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Utilizing Consumer Technology (Apple's ResearchKit) for Medical Studies by Patients and Researchers: Proof of Concept of the Novel Platform REach

Marleen MHJ van Gelder[1,2], PhD; Lucien JLPG Engelen[1]; Thijs Sondag[1,3], MSc; Tom H van de Belt[1], PhD

[1]Radboud REshape Innovation Center, Radboud University Medical Center, Nijmegen, Netherlands

[2]Department for Health Evidence, Radboud Institute for Health Sciences, Radboud University Medical Center, Nijmegen, Netherlands

[3]Process Improvement & Health Care Innovations, Radboud University Medical Center, Nijmegen, Netherlands

Corresponding Author:
Marleen MHJ van Gelder, PhD
Department for Health Evidence
Radboud Institute for Health Sciences
Radboud University Medical Center
PO Box 9101
Nijmegen, 6500 HB
Netherlands
Phone: 31 24 3666126
Email: Marleen.vanGelder@radboudumc.nl

Abstract

Medical research suffers from declining response rates, hampering the quest for answers to clinically relevant research questions. Furthermore, objective data on a number of important study variables, such as physical activity, sleep, and nutrition, are difficult to collect with the traditional methods of data collection. Reassuringly, current technological developments could overcome these limitations. In addition, they may enable research being established by patients themselves provided that they have access to a user-friendly platform. Using the features of Apple's ResearchKit, an informed consent procedure, questionnaire, linkage with HealthKit data, and "active tasks" may be administered through a publicly available app. However, ResearchKit requires programming skills, which many patients and researchers lack. Therefore, we developed a platform (REach) with drag and drop functionalities producing a ready-to-use code that can be embedded in existing or new apps. Participants in the pilot study were very satisfied with data collection through REach and measurement error was minimal. In the era of declining participation rates in observational studies and patient involvement, new methods of data collection, such as REach, are essential to ensure that clinically relevant research questions are validly answered. Due to linkage with HealthKit and active tasks, objective health data that are impossible to collect with the traditional methods of data collection can easily be collected.

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KEYWORDS

data collection; HealthKit; platform; PRIDE Study; smartphone; wearables

Introduction

The growing number of smartphones in both the developed and developing world (2014: 2.6 billion; 2020: 5.9 billion) and the rapidly expanding coverage of Long-Term Evolution (4G) networks [1], combined with numerous wearable devices such as activity trackers and smart watches, provide unique possibilities to reach potential study participants worldwide on a device they use multiple hours per day [2]. In addition, current technological developments may enable research being established by patients themselves provided that they have access to a user-friendly platform. For example, in the Health app that is available on iPhones since 2014, health and fitness data collected in other apps and wearable devices are put together in one place through HealthKit. Consequently, Apple introduced ResearchKit in March 2015, an open source framework that enables researchers to create iOS apps for medical research [3]. The first studies using ResearchKit for data collection have recently been published [4-7].

The core ResearchKit framework consists of 3 modules handling informed consent, surveys, and "active tasks". For the latter, data are collected through the iPhone sensors including the

accelerometer, gyroscope, Multi-Touch display, and microphone. However, although ResearchKit claims to be an easy-to-use platform for researchers to create research apps, involvement of a developer may in fact be necessary to incorporate all needs. For example, iOS and Swift programming skills are necessary to develop an app for a medical study using ResearchKit. Therefore, we developed REach, a platform that enables both patients and researchers to collect data through an app using the main features of ResearchKit. Its reliability and usability were assessed in a pilot study among postpartum women.

How the Innovation Works

REach was developed by the Radboud REshape Innovation Center in cooperation with patients and researchers from various medical disciplines, including epidemiology, health technology assessment, pediatrics, and medical informatics. It consists of two sections: a Web app in which the investigator (patient or researcher) can set up the study, and an app available in the App Store with which data are collected from participants. Using drag and drop, an informed consent procedure, questions, and active tasks may be easily added to a study in the Web app (Figure 1).

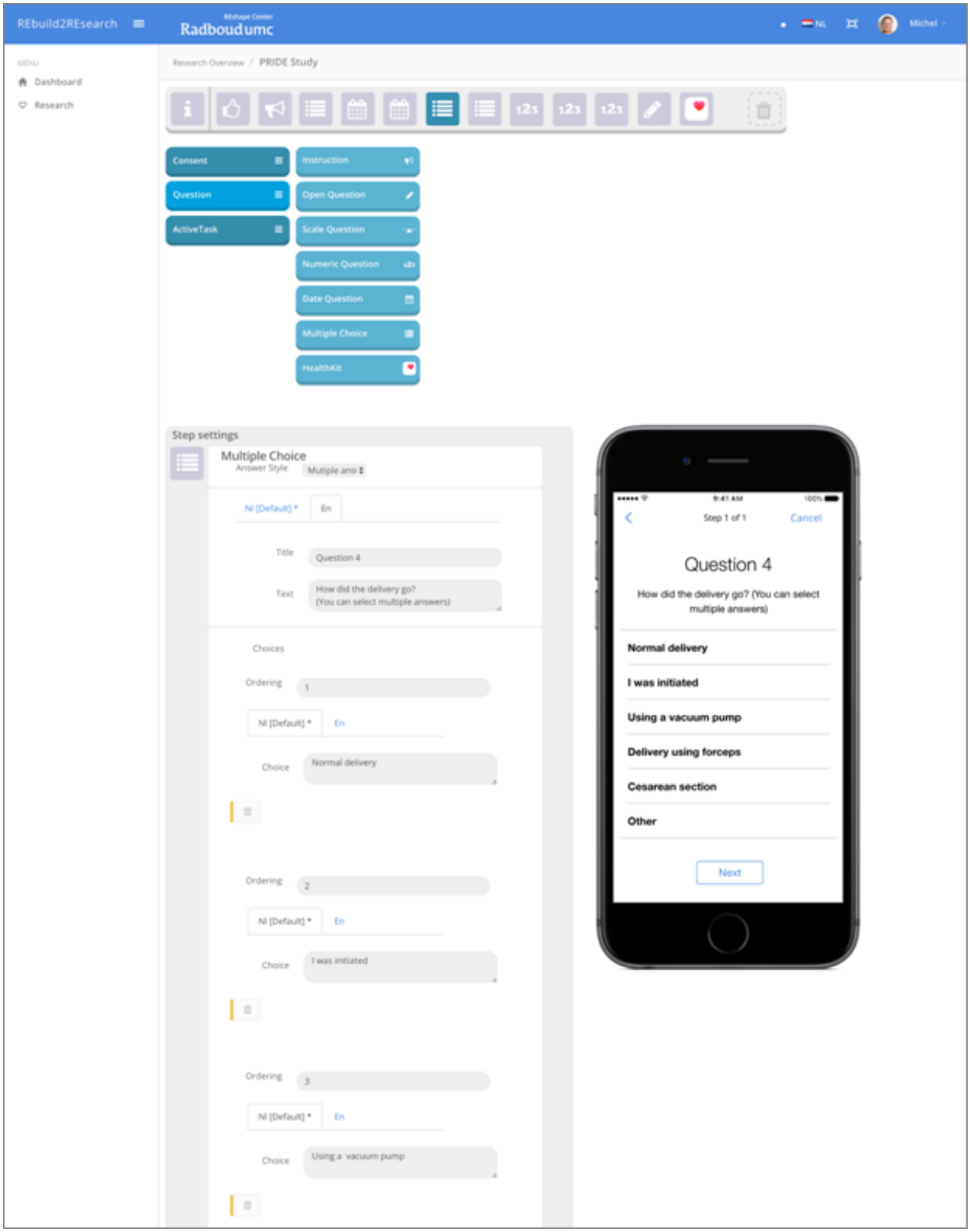
A full informed consent procedure, consisting of displaying the consent documents, participant name entry, and the participant's signature, is available in REach. The core of ResearchKit has already received numerous endorsements as a secure platform because the data are stored highly encrypted, only on the smartphone itself [8]. It is considered one of the most, if not the most, secure platforms available at present. Once the participant signs the informed consent form, the document is available for the investigator as a PDF file for archiving purposes.

Within the Web app, the investigator may build a regular questionnaire with instructions, multiple choice questions, open-ended questions (literal or numerical), rating scales, and date/time questions. Comparable to Web-based questionnaires, validity checks may be included to improve data quality. In addition, HealthKit questions may be added, in which the participant is asked for consent to share already collected data on for example body weight, heart rate, and steps. This enables investigators to easily collect unique and objective data on the health of study participants.

In addition to completing the questionnaire, data may be collected from the participants by having them performing active tasks. A number of active tasks are predefined in ResearchKit, which enable inviting participants to perform activities under partially controlled conditions using iPhone sensors for data collection. These active tasks fall into 6 categories: motor activities, fitness, cognition, voice, audio, and hole peg [9]. Currently, two active tasks are available within REach. With tone audiometry, the minimum amplitude for the participant to recognize the sound is determined. Reaction time uses the smartphone's accelerometer and gyroscope to collect data on device motion.

Once the study has been set up in the Web app, the investigator may start data collection. Studies in the app can be open to the public or by invitation only. For the latter, the email address of the potential participant should be available. The app may be free or paid, enabling possibilities for crowdfunding. There are no restrictions on the geographical location or number of study participants, but an individual can only participate once in a certain study. Furthermore, the app is available in multiple languages, depending on the language settings of the iPhone (default: English). In the dashboard, the investigator may monitor the status of the study (number of views, number of completed consent forms, and number of completed participations). The resulting data file can be downloaded at any time during or after completion of data collection and imported in statistical software packages.

Figure 1. Overview of the REach Web app.



Pilot Testing

Methods

Data collection through REach was pilot tested in a subsample of participants in the PRegnancy and Infant DEvelopment (PRIDE) Study [10]. All women who delivered a live-born singleton and completed the PRIDE Study's first postpartum Web-based questionnaire (2 months after the estimated date of delivery) between October 2015 and March 2016 were invited to test REach (n=463). The app was developed by a researcher without needing to consult the developer. Testing of the app involved providing informed consent, completing 10 questions

comparable to those in the Web-based questionnaire to get more insight into its reliability, and possible sharing of HealthKit data. The active tasks were not used in this population.

Using REach, we collected data on the occurrence of pregnancy complications ("check all that apply" format), estimated date of delivery and actual date of delivery (to calculate gestational age), birth weight, birth length, head circumference, birth defects, and closed-ended questions on mode of delivery, presentation, and infant sex. The questions in the Web-based questionnaire on perinatal outcome, including birth weight (intraclass correlation coefficient [ICC] 0.96) and birth length (ICC 0.90), were previously validated [11].

Furthermore, participants were asked to complete a short evaluation questionnaire, which included the System Usability Scale [12]. The app and evaluation questionnaire were administered at least 2 weeks after the postpartum Web-based questionnaire. To assess reliability, we calculated kappa statistics and ICCs with 95% confidence intervals for categorical and continuous variables, respectively. IBM SPSS Statistics for Windows, Version 22 (IBM Corp, Armonk, NY) was used for all statistical analyses.

Results

A total of 31 women tested the app. The results of the reliability analyses for the categorical variables are shown in Table 1. In general, there were very few discrepancies between the data collected through the app and through the Web-based questionnaire for pregnancy complications, mode of delivery, presentation at birth, and infant sex. The relatively high numbers of false negatives for nausea and vomiting of pregnancy and extreme fatigue mainly included women who reported these complication in the baseline questionnaire, which is administered at the end of the first trimester. Therefore, the effect of time may play a bigger role than underreporting of these two complications in the app itself.

