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Contents

Editorial

Original Papers

A Call to Recognize the Integral Role of Physician Associates and Nurse Practitioners in Modern Health Care: Editorial

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Abstract

Policies governing health care professionals must be evidence-informed and include meaningful representation of all stakeholders, or commitments to quality and equity will remain shallow rhetoric. Physician associates (PAs), nurse practitioners (NPs), and patients deserve full participation in decisions affecting practice and patient care. The current health care landscape faces unprecedented workforce challenges, requiring a shift toward evidence-informed policy and the meaningful representation of all stakeholders. This editorial aims to advocate for the full participation of PAs, NPs, or advanced practice providers and patient representatives in clinical and policy decisions, contrasting established global models with emerging frameworks to promote a more practical, team-based hierarchy. While recent reviews in the United Kingdom highlight a lack of localized, high-quality data, extensive evidence from the United States and other international contexts demonstrates that PAs and NPs provide safe, effective care with clinical outcomes comparable to physicians. We argue that recognizing these professionals as integral members of the health care workforce, rather than mere stopgaps, is essential for improving care quality and patient well-being. This editorial recommends standardized credentialing, integrated educational pathways, and the inclusion of patient representatives as voting members in policy decisions to foster a truly participatory medicine model.

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KEYWORDS

nurse practitioner; nurse anesthetist; physician assistant; participatory medicine; equity; evidence-based policy; patient safety

Introduction

We appreciate the thoughtful, emergent review by Greenhalgh and McKee [1], which provides timely insights into the evolving roles of physician associates (PAs) in the UK health care system. The authors' rapid scoping review, while acknowledging the limited and variable-quality data, emphasizes the need for robust evidence to inform policy and practice. We share their commitment to high-quality research and believe it is time to honor the significant contributions of PAs and nurse practitioners (NPs) as advanced practice providers, who are integral as professionals in health care, with equal access to recognized professional designations to include educational and research funding, especially given the substantial evidence of benefit from the United States.

Understanding the Roles of PAs and NPs as Advanced Practice Providers

It is critical we understand that in other countries, training and roles vary. For example, in the United States, NPs are advanced practice registered nurses who complete graduate-level education (master's or doctoral) and are nationally certified in their specialty areas. They practice independently or collaboratively, depending on state regulations, while providing a wide range of health care services in primary, acute, and specialty care settings [2]. PAs in the United States undergo rigorous medical education, including obtaining a master's degree and performing clinical rotations, equipping them to diagnose, treat, and manage patient care collaboratively with physicians, delivering care in primary, emergency, and specialty settings.

In the United Kingdom, PAs undergo a shorter training pathway, typically including a first degree and 2 years of postgraduate education, and work only under physician supervision. Unlike in the United States, PAs in the United Kingdom are not yet authorized to prescribe medications or order ionizing radiation independently [1]. The United Kingdom's PA/NP model is still evolving, and comparisons with the more established US model can provide valuable insights into optimizing their roles.

Evidence of Safety, Efficacy, and Value

Contrary to perceptions of limited evidence, global data demonstrate that advanced practice providers contribute significantly to health care systems, particularly in underserved and rural areas. These professionals provide safe, effective care, with clinical outcomes comparable to those of physicians [3]. Quantitative evidence from the United States and Canada further supports their value:

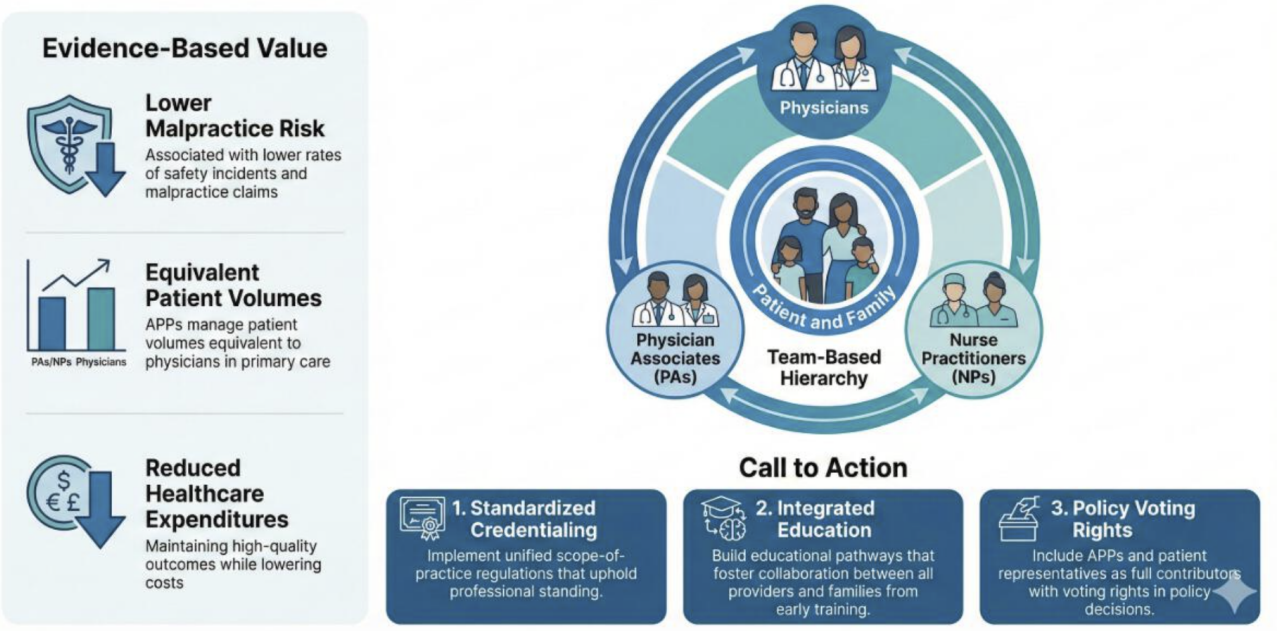
- Safety and malpractice—advanced practice providers are associated with lower rates of safety incidents and malpractice claims compared to traditional models, suggesting a high standard of patient safety and adherence to scope of practice [4].
- Cost and efficiency—meta-analyses of randomized controlled trials indicate that advanced practice providers positively impact health care costs while maintaining or improving quality of care and patient well-being [5-8].
- Primary care performance—in primary care environments, advanced practice providers consistently manage patient volumes equivalent to physicians while maintaining high patient satisfaction and positive health outcomes [8,9].
- Economic impact—systematic reviews of economic evaluations confirm that incorporating advanced practice providers can reduce overall health care expenditures while maintaining high-quality outcomes [9,10].

Furthermore, advanced practice providers demonstrated remarkable adaptability during the COVID-19 pandemic, filling critical gaps and maintaining care continuity during extreme system stress. Responsible advanced practice providers carefully work within their scope of practice to protect the best interests of their patients and reduce institutional liability.

Addressing Concerns With Collaboration and Clarity

Concerns about supervision and accountability, as highlighted in Greenhalgh and McKee's review [1], underscore the need for clear scopes of practice and well-defined roles within health care teams. In the United States, supervisory and collaborative agreements between PAs, NPs, other advanced practice providers, and physicians are governed by state laws and institutional policies, providing structured frameworks for safe and effective practice. Such frameworks could serve as models for the United Kingdom and in other areas where a national scope of practice for advanced practice providers is still under development. We draw the attention of readers to the integrated care model shown in Figure 1.

Figure 1. The integrated care model: beyond the stopgap. APP: advanced practice provider.



The collaborative nature of advanced practice providers enhances, rather than burdens, physician workflows. By managing lower-acuity cases and supporting team-based care, they allow physicians to focus on more complex cases, ultimately improving care delivery and reducing burnout among all health care providers. Recent research highlights how advanced practice providers play an essential role in sustaining health care systems amid workforce shortages, particularly in rural and underserved areas; worldwide, we face acute shortages of medical providers, particularly in rural and low-income areas [10].

Conclusion: A Path Forward With Evidence and Appreciation

As health care systems worldwide grapple with workforce challenges and rising costs, it is crucial to acknowledge and support the roles of advanced care providers, inclusive of PAs and NPs. We recommend a call to action:

First, develop standardized credentialing and scope-of-practice regulations that recognize and uphold advanced practice provider credentialing in state, federal, and international policy and provide advanced care providers with the same access to funding

and principal investigator status as other medical professionals. Second, ensure recognition and respect for advanced practice providers. While patients and families anecdotally praise their advanced practice providers for compassionate care and sensitivity in end-of-life discussions, informed shared decision-making, and coordination with other services, this is notably absent in the literature. Third, create integrated educational pathways that foster collaboration between physicians, PAs, NPs, patients, and their families from early training stages. Fourth, implement supportive supervision models that balance autonomy with appropriate oversight. Fifth, include advanced practice providers and patient representatives as full contributors with voting rights in policy decisions that affect practice and patient care. Sixth, issue an urgent call to societies and national funding bodies to recognize and fund the current gap in advanced practice provider research and policy with participatory research.

Advanced practice providers are not merely stopgaps but highly skilled professionals who contribute to safe, effective, and compassionate patient care. We advocate for a balanced, evidence-based approach to evaluating their roles, embracing opportunities to enhance their training, support their integration into health care teams, and recognize their contributions as essential members of the health care workforce.

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Authors' Contributions

KP and AP contributed jointly to the conceptualization, methodology, investigation, resources, data curation, writing (original draft), and writing (review and editing).

Conflicts of Interest

KP is a practicing nurse practitioner; AP is the editor-in-chief of the *Journal of Participatory Medicine*, published by JMIR Publishing, as of the time of publication.

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Abbreviations

NP: nurse practitioner
PA: physician associate

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Joint Adaptation of a Digital Mental Health Intervention for University Students: Inductive Qualitative Analysis

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Abstract

Background: Digital mental health interventions (DMHIs) can be particularly effective for young people, who live more of their lives online than older generations. Co-designing mental health support with young people can combat the challenges of a lack of engagement and sustained use. While this is increasingly common, there are often budget and timeline restraints in research settings that limit true co-design. As part of the Nurture-U project exploring a whole-university approach to student mental health, we coadapted an existing digital platform, i-Spero (P1Vital), with university students. This paper is a reflection on the impact that our student advisors had on the end product, and where the guidance of the young people was implemented, and not implemented, within the existing research parameters.

Objective: This study aims to present an inductive analysis of meeting notes and recordings of the co-design process, in order to highlight what aspects of DMHIs our advisors valued and what, as a research team, we were able to implement. The hope is that this will inform future mental health interventions in this age group.

Methods: The i-Spero digital well-being platform was developed over an iterative process with multiple rounds of feedback from student advisors in 2022-2024. An inductive qualitative analysis approach was implemented by 2 authors (NA and JD) on the detailed feedback reports and meeting summaries of this process to generate categories and themes from the student advisors' feedback.

Results: Three themes were created: "Relevance and Usefulness," highlighting the importance of comprehensive features linking in with all aspects university life, while treating young people as adults; "Simplicity and Clarity," with student advisors suggesting edits that removed burden from the user and eased access to support; and "Acceptability and Inclusiveness," ensuring awareness of the needs of students from different backgrounds, and what young people with mental health difficulties may be able to access in times of need.

Conclusions: There are some challenges in ensuring that DMHIs are both comprehensive and simple. These can be met by ensuring the aesthetic design and platform structure are consistent and clear. Co-design and development are crucial due to the difficulty in ensuring that online interventions are relevant to specific audiences in the constantly evolving digital landscape. The structures surrounding our joint adaptation of an existing intervention meant that not all the changes suggested could be implemented. Future work should explore the impact of different participation frameworks when coproducing interventions with young people.

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KEYWORDS

youth mental health; co-design; co-development; university students; digital platforms

Introduction

There are estimated to be more than 2 million mental health apps worldwide, with a market value of more than US $8 billion in 2025 [1,2]. While the popularity and growth of these are due in part to ongoing digital wellness trends [3], there is also an increase in need. Worldwide, there is a mental health care crisis with services unable to cater to those who require access [4]. This is especially the case for young people, who have had an exponential increase in mental health challenges in recent years and have been particularly affected by the COVID-19 pandemic [5]. As evidence of this, 7.5% of UK university students declared a mental health diagnosis in 2023, compared to 0.7% in 2011 [6]. Recent research indicates 57% of university students have a mental health condition [7].

In addition to the increase in need for digital mental health interventions (DMHIs), there is also a strong argument for their use for young people. Young people aged 18 - 25 years have grown up in a digital landscape. Overall, 79% of youth globally are online, compared to 65% of adults [8]. Additionally, young people have increased barriers to using mental health services due to a lack of mental health literacy, that is, understanding and knowledge of mental health conditions, how to get help, and how to prevent worsening of symptoms [9]. Hence, the accessibility of mental health support that can be accessed through a mobile phone or laptop could improve the well-being of young people [10].

However, there is a huge variety of apps that are designed to improve young people's mental health, with inconclusive research evidence on their effectiveness [1]. Only apps that are based on cognitive behavioral therapy, supplemented with therapist contact, have been shown to be effective [11]. There are many contextual factors as to whether people engage with DMHIs, including the relevance of the content, the length of the activities, and ease of integration into daily life [12]. Use of digital mental health apps is rarely sustained over time [13].

A solution to this is to include young people in the development and evaluation of DMHIs [1]. This has been argued to be particularly important in increasing the use of mental health support for marginalized and underserved groups, enabling product developers to identify aspects of interventions that cause users to engage or disengage [9]. There has been a recent growth in studies reporting on the codevelopment of interventions in a research setting. However, this has occurred alongside increasing concerns about the quality of the co-design process, with arguments that the amount that young people can truly impact an end product is always limited by time and budget constraints [14,15].

This paper describes the advice given by young people, namely university students, in the process of adapting a preexisting web-based digital tool (i-Spero) for use in the university setting in the United Kingdom. This was conducted as part of the UK Research and Innovation–funded Nurture-U project that explored the whole-university approach to student well-being [15,16]. The i-Spero is a mental health symptom monitoring and care planning tool which, prior to its use in Nurture-U, had been implemented in UK National Health Service (NHS) settings and shown to be effective in supporting students in a Canadian university setting [17]. The Nurture-U research team worked collaboratively with the project's student advisory group (SAG) to maximize the appeal, relevance, and usability for university students in the United Kingdom as part of a 3-year feasibility project. This study aims to present an inductive analysis of meeting notes and recordings of the joint adaptation process, aiming to highlight what aspects of DMHIs our advisors valued, alongside details on what changes were and were not implemented as a result. We will then reflect on this process in the discussion, highlighting the challenges in codeveloping DMHIs with young people. The hope is that this will inform future mental health interventions in this age group.

Methods

Existing Product for Development

i-Spero a web-based platform developed by P1Vital as a digital tool for mental health, contains mental health and well-being measures and allows users to complete these and monitor symptoms over time [16]. It was developed to help individuals work with clinicians, for example, general practitioners (GPs), to identify the effect of antidepressants and predict response levels as early as possible. Figure 1 shows the key areas of the platform, in the format used in the Nurture-U project. Figure 1A shows the user dashboard with graphs tracking well-being over time, using responses to questionnaires chosen by the user. The platform links users' answers on well-being questionnaires with in-built "well-being plans" (Figure 1B), which are categorized according to different types of support. Users can either choose their own well-being plans or i-Spero will suggest well-being plans based on their answers to the questionnaires (see "Notifications" in Figure 1B). The well-being plans also allow users to create "goals" and "actions" to improve their well-being (Figure 1C). Users can choose what to track and how often (Figure 1D). For example, if a user's answer on a mood questionnaire indicates low mood, the platform will show a message recommending well-being plans to alleviate mood, such as making social connections, exercising, or mindfulness exercises. Additionally, users can share their information through dashboards with health care professionals or friends and families.

Figure 1. Overview of the i-Spero platform.

Initial Joint Adaptation Process With the Nurture-U SAG

The Nurture-U SAG played a crucial role from the start of the project and fed into all aspects, from branding, content development, data collection, marketing, analysis, and dissemination. Students were recruited through university newsletters and groups from the 6 partner universities in the United Kingdom. There was no selection process for joining the SAG. Instead, on consenting to participation, students joined a mailing list where opportunities to input into different parts of the project were advertised. If the student advisor had capacity and an interest in that activity, they would email the group lead, who would add them to a working group for that project. Student advisors were paid £16 (US $21.48) an hour for attendance at meetings and work done outside of meetings. More details on the set-up and impact of the Nurture-U advisory group have been described elsewhere [18].

The opportunity to support the adaptation of i-Spero to Nurture-U was advertised to the SAG in December 2021 with an initial introduction to the tool from P1Vital. Four 2-hour meetings were held weekly in February 2022 on the following areas: in-built questionnaire design, well-being plans, notifications and messaging, flow, and evaluation. An average of 26 (SD 2.6) students attended per group. Following these intensive meetings, the research team adapted the design specifications using student feedback, and P1Vital implemented the Nurture-U adaptations to the i-Spero package for initial user testing.

Using Shier's participation model [19], as implemented in the scoping review by Larsson et al [15] in this area, this was a Level 4 participation framework. Shier's model has 5 levels, ranging from 1=listening to 5=sharing power. In our study, student advisors provided pointers and suggestions for edits to i-Spero, an existing product, and these were taken away by the research and software development team, who made the final decision on implementation according to practicality and relevance.

Development of University-Specific Content With the SAG

The development of i-Spero for the university setting was motivated by evidence that one of the key barriers to support for students is accessibility, with students reporting complex websites and disparate services [20]. To this end, a crucial part of the integration of i-Spero within universities was that it allowed personalized recommendations for university campus–specific support for students. This entailed 6 different iterations of i-Spero for the partner universities within Nurture-U. The project leads in each institution led on the compilation of this information and extensive testing to ensure links and contact details were up to date.

Additionally, the tool was developed with a research aim of collecting prospective mental health data from university students through the tool's mental health tracking feature, as a companion to a large-scale student mental health survey [21]. Alongside the development for university settings in the United Kingdom as part of the Nurture-U project, there was development for college students in Canada through the U-Flourish project [17].

User Testing and Feedback

The first prototype of i-Spero for Nurture-U was ready for testing by students and the research team in June 2022. This did not include all the questionnaires and well-being plans but allowed the students and researchers to experience the tool and provide feedback. Student advisors provided notes and comments in self-created Microsoft Word documents or Excel spreadsheets to the SAG facilitator (JD). JD synthesized these comments with the researcher team's comments and sent them to P1Vital to complete their adaptations.

The development was complete in November 2022. Plans for branding and marketing were built with the SAG, and it was rebranded as "the Nurture-U Wellbeing Toolkit." This was launched across the 6 Nurture-U partner universities in January 2023. The Toolkit was marketed through stalls on campus, newsletter bulletins, social media posts and advertisements, and emails to students.

As well as the broad marketing to all students, SAG members were specifically invited to test the Toolkit and provide qualitative feedback through an online focus group with Nurture-U researchers and the P1Vital team in July 2023.

This feedback led to the next iteration of the toolkit, which was available and promoted through the same avenues in January 2024. Again, SAG members were invited to test the toolkit and provide qualitative feedback in April 2024. P1Vital implemented the suggested changes, and the final iteration to be tested in the Nurture-U study was launched in September 2024. As stated previously, evaluation and analysis of the user data to establish the acceptability of the software is currently ongoing, with the latest information from this process available on the Nurture-U website [22].

Qualitative Analysis

The contents of 12 documents were analyzed. In total, 4 of the documents contained meeting notes from the initial development stage, with a range of 6 - 9 pages of text, and the remaining documents ranged from 1 - 9 pages of user feedback. A general inductive approach was implemented [23]. This is a method that aims to condense raw data into a concise summary for evaluation purposes. It is purely data-driven, with a bottom-up approach creating categories from participant quotes, using these to derive themes relating to the research question. This inductive process aimed to allow an overarching description of the student feedback across the different data sources.

Initial codes and categories stuck closely to the wording from the documents, for example, "if given too many options then too hard to engage" or "don't want it to feel like extra work." The initial inductive coding was completed independently using NVivo (version 14; Lumivero) by researcher JD and Nurture-U student advisor NA. JD and NA then compared initial codes, and then these were synthesized by JD into broader themes and checked by NA. This method of independent parallel coding is commonly reported in qualitative analysis as a method of ensuring rigor and trustworthiness [24]. As the author, JD had

a research team perspective and NA had a student advisor perspective. This allowed for reflexive discussions about positionality and an exploration of the impact that had on the coding.

Ethical Considerations

Ethical approval for the collection and publication of data related to the SAG was granted by the University of Exeter Centre for Life and Environmental Sciences Ethics Board (application ID 493946). All participants provided informed consent prior to taking part in the study. They were given clear information about the purpose of the research, what participation involved, and their right to withdraw at any time without penalty. All data were collected and processed in accordance with the General Data Protection Regulation and University of Exeter data protection policies and were only accessible to the research team. Personal identifiers were removed at the point of collection, and anonymized documents were used for analysis. Results are reported in aggregate form to ensure that individual participants cannot be identified. Participants were informed of their rights under the General Data Protection Regulation, including the right to access, rectify, or request deletion of their data.

Results

Overview

The Nurture-U student advisors provided input and feedback on the development of i-Spero in 4 different stages of its development over 2 years. A summary of changes that were and were not able to be implemented can be found in Textbox 1.

Textbox 1. Implemented and nonimplemented student feedback.

Student-led changes implemented into the final product

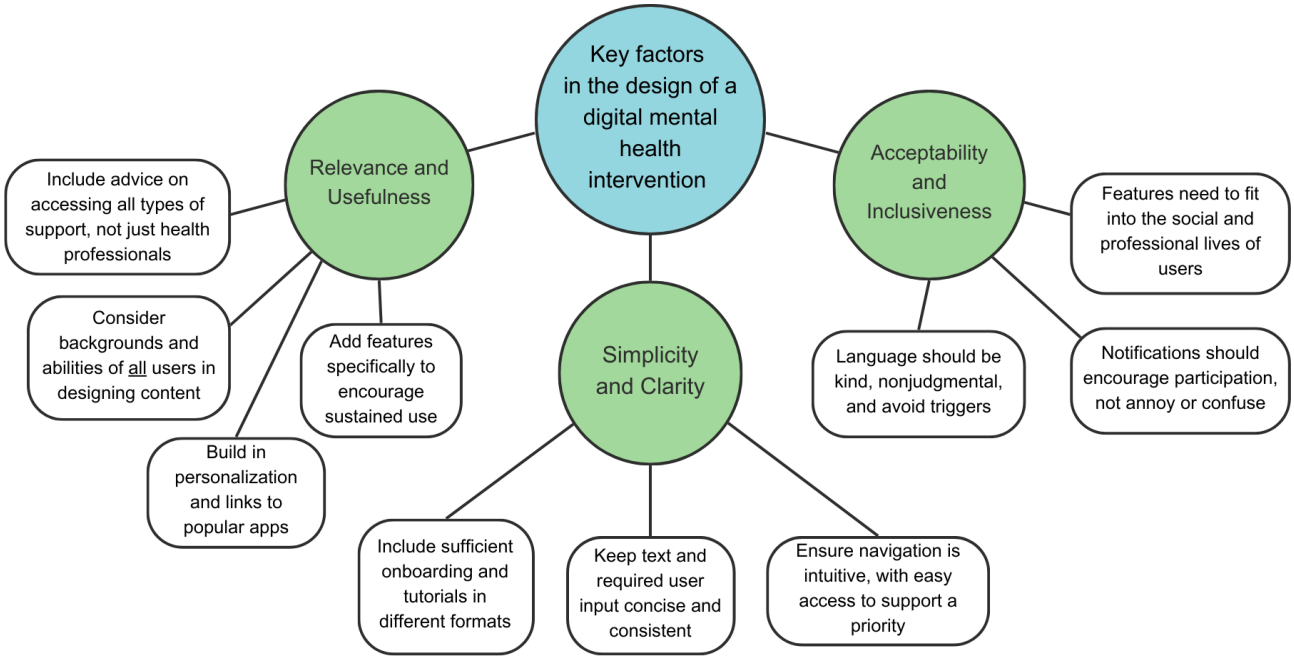
- All language suggestions for messages and notifications.
- Addition of student-designed questionnaires relevant to student issues.
- Changes to the color and layout of the interface.
- Addition and restructuring of well-being plans to enhance user experience.
- Addition of emojis and motivating messages.
- Inclusion and emphasis on methods of self-help.

