimuli with large amounts of content and for virtual design sessions. However, they generally require more staff time per participant, may be difficult to discern feedback from personal biases, and may need more sessions to reach design saturation compared to group formats. Conversely, group formats may be useful when the objective involves establishing consensus on design decisions, stimulating discussion (eg, new ideas and brainstorming) between participants, and using staff time efficiently. However, within groups, participants' opinions might influence others, scheduling conflicts might occur, and there is a greater need to manage group dynamics (eg, ensuring only one person does not dominate the discussion).

Sessions should be continued until reaching design saturation, which is when participants express satisfaction with the stimuli and their feedback no longer leads to substantive design changes pertinent to the primary visualization objective. Put another way, the research team comes to the consensus that they have arrived at the point of diminishing returns and concur that additional data will not further contribute to the accomplishment of the previously established visualization objectives.

It can be difficult to forecast how many sessions will be needed; we have done as few as 5 and as many as 21. The number of sessions needed for design saturation depends on group size (small groups may mean more sessions), the amount and complexity of the stimuli, how exploratory or novel the designs are, and the experience level of those making design decisions. Although the total number of participants and sessions matters, *the number of design iterations is of the greatest importance* because each iteration represents progress toward design saturation. The unpredictability of the design process makes it difficult to forecast how closely together sessions can be scheduled, especially at the beginning of the process, because the extent of the changes to be made before the next session is unknown. Occasionally, a freelance designer misses a deadline due to competing demands from other clients, which forces the research team to either postpone sessions or move forward without completing all of the planned changes to the stimuli. We suggest erring toward more, rather than less, time between sessions to avoid rushed work and rescheduled sessions.

Venue and Environment

The ideal venue for sessions offers a quiet environment for clear recordings and is private, especially if discussing sensitive topics. In-person venues should be large enough so that all participants can see each other when seated or interact as needed. The lighting must be adequate for reading and not distort the colors in the stimuli. If sessions are only audio recorded, it is advisable to use ≥2 recorders for adequate coverage if participants are seated far apart and to have back-up power sources or batteries for recorders. In group sessions, researchers should keep in mind that they must be able to distinguish between participants' voices when transcribing. While video recording in person, researchers should verify that camera angles and lighting provide detailed enough views of stimuli and participants' reactions (eg, body language and facial expressions) to be useful. In-person venues can also be helpful for observing what a participant is looking at, actively engaging with participants, and providing accessibility for people who do not use or have access to the necessary technology for virtual sessions. However, maintaining privacy, potential discomfort with being video recorded, potential difficulty with discussing sensitive topics, accessing transportation, or arranging care for children or older adults might be challenges.

If the sessions are held via videoconference, team members should ensure that participants have comfort with the technology being used and have a strong internet connection as well as an environment where background noise or distractions can be minimized. It can be particularly challenging to maintain focus during the design session if participants join a video call from unsuitable environments, such as during a commute or in a loud and distracting area. It is also preferable if the participant's full face is visible so the team can observe facial expressions and nonverbal cues. Furthermore, research teams can consider conducting training sessions to acquaint participants with the software before the design sessions [43]. The team must also be prepared with a plan for when participants encounter technical problems, such as loss of internet connection. Sessions via videoconference might become cumbersome with groups because discussion may be stilted, or audio may be of poor quality. However, videoconferencing is an effective method to facilitate video recording, minimize travel time and geographic restrictions for participant recruitment, and is particularly accessible for those who are homebound, caregiving, concerned about communicable disease transmission, or facing transportation difficulties.

Design Session Guide

We have found that a good design session guide, similar to prompts for semistructured interviews, orients participants to the people present and their roles, expected duration, ground rules of interaction, the purpose of the study, funder, and activities planned (refer to the sample in Multimedia Appendix 3) [44]. To reduce socially desirable responses, we specifically request feedback about anything participants dislike or find confusing because otherwise, we cannot improve the visualizations. Examples of tasks and prompts to include in the guide depend on the goals of the project and can be found under the Conducting Sessions section.

Stimuli

Our typical design process uses a "winnow and refine" approach (also known as "contracting the design space") [17], where we start with as many options as possible and then use early sessions to winnow down to the most promising ones, which are then refined in later sessions (refer to the asthma infographic pedigree chart [page 34] of the paper by Arcia and Spiegel-Gotsch [45] for a visual example of this process). For simple visualizations, this often means preparing multiple variations on the same design concept (eg, vertical and horizontal format or different color palettes), each of which will be a unique stimulus. However, this approach can be impractical for visualizations that incorporate multiple graphical elements, so the initial stimuli can instead be variations on each element, such as 3 different versions of a hand-washing icon. Once the graphical elements have been winnowed down, they can be assembled into prototype designs that will each represent 1 stimulus. It can be hard for participants to imagine alternatives based only on description, so it is prudent to err on the side of preparing these alternatives in advance, including feedback and insight from participants where possible [17,46]. Another consideration for researchers is whether to provide a stimulus preview (ie, participants see the stimuli in advance of the design session). There are benefits to working with naive participants (ie, no stimulus preview), such as the ability to assess comprehension and first impressions, including nonverbal behaviors and interactions with the stimulus. However, researchers must allow time for participants to read and review the stimuli; participants may become bored waiting for others. Researchers may choose to provide stimuli before the session through mail, email, or SMS text messages. This can be beneficial for getting feedback on stimuli with large amounts of content, and when thoughtful, detailed feedback is needed. However, the risks and challenges involved with this may include logistical challenges with coordination, a need for clear instructions for participants, loss of data if participants forget some of the thoughts they intended to share or neglect to review the material, and loss of control of the stimuli that may be shared with others before designs are finalized.

For in-person sessions, it is convenient for every person present to have their own printed set of all stimuli, in the planned order of presentation, that they can easily see and mark up directly. We prefer to print on cardstock as it takes less dexterity to handle than regular copy paper. As discussed subsequently, each stimulus should have a unique identifier on the back of the page or watermark in an inconspicuous footer. Sections of complex images can be numbered for easy reference. If printing is impractical, stimuli can be projected onto a large wall or screen.

For virtual sessions, stimuli can be shown via screen sharing. They can also be printed and mailed in advance with instructions to review in advance of the design session or not to open until the session, depending upon researcher preferences and objectives. Researchers should be aware that it may be logistically difficult to capture what participants sketch or annotate stimuli during sessions and should create a plan ahead of time to collect these data efficiently, whether that is through mailing in annotations, having an additional camera set up to show them, or annotating stimuli via screen sharing.

