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Research and Applications

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Feeling better on hemodialysis: user-centered design requirements for promoting patient involvement in the prevention of treatment complications

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ABSTRACT

Objective: Hemodialysis patients frequently experience dialysis therapy sessions complicated by intradialytic hypotension (IDH), a major patient safety concern. We investigate user-centered design requirements for a theory-informed, peer mentoring-based, informatics intervention to activate patients toward IDH prevention.

Methods: We conducted observations (156 hours) and interviews (n = 28) with patients in 3 hemodialysis clinics, followed by 9 focus groups (including participatory design activities) with patients (n = 17). Inductive and deductive analyses resulted in themes and design principles linked to constructs from social, cognitive, and self-determination theories.

Results: Hemodialysis patients want an informatics intervention for IDH prevention that collapses distance between patients, peers, and family; harnesses patients' strength of character and resolve in all parts of their life; respects and supports patients' individual needs, preferences, and choices; and links "feeling better on dialysis" to becoming more involved in IDH prevention. Related design principles included designing for: depth of interpersonal connections; positivity; individual choice and initiative; and comprehension of connections and possible actions.

Discussion: Findings advance the design of informatics interventions by presenting design requirements for outpatient safety and addressing key design opportunities for informatics to support patient involvement; these include incorporation of behavior change theories. Results also demonstrate the meaning of design choices for hemodialysis patients in the context of their experiences; this may have applicability to other populations with serious illnesses.

Conclusion: The resulting patient-facing informatics intervention will be evaluated in a pragmatic cluster-randomized controlled trial in 28 hemodialysis facilities in 4 US regions.

INTRODUCTION

For 2 decades, improving patient safety has been a nationwide priority.[1] Health informatics interventions play important roles, including preventing medication prescription errors[2] and healthcare-associated infection through workflow "bundles."[3] Recently, informatics research has turned to patient involvement,[4–6] highlighting opportunities to improve safety by supporting patient involvement.[7] We conceptualize patient involvement as patients taking an active part in their care and consultations with healthcare professionals.[8] Patient involvement is essential for accurate communication in the patient provider relationship and shared decision-making.[9,10] Patients are involved when they are informed, actively engaged, patient views are considered, and exchange of knowledge and experience takes place between patients and providers.[11,12]

This emerging research responds to national and international stakeholder organizations advocating for greater patient involvement in safety.[1,13–16] Advocates contend that patients should be engaged since they are at every treatment, provide important information, and are motivated to reduce harm.[17] However, reviews found knowledge gaps regarding patient involvement and prioritized research in this area.[17,18]

Patient involvement in safety initiatives have had mixed success,[19] likely due to inappropriate assumptions regarding preferences for involvement[20] and patient capacity to participate without education and support.[21,22] Efforts are rarely grounded in validated theories of behavior change,[19] relying instead on providing information such as care records[23] and instructions.[24,25] Rarely have interventions attempted to influence psychosocial mediators of health behavior—a critical component for success[26] (but see[27]). A recent model[7] highlights opportunities to incorporate behavior change theory into patient-facing tools. Furthermore, aside from a recent pilot trial of an online community for hospitalized patients,[4] little research has examined the potential for patients to assist each other in safety promotion. Nonetheless, there has been interest in peer-based healthcare approaches as trials have shown benefits in health outcomes and behavior,[28–30] including complex behaviors such as diet change. Enabling patient–peer support to promote patient safety has also been highlighted as a key research[7] area in informatics.[19,21–25,28–37]

To advance informatics interventions that support patient safety involvement, we investigate patients' user-centered design requirements in the context of hemodialysis safety. As in critical care[38] and surgery,[39] avoidable hemodialysis complications are a patient safety concern.[40] Hemodialysis, in which a dialysis machine replaces renal function, is the most common therapy for end-stage renal disease (ESRD), a condition in which people need a kidney transplant or dialysis to live. Hemodialysis-related complications are common; an average of 20% of sessions involve intradialytic hypotension (IDH) (low blood pressure).[41–44] IDH is linked to removing too much fluid from patients' bodies or removing it too quickly. IDH is associated with repetitive and cumulative cardiovascular and other organ system injuries. It can also cause cramping, dizziness, vomiting, and fainting and is associated with cardiovascular disease, hospitalization, and mortality.[41,42,45,46]

IDH may be preventable through intervention. A primary intervention involves preventing accumulation of excess fluid in the patient's body, especially between hemodialysis sessions. Fluid accumulation is driven by patient decisions regarding sodium, fluid consumption, and skipping or shortening sessions. Because early intervention in an IDH episode may prevent worsening, patients can prompt provider-based interventions by reporting symptoms.[47] Hemodialysis patients prioritize finding solutions to IDH.[48] Yet, few patient-facing interventions have investigated how to activate patients toward its prevention. Building on an existing ESRD patient peer-mentoring program, we investigated how to design an informatics intervention for hemodialysis patients to prevent IDH to be used in the dialysis clinic setting while patients are dialyzing. The existing, telephone-based peer-mentoring intervention offered to dialysis patients is provided by the National Kidney Foundation (NKF), the focus of which is psychosocial wellbeing.[49] The existing program does not focus specifically on behavior change nor does it concentrate on IDH prevention. In contrast, the intervention described in this article takes place via videoconference, lasts 5 weeks, and involves an IDH-prevention-focused curriculum and use of motivational interviewing techniques by peer mentors.

Patient peer mentoring is a promising approach to support patients while they dialyze. Peer mentors have successfully engaged hemodialysis patients in decisions about end-of-life care and organ transplants.[50–52] Peer mentoring has also succeeded in populations similar to hemodialysis patients, including older adults[53] and people with cardiovascular disease[54] and can be effective for African Americans and Hispanics,[55] who are overrepresented among hemodialysis patients.[56] While not previously applied to preventing treatment complications, peer mentoring may provide the education, support, and motivational enhancement needed to improve patient safety.[21,22]

Theoretical framework: social cognitive theory (SCT) and self-determination theory (SDT)

Social cognitive theory (SCT) posits that motivation toward health behaviors emerges from: (1) self-efficacy, or confidence in the ability to engage in a behavior; (2) outcome expectations, or beliefs about the likelihood of a valued result; (3) barriers and facilitators in the environment; and (4) goals.[57] Self-efficacy increases through observing peers perform an activity. Experiences of mastery, especially through performing tasks that gradually increase in difficulty, also increase self-efficacy. SCT underlies many peer-based health behavior interventions, especially those in which patients educate one another.[58,59]

Self-determination theory (SDT) posits that people are more likely to engage in a behavior when intrinsically motivated. Intrinsic motivation is internal motivation to engage in an activity one enjoys or finds satisfying. In contrast, extrinsic motivation necessitates outside approval, reward, or punishment. For intrinsic motivation, 3 needs must be met through pursuing an activity: (1) autonomy: the need to feel in control of and actively make decisions to change factors in one's life; (2) competence: feeling effective at dealing with work or situations one encounters, related to SCT's concept of self-efficacy; (3) relatedness: feeling part of a community and having meaningful relationships. SDT is the theoretical basis for the counseling approach of motivational interviewing, adopted in our intervention. Motivational Interviewing (MI) aims to resolve ambivalence toward behavior change by allowing people to process thoughts with nonjudgmental counselors. Patient peer mentors can be trained in MI to foster behavior change in others.[50]

These 2 theories have been used in non-informatics-based interventions supporting behavior change among dialysis patients.[60,61] However, little is known about designing informatics interventions to incorporate these constructs and tenets when involving patients to promote safety, particularly for hemodialysis patients.