Student suggestions not implemented by the research or software team

- Language suggestions for standardized research questionnaires.
- Removal or shortening of standardized research questionnaires.
- Addition of an area within the platform where users can connect with other users.
- Restructuring of software so that support can be accessed without well-being plans.
- Addition of motivational tools, such as a growing tree, or linking with other apps.
- Removal of signposting to medical and university settings.

Analysis of development notes and documents identified 4 key areas where students consistently highlighted the need for improvement: “Relevance and Usefulness,” “Simplicity and Clarity,” and “Accessibility and Inclusiveness.” These are summarized in Figure 2.

Figure 2. Core themes in i-Spero codevelopment.



Relevance and Usefulness

This theme encapsulates feedback from the student advisors that highlighted that the platform essentially had to be something that students actually want to use. The feedback was mostly positive; advisors highlighted the ease of navigation and appealing design, noting that the platform is accessible across different devices. Student advisors gave specific feedback from the perspective of young people on what aspects of the content were useful and what was not. For example, while they understood that repeated signposting to medical or university services in different areas of the platform may be necessary to ensure people get the care they need, they argued that this was not useful, as students already know this is where they can go for help.

> *It would be good to have specific apps and resources and not just to signpost people to Wellbeing Services and GP.*

They argued that students will be attracted to the platform because they are struggling to find where to get help or have a reason to want to avoid traditional support options. Hence, student advisors argued that:

> *The hierarchy should change for suggestions for contact. So start with (1) friends and family, (2) wellbeing services, and then (3) GP.*

Additionally, advisors fed back that vague language or advice was not helpful and could be found anywhere. They repeatedly highlighted where unnecessary words could be deleted. They also helped tailor advice so it was relevant to student contexts, for example, academic study. They also advocated for considering students from all backgrounds, for example, making alcohol-related content optional and creating specific content for underrepresented students, for example, those who are neurodiverse, or for parents or carers. Students advising on the initial iteration argued, for example, for the inclusion of a personality questionnaire, as something that would appeal to students at an age when they are learning who they are in the world.

The structure of the platform, tracking and setting goals, had mixed responses according to their relevance in the student context. Some advisors reflected that its usefulness lay in providing a bigger picture of emotions and mental health symptoms over time. However, the weekly "repetitive" questionnaires, some advisors argued, "felt like research" rather than something of use to them. They described the ability to set goals and tick them off as encouraging but reported little in the platform that encouraged sustained use and "ongoing management" of these goals when they were in place.

> *I don't find much reason to look back at the wellbeing plans I set myself.*

Some advisors suggested direct feedback, which congratulated users on sustained use.

> *Could there be some sort of visual feedback so that people have a sense of accomplishment when they complete a questionnaire? Because at the moment there is no positive feedback until you have filled it out over time. For example, there could be a tree or sapling that grows into a forest?*

An often-repeated aspect of feedback was to provide more areas for personalization, so users could individualize the content according to their preferences and experiences. Many advisors advocated for space in the platform for journaling and writing notes, creating a record of why they felt a certain way at different points over the academic year. Additionally, the ability to set their own reminders, notifications, and well-being plans so that they were experiencing the functioning in their own language and contexts was requested. They also repeatedly asked for the ability to link to apps they already use (eg, Spotify or exercise apps), or to include a social aspect such as a forum or the option to connect with other users and motivate each other to use the platform.

> *Could this Tool connect people together to talk about their mental health?*

Another factor that student advisors identified as important in young people finding the platform useful was that it should be motivating and positive. The danger that student advisors highlighted was that in tracking mental health over time and signposting to support, there was a risk that the platform would be repeatedly telling people they feel depressed or anxious, and that could be "disheartening." The largest impact that the student advisors made in adapting the platform was in rewriting all the notifications, messaging, and well-being plans to provide encouragement to users regardless of their outcomes on the questionnaires. Advisors described a nuance to this where positive messaging could be "slightly patronizing" and hence more practical messaging and advice would be most relevant to their context.

> *Motivational messaging might be condescending. We could have testimonies or real-life stories of people who use the Tool – this is more likely to make a user feel better rather than something overly positive.*

They emphasized how students were mostly young people who appreciated being "treated like an adult" as they began to build their lives away from home, and that the platform content needed to reflect this.

Simplicity and Clarity

The second ongoing aspect of student advisor feedback on the intervention was to increase its simplicity of use and clarity of the information provided. Student advisors stated that anything that felt like "extra work" would not appeal to students, who already have enough to juggle with academic work and navigating new social situations. Initial feedback highlighted a lack of clarity in how to use the tool.

> *It's very fiddly and complicated to use. The wellness plans still confuse me, and it doesn't seem easy to identify or access resources.*

While guidance was provided in later iterations in the form of video onboarding on sign-in and links to external, more detailed video tutorials, this feedback continued. Advisors argued that navigation around the platform should be intuitive. They highlighted the need for improvements in how the information was organized, such as increasing the directions on the home page, moving from having "history" and "upcoming" areas to view activity on the platform to having an ongoing timeline, and being able to mark all notifications as read in one click. These were all implemented by the software team.

Consistency was a key area that students highlighted as important to usability, for example, scales on graphs all going the same direction. Another example given was that postquestionnaire messaging could be contradictory, so if you answer indicating, for example, low mood on one questionnaire but good sleep on another, you may receive contradictory positive and negative messages about your well-being.

> *Is there a way they can "trump"' the other messages so they don't contradict each other?*

This solution, also implemented by the software team, was to have a hierarchy of messaging, where messages in response to mental health questionnaires (ie, mood or anxiety) would take precedence over lifestyle factors (eg, sleep or social connections).

In relation to the tracking element of the platform, an emphasis was made on avoiding burden for student users.

> *Won't long questionnaires mean the students will get bored?*

This led to the development of tracking questionnaires designed by student advisors, which involved branching elements where further questions were only asked in response to certain responses to initial brief questions.

> *This could start with a general question (e.g. "I've been feeling stressed a lot lately" rated from strongly disagree to strongly agree). You could then have follow up questions depending on your answer to the first general question, so if you indicate you are stressed you could have a list of things that might be causing you stress (for e.g. "what causes you to feel stressed?" with various categories (finance, relationships, academic work, cu), about frequency "how many days this week have you felt stressed?", or "what do you to deal with stress?". This could help find out the cause of stress and come up with coping strategies.*

Additionally, students designed the user satisfaction questionnaire so that it was as concise as possible. However, the fact that the platform was embedded in a research project meant that certain standardized mental health questionnaires needed to be retained, for example, the Patient Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorder 7 (GAD-7), and the wording of these questions could not be changed. The inclusion of these, alongside the additional questions designed by student advisors, led to a total of 33 questionnaires that student users could engage with. The student advisors who led the initial development of the questionnaires argued that all should be clearly labeled as to what they measure, including citations and links to sources, to enable students to engage with the ones that work best for them. Those that were designed by student advisors were named "student co-created." However, student advisors who tested the later iterations of the platform expressed some confusion about the number of questionnaires and how they were labeled.

The well-being plan function, where users could choose certain areas to work on (eg, managing their mood and academic stress) and then access specific information and set goals, was seen as too complicated for many:

> *I feel like the well-being plans are just extra work, so I did not want to do it.*

Advisors argued for a separate page where resources and signposting could be read outside of the well-being plan format for ease of access. This was implemented by the software team. The type and level of support wanted from the intervention was a subject of debate, with some advisors wanting "comprehensive" and detailed psychoeducation, as that is what

they saw as the function of the platform, while others wanted less information and text and instead practical and accurate signposting for different areas of need. Advisors argued that text should be broken into paragraphs and boxes to reduce "overwhelm." This was implemented by the research team.

Acceptability and Inclusiveness

Finally, student advisors were central to ensuring the design was acceptable to the student population, the majority of whom were under 25 years of age. A key factor in this was the aesthetic design and "feel," with initial feedback on the version that had been used in the NHS declaring it "outdated," "medical" and "bland." The Nurture-U brand colors [22] were decided upon as a potentially recognized design that was distinct from the participating universities and the NHS. Given the many iterations of the platform, with different versions for different campuses entailing many different stakeholders providing input, there were initial areas of inconsistency or errors in the language used, which student advisors highlighted as off-putting in an intervention targeting well-being. Hence, while student advisor input was built in for the purpose of ensuring relevance to students, they also provided basic error checks, which were extremely valuable.

A big part of the feedback on the acceptability of the tool for young people was the role of the notifications for engaging in the questionnaires and the well-being plans. Advisors provided the wider context of the use of the platform: students live busy social lives where their phones and laptops are often on display, and hence the subject line of reminder emails and texts needed to be neutral or "vague" to protect people's privacy. Notifications needed to be unintrusive but also engaging to encourage students to prioritize the platform over their other tasks.

> *We could make [the reminder message] more positive: "We've missed you! Click here to do your wellbeing questionnaire now"*

Notifications containing a list of "long, formal questionnaire names" were anxiety-provoking and would be identified as another burden in a busy period of academic work. These contextual descriptions of the target user allowed for changes, which it was hoped would encourage higher levels of engagement from students.

However, student advisors also highlighted that it was not only young people as a broad audience who would be using the platform, but young people who were likely to be experiencing challenges with their mental health.

> *Make it more organised and aesthetic - If a person is struggling, they don't want red bold text or long paragraphs. It should feel like a safe space.*

There were concerns from some of the advisors with lived experience of depression and anxiety that when they were experiencing more severe symptoms, they would not have had the energy and motivation to engage with tracking and goal setting. While some aspects to deal with this challenge also arose in the previous theme surrounding ease of access to resources, advisors also specifically discussed the "tone" of the information given. They asked for the removal of moral descriptions of behaviors as good or bad, advising that language should be neutral and warm:

> *We don't want the questions to be judgemental or triggering. For example, people may have different perceptions of what constitutes "good" sleep or diet depending on their lifestyles, experiences of eating disorders, cultural backgrounds. This is why more generic questions that people can tailor to their own personal experiences might work best. The language should be kind and inviting.*

Language should also be neutral and warm in describing lifestyle factors such as sleep or diet, which are individual and may vary according to background and experiences. They also highlighted instances of tonal mismatch, where messages starting with "hello" were too informal for serious notifications about mental health.

Student advisors argued that users would be logging on to the platform specifically for support, and, hence, ease of access to this support is of high importance. As discussed in the theme relating to simplicity, students argued that the well-being plan interface was a barrier and that students should not have to "commit to a plan" to get support. Similarly, in order to engage those who are having difficulties with their well-being and mental health, advice should be "reassuring": not telling students what to do but "talking to them on a level." Student advisors highlighted specific language changes that could achieve this, for example, normalizing experiences and pitching advice as "beneficial to lots of people," and not promising an unachievable cure but highlighting "useful steps" toward an improvement in symptoms. Finally, student advisors highlighted several reasons why users may have difficulty understanding certain terminology in the advice sections, whether it was a lack of mental health literacy, cognitive challenges due to poor mental health, or not having grown up in the United Kingdom. Hence, there were many aspects of the content where they suggested simplifications or the need for additional definitions to enhance accessibility. These were all implemented by the research team.

Discussion

Principal Findings

In the joint adaptation of the i-Spero platform for university student users, 3 key concepts were identified as crucial to designing DMHIs for young people. These core ideas of relevance and usefulness, simplicity and clarity, and acceptability and inclusiveness should be central to all elements of interventions, from the interface to the content to the notifications. While we were unable to implement all suggested changes within the Nurture-U project, this study aimed to specify what young people want from digital mental health support to inform future design.

Where the Nurture-U student advisors made the most impact in adapting i-Spero was in highlighting where information and support needed to be added for underrepresented groups and where edits needed to be made to remove burden from student users. These 2 areas of feedback, however, became contradictory over the development process: including questionnaires and

well-being plans that covered the needs of all students necessitated more text and information, which in turn created more content that student advisors identified as overwhelming. This is the key challenge in developing online mental health support: trying to appeal to all when everyone's needs are different [25-28]. There is a difficult balance, identified both by our advisors and in the wider literature, in making information comprehensive but also digestible [27]. What the advisors highlighted as key to engagement is not so much the amount of information contained in an intervention, but how it is presented and how easy it is for users to find what they need. A recent interview study with teenagers found that while a clinical approach to presenting information, such as that on NHS websites, promotes trustworthiness, it can be intimidating and difficult to read [27].

Student advisors overhauled the language used in the intervention. We were not surprised that they would highlight the need for clarity; clear and nonjudgmental language is well-known to reduce mental health stigma and promote support [29]. What perhaps was novel to the research team was the advisors' requirements for motivational language, positivity, and interaction to increase engagement. In a competitive online landscape, it is the "gamification" of apps and content, defined by creative thinking and activation, which encourages use [30]. To adapt to these suggested changes in mood and aesthetic of the intervention, we implemented all edits to language and messaging, including brighter colors, and minimized the use of buttons and extensive scrolling to achieve tasks. However, there were features in the original platform design, such as the format of the well-being plans and the research design, such as the language in the standardized questionnaires, which we were not able to adapt as the student advisors may have wished. We will see the impact of keeping these functions as we analyze the user data [22].

Another aspect of engagement that we had not anticipated was how much student advisors asked for personalization of the intervention. Research has shown that personalization of the mode of delivery of online health information can increase website satisfaction and information recall of participants, and that this effect was particularly strong with younger people [31]. However, research into how to personalize digital health interventions is relatively recent; where personalization is built in, it is usually for content over format, and there is not yet evidence on the effect of different levels of personalization on outcomes [29]. As personalization through algorithms is becoming more ubiquitous on social media, in search engines, and music and video streaming sites, this is something that is likely to become increasingly necessary to ensure engagement in DMHIs.

Another aspect that the research team was unable to change, despite the student advisor's recommendation, was to step back from signposting users to professional services for mental health. Highlighting the need to access GP or university well-being services was crucial for managing the associated risks of mental health difficulties, especially as the target user would be young people who are likely to be away from home for the first time. Research shows that many young people are not aware of where to get professional help for mental health difficulties [32]. However, advisors argued that student users would not only be aware of these options but actually may be accessing the platform specifically looking for other ideas to support their mental health. This mirrors Biddle et al [33] review of young people accessing support for suicidal thoughts online, where being referred back to a doctor was not only frustrating but also damaging to those in crisis: seeing this as the only option when it has not worked previously makes people think they cannot be helped. Those who develop mental health interventions must not see the user as accessing the intervention in isolation and be aware of the real-world contextual influences and experiences on the target user [27]. There is an ethical discussion as to whether apps that are targeted as mental health support should have a duty of care for users [34]. However, the context of this study, abiding by research ethics and university principles, meant that we needed to ensure all student users were aware of professional services and how to contact them if needed.

In conducting this study and reflecting on the findings in the context of previous literature, there is evidence of marked similarity in what young people want from digital mental health support between multiple different studies and reviews [12,14,15,33]. What this suggests is twofold: first, researchers working in this space need to do more to learn and build on preexisting research when they are designing and conducting projects in this space [35]. However, and conversely, this reflects the fact that the internet has created a rapidly changing social and political landscape where the factors that make a platform accessible and sustainable are constantly evolving [36]. One reason researchers repeat these elements of codevelopment is that while the overarching advice from young people may be the same, for example, ease of use or age-appropriate language, the specifics of this may vary according to context, be it geographical or cultural [37]. Including the target audience, especially in interventions aimed at young people, in mapping out the intervention theory and development of prototypes is crucial to creating DMHIs that have sustained benefits [28,35].

We placed our joint adaptation of the i-Spero intervention as a level 4 within Shier's participation framework: the student advisors were involved in the decision-making, but they did not share the responsibility for the ultimate decision (level 5) [15]. Shier emphasizes that his framework is not hierarchical, that different levels of participation are appropriate in different contexts [15]. However, there are increasing concerns that the growing prevalence of coproduction occurring without a critical and evaluative lens on power and decision making may be detrimental to the original aim of producing "socially robust" research outcomes [19]. In the case of DMHIs, this specifically means that placing limits on the extent of coproduction results in a product that may not fit user requirements. What our study highlights further, however, is the often-competing agendas that are at play in codeveloping DMHIs, especially in the context of research. First, where software developers have existing designs or researchers have existing research aims, this creates areas where those with lived experience have to be told "no." When considering working relationships, this builds a level of power imbalance where the advisors may lose faith in the project and their motivation to contribute wanes. A fully coproduced project, where people with lived experience colead or even lead

the process of designing and delivering a DMHI, would avoid these challenges, but would take far more time and resources. Further research in this field would be to compare the impact of DMHIs that are fully coproduced with people with lived experience, as compared to ones which only have user-testing elements, both on mental health outcomes for users and costs and resources.

There were strengths in our extended joint adaptation process of i-Spero with university students, including the rigor and transparency in the researcher and advisor feedback process [18]. Additionally, a reflection of the process as we have presented in this paper is crucial for effective participatory research [38]. However, there were some limitations. First, while the student advisors were the target audience in that they were university students, they had joined the advisory group because they had an interest in student well-being, not necessarily because they themselves were experiencing mental health challenges or seeking support. Hence, they may not have been the students that the intervention was designed for. Another limitation was that we only used focus groups or written feedback; more inventive or creative approaches could have garnered more detailed insights [15,28]. Additionally, as discussed above, while i-Spero was initially developed with co-design and research methodologies, by the time we were adapting the platform, there were some aspects that could not be changed within the research timeframe and budget.

Conclusions

To conclude, inductive analysis of our records of the joint adaptation process generated 3 key themes for designing DMHIs for young people: “Relevance and Usefulness,” “Simplicity and Clarity,” and “Accessibility and Inclusiveness.” While these are concepts that have been identified in other studies, it is important to recognize that they are also constantly changing entities. Hence, co-design with users from the inception of a digital intervention idea is key to ensuring effective and sustainable digital mental health support. However, there is a need for more research exploring the impact of different levels of user participation in codevelopment on intervention outcomes.

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Data Availability

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

Authors' Contributions

Conceptualization: JD (lead) and EW (equal)
Data curation: JD
Formal analysis: JD (lead) and NA (supporting)
Funding acquisition: EW
Investigation: JD
Methodology: JD
Project administration: JD
Resources: EW
Supervision: EW
Validation: NA
Visualization: JD
Writing – original draft: JD
Writing – review and editing: NA and EW

Conflicts of Interest

None declared.

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Abbreviations

DMHI: digital mental health intervention
GAD-7: Generalized Anxiety Disorder 7
GP: general practitioner
NHS: National Health Service
PHQ-9: Patient Health Questionnaire-9
SAG: student advisory group

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Integrated Knowledge Translation for Social Innovations: Case Study on Knowledge Translation Innovation Incubator

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Abstract

Background: The Knowledge Translation Innovation Incubator (KTII) initiative, launched by the Knowledge Translation program of the CHILD-BRIGHT Strategy for Patient-Oriented Research Network, provided funding support for researchers and partners to experiment with various approaches and strategies to support the development of innovative knowledge translation (KT) research in the context of neurodevelopmental disabilities.

Objective: We aimed to describe the process and contexts of innovation development in integrated knowledge translation (iKT) practices in patient-oriented research.

Methods: We applied an iKT practice to conduct the collective case study of 7 KTII-funded projects. We interviewed 10 researchers, 4 research trainees, 2 clinicians, 2 parentpartners, 2 patient-partners (1 adult and 1 youth), 1 community partner, 1 KT specialist, 1 designer, and 1 research program manager at the middle and the end of the project period. We conducted qualitative content analysis using the Consolidated Framework for Implementation Research to identify and assess patterns of determinants of (1) drivers of innovation, (2) facilitators and barriers to innovation development, and (3) enablers for sustainability of KT products.

Results: Innovative KT was majorly driven by the identified know-do gap to meet the needs of people with lived experience. Outer setting constructs, such as funding and partnerships and connections, were not only drivers but also facilitators to innovation development. iKT practices presented in this case study were fostered by researchers' approach to participatory design, involving iterations of listening to emerging ideas and feedback of patient-partners and other partners, and researchers' continuous reflections on their roles in knowledge creation. Despite the challenges in building consensus and the limited time of the fluid process, researchers' strong passion for engagement and value placed on lived experience led to flexible engagement and open communication to create KT products. Intangible outcomes included further relationships at individual and organizational levels, capacity building of young people, and a collective voice to influence communities. Sustainment of the KT products requires not only accessibility and adaptability of the product itself but also mechanisms at inner settings, such as training, continued interest of patient-partners and the community, and institutional partnerships to support the further uptake of the product.

Conclusions: This study illustrates the critical roles of researchers in addressing power dynamics and making the research partners' tacit knowledge visible for successful innovative KT. The research landscape should also change in terms of funding and timeline in order to foster researchers' mental models in designing thinking and actions on collaborative research engagement.

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KEYWORDS

integrated knowledge translation; innovation; patient-oriented research; disability; case study; research engagement

Introduction

Research on concepts, theories, and frameworks for knowledge translation (KT) and implementation has rapidly evolved in the past two decades [1]. The Canadian Institutes of Health Research (CIHR) defines KT as "a dynamic and iterative process that includes the synthesis, dissemination, exchange, and ethically sound application of knowledge to improve health, provide more effective health services and products, and strengthen the healthcare system" [2]. One element of KT science focuses on identifying, testing, and developing the best methods to meaningfully engage partners in research and to convey the findings and outcomes of scientific research to those that are interested in or affected by the research. It aims to implement findings and effective evidence-based interventions into health care, policy, and other areas of practice or clinical settings. In Canada, KT is strongly encouraged in the research process since the adoption of the Knowledge to Action Framework in 2006 [3], mainstreamed by the CIHR [4].

The CIHR's Strategy for Patient-Oriented Research (SPOR) initiative was created to emphasize the engagement with diverse partners in KT and the integration of "patients" as partners in the research process. To this purpose, "integrated knowledge translation" (iKT) has been put forth as a useful model for collaborative research. It is expected that engagement with patient-partners can improve study development and increase uptake of evidence. Despite the recent development in strategies to engage a variety of partners in the research process, challenges still remain: a misfit between the type of problem and the approach taken to address it and a lack of validated methods for research partner engagement in terms of how to measure outcomes of engagement and how to quantify and qualify what meaningful engagement is and what the best methods to conduct studies using this approach are [5,6]. The development of new strategies that address these challenges and evolve with the field of iKT is timely.