One woman reported diagnosis of a birth defect in both the app and the questionnaire. Agreement between the questionnaire and app was excellent for birth weight (ICC 1.00, 95% CI 1.00-1.00; Figure 2), but substantially lower for birth length (ICC 0.73, 95% CI 0.50-0.86; Figure 3). However, this outlier seemed to be caused by the respondent making a typo in the questionnaire. Omitting this subject from the analysis increased the ICC to 0.97 (95% CI 0.93-0.98).

HealthKit data were shared by 11 of the 31 participants (35%); only the number of steps per day was shared. For the remaining 20 participants, we cannot distinguish between those who granted sharing of data but had no data available, and participants who denied permission to share data. Although insight into this matter would be interesting from a research perspective, HealthKit does not allow sharing of these data to avoid information leaks and to protect user privacy.

We received 25 evaluation questionnaires. The participants did not report problems using the app. The mean score on the System Usability Scale was 83.9 (SD 10.7), indicating a nearly excellent level of satisfaction [13]. On a scale from 1 (worst) to 10 (best), the mean rating was 7.8 (0.7). Only 2 participants (8%) preferred a Web-based questionnaire to completing the questions through the app; the majority either preferred the app (56%) or had no preference (36%).

Table 1. Comparison of app and questionnaire data for categorical variables. N/A: not applicable.

Variable	App positive		App negative		Kappa statistic
	Questionnaire positive	Questionnaire negative	Questionnaire positive	Questionnaire negative	
Pregnancy complications					
Nausea and vomiting of pregnancy	6	0	5	20	0.68
Extreme fatigue	3	0	16	12	0.13
Gestational hypertension	1	1	0	29	0.65
Preeclampsia	0	0	0	31	N/A
Gestational diabetes	0	0	0	31	N/A
Thyroid disorders	0	0	0	31	N/A
Pelvic girdle pain	5	1	1	24	0.79
Anemia	1	0	1	29	0.65
Mode of delivery					
Unassisted vaginal delivery	24	0	0	7	1.00
Cesarean section	7	0	0	24	1.00
Breech presentation	2	0	0	31	1.00
Male infant	12	0	0	18	1.00

Figure 2. Comparison of birth weight (in grams) reported by mothers in the REach application and in the Web-based questionnaire (N=31).

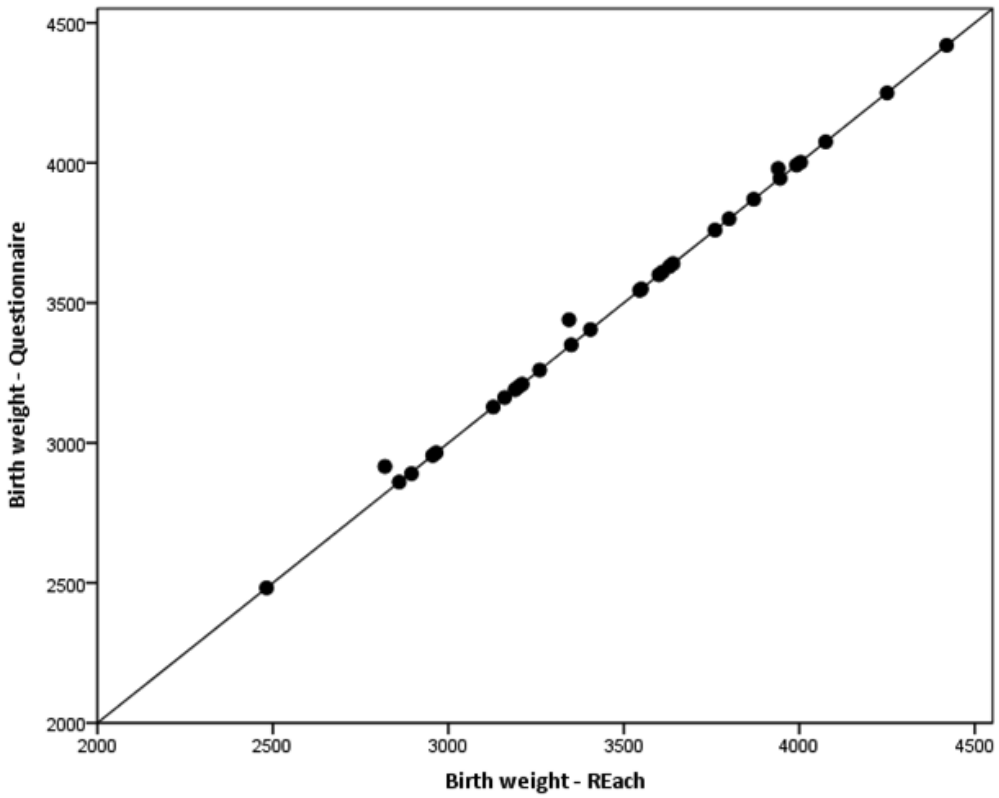
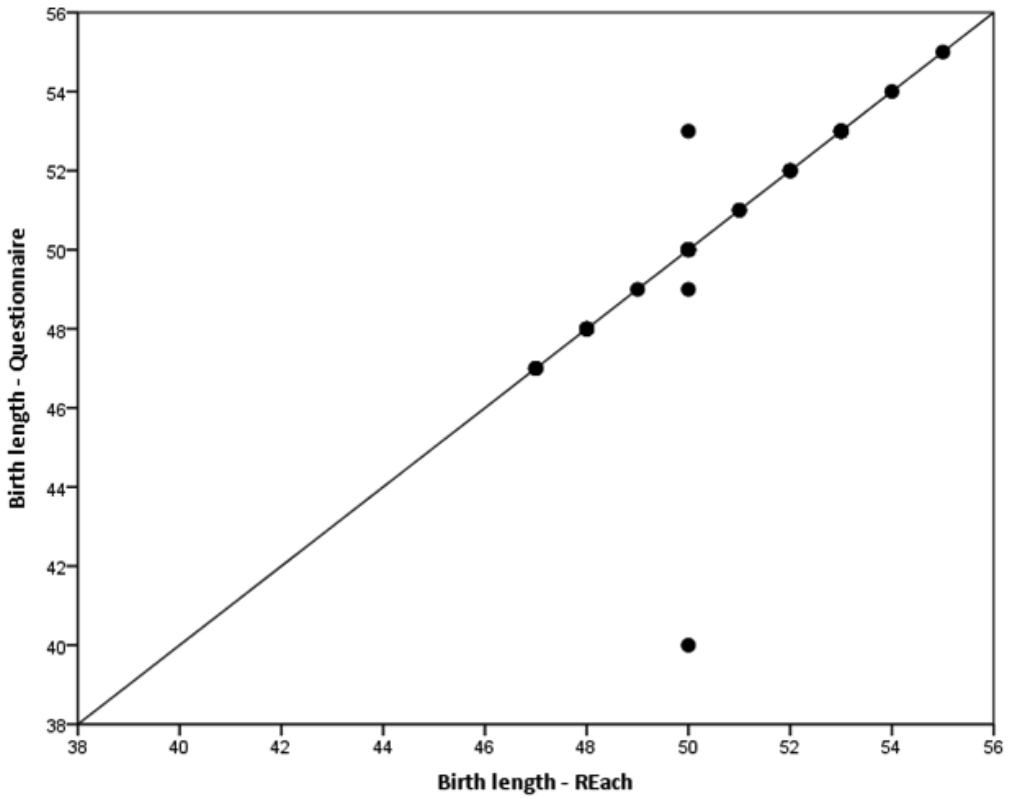


Figure 3. Comparison of birth length (in cm) reported by mothers in the REach application and in the Web-based questionnaire (N=29).



Conclusion

In the era of declining participation rates in observational studies and patient involvement [14,15], adding new methods of data collection to the toolbox of medical researchers, such as REach, is essential to ensure that clinically relevant research questions validly answered. Despite some methodological limitations of the pilot study, including the relatively small sample size and selective participation as only iPhone users could be included, study participants were very satisfied with data collection through smartphones and measurement error seemed minimal. Although no formal validation analyses were conducted in the few other studies in which ResearchKit was used for data collection, data quality was also reported to be high and consistent [5-7].

Due to the linkage with HealthKit and the incorporation of active tasks, objective health data that are impossible to collect with the traditional methods of data collection can easily be collected. However, HealthKit data will probably not be available for the complete study population due to declining to share this information or not using the HealthKit on the iPhone at all, yielding the possibility for selection bias.

REach is currently available through the website of the Radboud REshape Innovation Center [16]. More extensive tests of the platform, including patient-initiated studies, are ongoing and possibilities for platforms for other mobile operating systems, such as Android, are now being explored.

Conflicts of Interest

None declared.

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Abbreviations

PRIDE Study: PRegnancy and Infant DEvelopment Study
ICC: intraclass correlation coefficient

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Original Paper

Codesigned Shared Decision-Making Diabetes Management Plan Tool for Adolescents With Type 1 Diabetes Mellitus and Their Parents: Prototype Development and Pilot Test

Tamara S Hannon[1,2], MS, MD; Courtney M Moore[3], BFA; Erika R Cheng[2], MPA, PhD; Dustin O Lynch[3], BFA; Lisa G Yazel-Smith[1], MS; Gina EM Claxton[3], RD, MPH; Aaron E Carroll[1,2], MS, MD; Sarah E Wiehe[2,3], MPH, MD

[1]Pediatric and Adolescent Comparative Effectiveness Research, Department of Pediatrics, Indiana University School of Medicine, Indianapolis, IN, United States

[2]Children's Health Services Research Center, Department of Pediatrics, Indiana University School of Medicine, Indianapolis, IN, United States

[3]Community Health Partnerships Patient Engagement Core, Indiana Clinical and Translational Sciences Institute, Indiana University, Indianapolis, IN, United States

Corresponding Author:
Tamara S Hannon, MS, MD
Pediatric and Adolescent Comparative Effectiveness Research
Department of Pediatrics
Indiana University School of Medicine
Health Information and Translational Sciences Building
410 West 10th Street, Room 2039
Indianapolis, IN, 46202
United States
Phone: 1 317 278 5608
Fax: 1 317 944 3882
Email: tshannon@iu.edu

Abstract

Background: Adolescents with type 1 diabetes mellitus have difficulty achieving optimal glycemic control, partly due to competing priorities that interfere with diabetes self-care. Often, significant diabetes-related family conflict occurs, and adolescents' thoughts and feelings about diabetes management may be disregarded. Patient-centered diabetes outcomes may be better when adolescents feel engaged in the decision-making process.

Objective: The objective of our study was to codesign a clinic intervention using shared decision making for addressing diabetes self-care with an adolescent patient and parent advisory board.

Methods: The patient and parent advisory board consisted of 6 adolescents (teens) between the ages 12 and 18 years with type 1 diabetes mellitus and their parents recruited through our institution's Pediatric Diabetes Program. Teens and parents provided informed consent and participated in 1 or both of 2 patient and parent advisory board sessions, lasting 3 to 4 hours each. Session 1 topics were (1) patient-centered outcomes related to quality of life, parent-teen shared diabetes management, and shared family experiences; and (2) implementation and acceptability of a patient-centered diabetes care plan intervention where shared decision making was used. We analyzed audio recordings, notes, and other materials to identify and extract ideas relevant to the development of a patient-centered diabetes management plan. These data were visually coded into similar themes. We used the information to develop a prototype for a diabetes management plan tool that we pilot tested during session 2.

