



An mHealth Design to Promote Medication Safety in Children with Medical Complexity

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Abstract

Background Children with medical complexity (CMC) are uniquely vulnerable to medication errors and preventable adverse drug events because of their extreme polypharmacy, medical fragility, and reliance on complicated medication schedules and routes managed by undersupported family caregivers. There is an opportunity to improve CMC outcomes by designing health information technologies that support medication administration accuracy, timeliness, and communication within CMC caregiving networks.

Objectives The present study engaged family caregivers, secondary caregivers, and clinicians who work with CMC in a codesign process to identify: (1) medication safety challenges experienced by CMC caregivers and (2) design requirements for a mobile health application to improve medication safety for CMC in the home.

Methods Study staff recruited family caregivers, secondary caregivers, and clinicians from a children's hospital-based pediatric complex care program to participate in virtual codesign sessions. During sessions, the facilitator-guided codesigners in generating and converging upon medication safety challenges and design requirements. Between sessions, the research team reviewed notes from the session to identify design specifications and modify the prototype. After design sessions concluded, each session recording was reviewed to confirm that all designer comments had been captured.

Results A total of $N = 16$ codesigners participated. Analyses yielded 11 challenges to medication safety and 11 corresponding design requirements that fit into three broader challenges: giving the right medication at the right time; communicating with others about medications; and accommodating complex medical routines. Supporting quotations from codesigners and prototype features associated with each design requirement are presented.

Keywords

- ▶ medication management
- ▶ polypharmacy
- ▶ pediatrics
- ▶ user-centered design
- ▶ social networks

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Conclusion This study generated design requirements for a tool that may improve medication safety by creating distributed situation awareness within the caregiving network. The next steps are to pilot test tools that integrate these design requirements for usability and feasibility, and to conduct a randomized control trial to determine if use of these tools reduces medication errors.

Background and Significance

Medication Errors among Children with Medical Complexity

Children with medical complexity (CMC) are uniquely vulnerable to medication errors and preventable adverse drug events because of their extreme polypharmacy, medical fragility, and reliance on complicated medication schedules and routes (e.g., enteral tubes) managed by undersupported family caregivers.¹⁻³ Routine CMC care typically involves high-risk medications having severe consequences if doses are missed and toxicity if doses are in excess. In one study focused on in-home medication administration for pediatric patients, over half of medication errors identified during in-home observation were classified as having potential to harm the child; one-in-seven resulted in injury.⁴ However, even when administration errors do not lead to catastrophic adverse drug events, incorrect administration can lead to patient harms, such as undertreatment or continuation of unwanted symptoms.⁴

Challenges to Medication Safety among Children with Medical Complexity Caregivers

The systems' current reliance on family caregivers to manage complex medication regimens for their CMC creates a system prone to suboptimal outcomes. Challenges faced by caregivers who are managing complex medication regimens are well documented.⁵⁻⁷ Parents and nonmedical caregivers are expected to manage and administer medications in the home setting without formal training or CMC-specific tools to support medication administration accuracy, which may affect accuracy and safety.⁸⁻¹² Among the most complex pediatric patients, some caregivers must administer a median of 50 doses per day, comprised of both scheduled and as needed medications.¹³ Home medication errors have been documented with underlying reasons including communication problems between CMC caregivers and providers, misunderstandings about how to prepare and administer medications, and lack of medication-related tools (e.g., alarms, reminders) to help support caregivers who administer medications.^{4,14,15}

Medication Safety within a Caregiving Network

Caregivers of CMC are also uniquely challenged to distribute complex medication management across a network of caregivers. This network includes "secondary caregivers" (e.g., relatives, school aides, home health nurses), who are depended upon to deliver timely and accurate life-sustaining medications for CMC on a daily basis, despite having comparatively less familiarity with a given child's care plan.¹⁶⁻¹⁸

Currently, families are expected to develop and implement their own strategies for ensuring safe, standardized medication management across the network of secondary caregivers, but they struggle to do this.⁴

There is an opportunity to design tools that meet two distinct but related unmet needs: first, to support the accuracy and timeliness with which CMC caregivers administer medications; and second, to support the "networked" nature of medication management, acknowledging that it occurs across multiple caregivers whose communication is key to success. Health information technologies (HIT), or electronic tools that professionals and patients alike can use to store and share health information, are shown to be promising tools to facilitate adherence and communication in other clinical settings.^{19,20} Prior work focused on CMC enteral tube care at home indicates that caregivers of CMC require HIT to improve organization and communication among the caregiving network.²¹ This finding highlights the need for HIT that support CMC networks' medication management, including access to, awareness of, and exchange of medication information.²²

Objectives

The present study engaged family caregivers, secondary caregivers, and clinicians who work with CMC in a codesign process to identify: (1) medication safety challenges experienced by CMC caregivers and (2) design requirements for a mobile health application (mhealth app) to improve medication safety for CMC in the home.