The CHILD-BRIGHT Network is a pan-Canadian network that aims to improve life outcomes for children with brain-based developmental disabilities and their families. This network was funded by the Canadian Institutes of Health Research SPOR program, and therefore patient-partners (youth with disabilities and parents or caregivers of children with disabilities) are actively engaged as partners in all research projects and the activities of the network as a whole. The KT program of the network launched the KT Innovation Incubator initiative with the purpose of conceptualizing a vision for iKT, providing funding support for researchers and partners to experiment with various approaches and strategies to propose innovation and support the development of innovative KT research in the context of neurodevelopmental disabilities.

The current research challenge contends that many research engagement approaches are poorly specified and unvalidated [6]. In addition, children and youth with disabilities and their family members are not fully involved in the implementation of health research [7,8]. In this context, it would be beneficial to consider innovations in the process of conducting iKT practices. Innovation is here defined as a product, action, service, or relationship that has the potential to enhance health outcomes [9]. Innovative KT involves multifaceted innovativeness in developing and implementing tools that help the wide dissemination and uptake of new knowledge, engaging with diverse research partners. One example is the translation of evidence-based recommendations in clinical guidelines into educational tools and accessible resources to different target audiences by engaging with key opinion leaders, as well as the creation of a training program [10]. Seven Knowledge Translation Innovation Incubator (KTII) awarded teams had their own visions, approaches, strategies, and relationships for research engagement with diverse partners to bridge the gap between knowledge and practice in a particular context. In this context, this study aimed to describe the process and contexts of innovation development in iKT practices in patient-oriented research.

Methods

Research on Research

This study is best understood as research-on-research: a collective case study examining the processes and contexts of innovation within iKT practice happening in the context of 7 KTII projects [11]. We applied a case study, which is "an empirical enquiry that investigates a contemporary phenomenon in depth and within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident" [12]. We describe both the phenomena and the context to gain an in-depth understanding of how innovation happens in patient-oriented research, specifically in the area of neurodevelopmental disability. A collective case study can help us understand the differences and the similarities between the cases (ie, projects) and generate a broader understanding of a particular topic [11-13]. Our constructivist approach aimed to capture the perspectives of different participants and focus on how their different perspectives and meanings illuminate the context and process of innovation development in iKT practices [13]. The comparison between different partners in one case (eg, researcher vs nonresearcher partners) as well as between different cases (ie, projects) was made when mapping the codes on the Consolidated Framework for Implementation Research (CFIR) framework and reviewing the particular contextual information. While qualitative content analysis was used to support thematic synthesis, the primary aim was not theory development or phenomenological inquiry but structured reflection on the research process.

KT Innovation Incubator Initiative

The KT program launched the KTII initiative with the purpose of conceptualizing a vision for iKT, providing funding support for researchers and partners to experiment with various approaches and strategies to propose innovation and support the development of innovative KT research in the context of neurodevelopmental disabilities. The objective of this initiative was to study how innovation involving "the process of making changes to something established by introducing something new" [14] can be adopted into KT strategies in the context of a patient-oriented research network.

Seven Canadian KT projects were selected to receive funding (CAD $12,000, approximately US $9300 at the conversion rate of US $1 = CAD $1.29 in 2018) from this KTII initiative from 2018 to 2021 in order to promote and facilitate innovative KT products in childhood disability (Table 1). In 2018, the inaugural team, the Child-Sized KT project, proposed to co-design an online family portal that uses child and family partner stories about the value of research engagement. In 2019, the Making Sense of Connectedness project was awarded to work with neurodiverse youth to co-develop initiatives to promote sensory-friendly spaces in Montreal through a web-based hub. The Ready 2 Work team proposed to create an online platform to help young people with autism spectrum disorder successfully enter the workforce. In 2020, the WeeWheel project team aimed to develop and adapt the Wheelchair Skills Training Program educational resources for children through the creation of a training workbook, instructional posters, and a storybook. Another awardee, the Perspectives of Mental Health project, proposed to develop strategies and materials that could facilitate dialogues between youth and health care providers. In 2021, the Let's Go to the Library! team focused on the voices of young people to design and develop storybooks on different sexuality topics for preteens. Lastly, the CommuniKIDS team proposed to develop a freely accessible bilingual trial results communication tool in collaboration with youth and families impacted by different forms of child disability.

Table . Overview of the 7 KTII[a] projects.

Project title	Innovation incubation goal	PWLE[b]	Family or caregivers	Others	KT[c] approach	Methods	KT products
Child-Sized KT	Develop an interactive online platform for children and families to learn about health research	✓ (children)	✓	Health care providers and writers	Knowledge to Action Framework model	Qualitative interviews and meetings	Family stories and online family portal
WeeWheel	Develop and adapt Wheelchair Skills Training Program education resources for children to address the evidence-practice gap	✓ (children)		Health care providers, decision-makers, and knowledge users	Knowledge to Action Framework model	Focus groups and interviews	A storybook, instructional posters, and a training workbook
Ready 2 Work	Develop and pilot an online vocational/employment readiness platform for people with autism spectrum disorders, families, and vocational program professionals	✓	✓	Advocates and professionals from vocational and employment organizations	Need to Knowledge Model and iKT practice	Focus group, testing, feedback, and piloting	Websites
Making Sense of Connectedness	Give neurodiverse children and youth and their families an opportunity to build an online hub of sensory environments in Montreal to engage the public about the impact of these sensory spaces	✓ (youth)	✓	Community partners (decision-makers from research institutes), students, and designers	iKT practice	Meetings	Pamphlets, videos, bags, and T-shirts
Perspectives of Mental Health	Create digital stories of youth with neurodevelopmental disabilities that can facilitate more dialogue between youth and health care providers in mental health discussions	✓ (youth)	✓	Community partners	Co-KT Framework	Workshops	9 digital stories
Let's Go to the Library	Create a free book to support nonjudgmental conversations with preteens with disabilities on sexuality and disability	✓ (youth)	✓	Health care providers, educators, graphic designers, multimedia consultants, website developers, professional writers, and actors	iKT practice	Online meetings and the use of information-sharing platforms	Books (downloadable PDF or narrated version)

Project title	Innovation incubation goal	PWLE[b]	Family or caregivers	Others	KT[c] approach	Methods	KT products
CommuniKIDS	Develop a freely accessible trial results template in collaboration with youth and family advisors	✓ (youth)	✓	Health care providers or trialists, research ethics board (REB) committee members, and graphic designers	iKT practice	Virtual workshops	Trial results template, tip sheet for template users, and websites

[a]KTII: Knowledge Translation Innovation Incubator.

[b]PWLE: people with lived experience.

[c]KT: knowledge translation.

Use of Integrated Knowledge Translation in Our Case Study

We also used iKT, a model of collaborative research, to conduct the collective case study of 7 KTII-funded project teams [15]. The KTII funding applications were reviewed by the KT Program review panel, which included a number of researchers, research trainees, and nonresearchers (parents of children with disabilities, youth with disabilities, clinicians, and community partners). Each project was assigned to a dyad of peer reviewers constituted by 1 researcher and 1 nonresearcher, according to the research topic proposed (eg, KT projects directed at families were reviewed by a parent or researcher dyad). All members of the panel participated in the development of the application assessment forms and received equal training to rate applications. While the evaluation grid was used to standardize the rating of applications, each dyad had discussions to clarify their viewpoints and rationale for the rating results to provide the shared review results based on both the researcher and patient or parent-partner perspectives.

Our case study team—consisting of researchers, a project coordinator, parent-partners, and trainees—shared different research tasks throughout the case study series, including cochairing the review panel and addressing questions of panel members. Our parent-partner, who was part of the review panel, contributed to conceptualizing, designing, analyzing, and writing the case study as an integral part of the research team. While the researcher, who co-led the KT program with the parent-partner, guided the data collection and analysis process, both complimented each other's expertise—the researcher's expertise on the methodology and the patient-partner's expertise based on lived experience, along with her curiosity about the topic—and the collegiality enabled shared decision-making during the regular coleads meetings.

Ethical Considerations

Institutional ethical approval was provided by the Institutional Review Board at McGill University Health Centre-Research Institute (2019-4745). Written informed consent by participants was obtained prior to interviews. Participants did not receive compensation. The persons with lived and living experience who are coauthors were compensated following the CHILD-BRIGHT patient-partner compensation guidelines [16].

Participants and Data Collection

Participants were members of the KTII-funded projects' teams. The funding criteria included the inclusion of at least one nonresearcher as coprincipal investigator (including financial compensation for this person and other nonresearcher partners in the study budget description), the submission of a midterm and end-of-grant report that focused on reporting on the KT innovation and iKT methods, and the applicant's acceptance to participate in the KTII case study.

The studies' principal investigators and other partners who were members of the research team (not study subjects or participants) participated in two semistructured interviews. The interview guide was developed in partnership with the KT committee members for general input and in detail with the parent-partner, trainee, and researchers who accepted to participate in the specific project subcommittee. Interviews were conducted by a project coordinator at 2 points: midproject and end of the project. The interview at the midproject point focused on the definition of innovation, drivers of innovation, facilitators, barriers, and challenges of innovation development, innovation development process, and engagement with partners. The interview at the end of the project focused on the innovation development process, tangible and intangible outcomes, and sustainability of the developed KT innovation product (Multimedia Appendix 1). The interview recordings were verbatim transcribed for coding.

Data Analysis

Each KTII project is considered as a case in our analysis. We conducted qualitative content analysis [17,18]. First, a list of codes was cocreated based on the interview questions (eg, driver of innovation, engagement with partners, and enabler for sustainability) with the guidance of the senior researcher. After training on qualitative analysis by the research associate involved in the project with guidance from the senior researcher, parent-partners were paired up with a research trainee for analysis. They met on a regular basis, first with the entire research subcommittee, then with their dyads (parent partner-trainee). During the first meeting done via Zoom, all participants opened one Microsoft Word file (online) while the researcher shared her screen. One person volunteered to read the transcript, and the researcher led the prompts toward deductive coding. For example, she would prompt: "What do you think this is about? Does it speak to any of the items we

already have here such as innovation, engagement, sustainability, or is there something else that this participant is communicating? If so, what is it?" The initial codes were done in this fashion, using color codes and comments on the online Microsoft Word document. In parallel, a living document (online shared) of code definitions was created, where written comments prompted discussion for clarification and establishment of the common understanding (referred henceforth as "Journal"). This was done for a series of meetings until the first interview transcript was entirely coded, with breaks to clarification and for any process or content questions from all involved. Then the dyads met to code the same interview transcript and met with the entire group once a month to review what they had coded, including notes, questions, and reflections. While reviewing the results of their partners' coding and discussing the findings, new codes were added, and the creation date and rationale were added to the journal.

After the iterative process of both deductive and inductive coding, a research trainee reviewed all coded texts and consolidated coding results in NVivo 12 (Lumivero). The preliminary findings were shared with the team members to receive feedback. As the coding process continued, the trainee iteratively reviewed and organized the code list by referring to the updated CFIR [19,20]. The initial data analysis plan did not consider the use of an implementation framework. However, we adopted CFIR during the data analysis as we needed a standardized structure for building on findings across multiple cases, while comprehensively distinguishing a wide spectrum of contextual determinants ranging from external context to individual characteristics [21]. CFIR provides a guiding framework to identify and assess a range of contextual factors of innovation development and implementation in 5 major domains: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation. Determinant frameworks applied in CFIR helped us identify and assess patterns of determinants of (1) drivers of innovation, (2) facilitators and barriers to innovation development, and (3) enablers for sustainability of KT products across the intervention development process among different cases [20].

Engagement of parent-partners as well as research trainees shifted during the entire project period due to a shift in roles, personal conditions, and commitments. Although scheduling a meeting specific to the case study became difficult due to everyone's limited availability, we used regular meetings for the KT program coleads or committee members and email communication within the case study team to report on the progress of the interviews and to discuss the preliminary results of the analysis to ask specific questions and establish confirmability. In addition to the interview transcripts, midterm and final reports submitted by each KTII project were reviewed for data triangulation to gain a more comprehensive understanding of the project context when interpreting findings from interviews [22]. The midterm reports included information about achievements, engagement strategies, innovative KT approaches, and challenges faced by the project team. The final reports included future recommendations. The information validated what had been shared during the interviews, while adding other contextual information (eg, impact of COVID-19 and organizational change) which was not necessarily mentioned during the interviews. The research trainee who reviewed the reports took notes on new information about the process and context of the project. We used strategies to enhance analytic credibility—such as coding dyads, peer debriefing, and triangulation with project reports—but did not apply a full trustworthiness framework, as our aim was not to generate generalizable qualitative findings but to support learning about applied iKT practices.

Reflexivity

We position our research within social constructivist paradigms, and our stances on reflexivity deeply reflect this paradigm. Social constructivism posits that knowledge is created and applied through individuals' active interactions and learning in a particular social context [23]. SPOR's endorsement of the active partnership of research partners, including parent or patient-partners, researchers, health professionals, and decision-makers, shaped our attitude toward the way we as a team created new knowledge based on the shared value of collaboration and colearning. While team members' educational background and research experience varied, the spirit of colearning and the value of positioning parent-partners as equal research partners created each member's openness to different perspectives and points of view. The senior researcher learned about a different way of conducting qualitative analysis by partnering with a parent-partner in all steps of the data creation and analysis. This prompted reflections about qualitative methods and true partnered research, which had previously been done mainly on KT processes (eg, dissemination and feedback on outputs), not systematically through the creation of questions, analysis, and manuscript production. The parent-partner, who was the colead of the KT program, appreciated the expert knowledge from a senior researcher who guided the qualitative data analysis. The process gave the parent-partner confidence to contribute. Participating in the KTII case study allowed the research associate to bridge methodological rigor with meaningful partner engagement, ensuring that partners felt confident and supported in the qualitative analysis. The research associate role fostered richer, more nuanced interpretations and strengthened the integration of diverse perspectives in the final results. The project coordinator valued the collaborative nature of the iKT process, which created an adaptive learning environment where research team members not only learned about the different aspects of the research study (eg, qualitative analysis) but also appreciated how meaningful engagement of partners brings about relevant perspectives and enriches the process. The research trainees also appreciated parent-partners' critical insights into iKT practices, their strong curiosity, and active engagement through bringing questions during coding and analysis. It was also a learning process to reflect on the role of researchers and rethink what makes KT innovative beyond the existing common research practices.

Results

Synthesis

Participants included 10 researchers, 4 research trainees, 2 clinicians, 2 parentpartners, 2 patient-partners (1 adult and 1 youth), 1 community partner, 1 KT specialist, 1 designer, and 1 research program manager who were members of the KTII-funded projects' research teams.

Many participants described outcomes, as well as the approach and process of engagement with research partners in their KT project, as innovative. Innovative KT was majorly driven by the identified know-do gap to meet the needs of people with lived experience. Outer setting constructs, such as funding and partnerships and connections, were not only drivers but also facilitators to innovation development. iKT practices presented in this case study were characterized by researchers' listening to ideas of patient-partners and other various partners with specific expertise and their continuous reflections on their role in knowledge creation. Despite the challenges in building consensus and limited time, researchers' strong passion for engagement and value placed on lived experience allowed flexibility of engagement and open communication to create KT products. Intangible outcomes included further relationships at individual and organizational levels, capacity building of young people, and a collective voice to influence communities. Sustainment of the KT products requires not only accessibility and adaptability of the product itself but also mechanisms at inner settings, such as training, continued interest of patient-partners and the community, and institutional partnerships to support the further uptake of the product.

Drivers of Innovation

Interview participants commonly conceptualized innovations as creativity in thinking and actions under a vision for creating something new for improvement and problem-solving by thinking outside of the box and pushing boundaries. A critical driving factor for innovation development was a construct of the CFIR Inner Setting domain, tension for change, or the degree to which research partners perceive the current situation as intolerable or needing change (Multimedia Appendix 2). Multiple researchers reported that they had identified the evidence-practice gaps to adapt programs and services that are informed by people with lived experience.

In one case, the identified gap was a lack of knowledge uptake since the "wheelchair skills training program isn't adapted to the pediatric client and the clientele or the pediatric population" [Clinician, Project 4]. Similarly, a researcher in another case (Project 7) stated, "it seemed surprising that nothing like this (communication tool) was available to trialists who wanted to share trial results back to families...and the kids."

The identified unmet needs driving innovation in 4 cases can be described through a human rights lens or broader issues of injustice toward youth with disabilities (Projects 2, 3, 6, and 7). A project lead researcher (Project 6) stated that "it is a fundamental human right to be able to explore [your] sexuality and be a sexual person in whatever way that looks like for [you]" by referring to young people with disabilities who "don't have those opportunities to express their sexuality, to figure out their identity." A parent co-lead in Project 2 also stated, "I think what brought us into here...there are voice to be heard," by quoting her son, who described the sensory environment where autistic people do not feel welcomed and people's misunderstanding or ignorance as unfair and injustices. Similarly, a researcher in Project 7 explained why tailoring trial results communication tool to youth was needed because youth themselves "have that autonomy and the right to get the results back from their own trials as well."

Among the CFIR outer setting factors, funding and partnership and connections were common drivers for innovations. In Project 1, a researcher reported that a series of conversations among different research groups who already had good relationships with each other organically led to a partnership development to create a digital technology innovation. At the inner setting level, institutional strategy to adapt the Wheelchair Skills Program as a relative priority to the pediatric population was an additional innovation driver (Project 4).

In the individual domains, the project lead's motivation was an often-cited driver of innovation. Researchers in all cases expressed their motivations, passion, and interest in knowledge cocreation with patient-partners during the interview. They also shared their strong belief that lived experience is a valuable source of knowledge that provides a potential solution to the identified complex problem:

> *I feel like these individuals have some really unique strengths that employers could be utilizing, but we're having a hard time seeing past that. So, trying to find a platform that not only builds on their current skillset so that they can be seen, but also a platform that may possibly reach employers at some point, be able to see the abilities of this population, and the benefits that they can actually bring to their businesses.* [Researcher, Project 3]

Process of Innovation Development

Teaming, Assessing Needs and Context, and Planning

Most teams applying to this competition had a previously established relationship through ongoing clinical and research activities (eg, research meetings, conferences, and public events). These connections gradually expanded to include other partners, such as family partners, advocates, and designers, to build transdisciplinary teams and pull a project application together. By applying the iKT practice, research partners were involved from the beginning of the project.

At the inner setting, while the needs, priorities, and preferences of patient-partners were broadly identified at the beginning of the project, objectives were not necessarily clear. A researcher (Project 1) stated, "We falsely assumed we knew exactly what we were trying to do, despite having vagueness to what we're trying to do." The objectives for the project evolved to gradually address unmet needs through a concomitant process of reviewing the existing research evidence and listening to the voices of research partners.

> *We were listening to our groups. So even if we came up with certain ideas of what we wanted to present, this is like our participatory group here that, you know, our own stakeholders are coming in and saying what they think is important to them. And even like, be it outside consults or our team. And then that helped guide us to where we were going.* [Colead researcher, Project 2]

In the process, many researchers reflected on a shift in thinking of who obtains the most valuable knowledge.

> *The way I was trained in research was that "We're the experts. We go to them, they tell us how to do it," but I've found the opposite is true because if we start with them and say, "Okay, these are the things we're interested in. This is what the problem is from a research angle. How do we go about this?"* [Lead researcher, Project 5]

Similarly, a designer and a researcher in Project 2 stated, "the innovation is to flip how we think about expertise, that [young people] are ahead of the game, that they already know these things that would benefit lots of other aspects and people in society."

Tailoring

Once objectives became clear, projects adopted a series of different strategies, such as focus groups, interviews, and regular meetings with project partners, to design innovative products and strategies based on the initial wish list (ie, unmet needs and desires presented by project partners) and available evidence-based resources. After the brainstorming phase, researchers used different strategies to create something useful by integrating what was shared and considering feasibility. In all cases, teams designed a prototype of a KT product or a draft of a KT plan and continued refinement through iterative consultations, member checks, and integrating feedback.

> *What really helped was...just listening to everybody's opinions and trying to understand so that...what that does, it allows all the members of the project to add on one another or ask more questions, and so when you ask more questions, it makes the process more exhaustive. So like we truly understand everybody, as opposed to just that small group in the middle that thinks they know what they're talking about, but might not actually understand all of it.* [Youth, Project 5]

Participants expressed the complexity of tailoring the initial design of a KT product to adapt to the needs of patient-partners as a nonlinear process involved a great degree of uncertainty. The capacity to deal with uncertainty and adapt to change was integral inner setting characteristics of many projects.

> *Never in the iKT process do you see one linear phase of getting to, you know, here's your research question, here's the materials, the tools, and then they're up there the everyone starts using. That's not the way it goes. It's always this circle of, okay, here's what we have, we evaluate, here's what needs to be refined, we bring that back, and it's always that process of evaluation and follow-up and refining.* [Researcher, Project 4]

During the adaptation of KT products to the partners' needs, research teams showed the changes made due to the feedback received from research partners. A patient-engagement leader (Project 7) shared:

> *That was very well received. I mean, people wanna see that. They don't wanna give up on their time to not have an impact. So, for our youth and family stakeholders, I would say that through a combination of evaluating, you know, them, asking them, but also us making sure that we're accountable to them all the time, I think that's how we know the contribution is making an impact.* [Patient engagement leader, Project 7]

At the same time, outer setting characteristics such as funding and project management posed challenges. Reflecting on the fluidity of KT innovation with partners, a researcher of Project 3 found it a challenge when researchers had to make sure they respected the voices of their research partners while also meeting the expectations of the granting agency or partnership.

In addition, while multiple ideas in the development of projects were highly appreciated, building a consensus with a heterogeneous team was a challenge, as stated in two cases. Key challenges highlighted are related to creating a harmonious balance: (1) between research evidence and innovative elements underpinned by lived experience (Project 6) and (2) between individual preferences and an idea agreed upon by the majority of the team (Project 1). At the same time, a researcher in Project 1 reflected,

> *I think getting consensus in what we're trying to build, what exactly we're trying to build was [...] probably the biggest challenge. Then so to this question is what's the biggest successes that [...]. Once we got to that point, things felt very well, which is how it typically [goes] but not always. Sometimes once you start to get along somewhere [during] the iteration, people [start] saying, "Let's do this, let's do this," this sometimes can move [forward] whereas in this one in particular, we got to a point where we drive a process to get to that consensus and now it's around execution. We had good stakeholder, good feedback and people are engaged. Some of the patient-partners in particular were very helpful.*

Even though uncertainty characterized the experienced process of innovation development, it was also considered as an inevitable path leading to discovery, contributing to the adaptation of the intervention being proposed.

> *You go down a road and you don't know what you're gonna find on that road. So, it was kind of like, "Let's just do this, and let's just see what the result is." So I think that part was really exciting, too.* [Patient engagement leader, Project 7]

Even though things did not necessarily go as initially planned, researchers in the case study commonly highlighted that lived experience guided them during the iterative feedback process.

> *...youth had come together and...and kind of brought in their...their experience, and what was the best way for them to relay that information that their lived experienced, you know, to the...turn it into a tool that could be useful to others.* [Researcher, Project 2]

Despite the time-consuming nature of the process, it was also a valuable learning experience for many researchers. A researcher in Project 1 stated, "everyone has stuff to learn. We have things to learn about how to communicate better with our family partners." In Project 3, a researcher explained that a multiple-stage approach was adopted so that people with specific expert knowledge can lead the stage. For instance, "computer tech person will be taking the lead and we [researchers] will be learning from him. So, I think that's really kind of helpful" [Researcher, Project 3].