Tracking Iterations

To facilitate analysis, it is very important to have a unique identifier for every iteration of a stimulus to enable tracking of even the smallest changes (eg, a typographical error). Numerous schemes are possible for assigning identifiers to stimuli and keeping track of them. The important part of tracking is that key metadata are captured for each iteration: the relationships between iterations, reasons for changes, and when or to whom iterations were shown. In a hypothetical example, participants in design session 1 (English, July 8) agreed that the font size was too small in C18a (parent iteration), so it was increased in C18b (child iteration) and shown to participants in design session 2 (Spanish; July 15). Previously, we used spreadsheets for tracking, but files can become large and unstable because of the inclusion of many images, even at low resolution. Some qualitative software packages can manage images and thus might be useful for tracking.

To improve our process, we began using a commercially available relational database (Airtable [47]) that allows image files of stimuli to be dropped into individual records (rows) as shown in Figure 2. Records can then be tagged with multiple attributes and linked to one another as a parent or child. We use additional columns (not shown) for action items (ie, a summary of proposed design changes), completed actions, and notes. These records can also be linked to another table that lists the design sessions and their attributes (eg, date, time, location, language, number of participants, and stimuli shown) and, if needed, to files and artifacts containing details of complex design changes. A good tracking system facilitates summarizing what occurred throughout the design sessions, including how many stimuli were shown in a session and the total number of participants who saw any individual stimulus. If the design process itself will be analyzed for transferable insights, tracking—the centerpiece of the audit trail—is essential for qualitative rigor. Tracking has less importance if the design process will not be analyzed.

Figure 2. Excerpts from linked tables in a relational database. Top: each stimulus image is a record (row) and can be tagged with multiple attributes (eg, English and/or Spanish), linked to other records as a parent or child, and linked to specific design sessions (not shown). Bottom: each design session can be linked to the image IDs that were shown in that session.

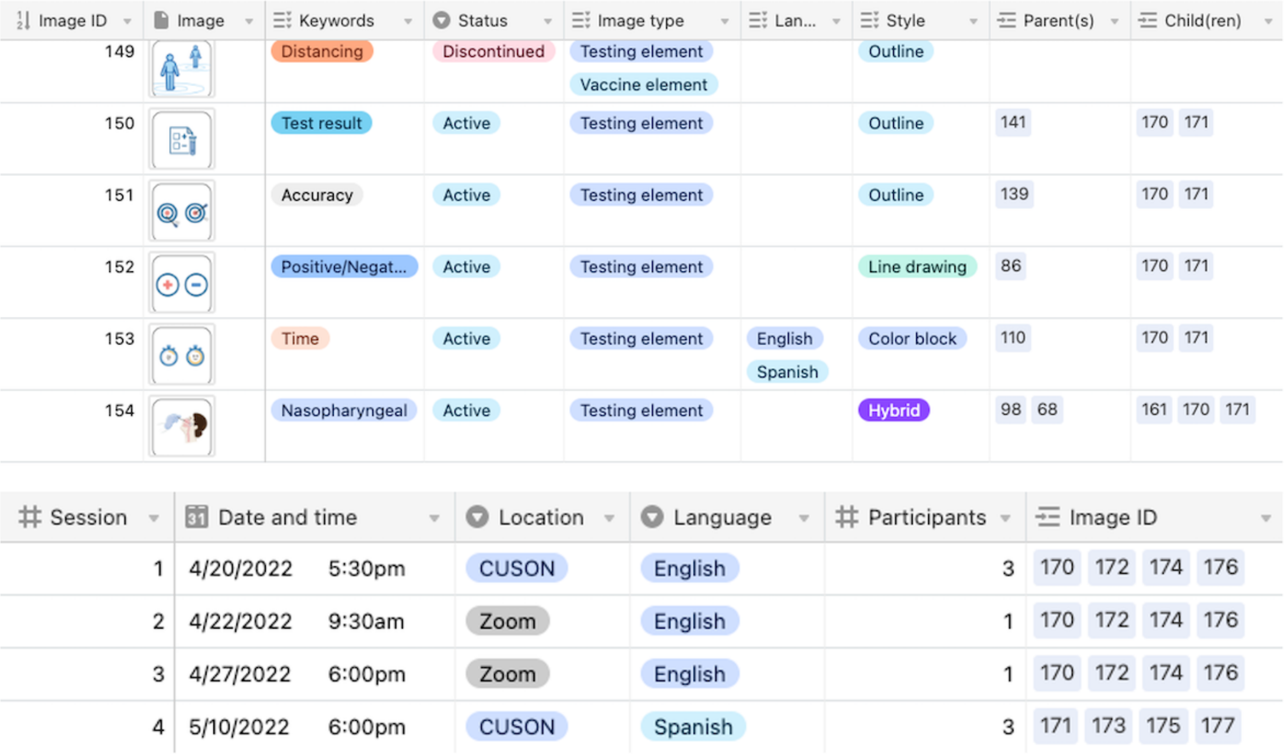


Image ID	Image	Keywords	Status	Image type	Lan...	Style	Parent(s)	Child(ren)
149		Distancing	Discontinued	Testing element Vaccine element		Outline		
150		Test result	Active	Testing element		Outline	141	170 171
151		Accuracy	Active	Testing element		Outline	139	170 171
152		Positive/Negat...	Active	Testing element		Line drawing	86	170 171
153		Time	Active	Testing element	English Spanish	Color block	110	170 171
154		Nasopharyngeal	Active	Testing element		Hybrid	98 68	161 170 171