Results: Session 1 identified 6 principal patient-centered quality-of-life measurement domains: stress, fear and worry, mealtime struggles, assumptions and judgments, feeling abnormal, and conflict. We determined 2 objectives to be principally important for a diabetes management plan intervention: (1) focusing the intervention on diabetes distress and conflict resolution strategies, and (2) working toward a verbalized common goal. In session 2, we created the diabetes management plan tool according to these findings and will use it in a clinical trial with the aim of assisting with patient-centered goal setting.

Conclusions: Patients with type 1 diabetes mellitus can be effectively engaged and involved in patient-centered research design. Teens with type 1 diabetes mellitus prioritize reducing family conflict and fitting into their social milieu over health outcomes at this time in their lives. It is important to acknowledge this when designing interventions to improve health outcomes in teens with type 1 diabetes mellitus.

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KEYWORDS

adolescent health services; patient-centered care; research design; diabetes mellitus, type 1; self-management

Introduction

Type 1 diabetes mellitus (T1DM) is diagnosed in approximately 1 in 400 US youth under the age of 20 years, making it one of the most common childhood chronic diseases [1]. Adolescents with T1DM have significant difficulty achieving optimal glycemic control due to challenges in shifting and evolving social priorities that can interfere with medication adherence, increasing insulin requirements characteristic of puberty, diabetes-related distress, and family conflict [2-4]. A principal challenge of intensive diabetes care is maintaining frequent self-monitoring of blood glucose (SMBG) and insulin dosing. A clinical strategy to increase adherence to medical recommendations is real-time sharing of adolescent SMBG or continuous glucose monitor data with parents. Health information technology (HIT) allows real-time sharing of SMBG and messaging between patient, parents, and health care providers (ie, HIT-enhanced SMBG). HIT-enhanced SMBG has been shown to improve reactive and proactive blood glucose management, provide adherence support, and promote intensification of treatment [5-7]. However, adolescents and parents are often reluctant to adopt this technology, which may be related to parental nagging, family conflict, and additional burden or stress placed on adolescents and parents [3,4,8-12].

The general well-being of patients and parents is significantly affected by the demands of daily diabetes care, the even lower glycemic control targets, and the monetary costs of diabetes therapies [13,14]. It is not surprising that patients, parents, and diabetes care providers can have conflicting ideas about optimal treatments and therapeutic goals, as some treatments may further increase patient burden, affecting clinical and psychosocial outcomes. For example, a health care provider may want the patient to use a newer technology for SMBG to improve glycemic control, but the patient may feel that this will further increase his or her stress levels, and stress may be the primary outcome of importance to them at this time. A patient-centered approach using shared decision making to identify self-care goals during the clinical encounter could reduce diabetes distress and improve diabetes self-care among adolescents with T1DM using HIT-enhanced SMBG. Shared decision making in person-centered care is a process in which clinicians and patients work together to make decisions and select care plans based on clinical evidence that balances risks and expected outcomes with patient preferences and values [15]. Diabetes self-care goals outlined with the diabetes care team in the form of behavioral contracts have been used to address (1) goals for the frequency of SMBG, (2) goals for the frequency of contact with the diabetes clinic team, and (3) parent and youth responsibilities [6,16-18]. However, these contracts can be perceived as punitive if they are not constructed using patient-centered communication, as adolescents can be sensitive to authoritarian treatment [19].

In this study we collaborated with a patient and parent advisory board (PAB) to (1) outline major causes of diabetes-related distress affecting quality of life; (2) identify the patient-centered health outcomes most important to the PAB participants; and (3) determine how to incorporate shared decision making in the clinic setting when a health care provider, a patient, and a parent may have different goals. The principal objective was to codesign, with the PAB, an intervention that used shared decision making in the creation of a diabetes management plan. We would then test the resulting clinic intervention in a future study of adolescents with T1DM using HIT-enhanced SMBG (NCT02115555). We hypothesized that a PAB-codesigned clinic intervention would prioritize outcomes that differed from routinely measured and highly emphasized medical outcomes. Here, we describe the strategy for working with a PAB on this project and the development of a PAB-codesigned shared decision-making tool for use with adolescents with T1DM and their parents.

Methods

Participants

To codesign the shared decision-making strategy, we first formed a PAB that consisted of adolescents with T1DM and their parents. Inclusion criteria required youth to be between 12 and 18 years of age, have T1DM diagnosed for at least 6 months, be a patient in our Pediatric Diabetes Program at the Indiana University School of Medicine, Indianapolis, IN, USA, and have a parent or guardian who agreed to participate. To convene the PAB, we invited adolescents (teens) between the ages 12 and 18 years with T1DM who were seen in our Pediatric Diabetes Program clinical practice in the past 3 months and their parent(s) to be advisors. The goals of the PAB were to allow for (1) active engagement between scientists and patients, (2) a partnership in designing the shared decision-making strategy, and (3) development of the implementation strategy for the funded randomized controlled trial. Teens and parents provided informed consent and participated in 1 or both of 2 PAB sessions, each lasting 3 to 4 hours.

To accomplish our study aims, we partnered with the Indiana Clinical and Translational Sciences Institute Patient Engagement Core (PEC), a team of human-centered designers that offers services to academic researchers related to patient-centered outcome measurement, recruitment, and study acceptability. With this approach, researcher and research participant hold parity and shared inquiry, and designers serve as translators to bridge the communication gap between researchers and patients. We used a systems design approach that could engage participants in the design thinking process. This would take participants through the stages of defining the problems and barriers, generating ideas and solutions, and prototyping an approach or tool to address a problem or barrier. Similar methods have been used in development approaches to address self-management of type 2 diabetes, pediatric asthma, and

quality improvement health care facilities [20-22]. The methods employed by the PEC are highly interactive and leverage the expertise of research participants in ways that exceed standard expectations for study participation [23-26]. By combining qualitative research methods with novel methods from design research, the PEC is able to create truly innovative approaches for the engagement of patients and caregivers in research [27-29]. This partnership allowed us to fully engage participants in the development process and provided an opportunity for PAB members to be open about their experiences without fear of judgment or reproach from physician stakeholders.

We managed study data using Research Electronic Data Capture (REDCap) tools hosted at the Indiana Clinical and Translational Sciences Institute and at the Indiana University Pervasive Technology Institute [30], which supports REDCap with information technology infrastructure and consulting resources.

Conducting the Type 1 Diabetes Patient and Parent Advisory Board Meetings

The PEC facilitated 2 sessions with the PAB that were designed to identify patient-centered outcomes important to the participants and recommendations for how to incorporate shared decision making to create a diabetes self-care contract in the clinic setting. Each session consisted of a variety of group activities designed to break down barriers and inhibitions to verbal participation, promote rapport, and engage participants. For the first session, the PEC designed activities to (1) elicit patient-centered outcomes related to quality of life, parent-teen shared diabetes management, and shared family experiences; and (2) facilitate discussion regarding the implementation and acceptability of the proposed intervention (self-care contract). The PEC used this information to develop a prototype for a diabetes management plan tool to be used in the clinic setting, which would guide shared decision making [27]. Acceptability and clinical implementation of this prototype were the focus of the second session. Table 1 presents participant characteristics and session objectives and activities. Session 1 was attended by 12 patient advisors (6 teens and 6 parents). Session 2 took place approximately 2 months after session 1 and was attended by 6 patient advisors (3 teens and 3 parents). Unfortunately, some participants were lost for session 2 due to scheduling difficulties.

Session 1

To assess important patient-centered outcomes, we asked participants to write their response to the question “How does diabetes most impact your life?” on a notecard. A PEC team member then read each response aloud to the entire group and asked them to guess whether the response was written by a parent or a teen. The purpose of this activity was to assess the extent to which diabetes affects parent and teen quality of life, while also uncovering any impacts of diabetes that are shared between teens and parents. A follow-up discussion followed to examine each quality-of-life impact shared by the teen and parent in more detail.

Because diabetes self-care in adolescents is often affected by conflict with parents, we considered the possibility that family conflict might be an important patient-centered outcome. A separate activity asked participants to reflect on aspects of diabetes management that cause conflict within their families. For this activity, we placed teens and parents in separate rooms and recorded their responses on flipchart paper. We then exchanged these responses, and we asked the teens to suggest solutions to the conflicts that the parents wrote, and asked the parents to suggest solutions to the conflicts the teens wrote.

Using standard diabetes self-management tasks as starting goals, and the feedback on how diabetes distress and family conflict affect the completion of these tasks that we collected from these discussions, PEC design team members (CMM and DOL) then developed a prototype for a diabetes management plan tool. The purpose of this tool was to guide shared decision making between teens and parents to establish patient-centered goals, propose diabetes self-care actions, and create behavioral rewards for both teens and parents.

Session 2

During the second session, we reconvened the PAB to discuss and pilot test the diabetes management plan tool prototype. The purpose of this session was to uncover any problems with the diabetes management plan tool process, its content, and its acceptability within individual and family contexts. In this session, we asked each parent-teen dyad to complete activities contained in the tool and to provide feedback. The PEC facilitators observed this activity and recorded notes; they did not assist with the process. Teens and parents provided feedback together and as separate groups. After meeting separately, the entire group reconvened to share the main points of their independent discussions. We also asked them to brainstorm solutions when issues with the prototype were identified (eg, readability, functionality, fit, challenges, or perceived value) and to discuss what should happen if future users of the tool were not willing to complete the activities.

Table 1. Patient and parent advisory board meeting objectives and activities.

Session	Participants[a]	Objectives	Activities
1	6 teens (4 male, median age 14.6, range 12.4-16.4 years), 6 parents	Patient-centered outcomes; negotiation tactics	Participant-generated card sorting; role reversal
2	3 teens (3 male, median age 14.7, range 14.0-16.6 years), 3 parents	Prototype testing; prototype refinement	Role play; observation; cognitive interview

[a]Demographic information such as race or date of diagnosis was not collected from participants.

Analysis

We based analyses for PAB-derived activities on Ackoff's data, information, knowledge, and wisdom scheme, which structures data collection and analysis in a manner that culminates in theory (explanations of human problems) and concept development (creation of new ways to handle problems) [31]. We used an inductive descriptive approach and thematic analysis [32,33]. This framework is applied in settings where computer-aided decision making is used, including informatics [34,35], but it is also used in design research [36]. This process evolves across 4 categories of interpretation: data (eg, written, audio, or video review), information (eg, items of importance or significance written on sticky notes), knowledge (eg, finding patterns to identify themes and areas of importance), and wisdom (eg, applying knowledge to create something new or to make decisions).

Using this framework, the PEC reviewed audio recordings and detailed notes from session 1 (data). They then analyzed notes and other materials generated during the sessions to identify and extract key ideas participants expressed that were relevant to the development of a diabetes care plan (information). These ideas were written onto separate sticky notes and then visually coded into similar themes (knowledge). Some of these themes dealt with domains of agreement terms to be included in the plan, and others dealt with the ideal use of such a plan and ideal interactions around its use. For each of the patient-centered diabetes themes (domains), we identified previously validated questionnaires, if possible, that addressed the corresponding patient-centered outcomes. We did not administer these questionnaires in this study, but they could be used in future outcomes research to assess diabetes distress.

The PEC investigators used the knowledge gained through gathering and analyzing session 1 data, as well as existing disciplinary knowledge (visual communication and design expertise) to create a tool to be tested in session 2. The prototype tool used in session 2 is the initial application of this knowledge (demonstrating wisdom). We then tested the tool and analyzed the resulting data using a deductive approach with specific domains of desired feedback determined ahead of the session. We analyzed these new data in the same fashion as above to identify new knowledge that further refined the developed wisdom.