Methods

Study Design

We conducted an established five-stage, multiperspective codesign process, which engages end user representatives as active members of the design team.²³⁻²⁵ The five stages of the design process include: problem identification, in which the challenge to be addressed is defined and described by codesigners; solution generation, in which codesigners creatively discuss possible ways of addressing the problem; convergence, in which codesigners reach agreement on the most appropriate design requirements to address the problem; prototyping, in which the research and design teams work together to translate the requirements into a rough prototype; and evaluation, in which designers provide feedback on the strengths and weaknesses of the initial prototype.²⁶ The activities associated with each stage of this process are

Table 1 Codesign process to understand medication safety challenges and design requirements

Design stage	Problem identification	Solution generation	Convergence	Prototyping	Evaluation
Designer type	August 2022	September 2022	October 2022	November 2022	December 2022
Family caregiver	Codesign session 1	Codesign session 2	Codesign session 3	Codesign session 4	
Secondary caregiver	Codesign session 1			Codesign session 2	
Clinician	Codesign session 1			Codesign session 2	
Research team	Met weekly to debrief codesign sessions, reach consensus on prototype features, and plan next codesign session User experience designer and software developer made changes to prototype during and between sessions based on codesigner and research team feedback				
Facilitator prompts	“Where can things go wrong with medication administration?” “What have you done to keep things from going wrong?”	“What do you want to see in a tool to facilitate medication safety?” “What else do you want a medications safety tool to do?”	“Do these changes reflect what you want in a medication safety tool?” “How could this prototype better meet your needs?”		
Design activities	Journaling Inventory current solutions Brainstorming and consensus building	Consensus building Live prototyping	Think-aloud prototype walkthrough		
Design tools	Qualtrics Miro	Miro Figma	Figma		

described in **Table 1**. Because codesign involves end users as designers, the resulting tools are more likely to be usable, useful, relevant, acceptable, and adaptable to end users' current routines.^{23,27} Further, because the data gained from codesign sessions are qualitative, the research team and software developers gain a richer understanding of end users' real worlds in which tools are used, why previous tools may have failed end users, and ultimately how to promote sustained use.^{28,29}

We defined medication safety as ensuring that the CMC received the right medications, at the right dose, and at the right time, no matter who gives the medication or where the CMC is. All codesign sessions were conducted between August and December of 2022 over teleconferencing software. The University of Wisconsin–Madison and Indiana University–Bloomington Institutional Review Boards reviewed and approved all stages of this project.

Participants and Recruitment

To ensure a heterogeneous and clinically informed perspective on medication safety in daily care, participants included family caregivers, secondary caregivers, and clinicians caring for CMC.²⁹ Eligibility criteria included speaking English, having internet access, and willingness to attend the majority of the respective group's codesign sessions (i.e., all family caregivers together, secondary caregivers together, and clinicians together). Family and secondary caregivers were offered \$25 per session.

A convenience sample of family caregivers and clinicians were recruited from a children's hospital-based pediatric complex care program (PCCP). Clinicians included nurses, doctors, and pharmacists who work with CMC. Study staff

worked with family caregivers and clinicians to compile a list of potential secondary caregiver participants.

Study staff sent potential family and secondary caregivers opt-out letters, describing the study and what their participation would involve, and then followed up by phone to further explain the study and assess their eligibility and interest. Clinicians were sent emails describing the study and what their participation would involve. All interested and eligible participants were asked about their availability for the codesign sessions, dates, and times for the sessions were chosen, and meeting invites were sent to all participants. In all cases, consent was obtained before participation.

Codesign Sessions

Pre-session Preparation

As preparation for the first codesign session, family and secondary caregivers responded to a journal prompt. The journal prompt asked them about things that can go wrong with the CMC's medication administration throughout the day, and what they have done to keep things from going wrong.

