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Original Paper

Actionable Items to Address Challenges Incorporating Peer Support Specialists Within an Integrated Mental Health and Substance Use Disorder System: Co-Designed Qualitative Study

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Abstract

Background: Peer support specialists offering mental health and substance use support services have been shown to reduce stigma, hospitalizations, and health care costs. However, as peer support specialists are part of a fast-growing mental health and substance use workforce in innovative integrated care settings, they encounter various challenges in their new roles and tasks.

Objective: The purpose of this study was to explore peer support specialists' experiences regarding employment challenges in integrated mental health and substance use workplace settings in New Hampshire, USA.

Methods: Using experience-based co-design, nonpeer academic researchers co-designed this study with peer support specialists. We conducted a series of focus groups with peer support specialists (N=15) from 3 different integrated mental health and substance use agencies. Audio recordings were transcribed. Data analysis included content analysis and thematic analysis.

Results: We identified 90 final codes relating to 6 themes: (1) work role and boundaries, (2) hiring, (3) work-life balance, (4) work support, (5) challenges, and (6) identified training needs.

Conclusions: The shared values of experience-based co-design and peer support specialists eased facilitation between peer support specialists and nonpeer academic researchers, and indicated that this methodology is feasible for nonpeer academic researchers and peer support specialists alike. Participants expressed challenges with agency restrictions, achieving work-life balance, stigma, and low compensation. We present actionable items to address these challenges in integrated mental health and substance use systems to potentially offset workforce dissatisfaction and high turnover rates.

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KEYWORDS

experience-based co-design; mental health recovery; substance-related disorders; peer support; peer support specialist; health workforce; patient experience; patient satisfaction; coproduction

Introduction

Background

Peer support specialists have a vital role in delivering new models of integrated mental health and substance use care. Peer support specialists are individuals with lived experience of a mental health condition or substance use disorder, or both, who are trained to provide support services (or "peer support") to others with similar challenges [1-3]. Peer support services augment traditional psychiatric care and have been shown to be effective in reducing stigma, psychiatric distress, and hospitalizations among service users [4-6]. Knowing the value of peer support services, 46 states across the United States have implemented Medicaid-reimbursable peer support specialist

training programs and services to develop a peer support specialist workforce of approximately 30,000 individuals [1-3]. Despite the benefits of peer support specialists to the mental health and substance use disorder system, peer support specialists in the United States have reported job dissatisfaction, which has resulted in high turnover rates [6,7].

Of note, one of the major challenges identified in the scientific literature is a general lack of understanding among peer support specialists of their role within the mental health system, resulting in feelings of exclusion [8,9]. The US National Association of Peer Supporters has developed supervision guidelines to offset these challenges in mental health systems [10] Yet, as peer support specialists are now increasingly being incorporated into *integrated* mental health and substance use systems, it is not known if additional challenges have surfaced.

Objective

As peer support specialists are considered essential workers during the COVID-19 pandemic and are part of a fast-growing mental health and substance use workforce in integrated care settings, it is imperative to understand challenges in their role in order to develop systems to support peer support specialist workforce satisfaction and retention. The purpose of this study was to explore peer support specialists' experiences regarding employment challenges in various integrated mental health and substance use workplace settings.

Methods

Experience-Based Co-Design Methodology

Using the experience-based co-design (EBCD) methodology, peer support specialists and academic researchers collaborated as equal partners. EBCD is a participatory action research method used for collaboratively improving health care services with academic researchers and service users working as partners in improvement in health care [11,12]. EBCD has been shown to be an effective method of services improvement in health care, as it facilitates the process to identify and address health care workforce culture, values, and behaviors [11,13].

The Manchester Peer Collaborative partnered with nonpeer academic researchers using EBCD and discussed peer support specialists' challenges in the integrated mental health and substance use workplace. The Peer Collaborative meets in person monthly and comprises 15 peer support specialists from New Hampshire, USA. Each of the 15 peer support specialists provides varying services, including traditional mental health peer support and integrated mental health and substance use peer support services. Conversations and concerns were brought forward by peer support specialists who were aware of potentially detrimental work experiences within the peer support specialist local work landscape. The Peer Collaborative had previously discussed major areas of concern, including high turnover rates, challenges with various staffing issues, and receiving supervision from traditionally trained clinical staff versus supervision from another peer support specialist. The Peer Collaborative wanted to further understand the issues and work experiences of locally employed, peer support specialists in order to improve the overall work environment. Bringing this to the attention of leadership, there was agreement that further resources and examination were needed. These initial conversations between nonpeer academic scientists and the Peer Collaborative and agency leadership led to this project's co-designed main objective: to explore peer support specialists' experiences regarding employment challenges in various integrated mental health and substance use workplace settings in New Hampshire.

Data Collection

Using a convenience sample, 2 trained peer support specialist research partners contacted 5 agencies employing peer support specialists via telephone. They described the purpose of the study to agency peer supervisors and assessed the agency's interest in having peer support specialists participate in a 90-minute focus group on-site. Next, the peer support specialist research partners scheduled focus groups. To reduce the burden, focus groups were scheduled for convenient times at the agency where focus group participants worked.

Peer support specialist research partners conducted 3 focus groups with 5 peer support specialists in each focus group (N=15), each lasting approximately 90 minutes. The focus groups were audio recorded. Peer support specialist research partners co-designed the focus group interview guide. Participants received no compensation to participate. Peer support specialist research partners were paid their normal rates. We conducted focus groups until no new information or themes were brought forward by the focus group (ie, until saturation was met; data saturation happens during qualitative research in which no new information is discovered from interviews or focus groups—this indicates to researchers they can stop collecting data) [14]. To reduce bias and allow for participants to speak openly, we held focus groups in private rooms without management personnel present. Before the start of each focus group, a verbal scripted consent form was handed out to participants and read aloud by peer support specialist research partners.

Focus Group Interview Guide Development

Peer support specialist research partners collaboratively developed questions for the focus groups with the principal investigator (PI; MA). Questions were based on peer support specialist research partners' experience as peer support specialists offering services within a variety of integrated mental health and substance use systems. The question topics asked about interviewing, hiring, training, and conducting peer support services across various integrated mental health and substance use systems. By developing the questions and an interview guide with peer support specialist research partners, we increased the likelihood of promoting objectivity and including culturally informed questions [15].

Peer Support Specialist Research Partner Training

Peer support specialist research partners independently completed an institutional review board (IRB) training online. To further support their research partner role, the PI trained peer support specialist research partners to conduct research activities to ensure the development of necessary interview skills (eg, drawing out reliable information from the focus group

participants) [16]. The training was conducted over 6 weekly meetings in approximately 90-minute blocks of time each. Specifically, peer support specialist research partners were trained in the following areas: research ethics and conflicts of interest, recruitment methodology, qualitative interview guide development, qualitative data collection, qualitative data analysis, manuscript writing, and dissemination. All training was offered in person, and information was presented to peer support specialist research partners verbally as well as with written material to support reinforcement of in-person training. Peer support specialist research partners practiced conducting and leading mock focus groups [17,18]. We conducted 2 mock focus groups in which peer support specialist research partners alternated being the mock note taker or facilitator role. The PI observed and provided feedback to support learning.

Ethical Considerations for Co-Designing With Peer Support Specialist Research Partners

We submitted a summary of the study protocol to all participating agencies and met with leaders as follow up for questions and feedback. At the lead agency, this study was first reviewed by the clinical services team, consisting of clinical directors from various service departments (eg, adults, children, emergency services, acute services). Nonpeer directors who supervise and employ peer support specialists were part of the review. Of note, we asked peer support specialist employees from multiple agencies to provide their input regarding setting-specific workforce challenges and to offer solutions to those challenges. As such, it was important to ensure that each agency agreed to provide a safe, confidential, open communication environment, to which all of the agencies agreed. In addition, we requested from each agency that supervisors of the participating peer support specialists not be present during focus groups and that a private room be available for the focus group to take place in. Furthermore, we requested a waiver of written consent. We submitted a scripted consent form to the IRB that researchers could hand out and read aloud prior to the beginning of each focus group obtaining verbal consent versus written consent to participate. The co-design team further protected the identity of participants in case of disagreement or repercussions by not collecting any individual identifiers (eg, name, email) in data collection.

After the review and discussion, a vote was taken and the study was approved with a letter of support generated and addressed to the PI. We then submitted this study for external ethics board review after the participating agencies submitted letters of support for the project. The review was conducted and approvals obtained by the New Hampshire IRB, which was the IRB of record for all agencies involved.

Data Analysis

After each focus group ended, 2 peer support specialist research partners and the PI met in person for 30 minutes to debrief and discuss the focus group themes and exchange ideas. Together, they discussed the most important themes and how each agency presented similar or different information [14].

Next, we transcribed audio recordings. The analyses of focus group data was informed by conducting a content analysis and then thematic analysis [19]. We reviewed and followed focus group analysis guidelines to ensure consistency in the transcript review process [20]. An initial meeting was conducted to review the entire transcript as a group. The PI and peer support specialist research partners then separately read the transcripts while taking notes and documenting impressions. We categorized relevant topics, themes, patterns, or other topics that were unexpected or recognized as important by participants. The peer support specialist research partners and the PI held 2 group data analysis meetings to review categories and discuss key themes emerging from the data and to achieve final consensus.

Results

Participants and Themes

All 5 agencies we contacted responded positively and invited every peer support specialist at the agency to attend 1 of the 3 focus groups; however, 2 agencies were unable to participate due to scheduling conflicts and staffing shortages, resulting in a 60% agency response rate.

The focus groups consisted of participants (N=15) employed as a peer support specialist by 1 of the 3 agencies: (1) a peer-led agency with a primary focus on substance use disorder recovery (n=5, 33%), (2) a peer-led agency focused on mental health wellness and recovery (n=5, 33%), or (3) an agency-led community mental health center (n=5, 33%). All agencies also offered various integrated mental health and substance use support and services. Of the participants, 53% (n=8) were male and 87% (n=13) were White; their ages ranged from 21 to 60 years. The majority of participants had received a 2- or 4-year college degree (n=8, 53%), 3 participants had received their high school diploma (20%), 2 participants had received some education after high school (13%), and 1 participant had received a master's degree (7%).

We identified 90 final codes relating to 6 themes: (1) work role and boundaries, (2) hiring, (3) work-life balance, (4) work support, (5) challenges, and (6) identified training needs.

Peer Work Role and Boundaries

The first theme was related to peer work roles and boundaries. Participants noted that they were not trained specifically to maintain clear boundaries with service users. Participants reported that they were trained to operate with flexibility based on the need of the service user. For example, following peer training, if a service user was feeling lonely, that could mean a peer support specialist could socialize with the service user (eg, going fishing together, or go out to eat); however, this would be considered unethical if a clinician were to conduct these activities. This boundary issue is highlighted in one participant's statement:

> *You don't want to live with regret about drawing a line in the sand and hold your boundaries and something catastrophic happens. It's a really slippery slope because it really sometimes is life or death of a client.*

Participants indicated they would be reprimanded if they conducted activities that violated clinical professional boundaries—not peer professional boundaries.

Participants also commented that they worked closely with clinicians who were often not familiar with peer specialist work activities or their role, and that the clinicians expected activities that were not in the job description. For example, participants reported they had been asked to feed a service user's cat or do an emergency room clinical assessment. Participants reported they were often misunderstood to be junior clinicians or community health workers. Agency-led employed participants added that it is important that all clinical supervisors take training on how to work with peers and that agencies need to train providers on understanding the peer role.

Hiring Peer Support Specialists

The second theme was related to hiring. Participants agreed that before hiring a peer support specialist, it is important to know that the potential peer employee is far enough along in their own recovery and are also able to have enough personal resources to give support to somebody else, and the ability to feel comfortable working with people who are in recovery. Peer support specialists agreed that recovery time alone is not the most important measure of recovery, that "Quality is more important than quantity." Participants employed at the peer-operated agencies were more comfortable hiring individuals who were still struggling with a substance use disorder and who may be at risk for reoccurrence. They felt that offering a "get-well" position is an incentive to help people get and stay in recovery. Get-well jobs can be paid or unpaid positions that are usually a less-demanding role just after achieving sobriety. These positions have manageable hours and fewer responsibilities to facilitate a pattern of showing up to work [21].

An emerging finding from the participants suggested the importance of knowing what is expected in the job and that discussing the idea of becoming a professional peer with a trusted friend, other peer specialist, a therapist, or recovery coach for outside perspective could be helpful. Agency-run organizations were more likely to have more requirements upon hiring. The agency-operated peer specialists reported that their agency made a point to hire those already certified or individuals working toward certification for Certified Recovery Support Worker and Certified Peer Support; however, participants noted it is not uncommon for other agencies to ask for existing recovery time prior to hiring.

Important hiring interviewing questions that we identified included asking potential hires what they are doing for their own recovery. Participants reported they would feel comfortable if a potential employer asked them about their own recovery. However, they stated they would feel uncomfortable if a nonpeer interviewer asked them about their personal recovery. One male participant explained that a new peer at a hiring interview can be "intimidated talking to nonpeers about their low times or legal issues to someone other than a peer."

