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The future of patient and family engagement in quality and patient safety

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Published in
Frontiers in Health Services

ISSN 1664-8714
ISBN 978-2-8325-7457-7
DOI 10.3389/978-2-8325-7457-7

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The future of patient and family engagement in quality and patient safety

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Citation
O'Hara, J. K., Smith, K., eds. (2026). *The future of patient and family engagement in quality and patient safety*. Lausanne: Frontiers Media SA.
doi: 10.3389/978-2-8325-7457-7

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 30 October 2024
DOI 10.3389/frhs.2024.1439410

OPEN ACCESS

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RECEIVED 27 May 2024
ACCEPTED 15 October 2024
PUBLISHED 30 October 2024

CITATION
Istanboulian L, Gilding A, Hamilton L, Master T, Bingler S, Hill M, Isani S, Kazi S, Coppinger S and Smith K (2024) Reported roles of care partners in a specialized weaning centre—perspectives of patients, care partners, and health care providers.
Front. Health Serv. 4:1439410.
doi: 10.3389/frhs.2024.1439410

Reported roles of care partners in a specialized weaning centre—perspectives of patients, care partners, and health care providers

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Background: Care partners are individuals chosen by a person with an illness to support their care during hospitalization. Patients with persistent critical illness have longer than average critical care admission and often other conditions including dysphagia, communication vulnerability, severe physical deconditioning, the need for an artificial airway, and difficulty weaning from invasive mechanical ventilation. Family presence has been identified as important for patients experiencing persistent critical illness in specialized weaning centers. Despite this, the role of care partners in clinical settings for patients with persistent critical illness has not been fully characterized, particularly from the perspectives of patients, care partners, and health care providers. The aim of this study was to gain insights into the roles of care partners during persistent critical illness from the perspectives of patients, care partners, and health care providers.

Methods: We used qualitative descriptive methodology including semi-structured interviews and content analysis. Interviews were audio recorded and transcribed verbatim. Included participants ($n = 30$) were patient survivors ($n = 7$), care partners of patient survivors ($n = 9$), and professionally diverse health care providers ($n = 14$) of adult patients with persistent critical illness from two specialized units in one community academic hospital in Toronto, Canada.

Results: Participants across all groups described care partner roles that included physical, mental health, cognitive, social, and spiritual support of the patient, including the perceived role of safeguarding the multiple dimensions of care for the patient who is experiencing persistent critical care in specialized care settings.

Discussion: The results of this study are being used to co-design, implement, and evaluate a sustainable care partner program that is acceptable, appropriate, and feasible to implement in clinical settings where the care of patients with persistent critical illness occurs.

Reporting method: Consolidated criteria for reporting qualitative studies (COREQ).

KEYWORDS

patient engagement, care partners, persistent critical illness, safety, critical & intensive care

1 Introduction

A care partner is an individual (often a family member) chosen by a person with an illness to support their care (1). The roles care partners take on depend on the person's needs but can include helping the care team to better understand the person's needs and preferences, monitoring disease-specific signs and symptoms, supporting physical care including feeding, bathing, and mobility, and organizing follow up appointments and care in the community (1). Emerging policies and research for the integration of care partners in complex and acute care centres recognize the unique positioning of care partners (who are often family members) as sources of insight and resilience in supporting the care quality and safety (2, 3). Particularly as COVID-19 pandemic conditions changed family presence policies and visitor restrictions, the importance of defining care partners, with a role beyond that of a visitor, emerged (2, 4, 5). Recommended foundational preferences from Healthcare Excellence Canada for the inclusion of care partners in facilities include clearly differentiating them from visitors, recognizing their value, and ensuring they play a role in the development of policies pertaining to care partner programs (2). The COVID-19 pandemic and research emerging during, and since, has illuminated the critical work of family members in protecting the safety of vulnerable patients who are more likely to experience safety gaps in their care (6).

An understudied patient population who experience significant health vulnerabilities and risks to safety both during and post-hospitalization are those with longer than usual intensive care unit (ICU) admissions, otherwise known as persistent critical illness. Up to 10% of patients in ICU experience persistent critical illness (7). Patients with persistent critical illness experience organ dysfunction, prolonged dependence on mechanical ventilation, and the need for tracheostomy (7). In regions where they are available, patients with persistent critical illness are often admitted to specialized weaning centres (8–10). Family presence has consistently been identified as important for patients experiencing persistent critical illness in specialized weaning center, however the specific ways in which they support patient care and safety is not yet clear (10–12). Furthermore, a scoping review of patient and family involvement in ICU identified research gaps including limited understanding of the bidirectional implications between patient and family involvement and the interprofessional team (13).

Although we know patients, family, and health care providers report the importance of family presence for patients experiencing persistent critical illness, little is known about the perception of the care partner role from the perspectives of patients, care partners, and health care providers. A fulsome understanding of the roles that care partners take on during persistent critical illness can therefore help improve how teams and policies can support their work, and ensure policies include their unique perspectives, and improve patient care quality and safety. This research will contribute to a body of knowledge that will aid care partner program design, implementation, evaluation, and potential spread. Thus, the primary aim of this study was to gain insights from the lived experiences of patients, care partners, and health care providers about the roles of care partners during persistent critical illness. The secondary aim was to compare care partner role descriptions between participant stakeholders.

2 Methods

2.1 Design

We conducted a qualitative descriptive study including the use of semi-structured interviews to understand care partner roles through participants' descriptions and use this knowledge to improve programs (14, 15).

2.2 Study setting

The study was conducted at a large, 500-bed, urban Community Academic Hospital located in Toronto, Canada. This setting has two units where patients with persistent critical illness are managed, including an eight-bed adult specialized weaning program that is set within an acute inpatient respiratory ward and a six-bed adult long-stay ICU program that is set within a medical surgical ICU. Both units have diverse multiprofessional care team members, including intensivists (i.e., medical physicians with critical care speciality), respirologists, nurse practitioners, and nursing and allied care. Both programs also admit ICU patients from external hospitals across Ontario.

2.3 Participants & sampling

We used a multi-modal and convenience recruitment strategy including the use of study posters, announcements at unit huddles, and members from patient and care partner circles of care identifying potential participants. Of all the potential patient and care partner participants approached, only two did not participate due to medical instability. Recruitment continued until we perceived our recruitment targets were met in terms of variation in participant characteristics, meaning that we had recruited sufficiently from the diverse professional body in both units, and as many patient and care partners as we were able to during the study period. We stopped recruitment when we felt we had understood the roles of care partners and had achieved sufficient information power for the relatively narrowly focused study aim and the specificity of our study participants (16).

2.4 Inclusion/exclusion criteria

Inclusion criteria for patient participants comprised (1) 18 years or older; (2) currently admitted to or recently discharged from the study setting (within 1 year, or longer if able to recall experiences); (3) medically stable according to medical provider; (4) able to communicate by some means (e.g., gestures, augmentative or alternative communication, phonation); (5) some English speaking at minimum; (6) able to provide informed consent (i.e., able to understand and appreciate the consequences of their decision to participate or not participate in the study).

Inclusion criteria for care partners comprised (1) 18 years or older; (2) a formal care partner (identified as a person who has a designated role for the patient, beyond that of a visitor) of a patient who is currently admitted to or was recently discharged from the study setting (within 1 year or longer if able to recall experiences); (3) able to provide informed consent (i.e., able to understand and appreciate the consequences of their decision to participate or not participate in the study), and able to speak some English. All care partner participants played active roles in the care of patients in the programs. care partners were only approached for recruitment if their related patient agreed.

Inclusion criteria for health care providers comprised only that they were employed at the study setting in the past year and had some experience working with care partners. There was no exclusion criteria for health care providers.

2.5 Data collection

Following informed consent, some members of the research team (LI/SB/TM/AG) conducted interviews using a semi-structured interview guide (See Supplementary Material S1) developed iteratively by the full research team. During the first two interviews we reviewed findings which confirmed no changes to the interview guide were required. Demographic information was collected at the time of the interview. Interviews were conducted in person with 17 (57%) participants, over the phone with 7 (23%) participants, or by using a videoconferencing platform (i.e., Zoom) with 6 (20%) participants according to their preference and availability. Interviews were between 20 and 62 min long (average 40 min), digitally recorded, and transcribed verbatim and coded using NVIVO (Version 14, Lumivero, Denver, CO). No repeat interviews were conducted. All patient and care partner participants were offered to have interviews conducted individually or in dyads, and therefore, 12 (75%) individual interviews were done, and 2 (4 participants, 25%) interviews were conducted as dyads per the preference of the participants. Preliminary discussions were used to establish a relationship with each participant and comfort with the subject area. Some participants were previously known to the interviewers. Notes were made on participant reactions to questions, responses, meaningful pauses, and reflections not otherwise captured by the digital recording or transcription.

2.6 Data analysis and reflexivity

Data analysis employed a team-based directed inductive content approach (17). Inductive content analysis included four distinct stages: (1) Decontextualization (meaning units identified (2) Recontextualization (including the content, whereby the meaning units were compared with the original data), (3). Categorization (where we identified convergences and divergences in the subcategorization and subjects), and 4. Complication (where we drew conclusions from the overall categories and sub-categories, including comparing across groups) (17). Throughout the process we worked in pairs to iteratively create and define categories. The team met regularly to compare findings, discuss and revise definitions, and to develop sub-categories within the main codes that comprehensively described the participant reported care partner roles.

The research team has extensive experience working with patients and family experiencing persistent critical illness and engaged in reflexive discussions during the data collection period and analysis. LI, SB, TM, and AG all work at the study setting and conducted the interviews. LI is a Nurse Practitioner, SB is a nurse and works in the Patient Relations Department, TM is a clinical educator, and AG works at the study setting as a research student. Three interviewers identify as women, and one as a man, and all have experience with semi-structured interview methods. Through reflexive group discussion we were able to discuss the interview transcripts, quotes, and contextual nuances of the roles described. These reflexive sessions between and at the conclusion of the interviews helped the team consolidate the main and sub-categories and compare results across the various participant groups.

2.7 Ethical considerations

Ethics approval was obtained from Michael Garron Hospital (883-2211-Mis-391) and Toronto Metropolitan University (REB 2023-357). Informed written consent was obtained ahead of the interview with assent audio-recorded before the interview commenced. Participants were coded by a number on the transcripts [e.g., HCP 001, Patient 002, or CP (for care partner) 003, etc.] to preserve anonymity.

2.8 Rigor

In accordance with recommendations for transparent and comprehensive reporting, we used the Consolidated Criteria for Reporting Qualitative Research guidelines to describe our methods and findings (18). To enhance the credibility and trustworthiness of the analysis a code book (See Supplementary Material S2 for final code definitions) and audit trail were created (19, 20).

3 Results

3.1 Participant characteristics

We recruited 30 participants (Table 1). Of these, 7 (23%) were patients, 9 (30%) were care partners, and 14 (47%) were health care providers. Participants were diverse in terms of self-identified gender, relationship to the patient, and professional role in the setting.

TABLE 1 Participant demographics ($N = 30$).

Participant	Demographics	Category	n (%)
Patient			7 (23)
	Gender	Woman	3 (42)
		Man	4 (58)
	Age	Years (mean, sd)	61.3 (14.7)
	Race	Caucasian	6 (86)
		Asian	1 (14)
Care Partner			9 (30)
	Gender	Woman	7 (78)
		Man	2 (22)
	Age	Years (mean, sd)	59 (13.7)
	Relationship	Partner/spouse	5 (56)
		Child	2 (22)
		Parent	2 (22)
	Race	Caucasian	7 (78)
		Asian	2 (22)
Health care provider			14 (47)
	Gender	Woman	10 (71)
		Man	4 (29)
	Age	Years (mean, sd)	44.9 (11.4)
	Race	Caucasian	9 (64)
		Asian	3 (21)
		Black	2 (14)
	Profession	Nurse	5 (36)
		Speech Language	2 (14)
		Physician	2 (14)
		Social Worker	2 (7)
		Physiotherapist	1 (7)
		Occupational Therapist	1 (7)
		Respiratory Therapist	1 (7)

TABLE 2 Reported roles of care partners as reported by patients, care partners, and health care provider participants.

	Patients	Care partners	Health care provider
Physical	Personal care and physical therapy	Personal care and physical therapy	Personal care and physical therapy
	Safety and surveillance	Safety and surveillance	Safety and surveillance
	Access to outside	Access to outside	Access to outside
	Access to equipment and food from home		
			Care planning and continuity of care
Mental health	Encouragement	Encouragement	Encouragement
	Emotional support	Emotional support	Emotional support
Social	Companionship	Companionship	Companionship
	Gatekeeping	Gatekeeping	Gatekeeping
	Sense of community	Sense of community	
Cognitive	Health literacy, decision making, advocacy	Health literacy, decision making, advocacy	Health literacy, decision making, advocacy
	Communication support	Communication support	Communication support
			Information transfer
			Delirium management and prevention
Spiritual	Normalcy	Normalcy	Normalcy
	Support values	Support values	Support values
	Manage outside life		

3.2 Reported roles

Patients, care partners, and health care providers reported a wide range of activities that care partners performed in support of the patient experiencing persistent critical illness (Table 2 and Supplementary Material S3 for additional quotes). Although there were some commonalities in participants' descriptions of the actions or roles of care partners, there were also some roles uniquely reported by some participant groups but not by others. Reflexive discussion of the coding categories led to our research team categorizing the support actions according to the type (i.e., physical, mental health, social, cognitive, and spiritual) of support provided, as this was the predominant way participants reported care partner roles. Health care providers additionally expressed that care partner roles vary from person to person and change over time with increasing comfort. The findings below are organized by the type of support provided to highlight convergences and divergences in care partner support roles during persistent critical illness.

3.2.1 Physical roles

Physical roles were defined as roles and actions care partners took to support the physical care, and physical safety of the patient. Physical roles were also ways the care partners enhanced physical access to the items or experiences that were needed or valued by the patient. Participants in this study described care partner physical roles in relation to 1. Personal care physical therapy, 2. Safety and surveillance, 3. Access to personal items and outside, and 4. Care planning and continuity of care.

3.2.1.1 Personal care and physical therapy

Patients, care partners, and health care provider participants all described physical care roles for care partners. These roles included hair washing, body-care, assisting with activities of daily living, and physical therapy. Patients and care partners also reported physical care activities that included touch such as massage. Participants from all three groups reported that care partner physical care "supplemented the care" provided by nurses and other members of the health care team (HCP 005) and was important because health care providers do not always "have the manpower" (HCP 009) to manage all patient care needs in a timely manner. Both patient and care partner participants noted this facilitating role.

> "Let's be honest, I guess if it's busy, are we going to wait out an hour for a nurse? [Be]cause my mom's going to help me put my pants on." (Patient 005)

> "So, I said probably instead of waiting for the nurse to put the food, you know, the feed. Yeah, probably I can do that." (CP 007)

The critical importance of providing physical care beyond what the health care team was able to provide was emphasized by one care partner, who stated:

> "I think had we not been there pushing him to get into his chair, communicating with him, I think he would be in worse shape than he is." (CP 006)

3.2.1.2 Safety and surveillance

Patients, care partners, and health care providers emphatically described the role care partners played in supporting the safety of patients through surveillance of the patient and their surroundings. From the patient's perspective, this included double-checking medications, scheduling tests, and ensuring continuity of care.

> "She was so diligent about checking the meds, checking with doctors and nurses and making sure that the delivery of health care was exceptional from the hospital." (Patient 001)

Similarly, one care partner reported:

> "The only thing that I said yesterday is that many, many times I saw the call bell unplugged and asked why is that?" (CP 007)

This quote emphases the safety surveillance role that care partners play in assessing the physical environment. Care partners detect and report fractures in care and protocols (e.g., having call bells plugged in and at the bedside) that are meant to keep patients safe.

Several health care providers described the roles care partner played in maintaining the safety of patients in these settings. One health care provider summarized many aspects of this role, stating,

> "And there's more than that, as well. So, I've also seen them, for example, draw attention to issues to the medical care team about changes in a patient's condition, about things from changes in respiratory rate, agitation, to a skin ulcer, for example, or things like that. So, they're also part of increasing the vigilance in the care of the patient, which I think is also critical." (HCP 012)

The vulnerability and medical fragility of these patients as they recover from critical illness demands an approach to care that includes care partners, particularly if they can detect and report issues as is described by the quote above.

3.2.1.3 Access to personal items and outside

Patients, care partners, and health care providers all reported that care partners often improved patient access to spaces outside their rooms, a significant role, given prolonged admissions in these settings for patients with persistent critical illness. One patient participant who had been in hospital for over a year stated:

> "They [care partner] would take me outside. I love the outdoors … I could smell the flowers and feel the fresh air. It was so nice." (Patient 008)

Only patient participants, however, reported that care partners provided access to personal equipment needed for therapy and care such as "footwear" (Patient 008) from home and even equipment from hospital clean utility rooms such as "urinals." (Patient 005). Patients also reported that once they were able to eat by mouth, care partners would bring in preferred food from home.

3.2.1.4 Care planning and continuity of care

Health care providers uniquely reported that care partners also played an integral role in care planning during the patients' admission, providing continuity of care, and transition support.

> "Because they're thinking ahead of us when we go home—'What does home look like—if we need to do this'. So, some will ask, 'Can you teach me how to do this?' And we'll walk them through certain things." (HCP 010)

And,

> "They're always included the care. So, it's nice to have the continuity of care, you know, what they were doing there." (HCP 006)

These statements highlight the value health care providers placed on the role of care partners in the planning and provision of safe care both during admission and during preparations for discharge planning and transition home.

3.2.2 Mental health roles

Mental health roles were defined as roles and actions care partners took to support the mental health wellness and experience of the patient. These roles included proactive (e.g., encouragement) and reactive (e.g., emotional support) actions towards the patient intended to support their emotional well-being. Participants in this study described care partner mental health roles in relation to providing 1. Encouragement, and 2. Emotional support.

3.2.2.1 Encouragement

Patients, care partners, and health care providers ubiquitously reported the supportive role that care partners played in providing patients with encouragement and motivation. One patient participant called his care partner his "greatest champion" (Patient 007), and another who stated,

> "Sure, it helped me. I can't explain to you, but when she was beside me, I felt better. Encouraging me, saying you're ok, you're not sick. You're coming home. [She] made me feel hopeful." (Patient 004)

With the prolonged and uncertain course of persistent critical illness, care partners also provided encouragement and hope for recovery. For example, one care partner participant said:

> "I think that emotionally, I think I helped her just to understand sometimes what was going on and just to constantly help her to stay hopeful." (CP 009)

Health care providers similarly reported:

> "They're the encouragement and the cheerleaders in order to keep them going through everything." (HCP 003)

3.2.2.2 Emotional support

Patients, care partners, and health care providers also described multiple ways in which care partners provided emotional support to patients with persistent critical illness. Distinct from visitors, who were also described as important to patients, care partners were the people with whom patients could share their concerns and fears with.

> "My [care partner] was a real source of emotional support and strength in that with … [them] I could vent or discuss things that I needed to get off my chest that you might not feel comfortable with a friend or visitor." (Patient 005)

Care partners described the importance of supporting patients by protecting their "emotional well-being" (CP 011) and reducing anxiety.

> "And look, my daughter probably didn't want to know as much as I did, but I would use what I knew to reassure her, give her hope, help her not to be anxious." (CP 009)

Like care partners, health care providers emphasized the importance of care partners in reducing patient anxiety, particularly in advancing ventilation weaning trial times or time sitting up in a chair.

> "The family members that are there help with their, with their trials, or reducing anxiety or fear or whatever." (HCP 009)

Other health care providers described a more ambiguous but no less important role care partners play emotionally supporting patients with persistent critical illness,

> "So, they are critical in ensuring that our patients' mental health is well supported. And that's a role that unfortunately, nobody else in the hospital can do. There's only so many antidepressants you can give somebody. So, I think they're critical in all of those aspects." (HCP 012)

This statement emphasizes the potentially complementary and uniquely suited role of care partners to pharmaceutical agents in managing mental health needs of patients with persistent critical illness.

3.2.3 Social role

Social roles were defined as roles and actions care partners took to support and manage the social needs and situation of the patient. Participants in this study described social roles of care partners in relation to 1. Providing companionship, 2. Creating a sense of community, and 3. Acting as gatekeepers.

3.2.3.1 Providing companionship

Patients and family both reported that a key role of care partners was to provide company and companionship during admission, particularly important for these patients with longer than normal lengths of stay. One patient participant aptly described this, stating,

> "It's nice when you have somebody to talk to and it helps to have someone to talk to because you stay so long in the hospital. It was like our home. Same thing, you know what I mean." (Patient 003)

Health care providers empathically described the role of care partners in protecting patients with prolonged admissions from social isolation.

> "I think it's very important to have people [at the] bedside—family members or friends. Because it can get really lonely in the hospital when you're alone." (HCP 009)

3.2.3.2 Creating a sense of community

Patient and family participants were particularly attuned to the impact that the regular presence of care partners in the care setting had on creating a sense of community for patients with persistent critical illness.

> "Yeah, but she knew about them [the staff] because I would talk about them. I could say so and so came and did physio with me or so and so came and gave me a bed bath and she knew who they were." (Patient 008)

Her care partner also noted the impact of her regular presence on the unit, and knowledge of the staff, stating,

> "And I think the fact that. I knew team members as well. I think I could speak to people because I came to know them, and they came to know me. And I think as I felt more comfortable, it helped her to feel more comfortable. She started to feel at home." (CP 009)

The displacement of patients from their homes due to prolonged admission put them at risk for social isolation, mitigated in part by care partner companionship and the sense of belonging and community created through social connections shared between patients, care partner, and health care providers.

3.2.3.3 Acting as gatekeepers

Patients, care partners, and health care providers all reported the role care partners played in monitoring and regulating would-be and actual visitors. In many cases, care partners would be the ones who took on the responsibility of restricting visitors if they were unwell or if the patient was fatigued. On this, one patient reported:

> "She does all my dirty work telling my friends to stay away when I don't have the heart to do it." (Patient 013)

And both care partners and health care providers similarly stated:

> "But the same goes with company and visitors. If someone wants to come, everybody has been very good and they will always reach out and say, can we come over? It's up to you if you don't feel like it. No one's feelings are going to be hurt. You need to be proactive. So that's where I feel like I'm stepping up and like, okay, I'll be the bulldog. You know." (CP 012)

And,

> "They are also the gatekeeper for visitors, they know who comes to visit and when they know they control those people who come to visit them." (HCP 005)

3.2.4 Cognitive roles

Cognitive roles were defined as roles and actions care partners took to support cognitive needs of the patient including understanding and directing care, as well as receptive and expressive components of communication. Participants in this study described care partner cognitive roles in relation to providing 1. Health literacy, decision making, advocacy, 2, Communication support, 3. Health information management, and 4. Delirium management and prevention.

3.2.4.1 Health literacy, decision making, advocacy

Participants from all stakeholder groups reported that a key role of care partners in this clinical setting was to support patient decision making. During acute critical illness this role more commonly falls to the substitute decision maker or power of attorney if one is appointed. During persistent critical illness, patient level of consciousness is improved, and at worse fluctuates. This makes the role of supporting decision making more complicated, but still an important one to consider when considering the role of care partner. One patient, who was unable to vocalize at the time of the interview, wrote:

> "[writes] [My care partner] talks to the doctors and nurse practitioner to get updates while I'm half-awake most of the time. He is my voice and my medical advocate." (Patient 010)

Similarly, a care partner explained:

> "And sometimes I would just explain a little bit of what they mean. The physicians were pretty good at explaining and [the nurse practitioner was] always good at sort of interpreting what they said for us. I also did that for her sometimes, and I think that also helped her. She's also actually kind of a shy person and not one to always speak up for herself." (Family 009)

Health care providers described another dimension of decision-making support and advocacy from the care partner resulting from their knowledge of the patient and the continuity of their care role over a prolonged period and settings. One health care provider described this role like this,

> "They will, you know, advocate like say, the patient, you know, doesn't want to take a certain medication at this time, maybe, because it makes them you know, like, the side effects aren't too good for them. So, they will ask us if we can, you know, like, hold it, or reschedule it, or talk to the doctor about changing it." (HCP 001)

3.2.4.2 Communication support

Related to decision making and advocacy, most participants across all groups reported the role care partners play in supporting patient communication. Patients focussed heavily on the expressive components of communication. For example, one participant emphasized the vulnerability felt by patients with communication disability during persistent critical illness.

> "And I think also when you're a patient you can't especially because while I had trouble speaking and so you can't really advocate for yourself very well. And even if you can speak, every patient is different, but you're in a vulnerable situation." (Patient 008)

Care partners similarly described the role they played interpreting the communication attempts made by patients and 'speaking for' their loved ones.

> "And I also found that when my husband couldn't communicate either because he was on a ventilator, he had been trached before he came here. But even with the trach, he couldn't, you know, talk, but you could at least see his lips move. You know, you're really going to need that care partner to help interpret and speak for the patient, because they, in many cases, will not be able to do that for themselves." (CP 002)

Health care providers shared this view as well, reinforcing the importance of the role care partners play in communication support for patients experiencing persistent critical illness. One health care provider stated,

> "And they are also the voice of the patient. And then often patients are not able to speak for themselves, or able to navigate the system because of everything that they're dealing with from a health-related standpoint." (HCP 012)

3.2.4.3 Information management

Health care providers described two additional dimensions of cognitive support of care partners including information management. Again, due to the protracted illness and length of stay, and impact on patient cognition and memory, care partners had information related to medical history that were not in the patient chart but are important to safety.