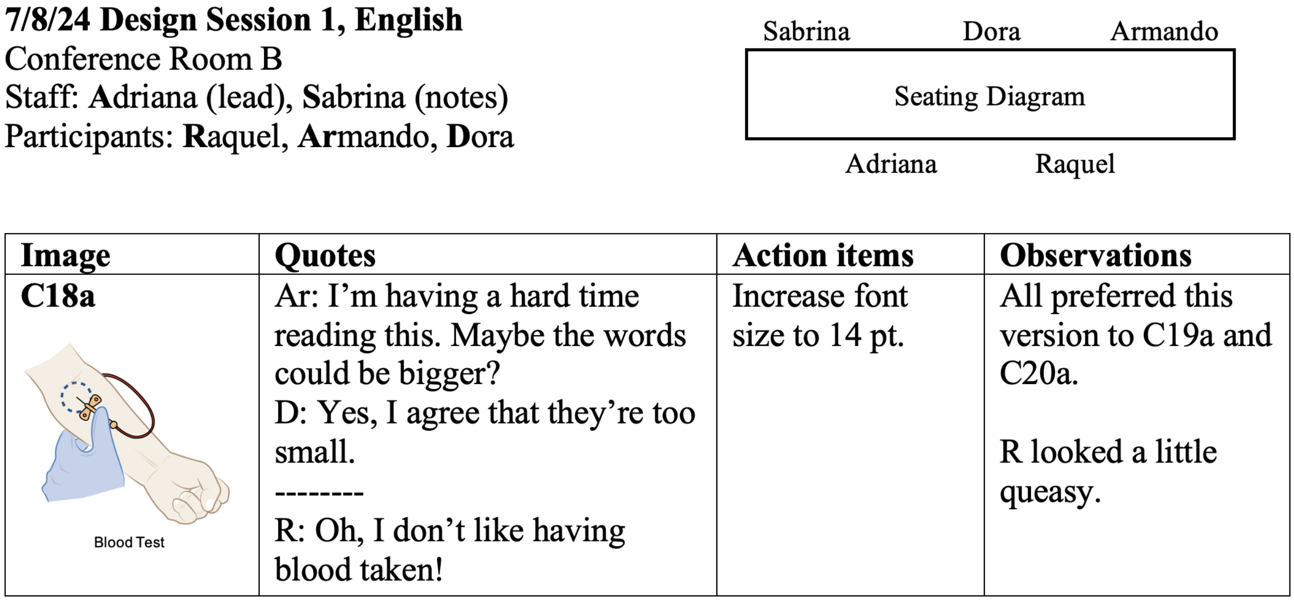
Session	Date and time	Location	Language	Participants	Image ID
1	4/20/2022 5:30pm	CUSON	English	3	170 172 174 176
2	4/22/2022 9:30am	Zoom	English	1	170 172 174 176
3	4/27/2022 6:00pm	Zoom	English	1	170 172 174 176
4	5/10/2022 6:00pm	CUSON	Spanish	3	171 173 175 177

Structured Note Templates

A structured note template helps to support both note-taking and analysis. In the hypothetical example in Figure 3, there are columns for stimulus ID codes and thumbnails, direct quotes, action items, and observations. Thumbnail images of stimuli are prepopulated in the left-hand column so the staff can quickly jot down an action item or make a note alongside its corresponding stimulus during sessions. Note-taking during a design session can support tracking rapid decision-making, help identify probing questions during a session, and facilitate analysis. These notes can serve as a supplement to transcripts and recordings.

Issues raised when the research team debriefs after a session are summarized in bullet points at the end of the document. After the session, direct quotes can be pulled from the transcript to substantiate participant perceptions, researcher observations, and action items for design changes. The criterion for what to include in notes (ie, “anything interesting”) is deliberately broad because even tangential or seemingly off-topic observations can become useful in aggregate during later analysis. Research staff may also make notes based on a review of a recording. This stage of note-taking can be helpful for thoroughly reviewing moments when participants did not express themselves clearly or the discussion was very fast paced and can also be helpful if no notetaker was present during the design session. However, if this is the only form of note-taking, it can be time consuming, and some initial observations and impressions about phenomena, such as body language, may be lost, especially if only working from audio recordings.

Figure 3. Excerpt of notes made using a template. Each stimulus has its own row and is shown in a thumbnail image in the first column, labeled with a unique identifier. The second column is for direct quotes from participants relating to the stimulus. Action items in the third column are planned tasks to be carried out in a subsequent iteration. The last column is for the notetaker’s observations, including body language, discussion summaries, and commentary on direct quotes, including emerging themes.



7/8/24 Design Session 1, English
Conference Room B
Staff: **Adriana** (lead), **Sabrina** (notes)
Participants: **Ra**quel, **Ar**mando, **D**ora

Sabrina Dora Armando
Seating Diagram
Adriana Raquel

Image	Quotes	Action items	Observations
C18a Blood Test	Ar: I’m having a hard time reading this. Maybe the words could be bigger? D: Yes, I agree that they’re too small. -------- R: Oh, I don’t like having blood taken!	Increase font size to 14 pt.	All preferred this version to C19a and C20a. R looked a little queasy.

Conducting Sessions

Team Roles, Responsibilities, and Competencies

Ideally, the session leader, who is typically the head of the research or design team, should be trained and have experience with qualitative data collection techniques. Furthermore, the session leader should be very close to the project, with a clear understanding of the objectives of the visualizations and overall project goals. During a session, the session leader guides the discussion and is ultimately responsible for design decisions and content accuracy. In our experience, if the session leader is not part of the core design team, the data they elicit and their follow-up probes do not fully satisfy the questions that arise in the design process. Standard qualitative rigor techniques (eg, bracketing) serve to minimize bias [48]. It is helpful in each session to have at least 1 notetaker. Ideally, the notetaker is experienced with qualitative methods but, at a minimum, has been trained on how to take notes on the provided template. The more comfortable the notetaker is with the provided stimuli and project goals, the better [25]. The notetaker’s responsibilities are to keep track of participants’ reactions to the stimulus and nonverbal cues during the design session and conduct a review of the recordings. Other team roles may include project management (eg, scheduling participants and supporting videoconference sessions) and a designer or illustrator. If the latter cannot be present, a team member must clearly and promptly communicate design decisions in a way that is actionable for the designer. Depending on expertise, team members may take on more than one role. All team members who interact with participants should complete safety of human participants training before beginning study activities. For more guidance on working with the designer or illustrator, please refer to our team’s related publication [25].

Tasks and Prompts

Upon starting the design session recording, have everyone present state their name or pseudonym so that voices can be properly attributed during subsequent transcription. It is important to ensure that everyone is looking at the same stimulus when they are providing feedback. Contextualize each stimulus by explaining what it is (eg, pamphlet or app screen) and when or where the viewer would encounter it (eg, “your nurse would discuss this with you during a visit”). The instructions and open-ended prompts relate to the objective of the visualization and the task at hand. Descriptions and examples of participant tasks are given subsequently.

Eliciting meaning or asking participants to describe their interpretation of a stimulus can be used to assess comprehension and first impressions or explore cultural associations. However, participants can only participate in the design process once because they must be naive to the stimuli being presented. The example prompt is as follows: “For this next page, please tell me what you think we are trying to tell you with this information, even if it seems really obvious.” Additional probing is often needed to reveal problem areas. For example, the leader may say, “Talk me through what you think is happening in the middle section,” and the participant may state that one should mix soap with hand sanitizer or realize, “Actually, this part isn’t very clear.” When showing multiple stimuli on the same topic, consider starting with the one expected to be most challenging to comprehend because otherwise, participants will learn from “easier” designs.