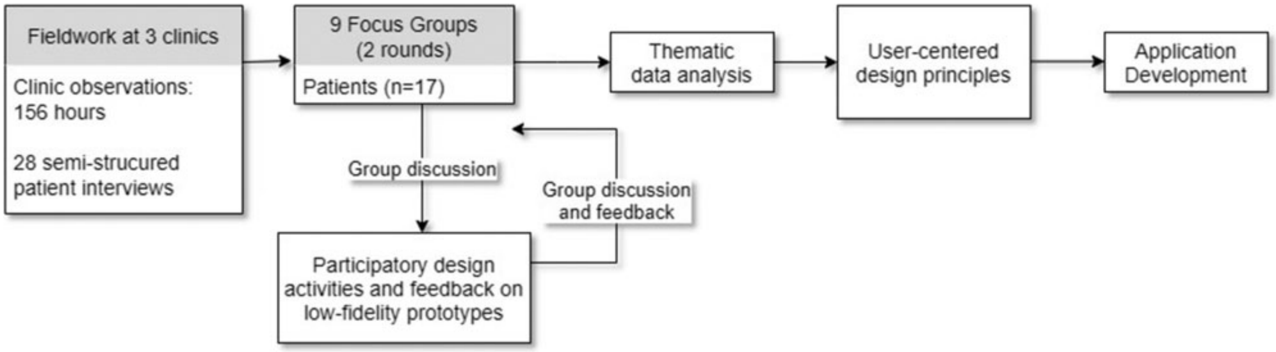


Figure 1. Study research design.

Study objectives

To identify user-centered design requirements informed by SCT and SDT for a peer mentoring-based informatics intervention for hemodialysis patients, with the goal of promoting patient involvement in preventing IDH.

MATERIALS AND METHODS

Overview

We define “user-centered design” as an “iterative process whose goal is the development of usable systems,” that is “achieved through involvement of potential users of a system in system design.”[62] The requirements emerging from this process refer to the “features/attributes” that the intervention “should have or how it should perform from the user’s perspective.”[63] The overall approach adopted the principles outlined in ISO 9241-210, including developing an explicit understanding of users, tasks, and environments through observations and interviews; involvement of patients and peer mentors through design and development through focus groups, including participatory design activities; use of user-centered evaluation to drive and refine the design by asking patients to provide feedback on low-fidelity prototypes; and an iterative process of design that focuses the whole user experience. However, our approach departed from the previous framework in its greater focus on understanding the potential implementation of theory in the intervention; this was a significant focus of all of the data collection and analysis activities. The existing peer mentoring intervention’s design influenced design of the intervention through the decision to leverage the existing infrastructure for recruiting, training, and supervising patients.

Data collection

As Figure 1 shows, we performed 156 hours of observations (51–53 hours at each site) in 3 hemodialysis clinics in a midwestern US state. Observations concluded after saturation was reached. We selected facilities that differed geographically (rural, urban, suburban) and in management structures (non-profit, for-profit). We adopted a nonmember role[64] at clinics and conducted observations at different times. Observations focused on the physical environment and interactions among people and with technologies such as TVs, dialysis machines, and smartphones. Specifically, the social interaction we focused on were the patient’s interactions with other social actors, including patients with family members, patients with other patients in the clinic, patients with staff at the clinic, and family member interactions with clinic staff. During observations, we developed field notes.[65]

We conducted 28 semi-structured, in-depth interviews[64] with patients at these clinics. Patients were theoretically sampled to include a range of observed in-clinic behaviors, including using technology. Interviews focused on experiences of ESRD and dialysis, including treatment complications, technology use, and interactions between patients and family.

Finally, we conducted 9 focus groups with patients; each was asked to attend 2 rounds. Project partner NKF recruited participants via dialysis clinics and patient organizations through social media postings, 3 e-mail lists (2,336 subscribers), and outreach to 3 organizations asked to share study information with patients (patient nonprofit organization, ESRD care quality improvement organization, renal social workers association) and an e-mail to NKF patient peer mentors. Initial focus groups focused on IDH and other complications, intervention ideas, and participatory design activities[66] in which participants drew responses to questions about their desired intervention. Participants showed and explained their drawings to the group. In a second round of focus groups, patients gave feedback on prototypes and workflows for the proposed intervention (Figure 1).

All participants provided informed consent. The research was reviewed by the Institutional Review Board at the University of Michigan.

Data analysis

Interviews and focus groups were audio-recorded and transcribed verbatim. Patient drawings were scanned; the transcripts and field notes were coded in NVivo 12. Following Saldaña’s (2013) guidance, we performed 3 coding cycles:[67] (1) structural coding to organize the data around the study objective; (2) pattern coding to identify emergent themes regarding user requirements (Figure 1); (3) connecting these themes to SCT and SDT to create user-centered principles informing the design of a tablet-based application (Figure 1). In these analyses, field notes provided important context for understanding the clinic environment and how this contributed to patients’ needs as expressed in the themes below (eg, connection with others, experiences of autonomy, individualized attention).

RESULTS

Participant characteristics

Slightly more males than females participated (Table 1). Most participants were White or African American. Focus group participants were younger and more educated than those interviewed at clinics.

Table 1. Characteristics of participants (n = 45)

	Semi-structured patient interviews (n = 28)		Patient focus groups (n = 17)	
Characteristics	Number	Percent	Number	Percent
Gender				
Male	15	53.6%	11	64.7%
Female	13	46.4%	6	35.3%
Age (mean)	67.1		54.7	
Race/ethnicity*				
White/European American	19	67.9%	6	35.3%
Black/African American	8	28.6%	10	58.8%
Asian/Pacific Islander American	1	3.6%	1	5.8%%
Native American	1	3.6%	0	0%
Hispanic/Latino	0	0%	0	0%
Education				
Grades 9–12, no diploma	3	10.7%	0	0%
High school graduate or equivalent	11	39.3%	1	5.8%
Vocational school associate degree or some college	10	35.7%	8	47.1%
College degree	3	10.7%	5	29.4%
Professional or graduate degree	0	0%	3	17.6%
No response	1	3.6%	0	0%

Design requirements for hemodialysis patients: four themes

The 4 themes derived from user research and characterized according to constructs of SDT and SCT are: (1) Collapsing distance between patients, peers, and family; (2) Harnessing the patient's strength of character and resolve in all parts of their life; (3) Respecting and supporting patients' individual needs, preferences, and choices; and (4) Linking "feeling better on dialysis" to becoming more involved in IDH prevention. Quotes supporting each theme are presented in Table 2. Each theme connects to a design principle used to inform the design of the intervention. Furthermore, as Table 3 shows, each theme also contains multiple theoretically informed design recommendations.

Theme 1. Collapsing distance between patients, peers, and family

Connection was a core patient priority for the design of an IDH prevention intervention. **Hemodialysis creates unwanted space and disconnection between patients and others (subtheme 1a)**: it confines them for 4 hours at a time and pulls them away from friends and family for 12 hours a week on average. It may be difficult to interact with others on dialysis days due to the *demanding treatment and schedule* (Table 2).

ESRD and hemodialysis care also produce experiential or psychological distance in that *family may have difficulty dealing with patients' health challenges* (Table 2) and not fully understand them. This distance means that they may offer insufficient support. Participants described a *lack of connections in their lives*; 2 attributed this to their older ages. Several expressed sadness about managing health problems or spending much time alone (Table 2).