> "Then again, they might know certain things about the patient's personality, care needs. Physical medical history, things that would, you know, play a role in the patient's health and safety." (HCP 002)

3.2.4.4 Delirium management and prevention

Health care providers also uniquely described the role care partners play in "orienting" (HCP 005) patients experiencing persistent critical illness, and the mitigating effect of their presence and activities on delirium. For example, one participant described how care partners can supplement the care team's role in orienting patients to a daily calendar or other "cognitive stimulating activities" (HCP 014).

3.2.5 Spiritual roles

Spiritual roles were defined as roles and actions care partners took to support and manage the spiritual care of the patient, including their quality of life and definition of self in relation to others. Participants in this study described spiritual roles of care partners in relation to supporting (1) Normalcy, (2) Supporting values, and (3) Managing outside life.

3.2.5.1 Normalcy

All groups reported the care partners role in supporting a sense of normalcy for patients experiencing persistent critical illness. Prolonged institutionalization and shifts in identity for both the patient themselves and in relation to others experienced during persistent critical illness underscores this role as uniquely critical for care partners to fulfil. Patients, for example, described how important it was for them to hear about life outside of their current medical concerns.

> "It's huge … with everything that happened and everything that we're enduring there's enough heaviness going on, so it's nice to keep things light. It's nice. It's nice not to have the conversation be 90% so what did the doctor say, what did the nurse say, what did the physio say, are what did they say about next steps … Let's have some what's going on at home." (Patient 005)

Care partners in turn described how they preserved bonding activities with patients. For example, one care partner participant reported,

> "We've become very close. I love her very much. And, uh, I just try to be around and do little things every day, like foot rubs and hairdos and yeah, watching our favorite music videos and stuff like that." (Family 014)

Health care providers described the ways in which care partners would alter the physical environment to reflect the individual patient, integrating personal elements such as family photos and cards.

3.2.5.2 Supporting values

In the same way that supporting a sense of normalcy was achieved by conversation and activities with care partners, patients described that these acts also reflected and supported their values, which they found protective and encouraging. To illustrate this, one patient reported,

> "I suffered vision loss. And I couldn't really even hold a book, so they would read to me. That was so helpful. She brought me some drawings that people, my nieces, and nephews had done, and she would tape them to the wall. And I could look at them and be encouraged just by looking at them." (Patient 008)

The importance of sharing with the care team who the person is, and what they value was reported by care partners, implying a state of departure from what the person was 'like' and how they are as they slowly recover from persistent critical illness. One family member described this role like this,

> "And so, you know, sort of trying to fill in some of this stuff about it to give you a more of a 360 view that when I say you, I'm telling the medical team that you do more of a 360 view of who this person is in the bed." (CP 002)

Beyond sharing values and protecting a sense of normalcy for the patient and relations, health care providers identified that prayer with the patient was for some an important role care partners played with patients experiencing persistent critical illness, especially for "patients that have very strong faith." (HCP 007)

3.2.5.3 Managing outside life

Only patient participants described the role care partners played in managing their outside life. These included maintaining domestic and financial responsibilities that patients themselves were unable to access while institutionalized, and usually voiceless.

> "They did a tonne for me. Like, can you run through this book, and you want to visit the bank? Can you get the set up for when I come home? And they're doing all that stuff." (Patient 005)

Preservation of normalcy, relations, values, and responsibilities outside of the hospital are all part of reported care partner supportive roles, and all potentially protect the identity of patients experiencing persistent critical illness.

4 Discussion

In this qualitative descriptive study aiming to describe care partner roles in clinical settings for adults experiencing persistent critical illness, activities supporting the physical, mental health, social, cognitive, and spiritual elements of care were reported by patients, care partners, and health care providers. Care partner roles that mitigate physical, mental health, social, and cognitive safety risks associated with persistent critical illness are discussed below, along with implications for policy, practice, and competency training.

Physical care roles such as hair washing, mobilization, and massage were among the most reported activities valued by care partners in this study. This is, perhaps, because they are the easiest to recognize and obvious to characterize as task-based actions. Supportive roles of family members at the bedside during weaning trials in the ICU have been long established and have been described by family to include acts of touch (both therapeutic and affectionate), talk (to the patient and health care team), and surveillance (interpretive and protective) (21). Similarly, a Swedish study of missed care in hospitals reported that basic care acts such as mobilization, turning, feeding, as well as health communication among the most reported care elements that were missed during inadequate staffing or urgent situations on the ward (22). Implications for missed care can include further deconditioning, skin breakdown and delays in recovery, making the work care partners do essential and physically protective for patients, particularly in high acuity clinical settings where the patient: nurse ratio is large. Thus, our results suggest the need for explicit role clarification including delineation of physical care actions that care partners are interested in and able to perform, as well as care partner training to be able to execute these roles competently and safely.

Reduction of anxiety and providing encouragement were reported as care partner roles supportive of mental health by participants in this study. Related to the emotional support provided by care partners, socially supportive roles beyond the social function of transient visitors were described. Although social isolation and living alone have been found to increase risk of hospital admission for respiratory disease, the experience of social isolation and loneliness during prolonged hospitalization and critical illness has not been well studied (23). A recent cohort study reported that social isolation before critical illness was associated with greater disability burden and higher mortality in the year following ICU admission (24). Happ et al. (21), reported persistent critical illness patients who had family present had significantly longer weaning trials than those without. The reported protective effect of the emotional and social roles of care partners during and post prolonged critical illness, though difficult to tease apart, is supported in this study with implications such as the need to reduce barriers for care partner to access and have sustainable contact with patients experiencing persistent critical illness. Furthermore, given the importance of care partner roles, a better understanding of the impact of being a care partners is needed.

Health care provider participants of this study reported that care partner roles are protective of patient cognition, and in particular, the experience delirium. A recent retrospective study of US adult ICU patients quantitatively reported a reduction in delirium duration in ICU with family presence or phone calls (25). Possibly related to the protective role of care partner on ICU delirium are the many ways in which they facilitate and support patient communication. In the cognitive domain, participants in this study also ubiquitously reported that care partners were not only the “voice” of patients when they were not awake enough to “speak” for themselves, but that they were able to interpret patient non-vocal messages and expression of needs better than anyone else because of their long-standing knowledge of the patient.

Care partners were also information brokers between patients and health care providers, which had great relevance and safety implications for patients with prolonged admissions and across multiple transitions. Family members have been known to be facilitators for patient communication during critical illness, a role sorely missed during peak visitor restrictions of the COVID-19 pandemic (26–28). Conceptualizing communication support through a safety framework for patients experiencing persistent critical illness may improve opportunities to identify and address contextual and individual level supportive interventions. Implications of these findings reinforce the need to support family presence during persistent critical illness, provide proactive and systematic communication competency training for both health care providers and care partners in these clinical settings, as well as integrate processes of care that take patient and family expertise and knowledge into account (12).

Given the breadth of the roles that care partners play in specialized clinical settings, and the multidimensional impacts on patient safety, recommendations include an urgent imperative to co-design and deploy supportive processes and policies to create sustainable care partner programs. Furthermore, an understanding of the impacts of care provision on care partners as well as implementation barriers and facilitators will strengthen the delivery of care partner programs in settings where patients with persistent critical illness are cared for.

5 Strengths and limitations

This study had several strengths and limitations. A strength of this study was that it included a sample of professionally diverse health care providers. It also included patients and families who were able to recall and describe their experiences with care partners during persistent critical illness. Another strength of this study was that it is the first the authors are aware of that explicitly aims to understand the roles of care partners during persistent critical illness and particularly from the perspectives of patients, care partners, and health care providers in specialized care settings.

Limitations include a self-selected sample and despite including a diverse range of participants across two hospital critical care units, the results of this single hospital study may not be generalizable to other organizations. Another limitation of this study is the self-selection bias of participants, which might limit reported experiences to include those of people with either very positive or very negative experiences. Also, as many of the participants were known to the principal investigator, we acknowledge that a limitation of this study might also include social desirability bias of participant responses.

6 Conclusion

In this descriptive qualitative study, we identified patient, care partners, and health care provider reported physical, mental health, cognitive, social, and spiritual roles of care partners that are protective of the safety of patients experiencing persistent critical illness. Findings from this study will contribute to the co-design, implementation, and evaluation of a formalized care partner program that is acceptable, appropriate, and feasible to implement in settings where the care of patients experiencing persistent critical illness.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by Toronto Metropolitan University Research Ethics Board and the Michael Garron Research Ethics Board. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

LI: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. AG: Data curation, Formal Analysis, Writing – review & editing. LH: Conceptualization, Formal Analysis, Funding acquisition, Methodology, Writing – review & editing. TM: Funding acquisition, Investigation, Writing – review & editing. SB: Funding acquisition, Investigation, Writing – review & editing. MH: Formal Analysis, Writing – review & editing. SI: Formal Analysis, Writing – review & editing. SK: Formal Analysis, Writing – review & editing. SC: Conceptualization, Formal Analysis, Funding acquisition, Methodology, Writing – review & editing. KS: Conceptualization, Formal Analysis, Funding acquisition, Methodology, Writing – original draft, Writing – review & editing.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article. This work is funded in part by the Michael Garron Hospital TD Health Community Solutions Fund (Grant #: 2022-06-RIC001) from the Michael Garron Hospital Foundation and Seed Funding from the Faculty of Community Services at Toronto Metropolitan University. Dr. Smith holds the Michael Garron Chair in Patient Oriented Research and is supported by the Michael Garron Hospital Foundation and the Agency for Healthcare Research and Quality (Grant: R18HS029356).

Acknowledgments

The authors wish to acknowledge the patients, care partner, and health care provider participants who shared their experiences with the research team.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2024.1439410/full#supplementary-material

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Frontiers in Health Services

TYPE Perspective
PUBLISHED 20 November 2024
DOI 10.3389/frhs.2024.1474149

OPEN ACCESS

EDITED BY
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RECEIVED 01 August 2024
ACCEPTED 31 October 2024
PUBLISHED 20 November 2024

CITATION
Sutton KM, Wyand S, Char CA and McCullers A (2024) Reimagining the approach for advancing maternal health equity through authentic patient engagement and research practices.
Front. Health Serv. 4:1474149.
doi: 10.3389/frhs.2024.1474149

Reimagining the approach for advancing maternal health equity through authentic patient engagement and research practices

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High maternal mortality and morbidity rates continue to significantly impact the United States, with Black birthing individuals being two to three times more likely to die from pregnancy related causes compared to other races. Ongoing discussions are crucial to improving care delivery and amplifying the experiences and needs of marginalized survivors of pregnancy-related psychological harm. Thus, this commentary leverages current literature and vignettes to deliver recommendations on authentically engaging patients in the cross-sectoral process of dismantling harmful clinical and research practices, thus building a safe, equitable future for maternal health.

KEYWORDS

maternal health, health equity, health disparity, patient engagement, research

Introduction

The United States (U.S.) faces a profound maternal health crisis, starkly illustrated by its disproportionately high Maternal Mortality Rates (MMRs), mainly affecting Black birthing individuals. Despite being a developed nation, the U.S. maternal mortality rate is the highest among its peers, exceeding that of countries like the United Kingdom, Australia, Spain, and Germany by a significant margin (1). In June 2022, The White House released a Blueprint for Addressing the Maternal Health Crisis, highlighting these alarming statistics and calling for urgent action to address systemic disparities (2).

A Centers for Disease Control and Prevention (CDC) study reported that Black birthing individuals were three times more likely than their white counterparts to experience maternal harm (3). This disparity widens with age, where Black-birthing individuals over 30 years old face four to five times higher mortality rates compared to white-birthing individuals (3). Moreover, MMRs have increased, and disparities have widened from 2018 to 2021 (4). A study analyzing vital registration and census data from across the U.S. revealed higher MMRs in 2019 among American Indian or Alaska Native (from 14.0 to 49.2 per 100,000 live births) and Black populations (from 26.7 to 55.4 per 100,000 live births) compared to Asian, Native Hawaiian, or Other Pacific Islander (from 9.6 to 20.9 per 100,000 live births), Hispanic (from 9.6 to 19.1 per 100,000 live births), and White populations (from 9.4 to 26.3 per 100,000 live births) (5).

Similarly, Severe Maternal Morbidity (SMM), including cardiovascular concerns, diabetes, bleeding, anemia, and depression and anxiety, follow similar trends as maternal mortality (6). A retrospective study examining hospital admissions in the United States from 2002 to 2014 revealed that Black birthing individuals in the United States have the highest proportion of SMM across all pregnancy intervals, experiencing a 70% greater risk of SMM during the antepartum period compared to white birthing individuals. In contrast, Hispanic birthing individuals exhibit a 19% lower risk during the postpartum period. These findings highlight varying racial and ethnic disparities in SMM types and timing, underscoring the need for targeted interventions and policies (7). In addition, a multistate retrospective cohort study analyzing data from 2015 to 2020 indicated that the rate of SMM has increased across all racial and ethnic groups, with disparities persisting and even widening (8). Black race, Hispanic ethnicity, and delivery at Black-serving delivery units independently and interactively increased the adjusted odds of experiencing SMM (8).

Disparities in SMM and MMR persist regardless of socioeconomic status, challenging the assumption that higher education or income levels provide protective benefits. A 2019 CDC report analyzing data from 2007 to 2016 found that college-educated Black birthing individuals faced a maternal mortality rate 5.2 times higher than their white counterparts of similar educational attainment (3). Additionally, a study in California found that Black mothers in the highest income brackets were twice as likely to die from childbirth than their White counterparts (9). These findings provide evidence that assumed "equalizing" factors such as income or socioeconomic fail to buffer the impact of racism, implicit bias, and other forms of injustice on maternal outcomes for Black birthing people.

Approximately 60% of maternal deaths and nearly 90% of SMM events are preventable (6). A national retrospective review found that the most frequent preventable factors of maternal morbidity were provider-related and/or system-related, including inadequately trained providers, misdiagnosis or failure to recognize high-risk status, and untimely or unsuitable treatment (10). These provider-related and system-related factors disproportionately affected Black birthing individuals. Given these realities—high rates of maternal harm, significantly elevated risks among Black birthing individuals, the preventability of most maternal harm incidents, and the frequent involvement of healthcare providers and systems—the issue transforms into a critical patient safety crisis. More precisely, it manifests as a maternal safety crisis that disproportionately impacts Black birthing individuals.

While morbidity and mortality rates capture part of the picture, they fail to encompass the enduring effects of maternal harm, which can significantly impact birthing individuals' future family planning, overall health, and ability to care for their families (10). Qualitative research has sought to amplify the mental health burden of maternal harm, with survivors of birthing trauma sharing testimonies about emotional wounds, fear, loneliness, disrupted relationships, and detachment from their infant (11–13). Media coverage, social media discussions, and documentaries frequently highlight maternal health disparities, further intensifying fear among Black birthing individuals. For example, the Hulu documentary "Aftershock," which highlights gripping stories of Black maternal mortality, makes information on health inequities and adverse birth outcomes more accessible to Black birthing individuals and may influence their perspectives on childbearing (14). Moreover, a Washington Post article entitled "For some Black birthing individuals, the fear of death shadows the joy of birth" highlights how awareness of these disparities overshadows what should be a joyful maternal experience (15). Findings from the Postpartum Mothers Mobile Study reveal that chronic concerns about racial discrimination in healthcare contribute to significant disparities in preterm birth rates between Black and White mothers (16). This underscores that racial discrimination within the healthcare system is not just a theoretical concern but a tangible source of stress for Black mothers, affecting their maternal health experiences.

For instance, meet Janine, who was pregnant with her first child and was admitted to the hospital due to experiencing symptoms of elevated blood pressure. During her hospital stay, Janine faced microaggressions, including assumptions that she was a single mother despite her husband Charles being present, unsolicited education about public benefits, and dismissal of her requests for information about her medication. Janine and Charles felt that the care she received was substandard and felt mistreated throughout the delivery of their baby boy. Although this was supposed to be the most exciting time for Janine and Charles, it turned out to be one of the most horrific experiences that still haunted them and affected their decision to have more children. Many stories similar to Janine's have occurred to Black birthing individuals and are independent of education and income level. Research on the psychological impact of traumatic perinatal experiences on birthing individuals and their families remains limited.

Discussion

Effectively addressing maternal psychological harm requires a holistic approach that integrates patient experience and perspectives into patient safety frameworks. While there are emerging frameworks that specifically provide strategies for improving maternal safety (17, 18), true equity in maternal health outcomes requires an "all hands" approach to maternal safety that employs not only maternal health leaders but also leaders across the spectrum of care provision, including health equity, mental health, and patient safety experts and advocates. Also, explicitly naming racism as a core determinant of maternal disparities should be regarded as a key priority in dismantling maternal inequities with a historically informed lens. Remedying the longstanding disenfranchisement, oppression, and injustice faced by communities harmed by structural racism goes beyond "acknowledgment." This work should extend to the confrontation of racist practices, such as implicit bias, that keep Black birthing individuals at disproportionate risk of maternal harm. Finally, recognizing and mitigating the psychological toll of racial discrimination and unequal treatment of Black birthing individuals within healthcare settings is essential for improving maternal health outcomes.

Therefore, our call to action for health service researchers is to center research on the lived experiences of patients and communities to understand the role of psychological harm. Approaches such as Community-Based Participatory Research (CBPR) exemplify how to engage patients and communities as equal partners, ensuring that research addresses their needs and priorities. Authentic engagement requires valuing and compensating patients for their expertise (19). Thoughtful integration of patient perspectives and experience is needed in (1) design, (2) process, (3) analysis, (4) implementation, and (5) evaluation. Models like Culturally Responsive and Equitable Evaluation (CREE) emphasize the importance of ongoing reflection and adaptation, ensuring research remains inclusive, culturally relevant, and responsive to patient feedback (20).

Incorporating mixed methods research—combining qualitative and quantitative approaches—advances understanding of the depth of patient experiences while also providing measurable evidence that can inform practice and policy. Mixed methods can reveal what is happening and why, offering a more comprehensive understanding of patient needs. Additionally, applying an intersectional lens is crucial, as it considers how overlapping identities such as race, gender, socioeconomic status, and disability shape patient experiences (21). This approach ensures that research captures the complexities of patients' lives, leading to more targeted and effective interventions.

Additionally, acknowledging and respecting the autonomy of birthing individuals is crucial for effective patient engagement in maternal health. Co-creating birthing plans is an effective strategy to enhance this engagement by aligning patient preferences with the care they receive. It is important to recognize that the successful implementation of birthing plans requires the active participation of patients and the support and respect of maternity healthcare professionals. These plans should be integrated into the care process in a way that reflects the individual's preferences and values while also considering the perspectives and expertise of the healthcare team. Ensuring that birthing plans are honored and adapted as needed throughout the care journey promotes a collaborative and respectful approach to maternal health care (22). Another tool to engage patients in maternal healthcare is text messaging to track depression and anxiety symptoms among birthing individuals (23). Though the approach could vary for different communities and patient populations, patient engagement and shared decision-making are central to the mission (24). It is important also to consider the broader factors, such as the availability of healthcare resources and the systemic barriers that affect access to care. By addressing these more significant issues, healthcare interventions can move beyond individual-level approaches, avoiding narratives that place undue blame on birthing individuals. This shift supports a more comprehensive strategy that

TABLE 1 Recommendations for action: amplifying voices in maternal health.

Recommend actions	For researchers	For healthcare facilities
1. Implement Authentic Patient Engagement and Shared Leadership * *Compensation for patients and community members for their time and insights is critical*	• Engage birthing individuals as co-leaders in research and safety initiatives. • Use focus groups, community advisory boards, and patient councils to gather insights and inform research. • Apply frameworks like Community-Based Participatory Research (CBPR) (14) or Patient-Centered Outcomes Research (PCOR) to ensure research addresses community needs (34).	• Establish patient advisory boards and integrate patient feedback directly into care protocols. • Train staff in active listening and culturally sensitive communication to ensure patient feedback leads to tangible changes in care delivery. • Implement shared decision-making models and collaborative care teams in healthcare systems
3. Enhance Communication and Trust-Building	• Study effective communication strategies that improve patient-provider relationships. • Develop interventions that address implicit biases and microaggressions.	• Foster a culture of trust by employing respectful communication strategies, affirming and culturally sensitive. • Use practices that affirm diverse experiences, such as active listening, maintaining eye contact, respectful acknowledgment of patient concerns, and family involvement in care discussions • Implement ongoing provider training to address implicit biases and microaggressions, ensuring equitable and empathetic care delivery.
3. Implementation of Tailored Birthing Plans	• Research best practices for co-creating birthing plans that align with cultural and individual needs. • Study barriers to implementing personalized birthing plans and explore strategies to enhance provider adherence to patient preferences.	• Encourage co-creating birthing plans that reflect individual values, cultural contexts, and medical needs. • Train healthcare providers to respect and adapt these plans throughout the care journey, upholding patient autonomy and promoting collaborative care.
5. Leverage Technology for Engagement	• Develop and evaluate digital tools, such as mobile apps and text messaging platforms, for tracking symptoms and collecting patient feedback. • Assess the effectiveness of these tools in improving patient-provider communication and care outcomes.	• Utilize technology to maintain ongoing patient communication, provide support, and gather real-time feedback on their experiences.
6. Monitor, Evaluate, and Measure Engagement Outcomes	• Routinely assess the impact of patient engagement strategies on maternal health outcomes using Culturally Responsive and Equitable Evaluation (CREE) principles (20). • Collect qualitative and quantitative data on how patient voices influence care quality and equity.	

recognizes the impact of social determinants of health on maternal mental health outcomes. Overall, these patient engagement strategies to advance maternal health equity (Table 1) include (1) a personalized approach- meeting birthing individuals where they are, (2) recognizing social drivers for care equity, (3) addressing holistic health, (4) clarifying and softening the experience of healthcare and, (5) instilling a sense of humility through warmth, connection, and representation (25).

Strategies such as meaningful patient engagement have proven influential in personal health decisions and scientific research, policy, and healthcare more broadly (26). This includes but is not limited to respecting and acknowledging the patient's perspective and using encouraging and affirming practices (27). Such practices include maintaining eye contact during patient interactions, acknowledging family members in attendance with the patient, and upholding strong empathy skills regarding the experiences and needs of patients of culturally diverse backgrounds (27). Previous research defines patient engagement as a collaborative effort involving patients, family members, and healthcare providers, where patients and their families actively participate in the healthcare team (22). The experiences of patients and their families play a crucial role in shaping healthcare delivery, and recognizing the diversity of these experiences is essential (28, 29). Not all birthing individuals share the same experiences, highlighting the need for personalized and inclusive approaches to care. Engaging patients and community members throughout the research process, from conceptualization to implementation, has become increasingly valued in healthcare settings, emphasizing their role as critical partners in improving health outcomes (30). However, the actual impact of patient engagement is not well known (30). Utilizing the AAMC Principles of Trustworthiness (31), we offer recommendations for incorporating and amplifying voices of birthing individuals into patient practice and safety. As scientists and clinicians, we are not the only experts. It is equally important for healthcare organizations to deem themselves worthy of the trust of birthing persons through intentional engagement and displays of humility.

We recognize that addressing challenges related to health disparities requires a multi-pronged approach, including national, regional, and individual-level solutions (32). Part of this approach is a nationwide commitment to ensure healthcare equitably through health insurance coverage, resource investment, public and clinical accountability, and adequately provisioned quality improvement strategies that engage patients (32). Additionally, we must develop and maintain community-based partnerships.