Engaging

Participants stated that innovation was not only reflected in the KT products created but also in their participatory design process. In many projects, flexibility was a key for active participation of research partners. In three cases (Projects 2, 3, and 5), multiple modes of communication were available so that participants could express their ideas and emotions in a way they would like to. Speaking a lay language was also necessary for researchers' engagement with patient partners so that everyone on the team remained on the same page. In all cases, researchers also made sure that voices of partners were heard throughout the entire engagement process.

> *I think that [a parentpartner] said she felt included. We went back and forth in terms of trying to make a decision about something and making sure everyone had input, but she would say, "Well, I defer to you on that because you have the background and quality at research," but then we'd say, "Well, as a parent, is this going to resonate with you? Or, what do you think is more important? How should we group these things?"* [Researcher, Project 1]

Particularly in cases involving children and young people, several approaches were taken to address inherent adult-youth power differentials. For instance, in Project 7, young people attended meetings led by another youth facilitator, separate from adult research partners.

> *For the youth meetings, we just have the one person, she's a young woman, you know, she's got a rare disease herself and, you know, and she facilitates those meetings and the rest of us turn our cameras off, and we're just in the background. We don't intervene at all. So, it's a different kind of approach, too. And that's just a decision that we made.* [Patient engagement leader]

In another project, when young people and their parents attended meetings together, a youth interviewee shared that "it's more like the parents are backing up what the youth say as opposed to the parents say it for the youth and then the youth just go on with it" [Project 5]. In Project 4, a researcher reported that a video created with a young patient-partner helped reach out to other young participants for recruitment.

Furthermore, reciprocity in research engagement in the form of adequate compensation such as honorarium, opportunities for skills development, and friendship building was also highlighted in 4 cases. In one case (Project 4), a researcher reported that financial compensation encouraged children to participate, while making them feel that they were given an important responsibility based on their knowledge and expertise in wheelchairs. A researcher in Project 2 shared,

> *Participant 1: Bringing this awareness out into the public, especially the young public, I think it was very good. Very positive effect. They responded wonderfully to it, they were excited I think to see it.*
>
> *Interviewer: So you have motivated youth.*
>
> *Participant 1: And vice versa, I now get to design a course around youth mental health for the spring. I won't design it without having a component where those youth have an opportunity to come in and teach the students. So, it equally influences us, maybe that's the whole...maybe that's also a part of the innovation, right? It is not a one-way research model. It changes everybody who comes into contact with it in a way, I think.*

An often-cited engagement challenge was keeping the team connected. Despite challenges in scheduling meetings, having regular meetings was reported to be helpful in three cases (Projects 3, 6, and 7). In Project 5, where clinicians' availability was limited, researchers used their routine meetings to present the KT product, which captivated the interest and also made them feel that the tools really met the need that was named by them in previous studies." In another project (Project 5), a researcher tried to be flexible by telling research partners, "if you can't make it, come when you can so that everyone who wants to participate can still participate."

Facilitators for and Barriers to Innovation Development

At the outer setting level, technology was identified as one of the facilitators for innovation development in three cases as it can enhance connections and engagement (Projects 1, 3, and 5) (Multimedia Appendix 3). In Project 5, a youth partner stated that the digital platform "becomes easier to communicate" and "easier to show other people what we are doing" since "most youth are automatically accustomed to most digital things [...] more reliant upon social media and the kind of network."

At the inner setting level, multiple relational constructs are reported to have facilitated the innovation development: (1) relational connections, which were built on the previous working relationships in many cases; (2) a culture that values lived experiences and appreciates patient-partners not only as users but also as knowledge creators; (3) transdisciplinary work that fostered collaborations with people from different organizations and disciplines; and (4) open communication that respects diverse viewpoints. The importance of good relations on the team was highlighted, as one researcher (Project 1) described their team as a "group of people who are super flexible, adaptive, [and] rigidity and boundaries weren't going to work."

In all cases, multidisciplinary composition of the team brought in a range of expertise and experiences, including (1) researchers, clinicians, community partners, and parent-partners and patient-partners (youth and adults with neurodevelopmental disabilities, children using wheelchairs, and families) and (2) people with specific expertise in fields such as computer programming, data informatics, behavior analysis, and knowledge brokering. Many researchers reflected on the importance of lived experiences and specific expertise and skills, such as communication designing, website designing, and story writing, as important components contributing to the KT innovation.

At the individual level, researchers' characteristics (perseverance, openness, passion, and being well organized) fostered patient-partner centered culture. In parallel, researchers often discussed that project team members' strong interest and willingness to make contributions kept the research team motivated to move forward. As one parent-partner (Project 1) stated,

> *It's a really strong team and they really have a heart for it. I think it'll just keep growing. Patient-family engagement is just the root of us so much that potential that has to be put in place. I think that's what they're trying to do very hard.*

Three cases (Projects 1, 2, and 7) also highlighted the capability of a knowledge translator and facilitator.

> *Our ability as a team to translate the youth knowledge was almost simultaneous with [designer] because she was quickly generating. She [...] will come and then she would pick up and then she would help start already the translation...When these youths would see that back again, to see their ideas in this kind of very...this format that's so official, you know, that it kind of solidified their own and ideas. I think it was really engaging. It was immediate. I think that really helped them to feel like they were part of something that was moving forward as a group.* [Researcher, Project 2]

Many researchers identified timeframe and availability of funds as barriers to innovation development at the outer setting level (Multimedia Appendix 4). A researcher (Project 7) pointed out, "[it is] double edge sword of innovation, right? It's innovative because it hasn't been done before, but then that also means that you haven't got anything to learn from before, so it is taking so much more time and other resources to work through this." Similarly, as one researcher (Project 2) described it as "reverse order of things," researchers stressed that the iKT practice cannot be done properly in a conventional research timeline that expects finishing the study and publications within a certain amount of time.

> *The time I ask [patient-partners] versus the time they give me a response, it could be a few days. It could be a week. Versus if I make that decision on my own, it's a lot faster, right? So, again, there's value and merit to that, but the time delay piece, again, in a world so obsessed with being so hyper-productive all the time can lose some of the value of what we're doing.* [Researcher, Project 5]

Therefore, the funder's flexibility to allow noncost extension was highly appreciated, as a researcher (Project 6) stated, "We have had to extend a couple of times and flexibility has been critical for us to produce this high-quality product."

Furthermore, 6 project teams were developing innovations during the COVID-19 pandemic (critical incidents at outer settings), which brought unprecedented barriers to innovation development and required creative, flexible thinking and acting on top of the planned innovation process:

> *COVID happened and COVID just really floored us. I mean, really, really floored us 'cause I think we were making really great strides up until then and then everything changed.* [Parent-partner, Project 2]

The pandemic gravely delayed the ethics approval process and changed the mode of participation from in-person to online. During this unprecedented event, research teams (Project 4) had to be creative to conduct interviews with a child:

> *Interviewee: What we did to overcome interviewing children online, because of the pandemic, we used a happy face system, um, where if they liked something or thought it was okay or didn't like it, they could do a green happy face, a yellow kind of straight face or a red sad face, or orange sad face. I think it was red.*
>
> *Interviewer: Yeah, yeah, yeah, yeah angry face or something like that, yeah.*
>
> *Interviewee: Exactly, and yeah, it worked okay. But the kids wanted to be doing other things. They didn't really wanna be sitting on a screen flashing and sad faces.*

Similarly, many interview participants found adaptation due to public health restrictions was a learning opportunity. A researcher (Project 5) described that it was the time to rethink the way they usually conducted research and be creative to make it inclusive. By switching from in-person format to online meetings, improved accessibility for participation was reported in two cases (Projects 3 and 5). It became unnecessary for young people to go to a meeting venue, which in turn opened up possibilities for participation for people in different geographic locations, as well as nonverbal youth participants who were able to engage in discussion by typing their ideas (Project 5).

In addition, limited funding was another barrier at the outer setting. One student (Project 3) described that "we tend to come with these kinds of pie in the sky ideas" when trying to develop something innovative. At the same time, the use of certain technology and hiring people for the development of programs, as well as for administration and coordination, is costly (Projects 1 and 3). In order to manage limited time and budget, some research teams tried to be realistic by selecting areas that everyone had agreed upon (Projects 1 and 2).

Outcome

In addition to the tangible KT products, many research teams reported additional outcomes had come out of their innovation development process, which they did not expect to see. Several

cases (Projects 6 and 7) named new partnerships (outer settings) for further collaboration opportunities.

> *Given that the organization that I'm representing here, [institution's name], has now worked with this particular group, I can see us working together on other projects moving into the future too. So while we delivered on the original intended outputs, I think we've kind of seeded things to maybe do other things together as a group.* [Researcher, Project 7]

Such connections were being made outside of research settings in two cases. In Project 2, researchers were excited to see the community members starting to reach out to invite youth groups for consultations. Youth's friendships were organically fostered in Project 5.

The project teams involving youth research partners highlighted opportunities for capacity building and empowerment (Projects 2, 5, and 7).

> *Some of the youth have said, you know, like "I showed this to some of my friends who have mental health challenges and have a neurodevelopmental disorder and they never thought that a kid with autism can do this", right? So again, it's almost breaking stereotypes for some kids as well that they're not broken or damaged, like they've been told before, but that they have kind of potential and are worthwhile.* [Researcher, Project 5]

In addition, another case stressed the collective voice of youth as the outcome that has the most potential for impact on the community (Project 2).

> *Researcher: You know, having like your pamphlets and so on. You're not just someone who sounds like, "Oh, I'm advocating for myself or I'm complaining." That's how people sometimes see you. But coming together as a collective and having it branded and having it, you know, sort of bringing in that credibility, you know, it brings in more gravitas. You have, you know, people's ear. And so I thought that was quite significant.*

Sustainability of Developed Innovation

The identified enablers of sustainability of the innovation products that each research team developed are multifaceted (Multimedia Appendix 5). In the innovation domains, accessibility and adaptability of the product to different populations were identified as a key enabler for the sustainable implementation of the innovation. Whereas a strategy to make materials available online through their own website or their partner organizations' website was put in place in many cases, one research project (Project 4) also pointed out the need to print resources in both a print and a digital version to share with families as well as clinicians.

Furthermore, innovation was seen in the ways that teams granted credibility to their KT products. In one case (Project 6), they obtained an ISBN as a strategy to increase the sustainable use of their book. They explained: "it helps [a library at our hospitals] to catalog our book and for us, it helps get the book out, so it is sort of both adding credibility but also helping other people get it out more." Another crucial enabler was funding to update and maintain the developed product relevant to the users and/or expand the users to different target groups (outer settings).

In the inner setting domains, in Project 4, whose target users include clinicians, researchers were aware of the need for training for implementation. Therefore, continuing education on the innovation (pediatric wheelchair skills training) was a work infrastructure in inner settings that was required to make a longer use of the developed KT innovation.

Some research teams found relational connections with existing and newly developed partnerships with other research teams as an enabler to innovation and help sustain the developed innovation products. For instance, a researcher (Project 7) stated, "even though the project team is formally disbanded, there is a commitment from [the name of an institute] as a partner organization to continue to update the website, and to continue to potentially make changes to the results template if we're hearing enough feedback from people that that should be done." Similarly, another project team (Project 6) believed that close relationships with the communications and public engagement department, as well as a very large network of partners, can help disseminate their KT product and guarantee better knowledge uptake and use.

Many project teams also found that continued interest of patient-partners and the community, which were part of the innovation development process, can help sustainable use of the developed product.

> *I'm looking forward to those benefits that I think will come as we build a community of people who are involved and actively participating on the [web]site because again, I'm the researcher and [...] I see my role as facilitating the process but it's meant to live as a result of the community who benefits from it.* [Researcher, Project 3]

The team of Project 2 discussed that sustainability is not just the product but also relationships to create changes in the community:

> *I do and that, you know, usually, we think of sustainability, like as an environmental or the longevity of a product, but it's essentially grounded in our relationships, right? And if people are empowered...I think you were both saying that P3 and P2 in different ways, like to...that they just know that they can create these changes. I mean, I think that's what we're trying to give people more than any actual product in a way.* [Researcher]

On the other hand, local attitudes in outer settings can be a potential barrier to the sustainable use of the KT product. The members of Project 3, who developed an online platform that provides resources and tools to people with autism in order to support their employment, noted that "we need to start challenging employers' perceptions of individuals with autism" by seeing them facing the structural barriers to employment. Furthermore, they also found that maintaining relational

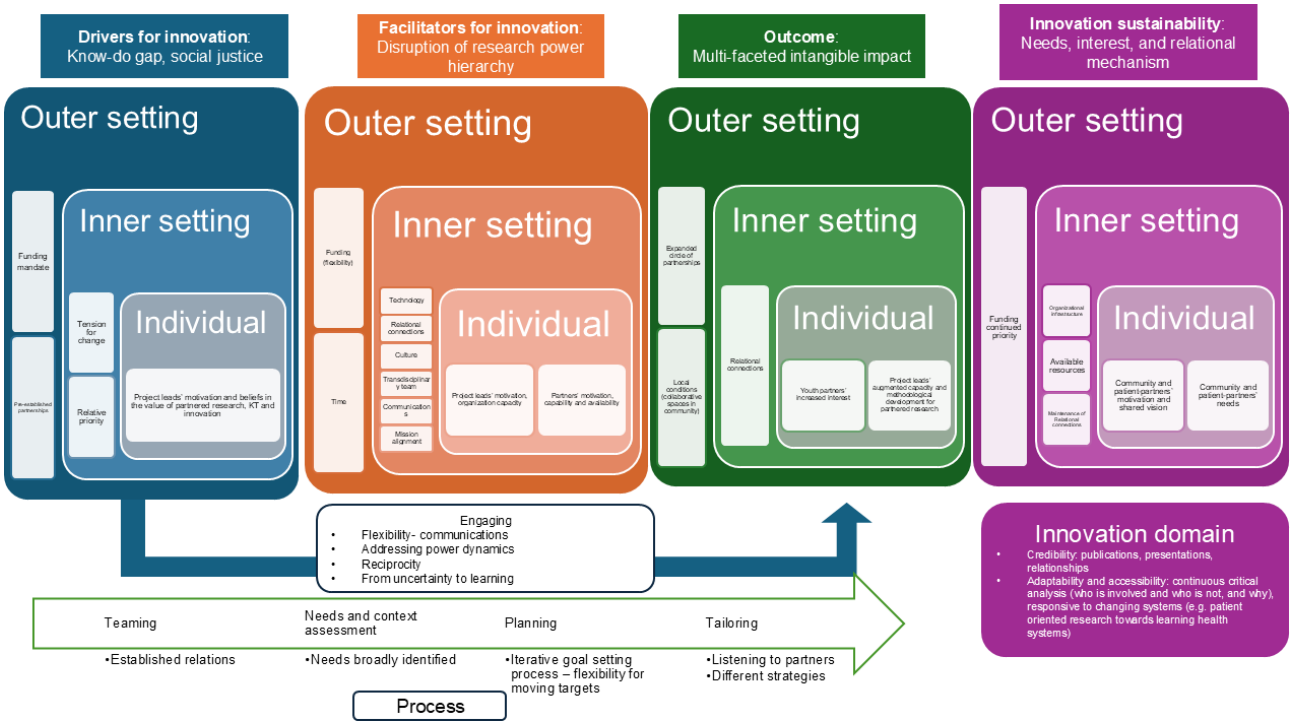
connections and networks that are aimed to be created by the developed platform can be a barrier to sustainable use, as people's needs can shift while the employment situation is always changing.

Discussion

Interconnected Contextual Factors

A range of contextual factors in different domains of the CFIR framework (outer settings, inner settings, and individual characteristics) are interconnected to shape the unique process of innovation development in each case (Figure 1).

Figure 1. Overall findings with CFIR constructs. CFIR: Consolidated Framework for Implementation Research.



Driver for Innovation: Closing the Know-Do Gap

In addition to resources such as funding and existing partnerships, identification of a clear know-do gap was a major driver for innovation development [24,25]. In four cases (Projects 2, 3, 6, and 7), a social justice lens focusing on the human rights of young people with disabilities was a driver for innovation development. Although little attention has been paid to social justice and equity in iKT discourses [24-26], these cases demonstrate that social justice can be a critical starting point for KT efforts to advance health equity.

Another critical driver for innovation development was researchers' attitude toward knowledge cocreation [27]. While the know-do gap was historically conceptualized as a problem of knowledge transfer (for instance, inadequate efforts to translate academic knowledge into practice), an iKT model considers the know-do gap as a problem of knowledge production [25]. In all cases, interviews reflected researchers' beliefs and philosophies in research partnership with patient-partners, which were also identified as facilitators for innovation development, and not only knowledge users.

Participatory Design in the Innovation Development Process

All research teams applied a participatory design approach where "participants are not only research subjects but also contributors to the design of a service of other outcome that will affect them" from the beginning of the project [28]. The collaborative process led to the creation of spaces where different types of knowledge were valued and shared, and solutions to address pressing real-world challenges were collectively created [29-33]. However, the existing hierarchies of value in knowledge systems are constructed against a background of social and institutional relations and cultural context [24,31,34]. Therefore, patient-partners' voices can be often neglected due to power imbalances or methodological structures for generating "valid" knowledge [35,36]. The issues of power imbalance encountered in the cases of this study were attenuated by a funding and reporting structure that valued and, in a certain way, regulated a collaborative and more equal structure [30].

This study highlighted the critical roles of researchers in making the research partners' tacit knowledge visible and turning the KT process into "collective making" [30]. The researchers' openness and listening to diverse views, respectful and accessible communication, and provision of multiple methods of participation facilitated relational connections and the team culture that recognizes people with lived experience as valuable knowledge partners [37]. Researchers also made intentional efforts to address the existing power difference by having a youth or a peer facilitator [35].

For some researchers in this case study, building consensus was not easy due to tensions of leveraging lived experience [38,39]. Nonetheless, they made the cocreation process accountable, transparent, and authentic by showing the changes made based on their input and acknowledging their contributions [30].

The space of "collective making" was gradually built by generating research partners' interest in the process, as well as having knowledge translators, facilitators, and specialists, such as IT specialists as knowledge brokers.

The traditional knowledge-to-action approach tends to hold linear assumptions that knowledge comes first, and it underlies effective action and practices [40]. By contrast, in this study, uncertainty was an inevitable part of the process yielding innovations, requiring researchers' openness to changes and funders' flexibility.

Outcomes

In addition to the tangible KT products, all cases have reported different types of other intangible outcomes, including expanded research relationships that can be leveraged for knowledge mobilization and further research opportunities, as the knowledge cocreation process became a "relational design" [41]. Considering the transformational aspect of the iKT practice leading to innovation sustainment, we posit that capacity building and empowerment through research engagement and raising awareness through community engagement should be considered as the iKT's primary goal for effective knowledge uptake and sustainment of knowledge application [37,41].

Keeping the Innovation Sustainable

While accessibility and availability are commonly identified as the key to sustainable use and implementation of the innovative product, a variety of funding should be available since human and financial resources are necessary to keep the knowledge updated and accessible. The innovation sustainment often requires changes in local conditions and attitude (outer settings) to create a favorable socioeconomic environment to address inequality and injustices that people with lived experience are facing in their daily lives and in the health system. Therefore, including a strategy to bring a positive change in the local conditions and attitudes through community engagement is important during the creation of KT products [42].

Implications

While several recommendations for forming and maintaining research partnerships are already drawn and presented somewhere else [43], this case study using the CFIR highlights that iKT practices require additional time, effort, and resources for a long-term engagement with research partners [44]. To support the relationship building, iterative participatory design process, and sustainable uptake and use of the product, we recommend flexibility and diversity of funding [5]. We also suggest that funding, reporting, and regulatory structures are put in place to allow for projects to develop in a context of uncertainty, but having the collaborations and partnerships at the center of the requirements.

In parallel, uncritical emphasis on participation without a shift in power dynamics may pose a risk of turning iKT into a new label for tokenistic research relationships [45]. In this case study, researchers were reflective of whose voice is missing, and their characteristics mediated to foster a positive team culture that values lived experiences as expert knowledge. This finding reiterates the importance of a shift in researchers' mental models, as defined as "particular set of conceptual knowledge, expectations, and causal beliefs," in KT [46]. While academics are not traditionally trained or rewarded for their interpersonal skills, their design thinking, "a problem-solving approach that emphasizes empathy, collaboration, and iterative prototyping to develop innovative and human-centered solutions," should be better valued in academia [32,44,47,48].

Limitations

This study has limitations. Even though a total of 24 participants were interviewed from the KTII-awarded projects, the participation of patient-partners was limited. Researchers often felt that they had asked enough of their partners, and participating in one additional interview could be onerous. This is an important consideration for mandates for partner engagement in research. More first-hand accounts of patient-partners as co-knowledge creators, particularly children and young people, as well as information about group-level demographics of interview participants, might have provided a novel and in-depth understanding of effective engagement approaches and processes for innovation development. Case studies including intersectionalities, such as Indigenous research partnerships, would also be beneficial to learn how a transcultural lens can be applied to decolonize iKT practices and to define what we consider innovation and how we respond to needs in different contexts and populations. In addition, all KTII-awarded teams had established research relationships at the time of grant application. Therefore, even though inclusion and equality underlie participatory design [28], critical examination of structural participation barriers related to diversity, inclusion, and representation was limited. Lastly, the collected data did not necessarily include the long-term impact of innovations after the knowledge dissemination activities were concluded. Future studies should also measure the long-term knowledge uptake and its impact on social and health conditions and the sustainability of research partnerships with diverse teams of partners.

Conclusions

This case study showed multidimensional aspects of innovative KT in patient-oriented research, particularly (1) a clear know-do gap is an opportunity for innovations, (2) innovation is a process as well as an approach of creating new knowledge from lived experience and other expertise of various research partners, (3) innovation disrupts the traditional knowledge hierarchy and power imbalance in research, (4) innovation requires flexibility in timeframe and funding, (5) a challenge can be an opportunity for another innovation, and (6) innovation can bring not only tangible but also intangible outcomes at individual, organizational, and community levels. For successful innovative KT, the research landscape should also change in terms of funding and timeline in order to foster researchers' mental models in designing thinking and actions on collaborative research engagement.