Codesign Session Process

Codesign sessions lasted 1 hour and were audio recorded. Each session was attended by at least four members of the research team: a facilitator (N.E.W.), a research coordinator (H.K.), a note-taker (A.J.), and a software developer and/or a user experience designer (S.O. or M.W.). To promote participation and equanimity, the facilitator used open-ended questions, probed quieter codesigners to speak, and encouraged the use of the teleconferencing platform's chat function.

The web-based tool Miro, which is a virtual whiteboard, was used to document and organize design requirements in real time.³⁰ The software Figma was used to adapt the prototype during and between design sessions.³¹

The agenda of each codesign session was designed to generate discussion among participants around challenges to medication safety and design requirements for a medication safety app. In the first session, the facilitator laid the “ground rules” for participation. Ground rules included suggestions that participants keep their cameras on, for example, and the request that we would like to hear from everyone. When necessary, the facilitator invited (but did not require) quieter participants to share. Each design session focused on one design stage in sequence from problem identification, solution generation, convergence, prototyping, and evaluating the initial prototype. Content for the first session (problem identification) was informed by presession journal prompts, and content for subsequent sessions built iteratively upon challenges identified in the first session. ►Table 1 depicts the design process, including design activities, design tools, and facilitator prompts.

Survey

After design session one, all participants completed a demographic survey, which included age, gender, race, ethnicity, and the highest level of education completed. In addition, family caregivers reported their relationship to the CMC, marital status, whether a language other than English is spoken at home, 2021 household income, and geographic area (urban, suburban, or rural). Family caregivers also reported the number of caregivers in CMC’s network with whom they interact at least monthly; medicines taken daily by the CMC; and hospital days in the last 12 months.

Data Analysis

The research team consisted of clinicians, a human factors engineer, a user-centered design expert, a software developer, research coordinators in the fields of pediatrics and human factors engineering, a pharmacist, and a CMC family representative. Data analysis occurred within and between codesign sessions. Within sessions, the facilitator-guided codesigners in generating, grouping, and converging upon medication safety challenges and design requirements. Between sessions, the research team discussed codesigners’ design requirements and assigned them a priority level, focusing on factors such as urgency; technological feasibility, from budgetary and software development perspectives; and relative emphasis from codesigners. The prototype was then modified in Figma, prioritizing higher priority design requirements.³¹ At each subsequent design session, the prototype was brought to codesigners for feedback on how to better meet their medication management needs. After all design sessions had completed, a research team member who was present for the design sessions (A.J.) listened to each session recording to confirm that all designer comments had been captured and extracted all challenges and design requirements to a spreadsheet. Presession journals were also extracted to this spreadsheet. A second and third team member (N.E.W., H.K.) who were

present for each design session reviewed medication safety challenges and design requirements for completeness. Last, these results were brought back to the full research team for refinement and discussion.

Results

Participant Characteristics

A total of $N = 16$ codesigners participated. Of the eight family caregivers, six attended at least three of four design sessions. Secondary caregivers included a school nurse and a home health nurse. Clinicians included two PCCP nurses, one PCCP doctor, two pediatric clinical pharmacists, and one outreach representative from a home health company. For demographic characteristics of family caregivers, secondary caregivers, and clinicians, and clinical features of CMC (►Table 2).

Medication Safety Challenges and Design Requirements

Analyses yielded three overarching challenges to medication safety: giving the right medication at the right time; communicating with others in the care network about medications;

Table 2 Demographic characteristics of codesigners and clinical characteristics of children with medical complexity

Demographic variable	N (%) or M (SD)
Gender	N (%)
Woman	14 (87.5%)
Man	2 (12.5%)
Race	M (SD)
White/Caucasian	16 (100%)
Age	37.6 (10.0)
Geographic area (family caregivers only)	N (%)
Rural	3 (37.5)
Suburban	4 (50)
Urban	1 (12.5)
Household income (family caregivers only)	N (%)
20,000–24,999	1 (12.5)
50,000–74,999	3 (37.5)
100,000 and above	3 (37.5)
Prefer not to say	1 (12.5)
CMC clinical characteristics	M (SD)
# of caregivers per month	10.8 (7.1)
Daily medications	10 (6.2)
Hospitalized days in past year	N (%)
None	3 (37.5)
1–4	3 (37.5)
5–10	1 (12.5)
11–20	1 (12.5)

Abbreviations: CMC, children with medical complexity; SD, standard deviation.

and accommodating complex medical routines. Medication safety challenges, corresponding design requirements, supporting quotations from codesigners and prototype features are presented in ► **Tables 3–5**.