The majority of participants reported that peers should be involved in the hiring process. In fact, 1 participant was already part of the hiring process. Specifically, participants suggested their role in hiring should include developing interview questions, selecting interviewees, and asking and interpreting interview questions. Peer support specialist involved in hiring would look for an employee with passion, altruism, self-reflection, and finding their own happiness through service to others. Peer support specialists would also look for hiring red flags such as not being able to identify one's potential reoccurrence triggers, not being mindful of their own interpersonal boundaries, not having dedicated time for self-care activities, and expecting significant financial gain.

Participants reported the need for supervisory support once hired. Participants reported that supervisors can be a peer themselves or a clinical staff member. Supervisors' characteristics should include honesty and respect, celebration of a peer support specialist's strengths, flexibility, and willingness to refine job skills after mistakes are made. Supervisors should also offer trainings.

Challenges Peer Support Specialists Experience in Clinical Environments

The third theme was related to challenges peer support specialists experience in the clinical environment. This theme comprised 3 subthemes: stigma, work-life balance, and low salary coupled with high job demands.

Stigma

All participants agreed that stigma associated with having a mental health condition or substance use disorder is the number 1 challenge they face as a peer support specialist. As peer support specialists, they, themselves, experience stigma, as well as observing it directed toward those they assist. Participants reported that stigma and the fear of the unknown are top reasons people do not seek help. One female participant explained:

> *Peers are not taken seriously, despite solid outcomes, and we are people with lived experience, so we carry that stigma of mental illness.*

Another male participant explained:

> *There is internal stigma and external stigma and the health care community itself sometimes contributes to ongoing stigma.*

Participants suggested the need for widespread education toward changing the culture of people who are not affected by a mental health condition or substance use disorder.

Work-Life Balance

Participants emphasized the importance of work-life balance. This subtheme was related to maintaining a work-life balance and avoiding burnout. Participants employed at a peer-led agency focusing primarily on substance use disorder recovery reported challenges with work-life balance. One participant reported:

> *We all work from home. We all take calls on our days off. We all do it.*

They acknowledged that their agency's work that focused on the community's opioid crisis had left staff experiencing

vicarious trauma. This compelled peer staff to be available when they, themselves, were not scheduled to work and were at home.

To address vicarious trauma, participants reported that peers checked in with one another, were vigilant if a peer colleague appeared exhausted and worn out, and sent tired peer colleagues home when rest was needed. They reported having access to supervisors regularly and participating in debriefings as needed. Participants reported they relied on and trusted one another to speak up and notice when a colleague was experiencing workplace burnout. All participants reported the importance of agency flexibility to send a peer home for self-care when needed.

Low Salary Coupled With High Job Demands

Low salary was a reported challenge. Participants reported lower hourly salary than for other positions even though there is still an ongoing shortage of peer support specialists at the agency. This shortage was especially prominent on the intensive treatment teams. Participants noted that 1 peer support specialist as assigned to each team, leaving them to cover large numbers of individuals. Participants suggested that a cost-effectiveness study may help show the value of peer services and impact salaries.

Training Needs of Peer Support Specialists

Self-care and other trainings were identified training needs. All participants identified training on self-care as the top training need. Additional needed trainings identified were how to cope with vicarious trauma, receiving updates on the topic of sex trafficking in their community, how to work with the chronic homeless population, what resources and strategies are available to peer support specialists working with perpetrators, and providing trauma-informed care. Participants wanted trainings on how to work with clinicians and their roles. They felt it was important as part of the agencywide orientation that all clinical positions have a training on this. One participant stated that peers "need training on how to work with clinicians and clinicians need training on how to work with a peer."

Discussion

Principal Findings

The aim of this study was to investigate peer support specialists' experiences regarding training, recruiting, hiring, management, work roles, and retention in the integrated mental health and substance use disorder workplace by partnering with peer support specialist experts using the EBCD methodology. Peer support specialists identified challenges with agency restrictions, achieving work-life balance, stigma, and low compensation. Peer support specialists detailed previously unidentified actionable items to address workforce challenges, including hiring procedures and trainings.

Peer support specialists in integrated agencies experienced challenges similar to those faced by peer support specialists in nonintegrated settings. Participants reported challenges with boundaries, work-life balance, and experiencing personal stigma in the workplace and confirmed the ongoing challenge of low compensation. This finding is consistent with the role of peer support specialists in nonintegrated agencies [22-24]. Participants reported stigma as the biggest challenge, either by experiencing stigma themselves, sometimes even from their own professional colleagues, or observing it directed toward those they assist. Challenges associated with stigma have been documented in previous studies [24], and a variety of strategies exist to create safe zones for people experiencing mental illness in the peer support agencies [25]. The peer support profession is not well understood across various agencies. Supervisory and leadership training for both clinicians and peers may educate agencies on the role of peer support specialists and also prepare peers to work with clinicians. Peer support specialists and nonpeer support specialists employed in integrated settings may not be receiving adequate training conducive to their roles. Improving and offering consistent training standards statewide could potentially improve the work experiences of peer support specialists, particularly in integrated clinical settings.

Training in self-care is paramount to being a caregiver, human services worker, or health care worker. Peer support specialists encounter this same need. Self-care training, while offered frequently, not only needs to be formally tailored to peer support specialists, but also should include a structure of support built into peer training programs. Peers in previous studies had reported challenges with work-life balance and burnout leading to negative outcomes [26]. To address and prevent the common experience of burnout and vicarious trauma that peer support specialists encounter while working alongside first responders and crisis workers, participants recommended a supportive organizational structure and specialized training in these areas.

Agencies looking to hire peer support specialists should involve already employed peer support specialists in the hiring process. Inclusive hiring policies and practices have been documented as an identified organizational characteristic indicating readiness to hire peer workers [27]. Participants provided guidance on what to look for in a new peer support specialist to find the right fit for the position and to identify interviewees who were (1) able to identify and hence avoid or manage potential reoccurrence triggers, (2) mindful of their own interpersonal boundaries, (3) capable of dedicating time for self-care activities, and (4) not expecting significant financial gain but to be rewarded by the role of helping others.

The shared values of EBCD and peer support specialists eased facilitation between peer support specialists and nonpeer academic researchers toward a mutual goal. EBCD and peer support specialist practice standards share a similar values system, including that (1) people from all backgrounds can provide knowledge, (2) people can give practical help to each other that provides mutual benefit to both parties, (3) individuals seeking services are equal to the care provider or academic researcher, and (4) experiential knowledge is valued [13,28]. These shared values are similar to that of a peer support values system that also is based on experiential knowledge, inclusion of all people, and mutuality [3]. Peer support specialist research partners expressed satisfaction with regard to the EBCD process and finding answers to the questions that they had regarding the peer support specialist's work experience.

Limitations and Strengths

We acknowledge that this study had several limitations. First, this study included a small convenience sample; however, we collected data until saturation was met. Second, this study was racially homogeneous, which may not be a good representation of a racially and ethnically diverse population response. Data saturation may have been met due to the racially and ethnically homogeneous population. As such, these findings should be interpreted with caution in generalizing to a racially and ethnically diverse population. Third, respondents may have felt pressure to give similar answers to the moderator's questions depending on the group dynamics in the focus groups. The peer support specialist research partners may have presented a bias by encouraging or discouraging answers with body language or voice inflection. Peer project leads were trained to mitigate bias by discussing common examples of interviewer bias to increase their awareness as part of their focus group training with the PI, and they were unpaid volunteers. The PI listened to the audio recording and did not identify any verbal biases. As peer support specialists are increasingly involved as research partners by taking on researcher roles, scientifically exploring methods to mitigate peer support specialist interviewer bias may help advance the role of peers as equal partners in research. Fourth, peer support specialist research partners wanted participants to remain completely autonomous; as such, this study did not collect participant names and demographics beyond what was reported, or match participants using a study ID.

While this study had limitations, a strength of this study was the use of EBCD approach to engage with peer support specialists and identify previously unidentified methods to address workforce challenges related to hiring procedures and trainings. This report can be used to guide the advancement of the peer workforce. The project's subject matter was also focused on peer support specialists in the integrated mental health and substance use disorder peer support services field, which is an area that requires continuing attention from the academic and health care communities.

Dissemination to Stakeholders

Upon completion of this study, the peer support specialist research partners (AD, BS) and the PI submitted a report of the focus group results to agency leadership. In addition, we set up a meeting with stakeholders, state peer support specialist leadership, and local agency leadership, allowing for further discussion and sharing of the focus group results that was conducted by the peer project lead support specialist (AD, BS). An ongoing effort with state and local leadership has been to bring awareness to the current national versus local practice. The Peer Collaborative met with state leadership and submitted a multiday training outline for peer support specialists in a community mental health setting. The training included an integrated care focused section. In these meetings we discussed that oversight at the state level for peer support specialists would be better served by a separate peer board than under an existing state-licensed alcohol and drug counselor board for peer support specialist expertise and workforce standardization. We will continue to use focus group findings to facilitate solutions identified by peers within the integrated mental health and substance use disorder systems.

Conclusions

This study produced actionable insights affecting the mental health and substance use disorder system from the perspective of peer support specialists. Participants expressed challenges with agency restrictions, achieving work-life balance, stigma, and low compensation. Participants' recommendations related to training, hiring procedures, management, work roles, and retention in the mental health and substance use disorder workplace may offset these challenges and work toward advancing the peer workforce. The shared values of EBCD and peer support specialists eased facilitation between peer support specialists and nonpeer academic researchers and indicate that this methodology is feasible for nonpeer academic researchers and peer support specialists alike. The partnership established collaboration and equality among research team members allowing for multiple areas of expertise to enhance research in the peer support specialist workforce field.

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Conflicts of Interest

KF offers consulting services through Social Wellness, LLC.

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Abbreviations

EBCD: experience-based co-design
IRB: institutional review board
PI: principal investigator

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Original Paper

Beyond Known Barriers—Assessing Physician Perspectives and Attitudes Toward Introducing Open Health Records in Germany: Qualitative Study

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Abstract

Background: Giving patients access to their medical records (ie, open health records) can support doctor-patient communication and patient-centered care and can improve quality of care, patients' health literacy, self-care, and treatment adherence. In Germany, patients are entitled by law to have access to their medical records. However, in practice doing so remains an exception in Germany. So far, research has been focused on organizational implementation barriers. Little is known about physicians' attitudes and perspectives toward opening records in German primary care.

Objective: This qualitative study aims to provide a better understanding of physicians' attitudes toward opening records in primary care in Germany. To expand the knowledge base that future implementation programs could draw from, this study focuses on professional self-conception as an influencing factor regarding the approval for open health records. Perspectives of practicing primary care physicians and advanced medical students were explored.

Methods: Data were collected through semistructured guide-based interviews with general practitioners (GPs) and advanced medical students. Participants were asked to share their perspectives on open health records in German general practices, as well as perceived implications, their expectations for future medical records, and the conditions for a potential implementation. Data were pseudonymized, audiotaped, and transcribed verbatim. Themes and subthemes were identified through thematic analysis.

Results: Barriers and potential advantages were reported by 7 GPs and 7 medical students (N=14). The following barriers were identified: (1) data security, (2) increased workload, (3) costs, (4) the patients' limited capabilities, and (5) the physicians' concerns. The following advantages were reported: (1) patient education and empowerment, (2) positive impact on the practice, and (3) improved quality of care. GPs' professional self-conception influenced their approval for open records: GPs considered their aspiration for professional autonomy and freedom from external control to be threatened and their knowledge-based support of patients to be obstructed by open records. Medical students emphasized the chance to achieve shared decision making through open records and expected the implementation to be realistic in the near future. GPs were more hesitant and voiced a strong resistance toward sharing notes on perceptions that go beyond clinical data. Reliable technical conditions, the participants' consent, and a joint development of the implementation project to meet the GPs' interests were requested.

Conclusions: Open health record concepts can be seen as a chance to increase transparency in health care. For a potential future implementation in Germany, thorough consideration regarding the compatibility of GPs' professional values would be warranted. However, the medical students' positive attitude provides an optimistic perspective. Further research and a broad support from decision makers would be crucial to establish open records in Germany.

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KEYWORDS

eHealth; medical records; open notes; personal health records; primary health care; qualitative research

Introduction

Giving patients access to their medical records aims at transparently informing them about their health-related data and enabling patient-centered care and shared decision making. While providing patients with access to copies of their records was already proposed in 1973 [1], the idea gained momentum since the open notes study was conducted in the United States in 2010: 105 primary care physicians encouraged more than 19,000 patients to access their medical notes [2]. According to the aim of the open notes study, open health records can be understood as a concept that includes all projects that "...provide patients with access to their medical records..." as seen on page 462 of Delbanco et al [2]. Confirmed by several studies, open access to medical records has led to (1) patients' enhanced health literacy, (2) improved adherence to therapy, (3) increased health-related self-care, (4) improved doctor-patient communication, and (5) improved quality of care [2-9].