Choosing the best option among graphical elements can be applied by first telling the participant what the intended concept is (eg, depression) and asking to choose from among ≥2 stimuli that best represent that concept. This task is helpful when narrowing down a pool of graphical elements or establishing consensus quickly. However, it is not acceptable for assessing comprehension, and researchers may need a second way to validate participants' choices (eg, "Explain your answer"), which may limit participants' creativity. This task is distinct from *eliciting meaning*—usually, one or the other is selected based on the objective of the design sessions. The example prompt is as follows: "We are trying to get across the idea that someone needs help walking. Do any of these icons say that clearly? Which one(s)?"

Feedback can be used to elicit suggestions to improve the stimulus or as a way for participants to vote for their favorite(s) from various stimulus options. Feedback is helpful for generating actionable design changes and winnowing down a pool of prototype designs. Researchers should be aware that participants may make suggestions that violate basic design principles, reflect personal idiosyncrasies (eg, "I just don't like blue"), or provide contradictory feedback. The example prompt is as follows: "How can we make this easier to understand?"

Generating new ideas can be used for participants to suggest design ideas beyond those already presented. This task is helpful for expanding the scope of design concepts or exploring the mental models of participants. However, similar to *feedback*, participants may make suggestions that violate basic design principles, may not have any suggestions at all, or may not be familiar with this type of task. There may be a lack of consensus on designs due to the increased variety of ideas. the example prompt is as follows: "What other images would help tell the story?"

Design surveys can be print or digital surveys used to collect data asynchronously for any of the aforementioned participant tasks. They can be useful for choosing design elements, boosting participant numbers to reach consensus, rapidly tallying preferences, and informing design decisions before design sessions (Multimedia Appendix 4). However, survey data are not as rich and informative as data from design sessions, and written responses are often terse and may not be easily interpretable.

Staff should reorient participants whenever the task changes and provide sufficient context so participants are clear on what the task is. The leader should pay particular attention to comments that reveal the participants' mental models (eg, "bad scores should be on the right because dementia only gets worse over time") [49]. Before closing, ask participants (1) what was missing from the content they saw, (2) if they have any unanswered questions, and (3) if there were questions that they should have been asked but were not. Close by thanking participants for their valuable contributions and reminding them to keep the conversation confidential.

Preserving Respect and Dignity

It is of utmost importance that participants feel that their contributions are appreciated even if their comments are surprising, tangential, factually inaccurate, or strange, as sometimes happens. This may be especially true when participants have low general, or health, literacy. In these situations, it is important to maintain an unflappable demeanor (ie, a good "poker face") and respond with openness and curiosity (eg, "That perspective is new to me! What are you looking at that led you to that conclusion?"). It can also mean providing a face-saving cover when eliciting comments that might reveal a lack of comprehension or other stigmatizing situations (eg, "Is there anything here that *other people* in your community might find hard to understand?" "Maybe someone you know has problems with alcohol. What might they think about this image?"). Furthermore, if the session leader notices that a participant has lower literacy or seems to be struggling with reading, they can thoughtfully avoid putting that participant on the spot by not asking them to read or interpret written information for the group. Table 3 presents suggested prompts and their uses.

Table . Useful design session prompts.

Prompt	Uses
Let’s all move on to the page that looks like this [hold up stimulus].	For in-person sessions; ensures participants are all looking at the same thing.
Talk me through what you think is happening in this [part of the] image.	Elicits interpretation of meaning in a more granular way. May need to add “even if it seems really obvious.”
Can you please tell me more about that?	Encourages participant to elaborate further.
What are you looking at in the image that led you to that conclusion?	Helps to tease out if participant’s comment is based on stimulus or something else, like prior knowledge. Can also help identify graphical elements that may be misleading.
What caught your attention first/stood out to you the most?	Pinpoints the parts of the stimulus that are most salient for the participant. Ideally, these are associated with the most important ideas/content rather than content of lesser importance.
How would you explain this to a loved one in your own words?	Good for visualizations that contain a lot of information because it helps identify the viewer’s main takeaways.
Was any of this information new or surprising to you?	Novel information is often the most important target for comprehension support with visualizations. Helps the session leader ask more focused comprehension assessment prompts.
That is a really interesting idea. Do you think others would see this in the same way?	Validates a participant’s contribution while prompting them to reflect on how widely shared their opinion might be. Useful for comments that one suspects might not generalize well.
Are there any words that we should change to make them more understandable to other people in your community?	Preserves participant dignity by providing socially acceptable cover for raising concerns about difficult words. Participants might respond, “I understand this, but some of our older folks might not.”
What questions do you still have after looking at this information? Is there anything missing?	Identifies gaps in the content.
The next pages all show the same information. Take a look at all of them and then we’re going to vote by show of hands for which you like best.	Re-orients participants to a new task, eg, from elicitation of meaning to expressing preference between options.
I’d like to hear from someone new on this one.	Encourages participation from quieter members of the group, especially if others are dominating the conversation.

Narration

A skilled leader narrates nonverbal behaviors to facilitate later analysis of the recording. The most important narration identifies the speakers and the part of the stimulus under discussion, such as “David, I see you pointing to the upper left part of the page.” Reactions, such as quiet laughter or pushing the paper away, also merit narration: “Belinda, you’re shaking your head no. Tell me more about what you’re thinking.” It is often possible to follow the participant’s gaze, especially if seated directly across from them, to observe what parts of the page they are looking at [50]. Observation can reveal what areas are the most salient (ie, where participants look first) and can lead to useful prompts (eg, “You looked surprised when you got to the bottom of the page, tell me about that.”).

Group Dynamics

Group dynamics can influence the productivity of design sessions. For instance, power dynamics can emerge between researchers and participants and therefore must be managed [16,51-53]. Methods to do this include modifying language to be less technical, emphasizing the value of participants’ voices, selecting design activities that participants are comfortable with, and designing from participant-informed stimuli. In addition, design session facilitators will need to guard against 1 or 2 participants dominating the conversation. It can be helpful for the researcher to have prompts prepared to help balance the participation in the session and guide less outspoken participants to provide opinions. Furthermore, factors such as age and gender can influence group interactions and how comfortable participants are speaking freely [54,55]. For instance, we experienced 1 session with older Dominican adults in which the 3 women fell into a pattern of letting or expecting the 1 man to speak first. If they seemed to always defer to his opinion, the leader would have had to gently intervene, but because the pattern was driven by shared cultural expectations and the women still expressed diverse opinions, the leader let it continue. If the participants had had starkly differing expectations about group interaction, the situation would have been trickier to navigate, underscoring the value of grouping participants strategically by important characteristics whenever possible. Group dynamics can also be challenging to manage over video calls. For example, some participants may talk over one another, or their speech might be unintelligible, making some comments unusable by the research team.