Although the clinic setting offered some sociability, and patient peers may understand their experiences better than family members, **patients find it difficult to interact at hemodialysis facilities (subtheme 1b)**. As discussed elsewhere,[68] noise, staggered schedules, infection control-related distance between chairs, and design that places barriers between patients or positions them facing away from one another all created social and physical distance (Table 2). Thus, *the clinic environment is not conducive to prolonged conversation* or forming deeper connections. Yet, some *patients express concern and beneficence toward others* (Table 2). This manifested in worrying if others missed sessions or seemed unwell.

The aforementioned factors necessitate informatics interventions to foster what SDT calls "relatedness" between patients and between patients and their family (Table 3). Relatedness is developed or restored through *helping friends and family relate to their experiences or forming connections with other hemodialysis patients*. Desires for relatedness were expressed through patients' design sketches. Figure 2, Panel A shows how a participant wanted to check in on other patients and ensure that they have someone who listens to them.

This requirement resulted in our first design principle: **Designing for depth of interpersonal connections** (Table 3, Principle 1). Patients saw technology as way to connect, with a preference for one-to-one interaction. *One-to-one videoconferencing or text messaging* could connect patients at the same clinic or *facilitate connections with patients more like them* elsewhere (Table 3, Recommendation 1b). Patients wanted to see each other, with photos or videos, to increase emotional connection, reciprocity, and trust (Table 3). A desire for reciprocity led several to request *profiles in which both parties share health- and non-health information about themselves* (Table 3, Recommendation 1c and Figure 2, Panel B). Reflecting this idea of reciprocity, Panel B shows a patient drawing of 1 interface for the patient and 1 for the peer mentor. The patient's interface showed information about the peer mentor, such as information about their family and things they like or activities they enjoy. Likewise, the peer mentors' screens showed information about the patient, their hobbies, and other personal information to help facilitate a close connection. Participants wanted a *mix of social and educational elements* in peer mentoring sessions, with time to talk about their lives, as well as IDH prevention counseling (Table 3, Recommendation 1d).

Additionally, patients wanted *education for family so that they could provide more effective support*, such as not panicking when something happened or making more realistic demands (Table 3, Recommendation 1e).

Table 2. Patient design requirements

Theme 1: Collapsing distance between patients, peers, and family	
Subtheme 1a: Hemodialysis creates unwanted space and disconnection between patients and others	
Demanding treatment and schedule	"I'm tired, and I don't do as much as I used to do. . .I usually talk to [son] about once a week, and my sister every other day. Usually, . . . on my days off. . .I don't talk on my days of dialysis." (Site2-W29)
Family may have difficulty dealing with patients' health challenges	"My son doesn't like to talk about it. . .. even when my son calls me once a week, he never asks [how my health is]." (Site2-W13)
Lack of connections in patients' lives	"I think that when you get over 70, you have a lot less people to talk with anyway. So, I. . .enjoy my own self and [am] very independent." (Site3-M11)
Subtheme 1b: Patients find it difficult to interact with one another at hemodialysis clinics	
The clinic environment is not conducive to prolonged conversation	"[Site2] has mostly chairs but also 6 hospital-type beds. Currently most of the beds are in a flat position, but the one nearest me has the top part raised somewhat at an incline, and the patient in it is lying on her side, asleep. (And thus, her back is turned to the patient in the chair next to her.) . . .There's a counter down the center of the dialysis room that splits it into 2 halves. The chairs there are placed on either side with their backs to the counter, so that patients there are facing away from each other." (Field-Notes-Site2)
Patients express concern and beneficence toward other patients	"You want to see [other patients] because you've got a bond with them, and it's that kind of dialysis bond where you don't want to see nothing happen to them. . .you always ask about them when you get here, 'Where's [Name] at today?'" (Site2-M17)
Helping friends and family relate to their experiences or forming connections with other hemodialysis patients	"I ask her how was her day. . .. I listen to what she has to say. . . so she can relieve herself and she can relax." (Patient-FG1-P9)
Theme 2: Harnessing the patient's strength of character and resolve in all parts of their life	
Subtheme 2a: "It's about the fighting"	
Inner strength from struggling with health challenges	• "You have a choice, live or die . . .it's hard. . .. The other people here [at dialysis], and they go through things and issues as well. So, it's all about the fighting. Some days, you might just not want to be bothered with it. That's how you feel today, fine. You know? Don't deal with it. There's always tomorrow." (Site 1-W28) • "I put what I want [peer mentor] to see as me. Joy. Strength. Overcoming. Victory. I don't want to see all that negativity. You know I'm a fighter." (Patient-FG1-P7)
Keeping going	• "I've always felt 1 of my missions in this earth is, whatever I've been through, it's to share it with people. . .to show people that they can go through it. You can continue to go on. . ." (Patient-FG4-P4) • "That's what you want, you want people to know that just because you're on dialysis, your life doesn't stop. . .you just adjust and keep going." (Patient-FG3 -P3)
Subtheme 2b: "Now I smile, I'm happy and everybody ask me where it come from"	
Stories of transformation	• "I was the [sad] person and now I smile, I'm happy and everybody ask me where it come from. But I was once that [sad] person." (Patient-FG1-P4)

(continued)

Table 2.. continued

Theme 1: Collapsing distance between patients, peers, and family	
	• "I went from being a non-compliant patient, angry, upset, kidney disease, oh woe is me. . .to being a person who watches what I eat, and I pay attention and all of that." (Patient FG1-P10) • "I just got almost tired of. . .going to dialysis and living and everything. . .but I. . . still want be here. I've got 2 daughters, and I just want to see them get older and graduate. . . it made me change my whole game plan up because, see, once you get on dialysis, your whole lifestyle going to change up anyway." (Site2-M3)
Accepting the need to develop a new lifestyle	• "Dealing with an illness like this is very serious. And very hard. This is a new life you're dealing with and you're married to the old life." (Patient-FG1-P3) • ". . .it becomes a lifestyle, whether you like it or not." (Patient-FG5-P1) • ". . .it was hard to change because I was used to putting salt on everything and eating a lot of fatty foods." (Site2-W21)
Dealing with IDH and other hemodialysis complications in daily life	• "Low blood pressure affected me very bad. I passed out in the street, passed out at church, and I had to drink the broth, and that helped me." (Patient-FG2:1-P2) • "Sometimes. . . when I go, home I might have to have something a little bit more salty and make sure I drink a number of fluids after [dialysis] to make sure that my blood pressure had increased enough that I could drive. . ." (Patient-FG4-P4)
Theme 3: Respecting and supporting patients' individual needs, preferences, and choices	
Needs for more individualized attention	• ". . .a good part of care for patient on dialysis I think was respect. Because we're doing a lot of tasks and sometimes you find lack of respect and lack of care and lack of attention." (Patient-FG2-P8) • ". . .some centers just are so busy, and they don't have enough staff to be that concerned about every single person every single time the whole time they're on." (Patient-FG5-P1) • "Sometimes [staff talk to me]. They are so busy now with all the cutbacks. . .these people are overworked." (Site3-M2)
Respecting patients' uniqueness to prevent complications	• ". . .every person is very individual in their health history, medications, diet. . .That's why they have to talk to their medical team about things that are going on that are problematic for them, to address those as soon as possible. But they gotta talk to the right people to guide them to make those right changes." (Patient-FG3-P4) • ". . .I have to adjust it to how my body feel- they [dialysis care providers] kind of put us all in the same boat, but we're not all in the same boat. We're all individual people. . . .I had to learn that, um, I can't take off so much weight so fast. Some people can, some people can't. . ." (Site2-M17) • "They put the [dialysis] machine down to 400. . .everything just flows so good. My

(continued)