The German government regularly supports research projects on patient-centered care and shared decision making. However, the successful implementation of projects that aim at facilitating patient-centeredness in routine care remains an exception [10]. This also accounts for open-record concepts: in Germany, patients are entitled by law to have access to their medical records and request copies of documents that specify their medical care [11]. However, there is no comprehensive master record per patient and no structured procedure that governs how patients can access information stored in commonly used, physician-managed electronic patient files as of yet, and patients still do not automatically have access to their content. Although the first research projects on cross-sectoral personal electronic health records (PEHRs) were conducted in Germany [12-15], the patients' unrestricted access to their records remains an exception: the patients' right to access their records is usually solely met by printing out test results, diagnostic assessments, or related parts of their medical record upon patient request [16]. Prior research on giving patients full access to their medical records focused on implementation barriers [5,7,17-24]. Besides barriers such as data security or the patients' potentially limited abilities to access and fully understand their records [18,20,22,24], physicians' concerns about opening their patients' records were recurrently described [18-21,23]. However, the reasons for physicians' reluctance regarding such a concept remained unaddressed. Little is known, in particular, about general practitioners' (GPs) perspectives on opening records and their perception of compatibility with the medical profession. Accomplished projects in the United States have proven that barriers can be overcome [2,7], which signals the need for understanding the perspectives of German GPs.

Opening records aims at facilitating transparency and cooperation between physicians and patients. These objectives might constitute a contrast to a GP's professional self-conception, which is influenced by specific shared values within the medical profession. Decades ago, Eliot Freidson's analysis of the nature of professions concluded that autonomy was the fundamental criterion that distinguished professions [25,26]. Freidson argued that professional autonomy depended on protection and tolerance for its sustainability and that the freedom from outside control was based on three claims: (1) professionals have an unusual professional skill and knowledge degree that nonprofessionals cannot evaluate, (2) professionals are responsible and may be trusted to work without supervision, and (3) the profession itself can be trusted to deal with incompetent or unethical members. His theory discussed the characterization of the medical profession by largely acknowledged autonomy and self-control, both legitimized by a knowledge monopoly accepted by society, and subsequently found broad support [27-31]. Legitimate professional autonomy provides physicians with freedom to practice their trained craft independently and to guide and instruct other health professions. This profession-defining autonomy entails professional self-control, which can be understood as freedom from external control. Both of these attributes are enabled and justified by the physicians' unique professional knowledge that stems from their systematic, specialized medical training [25,26]. This view on the medical profession can create a strong identification with the specific values and, therefore, can influence the professional self-conception of GPs. Thus, it might affect their approval for innovating concepts like open notes as well as their perception of implications and requirements for a similar implementation in Germany.

In recent years, the change from a paternalistic to a more participatory and patient-centered relationship between physicians and patients progressed noticeably [32]. Prior research on open record concepts found that these can contribute to patient-centeredness [3,7,8]. However, these studies did not explore whether the professional self-conception of GPs in Germany is compatible with such concepts. Therefore, the aim of this study was to improve the understanding of current and future physicians' perspectives and attitudes beyond already-known barriers. In order to identify potentially different perspectives, GPs and advanced medical students were interviewed. Based on Freidson's theory on professional self-conception of medical doctors, perspectives of both groups were explored with a focus on the potential impact on their approval for open health records. Anticipated implications, expectations for future records, and perceived conditions for an implementation of an open record concept in German general practices were addressed.

Methods

Study Design

This qualitative study was conducted to explore and assess GPs' and advanced medical students' perspectives and attitudes toward the concept of open records and a potential implementation in Germany. Differences between the two participant groups were to be explored as well. Data were collected through semistructured guide-based interviews with GPs and advanced medical students in the Rhine-Neckar region in Baden-Wuerttemberg, Germany. The interview guide (see Multimedia Appendix 1) was discussed with a group of junior researchers (peer students of JM) in a qualitative research colloquium (led by CU and RPD) at the Department of General Practice and Health Services Research, University of Heidelberg. Adjustments were made according to recommendations. The

open-ended interview questions were based on theoretical considerations and an extensive literature search. Additionally, a study-specific questionnaire was used to collect data on participant characteristics (see Multimedia Appendix 2).

For this study, ethical approval was given by the Ethics Committee of the University Hospital Heidelberg (S-529/2019). The study was reported according to the COREQ (Consolidated Criteria for Reporting Qualitative Studies) checklist for qualitative research [33].

Participants and Recruitment

Purposive sampling was conducted without calculating a formal sample size. Structural variance was provided through diversity in age and gender. Participants were eligible for inclusion when they were (1) a resident general or internal practitioner working in a general practice or (2) an advanced medical student; further eligibility criteria were (3) a fluent command of German or English and (4) working in a location in the Rhine-Neckar region. Physicians were to be excluded when they were hospital based or specialized in another medical field. Students were to be excluded when they had not yet successfully completed their first of three medical state exams.

GP names and contact information were identified from the official medical register of the Association of Statutory Health Insurance Physicians Baden-Wuerttemberg. Medical students were identified by receiving contact information through one of their peers who acted as a gatekeeper. There were no prior relationships with any participant. Between August 21 and September 9, 2019, recruitment emails were sent to 31 GPs and 10 medical students. An information sheet with detailed background information on the aim and details of the study was attached to the email. Follow-up calls were conducted after one week. Interest was expressed by 8 GPs and 7 medical students; 1 GP withdrew interest without specification. In total, 7 GPs and 7 students participated in the study. All participants gave their written informed consent for participation and audiotaping of the interviews. The participants' anonymity and confidentiality were ensured throughout the entire study. The participants did not receive any reimbursement for their participation in the study.

Data Collection and Analysis

All interviews were conducted by one female author (JM) with a background in health and nursing management, health services research, and implementation science. After 12 interviews (5 GPs [42%] and 7 medical students [58%]), data saturation was reached, and data sufficiency was assessed based on deviant observations and consistency of findings. No additional themes were identified in the 2 further interviews. To accommodate participant preferences, all interviews were performed face-to-face or via telephone. Nonparticipants were not present during the interviews. No additional notes were taken during or after the interviews, and no repeat interviews were carried out.

All interviews were audiotaped, pseudonymized, and transcribed verbatim following appropriate transcription guidelines. Transcripts were not returned to participants for verification. After completion of data collection, transcripts were analyzed by the author (JM). Analysis was conducted according to thematic analysis by Braun and Clarke [34]. The identification of themes was performed deductively a priori from the interview guide (see Multimedia Appendix 1) and inductively de novo from data during the analysis. All themes were organized into main themes and subthemes. Each theme was clearly defined by a quote from the interview transcripts (see Multimedia Appendix 3). Data, derived themes and subthemes, and the analytical process were discussed regularly with supervisors (RPD and CU) and peer junior researchers during the mentioned qualitative research colloquium. The coding of transcripts was conducted in MAXQDA Standard 2018, version 18.2.0 (VERBI Software). The participant characteristics were analyzed descriptively using Microsoft Excel, version 16.28.

Results

Overview

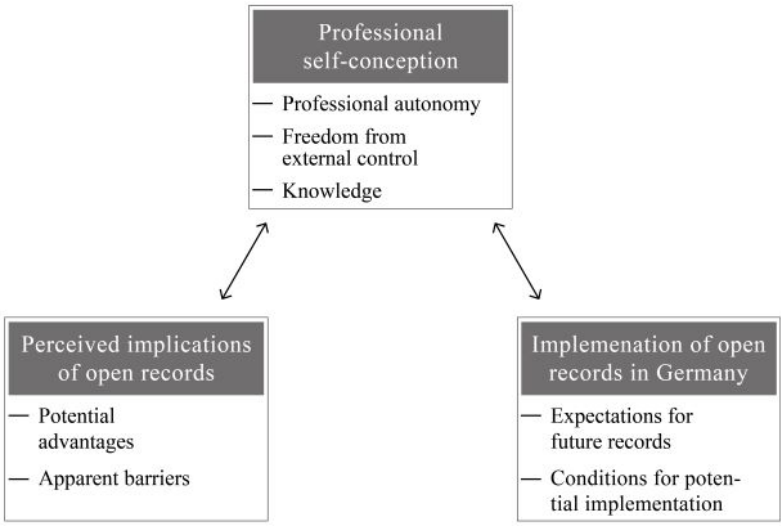
All 14 interviews were conducted between August 28 and September 25, 2019. GP interview durations ranged from 14 to 31 minutes (mean 20, SD 6), and student interview durations ranged from 14 to 42 minutes (mean 28, SD 11). To accommodate a GP request, 1 interview was performed face-to-face in a public café, while all other interviews were conducted via telephone. All student interviews were held face-to-face. Out of the 7 students, 4 were interviewed in a seminar room at the University of Heidelberg and the remaining 3 at JM's private domicile to accommodate participant preferences. Participant characteristics were collected from all interviewees. The age of GPs ranged from 40 to 60 years (mean 50, SD 8) and the age of students ranged from 22 to 26 years (mean 24, SD 2). A total of 4 GPs out of 7 (57%) and 3 out of 7 participating students (43%) were female. Table 1 provides further information on the participant characteristics.

The key findings of this qualitative study reflect the participating GPs' and advanced medical students' perspectives and attitudes and are presented with a focus on three main themes and associated subthemes identified from the data (see Figure 1). When applicable, themes were differentiated by participant groups. All provided interview quotes indicate the respective participant group and transcript position (TP) and were translated from German into English with due diligence. To transparently indicate the distribution of themes across interviews, their participant designation is also provided.

Table 1. Participant characteristics (N=14).

Characteristic	Value, n (%) or mean (SD), range
General practitioners (n=7)	
Professional specialization: general practice, n (%)	7 (100)
Years of practice, mean (SD), range	23 (8), 11-34
Age in years, mean (SD), range	50 (8), 40-60
Gender, n (%)	
Female	4 (57)
Male	3 (43)
Students (n=7)	
Practical experience: medical traineeship in general practice, n (%)	7 (100)
Years of study, mean (SD), range	5 (1), 4-6
Age in years, mean (SD), range	24 (2), 22-26
Gender, n (%)	
Female	3 (43)
Male	4 (57)

Figure 1. Overview of identified themes on participant perspectives and attitudes regarding open health records in this study.



Professional Self-Conception and its Effect on Attitudes Toward Open Records

Focusing on the GPs' reluctance, the concept of giving patients full access to medical records emerged to be incompatible with the GPs' professional values. As a first aspect of their professional self-conception, GPs considered their *professionalautonomy* an essential professional value. They advocated for maintaining their professional independency (GPs 2, 8, and 11-13) and voiced that opening records for patients would make them feel restricted in their profession (GPs 2 and 11-13).

> *Because we need a certain...freedom to do our job, that nobody has access to our own things. ...That would damage too much of our medical profession as we see it.* [GP 12: TP 249-253]

> *I write quite delicate things in my records which, as I said, should not be read by people.* [GP 2: TP 261-262]

It was important to the GPs that certain parts of the patient record, especially their additional personal notes of perceptions that go beyond clinical data, were to be kept confidential (GPs 2, 3, 8, and 11-14). They emphasized their autonomy by explaining that records were not meant for patients but rather for themselves. Even though GPs stated that they had already given patients access to their medical records by printing parts of them out on request (GPs 2, 3, 8, 11, 12, and 14), they repeatedly labelled the medical record as their personal property. This position was expressed in a rather possessive language, whereby GPs characterized the medical records as *my personal records* (GP 11: TP 39), *a DIARY for me* (GP 13: TP 126), or *MY fundamental right* (GP 12: TP 266).

> *I want MY notes and MY things for myself.* [GP 11: TP 87]

The GPs' aspiration for autonomy was also assessed by the medical students. Based on their experience from internships, they emphasized that GPs, especially, were used to working very self-sufficiently and that they insisted on the independency of the medical documentation (Students 1, 6, and 10). Moreover, it was mentioned that GPs would not want to share the entire patient record unconditionally (Student 6). Referring to their practical experiences, the students confirmed that GPs provided parts of the record on request. However, they emphasized that asking for access can be a barrier for patients and that, as a result, those requests rarely occurred (Students 1 and 10).

> *But there is a therapeutic privilege...that we don't always say everything, and I think many GPs want to keep that...* [Student 6: TP 298-300]

In contrast to the GPs' demand for autonomy, the students voiced a rather cooperative attitude when addressing their own professional behavior: they emphasized that not being the sole owner of the patients' data might facilitate shared decision making with patients (Students 1, 4, 7, and 10), support interprofessional exchange (Students 1, 6, 7, 9, and 10), and, therefore, improve quality of care (Students 1, 6, 7, 9, and 10).

Besides professional autonomy, the participating GPs insisted on their right for self-control, which was referred to as *freedom from external control*. By opening records, they anticipated being controlled by patients or third parties (GPs 2, 8, and 11-13). They highlighted that they would not want to be confronted with potential mistakes or divergent opinions, and they would, furthermore, not want to be forced to discuss and defend their decisions (GPs 2, 3, 8, and 11-13).