Challenge 1: Giving the Right Medication at the Right Time
An overarching risk to medication safety involved administering the right medication at the right time. This included administering the correct dosage via the correct route;

Table 3 Giving the right medications at the right time: design requirements, supporting quotations, and prototype features

Medication safety subchallenge	Design requirement	Supporting quotation(s)	Prototype features
Correct dosage, correct route	Ensure that all caregivers administer the correct dosage using the correct route	<p>“It would be nice if you could take your phone and like scan the [medication] bottle... if it like recognizes the text and prepopulates, that would be amazing.” [FCG, session]</p> <p>“Some of these medications can be very dangerous if he gets too much... I’ve even caught medications that someone has drawn up wrong, or even medications that I’ve drawn up wrong.” [FCG, session]</p> <p>“Some liquid cannot go down enteral feeding tubes... So is there a way that that [incorrect routes] could be flagged in the system as well?” [clinician, session]</p>	<ul style="list-style-type: none"> • Detailed “add medication” page, including dosage and route information • Caregivers can enter a medication name by hand, select it from a drop-down menu, or scan the bottle for the name to autofill • Caregivers can associate medications with different colors and icons • Daily chronological medication schedule with dosage and route for each medication • Doses in dangerous amounts or routes are flagged
Administering medications on time	Support all caregivers in administering medications at the right time	<p>“We used to have almost 12 medications being given at various times throughout the day and if we don’t have a system it could get mixed up.” [FCG, journal]</p> <p>“If a notification goes to the staff so many times, then the primary gets notified also.” [FCG, session]</p>	<ul style="list-style-type: none"> • Daily medication schedule • Push notifications sent to whoever is “on duty” when dose is due • Push notification sent to caregiver when a medication is past due
Accommodating medication changes	Alert all caregivers in a network when a medication has been skipped, a PRN medication has been added, or a medication has been removed	<p>“I want them to have the ability to [skip a medication] and then say why. Because there might be good reasons why they don’t give the medication and that’s okay.” [FCG, session]</p> <p>“It’s nice to be able to say, okay, now he’s sick, here are the things to try, here’s the dose that he gets, and here would be the frequency.” [FCG, session]</p> <p>“I’m just the parent that wants to know everything that’s going on with our child...but my husband would be annoyed, so [he’d want] a way he could go in and turn it off.” [FCG, session]</p>	<ul style="list-style-type: none"> • Allow caregivers to skip a medication and explain why it was skipped • User’s ability to “skip” medications can be turned on and off • Allow caregivers to drag PRN routines (“sick plans”) to daily routine • Suggest PRN medications when indicated by symptoms • Time-limited medications “drop off” the schedule automatically • Caregivers can turn push notifications on and off
Receiving timely refills	Help family caregiver to know the optimal time to refill a medication or reorder supplies	<p>“I do have one medication that’s super hard for me... sometimes he’ll get a 23-day supply, some days I’ll get a 25 day one, and my bottle is so dark... sometimes I really do have a hard time gauging it... that’s one for sure I really, really, really would like a reminder on.” [FCG, session]</p> <p>“Something we see kind of frequently is last minute emergency supply orders... Anything that can make it easier for parents to understand quantity on hand, how long that quantity is going to last them, and alerts them in advance or helps them set up a better monthly ordering routine...anything around supply management would be super helpful” [clinician, session]</p>	<ul style="list-style-type: none"> • Tracks remaining doses and supplies • Sends push notification to caregivers when a refill/reorder is needed • Refill reminder timing can be tailored (e.g., 3 d or 1 wk out)

Abbreviation: FCG, family caregiver.