Concurrent Analysis and Debrief

We typically engage in 2 levels of analysis: concurrent and post hoc. Concurrent analysis occurs during and immediately after the design sessions, and its purpose is to support the design decisions that lead to subsequent iterations [56]. Specifically, the goals are to identify pertinent design suggestions, verify the comprehensibility and acceptability of designs, and confirm the completeness of designs (that no important information is missing). Analyses conducted post hoc are discussed in the After Sessions section and are used to uncover broader, potentially generalizable themes.

The focus of concurrent analysis is on how designs are performing in relation to the stated visualization objectives. Therefore, if the objective is comprehension, then the team listens for a match between participants' interpretations of meaning and the intended meaning. If these are poorly aligned, it is the job of the design session leader to discover why. Further questioning should help identify the source of the problem.

Participants seldom make specific, actionable design suggestions because they are not design experts. However, they can help diagnose problems. Sometimes their diagnoses are general but direct: "This section needs to stand out more." Other times, they display symptoms that the team must diagnose. For example, if participants are consistently overlooking important information (eg, "Oh, I didn't notice that"), it might not be prominent enough. It is the researcher's job to communicate these "diagnoses" to the designer (particularly if the designer is not present during design sessions), so the designer can apply design principles in subsequent iterations (eg, draw attention with a contrasting color) to solve problems.

Research team members present at the session convene immediately afterward for a recorded debriefing to discuss impressions, review notes and key feedback, and come to a consensus about the next steps. The product of concurrent analysis and debriefing is a set of decisions: (1) which stimuli, if any, should be discontinued (we typically show a design in at least 2 sessions before discontinuing), (2) which stimuli should be shown again unchanged, (3) a list of design changes to be made before the next session, (4) design changes under considerations pending due to requirement of further data, and if necessary, (5) any new stimuli that should be created.

After Sessions

Transcription and Translation

Transcripts of recordings must be checked for accuracy—preferably by someone who was present at the design session—regardless of whether human or machine transcription was used. High-quality human transcription requires minimal cleaning and is preferable when speakers have heavy accents but takes much longer than machine transcription (d vs min) and is much costlier. Both can be useful within the same project. Even if there are many errors in a machine transcription, its quick availability and automatic time stamps can still be useful for locating specific passages within a recording to support design decisions during concurrent analysis; a more accurate human transcription can be used later for the post hoc analysis.

When key members of our research team are bilingual, we analyze transcripts in their original language, which helps maintain the accuracy and cultural context of the data. Additional time and resources are needed if the transcripts must be translated.

Post Hoc Analysis

Post hoc analysis is an opportunity to engage more deeply with the data and identify categories and themes that emerged across the entire design process. Multiple inductive approaches to post hoc analysis are possible. We typically use conventional content analysis to examine all study artifacts, including recordings, transcripts, and notes [57]. Post hoc analysis is optional because it does not contribute to the design of the project that generated the data. Rather, the purpose is to identify insights that may be transferrable to other projects in the future. For example, in 1 study with family caregivers of persons with dementia, the participants preferred that infographics related to dementia be scaled such that "good" values are on the left and "bad" values are on the right to match their perception that dementia leads to inevitable decline over time [49]. By contrast, when visualizing the caregiver's overall health, the same participants preferred "good" values on the right, suggesting a more optimistic frame. This observation led us to conclude that, regardless of the visualization topic, it is important to understand viewers' frames and scale the visualization to match. In other examples, post hoc analysis has helped us uncover common pitfalls (eg, overly literal interpretation) [26] and preferences for certain kinds of imagery (eg, the subjective experience of symptoms [11]; showing health risks explicitly [58]), among others [10,34,59-61].

Working Within Resource Constraints

The resources invested in participatory design generally influence the quality of the resulting visualizations. However, participatory design remains a feasible approach even if resources are scarce, as is demonstrated in the study by Stonbraker et al [10], which was completed in the Dominican Republic with a limited budget, and in other projects that have successfully implemented participatory design with limited resources [62-64]. Beyond social considerations, methods to reduce the cost of participatory design while maintaining the integrity of the process include assigning multiple roles to research team members (rather than hiring extra staff), using machine transcription, digitizing materials (eg, projecting prototypes instead of printing them), engaging students in the project, supplementing session data with design surveys, or working with a less-experienced designer to create visualizations. Notably, similar to other researchers [51-53], our team has found that special consideration should be made to minimize the power dynamic that frequently emerges between researchers and participants, as mentioned in the Group Dynamics section. This is especially true in resource-constrained settings when the researchers or other students or professionals from high-income countries are leading or conducting design sessions and participants are members of the local community. In these settings, it is imperative that the researchers or organizations leading the sessions either provide sufficient research staff for the sessions or reach an agreement with local staff on the amount of time they can spend on participatory design. Without this understanding, we have seen research teams lean too heavily on local staff, which creates an uneven burden on those in the local setting. Furthermore, working with the local organization to establish the time and space for participatory design sessions can strengthen partnerships and lead to less stressful and rushed sessions.

Discussion

Is It Worth the Trouble?

Participatory design takes time and requires resources and preparation, but we have always found it to be worthwhile, even essential, for producing visualizations that genuinely center the needs and preferences of the intended audience. For example, we have confidently tried out prototype designs that the literature suggested should be successful (eg, Isotype-style infographics [65]) only to have them fail spectacularly [26]. It is very gratifying when designs are successful and participants make comments, such as “Anyone could understand this.” We also find that many participants take pride in their contributions, having done their part to advance visual communication about health in a way they felt would benefit their community. For example, 1 participant said that if she ever saw the infographic in a medical office, she would know that she had made important decisions about how it looked. Consequently, design sessions are worthwhile not only for their creative output but also for their ability to empower and engage participants. Ultimately, the most important result is an impact on target visualization and health outcomes. Although research is still emerging that associates well-designed visualizations with specific health outcomes, such as improved comprehension of intended concepts [12] and understanding of concepts, such as risk [14], better communication [13], and better health behaviors (eg, adherence to medications) [12], this is a growing area, and more research is needed.

Limitations

Our practical recommendations for conducting participatory design sessions to develop information visualizations are not intended to be exhaustive or definitive; they are constrained by the limits of our experiences. As detailed earlier, there are also various limitations to each approach of participatory design sessions, from the challenges of navigating videoconference calls to the scheduling and transportation limitations of meeting in person. Moreover, successful participatory design research requires organization, planning, engaged interdisciplinary team members, and, importantly, flexibility. We present an overview of challenges and potential solutions but cannot guarantee that other, more nuanced challenges will not occur, particularly outside of the populations we have direct experience working with.