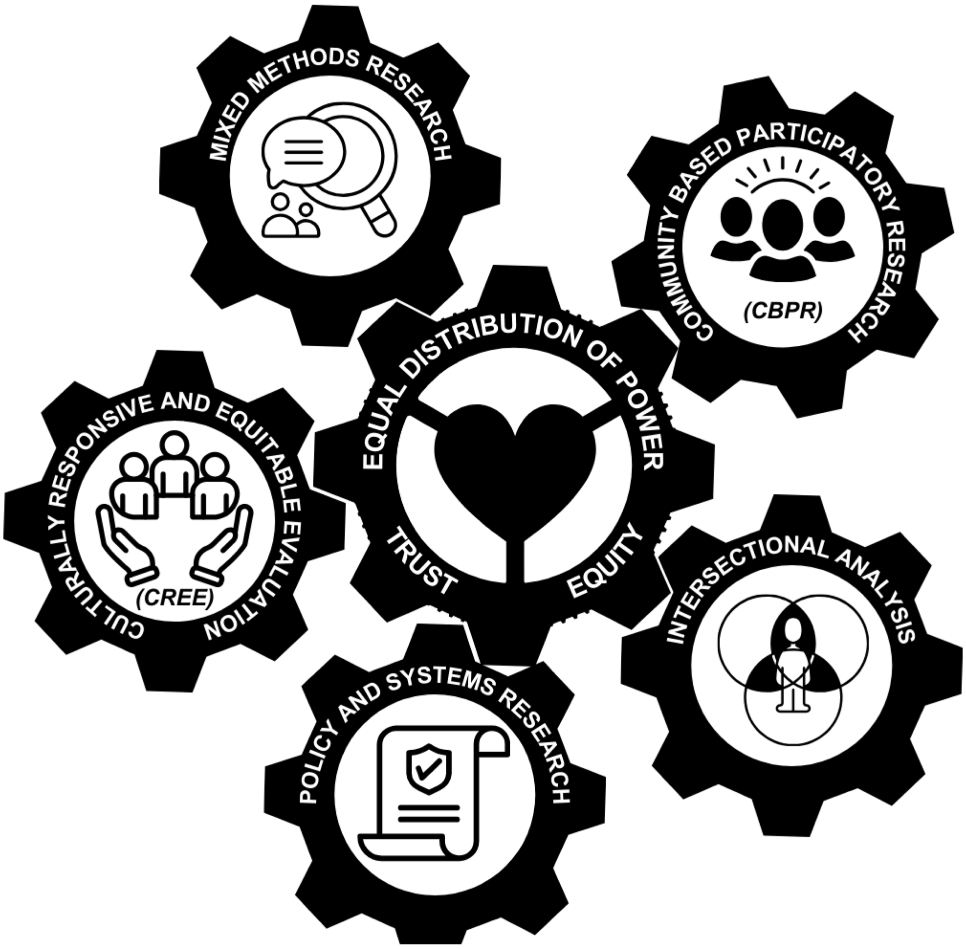

FIGURE 1
Conceptual framework for advancing maternal health research.

The emphasis on relationships between healthcare staff, patients, and community-based partners can enhance the healthcare experiences of birthing individuals (33).

Amplifying voices in maternal health

Figure 1 presents a conceptual framework highlighting key research approaches and guiding principles for addressing maternal health disparities. The interconnected gears symbolize the collaborative and integrative nature of these approaches. At the core, the central gear labeled "Equal Distribution of Power, Trust, Equity" represents the foundational values that guide the integration of diverse methodologies and perspectives, emphasizing the importance of shared power, mutual respect, and equitable practices in maternal health research.

Surrounding the central gear are five distinct yet interconnected approaches:

1. Community-Based Participatory Research (CBPR): Engages communities as equal partners, centering their voices in shaping research (19).
2. Culturally Responsive and Equitable Evaluation (CREE): Emphasizes culturally relevant evaluations that respect diverse maternal health experiences (20).
3. Mixed Methods Research: Integrates qualitative and quantitative data to capture the complexity of maternal health issues.
4. Policy and Systems Research: Examines the impact of health policies and systems, identifying barriers and opportunities for reform.
5. Intersectional Analysis: Explores how overlapping intersecting identities such as race, gender, and socioeconomic status intersect to influence maternal health experiences (21).

Together, these gears represent a cohesive, multidimensional strategy for maternal health research that promotes equitable, inclusive, and contextually relevant methodologies. By integrating these approaches, the framework aims to advance understanding and drive improvements in maternal health outcomes.

Conclusion

Reflecting on the story of Janine and Charles, we have work to do as researchers and change agents to protect birthing individuals from unjust maternal harm. It will take a multi-pronged approach to the research to move the needle in understanding psychological maternal harm. By adopting comprehensive patient-engaged research strategies that combine medical expertise with a nuanced understanding of psychological stressors through the lived experiences of birthing persons, healthcare systems can begin to dismantle systemic barriers and ensure equitable care for all birthing individuals, specifically Black birthing individuals.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Author contributions

KS: Conceptualization, Supervision, Writing – original draft, Writing – review & editing. SW: Project administration, Writing – original draft, Writing – review & editing. CC: Writing – original draft, Writing – review & editing. AM: Data curation, Project administration, Writing – original draft, Writing – review & editing.

Funding

The author(s) declare that no financial support was received for the research, authorship, and/or publication of this article.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 28 November 2024
DOI 10.3389/frhs.2024.1474073

OPEN ACCESS

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RECEIVED 01 August 2024
ACCEPTED 15 November 2024
PUBLISHED 28 November 2024

CITATION
Gleason KT, Yuan CT, Haskell H, Anderson MA, Evered JA and McDonald KM (2024) Patient-informed exploration of the aftermath of a diagnostic problem or mistake based on results of a national survey.
Front. Health Serv. 4:1474073.
doi: 10.3389/frhs.2024.1474073

Patient-informed exploration of the aftermath of a diagnostic problem or mistake based on results of a national survey

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Introduction: Despite the prevalence and devastating consequences of diagnostic breakdowns, there have been minimal efforts to systematically collect patient insight into diagnostic problems and mistakes. Collaborating with patient advocates to guide how patient-derived insights are interpreted and used is a critical, yet often overlooked, approach to identifying actionable solutions that speak to patients' priorities.

Objective: We collaborated with patient advocate co-authors to guide our understanding of findings from a mixed methods survey on diagnostic problems and mistakes, and report implications for patient engagement at three levels of action: (1) individual level before, during, after encounters (*micro*); (2) within health service delivery systems (*meso*); and (3) policy advocacy (*macro*).

Methods: Our research team applied narrative elicitation methods to conduct a novel survey about Americans' diagnostic experiences in a national, population-based survey. We shared early results with patient co-authors who highlighted the importance of further exploring how health systems and clinicians address the aftermath of diagnostic mishaps. Based on their input, we summarized the quantitative and qualitative survey results about the aftermath and worked with our patient co-authors to explore how findings might inform actionable next steps, including efforts to catalyze patient action, quality improvement efforts, and policy reform.

Results: Of the 3,684 survey respondents, about a third (33.0%, 1,216/3,684) of screened households reported diagnostic problems and mistakes in the past four years involving either themselves (18.9%, 697/3,684) or someone close to them (14.1%, 519/3,684). In the aftermath of a diagnostic mishap, over a third reported that someone in the healthcare setting where the mistake occurred acknowledged the mistake (35.9%, 432/1,204). In qualitative findings, reports that the health system "did nothing" surfacing as the most common response. Patient co-authors confirmed the results resonated with their experiences and emphasized the need for health systems to take accountability when a mishap occurs and to take follow-up actions to prevent future mishaps.

Discussion: Patients and care partners not only want and deserve acknowledgement of diagnostic problems or mistakes in their own care, they also want assurance that steps are being taken to prevent similar events from happening to others. Across micro-, meso-, and macro-levels of action, working with patients to understand and act on contributors to diagnostic breakdowns is aligned with high-reliability organizing principles.

KEYWORDS

diagnostic safety, patient safety, patient engagement, family engagement, quality improvement

Introduction

The need to improve diagnosis is urgent: diagnostic mistakes are the most deadly and costly of medical errors (1). Patient and care partner, a family or friend who partners in a patient's care, (hereon referred to as "patients") engagement is essential to healthcare transformation (2), including diagnostic quality improvement efforts (3). However, the invaluable insights patients can offer about breakdowns in the diagnostic process (4) and about other factors that adversely impact their diagnostic experiences (5–7) are not regularly collected or used for quality improvement and high reliability organizing (8–10). The latter paradigm, emerging from studies of high levels of safety in high hazard industries (including healthcare delivery), recognizes the importance of deference to expertise, defined as appreciating that the people closest to the work are often the most knowledgeable about that work (10). In healthcare delivery, there is no question that patients are among the people closest to the work.

Many in the healthcare community recognize the need to engage patients and care partners in the design and conduct of research and quality improvement efforts to drive improved care and high reliability performance in the healthcare system. While patient engagement in programs of research focused on treating or managing a specific health condition is increasingly common (11), patient engagement in diagnostic improvement efforts is less common and not yet applied as a critical and natural source of expertise for high reliability organizing for diagnostic safety. The nature of diagnosis adds to the challenge of patient engagement in improvement efforts: diagnosis often occurs over time across multiple settings with multiple clinicians, and reasons for diagnostic mistakes are often multifactorial. The complex nature of diagnosis makes identifying a main cause difficult even for expert clinicians and is aligned with high reliability organizing principles which eschew main cause thinking (e.g., an error occurred because of one clinician's mistake) in lieu of a systems approach (e.g., an error occurred because of a host of factors). However, these same characteristics of diagnosis and its variegated contexts make patient input even more essential: only patients know their full diagnostic trajectory, and this knowledge is critical for understanding where breakdowns may have occurred and informing individual, system-level, and policy-level efforts to improve quality of care.

The value of engaging patients in programs of research for diagnostic quality is clear. Best practice consensus is that patients should be engaged across the continuum of the research process, from project inception through dissemination (11). In practice, however, engagement activities have been typically concentrated in the bookends of the research endeavor, including the beginning (in which patients are engaged in the formative work that informs data collection efforts) and the end (in which patients are engaged in helping to translate and disseminate findings). A stage that often goes overlooked is engaging patients in the analysis of data, despite increasing recognition that patient partners lead to more comprehensive interpretation of findings, and more community-aligned solutions (2, 12). Recent patient-driven efforts, including the citizen scientist community for long COVID (12) and the Quantified Self Community (13), illustrate how meaningful patient engagement and leadership throughout the research process can lead to more comprehensive solutions. The principles of the citizen science community have yet to be robustly applied in improvement initiatives to address diagnostic errors, problems, and mistakes.

Drawing from our narrative elicitation project and recently fielded national survey on patient-reported diagnostic problems and mistakes, we report analytic findings for a key domain of patient experiences with diagnostic failures chosen by our patient advocate co-authors, and together derive learnings and potential actions from these findings. This paper aims to report implications for patient engagement driven by our patient-informed analysis summarized at three levels of potential action: (1) individual level before, during, after encounters (micro); (2) within health service delivery systems (meso); and (3) policy advocacy (macro).

Materials and methods

Research team reflexivity

The authors include two patient advocates (HH, MA), two clinician-researchers (KG, JE), and two organizational researchers (CY, KM). All authors report personally experiencing diagnostic problems and mistakes (also abbreviated as diagnostic mishaps and inclusive of diagnostic errors) as patients and/or care partners.

The authors adopt a patient-centered, whole-person approach to research and hold the beliefs that patients are experts in their health experiences, and that care partners often have a close-in view of their loved one's health experiences. The authors hold the contextual constructivist perspective that meaning is constructed through participants' understandings, the co-authors' interpretations (typically referred to as the researchers' interpretations), the sociocultural context and the interpretations of the scientific community (14). Thus, we recognize that our identities and experiences play a role in shaping our research and reporting.

Background of diagnostic problems and mistakes survey

We conducted a population-based survey drawing on the NORC AmeriSpeak® Panel, nationally representative sample in 2023. The survey was designed in part through work with a technical expert panel (TEP). Patient and care partner representatives, including co-authors, contributed to the TEP. We first pilot tested the survey on a sample of 671 respondents, using the open-ended descriptions of diagnostic experiences to verify characterization of diagnostic problems and mistakes. The survey is included in the Supplementary Material. The NORC AmeriSpeak® panel is a probability-based panel that provides sample coverage of approximately 97% of the U.S. household population. The study was approved by the institutional ethics boards at collaborating universities. Eligible participants were patients or care partners ages 18 or older with proficiency in English. Demographic data was collected from each participant: age, gender, race/ethnicity, and education. Of 3,684 individuals screened, those who had experienced diagnostic problems answered questions about one or more diagnostic experiences over the last four years in three iterations of the survey and in interviews with a subset. Participants who reported experiencing multiple problems and/or mistakes were guided to select a single problem and/or mistake for the survey responses. The resulting survey response rate was 26.5%, with 95.4% completing the entire set of questions. Rich data from more than 1,200 cases of lived experiences with diagnostic problems are available from this data source.

Collaboration with patient co-authors to identify domain for further analysis

After fielding the survey, the research team met with our patient co-authors and presented early results from five key domains of experience where the patient (care partner) is an essential source of information including: (1) how well providers communicated throughout the diagnostic process, (2) how any personal attributes of the patient, such as background, culture, identity or health needs, made diagnostic experiences better or worse, (3) whether a clinician or other person was a reliable source of guidance and support during the diagnostic process, (4) types and duration of harms associated with diagnostic problems that persist and affect patient or family well-being, and (5) what happens in terms of remediation, compensation, or other efforts from the health system/clinical team to address the diagnostic problem or mistake. The patient co-authors were most interested in deeper analysis of the fifth domain, focused on what we termed as the "diagnostic aftermath", and particularly emphasized current gaps in how clinicians and the health system learn from and address problems and mistakes.

Following the guidance from our patient co-authors, we conducted further exploration of the quantitative and qualitative data related to how the health system and providers addressed the aftermath of diagnostic mishaps. We examined responses to quantitative questions using summary statistics on whether the diagnostic problem or mistake was acknowledged by the healthcare team, whether the healthcare team apologized if an apology was necessary, and, if the patient (care partner) did not report the diagnostic problem or mistake to the healthcare team, why they did not report it (Table 1). We also preliminarily examined the qualitative responses to three open-ended survey questions related to what patients (care partners) perceived could have been done differently. We categorized the responses using a qualitative descriptive approach (15, 16) paired with inductive content analysis (17).

The patient co-author insights were chiefly gathered based on 3 h of live interaction (a one-hour meeting with both co-authors together and then one hour-long meeting with both patient co-authors separately). The co-authors were sent the findings in advance to review, and the sessions were focused on ascertaining their interpretation of the findings, and their initial ideas around patient-level, healthcare system-level, and policy level solutions. Asynchronous communication occurred throughout for revisions to and confirmation of the insights included.

Results

Of the 3,684 survey respondents, about a third (33.0%, 1,216/3,684) of screened households reported a diagnostic mishap in the past four years involving either themselves (18.9%, 697/3,684) or someone close to them (14.1%, 519/3,684). Of the 3,684 survey respondents, half were female (50.6%, 1,865/3,684) and the majority (62.6%, 2,307/3,684) identified as white, 12.8% identified as Black, and 17.9% as Hispanic. The majority of respondents reported that the healthcare delivery site where the mishap occurred did not acknowledge the mishap or offer an apology. For the engagement of patient co-authors in interpreting these emerging findings, we selected two preliminary categories from the qualitative analysis to focus our discussions, including: (1) post-event response experiences, and (2) post-event resolution experiences.

Prevalence estimates of patient and clinician actions in the diagnostic aftermath shared with patient co-authors

Over a third of survey respondents reported that someone in the healthcare setting where the mistake occurred acknowledged the mistake (35.9%, 432/1,204). Excluding those who reported that an apology was not necessary ($n = 377$), about one-third of respondents reported receiving an apology (33.0%, 275/839). Those who did not report the diagnostic problem ($n = 530$) identified the following reasons for not reporting: (1) they did not think it would do any good (43.8%, 232/530), (2) there was

TABLE 1 Quantitative and qualitative survey questions examined to explore post-event response and resolution.

Quantitative	Qualitative
1) Did anyone in the healthcare settings where the diagnostic mistake or problem occurred acknowledge to [INSERT PRONOUN] that something had gone wrong? a. Yes b. No 2) Did [INSERT PRONOUN] receive an apology about the diagnostic problem? a. Yes b. No, and an apology would have been appropriate c. No, and circumstances didn't warrant an apology	1) "After [you/they] realized that there was a problem with the diagnosis, what, if anything, did the doctors and other clinicians do or say that **made things better**? This could include things that improved [your/their] health, [your/their] medical care, or how you/they] felt about the diagnostic experiences?" 2) "After [you/they] realized that there was a problem with the diagnosis, what, if anything, did the doctors and other clinicians do that **made things worse**? This could include anything that negatively impacted [your/their] health, [your/their] medical care, or how [you/they] felt about the diagnostic experiences?" 3) "After [you/they] realized there was a diagnostic problem, what, if anything, do [you/they] **wish had been done** by doctors, clinicians, or others in the healthcare system to improve the situation?"

no way to do so anonymously (21.5%, 114/530), and (3) because they did not want to get anyone in trouble (17.4%, 92/530). Only one-tenth reported that someone on the care team offered information about a formal review or investigation to determine what caused the problem (10.9%, 135/1,216); more reported that they received an explanation of actions they were taking to prevent similar diagnostic problems (18.8%, 220/1,216). About a third reported that someone on the care team spoke openly and truthfully about the problems (426/1,216, 34.5%).

In the open-ended comments, "did nothing" was the most commonly noted post-event action by providers in the qualitative responses and was identified 325 times. Respondents were most likely to report that they wished the providers had done testing (identified 192 times) or that providers had tried hard and did not give up (identified 170 times).

Illustrative quotes about the diagnostic aftermath shared with patient co-authors

In open-ended comments, survey respondents described post-event response experiences, experiences of diagnostic problems that were not acknowledged, validated, or followed up on in their own care or for future patients. As an example, we shared the following verbatim quote with patient co-authors for discussion:

> Well, initially, on the initial phone call, after I called, and then later, when it went through other channels there, less so. They tried to invalidate what I said and invalidate what their own people said on the phone with me, and that's what led to the back and forth emails, until I finally got them to relent and – I mean, all I got out of it was from a financial standpoint, but whether they did anything on that end to correct anything, highly doubtful.

In exploring post-event resolution experiences, survey respondents explained how they perceived the liability culture of medicine and clinician orientation to protect one another undermined efforts to respond to mishaps. For discussion of this preliminary finding, we shared the following passage for co-authors' consideration:

> When no one answered my letter about what happened, it made me reluctant to use this practice. Since they are the only one of this type in this area (urogynecology) and I have ongoing issues, I did eventually go back to them. However, I missed annual checkups because I was upset at the way I was treated at the time [and] so what they did, they had one of the administrators of the hospital, she said she was going to file a complaint and I never heard anything. I never heard the results of the complaint. I think it was just a smoke screen, you know, just trying to I guess placate me and not really do anything. So they didn't really do anything. And you know, doctors, they will look out for each other, because they know that something like that could happen to them. It's easy to make a mistake and your career could be ruined. So I think they wanted to protect themselves and that's pretty much what happened.

Patient co-author insight on mixed-methods results

Table 2 describes the insights patient co-authors offered in responding to the quantitative and qualitative findings, including additional insights not described in the text. The finding of the mishap not being acknowledged by the health system was unsurprising to the patient co-authors, and resonated with their own experiences and those they knew about from their patient and family networks. They noted that there is a perceived pressure for clinicians not to admit responsibility for a mishap, and that this perceived pressure was highly correlated with the significance of the mishap (i.e., more serious mishap, less likelihood to admit responsibility). It was also noted that while there are mandates in place that require acknowledgement of medical errors, application of these mandates in practice may be inconsistent given the complexity of diagnostic errors. That the majority of the respondents who wanted an apology did not receive one was also unsurprising to patient co-authors, who also emphasized the value of a sincere apology.

The patient co-authors were interested in the quantitative finding of patients not reporting mishaps because patients did not think it would do any good, and they resonated with the

TABLE 2 Quantitative and qualitative emerging findings on post-event response and resolution experiences, and patient Co-authors insights.

Issue	Findings	Patient insights
Acknowledgement of Mishap	- Over a third of respondents reported that someone in the healthcare setting where the mistake occurred acknowledged the mistake (35.9%, 432/1,204). - "Did nothing" is the most commonly identified qualitative response (identified 325 times) to the question on what clinicians did after recognition of the problem or mistake.	- Difficulties in admitting fault and learning from mistakes, particularly in the context of doctors and hospitals harms patients and their care partners. - The pressure to never admit fault was identified as a significant issue. - Noted that such failures to respond were typical. - Noted a need for establishing protocols for acknowledging diagnostic errors and preventing future occurrences
Apology	- Excluding those who reported that an apology was not necessary (*n* = 377), only one-third of respondents reported receiving an apology (33.0%, 275/839).	- People want a sincere apology and assurance that measures are being taken to prevent similar incidents from happening again.
Perception that actions were seldom taken to prevent future issues	- Of the patients who did not report the mishap, almost half did not report because they did not think it would do any good (43.8%, 232/530). - Qualitative responses described a sense that no actions were taken to prevent the same mistakes or problems from happening to other patients	- Emphasized the importance of having a system in place to support such an approach, including access to necessary resources and regular follow-ups. - Clinical teams' busy schedules and an increased number of emails from a variety of sources often lead to default responses, possibly contributing to a resistance to change to a system where time is taken to recognize, acknowledge, and act on patient and care partner reported issues. - Noted that providers sometimes seemed to feel stressed at the idea that patients should feel empowered to ask questions and understand their rights and options.
Fear of legal liability is preventing accountability	- About one-fifth did not report because they did not want to get anyone in trouble (17.4%, 92/530). - Qualitative responses described a perception that clinicians would "cover" for each other and did not want to validate respondents' recognition of the problem or mistake.	- Noted fear of liability as a barrier to open communication. - It is understood concerns about liability exist, but they should not impact their patient care. - Emphasized that financial issues should be a last consideration, as they arise from failures in patient care and follow-up. - Fear of adverse consequences for themselves discourages doctors from providing feedback (e.g., there is a sense that clinicians do not want to acknowledge another clinician's error and report the error to them, as this may lead to negative repercussions for them). - Suggested incorporating training into medical education about mistake disclosure and accountability, and to shift away from the culture of covering up.

qualitative findings of patients reporting a mishap and perceiving that the health system did nothing to address the root causes of their mishap to prevent future harm to other patients. The importance of actions being taken to prevent future mishaps was viewed as particularly significant. Patient co-authors discussed how acting on patient-reported mishaps appropriately, so root causes could be identified and addressed, requires a health system to devote dedicated resources. They emphasized that having a person to respond to patient feedback and take phone calls meant little if that person did not also have resources to act upon what they heard. Patient co-authors viewed this exchange as a shared endeavor – when a patient reports a mishap, that patient should also be capacitated to request what changes they believe would be helpful to prevent future mishaps.

The fear of malpractice lawsuits was discussed as a barrier to openly communicating with patients when a mishap occurs. One patient co-author emphasized they consider a malpractice lawsuit to mean that the health system failed at taking steps to openly communicate and act on a patient-reported mishap; the malpractice lawsuit is a patient's last resort when they feel the mishap will not otherwise be recognized, including with actions taken to prevent mishaps happening to other patients. The other patient co-author pointed out that malpractice lawsuits are heavily emphasized in medical education training and practice, yet malpractice lawsuits themselves are relatively rare, and that training on mishap disclosure and accountability would not only do more to gain patients' trust and improve outcomes and patient safety, but also potentially prevent both mishaps and lawsuits from occurring. Both patient co-authors emphasized the need for accountability over issue avoidance when fears of a malpractice lawsuit override reality. Patient co-authors felt financial consequences to health systems arise from inaction, rather than from addressing patient concerns: the health systems having to manage financial issues resulting from a problem or mistake were seen as something that would only occur if health systems had not taken the appropriate actions to acknowledge and act on the identified problem.

Future-facing recommendations on micro-, meso-, and macro-level

Together as an authorship team, we discussed future-facing recommendations at the micro-, meso-, and macro-levels. On a patient-level (referred to as the micro level for individual actions), there is a need to raise patient awareness of their rights to report mishaps in care. To our knowledge, most United States' health systems have an office specific to patient experience, where problems can be reported and, when possible, addressed, and the existence of this office and its role should be known by every patient. When patients report a problem, they should be prepared to articulate their desired resolution from the health system, including actions to be taken to prevent future problems. Individual clinicians and clinical teams can also consider the value of openly communicating with patients, and acknowledging when they perceive that there may have been a mishap in their care.

On a meso level, health systems should take steps to build cultures of accountability in their processes for error remediation. Adequate resources are essential for gathering patient feedback on diagnostic process breakdowns and implementing solutions at all levels within the healthcare delivery system. In particular, guidelines are needed on how to respond when a mistake or breakdown happens that is not necessarily attributable to any one person or action, but nonetheless impacted patient care; not acknowledging these issues to the patient leads to diminished trust.

On a macro level (meaning external influences on meso and micro levels), the patient co-authors noted that the Centers for Medicare and Medicaid Services (CMS) require healthcare systems to have mechanisms for patients to report mistakes. However, the fact that issues around diagnosis, often occur over time and across settings without a clear "problem owner" was identified as a potential reason why healthcare systems may be less likely to receive and manage reports of diagnostic mistakes. They noted that healthcare systems could benefit from better guidance on how best to enable reporting, and what actions to take on a problem or mistake, including the important step of closing the loop with the patient.

Discussion

We present our learnings from working with patient co-authors to interpret quantitative and qualitative findings from a nationally representative survey on diagnostic problems and mistakes. These results suggest a path for "what to do next" on the patient, health system, and policy levels (also known as the micro, meso and macro levels) in response to insights from the experiences of many survey respondents. By employing the quantitative weight of these national estimates with accompanying qualitative illustrative quotes as motivators for changes to improve diagnosis in alignment with principles of high reliability organizing, the paper concludes with potential actions at multiple levels which were informed by patient advocate co-authors.

Patient co-authors identification of priority area for further analysis, and then leading our interpretation of the data, widened our understanding of the findings and contributed to a more comprehensive set of potential early solutions. Not only did the patient co-authors have their own firsthand experiences with diagnostic mishaps, they also regularly counsel others through their experiences with medical errors, and thus had wide knowledge of typical patient experiences in the aftermath of problems and mistakes. The patient co-authors' interpretation of analyses described in this paper will lay the foundation for future research by our study team focused on better understanding current practices in the aftermath, and how to improve.