Results

Session 1: Patient-Centered Outcomes

Using the "How does diabetes most impact your life?" notecards from session 1 and the ensuing discussion themes, we identified 6 principal patient-centered quality-of-life measurement domains affecting parents and teens. For each of these domains, we report representative quotes below. Table 2 shows these patient-centered domains, along with validated questionnaires that could be used to address these domains and diabetes distress in future outcomes research.

Stress

The theme of stress was the most common theme expressed by teens. Teens were stressed about whether they had all of the supplies they needed, remembering all of the tasks they were asked to perform, and fitting the additional requirements of diabetes self-care into their busy lives while still fitting in with peers. Some of these feelings are summarized by the following quotes:

> *Diabetes affects me by putting a lot of stress on me.* [Teen participant]

> *Diabetes doesn't limit my life, but it is a daily thing...I do worry every day about my health, even though I know how to take care of myself.* [Teen participant]

> *Yeah at my school, I'm the only diabetic...and the teachers hardly know what to do. There's no school nurse there either. So it's hard for me. I'm having to deal with school, homework, the sports I'm playing, and also my diabetes.* [Teen participant]

Fear and Worry

The theme of fear and worry related to diabetes was pervasive in nearly every aspect of the parents' daily lives. Of the 12 impact notecards, 7 included something about worry, stress, or fear. In contrast to teens, parents expressed concern about potential worst-case outcomes (eg, nighttime hypoglycemia), preparing their children for life on their own, and balancing giving their children freedom while keeping them safe. The following quotes illustrate the fear parents expressed feeling:

> *I just think all the parents locked in on the word fear. I think the difference between [fear for the child and parent is] the parents are programmed to be concerned for the kids. So, yeah we're all afraid for them and we all have their best interests at heart. The kids, on the other hand, I wonder if they realize how pernicious the stuff can be and what they're most concerned about is, "Don't label me. I want to be like everybody else. Let me live my life." And somewhere those have to meet for some success. And, you know, I was a teenager. Rules, to a certain extent, are meant to be broken I guess. It's how we, sort of, test the limit and how we grow. But I don't think we can afford that latitude here, which is why fear has a bigger heartfelt meaning for most of the parents.* [Parent participant]

> *I am afraid of the future for my child and afraid of nighttime lows that I won't be able to wake him up from.* [Parent participant]

Table 2. Quality-of-life measurement domains and pertinent diabetes distress outcomes measures.

Domain and desired outcomes	Study outcomes measures (questionnaires)
Stress	
Diabetes-related stress reduced for teens	DAWN Problem Areas in Diabetes Questionnaire[a]; Peds Quality of Life Inventory Diabetes Module
Fear and worry	
Diabetes-related stress reduced	DAWN Problem Areas in Diabetes Questionnaire; Parental Environment Questionnaire Peds Quality of Life Inventory Diabetes Module
Teens more effective at managing diabetes	Child Adherence in Diabetes Questionnaire; Laboratory results (hemoglobin A_{1c})
Teen to manage diabetes independently at times	Parental Environment Questionnaire; Child Diabetes Family Conflict Scale
Communicate productively about fear and worry	Child Adherence in Diabetes Questionnaire; Parental Environment Questionnaire; Child Diabetes Family Conflict Scale
Mealtime	
Mealtime isn't overly burdensome	DAWN Problem Areas in Diabetes Questionnaire; Child Adherence in Diabetes Questionnaire
Teen feels involved in activities and celebrations	DAWN Problem Areas in Diabetes Questionnaire
Assumptions and judgments	
Effectively communicate realities of diabetes	DAWN Problem Areas in Diabetes Questionnaire; Peds Quality of Life Inventory Diabetes Module
Skills to manage judgment and bullying	N/A[b]
Skills to advocate for needed support	DAWN Problem Areas in Diabetes Questionnaire; Peds Quality of Life Inventory Diabetes Module
Teens feel understood and accepted	DAWN Problem Areas in Diabetes Questionnaire
Normalcy or fitting in	
Teen feels involved with peers	DAWN Problem Areas in Diabetes Questionnaire; Patient Health Questionnaire[c] (PHQ-9)
Teen advocates for being treated as equal	DAWN Problem Areas in Diabetes Questionnaire; Peds Quality of Life Inventory Diabetes Module
Teen can express individual symptoms and needs	DAWN Problem Areas in Diabetes Questionnaire; Patient Health Questionnaire (PHQ-9)
Teen can take part in extracurricular activities	DAWN Problem Areas in Diabetes Questionnaire
Parent doesn't assume that expressions of emotion are diabetes related	N/A
Parents have similar rules for teens with and without type 1 diabetes	N/A
Conflict	
Teens and parents resolve disputes productively	Parental Environment Questionnaire; Child Diabetes Family Conflict Scale
Parents manage conflicts in consistent fashion	N/A
Parents don't yell, take frustrations out on teen	Parental Environment Questionnaire
Teen is honest about self-monitoring of blood glucose and self-care	N/A
Teen is given a chance to explain himself or herself	N/A

[a]DAWN Problem Areas in Diabetes Questionnaire has both a pediatric and a parent version.

[b]N/A: not applicable (available questionnaires lack the ability to assess competence in this area; further questions are needed).

[c]Assessment of depressive symptoms.

In addition, teens and parents discussed that many schools did not have the resources to properly care for their children during the school day and that many people, including teachers and coaches, did not seem to understand the seriousness of acute

and chronic management of T1DM. This was both a source of major concern for parents because it made their children vulnerable (amplifying their fear) and a source of frustration for teens when school staff minimized the daily struggles they face. Here are some representative quotes from parents:

> *When he was in junior high, there wasn't a nurse and there were two nurses for the entire school system and they go to each school like one day a week...Being worried all the time while he was at school, not knowing who was going to be taking care of him and that caused stress at my job. I was a manager at that time. I had a lot of phone calls back and forth throughout the day when the nurse wasn't there. He would drop really low, go really high, it was all over the place. It got to the point that it was enough stress at work that I was told I was either a manager or the mother of a diabetic. I stepped down.* [Parent participant]

> *My biggest concern is that our coaches in sports he's getting ready to play in high school are not going to take him seriously or they're going to be—pull him out when he looks bad. I don't want them to do that. I want him to know when he's low or when he's high instead of somebody else looking at him and saying, "Well he's diabetic, let's just..."* [Parent participant]

Mealtime Struggles

Mealtime struggles affecting the entire family were shared by parents and teens. Teens also reported feeling hungry but not being able to eat for reasons such as blood sugar levels not being in range, not wanting to eat certain foods that were available, or being full but having to finish their meal because they had already dosed insulin for it. Some of these struggles are represented by the following quotes:

> *You're growing and you get hungrier...You can't [eat] like normal people do. They can just eat whatever they want when they want. For us it's kind of harder because you can only eat so much at a time.* [Teen participant]

> *You put your insulin in before you eat and maybe you get full but you can't take that insulin back. So you gotta force it down.* [Teen participant]

Teens and parents specifically mentioned difficulties faced during holidays because many traditions are focused on food and, in many cases such as Valentine's Day and Halloween, focus on high-sugar foods. As expressed by the following quotes, an overabundance of sweets and food can be bothersome:

> *Holidays and Halloween and Valentine's Day are centered around candy and you just can't pop the 10 candy bars in your mouth like you used to be able to do.* [Teen participant]

> *Every holiday we have, we celebrate with food. We always have food...When you have to take insulin for it, you think about it more. We have food around us a lot.* [Parent participant]

Parents discussed how their child's diabetes dictates where families can go out to eat and what they can eat at home:

> *The one most impacting thing is EATING! It impacts the entire family and extended family. There are so many aspects of meals—timing, what we are eating, when, where, what...etc.* [Parent participant]

> *If she's very high and she wants to eat—you're 300, you're not going to eat right now. You need to wait until your blood sugar is down.* [Parent participant]

Assumptions and Judgments

The theme of assumptions and judgments included those felt by the teen or parent from others and assumptions that parents made when relating to their child with diabetes. Teens and parents discussed several points of frustration caused by assumptions and judgments that others placed on them or their child. These included misunderstandings about the difference between type 1 and type 2 diabetes and poor understanding about T1DM. Teens discussed facing criticism when they ate sugar, confusion from their peers about why they were not overweight, and stares when they performed SMBG and dosed insulin in public. The following quotes represent the feelings of teens, who sometimes felt ashamed to put their diabetes "on display:"

> *Diabetes has really impacted the way people judge what I can and can't do, and normally they don't know, they just assume. Most people assume I can't eat anything sweet or when I'm low, people judge me for that.* [Teen participant]

> *I remember...I told someone I had diabetes and they were like, "Eww get away from me" because he actually did think I was contagious and it was just the most awkward thing.* [Teen participant]

> *When I check my sugar [in class], I get stared at the entire time I do it and it's just extremely embarrassing. I just wanna leave. Every part of me is telling me to leave. I don't want them staring at me...I don't really want to have to do it in front of everyone.* [Teen participant]

> *The first couple years, my dad said that I had to go to the car...my mom got so mad if I [checked my blood sugar] in public. Indecency she thought. She's lightened up. That's why I do it in secrecy. It kind of rubbed off. I like go in my backpack because I try to be as discreet as possible.* [Teen participant]

Parents found themselves assuming that every mood swing is blood sugar related. This assumption frustrated teens, as they wanted to be able to express emotions without being tied to their T1DM. Parents recognized this, as exemplified in the quotes below:

> *I think I attribute a lot of things that probably have nothing to do with it. He'll do something and I'll [question him] and he'll be like, "No." That's the first thing I go to and I feel bad for that.* [Parent participant]

> *It's hard for me because we'll be joking around being silly and all of a sudden I'll be like, "Is he low?" and then he gets mad at me like, "can't I ever have fun without you thinking the worst?"* [Parent participant]

Feeling Abnormal

The theme of feeling abnormal was a major concern for teens. Teens discussed many ways in which diabetes prevented them from of having a sense of normalcy. As one teen put it:

> *I feel like I'm special needs or something.* [Teen participant]

Some teens and parents described how teens with diabetes were sometimes separated from peers during important activities in school, such as for testing. For some, this was seen as helpful because it allowed for some leeway in the event of diabetes complications, but for others, this separation was perceived as singling them out negatively. Some of the parents' thoughts on this are represented here:

> *We have a plan written to where...if he has a high or low during a test like that he can retake the test...but they've never taken him aside. They keep him with everybody else.* [Parent participant]

> *I found out a while back...when it was test time, they would take all of the type 1 kids and put them in a specific location. So it's almost a second-class setup—even if you perceive it as a benefit, which it is because they can monitor and see if they're low and stuff like that—the downside is, what do teenagers want? To be like everybody else.* [Parent participant]

Parents were also concerned about relating to their teen as numbers instead of as an individual person because of their focus on diabetes management. Parents also expressed their struggles to find a balance between keeping their children safe and allowing them the freedom to be a "normal" teen. Parents wanted their children to spend time with friends but were frustrated and worried when their teens neglected to perform diabetes self-care while at friends' houses. Their thoughts represented the internal struggle they had when their child with diabetes was away from them:

> *I won't let her just go to the mall or anywhere unless I know specifics or an adult is going to be there. Whereas before I would let her and a friend play outside for hours or go on a bike ride. I can't let her go on a bike ride. I need to make sure if she goes low someone is there. It's any activity that's out of your eyesight.* [Parent participant]

> *I have to know the parents well and I have to know the parents can take care of him before I [let my child spend time with them]. And he wants to go spend the night with who he wants to go spend the night with. There's a conflict.* [Parent participant]

> *They feel like they can handle this. And they don't understand that when they're low, they can't handle this.* [Parent participant]