Table 2.. continued

Theme 1: Collapsing distance between patients, peers, and family	
	heart don't race… I talked to my nephrologist and he said it's up to you, it's not up to that doctor because he don't know your body. He knows certain things, but you know how you feel. And now, they give me no problems. They keep it at 400." (Patient-FG1:1- P4)
Supporting patients in making more choices	• "…the feeling of helplessness, that they're not in control of their lives anymore, because their life has to…revolve around this schedule of dialysis, and diet, and fluid restrictions." (Patient-FG6-P2) • "…my [blood] pressure…once it reaches 90, I turn the [dialysis] machine off…. I don't want to take myself lower than that, regardless of how long my treatment is. I turn it. I decided, 90 is my cut off." (Patient-FG1:1- P10) • "To what extent are you going to permit people to have certain degrees of sodium and violate it from time to time, just to have that special something…a once-a-year barbecue is not going to kill them…I don't denigrate people that appreciate that there's a place for cheating in dieting." (Patient-FG2:3-P1) • "No sweet potatoes. So, you just get, you just get to live with it. I have, anyways …if I really think I have to have it, I'll allow myself to have a tablespoon. That works." (Site2-W3)
Theme 4: Linking "feeling better on dialysis" to becoming more involved in IDH prevention	
Feeling better on dialysis is a goal	• "Bottom line is I come here to feel better and not worse. When you're leaving out of here, and you feel worse than when you came, maybe you need to try something different." (Site2-M17) • W25: "Did you have a pretty good run?" [looking at Site1-M23, who looks up at her] • M23: "Well, you know how it is sometimes …." • W25: "Oh, I know. Sometimes it's better than others." [nods] • M23: "Wasn't so bad today." • W25: "Helps us feel better mostly though." (FieldNotes-Site1)
Feeling better on dialysis is a process	• "I remember back when I first started…I'd go home, you'd have to prepare a meal. It'd take me all evening because…I was tired. And I didn't feel good, but as time when by, I got to feeling better and now sometimes I wonder what I'm still doing here because I feel too good to sit in this chair." (Site2-W3) • "It took about 3 years before I started feeling better. There are those patients, oh they come skipping into the room, and they get stuck and they fall asleep and 4 hours later they wake up and then they skip out of the room and I'm like, I want that." (Patient-FG3-P1)

(continued)

Table 2.. continued

Theme 1: Collapsing distance between patients, peers, and family	
Understanding the consequences of behaviors	• "…people don't realize that salt is in everything. Being on dialysis…you're cramping, and you have all these side effects. People aren't understanding and realizing that that's a result of things that you are doing to yourself." (Patient-FG6-P6) • "Depending on how much [fluid] I take off, when I get up from the machine, that determines how I feel…. Because, I have low blood pressure and no one has ever discussed with me you could pass out or whatever." (Patient-FG2:1-P5) • "There used to be a time when I didn't know all this stuff, and I would come to dialysis, and I would come off the machine early." (Site2-M17)

Theme 2. Harnessing the patient's strength of character and resolve in all parts of their life

Patients stressed the many difficult experiences they had been through with ESRD and hemodialysis and that they had to "fight" to survive. One said, **"It's about the fighting"** (Table 2, Subtheme 2a). Learning to live with the pain, losses, and disruptions of ESRD and hemodialysis meant that patients had cultivated *inner strength that came from struggling with health challenges*. Patients believed this was expressed by *keeping going* (Table 2). Below, a patient contrasts how others might see her—as helpless or sad—with how she wants to be seen—as joyful and strong (Figure 3, Panel A).

Patients' resolve was evident in their *stories of transformation*. Transformations included becoming happier after sorrow or anger about ESRD, and moving from grief about, and resistance to, loss of foods and drinks that they enjoyed, to implementing behavior changes. Beginning hemodialysis therapy was a time of emotional suffering and patients wanted the intervention to help others through it; they wanted to communicate that "it gets better" with time.

Transformation meant *accepting the need to develop a new lifestyle*. This required relinquishing one's "old life," giving up things they enjoyed, yet still finding happiness. New lifestyles included rigorous dialysis schedules and major changes in types and amounts of food and drink consumed. This meant "training" oneself to engage in new behaviors such as drinking less water, and finding ways to make changes tolerable, such as reducing salt consumption gradually. Furthermore, changes meant *dealing with IDH and other* hemodialysis *complications in daily life*, which could leave patients exhausted and at risk for fainting, falls, or car accidents.

Patient preferences led to the second principle: **designing for positivity** (Table 3, Principle 2). This meant designing interventions offering *encouragement to build confidence and hope* (Table 3, Recommendation 2a), such as peer mentor sharing of stories, a core idea in Figure 3, Panel B. This desire relates to SCT's concept of self-efficacy, which is elevated by encouragement and peer role modeling. Encouragement could offer hope and promote positive emotions. Feedback on an intervention prototype revealed that MI-based content asking patients to reflect on their feelings about behavior changes, and SCT-inspired interactive features on identifying and overcoming barriers, provided desired encouragement (Table 3).

Encouragement was also provided visually. Patients wanted *bright colors to promote positive emotional states* (Table 3, Recommendation 2b) and *flower and garden motifs to affirm life and promote positive emotions (Table 3, Recommendation 2c)*, evident in Figure 3, Panel A. Reflecting this patient-generated motif, the intervention prototype included a "quiz garden" where patients earned flowers by completing quizzes about IDH prevention. This feature was appreciated for its symbolism and positive feedback.

Patients expressed a desire for *activities and feedback that acknowledge patients' strengths* (Table 3, Recommendation 2d). This is in line with SDT's concept of competence. Participants expressed appreciation for a prototype values clarification feature seen as starting from their strengths (Table 3). Furthermore, they appreciated features offering positive feedback, and interactive *activities that provide attainable challenges* (Table 3, Recommendation 2e), such as the quiz garden and a game that incorporated behavior changes into play.

Theme 3. Respecting and supporting patients' individual needs, preferences, and choices

Participants felt that their hemodialysis care providers were overly busy, which some linked to financial pressures. For instance, 1 clinic laid off staff members, leading to a perceived loss of opportunities to talk to staff (Table 2). Participants described difficulty getting attention during dialysis or feeling rushed to make way for the next patient. Several identified a *need for more individualized attention* during dialysis.

Participants highlighted the importance of *respecting patients' uniqueness to prevent complications* by providing tailored care. Patients sought such care by requesting lower ultrafiltration rates, fluid removal goals or dialysate temperatures that they could handle, lower blood flow rates, and rapid responses to falling blood pressure. Patients emphasized that getting individualized care could be a struggle; not all providers had the authority to make decisions, and some did not sufficiently respect patients' preferences. Figure 4, Panel B depicts a desire for an intervention that would help attain respectful, high-quality care.