High reliability organizing emphasizes deference to those closest to the process (10). There is no one closer to the diagnostic process than the patient (18). Yet, patients remain largely excluded from health care governance, including how mishaps are identified and managed (19). This exclusion not only further allows unacceptable practices, including not acknowledging a mishap once it has occurred, but also causes health systems to lose out on the substantial learnings enabled by patient inclusion. For example, it was continually emphasized that the very basics of patient communication - sincerely listening to the patient and acknowledging what they perceived as a mishap in their care, seem to have been lost by many healthcare sites. Future research that examines best practices in acknowledging a diagnostic mishap to the patient may benefit diagnostic quality overall.

Limitations

This work is not without limitations. Two patient co-author insights were chiefly gathered over 2 one-hour meetings (one hour-long meeting with both patient co-authors, and a subsequent one-hour meeting with each patient co-author separately). The findings of our study are complex and further time could have been spent with a larger number of patient advocates to gather a broader range of perspectives. Both the quantitative and qualitative analysis conducted of the patient-reported aftermath were preliminary, and we thus may be missing other important findings.

Conclusion

In conclusion, the urgent need for improved diagnosis in healthcare underscores the critical role of patient engagement. Patients possess invaluable insights into diagnostic breakdowns and adverse experiences that are often overlooked in traditional quality improvement efforts. By embracing patient engagement as a cornerstone of high reliability organizing, healthcare systems can harness the expertise of those closest to the work, fostering a culture of safety and driving meaningful improvements in diagnostic accuracy and patient outcomes.

Data availability statement

The datasets presented in this article are available upon reasonable request to the corresponding author. Requests to access the datasets should be directed to Kelly Gleason, kgleaso2@jhu.edu.

Ethics statement

The studies involving humans were approved by Yale Human Research Protection Program, Institutional Review Boards, FWA00002571. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

KG: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Project administration, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. CY: Conceptualization, Investigation, Methodology, Validation, Writing – original draft, Writing – review & editing. HH: Conceptualization, Validation, Writing – original draft, Writing – review & editing. MA: Conceptualization, Investigation, Methodology, Validation, Writing – original draft, Writing – review & editing. JE: Conceptualization, Data curation, Validation, Writing – original draft, Writing – review & editing. KM: Conceptualization, Funding acquisition, Investigation, Methodology, Resources, Supervision, Validation, Writing – original draft, Writing – review & editing.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article. AHRQ R18HS029350 (PIs Newman-Toker & McDonald), AHRQ R01HS029789 (PI Schlesinger), Gordon and Betty Moore Foundation Grant number 10781 (PI Schlesinger).

Acknowledgments

We acknowledge M. Schlesinger, R. Grob, E. Warne, and I. Darne for their role in acquiring funding to support this work, question creation, and in the qualitative coding of patients' and care partners' free-text responses.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2024.1474073/full#supplementary-material

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frontiers | Frontiers in Health Services

TYPE Perspective
PUBLISHED 09 December 2024
DOI 10.3389/frhs.2024.1471183

OPEN ACCESS

EDITED BY
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University of Toronto, Canada

REVIEWED BY
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RECEIVED 26 July 2024
ACCEPTED 31 October 2024
PUBLISHED 09 December 2024

CITATION
Kooijman A and Canfield C (2024) Cultivating the conditions for care: it's all about trust.
Front. Health Serv. 4:1471183.
doi: 10.3389/frhs.2024.1471183

Cultivating the conditions for care: it's all about trust

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This perspective article shares the viewpoints of two long-standing patient safety advocates who have participated first-hand in the evolution of patient engagement in healthcare quality and safety. Their involvement is motivated by a rejection of the common cruelty of institutional betrayal that compounds harm when patient safety fails. The advocates have sought to understand how it can be that fractured trust spreads so predictably after harm, just when it most needs strengthening. Instead, the abandonment of trust upends healthcare values and effectiveness at interpersonal, systemic and structural levels. They argue that authentic care (healthcare that is truly caring) transcends mere service delivery, thus embodying an inviolable commitment to mutual well-being, compassion and generosity. The advocates identify the influence of social determinants, such as culture, identity, and socioeconomic status, as critical to trust formation, where pathogenic vulnerability exacerbates existing inequalities and further impedes trust. The advocates call for a shift from transactional to relational, trust-based interactions that explore the potential for mobilizing restorative justice principles to repair harm and rebuild trust, enabling dialogue, mutual understanding and systemic improvement. Trust, they assert, is born in relationships, not transactions. The bureaucratic, legal and resource constraints that often impair meaningful interactions, also cause moral distress to healthcare providers and poor care quality for patients. They argue that central to the current healthcare crisis is the fundamental need for genuine connection and trust, framing this as both a practical necessity and a confirmation of humanity as intrinsic to healthcare. The advocates envision a future where patient engagement is integral to patient safety to prioritize epistemic justice, mutual respect and compassionate care, to restore healthcare as a cohesive, supportive and deeply human endeavor. They query what contributions a restorative approach could make to centre trust as necessary for cultivating the conditions for care in our healthcare system.

KEYWORDS

patient safety, patient engagement, trust, cultivating care, restorative approach

Introduction

We are grateful, as patient advocates, to have been asked to contribute to this special edition of Frontiers in Health Services: *The Future of Patient and Family Engagement in Quality and Patient Safety*. At first glance, the task of articulating what it is that we choose to do—the essence of our daily activism, what we eat, sleep, and breathe—might seem straightforward. Yet, we find it to be unexpectedly challenging. Perhaps it is because what we see to be most crucial in the healthcare space does not show up in the accounting: we do not measure it. Relational trust lies outside the balance sheet as a frivolous externality, if considered at all.

Our commitment to ensuring the patient voice is alive and well in quality and patient safety initiatives springs from the very depths of our experiences of betrayal, exclusion and fractured trust. It is anchored in profound pain and animated by unwavering hope. Our work and contributions are born of personal transformative experiences within the healthcare system, and driven by far more than the desire to improve; they arise from a relentless allegiance to trust and mutually compassionate caring. If you know either of us, you will know that our conversations often revolve around the need to cultivate the conditions necessary for authentic care to flourish—a care that transcends the mere delivery of services and touches the essence of what the “caring” in healthcare truly should be: an intensely human exchange for mutual well-being, compassion, generosity and trust.

To say we are passionate about patient engagement and safety barely captures the full spectrum of our emotions, as they are grounded in complex narratives, overlaid with years of frustration, determination and sorrow, with a perpetual optimism entwining our persistence. Our dedication is not meeting a professional competency, but rather a moral response to harm’s call to action, as witness and victim—a need to rectify, to heal, and to elevate, driven by our own narratives of loss, hope, and resilience. Our vision is not just about changes to systems and policies; it is about lives lived and lost, real suffering, and the stubborn belief that things can, and should, be better. We believe that involving those with lived experience in reform really can be transformative for the harmed and for those accountable.

When prodded to dream about “the future of patient engagement in patient safety,” we see a need to liberate activism from cold co-design jargon and recognize it for what it is—humanity—a thorough and careful sharing of truth between patients and those involved with healthcare improvement. This ‘engagement’ cannot be relegated to a mechanical listing of needs to be matched to services, the ticking of boxes. Rather it must nurture tentative relationships, eventually to blossom into aligned understanding, to fortify mutual respect and aid collaboration, to relax power gradients, and to emerge as allyship, even friendship. We know this because we have experienced partnerships built on mutual desires to move mountains, together. The future of patient engagement in patient safety could nurture this type of synergy to protect an open-hearted dance to evolve, to grow more intuitive and habitual, and to remain closely attuned to relational dynamics at its very core. We want to recognize a powerful creative honesty within the domain of patient engagement, when we embrace true partnership more deliberately. We want to tell you that we have found healing only where we could find trust, and then only through deeply invested generosity from within the system. We want to emphasize the centrality of cultivating and sustaining trust as a focal area for progress in the quality and patient safety space.

The social determinants of trust

A deep dive into the fundamental issues in our healthcare system means grappling with how we depersonalize, institutionalize and codify the most powerful and shattering human emotions where humanity intersects with illness, suffering, fear and mortality. Spanning the breadth of harm in health care invariably confronts life and death, also living with unexpected profound disability. By its very nature, harm tugs at healthcare’s roots in trust. In the domain of healthcare, trust is not merely an operational asset, but the fertility from which all forms of genuine caring arise. Healthcare’s dimensions of trust transcend the confines of professionalism and frame the sanctuary where mutual respect, safety and vulnerability stir. Within such a sanctuary, patients and providers may each find enough mutual recognition to lower their guard. This is where care happens.

We have some ideas about trust, the nature of trust, and what it demands. We believe trust underpins healthcare at interpersonal, system, and structural levels. We need to know that our healthcare providers trust sufficiently in themselves to hold our vulnerability, as well. We need to be able to trust each other as patient and provider, as we agree on the direction to travel through challenges we encounter together. We need to be able to trust that our institutions and policies are capable of confirming the trust of our healthcare providers, as they stretch their own vulnerability to represent the mandates of their employer. In this way, the exchange of trust and vulnerability becomes a reciprocal pair, equally authenticating emotional investment across teams, and even between society and those who stand publicly accountable for healthcare services.

Our willingness and ability to trust healthcare professionals and their institutions are affected by our upbringing, culture, racial identity, age, gender, education and economic status. Our willingness and capacity to trust healthcare are also affected by personal histories of illness and care, and vicariously by those of family, friends, and community. Vulnerability encompasses our worries over susceptibility to illness and suffering, our anticipation of rapid or intractable death, but also the social constructs of pathogenic vulnerability (1) that result from unequal or discriminatory social, political, economic arrangements and their aggravation, or their exacerbation. Trust provides a foundation for honest care where empathy and generosity circulate between patient and provider, transforming timed exchanges of information into moments of potent meaning-making.

The journey to embedding this level of trust across the healthcare spectrum is fraught with structural and cultural barriers. Bureaucratized healthcare strips interactions of their humanity, trading anchoring human exchanges for perfunctory transactions, marked by dizzying paperwork and protocol. Trust is born in relationship, not transaction. The shadow of legal ramifications casts a chill, corrosive fear of “the other”, inhibiting open communication for fear of litigation, which in turn drains the trust that is critical for transparent and generous dialogue to support care. Constant pressure on resources means that even the most dedicated providers may find themselves unable to deliver the level of care they aspire to. Under such constraints, the potential for meaningful interactions is impaired and diminished, leading to a cycle where trust is eroded, moral distress becomes the reality, and the requisite motivation to provide empathetic care is undermined (2). Navigating these challenges requires an intentional and conscientious effort to cultivate the conditions where trust can flourish. Reforming healthcare priorities and practices requires enhancing the capacity for empathy, promoting transparency, and fostering a collaborative atmosphere that welcomes contributions from both patients and providers.

On reflection, we have pondered whether it is too idealistic, or unhelpful, to speak of the need to deepen trust during a time of healthcare crisis; we are convinced that there is no better time. The current challenges only underscore the need for genuine human connection—a connection that has been eroded by the drive for transactional efficiencies which proliferate within the industrial healthcare system. Such interactions are commonly devoid of mindful presence, touch that once defined patient care and vested meaning for patient and provider alike. In a crisis, our call to elevate trust and to create conspicuous conditions for genuine care is not just about aspiring to an ideal. We advocate a thoughtful assertion of trust as the very essence of care and what it is to be human. We are constituted in and through our relationships with others (3) as inherently social beings; the integrity of our relational connections can increase our wellbeing, or cause harm. Our message is a reminder that healthcare, at its core, is about people caring for people, about meeting human needs with compassion and competence. The crisis we are truly facing is as much about restoring this fundamental truth about who we are as living, breathing and feeling beings, as it is about addressing the logistical and medical challenges at hand. Jointly, this is a crisis of trust and a crisis of care.

This emphasis on connection and trust is not a luxury but a necessity, critical to healing not only individual patients, but healing the healthcare system as a whole. In moments of crisis, the instinctive human response should be to come together, to support, and to understand—principles that are also pillars for the provision of quality patient care. By reinvigorating these principles, we can transform the landscape of healthcare from one that is fragmented and impersonal, to one that is cohesive and deeply human. In this sense, speaking pragmatically about trust and advocating for deeper connections in times of crisis, is perhaps the most grounded and practical approach we can take. It is an approach that attends to the complexities of human health, the limitations of medical knowledge, the vulnerabilities of bureaucratic systems, and the profound potential of human relationships. By shifting our focus to these accommodations, we are not just navigating a crisis but reshaping the future of healthcare culture into one that truly comes home to honour its purpose—to care, to heal, and to safeguard the well-being of the community it serves. We have lost our way in healthcare, but we have the capacity to reconnect.

This process of reconnection involves coming to grips with the course of events that have led to the current state of disconnection. The evolution of patient safety—from an early focus on professional dominance, to the more recent emphasis on systemic complexity and patient-centered care—has shaped our understanding of agency and influence. Initially, the field of healthcare viewed harms and errors through a lens on individual fallibility, responsibility and culpability. Over time, this perspective shifted towards viewing errors as preventable, but often the result of inherent system faults, allowing individual missteps and cascading failure. Increasingly the goal of "harm-free healthcare" has faded (4) as safety science has shifted from error prevention to understanding safety in complex systems (5). This shift has been instrumental in revealing how relationships of trust can animate healthcare systems, when we recognize shared responsibility for embracing complexity and the unpredictability of our healthcare system (6). As we examine the role of trust, it is essential to acknowledge how the evolution of patient safety influences and challenges current strategies, contexts and culture.

Why a restorative approach can help with our "trust" problem

Referencing *justice* in the context of patient safety has been often met with alarm by healthcare providers, eliciting fear, perhaps rightfully so when we have seen a default response seemly driven by litigation terror. This has been a challenging area of exploration for us when thinking through the needs of all parties caught in the throes of uncertainty when healthcare does go badly. While justice notions of fairness, transparency, moral action and epistemic justice (7) may be exactly what is necessary in this context, our legal structures evoke a justice that is less relational and more retributive. A new literature is reaching into the legal frameworks and orientations of healthcare, to report on outputs of alternative legal theories and positions (8). During our time in the safety realm, efforts to implement a *just culture* in healthcare have dwindled as we have collectively come to reckoning that it is not possible to have a just culture in a retributive system (9). Our experiences mirror the findings from Wailling et al., where responses to adverse events in our healthcare system are observed as often serving to compound the experience of harm for both patients and healthcare providers (10). Resonant to our own experiences of patient harm, Ray Nickson and Alice Neikirk relate their experience in learning about traditional responses to healthcare harm (11):

> The system that investigates and responds to medical negligence, we would learn, was not about justice. It was not about avoiding repetition of mistakes. It was certainly not about healing. It was not even about punishment. What we would have benefitted from was a process that revealed truth and encouraged dialogue between us, the hospital and the health professionals—a process that would have allowed us to hear, from the medical staff, a frank and honest narration of what had happened. We would have benefitted from a process that allowed us to express our pain and grief and to share how the actions of the healthcare professionals affected us. We wanted acknowledgment of those harms from the responsible parties. We wanted to be part of a process that helped doctors and families in the future to avoid the harms that we had experienced.

The time has arrived when the demand for social justice reverberates with clarity and urgency. Our institutions, and traditional notions of justice as punishment are not aligned or intended to delivery on the type of justice that is being requested. What is sought is a healing justice with quality and equality of relationship at its core. This is a justice where people are seen and heard as though they matter, and where the context and intersections in which they experience their reality, count. This is a justice where human fallibility is acknowledged as fact, and where examinng the past to learn, and working together to chart the best path forward will mean moving away from punishment, just as surely as away from "blame and shame". This view of justice is championed in the work of feminist relational legal scholar, Jennifer Llewellyn, who theorizes restorative justice as a relational theory of justice, grounded in a commitment to understanding "the fact of relationship and connection as central to the work of justice" (12, p. 89). Llewellyn further argues:

> Relational theory, thus, has significant implications for our thinking about justice. But it profoundly affects not only our thinking but also our approach to doing justice. Indeed, it requires an adjustment in the very way that we understand the work that justice requires. Taking relationship as the focal point of justice requires a contextual approach. The question of what justice requires, then, cannot be met by standard and formulaic answers but, rather, must take into account what is needed in a particular context to achieve just relationships between and among the parties involved (p. 98).

Furthermore, conversations within patient groups in quality and patient safety are moving towards increasingly sophisticated thinking around re-orienting towards a fresh perspective of systems and understanding of justice. This emerges from recognition of the system-centered environment in which healthcare providers are regulated and do their work: stressed systems which fail them too (13). We see great potential for a generosity of spirit and openness to listen and learn to create the allyship and space in which we can walk together in our collective effort to co-create the conditions in which trust and care will flourish.

Conclusion

Our journey as patient advocates underscores the transformative potential of trust and our view that a restorative approach to addressing the deep-seated lapses within our healthcare systems is necessary to humanize healthcare systems. Trust is not merely an operational asset; it is the generosity from which all authentic care arises. It is born in relationships, not transactions, and its erosion has had far-reaching consequences for both patients and providers. A restorative approach offers a relational and trauma-informed theoretical framework that shifts from assigning blame, to bringing understanding to the multifaceted impacts of harm on well-being. By fostering empathetic and respectful dialogue, restorative practices create conditions for psychological safety, allowing for the repair of broken connections and the validation of lived experiences. This approach invites all affected parties, ensuring every perspective can shape the understanding of what happened, and then guide the actions required for healing and learning.

The current healthcare crisis, marked by alienation and exhaustion from reliance on transactional exchanges, underscores the necessary urgency in reinvigorating foundational principles of trust and empathy. By embracing a restorative approach, we can remodel the healthcare landscape into one that is nurturing, cohesive and deeply human. This involves not only addressing the immediate needs arising from adverse events, but also embedding restorative values and principles within policies, governance structures, and organizational cultures. To achieve this, we must engage in authentic partnerships and consider cultural diversity, particularly the wisdom and practices of Indigenous communities. Policies must be co-created with all those affected, guided by restorative principles that honour inclusive dignity and respect. Building these perspectives into the design and evaluation will provide a protective buffer when harm in healthcare inevitably occurs, and will establish a system to flourish where learning and healing travel hand-in-hand.

Ultimately, the goal is to create a healthcare environment that honors the dignity and worth of every individual, fostering genuine care and enhancing both the quality of care and the quality of life for all involved. By taking a restorative approach, we cultivate the conditions necessary for genuine care and renewed trust in our healthcare system, allowing it to fulfill its purpose—to care, to heal, and to safeguard the well-being of the community it serves.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Author contributions

AK: Conceptualization, Writing – original draft, Writing – review & editing. CC: Conceptualization, Writing – original draft, Writing – review & editing.

Funding

The author(s) declare that no financial support was received for the research, authorship, and/or publication of this article.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 10 December 2024
DOI 10.3389/frhs.2024.1473848

OPEN ACCESS

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RECEIVED 31 July 2024
ACCEPTED 31 October 2024
PUBLISHED 10 December 2024

CITATION
Tully KP (2024) Birthing parent perspectives on measuring the quality of perinatal care: metrics, timing, and process.
Front. Health Serv. 4:1473848.
doi: 10.3389/frhs.2024.1473848

Birthing parent perspectives on measuring the quality of perinatal care: metrics, timing, and process

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Objective: Centering birthing parents is critical for improving reproductive health policies and practices. This study investigates patient perspectives on measuring the quality of perinatal care.

Methods: A cross-sectional qualitative research study was conducted at an academic medical center in the Southeastern United States. Individuals who had recently given birth participated in audio-recorded interviews between May 2020 and September 2020. This analysis addresses the research question, “If we were providing quality healthcare for families, how would we know?” Transcribed and translated responses were inductively coded to develop categories and identify themes.

Results: Forty birthing parents participated in the study. Metrics, timing, and process were identified as important components of meaningfully measuring the quality of perinatal care. Recommended metrics included asking patients whether their health priorities were addressed. Additional metrics of importance were whether coping strategies were provided, the clarity of information provided, patient comprehension of health information, the extent to which care planning was collaborative among patients and their healthcare team members, whether clinicians alleviated patient doubts, patient feelings of being taken care of, healthcare team mannerisms, clinician demonstrations of respect for patient autonomy, and postpartum visit attendance. With regard to timing, patients desired that their healthcare team members “check-in” with them as part of an ongoing, direct dialog. Birthing parents also wanted opportunities to provide feedback soon after encounters. As part of a robust measurement process, they wanted to share their insights with someone who was not a part of their healthcare team, for maintaining confidentiality. The patients desired a “serious platform” with accessible methods for all birthing parents to be able to convey nuanced accounts of their care. They also wanted to hear from the healthcare institutions about their feedback. Birthing parents sought assurances for their perinatal care feedback to be de-identified to protect them from potential retaliation. The participants recognized that they might need to utilize healthcare services from the same institution and individuals in the future.

Conclusion: Birthing parents expressed desire for their perinatal healthcare experiences to be understood. Meaningful quality measurement may be promoted through transparent and multimethod opportunities for patients to securely share insights. In addition to healthcare systems communicating assurances of patient confidentiality, institutional feedback in response to patient-reported experiences is recommended.

KEYWORDS

postpartum, measure, quality, patient-centeredness, respectful care in childbirth, perinatal, obstetric, patient safety standards

Introduction

Advancing safe, respectful maternity care and positive postpartum experiences is essential (1). The need to cultivate the vital conditions necessary to reduce perinatal mortality and morbidity and to support the thriving of new families is urgent (2). In the United States, the rate of maternal mortality is high, increasing, and disparate (3, 4). Furthermore, many pregnancy-related health complications are preventable (5) and health outcomes vary within and across birthing facilities (6). These childbirth inequities and the neglect of birthing parents through the postpartum period (6) are a call for strengthening healthcare systems. Centering birthing parents is critical for improving reproductive health policies and practices. Yet, existing national-level patient-reported perinatal quality metrics in the United States are not specific to labor, childbirth, or inpatient postpartum care.

The current standard of patient-reported measurement of the quality of perinatal care in the United States is the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. The 29-item HCAHPS survey is administered to a random sample of patients following their healthcare encounters (8). Survey enrollment and data collection are carried out through third-party vendors, typically by mail. The Centers for Medicare and Medicaid Services requires 100 of the HCAHPS surveys to be completed over four quarters for each hospital to receive a star rating (9). There is no HCAHPS survey or other national-level patient-reported quality care measure specific to perinatal care services. Furthermore, there are no requirements for calculating the percentage of perinatal patients who complete HCAHPS surveys or for carrying out survey completion among patients with limited proficiency in the English language.

Listening to diverse patients and following through on their priorities is key to providing respectful, equitable, and supportive healthcare services. The 2022 release of the White House Blueprint to Address the Maternal Health Crisis included the proposed establishment of a Birthing Friendly Hospital designation. This initiative was framed as part of “ensuring those giving birth are heard and decision makers” in quality obstetric care. The designation is intended to increase patient–families awareness of “which hospitals are taking steps to provide high-quality care” and for hospitals to be “more accountable for the quality of care they provide.” However, the designation metrics currently address only two items: first, whether a hospital participates in a statewide or national perinatal quality improvement collaborative program and second, whether the hospital implements evidence-based quality interventions to improve maternal health (10). Despite the importance of structuring healthcare services to address what birthing parents need to know, feel, and have happen to be safe and well (11), little is known about their perspectives on how the quality of labor, childbirth, and inpatient postpartum care might be measured. To inform initiatives such as the Birthing Friendly Hospital designation and HCAHPS, this study investigated patient perspectives on measuring the quality of perinatal care.

Methods

The research team conducted a cross-sectional qualitative study with birthing parents as part of a large mixed methods research project, the Postnatal Patient Safety Learning Lab. The study setting was an academic medical center in the Southeastern United States. Approximately 4,000 births per year are reported at the hospital. Patients who birth at the hospital are racially and socioeconomically diverse. They also have a wide range of medical acuity levels. The patient population ranges from low-risk birthing families cared for by certified nurse midwives to complex referral cases with multiple maternal and fetal comorbidities and supported by maternal fetal medicine physicians. In the postnatal unit, nurses admit maternal and infant patients and the healthcare team is then responsible for monitoring, treating, and providing information to postpartum patients. The postnatal unit stay includes daily rounds and nursing assessments. Interpretation services on labor delivery and the postnatal unit include in-person Spanish interpreters, as well as video and telephonic language lines. Prior to postpartum hospital discharge, clinicians provide patients with verbal and written health and safety information. This content includes health warning signs and information on clinical appointments.