> *It is not acceptable that patients have insight and...confront me with things they have read in the record.* [GP 8: TP 56-58]

Confirming this, the students also reported self-control as a significant factor for GPs. Referring to their experiences from traineeships, they indicated the undesirability of external control for GPs (Students 1, 6, 7, and 9). They voiced that GPs did not want to explain their professional behavior and that giving patients access to records would make GPs feel pressured to justify themselves and their actions (Students 6 and 7). Contrary to their perception of the GPs' attitudes, the students valued the patients' engagement and viewed the potential control as positive for their own profession: by encouraging patients to access their medical records, they expected themselves to reflect more on their medical actions (Students 1 and 7) and to be able to work more closely together with patients (Students 1, 4-6, and 10). Again, they assumed an increase in quality of care as a potential result (Students 1, 6, 7, 9, and 10).

> *I think the biggest chance is that you have to reflect on yourself and that you are able to do that. What you might not do if you just type it in.* [Student 1: TP 120-122]

Besides professional autonomy and freedom from external control, the GPs' *knowledge* was voiced as an aspect of their professional self-conception. The GPs emphasized that patients needed to trust the GPs' assessment due to their medical expertise and practical experience (GPs 2, 8, 12, and 13).

> *...the patient has to accept that the doctor knows the field of expertise better.* [GP 12: TP 166-167]

Doctors considered themselves to function as a professional filter that, based on their medical knowledge, needed to screen all information for patients (GPs 2, 12, and 13). Both the superiority of knowledge and the GPs' filter role were also indicated by the students who underlined the GPs' expertise with the length of their medical studies (Students 1, 4, 5, and 9). Another aspect was shared when the perceived power of knowledge was voiced: few students hypothesized that by giving patients access to their records and encouraging them to inform themselves, GPs might feel like they would be losing intellectual advantage and power (Students 1 and 6).

> *And I think it deprives the doctor of some of the power asymmetry he has due to his supposed knowledge.* [Student 6: TP 179-181]

However, for their own profession, the students anticipated the knowledge asymmetry between them and patients to decrease by opening records. Moreover, they demanded this in order to encourage the patients' acquisition of medical knowledge (Students 1, 6, and 9).

GPs assumed that the students' acceptance of open records would be higher than their own and that this potential openness might stem from their lack of practical experience. It was also assumed that as students become increasingly enculturated through practice, they would be more reluctant as well (GPs 2, 3, 8, and 11-13). The students saw the GPs' reluctance to change as a potentially obstructive factor to their approval for open records (Students 1, 4, 7, and 9). They anticipated the GPs' concern of losing their professional autonomy and the freedom from external control as potential reasons for a lower acceptance (Students 1 and 6).

Perceived Implications of Open Records

When contemplating open health records, potential advantages and apparent barriers were commonly mentioned. Among the potential advantages, *patient education and empowerment* were anticipated by both participant groups: both students and GPs expected that patients would be better informed about their health. They mentioned that reading their medical records might encourage patients to increase their health literacy (GPs 2, 3, and 12-14; Students 1, 6, 7, 9, and 10). Furthermore, the patients' adherence to treatments (GPs 2, 12, and 14; Students 1, 4-7, and 10) and their health-related self-responsibility (GPs 2, 3, and 14; Students 1, 4-7, 9, and 10) were assumed to increase. Moreover, besides these patient-related aspects, GPs and students anticipated a *positive impact on the practice*: they emphasized the advantage of sharing results between disciplines if patients could authorize other specialists to access their records (GPs 2 and 8; Students 1, 6, 7, 9, and 10). By providing patients with the innovative functions of open records, few participants envisioned a market advantage (GP 8; Students 6 and 7). A higher *quality of care* was expected by students only. They assumed the quality of care would increase when detecting

errors and improving diagnoses through the cooperation with informed patients (Students 7, 9, and 10).

Besides the potential advantages, the GPs and medical students assessed barriers. Among these, *data security* appeared to be an essential problem, voiced by all participants but one (GPs 3, 8, and 11-14; Students 1, 4-7, 9, and 10). When voicing this barrier, a contrast occurred between GPs and students: while GPs highlighted the demand for data protection, students rather assessed the fear of data abuse through hacking as a barrier, which they characterized as a particular aspect of the "German mentality" on data security. Besides data security, participants anticipated an *increasedworkload* when opening records for patients: although few participants were convinced that the workload would, if at all, only change at the start of an implementation phase (GP 14; Student 9), others expected patient requests to rise and the duration and number of patient contacts would increase permanently (GPs 2, 3, 8, and 11-13; Students 1, 4, 7, and 10). A higher workload was, furthermore, anticipated due to an intensified documentation effort in order to avoid misunderstandings (GPs 8, 12, and 14; Students 1, 6, 7, 9, and 10).

> *...patients think they understand it, but then a small note in the record would cause a misunderstanding. That would be disastrous. It would cost us an incredible amount of time and effort to resolve it.* [GP 3: TP 111-114]

As a consequence of the increased workload, few participants expected the practice's *costs* to increase. Furthermore, they assumed that these costs would not be reimbursed (GP 2; Students 6 and 7). Referring to the *patients' limited abilities*, GPs emphasized the patients' insufficient medical understanding (GPs 2, 3, 8, and 12) and the risk of provoking anxiety (GPs 2, 3, 12, and 13). A more optimistic view was reported by students: although they saw the risk of provoking anxiety as well (Students 1, 4, 7, and 10), they considered the patients' abilities sufficient for understanding their records. However, older age and the burden of disease were identified as limiting factors for the patients' understanding among students and GPs alike (GPs 2, 8, 11, 13, and 14; Students 4, 7, and 9). As another barrier, the *physicians' concerns* were reported by GPs and students. While GPs justified their hesitance with the mentioned barriers (GPs 2 and 14), the students assessed the GPs' reluctance to change and their professional self-conception as obstructing factors (Students 1, 6, 7, and 10).

Implementation of Open Records in Germany

Most students considered the implementation of open health records in German general practices to be essential and realistic within 10 years (Students 1, 5-7, 9, and 10). GPs could only imagine the implementation of *partly accessible records* in which GPs' additional personal notes, which go beyond clinical data, are kept nonaccessible to patients (GPs 2, 8, and 12-14). Besides the idea of open notes, GPs and students both anticipated future records in general practices to turn entirely *electronic* (GPs 2, 3, and 11-14; Students 1, 4-7, 9, and 10). Furthermore, they hoped for a *cross-sectoral compatibility* to facilitate the requests of findings between medical specialists from different sectors who are involved in a patient's care (GPs 3, 8, 12, and 13; Students 1, 6, and 7).

For implementation in Germany, *reliabletechnical conditions* were requested: the participants insisted on the security (GPs 3, 8, and 12-14; Students 1, 4-7, 8, and 10) and reliability (GPs 2, 8, and 14; Students 1, 4, 6, 7, 9, and 10) of a future system. Furthermore, participants suggested a translation program for medical terms to provide patients with easily comprehensible translations of medical jargon (GPs 3 and 8; Students 5 and 6). A strong emphasis, voiced by the GPs, was put on the availability of a "black box" within the system that enables them to keep additional personal notes, that go beyond clinical data, private (GPs 2, 8, and 12-14). Referring to the *participants' consent*, the students advocated for the patients' informed consent (Students 1, 5-7, 9, and 10), while the GPs indicated their own approval as essential (GPs 2, 11, and 12). Advocating for a comprehensive change of systems, few students proposed an obligatory implementation (Students 7 and 10), while GPs emphasized that this would lead to strong resistance (GPs 2 and 11). Therefore, the participants demanded the *GPs'involvement* in the development of the implementation project; for instance, providing reimbursement for participation (GP 2; Students 6, 7, and 10) and incorporating the GPs' demands (GP 2; Student 1) were considered mandatory.

Discussion

Principal Findings

The aim of this study was to explore GPs' and advanced medical students' perspectives and attitudes toward open health records. All barriers found in this study were reported by prior studies as well when addressing the general introduction of electronic health records [35,36] and when investigating physicians' perceptions on open notes implementations [17-20,23]. Although the reluctance of physicians is a frequently reported barrier, evaluation studies of former implementation projects showed that the physicians' initial concerns diminished after participating in pilot projects [2,19-21,37]. Also, the GPs' concern of an increased time effort has been disproven in the past [4]. The potential advantages discovered in this study were correspondingly reported when exploring physicians' expectations before participation [17-20,23] and when investigating effects of giving patients access to records [2,4]. Although advantages were confirmed and barriers were overcome in former studies with PEHRs in Germany [12-15], this study found that the GPs' perspectives on open records were characterized by hesitation rather than by optimism.

Findings of this study indicate that the GPs' professional self-conception as an underlying attitude can obstruct their approval for open records. GPs repeatedly emphasized their perception of professional values being threatened by opening records. Furthermore, the medical record was repeatedly referred to as belonging to the GPs rather than as the patients' property. Affirming previous findings [23], physicians strongly advocated for keeping the patient record within the professional group of medical doctors. When GPs were open toward sharing parts of the record, they primarily referred to the patients' option of requesting printouts instead of accessing them directly. In

contrast to this, patients in Germany are entitled by law to get access to their medical records [11], and former research such as the open notes studies [3] or research on PEHRs in Germany [20] has shown that patients indeed want to access their records. According to the student participants in this study, having to ask for printouts is, however, perceived as a barrier for patients, which was also found in previous research [16,19].

Although some GPs considered diagnoses or test results to be objective and would, therefore, give patients access to these, all of them strongly refused to disclose additional notes they take for their eyes only. This corresponds to prior research [2,21], which found that physicians were reluctant when they were asked to share their notes with patients. When GPs referred to the records as their property, a paternalistic attitude became apparent, which might be influenced by the German health care environment in which patient-centered concepts still remain an exception in routine care, even though they are considered beneficial [10].

The medical students' experiences with GPs confirmed the professional self-conception as a determining factor: they highlighted that the work of GPs was especially characterized by autonomy and freedom from external control, and they empathized with the GPs about their perceived loss of these values. However, the students' aspiration for enabling shared decision making through open notes became apparent: they saw the concept as a way to improve their own professional behavior and achieve optimized care for patients, and they emphasized that the advantages would outweigh the effort of overcoming barriers. Although they agreed that GPs have advanced knowledge, they advocated for reducing the asymmetry of knowledge and information between GPs and patients. While there is a shortage of research on medical students' perspectives on open notes, the positive attitude toward patient empowerment has been reported before [38].

The GPs' demanding attitude of acting as autonomous, self-controlled, and knowledgeable professionals and the medical students' striving for engaging patients through open records show a strong contrast. According to the GPs, this divergence might stem from the students' lack of practical experiences or even generational differences. It was reported before that professional values are developed and shaped by the social setting in which first practical experiences are gained during and after medical training [25,26,39]. Furthermore, research indicates that students of the current generation are generally open to using digital technology for their own health-related matters [40]. However, whether these are the main reasons for the students' evident optimism on open records remained unclear. The students indicated that the GPs' hesitance was caused by their desire for professional autonomy and their reluctance to change, which appeared to originate in the aspiration for maintaining their professional values. Some of the GPs' rather paternalistic perspectives correspond to the "doctor knows best" literature: prior research found that doctors, as well as patients, had difficulties in putting a less paternalistic way of communicating into practice and move toward shared decision making in routine care [41]. A systematic review on health care providers' perspectives on shared decision making showed that a lack of agreement with the concept was one of the main barriers for its implementation [42]. Even though the shift from paternalistic to participatory medicine gained momentum in the past decades [32], the physicians' professional self-conception still seemed to correspond to the traits discussed by Freidson [25,26]. While these studies support some of the current findings, there is still a lack of studies on physicians' professional self-conception. Besides the fundamental research on medical professions [25,26,31], no recent studies were identifiable. Although few studies found that physicians perceived a loss of autonomy when patients became more knowledgeable [43] or addressed the issue of merging the physicians' aspiration for autonomy with the concept of informed decision making [44], research on GPs' professional values and their compatibility with open health records is still pending. Even though identified conditions for an implementation of open records were reported previously [45-47], considering the physicians' attitudes based on their professional self-conception has not yet been researched.

Strengths and Limitations

This study focused on the underlying attitude of GPs and medical students toward the concept of sharing medical records with patients in German general practices. In contrast to previous studies, which mostly consisted of describing implementation barriers and enablers, this study provided a perspective beyond these already-known aspects as the first of its kind. The qualitative design allowed an in-depth view on the GPs' professional self-conception, which influenced their approval for open records. This focus highlighted a previously unaccounted fundamental barrier for the introduction of open records in the German context. Furthermore, this study incorporated a balanced sample of both GPs and advanced medical students. By providing an internal and external perspective by GPs and medical students, the findings were enriched and strengthened. Moreover, structural variance was accomplished through a balanced distribution in age and gender.

Some limitations must be acknowledged. In this study, only the Rhine-Neckar region in Germany as one geographic area was focused on. Specific national and regional factors might have influenced the results. By focusing on general practices, only one medical specialty was addressed. Both considerations might limit a general transfer of findings. The recruitment of medical students was facilitated through the use of a gatekeeper. Therefore, the sample might represent a positive selection of medical students as well as of GPs who might have participated due to their general interest in open records. Therefore, results must be interpreted with caution. Even though data saturation was reached, a higher number of participants could have led to more diverse results. All quotes were translated from German into English with due diligence. However, it is possible that fine linguistic characteristics in the translated quotes differ from the original German quotes. Furthermore, although different perspectives were ensured by discussing the study in a qualitative research colloquium, the interviews and analyses were only carried out by one researcher.