Participants also wanted an intervention *supporting patients in making more choices*. This was important because constraints related to ESRD and hemodialysis could promote feeling helpless. Some asserted their right to make choices to prevent complications;

Table 3. Design principles and Recommendations Themes 1 and 2

Design requirement	Design principle	Design recommendations	Supporting quotes
• Theme 1: Collapsing distance between patients, peers, and family • (Self-Determination Theory: Relatedness)	Principle 1: Designing for depth of interpersonal connections	*Recommendation 1a: One-to-one videoconferencing or text-based messaging*	• "I like that idea [of interacting with other patients using technology] . . .instant messaging . . .I bet you could text over these televisions. . .. that would be nice, if you had a computer that 1 person could communicate to." (Site1-M30) • "I think video. That makes each person real to the other person and it sets up an immediate investment in ways that nothing else does. . .when you're doing it person-to-person, it sets up an immediate reciprocity." (Patient-FG2:2-P1)
		Recommendation 1b: Facilitating connections with patients more like them	". . .you'd be able to touch more people. You know, not just the people you sit with every day because, you know, some people might need advice a little more than these people here or, you know, or some people might listen to a person who's their age or something like that, you know. Especially if you can show a picture of you. . ." (Site2-M17)
		Recommendation 1c: Profiles in which both parties share both health- and non-health information about themselves	"You should be given some information about who is your peer mentor. Who is this person, where are they from? . . .They know your information, what do I know about them?. . . maybe the last box could be something where it's just a bio. . .under the person, saying, 'This is who I am. This is my affiliation with dialysis.' and, 'My current treatment modality'. . .background so that they can also put that together with the face. . ." (Patient-FG2-P3)
		Recommendation 1d: Mix of both social and educational elements	• "It should probably have about 30% social content. Assuming that there is a relationship that is not necessarily just about the [education]. . . • there is a social relationship, and that's good. That's positive." (Patient-FG2:3-P1)
		Recommendation 1e: Education for family so they could provide more effective support	"I don't think family members always get themselves educated the way the patient does. . .they listen. . .when you have complaints, but they don't always get the information. . .. You have some family members. . .. they asking you to do something for them because they don't know what your dialysis days is. So, I think they do need to have, something whereyou educate those family members." (Patient-FG1-P1)

(continued)

Table 3.. continued

Design requirement	Design principle	Design recommendations	Supporting quotes
- Theme 2: Harnessing the patient's strength of character and resolve in all parts of their life - (Self-Determination Theory: Competence, - Social-Cognitive Theory: Self-Efficacy)	Principle 2: Designing for positivity	*Recommendation 2a: Encouragement to build confidence and hope*	- "…it's a process…Stick with it, do what you need to do…listen to the advice and protocol from the docs and the dietician…Things will improve, and you'll get to a point where things will be better…." (Patient-FG5-P4) - "They just get tired of the whole thing…. It's constant diet checking, and rechecking, the needle, you know, giving them issues, and the doctor visits, and back and forth with these procedures. There's a lot of them. I just try to encourage them as much as possible that I know it's a bad day, but it will get better." (Patient-FG5-P1) - "I especially like the [questions] about how do you feel about these things that will identify barriers…so that they can see the value of making these changes, and try to see things in a more positive light so they can actually participate in it more fully." (Patient-FG5-P1)
		Recommendation 2b: Bright colors to promote positive emotional states	- "I would like to see more bright colors on the screen." (Patient-FG1-P7) - "…the bright colors…it gives you a good feeling." (Patient-FG1-P4)
		Recommendation 2c: Flower and garden motifs to affirm life and promote positive emotional states	- "[regarding why she drew a flower for her design exercise] … everyone look at us like we should just stop living. And, that's something I don't believe. I keep going. And to me, I get defensive. I be on the defensive side where I hear people go, 'Aren't you look tired.'…like we just dying…So that's what the flower of life to me." (Patient-FG1-P4) - "…sometimes I go on the TV…and they'll have a screensaver thing. I think that might be really nice to have…some relaxing colors or a picture of a scenic spot or something that's soothing. I'm relaxed, they're relaxed, and…hopefully we'll have smiles on our faces." (Patient-FG4-P4)
		Recommendation 2d: Activities and feedback that acknowledge patients' strengths	- "I think you want to open the mentor up to what your strengths are. The things that you care about. Who you've been. Not who you are… The things that you love. The things that animate you. Really excite you." (Patient-FG1-P6)

(continued)

Table 3.. continued

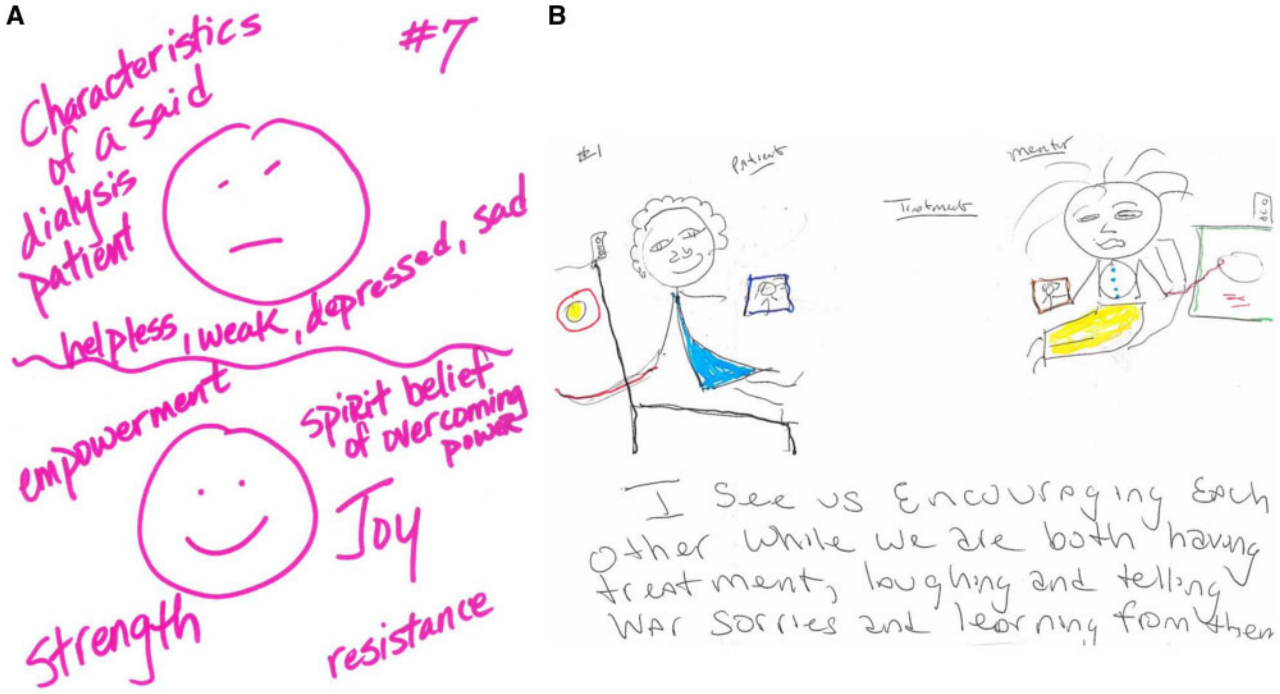
Design requirement	Design principle	Design recommendations	Supporting quotes
			• P1: [The values exercise] was my favorite part. I think identifying values is very important. It's like identifying their strengths and focusing on that. • P3: I agree with that. (Patient-FG5) • Interviewer: The quiz garden. If a flower popped up [when you got the right answer] • P5: That would be nice. • P1: Encouraging. • P2: Stimulating, you know? • P5: Or good job, whatever. Balloons, something. (Patient_FG2) • "[About the quiz garden] I love it. Seriously, it's the simplicity of, yet the relevance of the garden to knowledge. . .an eagerness to know more. . . .. I'm intrigued by the idea, oh my gosh, what are they gonna do next in terms of making my garden?" (Patient-FG2:2: P1)
		Recommendation 2e: Activities that provide attainable challenges	• ". . .most patients are not adequately challenged, and it's a big problem. . .Whether you almost have a sample pantry and a person needs to prepare a meal from that sample pantry. . .those kinds of experiences are how you get people engaged around the challenge of doing the diet. . .it's much more fun to do, 'Where in the world is there a product that can substitute for something?' How do you use herbs in lieu of sodium . . .?" (Patient-FG2-P2) • ". . .take this quiz of this module. . . so that would. . .feel like a nice little challenge. Because you're telling me about food restriction, now you're asking me what did I learn about it." (Patient-FG6-P2)

for instance, one adjusted her dialysis machine when her blood pressure reached a certain level (Table 2).