In addition, many parents reported feeling unsure of how they would be able to allow their teens with T1DM to have the same rules as older siblings and teens. These quotes highlight this struggle:

> *I think dating is going to be a real obstacle when it comes but when it does that'll be a different thing completely than what my brothers went through because with my brothers, they are just like "Okay have fun" but with me it'll be like "Make sure you do this, make sure you do this, make sure you do this." And then they're going to inform whoever I'm going out with, "Hey if he's doing this, do that, do that."* [Teen participant]

> *I always think about my 18-year-old daughter and the things she's able to do. Driving, of course, or going on Spring Break or she's been on some mission trips. And I worry about how am I going to let her do those things too and am I going to and...* [Parent participant]

Conflict

The theme of conflict was important for teens and parents alike. The PAB discussed conflict resolution between parents and teens, specifically in the context of 3 other domains identified in the session: stress, fear, and not being able to live like a "normal" teen. Both parents and teens cited conflict resolution as an important outcome. The main concern for teens was dreading having to tell parents when they have high blood sugar numbers because they did not want to be yelled at or questioned. They expressed a desire to explain themselves. Many of the teens had a parent they preferred to tell because the reaction was more desirable. Some examples of how teens feel about conflict over blood sugars are here:

> *When I have a high number, I'd much rather tell my mom—she's really scary too—but my dad's like scarier because...If I tell my dad I'm like 170 or something, he'll be like, "What's wrong with you? What did you eat?" and I was like, "I didn't do anything." My mom would be like, "Oh my god, you are in trouble" and I'll be like "Don't tell my dad." And she'll keep it low key but my dad will be like yelling at me.* [Teen participant]

> *I like to talk to my dad more about numbers and stuff because he's just more easygoing...my mom will yell at me and I don't think that really gets anywhere, yelling at me. Sometimes it's not my fault.* [Teen participant]

Teens understood and accepted parental concerns and associated parental behaviors. In turn, parents understood that their children must be able to manage their illness independently. Both parents and teens desired a better system for conflict resolution and better skills for working together.

Session 1: Acceptability of Intervention

None of the dyads in the PAB had an official written agreement related to diabetes management. The consensus in the group was that parents and teens tend to have an unspoken understanding wherein teens knew when to notify parents of blood sugar levels and that parents would review their children's SMBG. Both parents and teens in the PAB understood and

acknowledged the importance of comanagement in diabetes self-care. The group consensus was that 2 objectives were principally important: (1) focusing the intervention on conflict resolution strategies, and (2) working toward a common goal (Table 3).

Session 2: Diabetes Management Plan Tool Prototype

Figure 1 summarizes the diabetes management plan tool process. Both teens and parents received the tool with instructions to (1) independently choose diabetes self-care tasks (action items) they could do better at from a list of suggestions, or come up with their own; (2) choose or create suggested action items for their partner (teen or parent); (3) exchange their chosen action items with their partner; (4) compare action items with their partner and identify similar, agreed-upon, personal action items based on those they chose and those their partner suggested; (5) prioritize up to 3 action items in terms of how hard they thought the items would be to accomplish and decide whether they could make them goals; and (6) decide on a point tracking system to reward achievement of goals. We focused on 4 aspects of the prototype in this session: functionality and readability, content, use in context, and a reward system.

Multimedia Appendix 1 provides the initial parent and teen versions of the tool from session 2 and Multimedia Appendix 2 shows the final versions designed after the iterative process.

Functionality and Readability

Several issues became clear during the session and were later resolved through revisions to the prototype (Multimedia Appendix 1): (1) at least two dyads began by completing step 1 together rather than separately as it was designed, despite having separate tools for parents and teens; (2) it was not clear how to choose or create a goal; (3) some aspects of the tool were hard to read; (4) the arrangement of the steps on the tool was confusing; and (5) how to share the individual tools between parent and teen was confusing.

We addressed these issues through the following revisions: (1) simplifying the steps by combining steps 1 and 2, and visually highlighting this combination using a black box; and (2) improving visual signaling for important tasks such as setting rewards (creating a visual element to highlight “my reward” and “our reward”) and swapping pages (creating a swap symbol and using color in the text to specify which color sheets each partner should have at various steps in the process) (Multimedia Appendix 2).

Content

Parents and teens identified 2 specific words within the prototype as problematic: *yelling*, which was a turnoff for parents, and *fasting* (referring to the time period before the breakfast SMBG check), which some found confusing. We removed these in the final prototype.

Use in Context

Overall, parents and teens felt that the usefulness of the tool would depend on family dynamics. For example, one parent thought the tool seemed like “a step back” for their family because they already had an unwritten agreement in place that was working for them. Participants agreed that it would be of better use for families having at least some conflict. All parents agreed that it was important to gear a management plan toward improving *medical* outcomes (eg, hemoglobin A_{1c} in target range). The PAB recommended that a health care provider give guidance for establishing appropriate goal action items and making sure they were specific, measurable, achievable, and results focused. These did not affect the tool itself but were important considerations for how the tool should be used.

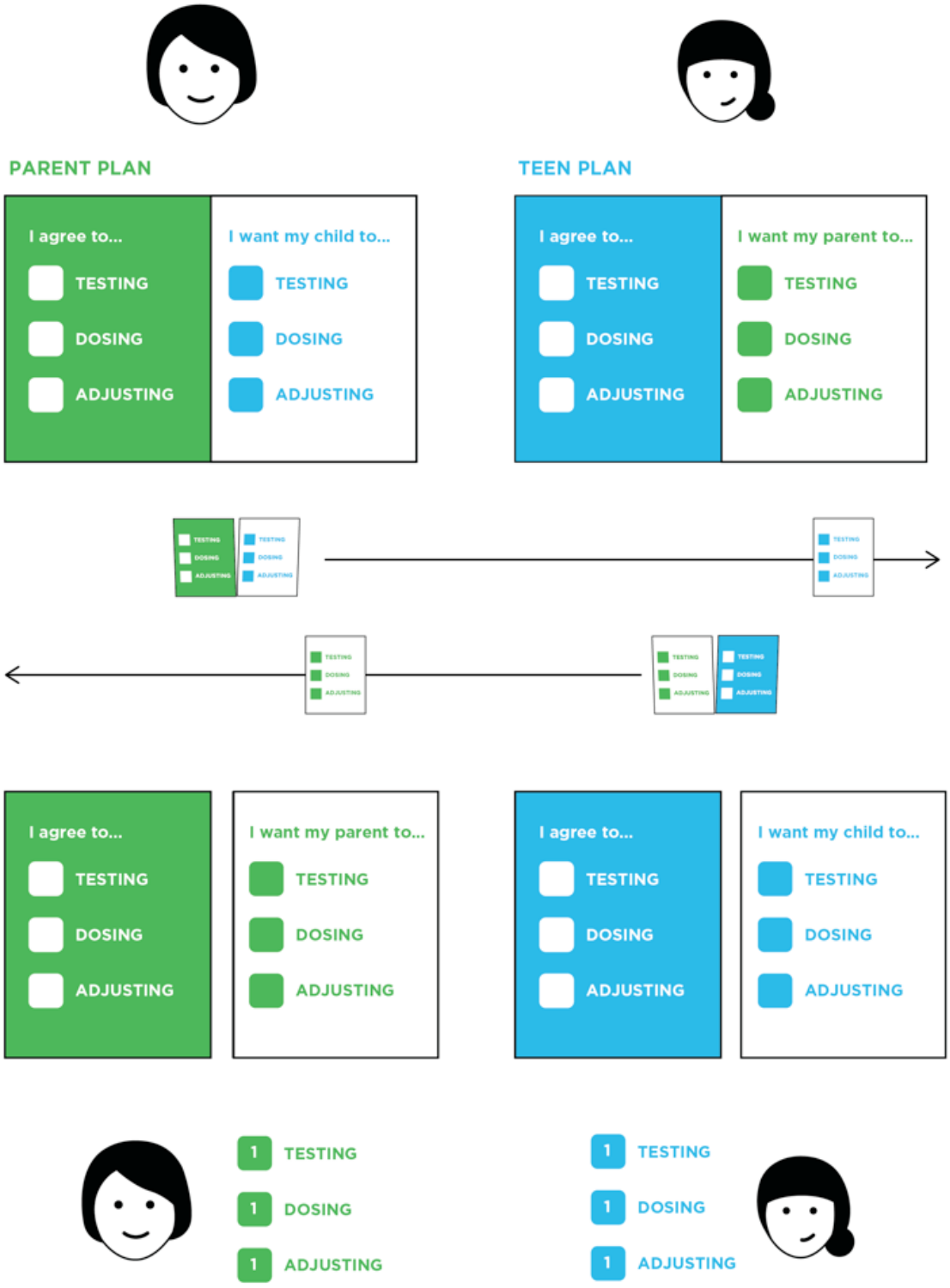
Reward System

In general, parents and teens thought that a reward system for achieving action items would be a helpful motivator. Some parents expressed that they used punishment only when their teen would not comply with their diabetes management and they felt that a reward might be helpful. The concept of a team reward for achieving action items was considered positive overall. However, one parent stated that punishment may be needed if teens didn’t follow through with action items. The PAB recommended to keep both individual and team rewards in the diabetes management plan tool. They thought that some parents were likely to use punishment whether or not the tool included these kinds of consequences for failure to uphold agreement terms. The personal and team reward remained in the final prototype based on this feedback.

Table 3. Acceptability of intervention.

Priorities	Incentives and desires	
	Teen	Parent
Comanagement and conflict resolution	Hold parents accountable for behavior, reactions, and projection of worry Better comanagement relationship	Hold teens accountable for self-care tasks Better comanagement relationship
Focus on common goals	Domains of fear and worry, normalcy, and conflict addressed; not just hemoglobin A_{1c}	Coparents agree to work together The process is customizable

Figure 1. Using the diabetes management plan tool consists of both parent and teen independently choosing action items, sharing these with their partner, and prioritizing and agreeing on issues to discuss with their diabetes care provider.



Discussion

Principal Results

Our objective was to codesign with a PAB an intervention that used shared decision making in the creation of a diabetes management plan. The PAB identified 6 principal domains related to diabetes distress that significantly affected their lives on a day-to-day basis. These were stress, fear and worry, mealtime struggles, assumptions and judgments, feeling abnormal, and conflict. These indicators of diabetes distress relate both directly and indirectly to the ability to perform diabetes self-care and achieve glycemic control [4,37-39]. For example, individuals can be knowledgeable and capable but not follow through due to prioritization of issues of greater importance to them at the present time (eg, fitting in with peers). We found that, although participants stated that routinely measured medical outcomes such as hemoglobin A_{1c} were important outcomes, they did not prioritize these over indicators

of diabetes distress (domains) listed by these families at this point in their journey with T1DM. Moreover, parents tend to depend on their diabetes care providers to set glycemic goals [40].

The PAB consensus was that 2 objectives were of principle importance when introducing a diabetes management plan for teens: (1) focusing on conflict resolution strategies, and (2) having an agreed-upon, common goal that was documented and discussed during the clinical visit (Table 3). Diabetes-specific family conflict is well known to affect glycemic control in teens with T1DM [8,41]. Research supports ongoing intervention designed to reduce family conflict in order to improve diabetes-related outcomes [8,11,12,16,42]. However, resources to address family conflict, including access to social work services, family counseling, and psychological services, are sparse in clinical diabetes care. The desires of patients to have these services and the evidence that they are related to superior diabetes outcomes should encourage the field to push for integrating them in the diabetes clinic setting.