Table 4 Communicating about medications: design requirements, supporting quotations, and prototype features

Medication safety subchallenge	Design requirement	Supporting quotation(s)	Prototype features
Communicating about medications at home	Inform caregivers when another care network member has administered a medication	“Lack of communication about whether a medication was given can lead to double dosing.” [FCG, journal] “Especially for us, the seizure med, if you’re doing emergency dosing, what time did it happen? You don’t want to double dose a kid with seizure meds.” [FCG, session]	<ul style="list-style-type: none"> Caregivers check a box to indicate when medication has been administered Caregivers can see whether a medication has been administered
Communicating about medications outside the home	Support medication safety in contexts outside of the home, such as school or vacation	“If the [school] nurse was out that day, or anything like that, or if they forgot to communicate it to you, it’s more stress on you honestly as a parent to not know exactly what’s going on.” [FCG, session] “If we have a complex kiddo who has to miss school for a bunch of appointments, we can medically excuse that but we always require a doctor’s note... if they can just upload a note and it’s right there, we can take care of attendance.” [SCG, session]	<ul style="list-style-type: none"> School nurses check a box to indicate if a medication has been administered Caregivers upload photos of doctor’s orders or doctor’s notes
Organizing asynchronous communication	Allow caregivers to write, organize, and tag each other in notes	“I could email [notes] or maybe just print them and have a printed list to bring in [to the doctor].” [FCG, session]	<ul style="list-style-type: none"> Caregivers can write, title, and organize notes Caregivers can search notes for a keyword Caregivers can tag each other in notes and see when a note had been “seen” Caregivers can send notes to themselves and others

Abbreviations: FCG, family caregiver; PRN, pro re nata; SCG, secondary caregiver.

administering the dosage at the right time; integrating prescribed or as-needed changes to medications; and completing medication refills on time.

To assist with giving the right medication at the right time, family caregivers requested that the app store information about each prescribed medication (including its color and shape) and its respective dose. They also sought the ability to color-code the medications (e.g., using a designated color for as-needed medications) or associate certain icons with certain types of medications (e.g., a snowflake for refrigerated medications), to further assist them in quickly differentiating between medications. Clinicians added that the app should warn the user if they enter an unlikely dosage or unsafe route when adding a new medication.

Family caregivers wanted the app to accommodate changes to the medication routine, including skipping a medication, adding a new daily medication, or adding PRN (pro re nata, i.e., as-needed) medications. Family caregivers asked that information about a child’s PRN medications and their respective doses be stored in the app, to be “dragged” to the daily schedule when needed. Clinicians requested that the app suggest PRN routines to users when indicated by the CMC’s symptoms; for example, the app could suggest administering propranolol if the CMC’s blood pressure was high.

Family caregivers and clinicians alike emphasized the challenge of ordering and receiving medication refills on time. Family caregivers thus wanted the app to automatically track how many doses were left and to remind them when a medication refill was due. Clinicians added that refill reminders should be sent not only for medications, but also for medical supplies.

Challenge 2: Communicating about Medications

Family caregivers described the challenge of communicating with others in the caregiving network (within and outside of the home) about medications, both synchronously and asynchronously. In the first design session, one family caregiver illustrated the challenge of communicating synchronously within the home: “We have a lot of ‘did I give that to him already? Did you give that to him?’” Family caregivers wanted the app to indicate when a medication had already been administered, when a dose had been missed, or when a secondary caregiver elected to skip a dose of a medication.

The communication challenge continued at school. One secondary caregiver, who was a school nurse, shared that receiving medication information from parents is not enough. “State statutes require written instruction from a physician,” she reported. The secondary caregiver agreed

Table 5 Accommodating complex medical routines: design requirements, supporting quotations, and prototype features

Medication safety subchallenge	Design requirement	Supporting quotation(s)	Prototype features
Remembering and communicating allergies	Ensure that all caregivers in network are aware of child's allergies	"Every time you click on another screen there's that picture of [child's name], but then there's also, in bold, those things that you want to make sure your child doesn't ever get." [FCG, session] "I was just thinking of my own son and I'd be like, do not give food mom hasn't provided." [FCG, session]	<ul style="list-style-type: none"> Allergies are "unmissable" in red, bold font Allergies "follow" user from page to page Caregivers can list anything that CMC should not consume Caregiver is warned if they are attempting to administer something that CMC should not have
Tracking all health-related events	Allow caregivers to track multiple health-related events and metrics	"I have to track temperature, blood pressure, and blood sugars, and how long said episode lasts." [FCG, session] "[Doctors] say, how often do you think this happens? How long do you think it lasts? And I'm like, I don't know." [FCG, session] "It may be nice to have a central place where we can describe things that are happening. Like, this child had ten seizures today. This is what they look like. This is more than they've had in the last 2 weeks. And then parents, rather than trying to remember what we said, or how we said it, or what we described the seizure looked like, can then take [the app] to their clinician." [SCG, session]	<ul style="list-style-type: none"> Caregivers can track different types of events (e.g., seizures) and health metrics (e.g. blood pressure) multiple times per day Each event or metric is time- and day-stamped
Completing nonmedication routines	Support the creation of all types of health-related routines	"If he missed [a feeding] he would go hungry or could get sick with over feeding." [FCG, journal] "For my vent dependent child who might, who when he's sick needs a wiggle vest, and some kiddos with tracks need a cough exist, is there like a type of other routine that you can add that's not nutrition or medication based?" [FCG, session]	<ul style="list-style-type: none"> Caregivers can use free text to create any type of routine (e.g., shaker vest, bath) Caregivers can add food or drink to a routine, including amount and route