The foregoing led to a third principle: **designing for individual choice and initiative** (Table 4). This aligns with SDT's concept of autonomy.[69] Patients wanted the intervention to support choice and initiative. They expressed interest in *alternative sources of information* (Table 4, Recommendation 3a) not provided at their clinics so they could learn about additional treatment options or gain clearer information. Additionally, *individualized information* (Table 4, Recommendation 3b) could be provided by peer mentors or adaptable technologies to connect health recommendations to personal experiences.

When using interventions, patients wanted choices. This was expressed by identifying topics to discuss with mentors, as in the patient drawing about *"My Health"* (Figure 5, Panel A), or for *choices of topics and goals* (Table 4, Recommendation 3c) when selecting topics or videos to click on (Figure 5, Panel B). Patients appreciated a menu in a goal-setting feature, but also wanted the ability to manually enter their own goals. Patients preferred choice when asked for feedback on 2 prototypes, 1 with linear navigation requiring step-by-step clicking through a module, and 1 with hierarchical navigation allowing direct clicking on topics of interest. *Hierarchical navigation was preferred over linear navigation* (Table 4, Recommendation 3d) because it allowed direct interaction with the most relevant content,

Figure 2. Panel A (left) patient illustration of dialysis patients checking in with and listening to one another using technology. Panel B (right) patient illustration of intervention interface with patients and peer mentors sharing health and nonhealth related information.



I See us Encouraging Each other While we are both having treatment, laughing and telling War Sorries and learning from them

Figure 3. Patient-FG1-P7contrasts how others might see her—as helpless or sad—with how she wants to be seen—as joyful and strong (Panel A). Patient-FG1-P1 drawing offering encouragement to build confidence and hope (Panel B).

rather than being *"forced to do anything"* (Table 4). This extended to *choice of interaction formats*: the ability to interact with peer mentors through video or text chat, synchronously or asynchronously, and to control print size (Table 4, Recommendation 3e).

Theme 4. Linking "feeling better on dialysis" to becoming more involved in IDH prevention

Feeling better on dialysis is a goal that patients often discuss with one another (Table 2); complications such as IDH undermine this goal. However, *feeling better on dialysis is a process* too, and often does not happen immediately. Patients adjusted to dialysis over time, with immense fatigue at the start, and gradual improvement (Table 2). Some found that IDH was personally common, leading to trial and error to identify remedies.

Patients need support for *understanding the consequences of behaviors* that increase the likelihood of IDH. At times, they felt that clinics did not offer needed education. However, learning could happen over time; for example, learning that salt consumption could

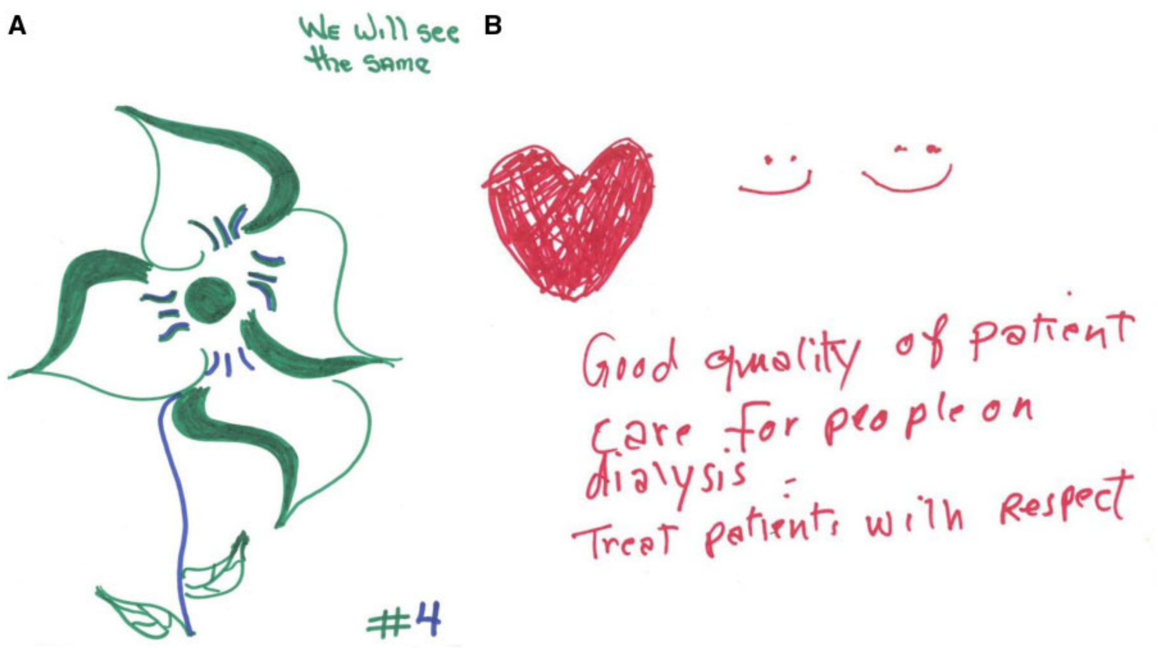


Figure 4. Peermentor-FG1:1-P4 drawing showing flower and garden motifs to affirm life and promote positive emotions (Panel A). Patient-FG-P8 drawing shows desire for an intervention that would help attain respectful, high-quality care (Panel B).

prompt higher fluid gains, resulting in misery during dialysis (Table 2). Learning could increase motivation for IDH prevention involvement.

This requirement links to SCT's concepts of *goals* and *physical outcome expectations* (Table 4, Theme 4). Feeling better on dialysis was a wanted end state that patients could learn was possible by observing others (Table 2). Patients can also gain experience with adjusting diet, requesting lower ultrafiltration rates, and other factors that lead to less IDH and feeling better.

This requirement relates to the principle: **designing for comprehension of connections, and of possible actions** (Table 4, Principle 4). Patients wanted information to be presented experientially, such as watching others' stories about IDH experiences and how they manage to have easier sessions now (Figure 5, Panel C). They felt that vivid images of feeling worse or better could help patients understand connections, *the notion of linking behaviors to experiences of positive and negative outcomes* (Table 4, Recommendation 4a). Additionally, patients advocated content for *learning to identify and manage treatment complications during hemodialysis* (Table 4, Recommendation 4b). This included providing clear descriptions to help identify IDH symptoms and take action to prevent greater suffering, and tips for managing related symptoms such as cramps.

Undergirding this was *education to support care involvement* (Table 4, Recommendation 4c); it would help patients rethink their roles. According to participants, it was important that intervention content help patients learn to ask questions, make requests, raise concerns, and refuse to participate if explanations were not satisfactory. This was critical to feeling better on dialysis.