Conclusions

In this guide, we provide information and recommendations on how to prepare, conduct, and analyze participatory design sessions for information visualizations. We also present the pros and cons of various approaches to participatory design, with the understanding that researchers will select the methods that best match the goals and objectives of their research. We hope that our hard-won lessons learned can streamline and demystify the process for others and thus encourage greater uptake of the method. That said, a written guide can only go so far; all the authors welcome email inquiries and continued discourse via papers and presentations in the spirit of advancing science.

Acknowledgments

The comic in Figure 1 was created by Ms Alexa de la Cruz. The authors are grateful to their frequent collaborators, Dr Suzanne Bakken and Mrs Niurka Suero-Tejeda, as well as their other designers, Mr Sergio Benenson, Ms Nicole Spiegel-Gotsch, Ms Rosi Solano, Mrs Tegan Wolfepack, Ms Nancy Yang, Ms Mai Joua Yang, and Ms Lauren Berger. The projects that informed this paper were funded by the Agency for Healthcare Research and Quality (1R01HS019853 and 1R01HS022961), New York State Department of Economic Development NYSTAR (C090157), National Institutes of Health (P30 AG059303, P30 NR016587, P30 NR016587-05S1, P30 NR016587-05S2, R01 NR014430-03S1, T32 NR007969, and UL1 TR001873), and an intramural grant from Columbia University School of Nursing. SS is supported by the National Institute of Nursing Research of the National Institutes of Health (K99/R00 NR017829). SM was supported by the National Institute of Nursing Research of the National Institutes of Health (T32 NR016913). ML is supported by the National Institute of Nursing Research of the National Institutes of Health (K23 NR019289).

Authors' Contributions

Conceptualization: AA (lead), SS (supporting), SM (supporting), ML (supporting)
Supervision: AA
Visualization: AA (lead)
Writing (original draft): AA (lead), SS (supporting), SM (supporting), ML (supporting)
Writing (review and editing): AA (lead), SS (supporting), SM (supporting), ML (supporting)

Conflicts of Interest

None declared.

Multimedia Appendix 1
Expertise and case studies.
[DOCX File, 27 KB - jopm_v16i1e64508_app1.docx]

Multimedia Appendix 2
Informed consent template.
[DOCX File, 22 KB - jopm_v16i1e64508_app2.docx]

Multimedia Appendix 3
Sample design session guide.
[DOCX File, 29 KB - jopm_v16i1e64508_app3.docx]

Multimedia Appendix 4
Design surveys.
[DOCX File, 1031 KB - jopm_v16i1e64508_app4.docx]

Multimedia Appendix 5
Design session preparation checklist.
[DOCX File, 24 KB - jopm_v16i1e64508_app5.docx]

References

1. Botero A, Hyysalo S, Kohtala C, et al. Getting participatory design done: from methods and choices to translation work across constituent domains. Int J Des 2020;14(2):17-34 [FREE Full text]
2. Vandekerckhove P, de Mul M, Bramer WM, de Bont AA. Generative participatory design methodology to develop electronic health interventions: systematic literature review. J Med Internet Res 2020 Apr 27;22(4):e13780. [doi: 10.2196/13780] [Medline: 32338617]
3. Restall G, Diaz F, Faucher P, Roger K. Participatory design and qualitative evaluation of a decision guide for workplace human immunodeficiency virus self-disclosure: the importance of a socio-ecological perspective. Health Expect 2021 Aug;24(4):1220-1229. [doi: 10.1111/hex.13252] [Medline: 33942929]
4. Dindler C, Smith R, Iversen OS. Computational empowerment: participatory design in education. CoDesign 2020 Jan 2;16(1):66-80. [doi: 10.1080/15710882.2020.1722173]
5. Alves Villarinho Lima B, Almeida LDA. Appropriation for interdisciplinary practice: the case of participatory design in Brazilian computer science. Presented at: International Conference on Human-Computer Interaction 2021; Jul 24-29, 2021; Virtual event. [doi: 10.1007/978-3-030-77431-8_23]
6. Khowaja K, Syed WW, Singh M, et al. A participatory design approach to develop visualization of wearable actigraphy data for health care professionals: case study in Qatar. JMIR Hum Factors 2022 Apr 8;9(2):e25880. [doi: 10.2196/25880] [Medline: 35394442]
7. Jänicke S, Kaur P, Kuzmicki P, et al. Participatory visualization design as an approach to minimize the gap between research and application. Presented at: VisGap2020; May 25, 2020; Norrköping, Sweden. [doi: 10.2312/visgap.20201108]
8. Ahmed R, Toscos T, Rohani Ghahari R, et al. Visualization of cardiac implantable electronic device data for older adults using participatory design. Appl Clin Inform 2019 Aug;10(4):707-718. [doi: 10.1055/s-0039-1695794] [Medline: 31533172]
9. Tiase VL, Wawrzynski SE, Sward KA, et al. Provider preferences for patient-generated health data displays in pediatric asthma: a participatory design approach. Appl Clin Inform 2021 May;12(3):664-674. [doi: 10.1055/s-0041-1732424] [Medline: 34289505]
10. Stonbraker S, Halpern M, Bakken S, Schnall R. Developing infographics to facilitate HIV-related patient-provider communication in a limited-resource setting. Appl Clin Inform 2019 Aug;10(4):597-609. [doi: 10.1055/s-0039-1694001] [Medline: 31412382]
11. Arcia A, George M, Lor M, Mangal S, Bruzzese JM. Design and comprehension testing of tailored asthma control infographics for adults with persistent asthma. Appl Clin Inform 2019 Aug;10(4):643-654. [doi: 10.1055/s-0039-1693713] [Medline: 31486056]
12. Stonbraker S, Liu J, Sanabria G, et al. Clinician use of HIV-related infographics during clinic visits in the Dominican Republic is associated with lower viral load and other improvements in health outcomes. AIDS Behav 2021 Dec;25(12):4061-4073. [doi: 10.1007/s10461-021-03331-8] [Medline: 34129143]
13. Houts PS, Doak CC, Doak LG, Loscalzo MJ. The role of pictures in improving health communication: a review of research on attention, comprehension, recall, and adherence. Pat Educ Couns 2006 May;61(2):173-190. [doi: 10.1016/j.pec.2005.05.004] [Medline: 16122896]
14. Garcia-Retamero R, Cokely ET. Designing visual aids that promote risk literacy: a systematic review of health research and evidence-based design heuristics. Hum Factors 2017 Jun;59(4):582-627. [doi: 10.1177/0018720817690634] [Medline: 28192674]
15. Spinuzzi C. The methodology of participatory design. Tech Commun 2005(2):163-174 [FREE Full text]
16. Smith F, Wallengren C, Öhlén J. Participatory design in education materials in a health care context. Act Res 2017 Sep;15(3):310-336. [doi: 10.1177/1476750316646832]