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Data Availability

The data that support the findings of this study are available to those who meet the criteria to access confidential data on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Authors' Contributions

SY led data analysis and manuscript writing. AZ was involved in participant recruitment, interviewing, qualitative coding, and coordination of the study. KR, RC, and ZB were involved in the reviewing panel and qualitative coding. CP was involved in conceptualization, study design, qualitative coding, and analysis. KS was involved with conceptualization, study design, and supervision. All authors provided critical feedback and helped shape the research, analysis, and manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide questions.
[DOCX File, 16 KB - jopm_v18i1e77581_app1.docx]

Multimedia Appendix 2
Drivers for innovations.
[DOCX File, 16 KB - jopm_v18i1e77581_app2.docx]

Multimedia Appendix 3
Facilitators for innovations.
[DOCX File, 17 KB - jopm_v18i1e77581_app3.docx]

Multimedia Appendix 4
Barriers to and challenges with innovation development.
[DOCX File, 15 KB - jopm_v18i1e77581_app4.docx]

Multimedia Appendix 5
Enablers to sustainable use of the knowledge translation product.
[DOCX File, 17 KB - jopm_v18i1e77581_app5.docx]

Checklist 1
GRIPP2 (Guidance for Reporting Involvement of Patients and the Public, second version) checklist.
[DOCX File, 18 KB - jopm_v18i1e77581_app6.docx]

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
CIHR: Canadian Institutes of Health Research
iKT: integrated knowledge translation
KT: knowledge translation
KTII: Knowledge Translation Innovation Incubator
SPOR: Strategy for Patient-Oriented Research

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Developing a Parent-Focused Decision Aid to Promote Child-Inclusive Shared Decision-Making in Pediatric Oral Immunotherapy: Pragmatic Exploratory Feasibility Study

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Abstract

Background: Shared decision-making is increasingly valued worldwide in pediatric care; nonetheless, its application in Japanese clinical practice remains in its early stages, particularly in areas with substantial medical uncertainty, such as food allergy (FA) management. Although oral immunotherapy is a promising option for children with FA, its long-term effectiveness and safety remain under evaluation, providing families with limited evidence to navigate emotionally complex decisions. Despite this clinical uncertainty, decision aids (DAs) are beneficial for organizing information and supporting patients and families in making value-congruent choices. Involving children in these decisions is increasingly recognized as ethically and developmentally appropriate. DAs clarify treatment options and promote informed collaborative decisions. However, most DAs target adult users and do not explicitly encourage engagement with children's views.

Objective: This study aimed to develop a culturally adapted DA for Japanese parents by considering their children's preferences and perspectives.

Methods: A paper-based DA was developed through iterative alpha testing and finalized by a multidisciplinary team. In total, 9 parents of children eligible for oral immunotherapy participated in this study and received the DA. Although intended for parents, the DA was structured to prompt reflection on the children's involvement in decision-making. Parents completed structured questionnaires before and 1 week after receiving the DA to assess uncertainty, anxiety, and the burden of FA management. A total of 4 children completed the quality-of-life (QoL) questionnaire. Subsequently, all 9 parents and 4 children participated in semistructured interviews. Parents discussed how they used the DA, their perceptions of its clarity, and their interest in involving their children in decision-making. The children shared their thoughts about participating in decision-making.

Results: All 9 parents read the DA and completed the follow-up assessment (100% retention rate). Among them, 4 children participated in pediatric QoL assessments and interviews. Parents' Decisional Conflict Scale scores significantly decreased from 58.3 (SD 29.9) at baseline to 26.7 (SD 24.1) postintervention (t_8=2.65; P=.03). The values clarity subscale also significantly declined, from 73.1 (SD 30.6) to 25.9 (SD 26.2) (t_8=4.50; P=.002). No significant changes were observed in parental anxiety and QoL. Overall, 7 of the 9 parents explained the treatment options to their child, and 6 reported actively seeking their child's feelings. The interview results suggested that the DA was associated with a shift in the family dynamic "from protecting to partnering."

Conclusions: Culturally adapted DAs appear practical and acceptable to Japanese families when making pediatric FA treatment choices. Facilitating parent-child dialogue may promote more inclusive decision-making. Nevertheless, further research with larger samples and longer follow-up periods is warranted to confirm these findings and refine the tool.

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KEYWORDS

decision support techniques; shared decision-making; food hypersensitivity; oral immunotherapy; parents; child; family-centered care; quality-of-life

Introduction

Background

Pediatric food allergies (FA) affect approximately 8% of children worldwide and present ongoing medical and psychosocial challenges to patients and their families [1-3]. Oral immunotherapy (OIT) has emerged as a therapeutic option alongside traditional allergen avoidance and emergency preparedness; notably, it is gaining popularity in several countries, including Japan. Nevertheless, OIT involves considerable daily workload and prolonged commitment; moreover, it can provoke mild-to-moderate symptoms and, on rare occasions, anaphylaxis [1,4,5]. Thus, because multiple reasonable options exist and value concordance influences outcomes, OIT is a prototypical preference-sensitive decision. Therefore, these trade-offs should be evaluated systematically through shared decision-making (SDM), which aligns with the family's values and risk tolerance. Additionally, the Canadian Society of Allergy and Clinical Immunology (CSACI) guidelines emphasize that SDM is ethically and clinically essential for OIT, ensuring that families make informed and personalized decisions [6].

SDM is a clinical practice model that integrates the best available evidence with patients' and families' values and can improve knowledge, reduce decisional conflict, and enhance adherence [7-9]. As a framework that supports the implementation of SDM, the Ottawa Decision-Support Framework (ODSF) identifies decisional needs, such as knowledge deficits, unclear values, and insufficient support, and organizes tailored interventions to address them [10,11].

Within the ODSF, patient decision aids (DAs) represent primary implementation vehicles, delivering evidence-based information, structuring value clarification, and prompting supportive dialogue. Recent systematic reviews have demonstrated that DAs are effective across diverse clinical contexts in increasing knowledge, promoting value-concordant choices, and reducing decisional conflict [10,11].

Implementing SDM in pediatrics entails additional complexity layers arising from a triadic structure, health care providers, caregivers, and the child, in which developmental stages, family roles, and emotional dynamics intersect [12,13].

Uncertainty regarding diagnosis, prognosis, and treatment outcomes constitutes a significant barrier to SDM in complex pediatric care; moreover, hierarchical power imbalances during clinical encounters further impede its implementation. Similarly, continuity of care, access to accurate and balanced information, and communication skills exert substantial influence. These patterns, synthesized in a recent scoping review of pediatric community health services, underscore the need for approaches supporting equitable partnerships and high-quality information exchange [14]. Furthermore, parents' strong protective orientation may limit the elicitation and incorporation of children's preferences. Thus, developmentally appropriate support for child participation and deliberately structured collaborative partnerships between parents and clinicians are essential [1,12,13]

In pediatric FA, anxiety regarding accidental exposure and ongoing at-home care workload imposes condition-specific emotional and practical burdens on families [1,6]. These condition-specific burdens intensify general barriers to pediatric SDM, making it necessary to design decision supports that not only structure information and value clarification but also surface and integrate the child's developmentally appropriate perspective alongside parents' values [14-16].

Knowledge Gap and Study Aim

In Japan, pediatric OIT is not widely recommended in routine clinical practice, and many families rely primarily on allergen avoidance within tolerated ranges [5]. Nonetheless, domestic preliminary reports [4] have documented an increasing number of institutions offering pediatric OIT, currently exceeding 100 nationwide. Despite this growth, opportunities for families to view OIT as a realistic option and engage in SDM that incorporates their children's preferences remain limited.

Importantly, these dynamics are more pronounced in the Japanese clinical context, where deference to medical authorities and high-context communication may amplify hierarchical power imbalances and hinder SDM implementation [17,18].

During emotionally charged visits, families may find it difficult to voice uncertainties, hopes, or questions [1,19]. Although children have the right to express their views on matters affecting them [16], meaningful participation in medical decisions remains limited. Moreover, Japan lacks OIT-specific DAs, and existing developments largely originate from outside Japan, leaving a gap in culturally adapted support. Consequently, there is a need for DAs that go beyond information provision and value clarification to activate dialogue, meet emotional needs, and enable parents to incorporate developmentally appropriate children's views and feelings into their decisions. Therefore, this study aimed to develop and evaluate the feasibility and acceptability of a culturally adapted, parent-focused DA designed to facilitate child-inclusive dialogue in pediatric OIT settings in Japan.

Methods

Study Design

We conducted a pragmatic exploratory feasibility study to assess the newly developed DA for families eligible for pediatric OIT. This type of feasibility work commonly enrolls 10 - 30 participants, which is an adequate range for identifying procedural issues and evaluating the initial signals of effect [20,21]. Guided by this benchmark, we enrolled 10 parents and 5 children. One parent-child dyad withdrew before the baseline assessment; therefore, the analyses included 9 parents and 4 children (N=13). Each participant completed structured questionnaires at baseline and 1-week postintervention, followed by a brief semistructured interview. To effectively integrate quantitative and qualitative data, numeric measures (eg, decisional conflict, state anxiety, and QoL) were paired with interview feedback (eg, parent-child communication and DA usability) [22,23]. This study was not powered to test efficacy but did generate preliminary data and highlight practical issues that should be addressed before a larger trial.

DA Development

We developed a parent-focused booklet DA to support SDM by prompting parents to elicit and consider their child's views and, where appropriate, to collaborate with the child, following a systematic development process [24], adhering to the Japanese adaptation of the International Patient DA Standards Instrument version 4.0, and meeting all 6 qualifying criteria [25].

Following the Ottawa Decision Guide, the DA is organized into 4 core sections: understanding the decision-making process, comparing treatment options, clarifying personal values, and assessing the current situation. To promote meaningful child involvement consistent with the UN Convention on the Rights of the Child [16], the DA includes brief information about the Convention and sample questions that parents can use to explore their child's feelings and is formatted as an easy-to-use booklet for parents and children (Table 1).

Table . Contents of the Let's Think Together About Treatment Options for Food Allergies decision aid.

Chapter	Contents	Setting
Option	• Guidebook objectives • Table of contents	• Read
Step 1	• Guidance on SDM[a] • How to make more informed decisions about treatment	• Read
Step 2	• Knowledge of illnesses and treatments available • Choosing between elimination and OIT[b] • Understanding food allergies • Understanding potential treatments and their characteristics • Understanding the lifestyle and psychological impact of treatments	• Read
Step 3	• Value-based decision-making • Clarifying what is important to you when you make a decision • Colum: Children's feelings about treatment • Let's ask your child about their feelings regarding the illness and treatment	• Read • Check • Read • Read and write
Step 4	• Treatment options that are currently under consideration • Clarifying your current feelings and organizing your concerns	• Read • Check

[a]SDM: shared decision-making.

[b]OIT: oral immunotherapy.

Development Followed a User-Centered, Multistage Process

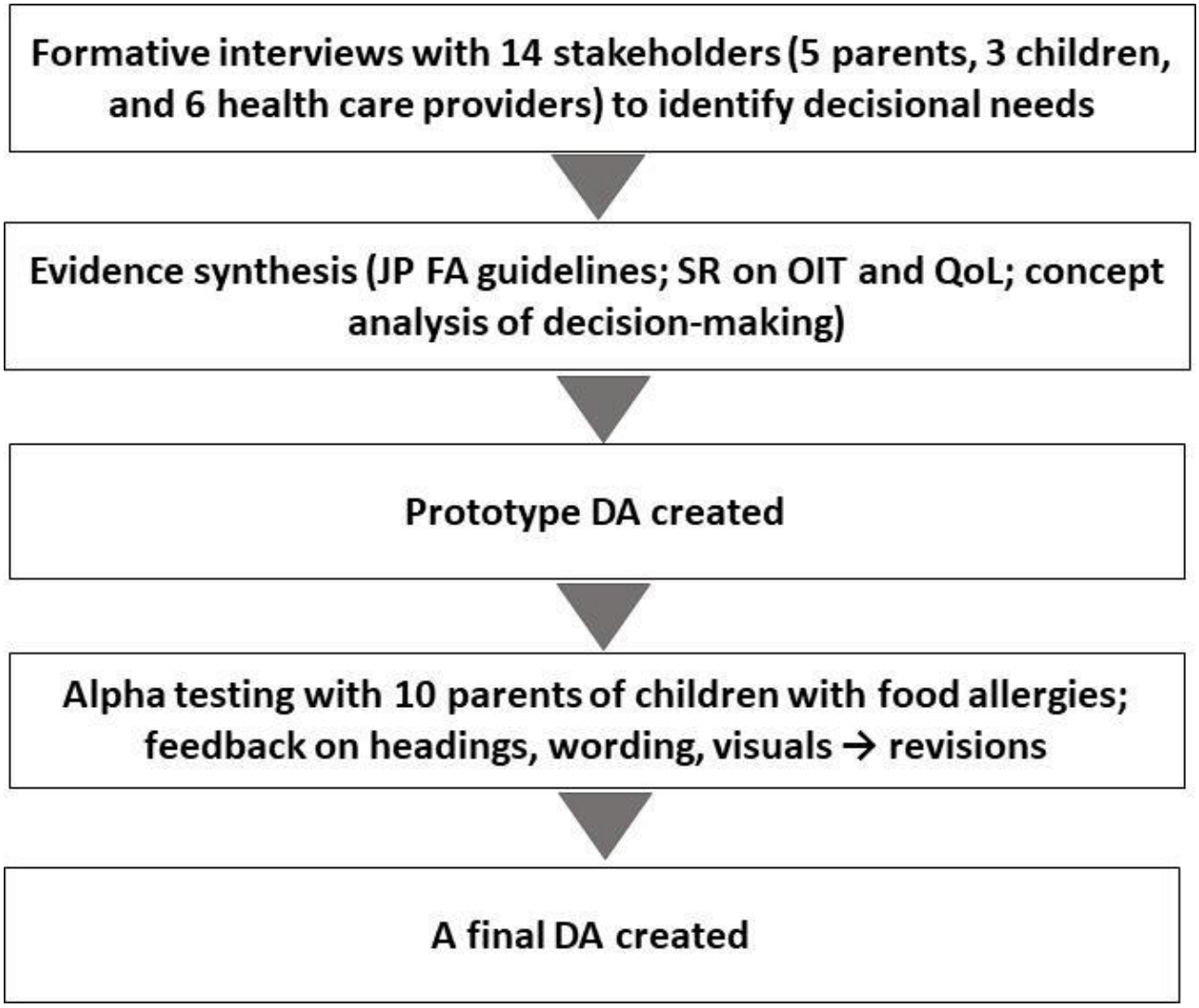
Formative interviews were conducted with 14 stakeholders, 5 parents, 3 children, and 6 health care providers, by purposively sampling families that had previously considered OIT (proceeded vs continued elimination; approval number 19R-272). Children expressed a desire to learn about options and to be invited to participate in OIT decision-making. Their input informed the parent-facing DA by adding nonleading prompts to elicit parents' children's views and by adopting age-appropriate wording.

Next, we synthesized evidence from the Japanese clinical guidelines [5], a systematic review of the impact of OIT on QoL, and a conceptual analysis of decision-making in pediatric chronic conditions. Using these inputs, a multidisciplinary panel (SDM specialists, pediatric allergists, and nursing researchers) specified the content, wording, and layout and produced a paper prototype.

Subsequently, the prototype was alpha tested with 10 parents of children with FA who had previously been considered for an OIT decision (approval number 21R-020). Acceptability was high: 9 (90%) and 1 (10%) rated the DA as "Excellent" and "Very good," respectively. Parents judged the information to be balanced between elimination and OIT, and the feedback emphasized clearer headings, simplified language, and greater use of visuals. Revisions were made accordingly, and an improved DA was used here.

The development process is summarized in Figure 1, and the final DA is provided in Multimedia Appendix 1.

Figure 1. Flow diagram of the decision aid development process. DA: decision aid; FA: food allergy; JP: Japanese; OIT: oral immunotherapy; QoL: quality of life; SR: systematic review.



Participants and Setting

The participants were recruited from a pediatric allergy outpatient clinic in Japan. Two groups of participants were eligible: parents and children. Parents could participate regardless of the child's age, whereas children were eligible only if they were in grade 1 or higher in primary school (typically ≥6 y). We set the eligibility according to the treating physician's clinical judgment regarding the appropriateness of discussing OIT in individual cases. In this study, "suitability for OIT" referred to children currently managed with an elimination diet for whom the physician judged that OIT could be considered and discussed as a potential option. Parent participation was not contingent on child participation; therefore, the parent and child sample sizes were not numerically matched.

The inclusion criteria are listed in Textbox 1.

Textbox 1. Inclusion criteria.

- Parents of children currently managed with an elimination diet for whom the treating physician judged that OIT could be considered and discussed.
- Children in grade 1 or above in a Japanese primary school (typically ≥6 y), with adequate cognitive capacity to participate in interviews and task-based procedures, and for whom the treating physician judged that OIT could be considered and discussed.

Recruitment and Consent

Physicians and nurses conducted the study during clinic visits. We used two invitation pathways: parent-only and parent-child invitations. For parent-only invitations, the physician or nurse explained the study to the parent and, if interested, asked the parent to contact the research team via the email address or phone number listed on the information sheet to minimize any perception of coercion. For parent-child invitations, the physician or nurse explained participation separately to the parent and the child using age-tailored information sheets (lower elementary, upper elementary, and junior high versions). The parents then confirmed the willingness of the child. Enrollment proceeded only when both parents and children expressed interest, after which the parents contacted the research team via email or phone. Before any study procedures, all parents

provided written informed consent, and the children provided age-appropriate assent.

Intervention and Data Collection Procedure

Overview

We conducted this study between October 2022 and May 2023.

At the single participating clinic, we approached 10 parents and 5 children, and all agreed to participate. One parent-child dyad was excluded before baseline because OIT was initiated before questionnaire distribution; accordingly, this dyad was not included in the analytic sample. Data from 9 parents and 4 children who completed both the baseline and 1-week questionnaires and postintervention interviews were included in the analysis.

Baseline

After obtaining parental consent and child assent, the parents (9/9, 100%) and children (4/4, 100%) completed the baseline questionnaire.

DA Provided to Parents

At the next clinic appointment (2 - 4 wk later), a physician provided a brief, nondirective orientation to the DA, highlighting that multiple treatment options existed and that the DA offered tips and prompts for SDM. To avoid influencing DA use or evaluation, we provided no option-specific counseling.

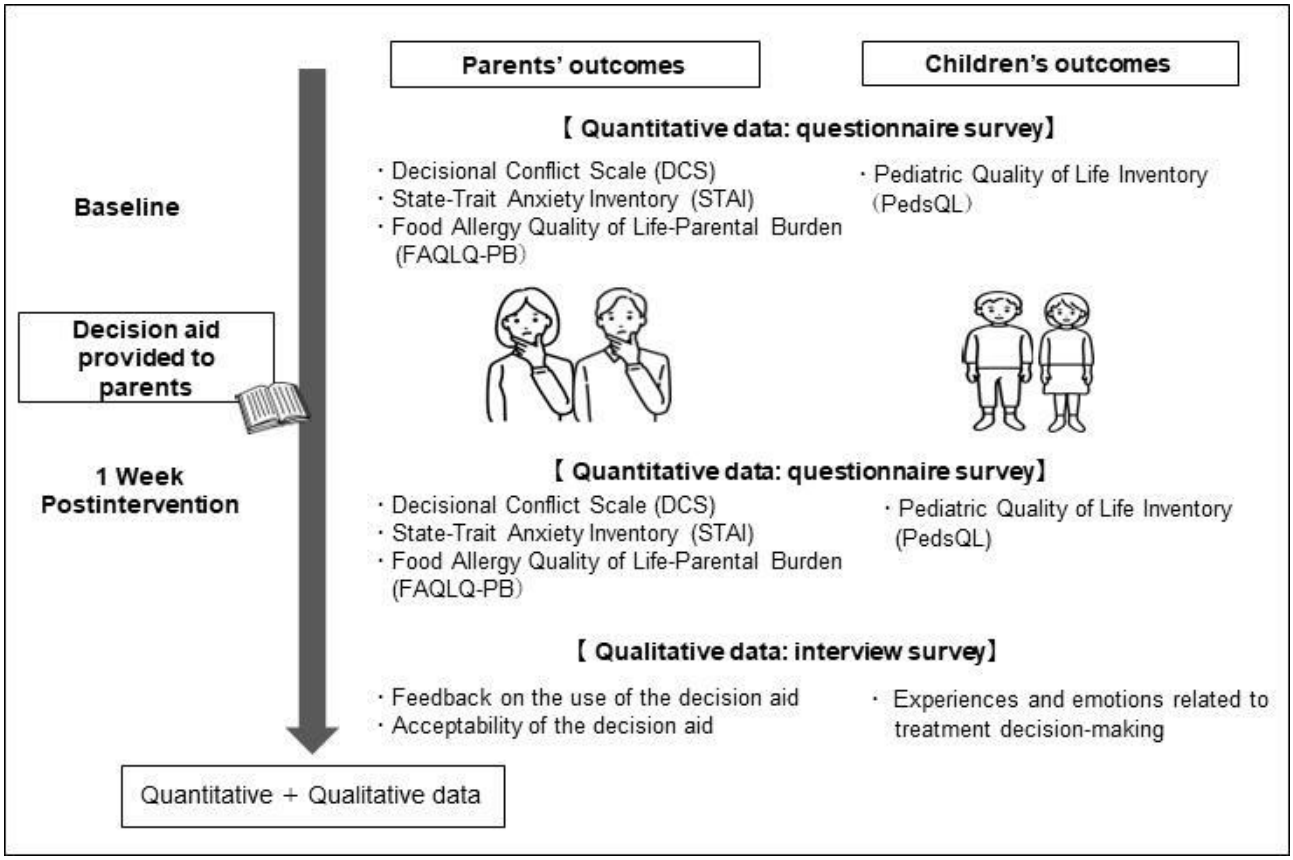
One Week Postintervention

At the 1-week follow-up, parents and children repeated the questionnaires and participated in brief semistructured interviews to explore their experiences with the DA.

Quantitative Outcome Measures

Guided by the ODSF, we prespecified the Decisional Conflict Scale (DCS) as the primary outcome and the State–Trait Anxiety Inventory, State Anxiety subscale (STAI-State), FA QoL–Parental Burden (FAQLQ-PB), and Pediatric QoL Inventory (PedsQL) as contextual measures, given evidence that DAs reduce DCS and improve decision quality [26,27]. We assessed parental outcomes, children's health-related QoL, and postintervention feasibility and acceptability. We used validated Japanese versions with published reliability and construct validity for the DCS, STAI-State, FAQLQ-PB, and PedsQL. Self-administered questionnaires were completed at baseline and 1-week postintervention. We measured postintervention feasibility and acceptability using study-specific items, as displayed in Figure 2.

Figure 2. Study flow diagram of recruitment, decision aid intervention, and 1-week follow-up.



Parental Outcomes (Pre- and Postintervention)

DCS, Japanese Version

This tool measures uncertainty and perceived difficulty in making health-related decisions [26]. The scale includes 5 subdomains: feeling informed, clarity of values, perceived support, uncertainty, and effectiveness of decision-making. Higher scores indicate greater decisional conflict. We chose this measure as the primary proximal outcome in the ODSF framework [10,27].

STAI, Japanese Version

This tool assesses the situational (state) components of anxiety [28]. We used only the state anxiety subscale in this study. Higher scores indicate increased anxiety. We included this measure to index the emotional burden relevant to preference-sensitive choices, consistent with the ODSF [27].

FAQLQ-PB, Japanese Version

This tool evaluates the psychological and practical burden among parents managing a child with a FA; higher scores indicate lower QoL [29,30]. To capture family-level impacts beyond decisional cognition, QoL sensitivity to SDM-oriented interventions has been reported in pediatric asthma trials [31].

Child Outcomes (Pre- and Postintervention)

We used different versions of the Japanese version of PedsQL based on age groups (5 - 7, 8 - 12, and 13 - 18 y) [32]. Higher scores reflect better QoL. We used it as a low-burden, developmentally appropriate child outcome (self-report when feasible; parent-proxy otherwise) and prioritized proximal parental outcomes.

Parental Feasibility and Acceptability Items (Postintervention Only)

The following parental feasibility and acceptability items were used:

1. Two yes-or-no questions assessing parent-child engagement in decision-making: (1) “Did you explain the treatment options to your child?” and (2) “Did you ask your child how they felt about those options?”
2. Likert-type items on DA clarity, format, ease of understanding, perceived usefulness, and willingness to use similar aids in the future.
3. One open-ended question asked parents what additional information or support they would have found helpful.