DISCUSSION

Hemodialysis patients' design requirements for an informatics intervention focused on involvement in IDH prevention yielded 4 themes focusing on supporting behavior change and meeting core psychological needs. In line with SCT, patients want technology that *harnesses the patients' strength of character and resolve in all parts of their life* and that *link "feeling better on dialysis" to becoming more involved in IDH prevention.* SDT's construct of relatedness was evident in the requirement of *collapsing distance between patients, peers, and family.* Autonomy, another SDT construct, was reflected in *respecting and supporting patients' individual needs, preferences, and choices.* Notably, meeting SDT's core psychological needs through technology design has been linked to usability experiences,[70] and with sustained use of health technologies.[71]

Dialysis patients desired design features that differ from those in prior patient-facing informatics interventions for safety. Previous interventions have involved medication reconciliation,[72] patient reporting of safety incidents,[73,74] online peer support groups,[4] and digital educational content such as animations.[27] In contrast, hemodialysis patients desired content focused on one-to-one interaction, goal setting, values clarification, patient stories, choice, and attainable challenges. IDH is a complex treatment complication with multifaceted causes related to both patient and provider behaviors. Thus, patient involvement involves changing everyday health behaviors as well as working with providers to reduce IDH risk. Although unique, findings address previously-identified informatics opportunities to facilitate patient involvement in safety: use of behavior change theory and patient-peer support.[7]

Previous informatics interventions primarily focus on hospitalized patients. In contrast, hemodialysis is an outpatient therapy in which patients contribute significantly to their treatment outcomes. Study results therefore align with observations about differences between inpatient and outpatient safety, where the latter requires more patient participation and attention to context.[75,76] Outpatient safety may be better understood through an injury prevention, rather than the error prevention lens that dominates inpatient safety efforts.[75] Injury prevention involves attention to pre-, during, and post-event periods (eg, between and during dialysis sessions), as well as patient, agent (eg, fluid removal by dialysis machines), and context (eg, dialysis care, family). Such a framework may be better

Table 4. Design principles and Recommendations Themes 3 and 4

• Theme 3: Respecting and supporting patients' individual needs, preferences, and choices • (Self-Determination Theory: Autonomy)	Principle 3: Designing for individual choice and initiative	*Recommendation 3a: Providing alternate sources of information*	• "I think that [having a computer] would be good because like I say, I see people just go away and just doing their thing on the computer and find out more things than regular [treatment] options." (FY-M3) • ". . . [it would be good] having somebody, having other sources that we can go to. . . [peer mentors] may have more simple information rather than the high-tech, medical information." (FY-W3) • "[Computers provide] freedom to explore stuff." (FY-M31)
		Recommendation 3b: Individualizing information	"Are you suggesting that as a flat number [daily fluid restriction] for everybody? Maybe it could be whatever your number is, you have a container with that amount. That would vary quite a bit." (Patient-FG5-P5)
		Recommendation 3c: Choices of topics and goals	• ". . .what would I like to see on the screen and what would the topic be. The topic would be more of my health. You know, that's what I would like to discuss with them, so that's what the topic would be. . .I was thinking that there would be a survey for them that they could fill out of which items that they're concerned about." (Patient-FG1-P4) • "[Regarding goal setting options] How about a blank where you can just fill in whatever it is that pertains to you if it's not on the list? I would prefer to type it. . ." (Patient-FG1-P5)
		Recommendation 3d: Hierarchical navigation preferred over linear navigation	• "I like the second version because you have your different categories. If you don't have higher or low blood pressure, you don't want to bother learning about that, you can go directly to the courses that interest you first." (Patient-FG1:1-P5) • "You're not forced to do anything. It's just a choice, I guess. . .I was in love with [prototype] A until I saw B and I was like 'what?' It went straight to it." (Patient-FG1:1-P2)
		Recommendation 3e: Choice of interaction formats	• "I'd also like to probably put some text box on the bottom, that way you can type in responses or communication back and forth just in case the users didn't want to do a video chat. . ." (Patient-FG4-P2)

(continued)

			• "In manipulating this, can you make the text bigger? Like it says, working with your dialysis care team, and then this paragraph is rather small underneath it. Can you enlarge that or no? . . . If you're on the internet and you want to make something larger you just spread your fingers and it goes larger." (Patient-FG2-P5)
• Theme 4: Feeling better on dialysis • (Socio-Cognitive Theory: Goals and outcome expectations)	Principle 4: Designing for comprehension of connections and of possible actions	*Recommendation 4a: Linking behaviors to experiences of positive and negative outcomes*	• "If you can make it personal to them about the impact of [leaving dialysis early], that would hit home. . .better. It's 1 thing to talk about statistics. . .but if you can talk about how it impacts on their daily life, short term and long term, that might get them more involved." (Patient-FG5-P5) • "It would have a picture of somebody in their chair with a dialysis machine, and then above it, 'How to have a great run on dialysis' or some other similar title on that, where it's just a clickable image. Then it would take them to the example of an actual patient describing their runs on dialysis, or how they improve their runs on dialysis." (Patient-FG5-P3) • "My thought was having a picture of a person running, like you're moving from this terrible dialysis thing. And maybe picture somebody in the chair with a better expression or something like that. Then have a heading of a better runs overview. . ..and then this would be a button you can click on to open that up. And then, going down for diet, medication, exercise. And then have testimonials with a picture of a patient. . .and then online resources. . .." (Patient-FG3-P3)
		Recommendation 4b: Learning to identify and manage treatment complications during hemodialysis	• "Explain to them how it feels like when your blood pressure drops. . . and what they could expect to feel if they're getting cramps and how to respond. Be vocal, raise your hand, shout, or whatever you've gotta do to get people's attention so you don't suffer through more than you have to." (Patient-FG5-P4) • "[When cramping] some [staff] will come and let you push your, put pressure on their thighs. . .. It helps." (Site3-W6)

(continued)

Recommendation 4c: Education to support patient involvement	• "I think it's really important that patients are educated that they are the left of the treatment. . .if it's not doing what it's supposed to do, they are to question that and do something about it." (Patient-FG6-P3) • "How to. . .ask questions of the doctor or the nurse practitioner, whoever's at the left-remind them that. . . you can ask anything you want and you can refuse if you don't like it." (Patient-FG4-P1) • "I specifically appreciated the module that encouraged the patient to have a voice, and to have their treatment more person-lefted, and be able to discuss their concerns with their medical team." (Patient-FG6-P1)

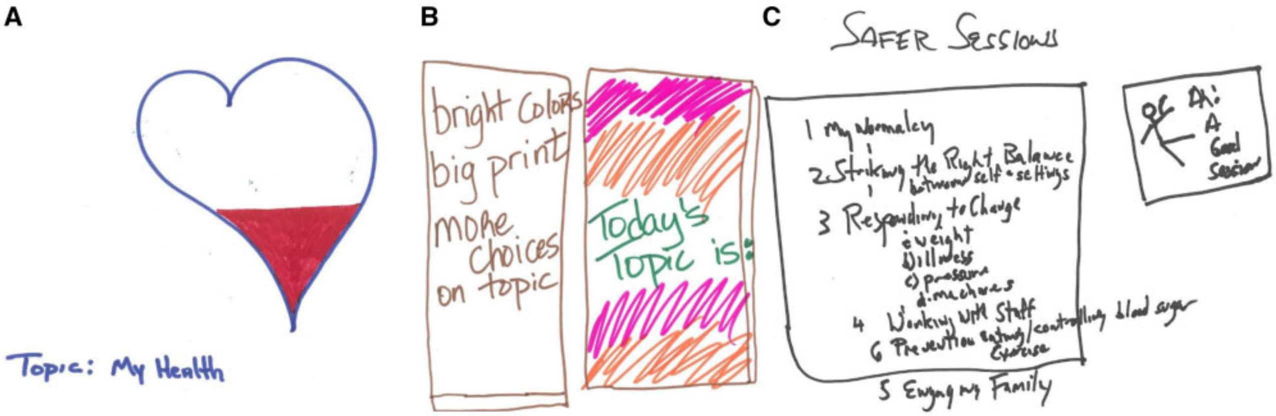


Figure 5. Patient-FG1-P4 drawing showing "My Health" as an important topic to discuss with mentors (Panel A). Or Patient-FG1-P7 showing choices of topics and goals (Panel B). Patient drawing showing topics important for having safer sessions (Panel C).

suited to hemodialysis care than predominant models. Given gaps in understanding of optimal outpatient safety interventions, the insight presented here offers a basis for future work leveraging patient participation.