One of the results of this work was a cocreated diabetes management plan tool for use in the clinic with teens and their parents. This tool aims to assist with patient-centered goal setting and to suggest that families reward themselves for successes with diabetes self-care. We designed the tool to be individualized. However, one teen expressed that the suggested goal behaviors were too easy and unnecessary because he did not have problems with most of the behaviors listed as examples. This indicated that some patients have trouble thinking outside the box or beyond what is written down on handouts. We also meant the tool to encourage positive reinforcement of both teens and parents by both teens and parents via incentives and rewards. There is evidence that incentives or rewards can have a positive impact on SMBG, but not necessarily on glycemic control [43]. Positive feedback can potentially lessen diabetes-specific family conflict though, and this is of great importance to families [44].

Most of the patient-centered diabetes distress domains discussed by the PAB could be measured using previously published questionnaires. The domains least easily measured are assumptions and judgments, and feeling such as being a “normal” teen, which includes advocating for being treated similarly to teens without T1DM and inclusion. These specific domains address whether parents and teens have the skills, confidence, and knowledge to educate themselves about diabetes and advocate for support and acceptance as needed to improve their quality of life. These skills represent self-efficacy, optimism, or resilience, which are more difficult to measure but have been linked with better health outcomes [28].

Limitations

This work involved a small number of participants who were recruited from a single geographic area, which could affect the generalizability of the findings. Individual responses could have been influenced by social desirability. Members of the PAB were representative of the condition of interest (teens living with T1DM and their parents). Some participants were lost for session 2 due to scheduling difficulties, which likely affected our findings. For example, the teen participants of the second session were all male, and it is possible that boys and girls have different diabetes care priorities. This likely affected the prototyping and development of the diabetes management plan tool, as other participants (or a larger number of participants) may have recommended differing suggestions for the tool. Although the small sample size included in this first project means that our results are not generalizable, the results have direct implications for our future work. As we test and further codevelop the tool with patients, we will want to involve as many participants as possible. It was not our intention to develop a generalizable intervention in this project, but to develop an intervention to be tested in a separate clinical study with significantly more participants.

Conclusion

Despite these limitations, our study is an important first step to examining patient-centered outcomes among teens with T1DM by demonstrating that patients with T1DM can be effectively engaged and involved in patient-centered research design. This is important for patient-centered outcomes research to help persons with diabetes achieve personal goals and address diabetes distress. Teens with T1DM prioritize reducing family conflict and fitting into their social milieu over health outcomes at this time in their lives. It is important to acknowledge this when designing interventions to improve health outcomes in teens with T1DM.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Diabetes management plan tool prototypes for parents and teens. Iteration 1 of the tool, with comments on changes made during the coparticipatory process.
[PDF File (Adobe PDF File), 300KB - jopm_v10i2e8_app1.pdf]

Multimedia Appendix 2
Diabetes management plan tool final product for parent and teens.
[PDF File (Adobe PDF File), 239KB - jopm_v10i2e8_app2.pdf]

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Abbreviations

HIT: health information technology
PAB: patient and parent advisory board
PEC: Patient Engagement Core
REDCap: Research Electronic Data Capture
SMBG: self-monitoring of blood glucose
T1DM: type 1 diabetes mellitus

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Original Paper

A Decision Aid to Support Shared Decision Making About Mechanical Ventilation in Severe Chronic Obstructive Pulmonary Disease Patients (InformedTogether): Feasibility Study

Melissa Basile[1], PhD; Johanna Andrews[1], MPH; Sonia Jacome[1], MSCH; Meng Zhang[1], PhD; Andrzej Kozikowski[1], PhD; Negin Hajizadeh[1], MD, MPH

Department of Medicine, Northwell Health, Manhasset, NY, United States

Corresponding Author:
Negin Hajizadeh, MD, MPH
Department of Medicine
Northwell Health
600 Community Drive
Suite 403
Manhasset, NY, 11031
United States
Phone: 1 516 600 1405
Email: Nhajizadeh@northwell.edu

Abstract

Background: Severe Chronic Obstructive Pulmonary Disease patients are often unprepared to make decisions about accepting intubation for respiratory failure. We developed a Web-based decision aid, InformedTogether, to facilitate severe Chronic Obstructive Pulmonary Disease patients' preparation for decision making about whether to accept invasive mechanical ventilation for respiratory failure.

Objective: We describe feasibility testing of the InformedTogether decision aid.

Methods: Mixed methods, pre- and postintervention feasibility study in outpatient pulmonary and geriatric clinics. Clinicians used InformedTogether with severe Chronic Obstructive Pulmonary Disease patients. Patient-participants completed pre- and postassessments about InformedTogether use. The outcomes measured were the following: feasibility/acceptability, communication (Combined Outcome Measure for Risk Communication [COMRADE], Medical Communication Competency Scale [MCCS], Observing Patient Involvement [OPTION] scales), and effectiveness of InformedTogether on changing patients' knowledge, Decisional Conflict Scale, and motivation.

Results: We enrolled 11 clinicians and 38 Chronic Obstructive Pulmonary Disease patients at six sites. Feasibility/acceptability: Clinicians and patients gave positive responses to acceptability questions (mean 74.1/89 max [SD 7.24] and mean 59.63/61 [SD 4.49], respectively). Communication: 96% of clinicians stated InformedTogether improved communication (modified MCCS mean 44.54/49 [SD 2.97]; mean OPTION score 32.03/48 [SD 9.27]; mean COMRADE Satisfaction 4.31/5.0 [SD 0.58]; and COMRADE Confidence 4.18/5.0 [SD 0.56]). Preference: Eighty percent of patients discussed preferences with their surrogates by 1-month. Effectiveness: Knowledge scores increased significantly after using InformedTogether (mean difference 3.61 [SD 3. 44], *P*=.001) and Decisional Conflict decreased (mean difference Decisional Conflict Scale pre/post -13.76 [SD 20.39], *P*=.006). Motivation increased after viewing the decision aid.

Conclusions: InformedTogether supports high-quality communication and shared decision making among Chronic Obstructive Pulmonary Disease patients, clinicians, and surrogates. The increased knowledge and opportunity to deliberate and discuss treatment choices after using InformedTogether should lead to improved decision making at the time of critical illness.

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KEYWORDS

Chronic Obstructive Pulmonary Disease; COPD; shared decision making; life support

Introduction

Background

The lung disease Chronic Obstructive Pulmonary Disease (COPD) develops over time. One-third of mortality in COPD patients is due to progressive respiratory failure and exacerbations [1]. In the event of severe exacerbation patients need to decide whether to accept invasive mechanical ventilator (IMV) support. The IMV–associated risks include the likelihood that patients cannot be extubated, tracheostomy, and admission to a long-term care facility [2,3]. Many patients and surrogates may accept IMV by default [4] without the chance to fully consider the risks and benefits, leading to potentially preference-incongruent decisions [3].

We developed a Web-based decision aid called InformedTogether to facilitate severe COPD patients' preparation for decision making about whether to accept IMV for respiratory failure (Multimedia Appendix 1). Development and usability testing of InformedTogether is described elsewhere [3,5-7]. InformedTogether was designed for implementation first in an outpatient clinic visit, between COPD patients and clinicians, and then by patients and surrogates. It communicates important information: the likelihood of respiratory failure in patients with severe COPD, treatment options (Full Code versus do not intubate; DNI), risks and benefits of these options, tailored prognostic estimates, and resources for decision making and advance-care-planning including Medical Order for Life-Sustaining Treatment (MOLST) forms [8]. Patients can take notes in comment boxes, and complete preference-elicitation exercises to help consider risks and benefits for each option. In this study we describe the results of feasibility testing of the InformedTogether decision aid in outpatient clinics.

Methods

We enrolled clinicians, patients, and surrogates in a pre-post feasibility study between April 2016 and September 2016. The clinician participants included the following: pulmonologists, geriatricians, and advance-practice providers (ie, nurse practitioners and respiratory therapists). The patient participants were adults diagnosed with COPD (Forced Expiratory Volume in the first second [FEV1]<50%) who were fluent in either English or Spanish and their surrogates.

Study Design

We selected the sample size based on other feasibility studies and our experience with recruitment from the outpatient clinics [9]. All participating clinicians first received thirty-minute in-person training on how to navigate the InformedTogether decision aid. Each week a research coordinator searched the electronic health records (EHR) to determine whether COPD patients meeting eligibility were scheduled for outpatient clinic visits or pulmonary rehab during that week. Before approaching the patient, we contacted their pulmonary clinician to determine whether or not there might be a reason why we should exclude that patient from the study. Patients were then approached during their regular outpatient visits. Enrolled patients completed baseline surveys assessing knowledge about COPD treatment choices, decisional conflict about advance-care-planning, and motivation to make an Advance Directive (AD). Patients then met with their clinicians who could choose whether and how much of the decision aid they would use with their patients. In order to determine the feasibility of implementing the decision aid in real-life clinical scenarios, we allowed the clinician to determine what portions of the decision aid were appropriate to share with a particular patient. This included choosing not to use the decision aid if they did not feel that it was the right moment to have an advance care planning discussion. Clinician-patient visits were audio-recorded. Patients were interviewed directly after the clinic visit, re-asked baseline assessment questions, asked about their reactions to the decision aid, acceptability of use and their satisfaction with clinicians' communication. Patients received Option Grids summarizing information in InformedTogether (Multimedia Appendix 2) [10]. Study materials were available in English and Spanish. All Spanish language documents were translated using a certified medical translator. Clinicians were interviewed after each visit. Patients were additionally interviewed via phone 1-month after the clinic visit, where we measured whether they accessed the decision aid, discussed it, and changed their motivation to make an AD. If patients agreed, we contacted their surrogates to measure surrogates' reactions to the decision aid, and their conversations about either InformedTogether specifically, or ACP in general with patient participants. Based on initial clinician feedback, we allowed decision aid use testing dedicated advance-care-planning appointments instead of regularly scheduled outpatient visits.

Primary Outcomes

The primary aim was to determine the feasibility and acceptability of implementing the decision aid in regular outpatient clinic visits. We also sought to assess the quality of the decision aid as measured by changes in knowledge, decisional conflict and motivation to make advance care plans. Secondary outcomes were the effect of the decision aid on communication and changes in decisions that were made over time. The outcomes measured included the following: (1) feasibility and acceptability of implementing InformedTogether in outpatient clinics (ie, questions focused on use of InformedTogether, recommendations to others, trust in content, fit within clinic workflow [Multimedia Appendix 3]); (2) outcomes important for informed decision making [11-15]: improved knowledge, Decisional Conflict Scale (DCS), and motivation to make an AD (ie, 5-point Likert Scale, completing an AD); and (3) quality of communication between clinicians and patients (ie, Combined Outcome Measure for Risk Communication [COMRADE], Medical Communication Competency Scale [MCCS], and OPTION scales [16-18]), and between patients and surrogates (ie, 1-month follow-up interviews).

Data Analysis

Descriptive statistics summarized the results to close-ended questions. Kappa statistics with 95% confidence interval were calculated for the degree of agreement between pre-post responses in knowledge, DCS and motivation to make an AD.

Univariable analyses were used to explore associations between variables. For example, the Two-Sample *t* test/Wilcoxon Rank Sum Test or the analysis of variance (ANOVA)/Kruskal-Wallis test was used for: (1) relationships between baseline demographics (analyzed as categorical variables), and (2) pre-post changes in the total scores (analyzed as continuous variables). The Spearman correlation coefficient measured the association between outcomes (ie, whether a change in the total score of knowledge was associated with a change in motivation score). To test whether there was a trend in level of shared decision making (OPTION scale) over time per clinician, we used a Linear Mixed Effects model.