Abbreviations: CMC, children with medical complexity; FCG, family caregiver.

that a picture of the written order would alleviate the need for parents to print the order out or for the school nurse to contact the doctor's office.

Caregivers imagined that a notes feature could facilitate asynchronous communication within the caregiving network. One family caregiver imagined that, in preparation for visiting the neurologist, she might assemble all her notes about seizure activity since their last visit. Another caregiver wanted the ability to "tag" another caregiver in a note and to see a visual cue when that caregiver had "seen" or "read" the note.

Challenge 3: Accommodating Complex Medical Routines

According to family caregivers, medication administration occurred in the context of other types of medical routines and risks. To that end, family caregivers requested that the app warn users about allergies; enable the users to track a

variety of health-related events; and enable users to complete nonmedication types of routines.

One family caregiver highlighted the importance of making her child's allergies salient for his entire network. "My son has a kidney issue. He should not use ibuprofen.... I don't want anybody to even *think* ibuprofen if he has a fever." Within the app, family caregivers wanted allergy information to be "unmissable." This also applied to food and drink that the CMC should not receive.

Family caregivers noted that there are many things that they track on their child's behalf, and often multiple times per day, such as oxygen levels, blood pressure, and seizure activity. One home health nurse felt the same pressure to keep track of everything: "[Parents will] ask me about specific symptoms or just a scenario about how [the CMC is] doing." With a health tracking feature, she said, "they would have that in the palm of their hand."

Caregivers acknowledged that medications are but one type of routine in a CMC's day. Family caregivers wanted to be able to add both medical tasks (e.g., using a ventilator, shaker vest, or cough-assist device) and general health-related tasks (e.g., feeding the child, giving the child a bath). Family caregivers wanted the ability to drag these nonmedication tasks to the daily calendar "as soon as I think of it" so that neither family nor secondary caregivers would forget to complete them.

Discussion

In this study, we engaged family caregivers, secondary caregivers, and clinicians caring for CMC in a codesign process to identify: (1) challenges to medication safety experienced by the caregiving network and (2) design requirements for an mhealth application that could improve medication safety in the home and community. Design sessions yielded 11 challenges to medication safety and 11 associated design requirements, which fit into three broader challenges: giving the right medication at the right time; communicating with others in the caregiving network about medications; and accommodating complex medical routines. Those creating HIT can use these findings to develop technologies to improve medication safety for CMC and their caregivers.

The challenges to medication safety identified in this study align with and build upon previous research. Like Walsh et al, we found that caregiving networks struggle with administering correct dosing (e.g., missing doses, double dosing, or administering the wrong dose) and with communicating between caregivers (e.g., communicating when a dose has already been administered or when the prescribed dose has changed).⁴ Our study expands upon these findings, adding that refilling prescriptions for medications or medical equipment is also a key challenge. Our findings also add to existing literature on secondary caregivers, which has demonstrated the challenge of communicating with family caregivers, other secondary caregivers working different shifts, and with CMC's clinicians.³² Our findings suggest that secondary caregivers want HIT to support verifying clinician orders, documenting care, and communicating with caregiving network members (e.g., health-related event tracking and tagging each other in notes).

Overall, our findings highlight the challenge of building and maintaining awareness of a CMC's medications across all caregivers, all contexts, and all conditions, which is critical to safe medication management. This degree of awareness could understandably overwhelm any one caregiver. Thus, our results point to the need for HIT that supports distributed situation awareness (DSA).³³ Within a caregiving network, situation awareness can and should be shared between human agents (i.e., caregiving network members) and non-human agents (e.g., notepads, medication labels, smartphones). Further, each agent varies in its perspective and knowledge of the system. In the context of the present study, a school nurse may know whether the CMC received their medication at school; a clinician may know what medication changes are necessary to improve health; and a medication

label may "know" the correct medication dose. Although the current system requires family caregivers to know all of this information, the reality imparted by DSA is that, within a complex system, no single agent ought to be responsible for all information at all times. The design requirements identified in this study support medication safety by supporting DSA—that is, by storing all medication information and distributing it to the relevant caregivers, in the appropriate contexts, and when certain conditions apply.