Conclusions

Giving patients access to their medical records can increase transparency in health care. Compatibility with physicians'

professional values and their acceptance is crucial for a successful potential implementation of open health record concepts in Germany. The medical students' commitment to engaging patients and accomplishing shared decision making provides an optimistic view. However, further research and broad support from decision makers is necessary.

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Authors' Contributions

JM drafted this manuscript as an essential part of her graduating thesis in the master's program of Health Services Research and Implementation Science at the University of Heidelberg, Germany. RPD was the primary supervisor of the thesis. JM, CU, and RPD designed this study. JM analyzed all generated data. CU and RPD provided methodological guidance throughout the study. JM, CU, and RPD all equally contributed to the revision of the manuscript, and all authors approved of the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Translated interview guide.
[PDF File (Adobe PDF File), 111 KB - jopm_v12i4e19093_app1.pdf]

Multimedia Appendix 2
Translated participant questionnaires.
[PDF File (Adobe PDF File), 84 KB - jopm_v12i4e19093_app2.pdf]

Multimedia Appendix 3
Definition of themes.
[PDF File (Adobe PDF File), 143 KB - jopm_v12i4e19093_app3.pdf]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Studies
GP: general practitioner
PEHR: personal electronic health record
TP: transcript position

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Original Paper

Persons Living With Primary Immunodeficiency Act as Citizen Scientists and Launch Prospective Cohort Body Temperature Study

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Abstract

Background: Although fever is considered a sign of infection, many individuals with primary immunodeficiency (PI) anecdotally report a lower-than-normal average body temperature on online forums sponsored by the Immune Deficiency Foundation (IDF). There is limited knowledge about the average body temperature and fever response in PI.

Objective: This study aims to compare median body temperatures between adults with and without PI diagnoses living in the same household and to engage individuals living with PI throughout the research process.

Methods: Patients with PI designed and launched a prospective cohort comparison study as citizen scientists. A multidisciplinary team designed and implemented a patient-informed study with continuous patient-driven input. Median body temperatures were compared between the 2 cohorts using the Mann-Whitney test with Bonferroni correction. The IDF conducted a post-study patient experience survey.

Results: Data from 254 households were analyzed (254/350, 72.6% participation rate). The PI population was predominantly female (218/254, 85.8%), White (248/254, 97.6%), and with a median age of 49 years. The non-PI population was largely male (170/254, 66.9%), White (236/254, 92.9%), and with a median age of 53 years. Common variable immunodeficiency was the most common PI diagnosis (190/254, 74.8%). Of the 254 individuals with PI, 123 (48.4%) reported a lower-than-normal nonsick body temperature, whereas 108 (42.5%) reported a normal (between 97°F and 99°F) nonsick body temperature. Among individuals with PI, when infected, 67.7% (172/254) reported the absence of fever, whereas 19.7% (50/254) reported a normal fever response. The recorded median body temperature was minimally but statistically significantly higher for patients with PI in the morning. Although 22.4% (57/254) of patients with PI self-reported illness, a fever of 100.4°F or higher was uncommon; 77.2% (196/254) had a normal temperature (between 97°F and 99°F), and 16.2% (41/254) had a lower-than-normal temperature (between 95.0°F and 96.9°F) when sick. For these sick patients with PI, the median body temperature was minimally but statistically significantly higher for patients in the morning and early evening. Overall, 90.9% (231/254) of participants would be very likely to participate in future IDF studies, although 94.1% (239/254) participants had never taken part in previous studies.

Conclusions: To our knowledge, this is the first study to evaluate average body temperature in individuals with PI. Although there were small statistically significant differences in body temperatures between PI and non-PI subjects, the clinical significance is unclear and should be interpreted with caution, given the methodological issues associated with our small convenience sample

and study design. As PIs are heterogeneous, more research is needed about how the fever response differs among diverse PIs compared with healthy controls. This study highlights that individuals with PI are knowledgeable about their health and can offer unique insights and direction to researchers and clinicians.

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KEYWORDS

fever; temperature; primary immunodeficiency

Introduction

Background

Primary immunodeficiency (PI) diseases represent a class of approximately 450 rare, genetic, and chronic disorders in which there is a defect in the human immune system [1]. To function properly, an immune system must detect and protect against a wide variety of pathogens. It must distinguish between foreign pathogens and their own cells. When any component is absent or dysfunctional, the result is a susceptibility to severe, persistent, unusual, and recurrent infections [1,2].

Normal body temperature is considered an oral measurement of approximately 98.6°F (37°C). Fluctuations in body temperature of 1°F (0.6°C) are known to occur throughout the day depending on the activity level and the time of day. This normal temperature was established in the 19th century; however, more recent studies suggest a lower body temperature [3]. Fever is a proinflammatory response that involves cytokine release, which may include tumor necrosis factor and interleukin-1 [4]. Fever is considered the immune system's response to pathogens to make the body a less favorable environment for infection.

At present, there is a dearth of literature on the average body temperature in persons with PI, and more information on the fever response in PI is needed. Fever is often considered the first sign of infection. Some, but not all, patients with PI can be deficient in generating cytokine responses that may also contribute to pyrogen release and fever response [5]. In PI, a patient may not receive critical antibiotics if a fever is missed; thus, it is essential to understand if a muted fever response exists. Missing an infection in PI may lead to delayed diagnosis or treatment, which can lead to decreased quality of life as well as increased morbidity and mortality for patients [2]. Moreover, it is unclear if and how different types of PI may impact a patient's ability to mount a fever response and baseline thermoregulation. As PIs are heterogeneous and involve different arms of the immune system, the ability of patients with PI to mount a fever response may partly depend on the underlying condition [5]. For example, patients with PI with autoinflammatory conditions, such as Familial Mediterranean Fever or familial cold autoinflammatory syndrome, are characterized by recurrent fever, whereas patients with toll-like receptor defects, such as interleukin-1 receptor-associated kinase 4 deficiency, fail to mount fever in the presence of pyogenic infections [1,5]. More information is needed to understand if individuals with PI have different body temperatures at baseline and when sick so that appropriate medical treatment can be provided in a timely manner.

There has been a recent expansion in the degree of patient involvement occurring in research studies. A recent review of 126 articles by the Patient-Centered Outcomes Research Institute in 2019 highlights how patients are being engaged as early as the study design phase in selecting study outcomes and tailoring interventions to meet patients' needs [6]. Valuable contributions from patients have been reported in research feasibility, acceptability, rigor, and relevance by aligning the needs and concerns of patients and their clinicians. Research is deemed more meaningful for patients, with less burden and with greater adherence to interventions [6]. Efforts to involve patients in the research process are thus considered here.

Objectives

The purpose of this study is to assess whether patients with PI exhibit lower-than-normal average body temperature compared with individuals without PI. The primary objective is to measure and compare resting body temperature at select time intervals in a cohort of individuals living with PI and unaffected controls who are adult family members without PI living in the same household. The secondary goal is to engage individuals who are affected by PI, including patients, family members, and caregivers throughout the research process as citizen scientists.

Methods

Overview

A prospective cohort comparison study was designed to compare 2 populations. This study was designed as a patient-stakeholder collaboration and supported by the Immune Deficiency Foundation (IDF) with oversight by the Advarra institutional review board. No outside funding was received. IDF is composed of patients with PI, along with their family, supporters, and health care professionals who work with the PI community. These stakeholders are involved in every facet of IDF and comprise the leadership, staff, board of trustees, and volunteers that enable the organization to serve the PI community in a comprehensive manner.

IDF improves the diagnosis, treatment, and quality of life of people affected by PI by fostering a community empowered by advocacy, education, and research. IDF provides accurate and timely information for patients and families living with PI and offers valuable resources. IDF sponsors education and outreach efforts for the medical community. In addition, IDF promotes, participates, and conducts research that has helped characterize PI and substantially improve treatment options. Patient needs are addressed by IDF through public policy programs and advocacy at state and federal levels.

Objectives

The purpose of this study is to assess whether patients with PI exhibit a lower-than-normal average body temperature compared with non-PI individuals. This study tested the hypothesis that there is no difference in mean body temperature between adults diagnosed with or without PI. The primary objective is to measure and compare resting body temperature at select time intervals in a cohort of individuals living with PI and unaffected controls who are non-PI adult family members living in the same household. All subjects were given the same questionnaires, thermometers, instructions, and schedule for taking their temperatures. The secondary objective is to engage individuals living with PI throughout the entire research process as citizen scientists.

Patient-Led Approach

This study was a patient-driven study with the participation of patients with PI from its initial inception to completion as citizen scientists. In 2017, several members of the IDF and participants in IDF online forums, such as IDF Friends and PI CONNECT, began a grassroots effort to address concerns of individuals living with PI. Although fever is considered an initial sign of infection, many individuals with PI have been reported to have a lower-than-normal average body temperature. On these online forums, patients with PI reported a temperature less than 100.4°F even when other indications of infection were present. Patients with PI expressed an interest in exploring this systematically through a patient-designed research project.

With these initial concerns, IDF participants subsequently approached IDF staff and leadership, who, in turn, contacted members of the IDF medical advisory board and PI researchers. From an online forum, a focus group at the IDF annual meeting was established to discuss concerns of patients with PI. This focus group morphed into a task force that inspired a patient-informed study. Several conference calls followed among patients with PI, IDF staff and leadership, PI clinicians, and PI researchers who expressed interest in designing and implementing a collaborative research project to assess body temperature in patients with PI. The proposed study design underwent several revisions, and a protocol was eventually agreed upon by all key stakeholders and PI representatives. Patient advocates from IDF were on the research team, which included active roles in project design, management, data collection, data analysis, and data reporting through dissemination of findings and manuscript preparation. Clinicians and researchers acted as content experts and advisors to provide input on best practices and rigorous study design, but all stakeholders agreed that the project would defer to the wishes of the patients with PI who were the ultimate drivers of the entire endeavor.

Patients with PI were involved at every step of the process. During study design, patients with PI voiced their interest among focus groups in studying differences in body temperature among healthy participants and participants with PI, which became the aim of the study. Patients with PI shared social media posts and newsletter announcements in subject recruitment and were the key participants in data collection. The materials in the study packets were generated, assembled, and mailed to participants by the IDF staff and volunteers, many of whom live with PI themselves. The study team, IDF staff, and volunteers collaboratively performed data entry, analysis, interpretation, results dissemination, and manuscript preparation. Preliminary research findings were shared with the PI community at IDF conferences and on the web as they became available.

Recruitment

A total of 350 adults with PI were recruited from IDF rosters, and 1 adult household member without PI was also recruited per patient to serve as a control. The IDF recruited participants through direct email, newsletter announcements, and social media posts among patients with PI. All patients identified as adults aged older than 20 years in the IDF databases received a recruitment email explaining the study and linking participants to a screening questionnaire. A promotional flyer is attached in the supplementary material (Multimedia Appendix 1).

Enrollment

The initial screening questionnaire, which was used by the IDF for subject selection, surveyed basic demographic and medical information from participants with and without PI. Inclusion criteria included adults with PI aged between 21 and 70 years, who were not acutely ill at study start and who had a willing member of his or her household without PI to serve as a comparator. Exclusion criteria included those aged below 21 years or above 70 years and those unable to take an oral temperature. Informed consent was obtained electronically from both household members of eligible participants before study enrollment. Participants who returned their signed data packets received a US $20 Amazon coupon per household as an incentive.

Interventions

Enrolled subjects received a welcome packet with instructions, a thermometer, a data collection booklet, and return envelopes for their booklets. All participants received and used McKesson digital oral thermometers (Model 01-413BGM) to record temperatures 3 times a day for 5 consecutive days for subject convenience. The 5-day study period was chosen based on input from IDF members who believed that this time frame would be acceptable and minimally obtrusive to the community of patients with PI and family members. Each participant took his or her own temperature on arising in the morning, in the early evening, and at bedtime, at approximately the same time of day for each of the 5 days. They recorded their temperatures in a data collection booklet that was returned to the IDF at the study conclusion. Detailed instructions with pictures were provided. Participants were instructed not to drink any hot or cold fluids, smoke, eat, drink, exercise, or perform other activities that may raise or lower temperature readings at least 30 min before taking their temperature. Subjects recorded if an infection was present daily. Of note, researchers could not verify this self-reported status of infection or no infection because of the self-report nature of the study. No collateral information (such as doctor's notes or laboratory testing) to verify this self-report was collected or analyzed in the study. After the study concluded, participants received a follow-up questionnaire to assess their overall study experience as well as their willingness to

participate in similar patient-driven research in the future with the IDF.

Statistical Analysis

Descriptive statistics were calculated. Hypothermic temperatures below 95.0°F were excluded from the analysis. The median body temperatures were compared between the 2 cohorts using the Mann-Whitney test. We also performed a subgroup analysis comparing the recorded temperatures of patients with PI and controls who self-reported being ill for each time point. Prism 6.0 (GraphPad Software) was used to perform the statistical analyses. Statistical significance was set at a *P* value <.05, and Bonferroni correction for multiple comparisons was applied.