Participant recruitment is illustrated in Figure 1. Following University of North Carolina at Chapel Hill Biomedical Institutional Review board approval #19-1900, the study team members identified potential postpartum participants at a hospital in the Southeastern

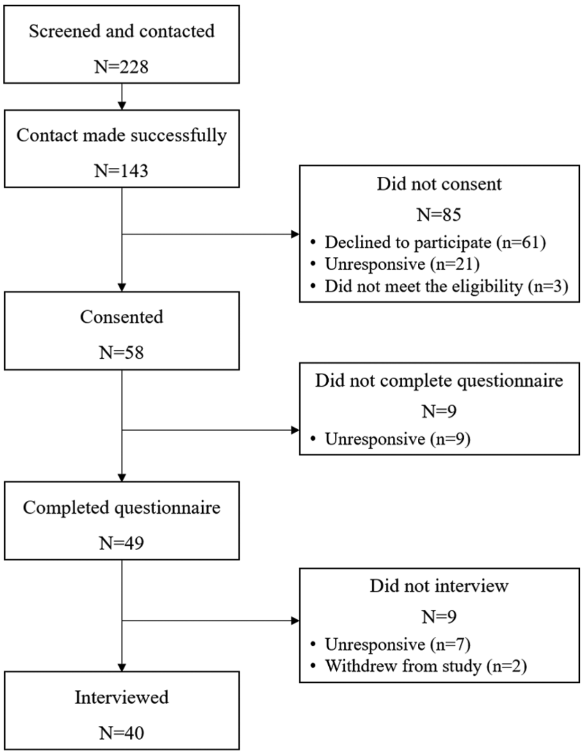


FIGURE 1
Participant recruitment, enrollment, and study completion.

United States between May 2020 and September 2020 using electronic medical records and clinician referrals (clinicians provided study enrollment information to potential participants). Individuals were eligible if they were at least 18 years old, the birthing parent of a live-born singleton or twins, less than 2 weeks postpartum at recruitment, spoke English or Spanish, had access to a phone or computer, and were discharged to a residence. The exclusion criteria included individuals with a preferred language other than English or Spanish, who were currently incarcerated, or whose infant(s) had planned placement for adoption.

A bilingual native-speaking (Spanish/English) research assistant contacted 143 individuals through convenience sampling. A total of 58 individuals consented to participate ($n = 61$ declined, $n = 21$ were unresponsive to follow-up, and $n = 3$ did not meet the full study inclusion criteria). Of these, 49 individuals completed a study questionnaire in the days prior to their telephone interview. Seven participants completed the questionnaire but could not be reached for an interview after two contact attempts. Two participants withdrew from the study (one was voluntary withdrawal and the other was ineligible). The participants were sent a $20 gift card electronically or by mail following the completion of the questionnaire. An additional $20 gift card was sent to those who completed the interviews, for a total of up to $40 each.

The semistructured interviews were conducted over telephone by team members who were not involved in patient care. The researchers were trained in qualitative methods and were either native English or Spanish speakers. Interview questions explored birthing parents' perspectives on their experiences with perinatal healthcare. The interviews were audio-recorded, with professional human translation and transcription. The study team members compared audio files with the transcriptions to check for accuracy. Transcriptions were entered into a spreadsheet verbatim, organized by interview question and participant study identification number. To get familiarized with the data, the author read all responses to the interview question of interest in this analysis: "If we were providing quality healthcare for families, how would we know?" Then, the author conducted thematic content coding (12). Similar keywords and phrases in the transcriptions were inductively coded. *In vivo* coding used words from the data as codes, such as "how are you coping?" The codes also described the attributes of the data, such as the descriptors "healthcare team practices" and "patient experiences." The codes were grouped into categories and then the author developed themes relevant to guiding future action. This analytic process entailed repeated review of quotes, codes, and categories with memos and comparisons throughout the process for refinement.

Results

Forty birthing parents completed an interview. Most of the participants gave birth ≥37 + 0 gestational weeks (95.0%) and had a vaginal delivery (60.0%). They primarily identified themselves as Hispanic (43.6%) or non-Hispanic Black (30.7%). The interview was conducted in Spanish with 40.0% of the participants. Participant characteristics are listed in Table 1.

TABLE 1 Characteristics of the 40 birthing parent–infant participants.

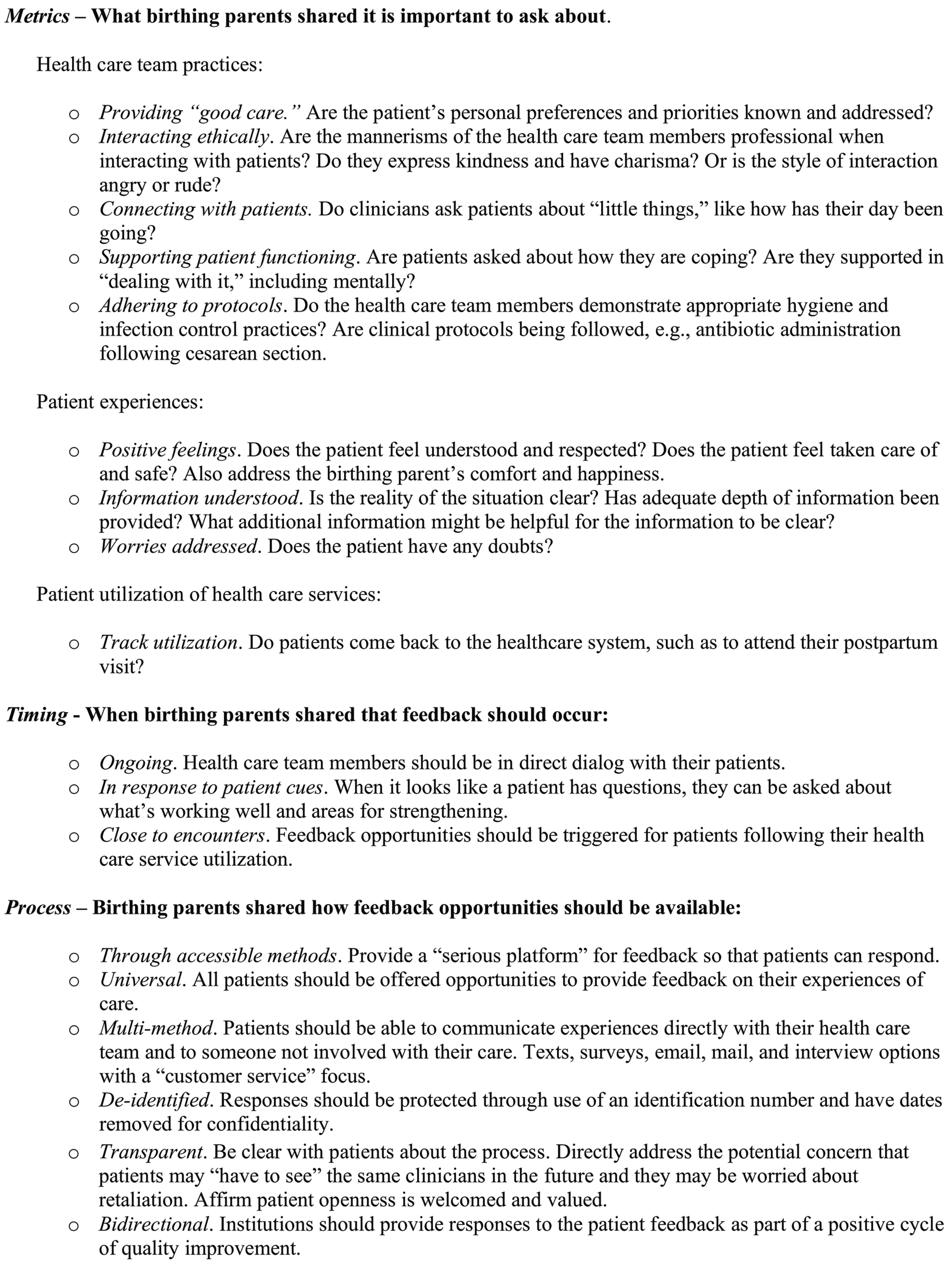
	n (%)
Birthing parent ethnicity and race	
Non-Hispanic Black	12 (31)
Non-Hispanic white	4 (10)
Hispanic	17 (44)
Asian	3 (8)
Native American	2 (5)
Multiple ethnicity and race	1 (3)
Birthing parent age	
18–24 years old	8 (21)
25–34 years old	22 (56)
35 years or older	9 (23)
Language(s) spoken at home	
English	29 (73)
Spanish	11 (33)
Other	2 (1)
Baby's gestational age at birth	
<34 weeks	1 (3)
34 + 0 to 36 + 6 weeks	1 (3)
37 + 0 to 39 + 6 weeks	29 (73)
40 weeks or more	9 (23)
Type of birth	
Vaginal	24 (60)
Cesarean section	16 (40)
Baby received care in the neonatal intensive care unit (NICU)	
No	31 (84)
Yes	6 (16)

The one participant who was categorized as multiple ethnicity and race selected non-Hispanic, Black, white, and Native American.

In response to the interview question, "If we were providing quality healthcare for families, how would we know?", metrics, timing, and process were identified as themes. Although a few participants said that they did not know about the quality of healthcare provided or that the healthcare system was good as it is, most of the birthing parents gave their perspectives about measuring the quality of perinatal care in relation to healthcare practices, patient experiences, and service utilization (*Metrics*), patients having ongoing opportunities to offer feedback (*Timing*), and having a robust, universally accessible, and confidential feedback system (*Process*). A patient summarized these interrelated components of measuring quality care thus: "I think always asking how we're doing, how we're feeling, what we need" (M37, Hispanic, Spanish-speaking birthing parent). The findings are described by theme below with illustrative quotes. Figure 2 presents a list of the results.

Metrics—healthcare team practices, patient experiences, and patient utilization of subsequent healthcare services as indicators of quality care

Recommended performance metrics of healthcare team practices addressed patient priorities. The comprehensiveness and



***Metrics* – What birthing parents shared it is important to ask about**.

Health care team practices:

- *Providing "good care."* Are the patient's personal preferences and priorities known and addressed?
- *Interacting ethically*. Are the mannerisms of the health care team members professional when interacting with patients? Do they express kindness and have charisma? Or is the style of interaction angry or rude?
- *Connecting with patients.* Do clinicians ask patients about "little things," like how has their day been going?
- *Supporting patient functioning*. Are patients asked about how they are coping? Are they supported in "dealing with it," including mentally?
- *Adhering to protocols*. Do the health care team members demonstrate appropriate hygiene and infection control practices? Are clinical protocols being followed, e.g., antibiotic administration following cesarean section.

Patient experiences:

- *Positive feelings*. Does the patient feel understood and respected? Does the patient feel taken care of and safe? Also address the birthing parent's comfort and happiness.
- *Information understood*. Is the reality of the situation clear? Has adequate depth of information been provided? What additional information might be helpful for the information to be clear?
- *Worries addressed*. Does the patient have any doubts?

Patient utilization of health care services:

- *Track utilization*. Do patients come back to the healthcare system, such as to attend their postpartum visit?

***Timing* - When birthing parents shared that feedback should occur:**

- *Ongoing*. Health care team members should be in direct dialog with their patients.
- *In response to patient cues*. When it looks like a patient has questions, they can be asked about what's working well and areas for strengthening.
- *Close to encounters*. Feedback opportunities should be triggered for patients following their health care service utilization.

***Process* – Birthing parents shared how feedback opportunities should be available:**

- *Through accessible methods*. Provide a "serious platform" for feedback so that patients can respond.
- *Universal*. All patients should be offered opportunities to provide feedback on their experiences of care.
- *Multi-method*. Patients should be able to communicate experiences directly with their health care team and to someone not involved with their care. Texts, surveys, email, mail, and interview options with a "customer service" focus.
- *De-identified*. Responses should be protected through use of an identification number and have dates removed for confidentiality.
- *Transparent*. Be clear with patients about the process. Directly address the potential concern that patients may "have to see" the same clinicians in the future and they may be worried about retaliation. Affirm patient openness is welcomed and valued.
- *Bidirectional*. Institutions should provide responses to the patient feedback as part of a positive cycle of quality improvement.

FIGURE 2
Birthing parent perspectives on measuring the quality of perinatal care. Recommendations for metrics, timing, and process.

timeliness of care was important: "Did you get everything you need during the time that they're there?" (M22, non-Hispanic Native American birthing parent). The participants also highlighted the importance of healthcare team members having positive mannerisms when interacting with them and paying attention to patients as individuals. Demonstrations of kindness and respect meant that instead of clinicians being "brutish" with patients, perhaps "they should just talk—ask about their family" (M09, Hispanic, Spanish-speaking birthing parent). The participants wanted their healthcare team to ask them how their day was going and for patients' mental health to be actively supported. Quality practice included patients being asked "if everything's okay" and "if your needs have been met" as part of making sure patients feel "secure, safe, and like they know everything and are on top of it" (M54, non-Hispanic Black birthing parent). Patient safety was also addressed in relation to healthcare team hygiene in the context of the COVID-19 pandemic and adherence to clinical care protocols (e.g., antibiotic administration after surgery).

Support for maternal coping was reported as critical to patient quality of life but typically absent from clinical practice. A non-Hispanic Black birthing parent described their chronic pain and escalation of emotional distress thus:

> "I think really what my health care providers should really ask their patients, really, really, is what is bothering you the most? Which issue is bothering you the most? Is it the migraines? Is it the back pain? What is bothering you the most? When it's bothering you, how do you cope with it? How are you dealing with it? How are you dealing with it mentally? 'Cause a lot of people don't ask—a lot of physicians don't ask their patients, 'You're in this type of pain on an everyday basis. How are you dealing with this mentally? How is it affecting you mentally?' You know, because if you can figure out how it's affecting them mentally, then you can figure out how to treat them because you've got people that are in pain 24/7 and mentally they're depressed and they're not even coming out the house. The only time they're coming out the house is to see their physician, and then they tell their physician, 'I'm in pain and this is what's going on,' and then the physician changes the medicine or ups the dosage. But they never asked, 'Mentally how are you doing? How are you coping with this? How are you dealing with this? Are you still going out? Are you still socializing or are you in the house all day? Are you underneath the covers?'… I'm telling you. If you look at a symptom and you work with trying to cure one of those symptoms, you have to figure out what the problem is. Trust me. It's gonna pop up. So pay attention…." (M31).

Recommended patient-reported experience metrics were all about patients feeling heard, comfortable, and safe—meaning that they are taken care of as a whole person and that they are not confused or worried about their care. The participants wanted to be "aware of all the [health care service] options … to make sure that we feel empowered to make decisions" (M30, non-Hispanic white birthing parent). Indicators of quality care also included the extent to which patients were meeting their goals, feeling happy with their care, and whether anything could be done better. A non-Hispanic Black birthing parent suggested asking whether people's needs have been met: "Making sure the patient feel secure, safe, and like they know everything and are on top of it" (M54). In addition, postpartum visit attendance was offered as a patient healthcare service utilization metric to indicate the quality of their previous perinatal care.

Timing—ongoing opportunities for patients to provide feedback

Participants described quality care as a system in which healthcare team members "check-in" with patients as part of an ongoing, direct dialog. At the same time, the participants noted that asking someone about their care directly will "not guaranteed to get an honest response" (M55, non-Hispanic Native American birthing parent). Birthing parents wanted opportunities to provide feedback on perinatal care experiences triggered soon after encounters and for these responses to be shared with someone who was not a part of their healthcare team. Opportunities for patient feedback and healthcare responses "along the way" were important for multiple reasons. A participant recommended that the quality of perinatal care be assessed after every healthcare encounter "because it could be different from visit to visit" (M52, non-Hispanic multirace birthing parent). Furthermore, knowing issues "when it's fresh and when it's happening" and dealing with it in real time was preferred instead of writing a review or complaint later "cause sometimes things can fester and then the report can turn into something much bigger because their emotions have now sat on it and it's made them feel worse or less" (M22, non-Hispanic Native American birthing parent). Timing consideration for meaningful measurement became a complex factor because of patient fatigue. The participants described their fatigue as being substantial in the postnatal unit and following hospital discharge, limiting patient ability to offer feedback on those healthcare services.

Process—establishing a robust, universally accessible, and safe feedback system

The patients desired a "serious platform" with accessible methods for all birthing parents to be able to convey nuanced accounts of their perinatal care. The participants described current healthcare evaluation surveys as helpful for efficient administration, standardized patient responses, and comparisons. However, an Asian birthing parent reported limited engagement with surveys and expressed doubts about their utility because they were overly clinical:

> "I mean, these patient satisfactory surveys that you get, no one fills them out. I think the questions are worded generally, they're worded so that it's almost like a black and white

> clinic kind of answer. And in most cases, it's really not a black and white kind of answer, and it really involves more digging, which you're not going to get through an electronic survey. I understand the need to do that because you need numbers, and you need to be able to standardize your answers, and it's an easy way to collect information. I think it's going to require more than that. I think what you're doing, for example, having these in-depth interviews and questions, almost like you're asking the same question ten times but in ten different ways. But you're really getting to the meat of things that way. So, I think that is one way to really assess if someone is getting the care that they needed, and if they didn't then you would find out why." (M27).

Similarly, a Hispanic Spanish-speaking birthing parent said it takes "more than a survey … to truly realize what the patient feels" (M39). Structuring multimethod (e.g., surveys or interviews) feedback opportunities for people to opt in as they like was described by another Hispanic Spanish-speaking birthing as promoting patient autonomy:

> "Personally, with me [measuring the quality of perinatal care] is what you're already doing now [through the research interview]. They arrive and they introduce themselves, they tell you their names, and their job, and what they do. They ask you how you're doing. And they say, 'I'm here for this reason and this and this.' For me it's what they explain, and they don't just come to say, 'I'll give you this.' And you don't know what it is. No. They go through the process and explain for you to understand. And if you don't want to do it, they say, 'Okay. You don't have to take it if you don't want to. You don't have to listen to this if you don't want to.'" (M29).

In addition to having comprehensible information about the potential to volunteer feedback, the participants wanted to know whether their perspectives were welcomed as part of healthcare system strengthening. A non-Hispanic Native American birthing parent said that there should be an opportunity to establish a supportive "circle of safety" for patients through "… dialogue with patients about letting them know that they can be honest and open … what you feel and what's happening or who you're encountering or what you're encountering" (M22). The need for clear communication around patient feedback was important to reduce patient worry about potential negative clinician response: "You never know how someone can respond to you" (M22, non-Hispanic Native American birthing parent). There was a specific concern about possible "retaliation" (M12, non-Hispanic Black birthing parent). As part of building trusting relationships, the participants desired institutional responses to patient feedback.

Discussion

In this qualitative study with diverse birthing parents in the Southeastern United States, we asked participants about how we, collectively, could know whether families were receiving quality perinatal healthcare. Their responses offer insights into what, when, and how we might appropriately measure healthcare service delivery and impact. The participants desired a robust and protected clinical feedback cycle, with multimethod opportunities for sharing healthcare practices and experiences throughout their perinatal journeys—not only retrospective survey assessments. They also sought institutional responses to feedback, as part of healthcare system accountability for the provision of ethical and effective perinatal services. Instead of a one-off, one-way measurement, the patients recommended an integrated cycle of communication for achieving quality perinatal care. The results suggest that public posting of healthcare evaluation, such as the one with Hospital Consumer Assessment of Healthcare Providers and Systems survey results in the United States, may be insufficient for promoting individual participation in clinical feedback opportunities. Instead, we might consider proactively communicating the ways in which patient input is heard and addressed by healthcare systems, for shared understanding that patient feedback is safe and worthwhile.

Participant responses in this study focused on aspects of perinatal care and experiences they desired. This positive framing is notable. The findings suggest that birthing parents conceptualize measurement of quality care focused on their feelings of being taken care of, not only on the absence of harm. Mistreatment of birthing people through perinatal care is unacceptably prevalent in the United States (13, 14) and beyond (15, 16). In addition to eliminating a "power-over" mentality in perinatal care and its manifestations (17), our findings underscore the importance of healthcare team–patient connection and collaboration. Previous research on welcoming, supportive perinatal care lists multilevel aspects of services that patients reported as helpful and impactful (18–20). The previous findings and our results identified the components of quality healthcare team member conduct that included an upbeat attitude, referring to patients by their names, and other feasible yet currently variable components of care. Maternity care, particularly postpartum services, is an opportunity to not only accommodate patient safety but also uplift birthing parents and families (7).

The study results are limited in their transferability to other settings because of the single-site design of the study. Other medical centers and obstetric facilities in the United States and beyond could partner with funded patient advisory councils and healthcare team members with protected time to consider the metrics, timing, and process recommendations offered through this research. Our results suggest that patient perceive quality care as multifaceted, which is probably more than the sum of its parts. A range of healthcare practices and patient experiences mattered to participants. At the same time, asking about measurement is not the same as comprehensively defining the components of quality care, which is an important area for future work. Perinatal care is a sacred life event and quality measurement therefore must extend beyond assessing user satisfaction and tracking health outcomes. National initiatives such as the Birthing Friendly Hospital designation could involve partnership with diverse patients, including those from various geographic locations, those with different health conditions, varied insurance coverage, different ages, those speaking different languages, and those with perinatal health outcomes, to develop tools and processes for widespread implementation and sustainment.

Approaches to measurement are critical, as feedback offers insight into the strengths of, and areas of opportunity for, quality care. Careful attention is necessary because the participants expressed worry not only about antagonizing clinicians, but also about the fear of retaliation. Patient worry about how information might be used against them and self-protective behavior in perinatal care are consistent with findings in previous research (19, 21). A continuous review of feedback utilization disaggregated by ethnicity, race, and other factors and subsequent follow-through to improve access is important. The people who are most marginalized may particularly not have the time, energy, or space to participate in offering feedback. In addition to health outcomes, emotional safety—before, during, and after healthcare encounters—is a critical component of patient safety (22).

Alignment and integration of patient-focused measurement is highly promising for improving the quality of perinatal care. At the same time, caution should be exercised to recognize scores as indicators of the ways people are being treated as part of a cycle to respectful care (23). Ratings on any quality measure, no matter how meaningful, are not sufficient when considered as a checklist. Healthcare systems are comprised of people, and all stakeholders should have opportunities to offer their insights into practice strengths and opportunities for improvement. Alongside patient accounts, future work could investigate the ways that the perspectives of frontline perinatal healthcare team members are leveraged for taking meaningful measures and initiatives. Creese et al. (24) identified organizational “deafness, disconnect between managers and frontline staff, and denial of the narratives and issues raised” as barriers to integrating “employee voice” in hospital administration. These researchers identified similar barriers to measuring quality care as our findings, including the current one-directional nature of communication and subsequent disengagement with the feedback system. For patients to be well, and because of the inherent value of all individuals and of meaningful work, healthcare team members need access to conditions to also enable them to thrive.

Conclusion

In this study, it was found that birthing parents expressed desire for their perinatal healthcare experiences to be understood. They outlined meaningful metrics, timing, and process considerations to establishing a “circle of safety.” Strengthening opportunities for feedback and ensuring accountability are ways to demonstrate respect, promote patient autonomy, and build trusting relationships through quality care. Creating and communicating assurances of confidentiality, given that patients are aware that they may see the same clinicians in the future, is an important and sobering component of improving healthcare services.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the author without undue reservation.

Ethics statement

The studies involving humans were approved by the University of North Carolina at the Chapel Hill Biomedical Institutional Review Board. The studies were conducted in accordance with the local legislation and institutional requirements. The ethics committee/institutional review board waived the requirement of written informed consent for participation from the participants or the participants’ legal guardians/next of kin because the IRB determined that verbal informed consent was appropriate for this qualitative research with adults.

Author contributions

KT: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Project administration, Validation, Visualization, Writing – original draft, Writing – review & editing.

Funding

The author declares financial support was received for the research, authorship, and/or publication of this article. This research was supported by the Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS) (Grant Number: R18HS027260). The funding organization was not involved in the data collection, analysis, and interpretation or the preparation of the article and therefore has no right to approve or disapprove the publication of the finished article. The author is solely responsible for the contents, findings, and conclusions of this document, which do not necessarily represent the views of the AHRQ.

Conflict of interest

The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 17 December 2024
DOI 10.3389/frhs.2024.1473296

OPEN ACCESS

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RECEIVED 30 July 2024
ACCEPTED 14 October 2024
PUBLISHED 17 December 2024

CITATION
Ramsey L, Hughes J, Hazeldine D, Seddon S, Gould M, Wailling J, Murray J, McHugh S, Simms-Ellis R, Halligan D, Ludwin K and O'Hara JK (2024) Humanising processes after harm part 2: compounded harm experienced by patients and their families after safety incidents.
Front. Health Serv. 4:1473296.
doi: 10.3389/frhs.2024.1473296

Humanising processes after harm part 2: compounded harm experienced by patients and their families after safety incidents

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Background: Healthcare organisations risk harming patients and their families twofold. First, through the physical, emotional and/or financial harm caused by safety incidents themselves, and second, through the organisational response to incidents. The former is well-researched and targeted by interventions. However, the latter, termed 'compounded harm' is rarely acknowledged.
Aims: We aimed to explore the ways compounded harm is experienced by patients and their families as a result of organisational responses to safety incidents and propose how this may be reduced in practice.
Methods: We used framework analysis to qualitatively explore data derived from interviews with 42 people with lived or professional experience of safety incident responses. This comprised 18 patients/relatives, 16 investigators, seven healthcare staff and one legal staff. People with lived and professional experience also helped to shape the design, conduct and findings of this study.
Findings: We identified six ways that patients and their families experienced compounded harm because of incident responses. These were feeling: (1) powerless, (2) inconsequential, (3) manipulated, (4) abandoned, (5) de-humanised and (6) disoriented.
Discussion: It is imperative to reduce compounded harm experienced by patients and families. We propose three recommendations for policy and practice: (1) the healthcare system to recognise and address epistemic injustice and equitably support people to be equal partners throughout investigations and subsequent learning to reduce the likelihood of patients and families feeling powerless and inconsequential; (2) honest and transparent regulatory and organisational cultures to be fostered and enacted to reduce the likelihood of patients and families feeling manipulated; and (3) the healthcare system to reorient towards providing restorative responses to harm which are human centred, relational and underpinned by dignity, safety and voluntariness to reduce the likelihood of patients and families feeling abandoned, de-humanised and disoriented.