Statistical Analysis

We analyzed quantitative data using IBM SPSS Statistics (version 25; IBM Corp). Descriptive statistics were calculated for each outcome. We used paired-sample *t* tests (2-tailed) to compare pre- and postintervention DCS, STAI, and FAQLQ-PB scores. We set statistical significance at $P<.05$.

Qualitative Data Collection and Analysis

Overview

One week following DA distribution, we conducted brief semistructured interviews with the participating parents (9/9, 100%) and children (4/4, 100%). All interviews were performed by the first author, a female registered nurse, academically trained in qualitative methods at the PhD level, with no prior relationships with participants or sites.

At the start of each interview, the participants were informed that the interviewer was an independent nursing researcher and university teacher with no prior relationship with them or the recruiting hospitals. We interviewed each participant once and recorded no field notes. After obtaining informed consent, we audio-recorded and transcribed all interviews. We provided the semistructured interview guides for parents and children in Multimedia Appendix 2.

Separateness and Modality

A trained interviewer conducted 9 individual parent interviews (5 in person, 4 online) and 4 child interviews (all in person). To maximize comfort, 1 child elected to be interviewed alone and 3 elected to be interviewed with a parent present.

Duration

Parent interviews lasted 20 - 40 minutes; child interviews lasted 10 - 30 minutes.

Data Management and Analysis

The transcripts were imported into NVivo 14 software (Lumivero) for data management. We analyzed the interviews using thematic analysis [33]. We analyzed parent interviews thematically using inductive semantic-level coding with iterative codebook refinement and peer debriefs. We summarized child interviews narratively (descriptive summaries with exemplar quotations) to contextualize parent themes and were not formally coded because of the small sample size in this feasibility study. We did not seek thematic saturation. We judged the analytical adequacy based on the coherence and stability of the parent themes and the illustrative value of the child narratives.

Data Presentation and Interpretation

To facilitate comparison, we used a side-by-side joint display that aligned each quantitative outcome row with a single qualitative column (related category and, when informative, a de-identified exemplar quotation) and positioned conceptually similar themes in parallel across the 3 measures (DCS, STAI-State, and QoL). Side-by-side displays are widely used in mixed-methods health research to integrate quantitative results with qualitative evidence and support interpretation [22,34].

Ethical Considerations

We conducted this study in accordance with the Declaration of Helsinki and the Ethical Guidelines for Medical Research Involving Human Subjects in Japan. The Ethics Review Board of our institution approved this study (approval numbers 22-AC044 and 22RC-040). All parents provided written informed consent and children provided age-appropriate assent. Interviews were audio-recorded with permission. We deidentified all data, removed potentially identifying information from transcripts and quotations, and stored files on password-protected systems accessible only to the research team. No compensation was provided.

Results

Parent-Child Characteristics

A total of 9 parents and 4 children participated in the study, and their characteristics are summarized in Table 2. Of the 9 parents, 8 were female. Their children, all deemed eligible for OIT by their physicians, exhibited a mean age of 7.6 (SD 4.2; range 2 - 14) years and were predominantly male (6/9).

Table . Demographic and clinical characteristics of parent-child participants.

Characteristics	Participants
Parents (n=9)	
Age (years), mean (SD; range)	42.7 (5.7; 35 - 52)
Sex, n (%)	
Male	1 (11.1)
Female	8 (88.9)
Occupation, n (%)	
Home worker	5 (55.6)
Part-time job	1 (11.1)
Self-employed	2 (22.2)
Other	1 (11.1)
Children's age (years), mean (SD; range)	7.6 (4.2; 2-14)
Children's sex, n (%)	
Male	6 (66.7)
Female	3 (33.3)
Children's allergies (duplicate entries), n (%)	
Eggs	2 (22.2)
Peanuts	3 (33.3)
Other	7 (77.8)
History of anaphylactic shock, n (%)	
Yes	4 (44.4)
No	5 (55.6)
Children (n=4)	
Age (years), mean (SD; range)	10.75 (4.2; 7-14)
Sex, n (%)	
Male	3 (75)
Female	1 (25)
Children's allergies (duplicate entries), n (%)	
Walnut	3 (75)
Peanuts	2 (50)
Others	3 (75)
History of anaphylactic shock, n (%)	
Yes	2 (50)
No	2 (50)

Of these 9 families, 4 children who completed the postintervention QoL assessments and interviews comprised a nested subsample. These participating children had a mean age of 10.8 (SD 4.2; range 7 - 14) years; 3 were male and 1 was female. They were allergic (with duplicate counts allowed) to walnuts (3/4, 75%), peanuts (2/4, 50%), and other foods (3/4, 75%). Two of the 4 patients had a prior history of anaphylactic reactions, whereas 2 had no such history.

Quantitative Outcomes in Parents

Table 3 presents the detailed quantitative results. As the primary outcome, parental decisional conflict decreased from 58.3 (SD 29.9) at preintervention to 26.7 (SD 24.1) at 1 week postintervention, a mean reduction of 31.6 points (95% CI 4.09 to 59.11; t_8=2.65; P=.03; paired d=0.88). Improvements were particularly pronounced in the subscales of values clarity (mean 73.1, SD 30.6 to mean 25.9, SD 26.2; P=.002), perceived support (mean 48.1, SD 32.8 to mean 20.4, SD 22.1; P=.04), and uncertainty (mean 62, SD 32 to mean 30.6, SD 23.2; P=.04).

Table . Parental outcome measures at baseline and postintervention following decision aid use.

Scores and subscales	Baseline, mean (SD)	1-week postintervention, mean (SD)	*t* test (*df*=8)	*P* value
DCS[a]				
Total	58.3 (29.9)	26.7 (24.1)	2.65	.03
Informed	54.6 (35.9)	25 (25)	1.89	.10
Value clarity	73.1 (30.6)	25.9 (26.2)	4.50	.002
Support	48.1 (32.8)	20.4 (22.1)	2.42	.04
Uncertainty	62 (32)	30.6 (23.2)	2.43	.04
Effective decision	54.9 (37.5)	30.6 (29.4)	1.59	.15
STAI[b]	37.9 (8.99)	35.9 (8.17)	2.03	.08
FAQLQ-PB[c]	25.6 (7.82)	26 (8.9)	−0.31	.77

[a]DCS: Decisional Conflict Scale.

[b]STAI: State–Trait Anxiety Inventory.

[c]FAQLQ-PB: food allergy QoL, parental burden.

For secondary outcomes, STAI-State decreased from 37.9 (SD 9) at preintervention to 35.9 (SD 8.2) at 1 week postintervention; the mean difference was 2 points (95% CI −0.27 to 4.27; t_8=2.03; *P*=.08), corresponding to a moderate standardized effect (paired *d*=0.68). FAQLQ-PB exhibited little change (mean 25.6, SD 7.8 to mean 26, SD 8.9); the mean difference was −0.4 points (95% CI −4.29 to 3.54; t_8=−0.31; *P*=.77), with a negligible standardized effect (paired *d*=−0.08).

Qualitative Explanations of Parental Outcome

Overview

Overall, 3 primary themes emerged from the interview data (Textbox 2). The first concerned communication with physicians, including environmental constraints and hesitation to voice concerns. The second pertained to emotional reactions and difficulties processing information related to treatment decisions. The third reflected emotional burdens, such as anxiety and uncertainty, which parents described before using the DA.

Textbox 2. Key category and illustrative quotations.

Difficulties in physician communication

- Time constraints: “Clinic is crowded; I hesitate to ask.”
- Need guidance: “When my child wants to eat, I’d like direction.”
- Uncertainty about asking: “I’m never sure how much I can consult.”

Challenges in obtaining reliable information

- Conflicting information: “Online advice is contradictory and confusing.”
- Information overload: “There’s so much data it’s overwhelming.”
- Child’s desire for autonomy: “I want to eat safely and have a say.”

Difficulties in coping with emotional uncertainty

- “I’m still anxious because there’s so much I don’t know.”

Difficulties in Physician Communication

These include difficulties related to interactions with physicians and obtaining reliable information. Within the first theme, parents described feeling constrained by busy clinical environments and were uncertain whether it was appropriate to voice their concerns. This was illustrated by comments such as “In outpatient settings, there are usually many people, so I felt it wouldn’t be right to take up too much time just for myself.”

Challenges in Obtaining Reliable Information

Under the second theme, parents reported frustration with conflicting or overwhelming online resources, for example, “Sometimes completely contradictory information comes up, right? I look things up because I don’t understand, but it just ends up confusing me even more” and “When I search the Internet, of course, information comes up. However, when I open it myself, there’s so much information that it becomes overwhelming.” These barriers appeared to directly contribute to high levels of decisional conflict before DA use.

Difficulties in Coping With Emotional Uncertainty

Several parents described feeling anxious or overwhelmed when considering treatment options, particularly because of uncertainty and lack of prior knowledge. Expressions of worry, such as "I'm still anxious because there's so much I don't know," highlighted the emotional strain experienced before using the DA. Emotional stress often coexisted with difficulties in processing information and hesitancy about how to proceed.

DA Acceptability and Parent-Child Communication

Parental responses regarding the acceptability of DA and parent-child communication are summarized in Table 4. All 9 parents (9/9, 100%) reported having read the DA, supporting its feasibility for home use. Most parents responded positively when asked about its acceptability: 89% (8/9) answered "yes" or "somewhat yes" to "was the DA easy to understand?" Nevertheless, 33% (3/9) reported writing in the open-ended sections of the DA. Although this may limit engagement with the writing component, it does not reflect poor acceptability. Rather, parents explained that because an OIT decision was not imminent, they did not feel the need to record their thoughts at that time. Instead, DAs are primarily used as reading tools or discussion guides in family conversations.

Table . Parental responses on collaboration with children, decision aid acceptability, and additional needs with illustrative quotations.

Variables	Quantitative (n=9), n (%)	Key category and illustrative quotations
Collaborate		
Explained options to the child	• Fully, 5 (56) • Partial, 2 (22) • Limited, 1 (11) • None, 1 (11)	• Assessing understanding: "I realized my child was actually thinking about the treatment..."
Considered child's feelings	• Definitely, 4 (44) • Somewhat, 2 (22) • Neutral, 1 (11) • Not, 2 (22)	• Respecting feelings: "You can't move forward without asking the child first."
Acceptability		
Read the DA[a]	• Yes, 9 (100) • No, 0 (0)	• Guide usefulness: "Reading the guide made the steps clear to me."
Wrote in the DA	• No, 6 (67) • Yes, 3 (33)	• Family reflection: "It's good to take this home and think about it together."
DA clarity	• Definitely, 5 (56) • Somewhat, 3 (33) • Neutral, 1 (11) • Not very clear, 0 (0) • Not clear, 0 (0)	• Reassurance: "Written explanations gave me peace of mind and were incredibly useful."
Additional needs	—[b]	• Early information: "I would have liked to receive information about OIT right after the diagnosis." • Peer stories: "Hearing others' experiences would be helpful as a reference."

[a]DA: decision aid.

[b]Not applicable.

Additionally, DA facilitated parent-child communication. When asked, "Did you explain the treatment options to your child?" 78% (7/9) of the parents responded affirmatively. Moreover, 66% (6/9) said they "listened to their child's feelings about those options." Parents emphasized that the DA prompted them to consider and discuss their child's perspective and values in greater depth than before.

Furthermore, qualitative responses revealed that although some parents were reluctant to write in the DA, they found structured prompts helpful in organizing family discussions.

Parent-Child Collaboration and Pediatric QoL

Four parent-child dyads participated in this study. Table 5 presents each dyad's decision-making collaboration, along with the child's PedsQL scores and illustrative quotations.

Table . Child engagement in decision-making processes and Pediatric Health-related Quality of Life; scores at baseline and 1 week postintervention following decision aid use.

Dyad (years)	Parent-reported items	PedsQL[ab] (child), baseline 1-week	Child voice	Decisional conflict	Preference direction	Child quotation
A (7 y)	• Explained options: yes • Asked feelings: somewhat agree	93.5, 93.7	Minimal ("mother decides")	Not expressed or low	Elimination	"My mother decides… I don't know."
B (10 y)	• Explained options: yes • Asked feelings: agree	97.8, 94.6	Clear (asks for dialogue)	Mild–moderate	Interested in OIT[c]	"I want to talk more… I've been kind of thinking about it."
C (14 y)	• Explained options: yes • Asked feelings: agree	97.8, 96.7	Clear (requests participation)	Low (direction set)	Favoring-OIT	"I'd like to try OIT and have a say when deciding."
D (14 y)	• Explained options: yes • Asked feelings: somewhat agree	92.4, 96.7	Clear (reasoned avoidance)	Low (stable stance)	Elimination	"I'm fine to keep elimination; I don't need treatment talks."

[a]PedsQL: pediatric health-related Quality of Life.

[b]Note: PedsQL indicates pediatric health-related QoL; higher scores reflect better HRQoL.

[c]OIT: oral immunotherapy.

All 4 parents (100%) reported explaining the treatment options to their children, and 3 of the 4 (75%) further stated that they asked how their children felt about those options. The PedsQL scores were uniformly high at preintervention (range 92.4 - 97.8) and demonstrated minimal change postintervention (range 92.4 - 96.7).

Child involvement varied by age. In lower elementary school (7 y), expressions of agency were minimal, and no verbalized conflict was noted (dyad A: "My mother decides… I don't know."). In upper elementary school (10 y), preferences were emerging yet ambivalent, with mild-to-moderate conflict (dyad B: "I want to talk more… I've been kind of thinking about it."). In junior high school (14 y), positions were clearer and conflict was low, but directions diverged, favoring OIT (dyad C) over continued elimination (dyad D). For example, the 7-year in dyad A stated, "My mother decides," whereas the 14-year in dyad C, after reading the DA with a parent, wished "to have a say." Multimedia Appendix 3 presents de-identified excerpts from the separate parent and child interviews, integrated and organized by dyad (A–D).

Discussion

Principal Findings

This feasibility study examined a culturally adapted parent-focused DA to support SDM for families considering pediatric OIT in Japan. Quantitative results indicated reduced parental decisional conflict, and interviews suggested greater engagement in parent-child dialogue and heightened awareness of children's involvement in decisions. Collectively, these findings provide preliminary support for integrating SDM tools into pediatric allergy care.

Reduction in Parental Decisional Conflict

The DA used in this study appeared to support a reduction in parental decision-making conflicts, particularly in the DCS subscales of value clarity, perceived support, and uncertainty. These results are consistent with those of previous trials on OIT-specific DAs [35]. Additionally, our study provides descriptive within-participant change data from clearly defined baseline measurements, suggesting that DA helps parents better understand treatment options and reflect on personal values in the context of complex, preference-sensitive decisions. When there was no single "correct" choice, the DA structure, which encourages clarification and comparison, may have contributed meaningfully to reducing decisional stress. Notably, changes observed over a 1-week period may reflect influences beyond DA exposure. Additional clinician contact or family discussions can improve perceived support and value clarity, whereas allergy-related events or conflicting online information can increase uncertainty and anxiety. These measurement effects may also have contributed. Interviews documented parent-child dialogue after DA receipt, consistent with gains in value clarity and support; however, because co-interventions and information seeking were not systematically recorded, observed DCS reductions should be interpreted as preliminary and potentially contingent on unmeasured influences. Conversely, emotional outcomes such as anxiety and QoL did not demonstrate any considerable changes. This divergence between the cognitive and emotional domains has also been noted previously, suggesting that reducing uncertainty does not always lead to

immediate emotional relief, particularly in high-stakes decisions such as OIT, where safety concerns persist [3,19].

Emotional Outcomes and Narrative Support

To support an emotionally responsive SDM model, DAs should address factual content and users' emotional needs. Recently, a narrative review noted that parents contemplating OIT can be confused by inconsistent or nonevidence-based online information and often report anxiety about allergic reactions, highlighting the importance of SDM approaches and DAs that help address misinformation while acknowledging parental concerns. This is particularly crucial, as parental fear and anxiety are recognized globally as major factors influencing treatment decisions for chronic conditions such as FA [1-3]. Similarly, our qualitative theme of "difficulties in coping with emotional uncertainty" echoes that observation and underscores the importance of embedding affective support, such as patient stories or peer testimonials, within future iterations of the DA. Nonetheless, the lack of considerable changes in anxiety and QoL may reflect the limited short-term sensitivity of the scales used and the brief 1-week observation period. The used QoL measure, which focused on chronic allergy management, may have been insufficiently sensitive to capture short-term shifts resulting from the decision-making experience. Additionally, continued parental expressions of concern in the interviews suggested the persistence of underlying uncertainty about OIT and its long-term effects, even after DA use. Collectively, these findings highlight the need for DAs to include information and components offering emotional support, reassurance, and peer feedback. As emphasized in previous studies, SDM is both a cognitive and relational process that requires supportive communication and trust [9,10]. Narrative elements, such as stories from similar patients, can promote reflection, empathy, and engagement, particularly in emotionally taxing contexts such as OIT [9,36,37]. Although the DA emphasizes evidence-based content and parent-child dialogue, future versions may benefit from incorporating narratives or links to peer support to foster emotional reassurance and decision confidence [38].

Timing and Multifaceted DA Use

All the parents read and rated the DA positively, indicating their initial engagement. Nevertheless, the intensity and mode of use varied, underscoring that the parent-focused DA served multiple functions, information, dialogue prompts, and planning, rather than a single point-of-decision tool. Notably, many families continued to avoid allergens during the study and were not immediately pressured to initiate OIT. This context may have reduced the perceived need for written reflections or explicit decision-making.

Crucially, 1 parent expressed a desire for earlier intervention, stating, "I would have liked to receive information about OIT right after the diagnosis." Furthermore, our needs assessment revealed that families often seek clarity on the flexibility of OIT, specifically whether "treatment can be stopped and later restarted or tried again" after a period of discontinuation. These themes point to an anticipatory role for the DA, positioning it early to support understanding and planning, and not only immediate choice.

FA is a chronic condition that requires ongoing management, and treatment decisions may need to be reassessed as children grow and their lifestyles change [1,2,6]. For instance, starting daycare or school, increased exposure to shared meals, and a child's curiosity or desire for autonomy may prompt families to reconsider OIT, even after extended periods of allergen avoidance. Accordingly, families benefit from clear information about the revisitable and stepwise nature of OIT decisions, including the option to defer, pause, or reconsider treatment, so that the choice is not experienced as irreversible [1,2,6]. In pediatrics, decisions warrant periodic reappraisal as children mature and assume greater autonomy [15,39].

Prior work indicates that DAs are valuable for decision-making and reflective preparation. DAs can help patients clarify their values and enhance their readiness to make future choices. Additionally, they support preference articulation before clinical encounters [40], foster emotional engagement and reflective thinking through the inclusion of narratives [36], and allow patients to organize their concerns and values before consultations [19]. Future research should explore when and for whom such DAs should be offered to maximize their effects.

Facilitation of Parent-Child Collaboration

This feasibility study suggests that the DA serves not only as an informational tool but also as a prompt for parent-child dialogue, making children's perspectives and preferences, which are infrequently elicited during clinical encounters, more visible [1,13,41]. Several parents reported that they had not previously asked their child about treatment preferences, and some recognized clear opinions for the first time when using the DA. Concurrently, certain parental statements appeared to invite child compliance or deferral, potentially diminishing the child's own voice [14,41]. Conversely, when parents asked nonleading decision-related questions, children tended to offer fuller accounts, consistent with reports that interaction styles influence children's participation [13,15,39].

The observed pattern was consistent with developmental theory. In early school-age years, self-expression is limited; in upper elementary years, interest and nascent preferences emerge but often remain ambivalent; and in adolescence, positions become more autonomous and self-referential [1,15,42]. Aligning with this gradient, some children prefer to participate directly in decisions, whereas others choose to defer to their parents, underscoring the need for developmentally aligned and flexible support for SDM [13,43]. To support this flexibility, future iterations of the DA should incorporate explicit parent-facing guidance on strategies for child engagement tailored to different developmental stages. These findings are also concordant with those of reviews emphasizing both the importance of children's involvement in medical decisions and the heterogeneity in how that involvement is expressed [13,41].

Overall, parents can use DA to elicit and incorporate their children's views into clinical decision-making, and age-aligned design features are likely to be useful [12,15,39,42,43]. To translate these insights into practice, the proposed DA revisions add explicit, developmentally tailored parent guidance: meaning-making with concrete examples and illustrations in early school age; value prioritization by listing 2 to 3 advantages

and concerns in upper elementary school; and self-referential reasoning combined with family consensus in adolescence. These staged supports enable children to select their preferred level of involvement and make triadic child-parent-clinician collaboration easier to implement. To build an evidence base, subsequent studies should evaluate age-stratified DA versions in larger, more diverse samples and co-design protocols for triadic collaboration that include parent-facing guidance [1,6].

Implementation in Japanese Clinical Settings

The DA includes prompts designed to help parents clarify their values and encourage dialogue with health care providers. However, several parents reported being unsure how to use the DA or feeling reluctant to ask questions because physicians were busy. Therefore, the effectiveness of DAs depends on both the content and the context in which they are introduced. Cultural norms in Japan, such as respect for medical authorities and hesitation to speak up, may inhibit families from actively engaging with decision-support tools, particularly during time-pressured consultations.

Unlike our Japanese setting, where deference to medical authorities and time pressure can dampen questioning, North American programs have actively evaluated and implemented OIT-focused, formal SDM workflows. A recent study reported a pediatric product-agnostic OIT DA with high acceptability and low decisional conflict among caregivers, positioning DAs as a practical adjunct to clinical encounters [35]. Consistent with this, national CSACI guidance [6] explicitly promotes patient-oriented, preference-sensitive OIT decisions, shared responsibility between families and the health system, and organizational solutions that embed SDM tools beyond the physician-patient dyad (eg, team-based introduction and previsit use). Conceptually, SDM in FA also emphasizes that clinicians must understand "where the patient is coming from," with DAs assisting values clarification rather than replacing dialogue, an approach that aligns with our qualitative finding that parents used the DA to "pause and reflect" even when consultation time was limited [1]. Taken together, these comparisons suggest that the previsit distribution and nonphysician-led onboarding of DAs are likely to mitigate Japan-specific barriers and facilitate shared deliberation within routine care.

Building on this mechanism, programs should specify when and for whom a DA is most useful. Likely triggers include decisional uncertainty, divergent family preferences, and limited consultation time. Clinicians can use brief, neutral cues to normalize values clarification without extending visits. Clear signposting on how to use the DA, age-appropriate sections for children, and plain-language summaries can further lower barriers where questioning is difficult.

Parents valued the credibility of the DA, noting that its development by health care professionals increased their trust in and willingness to use it. Additionally, receiving a DA allowed them to pause and reflect, suggesting that DAs can offer a psychological space that is not always available in typical consultations. The qualitative findings suggest that the DA served as a valuable reflective tool because the cultural context inhibited open questioning during consultations. Integrating SDM tools into routine care workflows, with endorsement from medical staff, can bridge cultural barriers and promote shared deliberation.