All clinician-patient encounters and 1-month follow up interviews were audio recorded and transcribed verbatim. Spanish language audios were transcribed by a certified translator. We analyzed transcripts from the patients' clinic visits and open-ended responses using qualitative methods. Three members of the research team read all transcripts, and developed a list of themes inductively (ie, allowing ideas to develop organically through reading the transcripts), and deductively (ie, hypothesis-driven and related to our outcomes, as well as to our theory that the impact of non-biomedical knowledge including prior lived experiences may impact a patient's ability to understand medical information or apply it to themselves when making decisions about their care). After developing the final set of themes, we developed a codebook consisting of the themes names; definitions; sample text; and inclusion and exclusion criteria. Using the codebook, two researchers (MB and AK) coded the transcripts using NVivo. Coding comparison performed on 10% of transcripts (n=7) showed 99.8% agreement and a Cohen kappa of 0.67, indicating good agreement [19]. Discrepancies were discussed between the principal investigator and the lead qualitative researcher to reach a consensus.

Declarations

Ethics, Consent, and Permissions

The study was approved by the Northwell Health Institutional Review Board and we obtained written informed consent from all participants.

Consent for Publication

This article does not contain individual patient data.

Availability of Data and Materials

All data sets are available from the corresponding author.

Results

In this study, we enrolled: 11 clinicians and 38 patients (after approaching 70 eligible patients) with severe COPD. Of these, 28 spoke English while 10 spoke Spanish. The study was conducted at 5 Pulmonary clinics (n=10 or 90% of the total participants) and 1 Geriatric clinic (n=1 or 10% of the total participants). A total of 38 clinician-patient encounters using InformedTogether were recorded. One-month after the clinic visit, we interviewed 30 patient participants (8 of the original study participants were lost to follow-up) and 7 surrogate caregivers of these participants (Table 1 and Multimedia Appendix 4).

Feasibility and Acceptability of Implementation

The clinician participants used 78%, with a mean of 21 minutes per patient, of InformedTogether in most visits. They preferred using the decision aid during separate advance-care-planning visits instead of during the regularly scheduled clinic visits. Clinicians gave strongly positive responses to acceptability questions with a mean 74.1 out of 89 maximum points (SD 7.2). Clinicians indicated that they found the images and diagrams depicting intubation and tracheostomy and the prognostic estimates to be particularly useful in communicating with their patients. Those who only used select portions of the decision aid focused on those pages.

The patient participants gave strongly positive responses to acceptability questions in 95% of the cases with a mean score 59.6 out of 61 (SD 4.5) indicating that they would highly recommend it to others. In fact, 80% stated they would definitely recommend it. They indicated a high degree of trust in the decision aid content, with 80.9% (SD 17.0) using a scale 0-100%, measured based on the following question: "How sure are you that the estimates given in the decision aid are correct?" (Table 2).

Communication

The clinician participants stated that InformedTogether improved their communication with a mean score 44.5 out of 45 maximum score (SD 3.0) on the MCCS. InformedTogether facilitated shared decision making based on a mean OPTION score of 32.0 out of 40 (SD 9.3). Statistically there was no significant difference in Option score between clinicians (Kruskal-Wallis Test χ^2=16.2; *P*=.06). However, with each clinician's additional use of InformedTogether there was a statistically significant OPTION score increase by 1.9 points (SD 0.5, *P*=.001) based on the Linear Mixed Effects Model.

The patient participants expressed a high degree of satisfaction with clinicians' communication with a mean COMRADE Satisfaction with Communication 4.3 out of 5.0 (SD 0.6) with COMRADE Confidence in Decision 4.2 out of 5.0 (SD 0.6). At 1-month follow-up, 80% of participants stated they had discussed the decision aid with their surrogates (Table 3).

Table 1. Basic demographics of patient participants (N=38).

Patient Characteristics	Results
Age, mean (SD)	66.6 (10.0)
Marital status, n (%)	
Single	6 (15.8)
Married	15 (39.5)
Divorced/separated	7 (18.4)
Widowed	8 (21.1)
Other	2 (5.3)
Gender, n (%)	
Female	19 (50.0)
Race/ethnicity, n (%)	
White	19 (50.0)
Black/African American	7 (18.4)
Hispanic/Latino	11 (29.0)
Other	1 (2.6)
Religious affiliation, n (%)	
Catholic	26 (68.4)
Jewish	3 (7.9)
None	3 (7. 9)
Other	6 (15.8)
Employment status, n (%)	
Employed full-time	4 (10.5)
Retired	23 (60.5)
Unemployed	11 (29.0)
Highest level of education, n (%)	
Less than grade 9	4 (10.5)
Grade 9 to 12	17 (44.7)
Some college or higher	17 (44.7)
Economic class, n (%)	
Lower class	7 (18.4)
Lower-middle class	5 (13.2)
Middle class	24 (63.2)
Upper-middle class or higher	2 (5.3)
Born in the US, n (%)	
Yes	32 (84.2)
Years Living in US if foreign-born	
Mean (SD)	24 (16.3)
Language(s) spoken at home, n (%)	
English	33 (86.8)
Spanish	9 (23.7)

Table 2. Feasibility and acceptability of implementation.

Feasibility & acceptability	Mean score (SD)
Clinician rated feasibility and acceptability (maximum score 89)	74.1 (7.2)
Patient rated feasibility and acceptability (maximum score 61)	59.6 (4.5)
Trust in the decision aid (how sure are you that the estimates given are correct; maximum score 100)	80.9 (17.0)

Table 3. Clinician-patient communication using the InformedTogether decision aid. MCCS: Medical Communication Competency Scale; OPTION: Observing Patient Involvement Scale; COMRADE: Combined Outcome Measure for Risk Communication.

Communication	Mean (SD)
Clinician self-rated Communication (modified MCCS, maximum score 49)	44.5 (3.0)
Observer-rated Shared Decision Making (OPTION scale, maximum score 48)	32.0 (9.3)
Difference in OPTION score with each additional use	1.9 (0.5)[a]
Difference in OPTION score between clinicians	16.2 (0.06)[b]
Patient-rating of satisfaction with communication (COMRADE sub-scale, maximum score 5)	4.3 (0.6)
Patient-rating of confidence in decision (COMRADE sub-scale, maximum score 5)	4.2 (0.6)

[a]*P*=.008; Linear Mixed Effects Model.

[b]Kruskal-Wallis Test.

Knowledge, Decisional Conflict, and Motivation

Overall, the participants in our study had improved knowledge, motivation to make an AD, and decreased decisional conflict after using the InformedTogether decision aid (Table 4).

Seven patients expressed emotional discomfort while viewing the decision aid (Multimedia Appendix 5). For these patients, their sense of discomfort ranged from feeling that the information was too much for them to handle at that moment; or surprise because they had never had an end of life or advance care planning discussion before. For others, there was sadness when recalling prior experiences with family members on life support or sadness thinking about how their families would react to seeing them intubated. Most of the 7 participants expressing discomfort rated their health as fair or better and had never thought about the need to make a decision about life supporting treatments. Despite this, all of these 7 patient participants stated they would recommend that the decision aid be used with other patients (mean 3.6 out of 4, SD 0.5). One participant stated, “It made me uncomfortable but I would still recommend it”. Among our 38 patient-participants, only 1 person asked to stop using the decision aid and this was due to her expressed discomfort at the information contained in the decision aid. One clinician chose not use the decision aid with a patient who had been diagnosed with lung cancer just after agreeing to participate in the study. The clinician did not feel it was appropriate to have an advance care planning conversation on the same day as she was going to give the patient this diagnosis.

At 1-month, 8 patient participants were lost to follow-up. Of these 2 were lost due to death and 1 due to hospitalization. Notably, 5 of these 8 participants had expressed discomfort viewing the decision aid. Twenty of the 30 patients (67%) interviewed at 1-month follow-up had accessed InformedTogether after the clinic visit, rating it as moderately easy to use with a mean (SD) of 6.4 (3.0) using a 1-10 scale.

Seven surrogate decision makers were interviewed 1-month after the clinic visit, and of these, 5 stated that they had seen the decision aid. All surrogate participants stated that the decision aid was informative and very easy to use (9.5 [SD 0.6]). Several mentioned that it helped them to understand their family member’s condition (COPD) better; and that using it led to “more discussion”, “in-depth discussion” about what their family member would want. Notably, two surrogates were spouses of participants who died during the 1-month time period. Both stated that the information contained in the decision aid factored into their spouses’ decision not to be intubated:

> *She had thought about it at that time and we […] discussed […] those charts you had given us with the percentages on it and the more you looked, it didn’t look like a very bright future because of the percentiles that had come in so far on these tests and I think that she just felt that she just wanted to be at ease with herself and she was ready to make peace […] I think there was a couple of questions that maybe we were thinking about going a different way–maybe going on a breathing tube for a period of time but then again, we didn’t know what the period of time would have been and what the end result would have been. I think coming out of the meeting and then going home and […] discussing it again with our children, we came to the conclusion that she felt what she really wanted to do [to decline intubation].*

Table 4. Effectiveness of InformedTogether decision aid on improving patients' knowledge of Chronic Obstructive Pulmonary Disease and motivation to engage in advance care planning, and reducing decisional conflict. DCS: Decisional Conflict Scale.

Effectiveness	Mean (SD)	*P* value[a]
Knowledge (maximum score 18)		
Pre-InformedTogether knowledge	8.2 (3.4)	
Post-InformedTogether knowledge	11.8 (3.0)	
Increase in knowledge	3.6 (3.4)[b]	*P*=.001
Number of participants with increased knowledge	32 (84.2%)	
Number of participants with no change in knowledge	2 (5.3%)	
Number of participants with decreased knowledge	4 (10.5%)	
DCS (maximum score 80)		
Pre-InformedTogether DCS	31.3 (25.1)	
Post-InformedTogether DCS	17.9 (15.9)	
Decrease in DCS	-13.8 (20.4)[b]	*P*=.006
Number of participants with increased DCS	3 (14.3%)	
Number of participants with no change in DCS	3 (14.3%)	
Number of participants with decreased DCS	15 (71.4%)	
Motivation (maximum score 5)		
Pre-InformedTogether motivation	4.3 (1.0)	
Post-InformedTogether motivation	4.4 (0.7)	
Post-InformedTogether motivation at 1-month	4.6 (0.8)	
Increase in motivation	0.1 (0.8)[b]	*P*=.54
Increase in motivation at 1-month	0.3 (1.1)[b]	*P*=.10
Number of participants with increased motivation	6 (17.1%)	
Number of participants with no change in motivation	23 (65.7%)	
Number of participants with decreased motivation	6 (17.1%)	

[a]*P* value shown when Wilcoxon signed rank test is performed.

[b]Wilcoxon signed rank test.

Effect on Change in Decision and Discussions About "Trial Intubation"

At baseline, among participants who had previously thought about whether to accept intubation, 10 chose Full Code, 5 chose DNI, and 6 were unsure. After InformedTogether, 11 chose Full Code, 5 chose DNI and 5 participants were unsure. At 1 month, all participants were asked about their preferred choice: 20 participants chose Full Code, and 8 chose DNI. Five participants stated their decision had changed after viewing the decision aid. For example, 3 from DNI to Full Code, 1 from Full Code to trial intubation, and 1 from Full Code to DNI. For an example of one patient's progression of the AD decision from baseline to the 1-month follow-up, see Multimedia Appendix 6.