KEYWORDS

patient safety, patient involvement, compounded harm, healthcare harm, safety investigations, healthcare litigation, qualitative research

1 Introduction

Patient harm is a persistent, and seemingly intractable, international issue that has been widely researched [e.g. (1)] and is the target of widespread policy directives (e.g. Patient Safety Strategy, NHS England), biomedical interventions [e.g. (2)] and improvement initiatives [e.g. (3)]. Substantial attention and resources are afforded to reducing avoidable patient harm. In England, this includes the Health Services Safety Investigations Body (HSSIB), NHS Resolution, the Parliamentary and Health Service Ombudsman (PHSO) and the Care Quality Commission (CQC). Indeed, Oikonomou et al. (4) revealed over 126 organisations that exert regulatory influence on NHS provider organisations to improve the quality and safety of care. Nonetheless, efforts to systematically reduce avoidable harm have been impeded by an increasingly complex and adaptive landscape facing various challenges, such as a growing and ageing population, increasing rates of comorbidities and mental illness, the rising use of digital technologies and a push to virtual home care. In cases of avoidable harm, investigations to explore what happened, how it happened and what can be learned to reduce the risk of it happening again are cornerstones of international patient safety policy. For example, the Patient Safety Incident Response Framework published by NHS England (5) is underpinned by a need for organisations to learn and reduce future avoidable harm.

However, there has been a growing recognition of the failure of organisational responses to acknowledge the wide-ranging human impacts on those affected, which can sometimes feel worse than the original harm itself (6–8). In addition to the initial harm resulting from patient safety incidents, 'compounded harm' can extend the harmful experience for everyone involved (9). Compounded harm refers to the harm that can be created after a safety incident, due to the processes that follow by 'neglecting to appreciate and respond to human impacts' and has been argued to be especially the case 'when people feel unheard or invalidated' (7, 10). Bismark and Paterson (11) proposed that organisations should respond in accordance with four simple sayings: honesty is the best policy, say sorry if you hurt someone, we can all learn from our mistakes, and treat other people the way you would like to be treated. While these represent modest moral bases to inform organisational responses to incidents, over five decades worth of well-documented care failings demonstrate that they do not always translate into practice [e.g. (12–16)]. The PHSO also recently suggested that compounded harm is 'often neglected in the process of understanding the impact of avoidable serious harm' (6).

Supportively, Wiig et al. (17) suggested that 'respect, dignity, listening, and good relationships are all crucial for a wholistic and sustainable approach to care' (18, 19). It has also been found that most patients and families value being involved in investigations of harm; however, it is important that investigations are flexible and sensitive to both clinical and emotional aspects of care (20). This literature review highlighted important factors including early active listening with empathy for trauma, sincere and timely apology, fostering trust and transparency, making realistic timelines clear and establishing effective non-adversarial communication. McQueen et al. (21) also suggested that meaningful involvement in investigations can help with reconciliation following a traumatic event and help restore faith in the healthcare system.

Warranting further attention is the extent to which patients and families should and could be involved. Smits et al. (22) developed a potentially useful model to consider this via categorising patient involvement from listener (i.e. given information), through to advisor (i.e. gives unsolicited advice) and partner (i.e. works as an equal). Vincent et al. (23) suggested that there should be an assumption that patients and families will be active partners. However, NHS England is built on a foundation of paternalism (24), which began to shift in the 1970s and 1980s as patient perspectives, skills and expertise began to be acknowledged as valuable and untapped resources (25–27). This period saw the early UK patient campaigns for increased autonomy in mental health, disabilities and maternity care (28–30), and the radical notion of coproduction being developed (31, 32). Hereafter, healthcare policy has made increasing promises to involve patients and their families as partners (e.g. 33–35), with the introduction of more recent initiatives such as Patient Safety Partners being rolled out in NHS England. The movement has also been fuelled by historical cases of overlooked warning signals raised by patients [e.g. (36)]. Martin (37) outlined two key rationales for involving patients and families – firstly, because it is a moral obligation of the health service and, secondly, because it provides otherwise omitted and clinically useful information [e.g. (38)].

To advance the current evidence base, we aimed to explore the types of compounded harm experienced by patients and their families as a result of organisational responses to patient safety incidents and propose how compounded harm may be reduced in practice.

2 Methods

A favourable ethical opinion for this interview study was received in July 2020 (REC Ref. 20/EE/0133). Interviews took place between September 2020 and April 2021. Participants were recruited using a targeted sampling approach to gain interest from those who had experienced a patient safety incident and subsequent investigation as a patient, relative, healthcare professional, investigator or legal staff within the United Kingdom. Interested people contacted the research team via email, were provided with an information sheet (easy-read when preferred) and were assessed for eligibility via telephone. Criteria stipulated that participants must be >16 years old, have experienced a 'serious incident' and subsequent investigation within a healthcare setting as defined by the Serious Incident Framework (39), have experienced the serious incident >1 year after consenting to take part, have no related ongoing police or legal involvement relating to the incident and have the capacity to consent. Eligibility assessment followed a detailed semi-structured guide. Participants were signposted to personalised sources of support where necessary.

A total of 117 people registered interest, 98 people were assessed for eligibility, and 66 were eligible, of which 42 consented to participate. Forty-two people with lived or professional experience of incident responses took part in individual and virtual semi-structured interviews with one of four researchers (LR, KL, RS-E, SMcH). Interviews were supported by a topic guide which enabled avenues of conversation to remain focused on the research questions, while also allowing flexibility to capture wider topics of interest, including exploring topics most important to participants themselves. Topic guides were tailored for each stakeholder group; however, all questions centred on experiences of incident response processes, their thoughts and feelings about, and experiences of, involvement and their experiences of interlinked processes including decisions to litigate. Interview duration ranged from 25 min to 2 h 32 min (average, 1 h 27 min). Further details of the recruitment strategy and interview methods are described elsewhere (40), as well as details of the primary analysis and findings which explored and compared the experiences of stakeholders including patients, their families, healthcare staff, investigators and legal staff. This paper focuses specifically on a secondary analysis, in which interview data were reconsidered to provide a considerably distinct perspective.

2.1 Analysis

The research team comprised four harmed patients/relatives whose experience related to physical ($n = 3$) and mental health ($n = 1$) care and eight health services researchers with disciplinary backgrounds in psychology ($n = 4$), sociology ($n = 1$), nursing ($n = 1$), applied sciences ($n = 1$) and medicine ($n = 1$). The 42 interviewees included six patients directly affected by the incident and 12 relatives. The 18 patients/relative experiences related predominantly to acute ($n = 13$) and mental health care ($n = 5$), although some spanned multiple settings and others also related to separate investigations or inquiries ($n = 2$) and were completed by an independent investigatory body ($n = 1$) rather than by a Trust locally. Incidents included delayed/misdiagnosis ($n = 6$), surgical error ($n = 4$), maternity harm ($n = 2$), suicide ($n = 3$), drug error ($n = 1$) and unexplained death ($n = 2$). Of the 18 incidents, 14 resulted in severe harm or death. The seven healthcare staff interviewed worked within acute ($n = 5$) or mental health settings ($n = 2$), and the 16 investigators interviewed worked in acute ($n = 3$), mental health ($n = 7$) and national settings ($n = 5$). One worked across settings as a bank investigator. One member of legal staff was also interviewed.

A secondary analysis was conducted as a broad thematic approach to qualitatively analysing data. This can arguably dilute the specific meaning of experiences for individuals and within the context of their own life. Sometimes this is overcome by conducting rich analyses such as case studies (41). However, typologies can bridge the gap between within-case and cross-case approaches. Mandara (42) defines a typology as a ‘system of categories used to organise objects according to their similarities and dissimilarities’. Therefore, framework analysis was used to identify the types of compounded harm experienced by patients and families following an iterative process (43, 44).

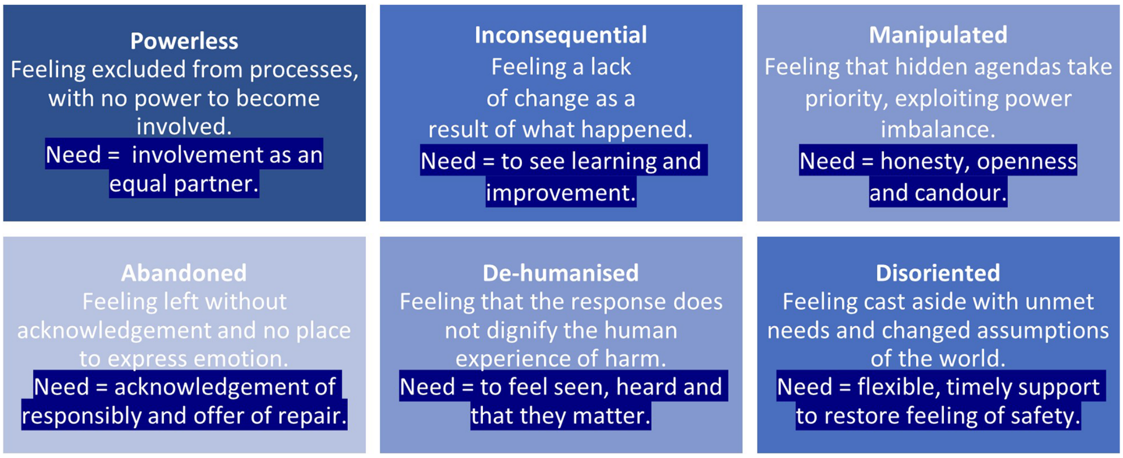
First, data were transcribed via Zoom or Teams software initially where possible and, after checking, were transcribed verbatim. Second, the authors involved based on their lived experience of safety incidents (DH, MG, SS, JH) underwent a basics in qualitative research training session focussing particularly on framework analysis (delivered by LR with support from Dr Giorgia Previdoli). Third, two researchers (LR, DH) extracted all interview data relating to compounded harm to Excel, whereby compounded harm referred to not the original harm of the incident, but harm created after due to the processes that follow (9). Due to the nature of the research questions, this related to compounded harm experienced by patients and their families only, but from all interviewees' perspectives. A total of 672 excerpts were extracted for coding. Fourth, extracted data were thoroughly read multiple times to gain a holistic view, noting descriptive initial impressions as well as convergence and divergence. Discussion between authors, focusing on the significant and common features across the data, led to a provisional coding framework being developed. Iterative discussion between authors led to ongoing refinement of the framework until a consensus was reached. One researcher (LR) then systematically coded the data according to the agreed framework, with significant data helping to define and further refine each type. Where it was deemed appropriate, data were coded multiple times. Ten per cent of anonymised data were independently coded a second time to ensure consistent interpretation and application of the framework. Finally, a matrix was developed to summarise the titles, definitions and number of cases. All data sources were included in the analysis; however, the representation of data sources was not necessarily equal, and all sources were not necessarily represented but included depending on data relevance, quality and significance.

3 Findings

Authors extracted a total of 672 interview excerpts relating to compounded harm experienced by patients or their families as defined by Wailling et al. (9). These data represented 39 of the 42 interviewees, as three staff interviews did not refer to this concept. Table 1 provides a summary of how data were coded for the purpose of transparency, rather than to indicate statistical significance. Based on these data, a typology was developed outlining six key types of compounded harm that patients and their families experienced following safety incidents. The types centred on feeling (1) powerless, (2) inconsequential, (3) manipulated, (4) abandoned, (5) de-humanised and (6) disoriented. The 672 excerpts were coded a total of 721 times, as 33 excerpts were coded multiple times (see Figure 1 for a summary of the types of compounded harm).

TABLE 1 Data coded according to the typology of compounded harm experienced by patients and families.

	Powerless	Inconsequential	Manipulated	Abandoned	De-humanised	Disoriented	Other	Total
Total no. of codes	147 (20.4%)	38 (5.3%)	179 (24.8%)	74 (10.3%)	98 (13.6%)	178 (24.7)	7 (1.0%)	721
No. of codes from patient/ relative interviews	86 (15.8%)	35 (6.4%)	159 (29.3%	42 (7.7%)	66 (12.2%)	151 (27.8%)	4 (0.7%)	543
No. of codes from staff interviews	9 (22.0%)	0 (0.0%)	9 (22.0%)	5 (12.2%)	14 (34.1)	3 (7.3%)	1 (2.4%)	41
No. of codes from investigator interviews	47 (36.2%)	3 (2.3%)	11 (8.5%)	27 (20.8%)	18 (13.8%)	22 (16.8%)	2 (1.5%)	130
No. of codes from legal interview	5 (71.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (28.6%)	0 (0.0%)	7



Powerless
Feeling excluded from processes, with no power to become involved.
Need = involvement as an equal partner.

Inconsequential
Feeling a lack of change as a result of what happened.
Need = to see learning and improvement.

Manipulated
Feeling that hidden agendas take priority, exploiting power imbalance.
Need = honesty, openness and candour.

Abandoned
Feeling left without acknowledgement and no place to express emotion.
Need = acknowledgement of responsibly and offer of repair.

De-humanised
Feeling that the response does not dignify the human experience of harm.
Need = to feel seen, heard and that they matter.

Disoriented
Feeling cast aside with unmet needs and changed assumptions of the world.
Need = flexible, timely support to restore feeling of safety.

FIGURE 1
Six types of compounded harm experienced by patients and families and the underlying need.

Examples of interview data classified according to the typology are provided both within the detailed explanations of each type of compounded harm and within a separate table (see Tables 2–7).

3.1 Powerless

This type of compounded harm refers to patients and families feeling excluded from investigation processes, with no power to become involved (see Table 2 for additional data). Patients and families described feeling without strength, ability or power to act, influence or prevent things from happening throughout investigatory processes.

> The whole process went on as though we didn't exist… If we hadn't have been persistent, to this day it would have all been brushed under the carpet. Totally, we were not in the picture. (Relative)

Initially, most patients and families were overwhelmed while managing the physical, emotional and/or financial aftermath of the incident. This meant that their abilities to proactively 'reach in' to the investigatory system were compromised. Having never been through an investigation of a patient safety incident before, patients and families also felt unequipped and described expectations of individuals within the system to instead, proactively 'reach out' and support them in due course. On that basis, most proceeded in good faith and put their trust in the staff they initially encountered. Some described being given false promises of involvement that never materialised and were later left to make sense of why they were not being supported, with some questioning if staff were busy making progress with the investigation without them, or if they were purposefully excluding them.

> Don't just send me a report in the post and expect me not to have questions or not to want to discuss it. At some point, surely the patient should be brought in to have these things discussed… Talk to me. Include me. Don't sit in a room and talk about my situation behind my back and then send me a report. Let me be there. (Patient)

Over time, it became clear to families that they themselves had to 'work' in the absence of guidance and clarity to navigate the complex system designed without their needs in mind. Some underwent what felt like a 'self-taught crash course' in

TABLE 2 Interview data relating to feeling powerless.

'They're left there knowing that there's an investigation but they've no control… they've no control over the findings, they've no control over what happens afterwards, you know, the sense of control - it seems, they don't have any'. (Investigator)
'Why didn't they engage with the family more, who know this person, who have lived with this person for 30-odd years?' (Relative)
'She couldn't understand why, you know, six or seven months after her partner's death, someone was suddenly ringing her up… I found it difficult because her concerns weren't part of the actual purpose of the investigation. When I tried to explain, no, you can't include that in the investigation… the lady actually specifically said to me, you know, "No one has involved me in this, you're ringing me up with this process I knew nothing about, no-one's involved me, no-one's listened to me, no-one's talked to me." So, I found the whole thing really difficult'. (Investigator)

TABLE 3 Interview data relating to feeling inconsequential.

'Part of me is like, did the outcome mean nothing? It was brushed off'. (Patient)
'I personally struggled with the report… it didn't dig deep enough… there was so much information under the system, questions that didn't get asked… "she was offered medication, she was offered this, she was offered that, oh, we've got nothing to learn then, really." We've always got things to learn…' (Staff)

TABLE 4 Interview data relating to feeling manipulated.

'It's all so cloak and daggers, isn't it. Professionals are so scared that if they admit anything they're going to get done, and so everyone's so hush-hush about it and it's wrong, it should be so much more open'. (Patient)
'I have found that the, the untrustworthy nature of my experience is not unique… I have found hundreds of people who had the same kind of story to share of fraudulent amended medical records, flat-out lies, evidence disappearing, you know, twisted language to try and create an impression of one thing when it's really another. It's a cesspit… the exact opposite of what I expected to find'. (Relative)
'We were denied [the truth] by a secretive Trust that wanted to cover their own backs and that should not be. It's happening now, we know it is because we meet families, and that's got to stop'. (Relative)
'All they were doing, they were covering their arses and preventing legal issues. Or, you know, minimising the cost to the Trust, and that unfortunately creates a world that is not right or fair'. (Patient)
'They denied ever sending me this letter, but they did. When I went back for my review, all my notes were missing. Somebody had shredded some of the files, deliberately lost files, misplaced files. So, I had four volumes, apparently, of my records, and I now only have two, you know, a massive cover-up. There were two conflicting reports, both with the same report number. So, for me, it turned into years of this fight, (1) to get the truth for myself and then, (2) to get the truth for other people'. (Patient)
'It's not easy when you're amongst these professionals who think they know it all. History has shown that they don't know, they don't know it all'. (Relative)
'There was always like a bit of doubt with that case because when you meet with clinicians, you can only rely on what they're telling you, and, you know, sometimes I kind of got this feeling that, are you all closing rank? you know, is there something, you know, that, we didn't have enough evidence to know what went on, on that shift when she died… there was always this little seed of doubt in my mind, you know, but you're limited, if you haven't got the evidence, you haven't got the evidence… that doesn't feel great'. (Investigator)
'The trust said, 'Oh no, the records show that…". And it's that kind of, and I'm going to say it quite bluntly, that kind of stupidity… I've then got to say to the family that they don't know the difference between a man and a woman… to suggest that their memory recall is less accurate than the staffs' and that the clinical records are always 100% correct and accurate. It is utterly ridiculous'. (Investigator)
'I've worked with probably half a dozen or so families in the last 16 years who stick in my mind, who have been given a really bad time by the NHS, labelled as vexatious when they have not been. Not given honest answers to their questions… they've been given the run-around… the way an NHS Trust has written its report… was either not at all clear or had been worded in a way that wasn't an exact lie but was also disingenuous… you can't have a half-truth if you're working in an open and honest, transparent way with a family'. (Investigator)

TABLE 5 Interview data relating to feeling abandoned.

'You almost think, well, have they forgotten about us? That's how it kind of feels'. (Relative)
'I wrote a really carefully worded complaint letter. I put a lot of thought into it, even though, you know, I did feel angry and upset, I tried to make sure that the letter wasn't aggressive or pointing the finger… but when I got the response, I've often said that was the worst day of my life'. (Patient)
'As a Trust we don't have designated bereavement support for an unexpected death… as a team we've got families who, you know, you just feel that they're left floundering… you just sometimes feel it's only a Level 1, they're nothing to do with us, but actually they've been involved in an incident'. (Investigator)
'It seems that the focus is on getting that duty of candor letter out within this timeframe and then obviously, you know, the ward have moved on, the investigation has been declared and it's now in the hands of an investigator'. (Investigator)
'If we don't engage with the families correctly, we lose the opportunity to retain trust and faith in the NHS and we lose the opportunity to help families in a healing journey following avoidable healthcare harm. Just simple as that… We're not counsellors, we're not therapists, we're not there for that. Definitely not our role, but I think it can help and assist if a situation is managed correctly, or you can do great harm'. (Investigator)

TABLE 6 Interview data relating to feeling de-humanised.

'There was a bank of journalists outside the court wanting to photograph me and a friend who was a victim and another lady that was there, and they thought it was great to just photograph us all crying, you know, and really upset'. (Patient)
'It was like a conveyor belt at times… I could have eight or nine reviews on the go… you're ready to explode with all the balancing it all. I'd say it was the hardest role I've ever done actually'. (Investigator)
'What really shocked me was when I went back to the family home to deliver the report… I think it was eleven months later, this baby, she was a big baby… but it wasn't doing anything… it was just laid there, looking up, vacant… having to be tube fed through the nose, and for the first time I thought, I've never even considered the babies that are affected. This is the life this family's got, and it shocked me, it upset me, because I came away thinking, 'Why have I never?"… because I've never seen it… the implications and the effect it had on that family… That's really helped me looking at cases now to remember there's a family, there's a baby, and why we're doing this and why it's so important'. (Investigator)

TABLE 7 Interview data relating to feeling disoriented.

'The only way I could get what had happened to me in writing, really, was to go and see a solicitor and get an independent review of my medical notes. So that's what I did… it was like a breath of fresh air, actually being told the details, it was such a massive relief, because I felt like I was going mad. You know when you know inherently there's something wrong because you can hear enough information, but you can't join all the dots, nobody's joining the dots for you, you've got to try and eke out like little bits of information, and then to actually read that I didn't need [the procedure]'. (Patient)
'Often you don't need, you don't want to make a complaint, you just want to be acknowledged that it happened'. (Patient)
'People take legal action as a last resort because of the defensiveness of the Trust'. (Relative)
'We'd got a final report, and the father wasn't happy… I felt I had no option but to ask him to resubmit it as a complaint… because that was handled in a different way… they would have had a point of contact… it would be looked at by our head of governance… a better process than we had for the actual investigations… the matron would have a family meeting where we'd go through and literally all the questions we answered, and if the family weren't happy about anything then it would be looked at, but that's what we weren't doing with our investigations'. (Investigator)
'We come up with recommendations and we come up with an action plan. And that's shared with the family. But then it's like they fall off a cliff… we are improving our services, and we are learning lessons… I think we kind of need to demonstrate that to the, the people that have helped, you know, influence that process… But I don't know whose role that is'. (Investigator)

understanding investigation processes. Ambiguity surrounded elements including the indistinctness of the investigation itself and other interlinked processes (e.g. complaint, litigation, and inquest), how terms of reference had been determined and why certain elements were excluded, the roles and responsibilities of various personnel, and trying to understand what had already happened in the investigation process without their knowledge. For some, a key point in the investigation was receiving an investigation report. Reports often reinforced divergence in expectations and were described as using inaccessible language. For most, the report presented a narrative that was incongruent with the patients' and families' experiences and expectations. For example, for some, it provided 'new' information and, for others, it was the point at which they realised that promises had been broken and their questions had not been acknowledged or answered. As a result, this was also a difficult and uncomfortable stage in the process for investigators.

> In terms of involving the family, it would be at the end of the report process. So, we'd have done the investigation. They might not have even known an investigation was going on, or the ins and outs of it. But once the report was ready, we would then offer meetings… And I remember sitting in meetings offering this final report, and the family being very upset. We hadn't achieved anything in terms of trying to answer family's questions, we hadn't even asked them what the questions were. (Investigator)

Frustration was also felt as the report was perceived to be accepted as an objective truth, with no right of reply. It was often considered too late to be meaningfully involved and influence the report in the ways many would have liked to with hindsight rendering a sense of powerlessness. Ultimately, people needed to be offered to be involved as an equal partner, and for that offer to materialise for those who wanted it to.

3.2 Inconsequential

This type of compounded harm refers to feeling a lack of change as a result of what happened (see Table 3 for additional data). For some, needing reassurance that there was organisational learning and that the same would not happen to others in the future was a key motivation. However, many described neglected opportunities to learn.

> I just feel that yes, I went through this and anyone else can go through it again afterwards. No one's learnt anything from it. (Patient)

This centred on investigation blind spots because of misaligned and narrowly focused inquiry, restricted opportunities to look back at care history and failure to take account of cross-setting interactions with services. Others raised concerns of history repeating itself, as the issues seen in care then became intertwined within the investigation, such as poor communication, delays and evasive reporting. Some perceived that this was due to procedural constraints, whereas others surmised that the organisations chose not to see and confront issues head-on but rather circumvent the real issues that needed attention. Others raised concerns of arbitrary recommendations that did not indicate that organisational learning would take place. One patient described how they had to revisit the same care setting again for a similar procedure and witnessed first-hand that a recommendation had not been actioned. Similar frustrations were expressed by investigators and healthcare staff.

> You can't go back to the family and say, right, I've done this, this is what's going to happen because you've got no idea whether any of it is actually going to happen. I know we'd like to think that once we've done it everything that you suggest is going to happen, but you know full well that, you know, some things can happen, and other things can't, and some things will and others won't. (Investigator)

Ultimately, people needed to see learning and improvement.

3.3 Manipulated

This type of compounded harm refers to patients and families feeling that hidden organisational agendas take priority, exploiting power imbalance (see Table 4 for additional data). All stakeholders felt that investigatory systems were built on an assumption of honesty and good intention; however, most perceived a degree of manipulation as the process unfolded.