Results

Participants

Of the 350 eligible households that were invited, 254 participated in the study (254/350, 72.6% participation rate). The PI and non-PI cohort demographics are summarized in Table 1. The PI population was predominantly female (218/254, 85.8%), White (248/254, 97.6%), and with a median age of 49 years. These participant demographics are similar to those of other studies from IDF [7]. The non-PI population was largely male (170/254, 66.9%), White (236/254, 92.9%), and with a median age of 53 years.

Table 1. Participant demographics.

Demographic	PI[a]	Non-PI
Age (years), median	49	53
Age group (PI only; years), n		
21-34	53	37
35-44	52	43
45-54	61	64
55-70	88	110
Sex, n		
Male	35	170
Female	218	83
Transgender	1	1
Race and ethnicity, n		
American Indian or Alaskan Native	2	1
Asian or Pacific Islander	0	4
Black or African American	1	1
Hispanic or Latino	5	10
White, non-Hispanic	248	236
Two or more races	5	4

[a]PI: primary immunodeficiency.

PI Diagnoses

The diagnoses of the PI cohort are summarized in Table 2. Humoral immunodeficiencies predominated with common variable immunodeficiency being the most prevalent (190/254, 74.8%). Of the total 254 cases, nonhumoral defects comprised 3 (1.2%) of the diagnoses, including chronic granulomatous disease 1 (0.4%), combined immunodeficiency 1 (0.4%), and complement deficiency 1 (0.4%).

Table 2. Primary immunodeficiency diagnoses.

Primary immunodeficiency diagnosis	Participants (n=254), n (%)
Common variable immunodeficiency	190 (74.8)
Hypogammaglobulinemia	32 (12.6)
Immunoglobulin G subclass deficiency	12 (4.7)
Selective Immunoglobulin A deficiency	8 (3.1)
Specific antibody deficiency	8 (3.1)
Agammaglobulinemia	1 (0.4)
Chronic granulomatous disease	1 (0.4)
Combined immunodeficiency	1 (0.4)
Complement deficiency	1 (0.4)

Body Temperature Perceptions

We asked 254 PI respondents about their body temperature perceptions (Table 3). Of the 254 respondents, 123 (48.4%) PI respondents reported a lower-than-normal nonsick body temperature, whereas 108 (42.5%) reported a normal (between 97°F and 99°F) nonsick body temperature. When infected, 67.7% (172/254) of the PI respondents reported absence of fever with infection, whereas 19.7% (50/254) reported a normal fever response with infection. As summarized in Table 3, most participants with PI reported an abnormal nonsick body temperature when well and an absence of fever with infection when sick. These findings underscore the need to better define body temperature in patients with PI.

Table 3. Body temperature perceptions.

Body temperature perceptions	Frequency, n (%)
Well condition: Which of the following statements is closest to your experiences with your day-to-day, nonsick, body temperature?	
My nonsick body temperature is normal (between 97°F-99°F)	108 (42.5)
My nonsick body temperature is lower than normal (between 95.0°F-96.9°F)	123 (48.4)
My nonsick body temperature is higher than normal (≥99.1°F)	2 (0.8)
Not sure/don’t know	21 (8.3)
Sick condition: When you have an infection, which of the statements below is closest to your experiences?	
I have a normal fever response when I get an infection	50 (19.7)
I do not get a fever when I have an infection	172 (67.7)
I get a very high fever when I have an infection	10 (3.9)
Not sure/don’t know	22 (8.7)

Body Temperature Measurements

The next step of the study focused on measuring the body temperatures of participants with PI to determine whether there were any cohort differences at baseline. During the objective measurement phase of the study, the median body temperatures for each time point on all 5 days and for the week were recorded and are summarized in Table 4.

Table 4. Objective median body temperatures (°F).

Time of day	PI[a], °F (range)	Non-PI, °F (range)	*P* value
Daily temperatures			
Monday morning	97.5 (95.2-100.1)	97.2 (95.2-99.4)	.03
Monday early evening	97.8 (95.0-99.6)	97.8 (95.1-99.3)	.81
Monday bedtime	97.6 (95.2-100.4)	97.5 (95.2-99.8)	.28
Tuesday morning	97.4 (95.3-99.3)	97.2 (95.4-98.9)	.002[b]
Tuesday early evening	97.8 (95.0-99.8)	97.7 (95.4-99.8)	.06
Tuesday bedtime	97.5 (95.4-100.5)	97.4 (95.1-100.7)	.65
Wednesday morning	97.5 (95.0-99.6)	97.2 (95.0-99.6)	.001[b]
Wednesday early evening	97.8 (95.3-99.7)	97.7 (95.1-99.8)	.40
Wednesday bedtime	97.5 (95.4-99.6)	97.4 (95.0-99.6)	.67
Thursday morning	97.4 (95.0-99.5)	97.2 (95.1-99.0)	.06
Thursday early evening	97.8 (95.0-99.6)	97.7 (95.0-100.5)	.14
Thursday bedtime	97.4 (95.7-99.5)	97.4 (95.0-100.6)	.32
Friday morning	97.4 (95.2-99.5)	97.1 (95.1-101.0)	.001[b]
Friday early evening	97.7 (95.0-99.9)	97.7 (95.5-101.2)	.71
Friday bedtime	97.4 (95.1-99.9)	97.5 (95.0-100.9)	.91
Weekly temperatures			
(Monday to Friday) morning	97.4 (95.0-100.1)	97.2 (95.0-101.0)	<.001[c]
Early evening	97.8 (95.0-99.9)	97.7 (95.0-101.2)	.05
Bedtime	97.5 (95.1-100.5)	97.4 (95.0-100.9)	.37

[a]PI: primary immunodeficiency.

[b]Statistically significant after Bonferroni correction of *P* value (0.05/15=0.003).

[c]Statistically significant after Bonferroni correction of *P* value (0.05/3=0.017).

Group Comparisons

Figure 1 graphically shows that compared with controls without PI, individuals with PI had minimally higher median body temperatures in the morning, but not early evening or bedtime, on 3 of 5 days (Tuesday, Wednesday, and Friday) in the top left panel. In the top right panel, Figure 1 further demonstrates that PI subjects had a minimally higher median temperature in the morning during the study.

To examine if these differences in body temperature varied with infection, we compared the temperatures of each cohort during the time of a self-reported illness. Respondents were asked if they perceived themselves to be sick with an infection during each day of the study, but the study design did not permit us to corroborate respondent self-report with an objective assessment such as laboratory testing or physician examination. To assess how subjects' self-reported perception of being sick matched with their recorded temperatures, we tabulated their subjective responses with their recorded temperatures in Tables 5 and 6 for subjects with PI and no PI, respectively. Table 5 shows that 22.4% (range 20.9%-23.6%) of PI subjects self-reported being sick at some point during the study period and that fever with temperature ≥100.4°F only occurred twice. Moreover, 77.2% (range 64.4%-87.9%) reported having a normal temperature (between 97°F and 99°F), whereas 16.2% (range 6.8%-28.8%) reported having a lower-than-normal temperature (between 95.0°F and 96.9°F) when sick.

Figure 1. Objective median body temperatures in patients with PI and control nonprimary immunodeficiency household members. Part A depicts all daily objective body temperatures. Statistically significant *P* value (.003) after Bonferroni correction. Part B depicts all weekly objective body temperatures. Statistically significant *P* value (.017) after Bonferroni correction. Part C depicts all daily objective body temperatures when they perceive an infection. Statistically significant *P* value (.003) after Bonferroni correction. Part D depicts all weekly objective body temperatures when sick. Statistically significant *P* value (.017) after Bonferroni correction. Con: control; PI: primary immunodeficiency.

Figure 1A

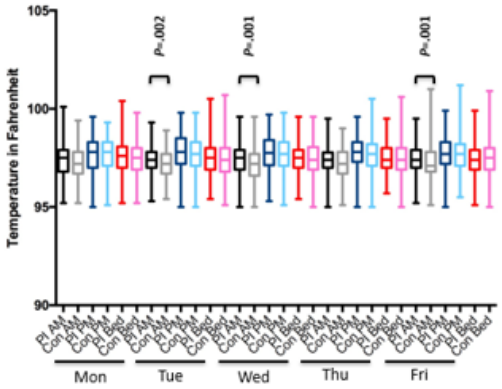

Figure 1B

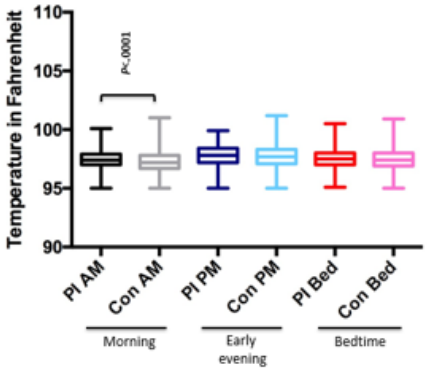

Figure 1C

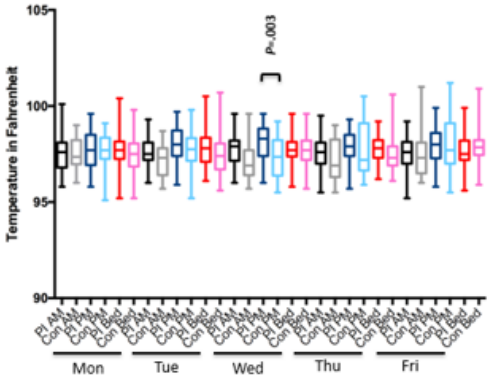

Figure 1D

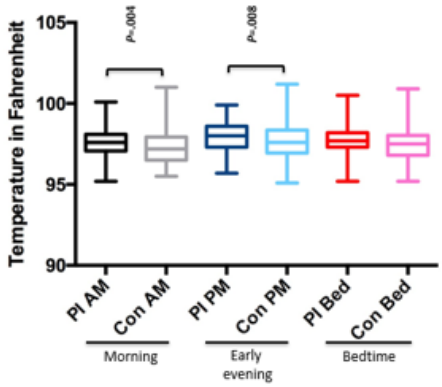

Table 5. Frequency of reported body temperature when sick among primary immunodeficiency subjects.

Time of day	Primary immunodeficiency respondents		Temperature (°F), n (%)				
	Number of respondents	Percentage of respondents who reported being sick, n (%)[a]	≥100.4	99.1-100.3	97.0-99.0	95.0-96.9	Did not record
Monday morning	59	59 (23.2)	0 (0)	2 (3.4)	40 (67.8)	17 (28.8)	0 (0)
Monday early evening	59	59 (23.2)	0 (0)	6 (10.2)	38 (64.4)	15 (25.4)	0 (0)
Monday bedtime	59	56 (22.0)	1 (1.7)	1 (1.7)	50 (84.7)	4 (6.8)	0 (0)
Tuesday morning	55	55 (21.7)	0 (0)	2 (3.6)	44 (80.0)	9 (16.4)	0 (0)
Tuesday early evening	55	54 (21.3)	0 (0)	5 (9.3)	42 (77.8)	7 (13.0)	1 (1.9)
Tuesday bedtime	55	53 (20.9)	1 (1.9)	1 (1.9)	39 (73.6)	12 (22.6)	2 (3.8)
Wednesday morning	60	60 (23.6)	0 (0)	3 (5.0)	48 (80.0)	9 (15.0)	0 (0)
Wednesday early evening	60	58 (22.8)	0 (0)	8 (13.8)	43 (74.1)	7 (12.1)	2 (3.4)
Wednesday bedtime	60	58 (22.8)	0 (0)	2 (3.4)	48 (82.8)	8 (13.8)	2 (3.4)
Thursday morning	58	58 (22.8)	0 (0)	2 (3.4)	43 (74.1)	13 (22.4)	0 (0)
Thursday early evening	58	55 (21.7)	0 (0)	3 (5.5)	48 (87.3)	4 (7.3)	3 (5.5)
Thursday bedtime	58	58 (22.8)	0 (0)	1 (1.7)	51 (87.9)	6 (10.3)	0 (0)
Friday morning	58	58 (22.8)	0 (0)	1 (1.7)	45 (77.6)	11 (19.0)	1 (1.7)
Friday early evening	58	57 (22.4)	0 (0)	5 (8.8)	42 (73.7)	8 (14.0)	2 (3.5)
Friday bedtime	58	55 (21.7)	0 (0)	4 (7.3)	40 (72.7)	9 (16.4)	4 (7.3)
Mean[b] (%)	N/A[c]	22.4	0.2	5.4	77.2	16.2	2.0

[a]Percent sick is based on 254 respondents. For each temperature, percentage is based on the number of sick.

[b]Means are the average of all percentages per column.

[c]N/A: not applicable.

Table 6 shows that 6.3% (range 3.9%-8.7%) of subjects without PI self-reported being sick at some point during the study period and that fever only occurred 7 times. Furthermore, 60.9% (range 42.1%-80.0%) reported having a normal temperature, whereas 30.8% (range 10.0%-53.8%) reported having a lower-than-normal temperature when sick.