17. Mackay WE, Beaudouin-Lafon M. Participatory design and prototyping. In: Vanderdonckt J, Palanque P, Winckler M, editors. Handbook of Human Computer Interaction: Springer; 2020:1-33. [doi: 10.1007/978-3-319-27648-9_31-1]
18. Schuler D, Namioka A. Participatory Design: Principles and Practices: CRC Press; 1993.
19. Luck R. Dialogue in participatory design. Des Stud 2003 Nov;24(6):523-535. [doi: 10.1016/S0142-694X(03)00040-1]
20. Galleguillos MLR, Coşkun A. How do I matter? A review of the participatory design practice with less privileged participants. 2020 Presented at: 16th Participatory Design Conference 2020; Jun 15-20, 2020; Manizales, Colombia. [doi: 10.1145/3385010.3385018]
21. Stonbraker S, Flynn G, George M, et al. Feasibility and acceptability of using information visualizations to improve HIV-related communication in a limited-resource setting: a short report. AIDS Care 2022 Apr;34(4):535-541. [doi: 10.1080/09540121.2021.1883517] [Medline: 33565321]
22. Semouchkina V. Advancing visual design culture in STEM lab groups [Thesis]. : University of Washington; 2021 URL: http://hdl.handle.net/1773/47292 [accessed 2024-12-05]
23. Stalmeijer RE, Mcnaughton N, Van Mook W. Using focus groups in medical education research: AMEE Guide No. 91. Med Teach 2014 Nov;36(11):923-939. [doi: 10.3109/0142159X.2014.917165] [Medline: 25072306]
24. Arcia A, Woollen J, Bakken S. A systematic method for exploring data attributes in preparation for designing tailored infographics of patient reported outcomes. eGEMS 2018 Jan 24;6(1):2. [doi: 10.5334/egems.190] [Medline: 29881760]
25. Mangal S, Berger L, Bruzzese JM, et al. Seeing things the same way: perspectives and lessons learned from research-design collaborations. J Am Med Inform Assoc 2024 Jan 18;31(2):542-547. [doi: 10.1093/jamia/ocad124] [Medline: 37437899]
26. Arcia A, Suero-Tejeda N, Bales ME, et al. Sometimes more is more: iterative participatory design of infographics for engagement of community members with varying levels of health literacy. J Am Med Inform Assoc 2016 Jan;23(1):174-183. [doi: 10.1093/jamia/ocv079] [Medline: 26174865]
27. Papoutsi C, Wherton J, Shaw S, Morrison C, Greenhalgh T. Putting the social back into sociotechnical: case studies of co-design in digital health. J Am Med Inform Assoc 2021 Feb 15;28(2):284-293. [doi: 10.1093/jamia/ocaa197] [Medline: 33043359]
28. Sanz MF, Acha BV, García MF. Co-design for people-centred care digital solutions: a literature review. Int J Integr Care 2021 Apr 30;21(2):16. [doi: 10.5334/ijic.5573] [Medline: 33981193]
29. Arcia A, Grossman LV, George M, Turchioe MR, Mangal S, Creber RMM. Modifications to the ISO 9186 method for testing comprehension of visualizations: successes and lessons learned. Presented at: 2019 IEEE Workshop on Visual Analytics in Healthcare (VAHC); Oct 20, 2019; Vancouver, BC. [doi: 10.1109/VAHC47919.2019.8945036]
30. Arcia A, Velez M, Bakken S. Style guide: an interdisciplinary communication tool to support the process of generating tailored infographics from electronic health data using EnTICE3. eGEMS (Wash DC) 2015;3(1):1120. [doi: 10.13063/2327-9214.1120] [Medline: 25848634]
31. Meloncon L, Warner E. Data visualizations: a literature review and opportunities for technical and professional communication. Presented at: 2017 IEEE International Professional Communication Conference (ProComm); Jul 23-26, 2017; Madison, WI. [doi: 10.1109/IPCC.2017.8013960]
32. Rajwan YG, Kim GR. Visualization to improve patient learning and communication. SPIE. 2011 Feb 28. URL: https://www.spie.org/news/3492-visualization-to-improve-patient-learning-and-communication#_=_ [accessed 2024-12-05]
33. Adar E, Lee E. Communicative visualizations as a learning problem. IEEE Trans Visual Comput Graphics 2020;27(2):946-956. [doi: 10.1109/TVCG.2020.3030375] [Medline: 33048702]
34. Arcia A, Spiegel-Gotsch N, George M. Design of tailored asthma control status infographics. Inf Des J 2023 Oct 6;28(2):115-140. [doi: 10.1075/idj.23004.arc]
35. Becker MH, Radius SM, Rosenstock IM, Drachman RH, Schuberth KC, Teets KC. Compliance with a medical regimen for asthma: a test of the Health Belief Model. Pub Health Rep 1978;93(3):268-277. [Medline: 652949]
36. Bandura A. Self-Efficacy: The Exercise of Control: WH Freeman and Company; 1997.
37. Glanz K, Bishop DB. The role of behavioral science theory in development and implementation of public health interventions. Annu Rev Public Health 2010;31:399-418. [doi: 10.1146/annurev.publhealth.012809.103604] [Medline: 20070207]
38. Klein G, Phillips JK, Rall EL, Peluso DA. A data-frame theory of sensemaking. In: Hoffman RR, editor. Expertise out of Context: Proceedings of the Sixth International Conference on Naturalistic Decision Making: Lawrence Erlbaum Associates Publishers; 2007:113-155 URL: https://psycnet.apa.org/record/2007-07680-006 [accessed 2024-12-05]
39. Lakoff G, Johnson M. Metaphors We Live By: University of Chicago Press; 2008.
40. Parsons PC. Conceptual metaphor theory as a foundation for communicative visualization design. Presented at: IEEE VIS Workshop on Visualization for Communication (VisComm 2018); Oct 21, 2018; Berlin, Germany URL: https://www.viscomm.io/2018/papers/metaphor.pdf [accessed 2024-12-05]
41. Eccles MP, Grimshaw JM, Shekelle P, Schünemann HJ, Woolf S. Developing clinical practice guidelines: target audiences, identifying topics for guidelines, guideline group composition and functioning and conflicts of interest. Impl Sci 2012 Jul 4;7(1):60. [doi: 10.1186/1748-5908-7-60] [Medline: 22762776]
42. Busetto L, Wick W, Gumbinger C. How to use and assess qualitative research methods. Neurol Res Pract 2020;2:14. [doi: 10.1186/s42466-020-00059-z] [Medline: 33324920]