Study results also advance understanding of design of informatics interventions for hemodialysis patients. Prior research has evaluated group-based online peer mentoring for young adults on hemodialysis,[77,78] and information seeking and use in clinic settings and online patient communities for dialysis patients.[79–81] However, it has not identified the *meaning* of intervention design choices for patients, and how these link to experiences of ESRD- and treatment-related constraints, complications, and health challenges. Thus, findings offer new resources for informaticists to cultivate empathy toward this group; critically, empathy is a key feature in successful technology design, especially across differences in needs and beliefs.[82,83] Accordingly, findings offer broader guidance for future design for this group. This is important in itself, since hemodialysis patients have an annual mortality rate of 16.6%,[84] and suffer low quality of life,[85] pain, fatigue, social restrictions, and distress.[86–89] Additionally, the leading causes of ESRD in the US are diabetes and hypertension.[84] Cardiovascular disease is also common: 40% of dialysis patients have had heart failure.[90] Design recommendations herein may thus have relevance for engaging patients with multiple chronic conditions.

This study also contributes a novel approach to translating behavioral science theory into design principles. Use of theory in designing patient-facing technologies is increasing; however, there is a lack of guidance for implementing behavior change theories in specific interventions. Techniques, such as intervention mapping,[91] have been proposed but do not specifically consider technology. The present approach sequentially mixes observational research with design research, producing findings that identify how theoretical constructs are meaningful in dialysis patients' lives and link to preferences regarding content and functionality, as well as user interface characteristics such as navigation, interaction design, and sensory design.[92] As a next step in the design process, Figure 6 shows a model developed specifically for this intervention based on the present research. The model links the design principles and recommendations to psychosocial and behavioral outcomes. Following Cole-Lewis and colleagues' distinctions concerning engagement,[93]

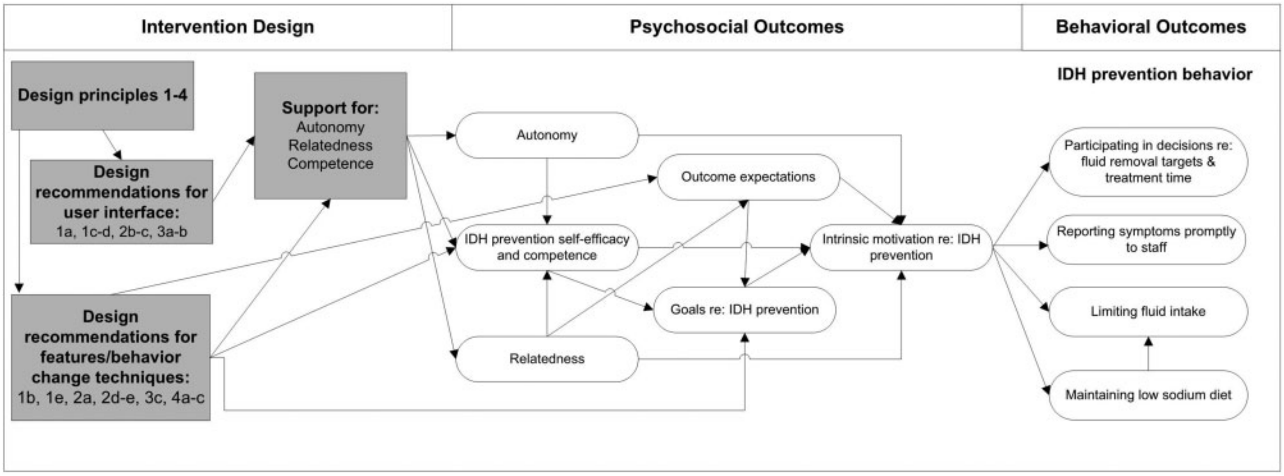


Figure 6. Conceptual model for patient intervention linking design principles and recommendations to psychosocial and behavioral outcomes.

the model partitions the recommendations based on those primarily focused on the user interface (eg, colors, flower and garden motifs) from behavior change techniques (BCTs, eg, encouragement to build confidence and hope).[94] BCTs, which may be features of an informatics intervention, are the "smallest component parts of widely used theories of health behavior."[93] In the context of the present intervention, BCTs align with the SCT and SDT constructs that emerged in the present study (Table 3, Table 4). Additionally, SDT's key mechanisms of intrinsic motivation and "support for" SDT's autonomy, relatedness, and competence are included in the model.[95] Posited relationships in the model between constructs are drawn from previous theoretical literature.[95,96] As a next step, there is a need for validation of this model to determine whether the intervention is functioning as intended; that is, whether elements of the user interface do indeed engender experiences of relatedness, competence and autonomy, and whether features/behavior change techniques actually have an impact on patient self-efficacy, outcome expectations, and goals. Once the intervention is deployed, this can be accomplished through assessment of exposure to the intervention (eg, interactions with user interface components and features/BCTs measures by digital trace data) and potential impacts on psychosocial outcomes (measured by surveys) and behavior (measured by surveys and clinical data, such as interdialytic weight gain).[93] Approaches that compare data gathered from these sources to hypotheses generated from this a priori model can advance understanding of relationships between intervention design decisions, health behavior, and its determinants.[93] Overall, this approach provides an empirical basis for moving from theory to technology.

This study has several limitations. We conducted observations and interviews in a single state; other patterns may exist elsewhere. However, the focus groups drew participants from 4 US regions, suggesting broader generalizability. Findings reflect the priorities of hemodialysis patients, and IDH is a complex safety problem that may require more effort from patients than others. Therefore, the principles require validation, and possible extension, with other patient groups. Nine patients in the focus groups had previous experience as peer mentors; although this was essential to our study goals, these patients may be more sensitized to patient safety and more oriented toward care involvement than other hemodialysis patients. However, clinic-based observation and interviews yielded support for the study's themes in a sample without such experience. Study participants were also primarily White or African American; additional studies with greater participation of other groups with elevated rates of kidney disease are warranted; these include Hispanic/Latino, Native American/Alaska Native and Native Hawaiian/Pacific Islander people.

Findings have informed the design of a patient-facing informatics intervention designed on a tablet optimized for use as patients dialyze. This intervention will be evaluated in a pragmatic, cluster-randomized controlled trial in 28 hemodialysis facilities in 4 US regions. This trial will compare the impact of this patient-facing intervention with a provider-focused intervention that includes a tablet-based checklist[97] and team training on the primary outcome of IDH.

CONCLUSION

We identified 4 user requirements and design principles, all linked to SDT and SCT, relevant to the design of informatics interventions to facilitate patient safety involvement among hemodialysis patients. The resulting patient-facing intervention will soon be the subject of a comparative effectiveness trial.

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AUTHOR CONTRIBUTIONS

TV supervised the project and study design, TV designed data collection instruments for the observations and individual interviews, and LH designed focus group data collection instruments. TV, LH, and MA collected data, and LH conducted first-cycle data analysis. ZH designed ideas for the application and developed the application. MAW and TV conducted the literature review, analyzed data, developed the theoretical framework, and drafted the manuscript and revisions. RS, MA, JBG, SLK, BG, and KZ provided input into design of the study, substantive review, and final approval.

DATA AVAILABILITY STATEMENT

The data underlying this article cannot be shared publicly in order to preserve the privacy of individuals that participated in the study.

CONFLICT OF INTEREST STATEMENT

None declared.

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