In 13 clinician-patient encounters the information presented about tracheostomy (for patients who cannot be extubated) led to a discussion about 'trial intubation' as an additional decision point not formally presented in the decision aid. For many, this was prompted by the patient (Multimedia Appendix 6). Some patients initially brought up trial intubation with their clinicians during their initial use of Informed Together. Other patients initially stated during their discussions with their clinicians that they would not want intubation, but, during the one month follow up interview, they expressed an interest in trial intubation. Several of these patients asked if it would be possible to put a specific length of time for a trial in their ADs. At 1-month, 9 participants stated that they would choose 'trial intubation' after seeing InformedTogether. Among the 13 people who brought up the topic of trial intubation, 8 of them had slightly lower DCS scores after seeing InformedTogether, (16.8 out of 64). Among the 22 who stated they had previously thought about whether to accept IMV, 9 of them did not discuss trial intubation with their clinicians while viewing the decision aid. On average, decisional conflict scores were slightly higher among this group for an average DCS 19.6 out of 64 compared to the group who had discussed trial intubation with their clinician (Table 5).

Table 5. Change in decision. DNI: do not intubate.

Change in Decision	Stated preference by number
Pre-InformedTogether decision in those who had thought about intubation before viewing InformedTogether	10 Full Code; 5 DNI; 6 unsure
Post-InformedTogether decision in those who had thought about intubation before viewing InformedTogether	11 Full Code; 5 DNI; 5 unsure
Direction of change in decision among 'Full Code' at baseline	8 stayed Full Code, 1 DNI, 1 unsure
Direction of change in decision among 'DNI' at baseline	2 stayed DNI, 2 Full Code, 1 unsure
Direction of change in decision among 'unsure' at baseline	4 stayed unsure and 2 DNI

Univariable Analysis Results

See Multimedia Appendices 7-Multimedia Appendices 9)

In exploring associations between patient factors and outcomes, we found changes in knowledge were greater in participants with lower education levels (9.1; *P*=.05), and lower QOL (6.1; *P*=.02). There was a smaller decrease in DCS score in those expressing a religious affiliation (3.9; *P*=.05). There was a higher level of decisional conflict after viewing the decision aid in those with a lower QOL (6.0; *P*=.02). There were significant associations between change in motivation at 1-month follow-up and QOL (6.3; *P*=.01), and a history of frequent hospitalizations (5.1; *P*=.02).

In exploring associations between outcomes, we found a negative correlation between satisfaction with communication and DCS (Spearman Correlation Coefficient -0.5 for Satisfaction with Communication Scores 11-20 [*P*=.005]), indicating that those expressing higher satisfaction with clinician communication had lower DCS after viewing the decision aid. Additionally, there was a trend suggesting that increased knowledge was associated with decreased DCS (Spearman Correlation Coefficient -0.4 [*P*=.08]).

Discussion

Principle Results

We found that it is feasible to implement InformedTogether in outpatient clinics. InformedTogether was acceptable to users, supported high-quality communication, and shared decision making between clinicians and patients, and patients and surrogates. Half of participants who did not have a decision at baseline, had made one at 1-month follow-up. This included both those participants who indicated that they had made an AD within 1 month of viewing the decision aid, and those who had conversations with their family members regarding their preferences – several of whom had shown the decision aid to their family members, but who did not formalize their preferences in an AD. Decisions made after using InformedTogether were more fully informed, as indicated by increased knowledge and changes in the decision over time. InformedTogether was also effective in prompting conversations between patients and surrogates. Poignantly, surrogates for the 2 participants who died during the study period stated InformedTogether had facilitated decision making at the time a decision became necessary.

Most participants stated they would choose intubation over DNI. Qualitative analysis suggests this may be due to discussions about 'trial intubation'. Although tracheostomy was only discussed in the context of patients who cannot be extubated, it was correctly seen as a separate decision point where individuals can decide to stop IMV and move to comfort-only measures. We speculate that this may lead to reduced decisional conflict for those people who may be comforted by the fact that they can revisit their decision to be intubated (ie, they can try intubation and decide to be removed if they choose). While this represents practice in many ICUs and serves as an attempt to reduce uncertainty about outcomes, it remains unclear what the optimal trial timeframe should be, which is an important area of future investigation.

InformedTogether communicates different treatment options and estimated prognosis, and guides patients through preference elicitation exercises to help identify and communicate outcomes which are most important to patients. A common criticism of ADs is that they may not be applicable to different situations and that surrogate decision makers would benefit more from understanding general preferences for outcomes over single-scenario treatment decisions [20]. The recent shift to advance-care-planning as opposed to documenting an AD emphasizes discussions about choices and preferred outcomes over time [21]. InformedTogether facilitates these iterative discussions and deliberation for both patients and their surrogates.

We measured change in knowledge, motivation to make a decision, and decisional conflict as indicators of informed decision making [11-13,22] and found improvements in each of these outcomes after using InformedTogether. However, DCS increased in three patients. In conventional representations of informed decision making, as knowledge increases decisional conflict should decrease [22]. Decisional conflict may increase with knowledge, particularly for decisions with a high degree of uncertainty about outcomes [23,24]. This increase may therefore represent a necessary step in deliberation, and with time, decisional conflict could in fact, decrease.

Discomfort with the discussion is known to be a barrier to clinicians initiating advance-care-planning conversations with patients [25]. The use of sensitive language within InformedTogether helped clinician-patient conversations, and patient participants strongly recommended the decision aid for use with other patients. We found that among those clinicians who used InformedTogether multiple times during the study, there was an increase in OPTION score with each use. This suggests that over time, as clinicians became more comfortable using the decision aid, their ability to engage in high quality shared decision-making conversations with their patients

improved. This includes the extent to which the clinician involves that patient in decision making, ensures that the patient understands what the decision to be made involves, makes that patient aware that there is more than one choice for their clinical problem, and clearly explains the pros and cons of each choice, all of which are measured through the validated OPTION scale. These findings support the use of InformedTogether to facilitate shared advance-care-planning conversations partly because of the patient-centered language that clinicians can either read or adapt over time to tailor conversations as needed.

Limitations

An important limitation of our study is that we were not able to follow participants beyond one month and therefore have limited data to suggest effectiveness of the decision aid on actual decision making at the time of exacerbation. We also do not have a comparison of relative effectiveness compared to other forms of information communication and/or standard care. Although an increase in knowledge and the opportunity to engage with surrogate decision makers about treatment choices and preferences will likely lead to more informed decision making during exacerbation, it remains to be seen whether this in fact leads to more preference-congruent care and satisfaction with an actual decision. Ultimately, these are the outcomes that InformedTogether is designed to improve and will be the focus of future studies.

Notably, we were unable to contact 5 of the 38 patients who were interviewed for 1-month follow up. It is very possible that this subgroup of patients had different opinions about the decision aid's feasibility and their use of the decision aid with their family after the clinic visit. Our inability to assess this is a limitation of the study and inherent in the risk of loss to follow up within many clinical studies.

A further limitation is that we did not have a large enough sample size to draw conclusions about potential associations between patient factors and outcomes found in univariate analysis. These are; however, hypothesis generating and will be further explored in a larger future trial.

Comparison with Previous Work

We tested the feasibility and effectiveness of implementing a decision aid (InformedTogether) which includes personalized prognostic estimates for patients with severe COPD, in outpatient pulmonary and geriatric clinics. InformedTogether includes a prognostic model which is tailored based on a patients' age, and estimates both in-hospital survival, discharge to nursing home versus home, rehospitalization and 12-month survival.

We are the first group to test the feasibility of communicating personalized prognostic estimates to inform advance care planning in outpatient clinics for patients with severe COPD, and to test the feasibility of translating comparative effectiveness research results into accessible and usable formats for shared decision making. InformedTogether was tested in both English and Spanish languages and found to be acceptable to both patients and clinicians, as well as the surrogate decision makers of patients. In addition to finding that InformedTogether was well received by participants, we also found it to effectively change knowledge, decisional conflict and motivation to make advance care plans for individual patients. Importantly, InformedTogether promoted high quality communication and shared decision making between clinicians and their patients, and clinicians used the information and language within the decision aid to personalize the information and to guide their patients' decision making.

Conclusion

Our study demonstrates that the InformedTogether decision aid facilitates high quality communication between clinicians and their severe COPD patients about treatment choices and likely outcomes in the event of acute respiratory failure. The improved knowledge, reduced decisional conflict and increased motivation seen as a result of using InformedTogether should support patients and their families to make more informed decisions about whether to accept life supporting technologies in the event of critical illness. Iterative discussions using decision aids such as ours, which include patient-centered communication about tailored prognostic estimates and treatment choices, can facilitate deliberation and communication about treatment choices so that patients and families are more prepared to make preference-congruent decisions about life-supporting technologies. Preparation for decision making about life supporting technologies is particularly important for patients with advanced chronic diseases who are at highest risk for complications, and patients and families need to be informed about the possible short and long-term consequences of their treatment choices. Clinicians can support this informed decision making by initiating conversations about advance care plans, and decision aids such as InformedTogether can overcome several barriers to initiating these discussions.

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Authors' Contributions

MB contributed substantially to the data collection, analysis and interpretation of the qualitative data and to writing of the manuscript. JA, SA contributed substantially to the data collection. MZ was the biostatistician who analyzed and summarized all of the quantitative data from the study. AK contributed substantially to the analysis and interpretation of the qualitative data. NH, the principal investigator of the study, was responsible for the design of the study, had full access to all of the data, contributed

substantially to: analysis and interpretation of the quantitative and qualitative data from the study, and to the writing of the manuscript.

Conflicts of Interest

None Declared

Multimedia Appendix 1
Screen Shots of The InformedTogether Decision Aid.
[PDF File (Adobe PDF File), 2MB - jopm_v10i2e7_app1.pdf]

Multimedia Appendix 2
InformedTogether Option Grid for a COPD Patient Age Range 66-70 Years Old.
[PDF File (Adobe PDF File), 72KB - jopm_v10i2e7_app2.pdf]

Multimedia Appendix 3
Feasibility and Acceptability Questionnaires.
[PDF File (Adobe PDF File), 47KB - jopm_v10i2e7_app3.pdf]

Multimedia Appendix 4
Additional Demographic Characteristics.
[PDF File (Adobe PDF File), 35KB - jopm_v10i2e7_app4.pdf]

Multimedia Appendix 5
Distress experienced while viewing decision aid.
[PDF File (Adobe PDF File), 27KB - jopm_v10i2e7_app5.pdf]

Multimedia Appendix 6
Patient Interest in Trial Intubation.
[PDF File (Adobe PDF File), 27KB - jopm_v10i2e7_app6.pdf]

Multimedia Appendix 7
Univariable Analysis Associations between Communication and Outcomes.
[PDF File (Adobe PDF File), 21KB - jopm_v10i2e7_app7.pdf]

Multimedia Appendix 8
Univariable Analysis Associations between Outcomes and Patient Demographics.
[DOCX File, 13KB - jopm_v10i2e7_app8.docx]

Multimedia Appendix 9
Univariable Analysis Associations between Outcomes and Patient Self-Rated Health.
[PDF File (Adobe PDF File), 23KB - jopm_v10i2e7_app9.pdf]

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Abbreviations

AD: advance directive
COMRADE: Combined Outcome Measure for Risk Communication and Treatment Decision Making Effectiveness

COPD: Chronic Obstructive Pulmonary Disease
DC: decisional conflict
DCS: Decisional Conflict Scale
DNI: do not intubate
HER: electronic health records
IMV: invasive mechanical ventilation
MCCS: Medical Communication Competency Scale
MOLST: medical order for life-sustaining treatment
OPTION scale: Observing Patient Involvement scale

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Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org