Table 6. Frequency of reported body temperature when sick among subjects with no primary immunodeficiency.

Time of day	Respondents with no primary immunodeficiency		Temperature (°F), n (%)				
	Number of respondents	Percentage of respondents who reported being sick, n (%)[a]	≥100.4	99.1-100.3	97.0-99.0	95.0-96.9	Did not record
Monday morning	17	17 (6.7)	0 (0)	0 (0)	13 (76.5)	4 (23.5)	0 (0)
Monday early evening	17	17 (6.7)	0 (0)	1 (6.9)	13 (76.5)	3 (17.6)	0 (0)
Monday bedtime	17	17 (6.7)	0 (0)	1 (5.9)	11 (64.7)	5 (29.4)	0 (0)
Tuesday morning	22	22 (8.7)	0 (0)	0 (0)	13 (59.1)	9 (40.9)	0 (0)
Tuesday early evening	22	22 (8.7)	0 (0)	2 (9.1)	16 (72.7)	4 (18.2)	0 (0)
Tuesday bedtime	22	21 (8.3)	1 (4.8)	0 (0)	11 (52.4)	9 (42.9)	1 (4.8)
Wednesday morning	19	19 (7.5)	0 (0)	1 (5.3)	8 (42.1)	10 (52.6)	0 (0)
Wednesday early evening	19	18 (7.1)	0 (0)	1 (5.6)	10 (55.6)	7 (38.9)	1 (5.6)
Wednesday bedtime	19	19 (7.5)	0 (0)	2 (10.5)	13 (68.4)	4 (21.1)	0 (0)
Thursday morning	13	13 (5.1)	0 (0)	0 (0)	6 (46.2)	7 (53.8)	0 (0)
Thursday early evening	13	13 (5.1)	1 (7.7)	2 (15.4)	6 (46.2)	4 (30.8)	0 (0)
Thursday bedtime	13	11 (4.3)	1 (9.1)	0 (0)	7 (63.6)	3 (27.3)	2 (18.2)
Friday morning	11	11 (4.3)	1 (9.1)	0 (0)	6 (54.5)	4 (36.4)	0 (0)
Friday early evening	11	11 (4.3)	2 (18.2)	1 (9.1)	6 (54.5)	2 (18.2)	0 (0)
Friday bedtime	11	10 (3.9)	1 (10.0)	0 (0)	8 (80.0)	1 (10.0)	0 (0)
Mean[b] (%)	N/A[c]	6.3	3.9	4.5	60.9	30.8	1.9

[a]Percent sick is based on 254 respondents. For each temperature, percentage is based on the number that is sick.

[b]Means are the average of all percentages per column.

[c]N/A: not applicable.

For those patients and controls who reported being sick, the median temperatures at each time of day are tabulated in Table 7.

Figure 1 shows that individuals with PI who self-reported being sick had minimally higher median body temperatures in the early evening midweek on Wednesday in the bottom left panel. The bottom right panel in Figure 1 further demonstrates that the same PI subjects had minimally higher median temperatures in the morning and early evening in the bottom panel during the study. Overall, we found the majority of participants, regardless of PI status, had normal measured temperatures during times of reported infection, and that fevers were rare.

Table 7. Objective median body temperatures (°F) when sick.

Time of day	PI[a], °F (range)	Non-PI, °F (range)	*P* value
Daily temperatures			
Monday morning	97.6 (95.8-100.1)	97.3 (96.0-99.0)	.99
Monday early evening	97.7 (95.8-99.6)	97.7 (95.1-99.1)	.87
Monday bedtime	97.7 (95.2-100.4)	97.5 (95.2-99.8)	.17
Tuesday morning	97.5 (96.0-99.3)	97.3 (95.7-98.7)	.09
Tuesday early evening	98.0 (95.9-99.7)	97.8 (95.2-99.8)	.14
Tuesday bedtime	97.8 (96.1-100.5)	97.4 (95.6-100.7)	.11
Wednesday morning	97.9 (96.0-99.6)	96.9 (95.7-99.6)	.01
Wednesday early evening	98.3 (96.0-99.6)	97.4 (95.5-99.2)	.003[b]
Wednesday bedtime	97.7 (95.8-99.6)	97.7 (95.7-99.6)	.54
Thursday morning	97.6 (95.5-99.5)	96.9 (95.5-99.0)	.29
Thursday early evening	97.9 (95.7-99.3)	97.2 (95.9-100.5)	.18
Thursday bedtime	97.8 (96.2-99.2)	97.3 (96.1-100.6)	.10
Friday morning	97.6 (95.2-99.2)	97.3 (96.0-101.0)	.48
Friday early evening	98.0 (95.8-99.9)	97.7 (95.5-101.2)	.92
Friday bedtime	97.5 (95.6-99.9)	97.9 (95.9-100.9)	.39
Weekly temperatures			
(Monday-Friday) morning	97.6 (95.2-100.1)	97.2 (95.5-101.0)	.004[c]
Early evening	98.0 (95.7-99.9)	97.6 (95.1-101.2)	.008[c]
Bedtime	97.7 (95.2-100.5)	97.5 (95.2-100.9)	.04

[a]PI: primary immunodeficiency.

[b]Statistically significant with Bonferroni adjusted *P* value (0.05/15=.003).

[c]Statistically significant with Bonferroni adjusted *P* value (0.05/3=.017).

Poststudy Patient Experience Survey

The research team developed a postassessment survey to obtain participant feedback because this was the first time that IDF used such a citizen science approach to research. A total of 67 participants (67/254, 26.4% participation rate) completed the poststudy assessment. Of the 67 participants, a total of 65 (97%) respondents were participants with PI. Overall, the respondents appeared to have a positive experience with this research endeavor: (1) 94% (63/67) reported that it would be *very likely* for them to read a summary report of the study when posted on IDF's website; (2) 81% (54/67) reported it would be *very likely* that they would read a published peer-reviewed article; and (3) 91% (61/67) indicated that it would also be *very likely* that they would participate in future IDF research studies, although 93% (62/67) of participants had never taken part in previous IDF research studies. Overall, participants were enthusiastic about the research process that was participant-driven at every step. Members of the PI community, including those not directly involved in the research, were very engaged when preliminary study results were presented at IDF meetings. Members of the research team and other key stakeholders anecdotally reported witnessing and participating in many interesting conversations about the findings at various IDF events and online forums. Highlighting the overwhelming positive response to the project and the expectation that this work would be shared outside the IDF community are among the driving forces behind publishing this manuscript.

Discussion

Principal Findings

Although discrepancies between subjective and objective core body temperatures in chronic disease have been reported previously, limited literature exists on average body temperature in persons with PI [3,8]. Hamilos et al [8] monitored continuous 24-hour body temperature recordings of 7 patients with chronic fatigue syndrome (CFS) and compared them against 3 sets of age-, sex-, and weight-matched cohorts (normal controls, subjects with seasonal allergy, and subjects with major depression). Despite frequent self-reports of subnormal body temperature and low-grade fever, CFS subjects were found to have normal core body temperatures [8]. To our knowledge, our study is the first to evaluate average body temperature in PI subjects, thus improving our understanding of another chronic disease and addressing an important knowledge gap.

Interestingly, our study did not corroborate the beliefs of patients with PI and their caregivers regarding their temperatures when ill and in their usual state of health. Many caregivers and persons

living with PI believe that patients with PI run lower-than-normal sick and nonsick temperatures. Of the 254 participants, 123 (48.4%) participants subjectively reported this, whereas 108 (42.5%) reported normal nonsick temperatures. Of the 254 participants, 172 (67.7%) respondents subjectively reported an absence of fever during infection, whereas 50 (19.7%) reported fever with infections. Our findings suggest that patients with PI appear to have minimally higher morning temperatures compared with controls even after adjusting for multiple comparisons [9]. However, these results need to be interpreted with caution, given our small sample size and methodological study design issues. Less than 25.0% of the subjects with PI self-reported being sick at some point during the study period. Of these, the majority (196/254, 77.2%) reported a normal temperature, (42/254, 16.4%) had a lower-than-normal temperature, and (1/254, 0.2%) had a fever. Less than 7.0% of the subjects with no PI self-reported being sick at some point during the study period. Of these, most (155/254, 60.9%) reported a normal temperature, whereas (78/254, 30.8%) had a lower-than-normal temperature and (10/254, 3.9%) had a fever. Our findings suggest that patients with PI may have minimally higher morning and early evening median temperatures compared with healthy controls when subjects self-report being sick. Such small differences fall within normal variation for daily temperatures and are likely not clinically meaningful.

Although we found statistically significant differences in body temperatures between subjects with PI and no PI when they self-reported being sick or healthy, the clinical significance of such small differences is unclear and should be interpreted cautiously. Previous studies have shown variations in thermoregulation among the general population. An observational cohort study of 35,488 patients (mean age 52.9 years, 64% women, 41% non-Whites) from a large academic hospital from 2009 to 2014 showed that of 243,506 outpatient temperature measurements, the mean temperature was 36.6°C (97.9°F) with a 95% CI of 35.7°C-37.3°C (96.3°F-99.1°F; [10]). Older individuals were the coolest (−0.021°C for every decade; P<.001), and African American women were warmer than White men (+0.052°C; P<.001). Several comorbidities were linked to lower temperatures, including hypothyroidism (−0.013°C; P=.01) as well as higher temperatures including cancer (+0.020; P<.001) and BMI (+0.002 per kg/m^2; P<.001). Measured factors explained only 8.2% of individual temperature variation, whereas unexplained temperature variation was a significant predictor of subsequent mortality: controlling for all measured factors, an increase of 0.149°C was linked to 8.4% higher 1-year mortality (P=.02; [10]). Possible explanations for higher median body temperatures in patients with PI, which should be considered in future studies, include differences in subclinical infection/inflammation, hormone levels, thyroid function, comorbidities including malignancy, dietary intake and activity level, and body composition.

As many of our subject with PI were women of childbearing age, future studies are needed to elucidate the potential roles of hormonal changes and the menstrual cycle on body temperature, given this major difference in sex between our study and control populations. A study of core temperatures in young, healthy women with regular menstrual cycles and baseline fluctuations of >0.5°C in basal core temperature during luteal and follicular phases revealed consistently higher temperatures in the luteal phase than in the follicular phase [11]. The small variation in temperature between PI and non-PI participants in this study may be related to hormonal effects causing fluctuating body temperatures in menstruating females, so future studies of body temperature differences should account for menstrual cycles, especially if large sex differences in study populations exist, as is the case in this study.

It is also possible that the fever response fundamentally differs between subjects with and without PI, and future studies are needed to elucidate the involved immunocytes and cytokine milieu of fever in patients with PI [12]. PIs are diverse, and the arms of the immune system that are affected in these heterogeneous conditions likely differentially impact thermoregulation and the ability to mount a fever response. Future studies are needed to assess whether this difference in fever response is a manifestation of immune dysregulation among patients with PI.

Study Strengths

Our study had several strengths, including the prospective study design, and continued collaboration from the community from initial inception to study completion. This commitment from the PI community enabled the study to be done in partnership with participants at all stages of the endeavor, which facilitated high participation and engagement. The experience of working with citizen scientists was positive for collaborators as well. There was a conscious decision by all stakeholders that we would always err on following the wishes of the participants who were the driving force behind the project. The innovative, patient-driven, and team-based approach to this study was well received by the PI community, as seen in the poststudy assessment as well as collaborators. The research team and the IDF staff will continue to build upon this experience by adopting this paradigm of actively engaging persons living with PI at all stages of research endeavors in future projects.

Limitations

However, we acknowledge that our study has several limitations, such as differences in household settings and individual differences in taking a temperature. As participants were not observed directly, we cannot exclude the possibility that temperatures may have been taken inconsistently or in slightly different household settings with different thermostat settings. Providing the same thermometer and instructions partially mitigates this concern. In addition, we acknowledge that our analyses do not control for daily medications (eg, antipyretics), activity, or subclinical illness symptoms. Notably, our study did not assess the impact of immunomodulator use, such as steroids or biologics, which can interfere with fever response. Infections were self-reported by patients and not verified by providers or objective collateral information, which limits data interpretation. A major limitation of this study is that infection was not defined explicitly to participants during the study period, which vastly limits the ability to draw definitive conclusions about body temperature differences during times of illness in this study. Because these limitations potentially seriously

compromise the scientific integrity and validity of our study, all stakeholders participated in extensive discussions with content experts in study design, statistics, and immunology, regarding these weaknesses during the inception and planning stages. Ultimately, stakeholders jointly decided to err on the side of following what patients with PI stated that they could and were willing to do for the study.

Our study was also not designed to assess the impact of the *wearing off effect* that some patients with humoral immunodeficiency on monthly intravenous immunoglobulin G (IgG) infusion can experience before their next dose [7,13,14]. The wearing off effect is associated with decreased treatment efficacy, increased infection susceptibility, and diminished quality of life. This effect should be considered since a 2003 IDF study consisting of 1186 subjects showed that 308 (25.96%) of patients with PI reported feeling wearing off occasionally, whereas 498 (41.99%) reported wearing off as a typical experience of their therapy. Patients experiencing a wearing off effect can benefit with more frequent dosing (every 3 vs 4 weeks) or with switching to a subcutaneous route [15]. Future studies are needed to determine how body temperature among patients with PI might be influenced by this phenomenon and whether the IgG replacement route plays a role.