> She was very guarded, and I just felt that all the staff that were interviewed were protecting their position. And at that point, it was very obvious that they were closing ranks. (Relative)

Patients and families, in general, felt that investigation processes were not set up to meet their basic needs but, instead, aligned with organisational needs. Factors that raised concerns included lacking transparency, contrived communication, limited investigation scope and the instigating of adversarial relationships.

> But it's like the terms of reference of an inquiry, they're sometimes set out not to get to the truth. (Relative)

Despite understanding why patients and families may feel manipulated in such circumstances, similar concerns were also raised by investigators and healthcare staff.

> It's in the bones of the NHS… there's so much covering of backs, it's so in-ground in our system, and I can really understand that, especially because I've just been investigated [laughs]. You know, you can be struck off, so I can really understand it, but I think it can get in the way of meaningful conversation and dialogue with people because of this fear of litigation. (Staff)

Some felt that the timeline of investigations strategically dissuaded people from seeking answers and others felt accused of causing the outcome themselves. Reports were described as disheartening, disrespectful, dishonest and defensive. Many felt that the report withheld, concealed or covered-up information, and others felt that the information they had desperately waited for only became available due to organisational deadlines. Frustration was also felt when staff within the organisation privately raised concerns but were not prepared to go on record for fear of disruption and personal consequences. There was a perception that more weighting was given to protecting the organisation, than objectively understanding what happened from all perspectives.

> As time's gone on their behaviour continues to show that they're not listening and not engaging… it feels that their priority is one of, yeah, defending themselves as opposed to learning and listening to families. (Relative)

Some were discouraged that the investigation happened internally which was perceived to deny real scrutiny. The few that were happy with the report tended to feel that it was not designed with them in mind, but for the organisation. Some described how only with hindsight was it clear how power imbalances had been exploited. Being forced to live with perceived naivety and unfair treatment weighed heavily for some. For some, these issues were offset by having a single point of contact, knowledge and support. Some called for an established advocacy role with relevant skills and knowledge. Ultimately, people needed honesty, openness and candour.

3.4 Abandoned

This type of compounded harm refers to patients and families feeling left without an acknowledgement of responsibility, often centred on absent or insincere apologies (see Table 5 for additional data). Following a patient safety incident, a shift in relationship dynamics with the healthcare system was described, sometimes sudden and obvious.

> Nothing like "we're really sorry that this is happening to you, and we'll do our best to sort it", it wasn't like that at all… it didn't feel like anyone was like holding my hand through it. (Patient)

For others, the diminution of the duty of care was more subtle. These breakdowns in relationships were manifested in a variety of ways, including failing to acknowledge the potentially profound and permanent impacts of the incident and the increasingly adversarial nature of communication. Often, people felt that their emotion, distress or anger was an unwelcome complication, despite what had happened.

> We were grieving. No one actually realised that… No support at all. (Relative)

Patients, families and staff also raised the potential therapeutic value in coming together to set the basis for mutual understanding, apology and healing; however, most experienced a cease in communication with direct care providers due to organisational policy. From a patient and family perspective, compassionately attending to these needs was considered a basic step towards making amends when something had gone wrong. These experiences jarred with, and in some cases shattered assumptions, understandings and expectations of what caring organisations were supposed to do, particularly at a time when they relied upon them most.

> You want some sort of apology. Not necessarily an apology of what they've done wrong. I mean yes that would be brilliant. But even just an acknowledgement that you've gone through an awful time… Getting their letters I just cried because it's so, so awful. They were so unfeeling, so apparently uncaring. (Patient)

Some suggested that this change was driven by a culturally engrained fear of litigation or blame for individual staff and teams, as well as wider reputational concerns. Others suggested that there was a lack of clarity surrounding whose role and responsibility it was to engage with the patient and family and a lack of support system for them to do it well.

> There's always that sort of confusion around who should be involved, from the staff team, with the relatives. You know, so when you get that phone call of, say, someone's taken their life or someone's been killed, if you've been working with them you just want to go and see them… often then the managers come in and then they're the ones that have contact, because it just goes into the policy of, right, it's a serious incident, so A, B, C and D happens… It might say it on the policy, but that should only be a guideline. (Staff)

Ultimately, people needed an acknowledgement of responsibility and an offer of repair.

3.5 De-humanised

This type of compounded harm refers to patients and families feeling that their dignity was not supported or maintained, where dignity refers to a value-based and humanistic concept that demands respect for the integrity of human beings and their beliefs (see Table 6 for additional data).

> There's no human element in there at all. It's just words on a piece of paper typed up by somebody and thrown in the post and that's the end of it really, you know, that's it. (Patient)

Examples included an unrequited desire to make sense of things most important to them, a lack of space to voice their needs, perceived careless inaccuracies in written and verbal communication such as copied and pasted information and typos, the insensitive delivery of unexpected information and being forced to live with unanswered questions.

> I thought oh my god, you know, this is my life they're talking about and the first I know that mistakes have been made is an apology through the post, not even a face-to-face, just a random letter through the post. Like I'm some kind of pack of meat on the supermarket shelf. I was gobsmacked. (Patient)

Patients and families also felt that staff and investigators often wanted to circumvent difficult conversations which made things worse, such as avoiding mentioning the name or death of a patient. These factors indicated organisational ambivalence about the most important thing to them, and that sight of the affected family had been lost, devaluing the experience they had been through. It appeared that while the family suffered sometimes life-changing consequences, the incident was insignificant to the organisation and did not demand the care and attention they felt it deserved.

> He died and he'd been an impatient and his belongings had just been like literally, bundled together in a black bin liner. That looks like a little thing to a busy staff member, and obviously they didn't think, but this is the last time she's going to be given his belongings back, and they were sort of chucked in a bin liner. (Staff)

One family described how they felt they were not treated as a human being, but a 'cog' in a process. Overall, people felt that investigation processes were experienced as a challenge, during a time of sometimes extreme vulnerability, which was felt as de-humanising. However, from an investigator perspective, many did not have adequate protected time within their job plan, or appropriate skills, to engage with families in the ways that they needed.

> There's nothing worse than somebody ringing you and started talking about a death and you've absolutely no idea what they're talking about because you've just got so many. (Investigator)

Ultimately, people needed to feel seen and heard and that they and their experiences mattered.

3.6 Disoriented

This type of compounded harm refers to feeling cast aside with unmet needs, resulting in changed assumptions of the world (see Table 7 for additional data).

> I am not the same person that came into this … I view the whole world very, very differently as a result of this experience, and I know that sounds very profound, almost an over-exaggerated thing to say, but I assure you it's not. I was somebody who would always have a default position of trusting somebody until they gave me cause not to… now I am exactly the opposite. (Relative)

Investigation reports marked a conclusion for organisations, yet often left patients and families in a state of disorientation that continued to torment them. As a result, some no longer trusted health services. For others, a lack of trust affected their worldview more widely, eroding their basic trust and sense of safety.

> This is an unfinished journey for me… but I had to sort of step back and take a breath, and when I looked around me to all the years I'd spent… the rest of my life crumbled around me. (Relative)

Dissatisfied, many felt forced into additional procedures they hoped would be able to respond to their unmet needs. This included complaints, litigation, escalating via a local member of parliament, independent inquiries, seeking clinical advice and connecting with other patients and families affected by incidents. Often, decisions were not financially motivated, but people felt forced into finding new ways of meeting their needs.

> I felt like I got pushed towards the legal approach because I didn't want money, like, you know, this wasn't about that. This was about getting a proper investigation. (Relative)

For some, this was an exhausting, emotional and lonely journey that had a ripple effect on wider aspects of their life, which were sometimes already in turmoil because of the incident, e.g. loss of career, lifelong disability, loss of identity, ongoing treatment, disruption of family dynamics, trauma, fear of revisiting services and mental health decline. Some also described how what happened became a taboo topic; how being drip-fed information then raised more questions for which they sought answers; or how they felt defeated by the process they felt forced to engage with.

> I have this big, massive guilt complex, to think that all of this stress could have caused [my daughter] to have cancer, you know, it might seem illogical, but that's what gets me, is that it could have affected my kids. I had to say to [my son], look, I'm really sorry, I know it's our holiday, but I need to know what's going on in the court. I can't settle. He was caught up in it and obviously worried, they've all been worried about me. It's had a massive impact on my husband, everything. It's been really, really tough. People do say to me, you need to give it up now [laughs]. I suppose with me there's an element of, it's still anger, I guess. I try not to let it rule my life, but it's been quite all-encompassing. It's about fighting for, you know, rights. But I have to pace myself because I don't want to stress myself out totally… I've been asked by the NHS, can I refer this patient to you? This is in my own time… nobody pays me to do this. I also have my own time and my own things that I want to do, but they do refer people to me, and I'm thinking, it's probably not right, but who else do they go to? (Patient)

Families perhaps felt particularly beholden to continue in what felt like a quagmire of hope that something meaningful would come of their efforts, if harm resulted in the death of a close loved one such as a parent, spouse or child. This was an ongoing internal conflict for some who felt a sense of obligation to continue fighting for their loved one who had been harmed, but also owing to themselves to step back. This internal conflict sometimes occurred over a protracted period as they became stuck in a cycle of investigation, feeling forced to keep what happened in the forefront of their mind and constantly reliving what happened. Some spoke about the emotional impact of becoming a support for other harmed patients and families yet feeling compelled to continue to do so in the absence of formal support. Ultimately, people needed flexible, timely support to feel safe in the world.

Of the 615 excerpts extracted, 7 could not be classified according to the typology described. Four of these were from patients/families, of which three were from the same participant. All four excerpts referred to the existence of an investigation making them feel more anxious and worried about what had happened. For example, 'I've gone away, and thought, actually, maybe I have not taken it as seriously as I thought I should have done. And then that's a whole different thing. You think, actually that was really serious and then it kind of plays on your mind' (Patient). One excerpt was from staff, and one of the two excerpts from investigators spoke to the same issue for example, 'They were very perplexed by being phoned up. They couldn't understand why someone was contacting them about it… it seemed to be raking it up and going through things that they had spent a lot of time dealing with and coming to terms with… the perception was, well we're saying this is a problem when actually the patient had come to the conclusion it's not a problem. You're stirring a hornet's nest up' (Investigator). The second investigator excerpt referred to patients and families requiring 24/7, 365 days a year support that they could not offer.

4 Discussion

In this paper, we present a newly developed typology of how compounded harm may be experienced by patients and families, as a consequence of investigatory processes that follow patient safety incidents. Our typology consists of six features of compounded harm, which leave patients and families feeling (1) powerless, (2) inconsequential, (3) manipulated, (4) abandoned, (5) de-humanised and (6) disoriented. This is an important advancement of the concept of compounded harm, a term which has gained a lot of traction recently in academic publications (9, 45) as well as guidance and policy documents [(6); NHS England, PSIRF]. It provides a delineation of the general concept and supports the development of interventions and approaches which specifically attempt to avoid or reduce different features of compounded harm. With this in mind, we present a set of recommendations for policy and practice (see Box 1) that combine our findings, with existing theory and empirical literature, before exploring three related key concepts – justice, restorative responses and accountability, in detail.

BOX 1 Recommendations for policy and practice according to the types of compounded harm experienced by patients and their families.

1. The healthcare system to **recognise and address epistemic injustice** (46) and equitably support people to be **equal partners** throughout investigations and subsequent learning (23), to reduce the likelihood of patients and families feeling **powerless** and **inconsequential**.
2. **Honest and transparent regulatory and organisational cultures** to be fostered and enacted (47), to reduce the likelihood of patients and families feeling **manipulated**.
3. The **healthcare system to reorient** towards providing **restorative responses** to harm (9) which are human-centred, relational and underpinned by dignity, safety and voluntariness to reduce the likelihood of patients and families feeling **abandoned**, **de-humanised** and **disoriented**.

4.1 Justice after harm

Research has suggested that there are multiple justice lenses that should be considered in the aftermath of healthcare harm (48). One interesting lens through which to look at our findings is that of epistemic injustice (46), which is of significance for patients and families. Epistemic injustice is a way of understanding how people can be 'wronged' in the context of their capacity as a 'knower' (49). Asymmetries in power dynamics between patients, families and the health service were illuminated in our study, which materialised in both obvious and more subtle ways. For example, our findings highlight the sometimes crippling and limited space to express emotion after experiencing healthcare harm, leaving people feeling abandoned. This could perhaps be conceptualised as a termination of the duty of care and deemed antithetical to healing. This was despite well-intentioned investigators who felt unequipped to support people and a confusion and diffusion of responsibility. Concerns were also raised about compounded harm potentially being experienced more profoundly for those who experience other social injustices, evidenced in other fields of research due to factors such as systemic racism [e.g. (50)], poverty [e.g. (51)], disability [e.g. (20)] and religion or belief (52). Fricker (46) proposed that patients and families are prone to suffer epistemic injustice; for example, when their testimonies do not suit the structure of an investigation, they may feel quietened or silenced – also termed epistemic exclusion (53). Fricker conceived of two forms of epistemic injustice: (i) testimonial injustice which 'occurs when prejudice causes a hearer to give a deflated level of credibility to a speaker's word' and (ii) hermeneutical injustice which occurs 'when a gap in collective interpretive resources puts someone at an unfair disadvantage when it comes to make a sense of their social experiences' (49; p.1).

Drawing on theories of epistemic injustice, Kok et al. (54) explored responses to healthcare harm in the Netherlands and identified several structures in the incident investigation process, which can promote or hinder epistemic contribution in the process of incident investigations. Our findings support this work, which illuminated multiple instances of testimonial injustice to eliminate emotion from their testimony to heighten credibility, reporting that 'the emotions that interviewed actors may have, are frequently framed as problematic for a team's fact-finding quest' (54). What was also evident was the lack of a 'right of reply' to the established narrative of what happened contained within the final report (54), which has also been identified within mesh and maternity inquiries (7, 16). Adams, Maben and Robert (55) reported related findings in the context of healthcare complaints, where patients were thought of as 'inexpert, distressed or advantage seeking'. Parallels of epistemic justice can also perhaps be drawn from social injustice seen in entirely different contexts, such as the Hillsborough disaster, Grenfell and the Horizon Post Office scandal. However, like Kok and colleagues, understanding the extent of hermeneutical injustice in this context is more difficult, as it would require evidence that testimony was deflated because of a conceptual deficit. Further research on epistemic injustice and its various forms would benefit from an explicit focus and longitudinal understanding of experiences of investigations over time and from different social statuses, both of which were beyond the scope of this study. Kok et al. (54) concluded that repeated calls to 'involve more' should be replaced with encouraging policymakers to be mindful of and address the structures that can cause epistemic injustice.

One viable way to recognise and address epistemic injustice, proposed by Fricker, is by 'cultivating habits of virtuous listening' (46), which is perhaps needed much more widely across the healthcare system, and not just following healthcare harm. Hicks (56, 57) argues that 'relationships have potential to make us feel our best and to make us feel our worst', and by honouring the dignity of others, we give rise to resolving conflict and rebuilding relationships that make people feel their best. Hicks defines dignity as 'the mutual recognition of the desire to be seen, heard, listened to, and treated fairly; to be recognized, understood, and to feel safe in the world'. Herring (58) further suggests that one of the essential markers of 'care' is that it 'expresses respect for the dignity of the recipient'. In the context of responding to harm specifically, Janoff-Bulman's work (59, 60) looked at traumatic life events and suggested that because of trauma, there is a loss of illusion and unspoken fundamental assumptions about the self and the world are shattered. Evident here is that when patients and families experience healthcare harm, their assumption that the healthcare service is inherently safe is shattered. Janoff-Bulman (59, 60) uses another term for disoriented and argues that subsequent 'disequilibrium' can force people to rebuild from scratch their internal conceptual system about the world and their place in it. In addition, undignified treatment in the wake of trauma – especially by those deemed responsible – can cause huge problems for this necessary rebuilding of internal conceptualisations, continuously compounding harm.

4.2 Restorative responses to harm

Restorative responses offer an approach to meet repeated calls to re-humanise investigation processes (7–9, 61, 62). Wailling and colleagues' (9) argument – that 'a restorative response is likely to reduce the level of compounded harm experienced by all the people affected' and that the 'risk [of compounded harm] may be reduced when investigations provide the opportunity for healing alongside models that seek system learning, with the former having been consistently neglected' – has subsequently been further explored and evidenced (63). Underpinning a restorative approach is the recognition that 'we are relational creatures all the way down, from the first moment of conception to the last gasp of death' (64). Specifically, a restorative response aims to create safe and supportive conditions. Wailling et al. (65) proposed three justice needs as the basis of this approach (1) substantive needs, the actual harm that needs to be remedied; (2) procedural needs, the process of interacting, communicating and making decisions about the harms; and (3) psychological needs, the way one is acknowledged, respected and treated throughout the process, ensuring those affected can honestly communicate their differences, concerns and potential similarities with each other in a safe way. A resotrative just and learning culture approach has been piloted in a mental healthcare context in Australia (66, 67) and England (68). The New Zealand Ministry of Health also applied a restorative approach to the context of surgical mesh harm (7). In arguing for the use of a restorative approach, Nickson and Neikirk (45) suggested that a fundamental principle is voluntariness, further supporting calls for divergent conceptions of justice to be acknowledged and considered (48).

Despite providing great promise, our findings suggest that a restorative approach is at odds with how investigatory systems currently operate in the United Kingdom, as all stakeholders in our analysis perceived a culture of manipulation following healthcare harm. As the most talked about type of compounded harm, it is essential to acknowledge and attend to the unspoken notion, not just in rare cases of intentional criminal acts but also in relation to well-intentioned investigatory processes of well-intentioned care. One possible way to alleviate feelings of being manipulated is investigatory working having independent oversight. For example, de Kam et al. (69) explored the perceived value of an external chair on incident investigation committees and concluded that they were both valuable and critical for impartial inquiry. However, New Zealand research concluded that when such 'external or impartial' institutional or professional responses are characterised by ownership of the harm, they can still be experienced as manipulative and compound the harm for all involved (63). Lewicki et al. (70) also noted the importance of apology, with key tenets identified as acknowledging responsibility and offering repair. Therefore, with or without independent oversight, substantive systemic cultural reorientation is likely required, supporting calls to foster honest and transparent regulatory and organisational cultures (47), as well as the appropriate underpinning personnel, training and resource. This cultural adaptation is not to be underestimated and indicates that there is still work to do following the publication of the Francis report over a decade ago (2013). Here, following devastating failings of care at Mid Staffordshire Foundation Trust, a total of 290 recommendations were made. These provided a clear focus on transparency and introduced a requirement for organisations to be held accountable for poor episodes of care. This included introducing the Duty of Candour as a standard for healthcare providers, meaning that organisations were legally obliged to be open and honest with patients and/or their families when something went wrong that had, or could, caused harm. Ultimately, further work is required to understand if and how a restorative approach should be embedded over time within the English healthcare system and if the restorative approach should run in parallel with the existing investigatory system arguably geared towards learning.

4.3 Accountability after harm

Another interesting lens to look at our findings is accountability. Whilst accountability is a commonly used term, the reality of what it means in practice is opaque. Over two decades ago, and in response to one of the key publications that prompted the patient safety movement in the United States and globally (Institute of Medicine, To Err Is Human), the Hastings Centre initiated a 2-year programme to explore the ethics of patient safety policy and improvement. One of the cornerstone elements of this work was to understand accountability. Sharpe (71) usefully described two important components of accountability – backward-looking and forward-looking. Backward-looking accountability is the act of taking responsibility for something that has already happened; accepting accountability for an outcome or experience (71). Forward-looking accountability refers to the roles, responsibilities and obligations of those who, in the case of patient safety incidents, might be tasked with repair. Sharpe describes '…whereas responsibility in the retrospective sense focuses on *outcomes*, prospective responsibility is oriented to the deliberative and practical *processes* involved in setting and meeting goals' (71; p.14). It is clear from our analysis that whilst in the two decades since, healthcare has made some movement towards recognising the need for greater backward-looking accountability (e.g. Duty of Candour within the United Kingdom) – there is much to do to shape and sustain an infrastructure to understand and support obligations of health and social care in achieving forward-looking accountability.

5 Limitations

First, while the focus of this paper was compounded harm experienced by patients and their families specifically, we recognise that harm can be compounded for all stakeholders involved. Wailling et al. (9) refer to this in their definition of compounded harm, and it is explored in the primary interview analysis (40). Second, we have identified that epistemic injustice plays an important role, and a restorative approach underpinned by restorative justice shows promise. However, as indicated by Cribb, O'Hara and Waring (48), there needs to be more research to understand how people conceptualise justice in the health setting differently and to inform the development of systems. In addition, we recognise that, perhaps due to the self-selecting nature of the study, most patients and relatives who took part experienced severe harm or death and had a negative experience of their investigation. Therefore, further research exploring positive experiences of investigations and experiences relating to incidents such as near misses and mild to moderate harm is needed to inform policy and practice.

6 Conclusions

Our newly developed typology outlines six ways that compounded harm may leave patients and families feeling: (1) powerless, (2) inconsequential, (3) manipulated, (4) abandoned, (5) de-humanised and (6) disoriented. We argue that the health service would benefit from prioritising three recommendations: (1) the healthcare system to recognise and address epistemic injustice and equitably support people to be equal partners throughout investigations and subsequent learning to reduce the likelihood of patients and families feeling powerless and inconsequential; (2) honest and transparent regulatory and organisational cultures to be fostered and enacted to reduce the likelihood of patients and families feeling manipulated; and (3) the healthcare system to reorient towards providing restorative responses to harm which are human-centred, relational and underpinned by dignity, safety and voluntariness to reduce the likelihood of patients and families feeling abandoned, de-humanised and disoriented.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Health and Care Research Wales. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

LR: Writing – original draft, Writing – review & editing. JH: Writing – review & editing. DH: Writing – review & editing. SS: Writing – review & editing. MG: Writing – review & editing. JW: Writing – review & editing. JM: Writing – review & editing. SM: Writing – review & editing. RS-E: Writing – review & editing. DH: Writing – review & editing. KL: Writing – review & editing. JO: Writing – original draft, Writing – review & editing.

Funding

The authors declare financial support was received for the research, authorship and/or publication of this article. This study was funded by the National Insitute for Health and Care Research (NIHR) Health Services and Delivery Research Programme (18/10/02; ISRCTN14463242) and the NIHR Yorkshire and Humber Patient Safety Research Collaboration (NIHR YH PSRC). The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

Acknowledgments

Firstly, we would like to thank all of those who participated in the interview study and shared their experiences about such a personal and emotive topic. Secondly, we would like to thank an active patient and family advisory group, a staff advisory group and a steering group who provided guidance at each stage of the programme. Some members of the patient and family advisory group co-authored this paper (JH, DH, SS, MG) and others provided wider steer. This includes Faye Waddams, James Titcombe, Penny Phillips, Sara Ryan, and Scott Morrish. Members would like to dedicate their involvement to the loved ones they have so sadly lost and to the remarkable legacies they have left behind. Thirdly, we would like to thank Isabelle Baker and Bethany Holden – Research and Implementation Assistants at The Yorkshire Quality and Safety Research (YQSR) group, who checked 10% of anonymised data coding for accuracy. Finally, we would like to thank Dr Giorgia Previdoli who gave practical, methodological and relational support to members of the patient and family advisory group involved.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 03 January 2025
DOI 10.3389/frhs.2024.1473256

OPEN ACCESS

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RECEIVED 30 July 2024
ACCEPTED 29 October 2024
PUBLISHED 03 January 2025

CITATION
Ramsey L, Sheard L, Waring J, McHugh S, Simms-Ellis R, Louch G, Ludwin K and O'Hara JK (2025) Humanizing processes after harm part 1: patient safety incident investigations, litigation and the experiences of those affected.
Front. Health Serv. 4:1473256.
doi: 10.3389/frhs.2024.1473256

Humanizing processes after harm part 1: patient safety incident investigations, litigation and the experiences of those affected

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Background: There is a growing international policy focus on involving those affected by healthcare safety incidents, in subsequent investigations. Nonetheless, there remains little UK-based evidence exploring how this relates to the experiences of those affected over time, including the factors influencing decisions to litigate.
Aims: We aimed to explore the experiences of patients, families, staff and legal representatives affected by safety incidents over time, and the factors influencing decisions to litigate.
Methods: Participants were purposively recruited via (i) communication from four NHS hospital Trusts or an independent national investigator in England, (ii) relevant charitable organizations, (iii) social media, and (iv) word of mouth to take part in a qualitative semi-structured interview study. Data were analyzed using an inductive reflexive thematic approach.
Findings: 42 people with personal or professional experience of safety incident investigations participated, comprising patients and families ($n = 18$), healthcare staff ($n = 7$), legal staff ($n = 1$), and investigators ($n = 16$). Patients and families started investigation processes with cautious hope, but over time, came to realize that they lacked power, knowledge, and support to navigate the system, made clear in awaited investigation reports. Systemic fear of litigation not only failed to meet the needs of those affected, but also inadvertently led to some pursuing litigation. Staff had parallel experiences of exclusion, lacking support and feeling left with an incomplete narrative. Importantly, investigating was often perceived as a lonely, invisible and undervalued role involving skilled "work" with limited training, resources, and infrastructure. Ultimately, elusive "organizational agendas" were prioritized above the needs of all affected.
Conclusions: Incident investigations fail to acknowledge and address emotional distress experienced by all affected, resulting in compounded harm. To address this, we propose five key recommendations, to: (1) prioritize the needs of those affected by incidents, (2) overcome culturally engrained fears of litigation to re-humanize processes and reduce rates of unnecessary litigation, (3) recognize and value the emotionally laborious and skilled work of investigators (4) inform and support those affected, (5) proceed in ways that recognize and seek to reduce social inequities.