Implications for Health Care Practice and Policy

Mechanistically, the DA structured and balanced information helps organize concerns and form realistic expectations, thereby potentially reducing uncertainty. Nonleading decision-related questions from parents promote clarity of values and shared understanding within family conversations. Furthermore, developmentally aligned, parent-facing guidance can enable children to choose their preferred level of involvement and may facilitate triadic child–parent–clinician collaboration. These preliminary findings offer cautious insights into enhancing SDM in pediatric allergy care through improved health care practices and supportive policies.

Therefore, tailored strategies are crucial. Considering that health care organizations and their configurations vary considerably across countries, effective SDM integration warrants tailored workflow solutions [13]. The potential role of nurses in this context is particularly noteworthy. Nonphysician health care professionals, including nurses or educators, can efficiently introduce and support DA use, particularly in time-limited outpatient settings. Therefore, distributing the DA before clinical encounters or having nonphysician professionals, such as nurses or certified allergy educators, briefly introduce the tool may be more practical. Nurses, particularly certified allergy educators in Japan, may be well-positioned to facilitate DA use by initiating conversations, clarifying treatment options, and supporting family communication.

Furthermore, DA integration outside the consultation room is essential. Additionally, providing a digital version accessible at home or in waiting areas may help families engage with the content at their own pace, as previous studies have emphasized that DAs are more likely to be used outside consultations. Institutional measures, including SDM training and supportive care protocols, may gradually increase the clinical environment's readiness to incorporate decision-support tools. Furthermore, the successful integration of DAs and SDM principles into routine care will likely require a collaborative, multidisciplinary approach involving physicians, allied health professionals, and dedicated nursing staff. These directions are consistent with international recommendations, such as those of the CSACI, emphasizing the value of SDM in allergy care [6].

Beyond such system-level measures, the chronic and recurrent nature of FA itself underscores the need to prioritize the "knowledge" function of DAs. FA care entails recurrent choices across the child's life course, as developmental transitions (eg, entry to daycare or school, expanding peer eating contexts, and emerging autonomy) prompt families to revisit OIT even after prolonged avoidance. Acquiring accurate knowledge in advance is not only a proximal outcome of DA exposure but also an anticipatory resource for future deliberation. Consistent with the International Patient DA Standards, knowledge is a core component of decision quality [44]. Notably, a Cochrane review demonstrated that patient DAs consistently improve knowledge and the accuracy of risk perceptions and can be used before consultations without harming satisfaction or health outcomes [11]. Thus, incorporating a brief DA-aligned knowledge

assessment would strengthen our evaluation and clarify the pathway by which an evidence-focused DA may reduce decisional conflict in the short term while supporting repeat decisions over time. Moreover, recent FA guidelines underscore structured education and consent as prerequisites for OIT preparation, reinforcing the rationale for early preparatory DA use to scaffold later reevaluations as circumstances change [6].

Limitations and Future Research Directions

This single-center feasibility study was limited by its small sample size. A post hoc sensitivity power analysis indicated that, at 2-sided α=.05 with 80% power, the minimal detectable standardized effect size was approximately 1.06 for n=9, indicating that only very large effects were detectable. While the primary outcomes (DCS) improved, estimates for the secondary outcomes (STAI and FAQLQ-PB) were imprecise; therefore, confirmation with adequately powered samples is warranted.

The participating children spanned a wide age range, and the analyses did not prespecify age stratification, rendering the observed age-related patterns descriptive rather than inferential. The 1-week follow-up was likely insufficient to capture the psychosocial effects. Coronavirus disease 2019–related constraints limited face-to-face interactions and may have influenced the recruitment and interview procedures. Finally, knowledge acquisition, which is an important target of DAs, was not measured. Future work should enroll larger and more diverse samples, including prespecified age strata, and extend the follow-up period to evaluate age-specific outcomes and engagement. Comparative qualitative approaches and case studies (eg, contrasting subgroups by age, disease severity, or parent-child dyad dynamics) may elucidate the context-dependent use of decision support. Iterative refinement of the parent-focused DA, together with co-designed, age-appropriate child components or digital modules, could improve process quality and enable the longitudinal assessment of knowledge gains.

Conclusions

A culturally adapted DA may mitigate parental decisional conflict and improve parent-child communication in Japanese pediatric FA care. Despite the small-scale setting, these findings lay the groundwork for larger studies and the future implementation of DAs in routine pediatric care. Future research should focus on co-design approaches, long-term outcome evaluations, and the integration of DAs into multidisciplinary care frameworks to support family-centered and value-based decision-making in allergy treatment. Future work should involve large multisite trials to confirm its effectiveness, coupled with family co-design and age-specific adaptations.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
English translation of the decision aid.
[PDF File, 1388 KB - jopm_v18i1e77782_app1.pdf]

Multimedia Appendix 2
Semistructured interview guides (parent-child).
[DOCX File, 14 KB - jopm_v18i1e77782_app2.docx]

Multimedia Appendix 3
Deidentified parent-child excerpts by dyads A-D.
[DOCX File, 28 KB - jopm_v18i1e77782_app3.docx]

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Abbreviations

CSACI: Canadian Society of Allergy and Clinical Immunology
DA: decision aid
DCS: Decisional Conflict Scale
FA: food allergy
FAQLQ-PB: Food Allergy Quality-of-Life Questionnaire–Parental Burden
ODSF: Ottawa Decision-Support Framework
OIT: oral immunotherapy
PedsQL: Pediatric Quality-of-Life Inventory
QoL: quality-of-life
SDM: shared decision-making
STAI: State–Trait Anxiety Inventory

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Original Paper

Barriers and Facilitators of Digital Transformation in Health Care: Mixed Methods Study

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Abstract

Background: Digital transformation is now a fundamental component of health care systems worldwide. To develop effective digital health strategies, it is essential to examine physicians' perspectives on the barriers and facilitators of implementation, with particular attention to regional and cultural factors influencing technology adoption.

Objective: This study aims to identify and analyze key barriers and facilitators to the implementation of digital health technologies from physicians' perspectives in Russia.

Methods: A 2-phase nationwide mixed methods study was conducted involving 460 physicians from various specialties. The first phase comprised in-depth interviews with 10 physicians to develop a specialized questionnaire. The second phase involved a nationwide cross-sectional survey with 450 physicians using the developed questionnaire. Inclusion criteria were working in a Russian city with a population of more than 100,000, age 22 years and older, at least 3 years of specialty experience, and employment in public or private health care institutions. The analysis focused on 4 categories of digital health technologies: remote consultations, remote monitoring, digital diagnostic solutions, and clinical decision support systems.

Results: The main barriers identified were fear of making erroneous decisions (25% of physicians), technical difficulties (up to 25%), and legal insecurity (21% of physicians). Notably, the barrier profile varied depending on the type of technology. Key drivers for implementation included time saving (59% of physicians), practical benefits (55% of physicians), and legal security (54% of physicians). Additionally, a convenient training organization was a crucial motivator, with the availability of free training (53% of physicians) and provision of study leave (52% of physicians). These facilitators were consistent across all categories of digital solutions. Based on these findings, key recommendations for the implementation of digital transformation in medical organizations were formulated.

Conclusions: The findings highlight the need for comprehensive, technology-specific digital implementation strategies to improve health care digital transformation effectiveness, considering physician concerns about decision-making accuracy, technical challenges, and legal frameworks.

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KEYWORDS

digital transformation; physician barriers; technology acceptance; health care innovation; digital health; telemedicine; remote patient monitoring; clinical decision support systems; eHealth; mHealth

Introduction

Digital transformation has become an integral part of modern health care systems around the world [1]. Technologies, such as telemedicine, remote patient monitoring, artificial intelligence–based diagnostics, and clinical decision support systems (CDSS), are increasingly seen as essential tools to address current and future challenges in health care [2]. The

COVID-19 pandemic, in particular, has accelerated the adoption of certain digital solutions in health care, demonstrating their potential to support care continuity and mitigate public health crises [3,4]. Back in 2020, the World Health Organization approved the development of the Global Strategy on Digital Health 2020-2025 at the 73rd World Health Assembly [5].

The willingness of health care professionals, especially physicians, to accept new technologies and actively use them is a determining factor in the successful integration of digital solutions in health care [1]. Physicians play a key role in the implementation of digital solutions, influencing both their use and acceptance of digitalization by patients [6]. Therefore, understanding the specific barriers to implementation and factors that facilitate it, from a physician's standpoint, is crucial for developing effective strategies for the implementation of digital solutions in health care [7]. At the same time, regional and cultural characteristics can have a critical impact on the typology of barriers and motivators in using various digital technologies.

This study aims to investigate the main barriers faced by physicians in using various digital technologies and to identify key drivers of health care digitalization in Russia.

Methods

Study Design

A 2-phase nationwide mixed methods study was conducted involving 460 physicians from various specialties.

First Stage

At the first stage, in-depth online interviews (up to 1.5 hours) were conducted with 10 Moscow physicians with experience in using digital technologies. Among interview participants were 8 outpatient and polyclinic physicians and 2 inpatient physicians; 8 respondents represented the public sector, and 2 represented private clinics.

The analysis of the interviews allowed identifying key factors that facilitate and hinder digital transformation in health care. Based on the data obtained, a new questionnaire was developed to assess the attitude of physicians to digital transformation in health care and their experience of using digital technologies (Digital Health Readiness and Barriers Questionnaire for Physicians).

Second Stage

At the second stage, an observational all-Russian study was conducted with 450 physicians using the questionnaire developed at the first stage.

To be included in the study, a physician had to meet the following criteria:

1. Work in a Russian city with a population of more than 100,000 people.
2. Age 22 years and older.
3. Work experience in the specialty for at least 3 years.
4. Work in public or private institutions (physicians working in departmental medical institutions were not allowed to participate).

To ensure an even and representative distribution of respondents, quotas were established for medical specialty and city of residence.

All respondents completed the online questionnaire developed in the first stage of the study. Completion of the questionnaire was voluntary and was processed anonymously and depersonalized.

This study analyzes the barriers to digital transformation in health care. The block includes 2 questions. The first one is devoted to the most significant obstacles to the implementation of digital technologies in practice. The physician is given 22 answer options; the respondent can mark up to 5 most relevant options. The full text of the question is provided in Multimedia Appendix 1.

For the ease of analysis, 22 statements were allocated into 5 domains—motivational, ability-related, process-related, physical (environmental factors), and social—reflecting the Motivation, Ability, Processing, Physical, and Social (MAPPS) framework grounded in behavioral theory. A comprehensive rationale and detailed description of each barrier group are provided in Multimedia Appendix 2.

The second question aimed to identify key factors that help overcome barriers to the implementation of digital technologies. Physicians were offered a list of 19 statements reflecting various advantages of using new digital solutions. Respondents assessed how likely it is that they would start using or use the relevant technologies more actively if the specified benefits were realized, using a 7-point scale: from 1 (definitely would not use or use more actively) to 7 (definitely would use or use more actively). The full text of the second question is provided in Multimedia Appendix 3.

The survey analyzed 4 categories of digital technologies (Table 1), with respondents separately noting the main barriers to the implementation of the relevant solutions for each category. This approach made it possible to identify the specifics and frequency of barriers depending on the type of digital technology, as well as to assess which barriers are most significant in each area of digital transformation in health care.

Table 1. Categories of digital technologies.

Abbreviated name	Full wording used in the survey
Remote physician-patient or physician-physician consultations	• Remote (telemedicine) physician: patient consultations using audio or video communication • Remote (telemedicine) physician: physician consultations using audio or video communication (eg, for emergency cases, scheduled consultations, online consultations)
Remote patient monitoring	• Remote patient monitoring (eg, using medical sensors or an app to transmit one's readings remotely to the physician via an app)
Technologies for diagnostics	• Technologies for diagnostics (eg, computer vision to recognize X-rays, computed tomography scans, magnetic resonance imaging, and moles)
Clinical decision support systems	• Systems to support physicians in making medical decisions (analysis of patient medical records, anamnesis, symptoms, results). For example, Webiomed, TOP-3, Sapia, and Onqueta.

The survey was conducted online from February 24 to March 17, 2025. The sample frame was created by randomly sending invitation links to all physicians registered on the Ipsos Comcon platform "Healthcare Professionals." Emails containing a link to the survey were sent to 12,629 physicians; 1120 opened the link and viewed at least the first page and 450 physicians completed the survey. The survey response rate was 3.6%. Respondent recruitment was conducted using a quota sampling approach. A detailed description of the survey methodology, prepared in accordance with the CHERRIES (Checklist for Reporting Results of Internet E-Surveys), is provided in Multimedia Appendix 4.

Statistical Data Processing

Descriptive statistics of the analyzed group are presented as percentages for qualitative variables. For quantitative variables, mean values and SDs were calculated. The study data were weighted according to official statistics on the distribution of primary care physicians and specialists in Moscow, St. Petersburg, and other cities [8]. Percentage calculations and data processing were performed using IBM SPSS Statistics (version 27).

Ethical Considerations

Ethical Approval and Informed Consent

This study was approved by the Independent Ethics Committee of the Federal State Budget Scientific Institution "N.A. Semashko National Research Institute of Public Health" (protocol number 7, 2025). Written informed consent was obtained from all interview participants prior to conducting and audio recording the interviews. The study information materials provided comprehensive details regarding the research objectives, participant selection criteria, study procedures, time requirements, potential risks and benefits, participant rights and responsibilities, and data protection measures. Online survey respondents provided their consent by selecting the "Start" button following review of the introductory page, which contained information about survey content, estimated completion time, anonymity provisions, confidentiality protections, and research objectives. All participants were informed of their right to refuse participation or discontinue involvement in the research at any point without penalty. Informed consent was secured from all study participants. Participants in the online survey were offered a monetary incentive as compensation for their time and participation. Specifically, respondents were offered an electronic certificate worth 500 Russian rubles (US $6.44) for use at online hypermarkets. Interview participants did not receive monetary compensation.

Privacy and Confidentiality Protection

All survey responses were collected using anonymous data collection methods. Interview audio files and written transcripts underwent encryption protocols. Encrypted data access keys were maintained in a secure, password-protected local database with restricted access limited to MB, ES, and MZ only.

Results

Demographic Characteristics of the Sample

The survey on digital transformation in health care covered 450 physicians from 8 federal districts of Russia. Table 2 provides the characteristics of the study cohort of physicians.

The objective of the study was to obtain a result that would be representative of the digital transformation of physicians in Russia. It is obvious that the situation in large cities may differ from the results of the study in towns. According to official statistics, the share of physicians from Moscow and St. Petersburg (the 2 largest cities in the country) is 19% of all physicians in the Russian Federation [8]. The share of respondents practicing in Moscow and St. Petersburg was 28% (128/450) of the total sample, which indicates an insufficient representation of physicians from other regions and possible sample bias. To correct for this imbalance and ensure the representativeness of the data obtained, we applied poststratification weighting using official statistics on the regional distribution of physicians. The data below are given taking into account the weighting for the distribution of physicians by locality.

Table 2. Clinical and demographic characteristics of doctors.

Characteristics	Values (N=450)
Gender, n (%)	
Men	57 (12.7)
Women	393 (87.3)
Age (years), mean (SD; range)	41.2 (9.57; 26-76)
Age (years), n (%)	
Up to 30	53 (11.8)
31-40	184 (40.9)
40-50	129 (28.7)
50+	84 (18.7)
Region of residence, n (%)	
Central Federal District	153 (34)
Northwestern Federal District	46 (10.2)
Southern Federal District	41 (9.1)
North Caucasian Federal District	4 (0.9)
Volga Federal District	115 (25.6)
Ural Federal District	30 (6.7)
Siberian Federal District	55 (12.2)
Far Eastern Federal District	6 (1.3)
City of residence, n (%)	
Moscow and St Petersburg	128 (28.4)
Other regions	322 (71.6)
Specialty, n (%)	
General practitioner or physician	110 (24.4)
Endocrinologist	71 (15.8)
Pediatrician	56 (12.4)
Gynecologist	45 (10)
Cardiologist	43 (9.6)
Neurologist	30 (6.7)
ENT[a]	17 (3.8)
Gastroenterologist	18 (4)
Surgeon	18 (4)
Pulmonologist	13 (2.9)
Ophthalmologist	8 (1.8)
Allergist	9 (2)
Urologist	9 (2)
Oncologist	1 (0.2)
Anesthesiologist-resuscitator	1 (0.2)
Functional diagnostics doctor	1 (0.2)
Average length of service (years), mean (SD; range)	15.6 (8.96; 3-45)
Scientific degree, n (%)	
None	422 (93.8)
Candidate of Sciences	26 (5.8)

Characteristics	Values (N=450)
Doctor of Sciences	2 (0.4)
Type of institution, n (%)	
State	345 (76.7)
Municipal	228 (50.7)
Regional	94 (20.9)
Federal	23 (5.1)
Private	105 (23.3)
Type of admission, n (%)	
Outpatient	422 (93.8)
Inpatient	28 (6.2)

[a]ENT: ear, nose, and throat.

Key Barriers to Using Digital Technologies

Table 3 presents data on the frequency of various barriers that physicians encounter when implementing 4 digital technologies: remote consultations, remote patient monitoring, diagnostic technologies, and CDSS. The barriers were classified into 5 main groups: motivational, capability-related, process-related, physical, and social (MAPPS model). This classification was developed by Ipsos Comcon based on the behaviorist approach. For a detailed description and theoretical justification of barrier groups, see Multimedia Appendix 2.

For understanding the original distribution of responses, Multimedia Appendix 5 presents statistics corresponding to Table 3 based on the initial unweighted data, without adjustment for physician distribution. The results demonstrate that each type of technology is accompanied by a unique profile of barriers. For ease of perception, Table 4 shows the top 5 main barriers that physicians identified for each technology.

Table 3. Identification of barriers to the implementation of digital technologies.

Barriers[a,b]	Remote consultation (%)	Remote monitoring (%)	Technologies for diagnostics (%)	Systems to support physicians in making medical decisions (%)
Motivation barriers[c]	42	39.2	37.2	45.7
I don't see any practical benefit from using this technology in my daily work.	5.3	5.5	5.7	5.1
I am concerned about data privacy issues when using this technology.	20.9	15.7	9.3	15.3
I am concerned about the problem of excessive control over my work when using this technology.	9.4	5.2	4.3	9.8
This technology reduces the importance of physician's work.	8.4	6.3	7.6	9.7
I don't trust the quality of this technology.	4.6	6	6.5	10.7
I am concerned about overdiagnosis when using this technology.	7.6	9.8	15.8	11.9
Capability-related barriers[c]	28.7	38.9	48.5	48
I don't have time to master this technology.	5.8	8.5	7.5	6.1
This technology is too complex to master.	1.4	2.5	4.2	5
I have no knowledge of specific products within this technology that could be used in my practice.	12.4	17.5	24.7	26
I don't have access to training courses to master this technology.	13.2	16.8	20.8	19.9
The technology requires personal investments to master it.	5.2	5.7	5.1	4.7
Process-related barriers[c]	49.7	53.7	40.8	39.8
I am not sure that this technology will work stably without delays and breakdowns.	25.3	29.2	18.9	18.2
I am afraid of making wrong decisions when using this technology.	22.2	26.4	26.8	22
Technology takes time without making work easier.	13.5	12.9	3.2	9
Environmental (physical) barriers[c]	44.4	39.4	45.4	47.5
I do not have technical base to master this technology (suitable equipment, software, communications).	20.5	24	31.6	26.7
Existing regulations do not include this technology or need to be revised.	20.5	13.4	12.5	15.3
This technology does not have qualified technical support.	14.8	11.3	10.4	13.3
Social barriers[c]	47.5	39.3	33.9	40.4
Management of my health care facility is not interested in using this technology.	13.9	15.1	14.3	20.7
My environment condemns the use of this technology.	1.1	0.9	0.6	1.5
I prefer to use other long-proven methods rather than this technology.	8.6	5.8	9.8	5.9
I feel a lack of legal security when using this technology.	29.8	21	14.9	17.5
None of the above.	14.2	13	13.6	11.1

[a]The data provided are weighted by the distribution of physicians across populated areas of the Russian Federation. Multimedia Appendix 5 provides unweighted data.

[b]The table shows the percentage of doctors who selected each answer. Each respondent could select up to 5 answers.

[c]The total for each category shows the percentage of doctors who selected at least one of the category barriers.

Table 4. The top 5 main barriers to different types of digital technologies in health care.

Barriers to using digital technologies[a]	Values (%)
Barriers to remote consultations (top 5)	
Lack of legal protection	29.8
Doubts about stable operation of technology	25.3
Fears of making wrong decisions	22.2
Data privacy concerns	20.9
Lack of technical base	20.5
Barriers to remote monitoring (top 5)	
Doubts about stable operation of technology	29.2
Fear of making wrong decisions	26.4
Lack of technical base	24
Lack of legal security	21
Lack of knowledge about products	17.5
Barriers to technologies for diagnostics (top 5)	
Lack of technical base	31.6
Fear of making wrong decisions	26.8
Lack of knowledge about products	24.7
Lack of training courses	20.8
Fear of overdiagnosis	15.8
Barriers to systems to support physicians in making medical decisions (top 5)	
Lack of technical base	26.7
Lack of knowledge about products	26
Lack of interest from management	20.7
Lack of training courses	19.9
Lack of legal protection	17.5

[a]The data provided are weighted by the distribution of physicians across populated areas of the Russian Federation.

Remote Physician-Patient or Physician-Physician Consultations

The most common barriers for remote consultations are social barriers (47.5%) and process-related barriers (49.7%). The most frequently mentioned barriers include lack of legal protection (29.8%, the highest rate among all technologies), doubts about the stability of the technology (25.3%), and fears of making wrong decisions (22.2%). In addition, 20.9% of doctors expressed concerns about data privacy, which is the highest rate for this barrier among all technologies. Motivational barriers were encountered by 42% of doctors. It is the second most frequent value among all groups.

Thus, despite their relative prevalence and technical accessibility, remote consultations are often perceived by physicians as legally and organizationally vulnerable, especially in conditions of insufficient regulatory support and lack of confidence in data protection.

Remote Monitoring

For remote patient monitoring technologies, process-related barriers were dominant (53.7%), which was the highest value among all barrier categories. The most frequently noted barriers were system instability (29.2%) and concerns about decision-making errors (26.4%).

There was also a high proportion of physicians who indicated a lack of technical expertise to master this technology (24%), a feeling of legal insecurity (21%), and a lack of knowledge about specific products (17.5%).

Thus, physicians face challenges in integrating remote monitoring technologies into daily practice due to a wide range of concerns, but technical and methodological barriers related to reliability, safety, and the need for new professional skills come to the fore.

Technologies for Diagnostics

As barriers to implementation of diagnostic technologies, physicians most often indicated insufficient technical base (31.6%) and fear of making wrong decisions (26.8%) when using technology.

Technologies for diagnostics provided the highest values in terms of opportunity-related barriers (48.5%), particularly lack

of product knowledge (24.7%) and lack of access to training resources (20.8%).

Also, 15.8% of respondents expressed fear of overdiagnosis**,** which is the highest among all technologies.

These results indicate that digital diagnostic solutions are perceived by physicians as technologically complex and not transparent enough, requiring serious support for implementation and methodological adaptation.

CDSS

CDSS turned out to be the least acceptable for respondents in terms of motivational barriers (45.7%) and environmental barriers (47.5%).

For this group of technologies, the most common problems were lack of technical base (26.7%), lack of knowledge about products (26%), and unavailability of training courses (19.9%).