In addition, our study used a convenience sample without randomization. We cannot exclude the possibility of participation bias among different types of patients with PI with respect to diagnosis or other demographic factors. Subjects were not well balanced in the type of PI or gender; thus, our findings need to be interpreted cautiously. However, as humoral immunodeficiencies account for most PIs, with common variable immune deficiency being the most common, it is not surprising that our cohort is skewed this way. Our study design cannot assess the potential effect of hormones, sex, or age on the outcomes of interest. Future studies specifically including men, children, young adults, and older adults with PI and appropriate controls that are matched by age and sex are needed.

Online forums pose unique challenges for patient-led studies. There is a unique non–face-to-face platform for interactions and the possibility of unpredictable security issues that may complicate informed consent. An interdisciplinary team, including team members with expertise in computing and ethics, may be important for troubleshooting such difficulties. Special considerations such as whether a forum should be facilitated or moderated, an informed consent process that is not done in person, language use, and data analysis are all factors considered in previous studies of online forums [16]. Considering how the start of this study began on an online forum, it is important to pay attention to these factors in future studies.

Poststudy Survey

Our poststudy questionnaire encouraged feedback from the PI community after study completion. An important caveat is that the questionnaire only had a 26.4% (67/254) participation rate. Nonetheless, this rate is comparable with that reported in other studies conducted by IDF. Although many respondents were first-time participants in IDF research, the patient experience was largely positive. Participants were engaged in the study, and 91% (61/67) reported that they would most likely participate in future IDF research studies. Most participants were also interested in reading study results, which we are enthusiastic to share. Closing the loop with a poststudy questionnaire highlights the patient-driven approach of this study and underscores the investment of the target population in research that directly benefits their community.

Conclusions

This study highlights that individuals with PI are knowledgeable about their conditions and can offer unique insights and direction to researchers. Similarly, this study also demonstrates that collaboration with patient advocacy groups may facilitate high participation among the target population, giving new meaning to the concept of patient-centered and patient-driven research for future studies. We acknowledge that our study has several methodological shortcomings and did not clearly resolve the original research question posed by the PI community. Nonetheless, this endeavor demonstrates that the PI community has the desire and ability to conceive, design, and implement citizen science when given the support to do so.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Promotional flyer for the Immune Deficiency Foundation fever study.
[DOCX File , 482 KB - jopm_v12i4e22297_app1.docx]

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Abbreviations

CFS: chronic fatigue syndrome
IDF: Immune Deficiency Foundation
PI: primary immunodeficiency

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Patient Perspectives

Does a Pandemic Preempt Participatory Medicine?

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Abstract

For those of us who believe deeply in a collaborative relationship between patients and doctors, the chaos created by the COVID-19 pandemic has brought an uncomfortable question to the fore: Is participatory medicine still relevant during a pandemic? Drawing liberally upon the Jewish tradition of Talmudic reasoning, I would like to offer 3 considered replies: "Yes," "no," and "it depends." Sometimes, patients may have no choice but to cede control to medical professionals, even though patients are still the experts on their own lives. Other times, the shared control of participatory medicine is both an ethical and clinical imperative. However, as the worldwide toll exacted by COVID-19 has made us grimly aware, no one is really in control. That is why, in these uncertain times, the path forward requires maintaining mutual trust between health care providers and patients, whatever the circumstances. After all, it is our bodies and our selves at stake.

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KEYWORDS

participatory medicine; COVID-19; pandemic; Fitbit; DETECT study, Body Politic; wearables; sensors; patient-generated health data; shared decision making

Consider the following scenario: you are at home with your significant other, and that low-grade fever you have been running is rising. You have also developed a persistent cough, and you are losing your sense of smell. In a panic, you phone your doctor, who tells you to go immediately to a special area set aside for patients with COVID-19 by your local hospital. He will call ahead.

"Thank you so much, doctor," you blurt out. Yet even in your dazed state, you know there are a few more questions you just have to ask.

"As an informed consumer," you begin, "I'm wondering if the hospital's online price list includes COVID-19 treatment costs." You add, "I also want to make sure the emergency room physicians understand that I expect to be a partner in the coproduction of my care [1]—you know, full access to my electronic health record, including clinical notes. I prefer an API (application programming interface) readable format [2], but I'm willing to accept a PDF emailed to me every evening."

Your significant other violently grabs the phone and starts apologizing profusely. "I'm really sorry," they tell the doctor. "That must be the fever talking. We're on our way to the hospital right now."

For those of us who believe deeply in a collaborative relationship between patients and doctors, the chaos created by the COVID-19 pandemic has brought an uncomfortable question to the fore: Is participatory medicine still relevant during a pandemic? Drawing liberally upon the Jewish tradition of Talmudic reasoning, I would like to offer 3 considered replies: "Yes," "no," and "it depends."

Let us start by expanding on the "no" answer. The term "participatory medicine" [3] contains 2 important assumptions. The first is that the patient and the patient's family (ie, a term used here to include all those the patient chooses to involve in care) are in a position to participate. The second assumption is that this participation adds information of value.

Neither of these assumptions is invariably true. Someone rushed into surgery after a serious accident, for example, is in no position to speak up with a perspective on how the surgeon should close their wounds, nor would it be helpful to engage in shared decision making about staples versus sutures. A drug allergy or similar critical information that a family member or caregiver might provide is, of course, a different matter. Unfortunately, caring for a SARS-CoV-2 infection still too often feels like an emergency. There is extraordinary stress not just

on patients and family, but also on the medical staff, as they, too, worry about getting sick or infecting others [4]. Perhaps most importantly, there is tremendous clinical uncertainty. Participatory medicine may sometimes have to take a temporary back seat to avoid being a harmful distraction. However, there are other circumstances in which participatory medicine could be relevant and constitute the cornerstone of an effective COVID-19 response.

To be clear, the term "participatory" in this context does not mean the kind of public health actions that everyone, infected or not, should be participating in (eg, wearing a mask, practicing social distancing, and washing one's hands). Rather, it refers to the deliberate incorporation of the patient voice into the national COVID-19 response. For instance, in June 2020, the National Institutes of Health launched a data analytics platform, and its usefulness will ultimately depend upon Americans with COVID-19 sharing their electronic health record information. This platform was opened to researchers in September 2020, and it incorporates analytic techniques that are designed to examine everything from potential COVID-19 risk factors to the effectiveness of different therapies [5].

The pandemic has prompted clinicians, employers, and public health officials to ask individuals to self-monitor at different times, such as when they are healthy, if and when they become symptomatic, and during recuperation. Digital tools for web-based symptom checks and consultations are key components of combating the COVID-19 pandemic [6]. As a result, we may be entering a new age of prioritizing digitized, patient-generated health data. This is in essence the mainstreaming of the "e-patient," a term coined by Dr Tom Ferguson to describe individuals who are "equipped, enabled, empowered and engaged in their health and health care decisions" [7].

To give an example of the central role being played by patient-generated health data, Fitbit Inc has developed a COVID-19 symptom tracking service called Ready for Work. It lets employees self-report their symptoms on a Fitbit device and lets employers see worker information on a central dashboard. This helps employees and employers determine when it is safe to return to the workplace. Preliminary data from a nonpeer-reviewed Fitbit study written in mid-August 2020 has suggested that "hospitalization risk can be calculated from self-reported symptoms, and relevant and predictive physiological signs related to COVID-19 may be detected by consumer-wearable devices" [8].

Similar initial results were reported at the end of October 2020 by the Scripps Research Translational Institute in its DETECT (Digital Engagement and Tracking for Early Control and Treatment) study, which involved large-scale epidemiological research on consumers who use a wide range of smart wearables [9]. Additionally, in one estimate, the number of sales for wearables capable of tracking and monitoring COVID-19 symptoms and other conditions will jump from 30 million devices in 2020 to 104 million by 2025 [10].

Clinical uncertainty about COVID-19 has also given birth to online patient support groups, such as Survivor Corps, COVID-19 Recovered - Survivors, and the Body Politic COVID-19 support group. Participation in these support groups now includes tens of thousands of individuals around the globe. As Fiona Lowenstein, founder of one such group, wrote in Vox, "As we wait for institutions to catch up with a new and fast-moving virus, parallel forms of information-sharing via communities, personal stories, and support groups…have become crucial" [11].

Now that we have seen the "yes" and "no" arguments for the relevance of pandemic-era participatory medicine, here is the last answer: "It depends."

Listen for a moment to a woman named Byllye Avery recounting what she learned from fellow patients after a traumatic encounter with the health care system. "If you don't know how to take care of yourself, you are basically ignorant," she wrote. "And health information," she added, "had to be shared within the context of one's life. [There was a] right to have medical information and…patient participation."

That advice was given to Avery nearly a half century ago at a 1971 women's health meeting whose attendees were part of a group that authored the book, *"Our Bodies, Ourselves"*. Avery, who later founded the Black Women's Health Imperative, shared her memories in a preface to that groundbreaking book's 25th anniversary edition [12]. As noted in a history of participatory medicine, the movement owes a large debt to feminists [13].

Although it has taken decades, the health care system has finally accepted the principles of participatory medicine as valid. However, putting all these principles into practice may not always be possible, especially at a time when patients, their friends and loved ones, and health care providers are all extraordinarily stressed by the mortal threat of a dangerous and incompletely understood pandemic. Health care, like much of life, is complicated and messy. Evolving circumstances dictate the appropriate response. Nonetheless, whether during a period of pandemic or relative placidity, certain bedrock principles must remain part of the relationship between professionals and patients. These principles include honesty, mutual respect, and the mutual sharing of information. Such sharing needs to continue, even when it means admitting to uncertainty, fear, guilt, or other uncomfortable emotions.

Sometimes, patients may have no choice but to cede control to medical professionals. This decision, though, does not relieve medical professionals of the obligation to listen to patient and family concerns; patients are still the experts on their own lives. Other times, the shared control of participatory medicine is both an ethical and clinical imperative [14]. However, as the worldwide toll exacted by COVID-19 has made us grimly aware, no one is really in control. That is why, in these uncertain times, the path forward requires maintaining mutual trust between health care providers and patients, whatever the circumstances. After all, it is our bodies and our selves at stake.

Conflicts of Interest

None declared.

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Abbreviations

API: application programming interface
DETECT: Digital Engagement and Tracking for Early Control and Treatment

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Corrigenda and Addenda

Correction: Non-Hispanic White Mothers' Willingness to Share Personal Health Data With Researchers: Survey Results From an Opt-in Panel

Adam Bouras[1,2], MSHI, MHA, MSc; Eduardo J Simoes[1,2], MD, MPH; Suzanne Boren[1,2], PhD; Lanis Hicks[1,2], PhD; Iris Zachary[1], PhD; Christoph Buck[3], PhD; Satvinder Dhingra[4], MPH; Richard Ellis[4], BSc

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In "Non-Hispanic White Mothers' Willingness to Share Personal Health Data With Researchers: Survey Results From an Opt-in Panel" (J Participat Med 2020;12(2):e14062) the authors noted three errors.

One co-author, Cristoph Buck, was not included in the author list of the originally published manuscript. As well, the name of author Eduardo J Simoes was originally listed as "Eduardo Simoes". Authors were listed as follows on the published manuscript:

> *Adam Bouras[1,2], MSHI, MHA, MSc; Eduardo Simoes[1,2], MD, MPH; Suzanne Boren[1,2], PhD; Lanis Hicks[1,2], PhD; Iris Zachary[1], PhD; Satvinder Dhingra[3], MPH; Richard Ellis[3], BSc*

This was incomplete, and has been corrected to:

> *Adam Bouras[1,2], MSHI, MHA, MSc; Eduardo J Simoes[1,2], MD, MPH; Suzanne Boren[1,2], PhD; Lanis Hicks[1,2], PhD; Iris Zachary[1], PhD; Christoph Buck[3], PhD; Satvinder Dhingra[4], MPH; Richard Ellis[4], BSc*

Cristoph Buck's affiliation is as follows:

> *Centre for Future Enterprise, QUT Business School, Queensland University of Technology, Brisbane, Australia*

This affiliation is listed as affiliation 3 in the corrected manuscript, and the previously listed affiliation 3 (for authors Satvinder Dhingra and Richard Ellis) is renumbered to affiliation 4. Affiliations 1 and 2 remain unchanged.

Additionally, the original manuscript was missing the following funding statement:

> *The work of EJS was made possible with support from Washington University in St. Louis CDTR (Grant Number P30DK092950 from the NIDDK). The content is solely the responsibility of the authors and does not necessarily represent the official views of the CDTR or NIDDK.*

An "Acknowledgments" section containing this statement is included in the corrected manuscript.

The correction will appear in the online version of the paper on the JMIR Publications website on November 3, 2020, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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