43. Morse B, Soares A, Ytell K, et al. Co-design of the transgender health information resource: web-based participatory design. J Particip Med 2023 Jan 10;15:e38078. [doi: 10.2196/38078] [Medline: 36626222]
44. DeJonckheere M, Vaughn LM. Semistructured interviewing in primary care research: a balance of relationship and rigour. Fam Med Community Health 2019;7(2):e000057. [doi: 10.1136/fmch-2018-000057] [Medline: 32148704]
45. Arcia A, Spiegel-Gotsch N. Asthma control infographics, 2017-2018. Columbia Academic Commons. URL: https://academiccommons.columbia.edu/doi/10.7916/d8-w8hz-w605 [accessed 2024-12-05]
46. Stonbraker S, Porras T, Schnall R. Patient preferences for visualization of longitudinal patient-reported outcomes data. J Am Med Inform Assoc 2020 Feb 1;27(2):212-224. [doi: 10.1093/jamia/ocz189] [Medline: 31670816]
47. Airtable. URL: https://www.airtable.com/ [accessed 2024-12-05]
48. Fischer CT. Bracketing in qualitative research: conceptual and practical matters. Psychother Res 2009 Jul;19(4-5):583-590. [doi: 10.1080/10503300902798375] [Medline: 20183407]
49. Arcia A, Suero-Tejeda N, Spiegel-Gotsch N, Luchsinger JA, Mittelman M, Bakken S. Helping Hispanic family caregivers of persons with dementia “get the picture” about health status through tailored infographics. Gerontol 2019 Sep 17;59(5):e479-e489. [doi: 10.1093/geront/gnz085] [Medline: 31185098]
50. Bock SW, Dicke P, Thier P. How precise is gaze following in humans? Vis Res 2008 Mar;48(7):946-957. [doi: 10.1016/j.visres.2008.01.011] [Medline: 18294671]
51. Corsini L, Aranda-jan CB, Cassi H, Moultrie J. Recommendations for participatory design in low-resource settings. Conf Proc Acad Design Innov Manag 2019 Nov;2(1). [doi: 10.17863/CAM.64839]
52. Mejía GM, Guest MA, Zheng W, et al. Who’s ideating, prototyping, and evaluating? A case study of resource-limited participatory design for health and aging. Educ Gerontol 2024 Mar 3;50(3):217-228. [doi: 10.1080/03601277.2023.2250214]
53. Harrington C, Erete S, Piper AM. Deconstructing community-based collaborative design: towards more equitable participatory design engagements. Proc ACM Hum Comput Interact 2019;3:1-25. [doi: 10.1145/3359318]
54. Curry LA, O’Cathain A, Clark VLP, Aroni R, Fetters M, Berg D. The role of group dynamics in mixed methods health sciences research teams. J Mix Methods Res 2012 Jan;6(1):5-20. [doi: 10.1177/1558689811416941]
55. Wheelan SA. The Handbook of Group Research and Practice: Sage Publications; 2005.
56. Vindrola-Padros C, Johnson GA. Rapid techniques in qualitative research: a critical review of the literature. Qual Health Res 2020 Aug;30(10):1596-1604. [doi: 10.1177/1049732320921835] [Medline: 32667277]
57. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res 2005 Nov;15(9):1277-1288. [doi: 10.1177/1049732305276687] [Medline: 16204405]
58. Mangal S, Carter E, Arcia A. Developing an educational resource for parents on pediatric catheter-associated urinary tract infection (CAUTI) prevention. Am J Infect Control 2022 Apr;50(4):400-408. [doi: 10.1016/j.ajic.2021.09.006] [Medline: 34543706]
59. Arcia A, Suero-Tejeda N, Bakken S. Development of pictograms for an interactive web application to help Hispanic caregivers learn about the functional stages of dementia. Stud Health Technol Inform 2019 Aug 21;264:1116-1120. [doi: 10.3233/SHTI190399] [Medline: 31438098]
60. Lor M, Yang NB, Backonja U, Bakken S. Evaluating and refining a pain quality information visualization tool with patients and interpreters to facilitate pain assessment in primary care settings. Inform Health Soc Care 2023 Oct 2;48(4):353-369. [doi: 10.1080/17538157.2023.2240411] [Medline: 37603830]
61. Lor M, Hammes AM, Arcia A. Development of a culturally appropriate faces pain intensity scale for Hmong patients. Pain Med 2024 Jan 4;25(1):89-92. [doi: 10.1093/pm/pnad109] [Medline: 37584702]
62. Mauka W, Mbotwa C, Moen K, et al. Development of a mobile health application for HIV prevention among at-risk populations in urban settings in East Africa: a participatory design approach. JMIR Form Res 2021 Oct 7;5(10):e23204. [doi: 10.2196/23204] [Medline: 34617904]
63. Asipade AI, Thomas JO, Rankin YA. Implementing community-based participatory design and mixed methods to capture and analyze mental models of no/low literate users. Presented at: 2021 IEEE 9th International Conference on Healthcare Informatics (ICHI); Aug 9-12, 2021; Victoria, BC. [doi: 10.1109/ICHI52183.2021.00062]
64. Gregg ES, Colton J, Matin MA, Krupnik TJ. Efficient and participatory design of scale-appropriate agricultural machinery workshops in developing countries: a case study in Bangladesh. Dev Eng 2020;5:100046. [doi: 10.1016/j.deveng.2019.100046] [Medline: 33426261]
65. Haroz S, Kosara R, Franconeri SL. ISOTYPE visualization: working memory, performance, and engagement with pictographs. Presented at: 33rd Annual ACM Conference on Human Factors in Computing Systems; Apr 18-23, 2015; Seoul, Republic of Korea. [doi: 10.1145/2702123.2702275]

Abbreviations

ISO: International Organization for Standardization

Edited by T Leung; submitted 18.07.24; peer-reviewed by GR Longworth, H He, JV Delden; revised version received 20.10.24; accepted 24.10.24; published 13.12.24.

Please cite as:
Arcia A, Stonbraker S, Mangal S, Lor M
A Practical Guide to Participatory Design Sessions for the Development of Information Visualizations: Tutorial
J Particip Med 2024;16:e64508
URL: https://jopm.jmir.org/2024/1/e64508
doi:10.2196/64508

Publisher:
JMIR Publications
130 Queens Quay East.
Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org