Also, 20.7% of doctors indicated a lack of support from management of the health care facility (which is the highest indicator of this barrier among all technologies). This result demonstrates the importance of active participation and the initiative of management in integrating digital solutions into clinical practice.

An important issue for physicians remains legal security (17.5%) when using this group of technologies.

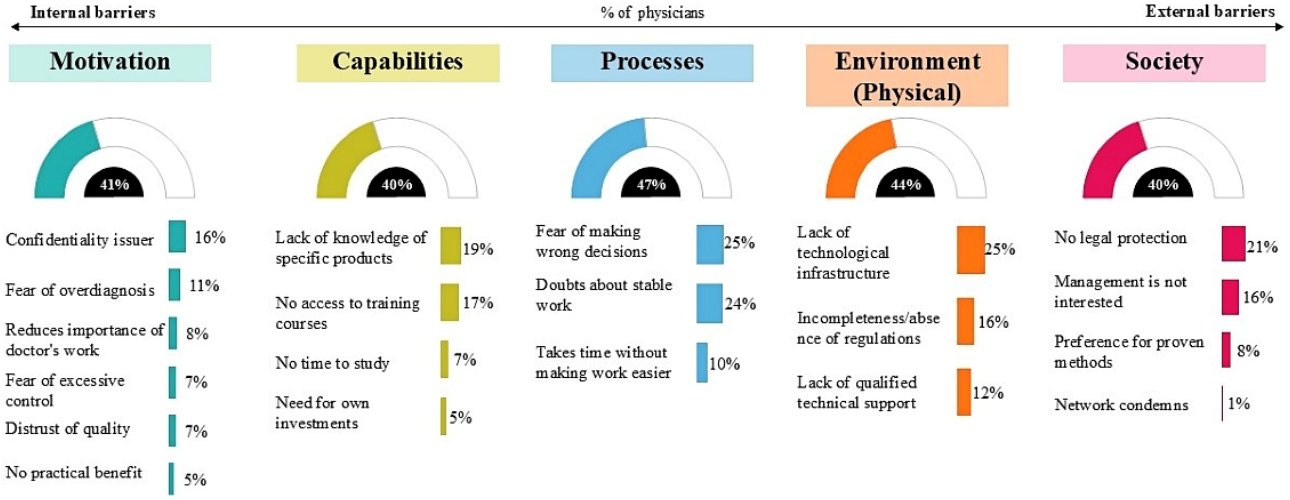
Physicians also noted a lack of trust in the quality of technology (10.7%), a feeling of excessive control over their professional activities (9.8%), and a decrease in the significance of the role of physicians (9.7%). Although these motivational barriers were selected by a relatively small number of respondents, they were most frequently identified for CDSS compared to other types of digital technologies, which characterizes the low level of trust of doctors in this type of technology.

Thus, CDSS is perceived by physicians as a problematic technology both in terms of technical infrastructure, organizational support, and professional trust.

Overall, the most common barriers to implementation of all digital solutions are technical and organizational difficulties, fear of making wrong decisions, and a sense of legal insecurity (Table 4). At the same time, the intensity of the expression of individual barriers varies depending on the type of technology: for example, for remote consultations, legal and regulatory barriers come to the fore, while for the other 3 types of digital technologies, technical difficulties play a key role. This emphasizes the need for differentiated implementation support strategies that take into account the specifics of each type of digital tool.

Figure 1 shows a generalized distribution of barriers that physicians face when implementing digital technologies in clinical practice (the total result for all types of technologies).

Figure 1. General distribution of barriers to the implementation of digital technologies in health care from the point of view of doctors. The graph shows the percentage of physicians who selected a particular answer option. For category data, the percentage of physicians who selected at least one of the category barriers is shown. The data presented are weighted by the distribution of doctors across populated areas of the Russian Federation.



Although the distribution of barriers was generally fairly even (from 40% to 47%), procedural difficulties came to the fore, noted by 47% of physicians. Most often, they indicated fear of making wrong decisions (25%) and doubts about the stable operation of digital systems (24%).

Among environmental barriers (44%), the leading one is the lack of technical base (25%), and among social barriers (40%), the first place is taken by the lack of legal security (21%).

A significant proportion are also capability-related barriers (40%), primarily a lack of knowledge about specific products (19%). Likewise, motivational barriers (41%) reflect physicians' internal doubts: primarily concerns about data privacy (16%).

Thus, the figure illustrates that barriers to implementation of digital technologies in health care are multifaceted and cover both the internal attitudes of doctors and external organizational and legal restrictions, which require comprehensive solutions at the level of the health care system.

Drivers of Digital Technologies Implementation in Health Care

Table 5 shows the top 5 main drivers that, in the opinion of physicians, can help overcome barriers to implementation of digital technologies (Multimedia Appendix 6 provides a complete table of the distribution of drivers for different types of technologies).

Notably, while the barrier profile differed depending on the type of digital technology, the leading drivers were similar across all technology types.

Time-saving potential was consistently ranked first, with 56% to 62% of votes. Also, practical benefits were in the top 3 drivers for all technology types. This highlights that physicians are primarily interested in real functional efficiency and time savings in a busy practice environment.

For all types of technologies, legal security was included in the top 5 main criteria necessary for using the technology. This criterion was most significant for remote consultations (57.7%) and remote monitoring (54.6%).

Table 5. The top 5 main factors contributing to the introduction of digital technologies in health care, according to physicians.

Drivers of digital technologies implementation in health care[a,b]	Values (%)
Drivers to remote consultations (top 5)	
Technology will save time	62.2
Technology will deliver practical benefits in daily work	58.3
Legal protection when using this technology	57.7
Free or at the expense of the health care institution	55.8
Management will allow taking study leave	54.4
Drivers to remote monitoring (top 5)	
Technology will save time	58.1
Legal protection when using this technology	54.6
Technology will deliver practical benefits	54
Free or at the expense of the health care institution	53.2
Management will allow taking study leave	51.1
Drivers to technologies for diagnostics (top 5)	
Technology will save time	56
Free or at the expense of the health care institution	52.8
Technology will deliver practical benefits	52.2
Management will allow taking study leave	51.7
Legal protection when using this technology	51.4
Drivers to systems to support physicians in making medical decisions (top 5)	
Technology will save time	58.3
Technology will deliver practical benefits	54.5
Legal protection when using this technology	51.2
Free or at the expense of the health care institution	50.3
Interface will be accessible and understandable	49.4

[a]The data provided are weighted by the distribution of physicians across populated areas of the Russian Federation.

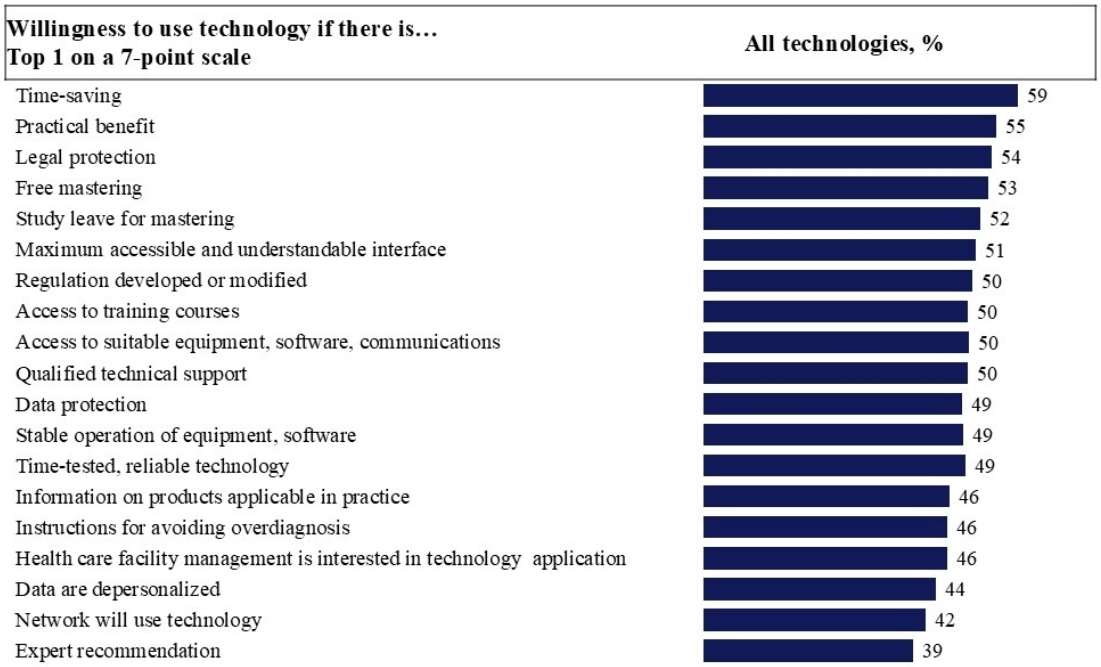
[b]Based on the answers to the question: "How likely is it that you would start using/more actively use the following technologies when implementing the ideas on a scale from 1 to 7?" The table shows the percentage of respondents who chose 7 points for this answer (a physician would definitely start using digital technology if the conditions specified in the statement were met).

Another important block of incentives is related to the reduction of barriers to learning and the technical ease of using the technology: availability of free training, study leave, and a simple interface were also included in the top 5 factors. This indicates the need not only to implement technologies, but also to create a supportive learning environment, especially in conditions of time constraints for medical personnel. All drivers for different technologies are summarized in Figure 2.

The results highlight that physicians perceive digitalization primarily through the prism of daily efficiency, legal security, and organizational support.

The main driver for the implementation of all digital technologies is saving doctors' time. This is important to consider when implementing digital technologies in health care institutions.

Figure 2. Key factors contributing to the implementation of digital technologies, according to physicians. The data presented are weighted by the distribution of doctors across populated areas of the Russian Federation. Based on the answer to the question: "How likely are you to start using or more actively use the following technologies when implementing ideas on a scale from 1 to 7? The figure shows the percentage of respondents who chose 7 points for this answer (a physician would definitely start using digital technology if the conditions specified in the statement were met).



Discussion

Barriers to Implementation of Digital Technologies in Health Care

In recent years, digitalization in health care has become an integral part of medical practice. However, the introduction of digital technologies is accompanied by a number of barriers that must be taken into account for the successful integration of innovations into clinical practice.

The study of 450 physicians in Russia found that key barriers to the implementation of digital technologies include technical difficulties, fear of making wrong medical decisions, and concerns about legal insecurity.

Lack of technical infrastructure (25%) and doubts about the stability of technology (24%) were the key barriers to the implementation of digital technologies. These data are relevant to that from the international studies, in particular, according to the largest umbrella meta-analysis of 108 systematic reviews [1], infrastructural and technical barriers to implementation of digital technologies in health care rank first in frequency worldwide.

Along with technical difficulties, fear of making wrong decisions (25%) based on the use of digital technologies was ranked first in this study. A number of studies also demonstrate that it is the fear of physicians to make a mistake when relying on digital tools that is an important barrier to the implementation of digital technologies. Thus, a survey of 1449 physicians by the American College of Physicians, conducted in 2019, showed that 29% of specialists see the risk of potential medical errors as one of the main obstacles to the implementation of telemedicine [9,10].

Another study showed that 42.1% of American doctors are concerned about a decrease in the quality of care provided when using telemedicine [11]. It is worth noting that this fear has certain grounds. Thus, in a study of medical malpractice cases related to the use of remote telephone consultations, the most common accusation was incorrect diagnosis (68%), and the most common form of damage was death (44%) [12]. Systematic review by Kim et al [13] found that IT issues in health care can significantly disrupt care processes and lead to errors in clinical decision-making, delays in treatment, and even harm to patients. In 53% of the included studies, IT-related issues were associated with actual or potential harm to patients, including deaths.

Thus, in addition to technical difficulties, it is the fear of physicians to make mistakes due to inaccuracies in digital systems that remains the key barrier to digitalization in health care. It can be overcome by improving the validation of algorithms, ensuring transparency of systems, and clear legal regulation in digital technology use.

The feeling of legal insecurity when using digital technologies, identified by 24% of Russian physicians, reflects one of the most significant and persistent problems in digital transformation in health care. This barrier manifests itself in the concerns of medical workers about the possible legal consequences of errors associated with the use of digital solutions, as well as in the unclear distribution of responsibility between a physician, an institution, and a technology developer [14,15].

Legal and regulatory risks are one of the main factors hindering the implementation of digital solutions in clinical practice [16]. In particular, it is noted that the existing legal framework is often not adapted to the specifics of digital technologies: there are no clear standards for medical data storage, transfer, and

processing, as well as for determining liability in the event of errors or incidents related to digital tools [9,14,16]. This leads to the fact that physicians are forced to rely on general norms of professional duty and ethics, which increases uncertainty and reduces the willingness to use innovations [14].

Thus, the feeling of legal insecurity is not only a subjective fear, but also an objectively determined barrier associated with the insufficient development of the regulatory framework, absence of clear standards and mechanisms for distributing responsibility. To overcome this obstacle, it is necessary to develop and implement modern legal and ethical standards adapted to digital reality, as well as professional medical communities, to actively participate in the formation of regulatory policy [9,14,16].

Another important conclusion from the study is that a significant portion of physicians (16%) identified the lack of management support in the implementation of digital technologies as a key barrier. Specifically, for the CDSS, this factor was among the top 3 barriers and was noted by 20.7% of physicians. Organizational support and management interest are often considered important factors in the successful implementation of digital technologies in health care [17,18]. This study emphasizes the need for strategic management involvement and the development of leadership competencies for the successful implementation of digital technologies.

A literature review revealed that a significant number of studies have identified concerns among health care professionals that implementation of digital technologies will increase their workload, which is a significant barrier to digital decision-making [1,19-21]. This fear appears paradoxical, since many digital technologies are initially developed to optimize workflows, save time, and improve the efficiency of clinical decision-making [22-24]. However, this phenomenon requires serious attention from researchers and practitioners, since health care professionals' perception of a potential increase in workload remains a significant barrier to digital transformation.

In this study, the fear of losing time was also mentioned by physicians, although it did not come to the forefront. Only 10% of physicians identified "takes time and does not make work easier" barrier, and only 7% of physicians were not ready to spend time mastering the technology. It is also worth noting that according to this study, only 7% of physicians identified distrust of digital technologies as a barrier, and 5% a low level of practical benefit. This may indicate a high psychological readiness of Russian medical workers for digital transformation. Such differences emphasize the importance of taking into account national and cultural contexts when developing strategies for implementing digital solutions in health care.

In general, the spread of barriers among the 5 MAPPS categories was fairly uniform, ranging from 40% to 47% of respondents per category (Figure 1). This distribution highlights the need for a comprehensive and multilevel approach to addressing various obstacles to successfully advancing digital transformation in health care.

A more detailed analysis revealed that process-related and environmental barriers received somewhat higher ratings, 47% and 44%, respectively. These included fears of making errors, doubts about the stability of digital systems, and a lack of technical infrastructure with qualified support. Meanwhile, motivation, capability-related, and social barriers were noted by slightly fewer respondents, approximately 40%-41%. This pattern suggests a relatively high level of motivation among Russian physicians and a general readiness within the medical community to adopt digital technologies. At the same time, it underscores the critical need to enhance technical infrastructure and ensure the stable operation of digital tools with professional technical support.

The barriers were unevenly distributed among different technology groups. For example, for telemedicine technologies, a notably high percentage of physicians (47.5%) reported encountering social barriers, primarily linked to perceived legal insecurity. In contrast, for systems to support physicians in making medical decisions, process-related barriers (39.8%) and social barriers (40.4%) were minimal, whereas motivation barriers (45.7%) and capability-related barriers (48%) predominated. This divergence reflects the specific perceptions and challenges associated with implementing different digital solutions in clinical practice and underscores the necessity for a differentiated approach to their support and regulation.

The study findings emphasize the need for a comprehensive and tailored approach to overcoming barriers. This approach should consider the specific type of technology to determine the most effective implementation strategies.

Drivers of Digital Technologies Implementation in Health Care

In contrast to the diverse profile of barriers, the Russian study found remarkable consistency in the leading enablers of technology adoption across all 4 categories of digital technologies, pointing to universal motivators for physicians.

Physicians value digital solutions primarily for 2 specific advantages: time savings and real practical benefits. It is important for them that the technology makes work easier and speeds it up, rather than adding extra tasks [1,19,20]. If developers clearly show how much time the new system saves and how it fits into the routine process [25], physicians are willing to use it. Thus, it is important to demonstrate to physicians how the digital tool simplifies the routine and frees up time for the patient and other important matters.

Perceived legal security consistently ranked among the top 5 factors facilitating adoption for all types of technologies, being most significant for remote consultations (57.7%) and remote patient monitoring (54.6%). The lack of legal clarity is a significant barrier, and conversely, its presence acts as a powerful catalyst for the adoption of digital technologies. Physicians seek concrete assurances that they will not face undue professional or legal liability for potential errors, data breaches, or unintended consequences arising from the use of new, complex digital tools [9,14,16]. Thus, it is necessary not only to create a clear and transparent legal framework for the use of digital technologies in health care, but also to ensure that physicians are informed about the relevant legal norms and regulations in an accessible and understandable manner.

"Free learning/at the expense of the health care institution" and "management will allow taking study leave" were among the top 5 factors of assistance for all types of technologies. This underlines the readiness to learn and the importance of competent organizational support for this process.

Unfortunately, the introduction of new technologies often requires physicians to master new skills without interrupting their clinical practice. Thus, this only increases their workload during the period of mastering the technology. This explains why, in a number of studies, the key barrier to implementation of digital technologies was the fear of increasing physicians' workload [1,19,20].

Our research shows that study leave and management-paid training make new technologies much more attractive to physicians.

Thus, the implementation of digital technologies in health care is a complex process of creating a supporting organizational ecosystem. Key factors in this process are the provision of technical infrastructure, legal transparency, training, and management support. The absence or weakness of any single component can undermine the entire digital transformation effort. True, sustainable transformation requires a coordinated, systemic approach in which all these elements are strategically aligned and continuously strengthened.

Limitations

This study has several limitations that should be considered when interpreting the findings. First, the study inclusion criteria required physicians to work in large urban centers in Russia, which inherently limits the generalizability of results to health care providers practicing in smaller towns or rural areas. The experiences and barriers faced by physicians in less populated or resource-constrained settings may differ significantly from those in larger urban centers.

Second, the reliance on online questionnaires might have introduced a selection bias, as physicians without reliable access to the necessary technology or internet connectivity were unable to participate.

Third, data collection was based on self-reported questionnaires, which are subject to inherent biases, including social desirability bias. Respondents may have underreported negative attitudes or challenges due to perceived social or professional expectations.

Despite these limitations, the study provides valuable insights into physician perspectives on digital technology adoption in health care within the sampled population. Future research should aim to include a more diverse sample and consider mixed data collection methods to minimize bias and enhance generalizability.

It is important to note that the process of health care digitalization depends not only on physicians but also significantly on patient readiness and engagement. Therefore, studying patient-related factors is crucial and represents a key focus for our future research endeavors.

Conclusions

The study showed that the key barriers to the introduction of digital technologies in health care in Russia are technical difficulties (lack of infrastructure, unstable operation of systems), fear of making wrong decisions based on digital data, and a feeling of legal insecurity.

Lack of knowledge about specific products, lack of management support, and limited training opportunities also play a significant role. The profile of barriers varies depending on the type of digital technology, which highlights the need for differentiated approaches to their implementation. At the same time, the leading drivers for physicians are time savings, practical benefits, legal protection, availability of free training, and organizational support. These motivators are universal for all categories of digital solutions and reflect doctors' desire to improve efficiency and reduce workload in a busy environment.

Based on the conducted research, we formulated key recommendations for the implementation of digital transformation in medical organizations.

1. Development of technical infrastructure: ensuring stable operation of digital systems, access to necessary equipment, and integration with existing work processes.
2. Improvement of the legal and regulatory framework: development of clear standards and mechanisms for sharing responsibility, and ensuring that physicians are clearly informed about current legal regulations.
3. Implementation of educational programmes: arranging free training and providing physicians with study leave to master new technologies, which will increase digital literacy and reduce resistance to change.
4. Strengthening of organizational support: involving management of medical institutions in digitalization processes, forming a culture of leadership and support for innovation.
5. Demonstration of practical value: demonstrating to clinicians how digital tools save time, simplify routine tasks, and improve the quality of care.
6. Considering specifics of technologies: developing implementation strategies taking into account the specifics of each category of digital solutions and the profile of relevant barriers.

The comprehensive implementation of these measures will increase the readiness of the medical community for digital transformation and ensure sustainable implementation of innovative solutions in health care.

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Data Availability

The datasets generated or analyzed during this study are not publicly available due to confidentiality and ethical restrictions protecting participant privacy, but are available from the corresponding author on reasonable request, in compliance with institutional and ethical guidelines.

Authors' Contributions

Conceptualization: MV (lead), MB (equal), MK (support), and EK (support)
Data curation: ES (lead) and MZ (equal)
Formal analysis: ES (lead), MZ (equal), and EK (support)
Funding acquisition: MV (lead) and PG (support)
Investigation: ES (lead) and MZ (equal)
Methodology: MB (lead) and PG (support)
Project administration: MV (lead) and MB (equal)
Resources: MB (lead) and MK (support)
Supervision: MV (lead) and MK (support)
Validation: MV (lead), MB (equal), MK (support), and PG (support)
Visualization: ES (lead) and MZ (equal)
Writing – original draft preparation: PG (lead) and EK (support)
Writing – review and editing: PG (lead) and EK (support)

Conflicts of Interest

Ipsos Comcon served solely as a coexecutor for data collection and analysis, funded by the Moscow School of Management Skolkovo under a collaboration agreement number 13790350-23.

Multimedia Appendix 1
Question 1. Different physicians mention different barriers to using digital technologies in healthcare. Are there any that are also relevant to you? Please select up to 5 answers. The physician is asked to answer a question on each of the four categories of digital technologies separately.
[DOCX File , 16 KB - jopm_v18i1e83551_app1.docx]

Multimedia Appendix 2
Justification for the division of barriers in accordance with the MAPPS model.
[DOCX File , 16 KB - jopm_v18i1e83551_app2.docx]

Multimedia Appendix 3
Question 2: A team of experts has already thought about some of the problems that arise when implementing digital technologies in the life of a physician. Now we will show you some ideas, please rate how likely it is that you would start using / use the following technologies more actively when implementing these ideas on a scale from 1 to 7, where 1 - definitely would not start using / use more actively, 7 - definitely would start using / use more actively. The physician is asked to answer a question on each of the four categories of digital technologies separately.
[DOCX File , 16 KB - jopm_v18i1e83551_app3.docx]

Multimedia Appendix 4
CHERRIES Checklist.
[DOCX File , 16 KB - jopm_v18i1e83551_app4.docx]

Multimedia Appendix 5
Identification of barriers to implementation of digital technologies.
[DOCX File , 14 KB - jopm_v18i1e83551_app5.docx]

Multimedia Appendix 6
Main drivers for overcoming barriers. The data are weighted by distribution of physicians by populated areas of the Russian Federation. The table shows the percentage of respondents who chose 7 points for this answer (physician would definitely start using digital technology if the conditions specified in the statement were met).
[DOCX File , 17 KB - jopm_v18i1e83551_app6.docx]

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Abbreviations

CDSS: clinical decision support system
CHERRIES: Checklist for Reporting Results of Internet E-Surveys
MAPPS: Motivation, Ability, Processing, Physical, and Social

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