All types of caregivers in the present study identified communication among caregiving network members as a key challenge to medication safety. Indeed, previous research demonstrates that communication failures are commonly associated with medication errors in the home.^{4,15} Family caregivers in this study wondered if medications had already been administered and when medications were due for a refill. Secondary caregivers wondered what happened during the previous shift, and how to communicate what happened during their own. Family and secondary caregivers alike sought an easier way to synthesize and communicate clinical data with clinicians. HIT that centralizes, organizes, and facilitates communication within the caregiving network has great potential to address communication-related medication errors for CMC in the home and community.

Limitations

This study had limitations. First, all family caregivers identified as Caucasian, identified as female, lived in the same state, and lived above the poverty level in that state. It is possible that a more socially and economically diverse sample of caregivers, as well as a more clinically diverse sample of CMC, would identify different risks to medication safety and thus different design requirements. Thus, intentionally enrolling diverse participants is a vital next step.³⁴ Second, all participants' CMC were enrolled in a complex care program. Medically complex children without access to a PCCP may face different risks. Third, the design requirements identified in this study have yet to be tested for usability, feasibility, and effectiveness at reducing medication errors. Future research on the prototype described in this study will both qualitatively and quantitatively describe the results of testing.³⁵ It is likely that end users will identify new or different needs upon extended use of the prototype. Last, achieving equal participation among group members in codesign is challenging, and in the present study we did not measure nor document the equality of participation. It is vital that future codesign studies measure and take steps to promote equity and inclusivity in group research settings.³⁶

Conclusion

This study identified key challenges to CMC medication safety in the home and generated design requirements for a tool to improve medication safety. The next steps to improving CMC medication safety are to pilot test the tool for usability and feasibility, and then to conduct a randomized control trial to determine if use of the tool reduces medication errors and improves CMC clinical outcomes.

Clinical Relevance Statement

Medication administration within the caregiving networks of CMC is prone to sometimes dangerous errors. In our study, caregivers and clinicians identified design requirements of a mhealth application that could improve medication safety at home by empowering caregivers to give the right medication at the right time, facilitating communication between caregiving network members, and accommodating the complex medical routines of CMC.

Multiple-Choice Questions

- Which of the following mhealth application features is intended to support an end user in administering the right medication at the right time?
 - Caregivers can write, title, and organize notes
 - Push notification sent to whoever is “on duty” when medication dose is due
 - Allergies are “unmissable” in red, bold font
 - Caregivers can track different types of events and health metrics

Correct Answer: The correct answer is option b. Push notifications remind the caregiving network member who is “on duty” when a dosage is due, which supports an end user in administering the right medication at the right time. Answer a supports an end user in asynchronous communication about medications with other network members. Answers c and d support caregivers by accommodating complex medication routines.

- Which of the following concepts represents how caregivers of CMC share work across the human and nonhuman agents involved in medication safety?
 - Participatory codesign
 - Accommodating complex medical routines
 - Asynchronous communication
 - DSA

Correct Answer: The correct answer is option d. DSA describes how caregivers of CMC share work across the human and nonhuman agents involved in medication safety. In the present study, the mobile health application supported DSA by storing all medication information and distributing it to the relevant caregivers, in the appropriate contexts, and when certain conditions apply, as well as by facilitating synchronous and asynchronous communication between agents. Answer a (participatory codesign) is an approach to the design of tools or interventions that includes the end users in the design process. Answer b (accommodating complex medical routines) is a challenge to medication safety described by caregivers of CMC, including aspects of medical care such as allergies, tracking health-related events (e.g., seizures), and completing nonmedication routines (e.g., bathing, feeding, using a shaker vest). Answer c (asynchronous communication) describes communication in which there is a time

lag between one agent providing the information and another agent receiving it.

Protection of Human and Animal Subjects

This minimal risk study was reviewed and approved by the University of Wisconsin–Madison and Indiana University–Bloomington Institutional Review Boards.

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Conflict of Interest

None declared.

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