KEYWORDS

patient safety, patient involvement, staff involvement, healthcare harm, safety investigations, healthcare litigation, qualitative research

1 Introduction

Identifying and investigating safety incidents has been a longstanding, ubiquitous and global focus for the field of patient safety [e.g., (1, 2)]. In the English National Health Service (NHS), these activities are most recently governed by the Patient Safety Incident Response Framework (PSIRF) (3, 4), replacing the previous Serious Incident Framework (SIF) both published by NHS England (5). Both national policy directives have mandated the involvement of those affected by incidents within investigations for almost a decade but have not yet appeared to have translated into routine practice locally [e.g., (6–8)]. This is despite a lack of involvement being repeatedly blamed for a history of well-documented care failings across settings [e.g., (9, 10)], and a growing body of evidence highlighting multiple key reasons to meaningfully involve those affected by incident investigations.

One reason to involve those affected in incident investigations is that it meets a democratic consumer right, and speaks to a restorative view of justice, whereby genuine attempts to rebuild trusting relationships are central (11–13). Evidence suggests that patients and their relatives, as well as staff, report physical, financial and/or emotional vulnerability following healthcare incidents (14–17) and during investigations (18, 19). Morrison et al., described investigations as a "painful journey; for most, a pain yet to heal" (20), resulting in outcomes such as poorer health, work absenteeism and difficulties contributing to society (21, 22). It has been argued that supporting those affected in these circumstances is a system-wide responsibility (23). This field of thought has been increasingly recognized over the past two decades in the UK, albeit slowly. For instance, the Being Open Framework (24) was launched, followed the right to an apology, support through complaints of poor quality or unsafe care, and the commitment to learn and improve services being written into the NHS Constitution (25). The professional Duty of Candour was also legislated in 2014 [Health and Care Act (26)] and NHS England launched the Just Culture guide (2018) in more recent years. Nonetheless, a report from the former Healthcare Safety Investigation Branch (27) highlighted that staff continue to lack support following incidents, and Cribb, O'Hara and Waring (11) call for a more sophisticated understanding of "justice" and justice for whom, in these circumstances.

A second reason—sometimes called the technocratic rationale—to involve those affected in incident investigations is that it enables the healthcare service to learn from their valuable perspectives (13). Since the early call from Vincent and Coulter (28) for an active role for patients in patient safety, research has established that they and their families are a key source of often untapped information that could help support the monitoring, measuring and management of healthcare safety (29–34). The technocratic rationale for involvement underpins the introduction of recent initiatives, such as Martha's Rule—a patient safety initiative in the NHS that gives patients, families, carers, and staff access to a rapid review from a separate care team at any time (35). Nevertheless, despite a growing emphasis on stakeholder involvement, there remains a surprising lack of evidence to support the effectiveness or impact of recommendations resulting from investigations (36).

Other, under-researched considerations are reasons for pursuing litigation. There are an estimated 11,000 reported incidents causing severe harm or death in the UK annually (37), resulting in approximately £1.7billion worth of clinical negligence claims, with a further £1.8billion to administer and settle claims, and long-term liabilities amounting to £65billion (38). The literature is also inconsistent as Anderson, Allan and Finucane (39) found no link between complaints and litigation, and suggestions that legal implications are a key barrier to participation (40), yet NHS Resolution (41) proposed that some claims were driven by frustration and poor experiences of investigation processes, suggesting that involving patients and families earlier would see reduced complaints (41).

In summary, there is growing interest in involving those affected in investigations of incidents, yet there remains little UK-based empirical evidence exploring the experiences of key stakeholders over time, including factors influencing decisions to litigate. Therefore, we sought to explore the following research questions: (i) What is the experience of patients, their families, healthcare staff, investigators and legal staff who have been involved in an incident investigation over time? (ii) What might influence the patient or families decisions to litigate?

2 Methods

This interview study received favorable ethical opinion in July 2020 (REC Ref—20/EE/0133). Interviews took place between Sept 2020 and April 2021.

2.1 Recruitment

A targeted sampling approach aimed to recruit participants via: (i) a personal invitation letter, general communication method or snowball sampling at four NHS Trusts and an independent investigatory body in England (ii) advertisement via relevant charitable organizations (Care Opinion www.careopinion.org.uk/, AvMa www.avma.org.uk/, Harmed Patients Alliance harmedpatientsalliance.org.uk/), (iii) advertisement via social media, or iv) word of mouth. The method of recruitment was purposive and directed towards patients, relatives and staff who had been involved in safety incidents and subsequent investigations. People registered their interest by email, were provided with a detailed information sheet (in easy-read when preferred) and were assessed for eligibility via telephone. Criteria stipulated that participants must: be >16 years old, have experienced a "serious incident" and subsequent investigation within a healthcare setting as defined by the Serious Incident Framework (5), experienced the serious incident >1 year after consenting to take part, have no related ongoing police or legal involvement relating to the incident, and have capacity to consent. Eligibility assessment followed a detailed semi-structured guide. Participants were signposted to personalized sources of support where necessary.

117 people registered interest, 98 people were assessed for eligibility and 66 were eligible, of which 42 consented to participate (see Figure 1). Decision to stop recruitment was made based on collaboratively feeling that we had “understood enough” and “heard enough” (42), as well as being guided ethically, wanting to avoid unnecessarily causing distress to those not eligible, consenting participants and the research team. Specific demographic data was not collected from participants.

2.2 Interviews

Interviews followed a topic guide which enabled avenues of conversation to remain focused on the research questions, while also allowing flexibility to capture wider topics of interest, including exploring topics most important to participants themselves. Topic guides were tailored for each stakeholder group, however, all questions centered on experiences of incident investigation processes, their thoughts and feelings about, and experiences of, involvement, and their experiences of interlinked processes including decisions to litigate. The topic guide was developed based on the focus of the research questions, the exploratory nature of the study and also to reflect existing research findings from the wider programme of work [e.g., (6, 18)]. With guidance and support, participants were given the option of producing and sharing a timeline to organize and structure their thoughts and ensure that they were able to share details of events that were most important to them personally, as well as helping the researcher to understand the order of events during the interview (43). However, timeline data were not included in the analysis.

Interviews took place virtually due to COVID-19 restrictions, held via Zoom ($n = 36$), Teams ($n = 2$) or telephone ($n = 12$) and were video and/or audio recorded. Interview duration ranged

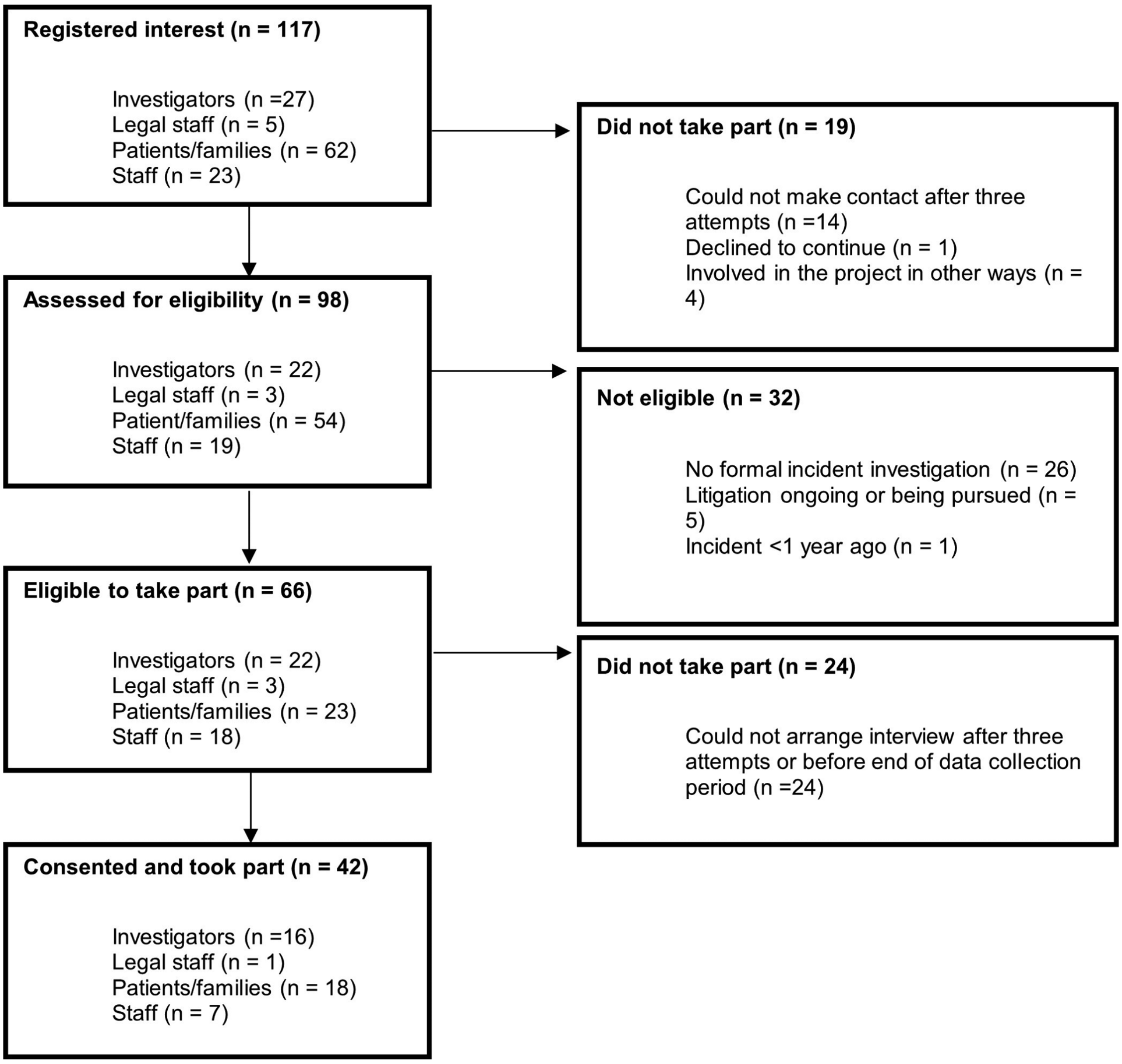

FIGURE 1
Participant flow.

from 25 min to 2 h 32 min (average 1 h 27 min). Researchers followed a detailed distress protocol aiming to support both participants (e.g., via signposting to tailored support) and researchers (e.g., debriefing after each interview), led by a researcher with a background in counselling (RSE).

2.3 Analysis

Data were auto-transcribed via Zoom or Teams software initially where possible and corrected, or transcribed. An inductive reflexive thematic approach was taken to analysis (44), aiming to develop overall findings representing the commonality of experience across the stakeholder groups, and explore divergence. Weekly "data sessions" were held with interviewing researchers to reflexively discuss initial impressions, and develop a descriptive account based on patterns of meaning and similarities and differences within and between participants and stakeholder viewpoints. Researchers then aimed to elucidate the descriptive accounts, and ensure they were grounded within the data. This involved reading each transcript to become immersed within the data, and making descriptive notes in the margins, as well as highlighting significant quotes and summarizing key details of each account, before independently and collaboratively collating ideas analytically. Further discussions were held with the wider research team, including qualitative experts (LS, JW), a patient and family advisory group and a staff advisory group, to develop, evidence and refine the themes until a consensus was reached.

2.4 Findings

Forty-two eligible people with lived or professional experience of incident investigations took part in individual semi-structured interviews with one of four researchers (LR, KL, RSE, SMcH). The 42 interviewees included seven patients directly affected by the incident and twelve relatives. Thirteen of those experience related predominantly to acute care and five related to mental health care, although some spanned multiple settings. Two others related to separate investigations or inquiries and one was completed by an independent investigatory body rather than a local Trust. Incidents included six delayed/misdiagnoses, four surgical errors, two maternity harms, three suicides, two unexplained deaths and one drug error. Five healthcare staff and three investigators worked within acute care and two healthcare staff and three investigations worked within mental healthcare settings. Five investigators worked within national settings and one worked across settings as a bank investigator. One legal staff took part. We constructed five themes that reflect and address the research questions.

2.5 Cautious hope colliding with fear

Patients and families described vulnerability, largely emotionally, following harm while under the care of a service they inherently trusted.

> "I was very distressed. I find myself quite a resilient person. I can manage my emotions quite well. But I think I was very, very vulnerable in that situation." Patient

Due to the range and complexity of emotions that some experienced while coming to terms with the immediate and longer-term implications of what had happened, patients and families struggled to know what to do, particularly in the absence of support.

> "When you're low like that you don't know what to do, you don't know how to raise issues, you don't know where to go… To start with I did nothing. I was just like, completely dumbfounded." Patient

Having never experienced an incident before, some described difficulties disentangling their experiences of care and what happened next, as well as feeling overwhelmed by opaque and unfathomable processes. This became more complex when interrelated processes ran alongside investigations, with overlapping timelines and unclear remit (e.g., coroner's inquest, police investigations, patient advice and liaison services, formal complaints, funeral planning, litigation, public inquiries, and independent investigations).

> "We were getting drip-fed information, and because there were so many different agencies sort of involved… the whole thing's really, really difficult. Really difficult… I just don't think that anyone has sort of, really helped us at all." Relative

However, most proceeded with cautious hope. Caution was fueled by the incident itself, as well as perceptions of delayed or disregarded escalation attempts and histories of fractious relationships and poor communication with care teams. Hope, on the other hand, was fueled by reassurance at the existence of investigation processes bringing an opportunity to be heard, and wanting to feel able to trust the healthcare service again for some good to come of what happened.

> "During the time of my mum being looked after, she was not listened to and also as a family we weren't listened to, so it felt like an opportunity, finally, to be listened to." Relative

Most described placing good faith in the system, with expectations of being proactively supported with empathy and compassion. How that good faith was handled then laid the foundations for ongoing relations. Over time, a sense of injustice was fostered, not only by what happened (e.g., jarring and defensive tones to communication), but also what did not happen (e.g., apology or offers of support).

> "We didn't realize that we were going to be met with such hostile feelings. We thought everyone would have wanted to get to the bottom of what happened… We didn't realize it was all going to become a, well I don't know, just, 'let's

> sweep it under the carpet,' because nobody wanted to be blamed." Relative

This was perceived to be largely driven by fear of legal repercussions, seen as a barrier to rebuilding trust, transparency and learning.

> "There's a lot of fear in involving the family or apologizing because it gets confused with some sort of admission of blame or liability." Investigator

This was a fear that was deemed culturally engrained and difficult to overcome.

> "I think it's difficult to, you know, as a Trust [to] put yourself in the path of inviting litigation." Staff

For staff, investigations invoked shame, blame and fear of what that meant for the patient, as well as their reputation and the security of their professional position. Often continuing to work clinically in the immediate aftermath, staff described a lack of time and mental space to process their experience. Other times, staff were made formally aware of an investigation by management, sometimes perceived to be insensitive, unsupportive and questioning of their professional capabilities, having lasting impacts on them, or learned of investigations informally via colleagues or patients.

> "It was almost a case of, the nursing staff, you know, had almost been told, oh, just be careful of this one. So, it felt very isolating… I felt very scrutinized." Staff

2.6 On the side lines of organisational agendas

Over time, patients and families experienced widening power gaps, leaving them disillusioned by a lack of compassion, acknowledgement and accountability. Some felt that they had to present in an emotionless manner to be perceived reasonable resulting in further breakdown of relationships. Muddling through a complex system with limited knowledge, resource and power, designed without their needs in mind meant that everything became a challenge at a time they needed support.

> "I didn't have the information or knowledge to explain exactly, and my eyes started filling up… when you know inherently there's something wrong because you can hear enough information, but you can't join all the dots, nobody's joining the dots for you." Patient

In the meantime, some blamed themselves for the outcome or felt made to question their own memories and realities, leaving them more vulnerable.

> "You begin to believe that you're making it up somehow. I remember that at one point thinking 'well if no-one's believing me, it must be my fault' and of course it wasn't, and even if it was then I needed help, you know." Patient

Some persisted. Others with limited power, strength, assertiveness, systems intelligence, and social capital withdrew. Legal involvement was also a barrier to rebuilding relationships, as communication went through additional layers of scrutiny and demanded the involvement of different personnel.

> "I think it's sad because if there are solicitors for the family, I think the Trust are obliged to have our Trust solicitors… it's escalated to a different level and makes it less personal." Investigator

Staff experienced parallel isolation, sometimes separated from the patient and family they cared for going against naturally caring instincts to reach out to them. This distancing was thought to be designed to protect staff, but inadvertently fostered unresolved feelings, guilt and apprehensions of unknown outcomes, as well as fear of how events may unfold if they came into contact informally. Generally, there was a sense that processes were designed to protect the organization, over and above learning or supporting those affected.

> "The terror that the thought of an investigation just still instils in staff… I recall being investigated… like I've seen it from different angles, erm, and I'm very aware of how people feel… I had been a midwife for ten plus years." Investigator

Concerns surrounded the combination of accountability and ambiguity, as well as perception that the system was unfair, biased and purposefully excluded them.

> "It felt very sneaky… I was told to my face 'now, this is all about transparency and getting to the bottom of what happened, and improving patient safety' and all the rest of it, and then, when I saw the report it was abundantly clear that's exactly not what was happening." Staff

For some, seeking support was considered an unnecessary indulgence. Staff described the longer-term impacts this had on their well-being and job satisfaction, contributing to decisions for some to avoid working in certain settings or ultimately leave their role.

> "It was really difficult for me because it wasn't a case of this is in your best interests or whatever, it was more of it's in the best interests of your employers, the Trust, or my manager." Staff

Investigators also had complex social identities, entangled with personal beliefs and the motivations of patients, families and staff, as well as organisational pressures from legal teams, governance structures, and wider local and national policy directives.

> "I can hear from the family. I can hear from the staff… You don't have an allegiance to either camp. So, holding both camps, is what we have to do, in my view, what you have to do if you're a compassionate investigator… It is exhausting. I have a view that actually a better model, is why doesn't our families have an independent advocate of their own?… Then I know the family is properly looked after and I can get on with my job without feeling pulled. And it's not that I won't have a relationship with the family. I think it just puts us a little buffer zone there." Investigator

Factors including their background (e.g., some investigators were current or ex-clinical staff), power (e.g., influence of senior or legal teams), morality (i.e., what felt like the right thing to do) and organizational culture (i.e., the way things tended to be done), shaped their approach.

> "The culture of how we treat families comes from the top." Investigator

Some were keen to distance themselves from "organizational agendas", experiencing isolating internal conflict as a result.

> "It's quite an isolated role, you know, I'm not part of the team. I mean, technically I am… but even before Covid I would be working at home for most of the time. I like that distance." Investigator

Additional challenge included feeling inadequately equipped with skills and knowledge in working sensitively and meaningfully with those affected by safety incidents, as well as investigating alongside a demanding clinical role.

> "I've always really struggled with erm, I wouldn't say the lack of support we provide to families, but how it's been quite difficult in my role, because by default, there's nothing else. I almost become that kind of support or signposting for families. And that's something I feel really strongly about… I get sworn at a lot… it's never going to be a great, you can't make this process sound like a nice day out, because there's tragedy involved." Investigator

However, the independent investigatory body had relatively well-established processes, in which investigating was their only role, and with organizational investment in training and support, of which most spoke positively about. Nonetheless, across contexts, being the human face following healthcare harm was emotionally laborious, with risk of burnout and suggestions that the role was potentially unsustainable long term.

> "I don't think anyone should do this job longer than three or four years… there is a chance that people will become emotionally burnt out… it's certainly a job that, you know, you wouldn't want to still be here ten years down the line dealing with these sorts of incidents." Investigator

Some felt unsupported in their role, with no outlet for the emotional toll the role took on them. The combination of emotional labour and lacking protected time in their job plan, meant that some investigators did not reach out to patients and families as much as they would have liked to.

> "People are trying to do it when they've got a spare hour." Investigator

2.7 Awaited, yet unwelcome report

Investigators were tasked with producing a coherent narrative report, despite messy realities, conflicting accounts and gaps in their understanding of what happened. Some investigators were also frustrated at the repetitious and inevitable nature of investigations, and lacking confidence that recommendations would be implemented.

> "Then the family always ask me, how do we guarantee that they are going to act on the findings, that is literally the first question. And that's quite a tricky one to answer because we don't have any empowerment to be able to do that… in all reality, a Trust could take your report and put it in a drawer and it never see the light of day again… they want their baby's story to make a difference and make that service safer. So, it is quite difficult, as an investigator, for me to be able to then say, well, actually I have zero control of what they do with that." Investigator

Patients and families waited in anticipation of the report, marking a key point in the process at which divergent perspectives came together. Reports were often described as disheartening, disrespectful, dishonest, paying lip service, defensive, lacking empathy, and avoiding accountability.

> "I can safely say—I've been around for a while now, and in all those years I've never ever seen my mum more angry or upset than the day I turned up at her house to see her reading through that report." Relative

Some also felt that the report insensitively delivered unexpected information, indicated ambivalence and that the organization had lost sight of the affected family, devaluing their experience and disregarding the questions they had raised.

> "The report doesn't really even sort of acknowledge the fact that she died… Small things like typos which maybe in another context you would let go… at various points they refer to her as Mr… in this context feels just really disrespectful." Relative

Frustration was also felt by patients and families where there was no right to discuss, reply or refine what had been written and it was often considered too late to become meaningfully involved and influence the report in the ways they would have liked to with hindsight.

> “I was really trying to be an advocate for this family. It got escalated quite high up, through our head of midwifery into the governance lead for the area. It basically was a blanket, ‘no, that’s the end of the report and that’s it’, and it was awful, it was absolutely awful. Working like that, where the family obviously were not happy and there were things I wanted changing.” Investigator

Following receipt of the report, some were offered bereavement support, funeral planning advice, counselling service access, and signposted to relevant charities. Others were invited to meet with representation from the healthcare organization to ask any outstanding questions. However, for some, offers of support were absent, inappropriately timed, or considered tokenistic or inaccessible. Instead, some sought to build informal relationships with others who had experienced similar situations and developed their own support networks.

> “We were given a booklet with various charitable organizations to ring… I actually had a friend, her husband had taken his own life. And she’d rung one of these organizations on the list and said she got someone at the end of the phone who was not very warm. And she didn’t think it was particularly helpful… sadly I know, two or three people that, their husbands have taken their own lives, and so I’ve had support from them more than anything… I think we could have done with some more help… the fallout that it’s had on the family as a whole has been enormous. It’s totally changed our lives. In some ways the shock in the early days you can’t, you’re not open to help.” Relative

2.8 Left with an incomplete narrative

Once reports were published, there was a general sense that it was the end of the organisational process, leaving those affected—including staff, to pick up the pieces, sometimes with their life sometimes in turmoil.

> “I had such a terrible experience that really scarred me, to the point of wondering for a while, whether I still wanted to be a doctor… I hated going to work, I absolutely dreaded it. I love my job, but I hated it with a passion… not one person at any point asked me if I was okay… I’m lucky to have friends and family… but my God, they could have ended up with a very, very different outcome, had I not had support. And that really angers me… It’s really important that we don’t traumatize already traumatized staff further.” Staff

Patients and families experienced a heightened sense of fear, confusion and disorientation, continuing to live with profound personal impacts, as well as having concerns for the mental toll it took on those around them. For some, life became an all-consuming effort to get answers to their questions and help to prevent the same thing happening to others, which was described as an exhausting, emotional and lonely journey that continued to have a ripple effect on their life.

> “I had to sort of step back and take a breath, and when I looked around me after all the years I’d spent… intensely engaged in this, but the rest of my life crumbled around me… it broke me, if I’m honest.” Relative

People also reflected on being drip-fed information, leading to more questions they felt compelled to gain answers to via activities such as liaising with clinical experts, regulatory bodies and members of parliament, as well as sourcing relevant information including recent reports and policy linked to the incident.

> "I’ve had cause to touch base with the police, with home office pathologists, with countless regulators… I have spent hundreds of hours watching live surgical procedures… I reckon I could take a decent stab at performing this procedure… We are kind of forced into the level of detail that no normal person outside of medicine would ever have to get involved in, but you’re forced down that route in order to understand.” Relative

The sense that opportunities to learn were neglected also contributed to compounded harm, as some felt that their experience was of no consequence. Some perceived that this was due to procedural constraints, whereas others evaluated that the organizations chose to circumvent the real issues that needed attention. Others raised concerns of arbitrary recommendations.

> “It makes it feel that what you’ve gone through hasn’t been completely in vain… I just feel that yes I went through this and anyone else can go through it again afterwards, it’s, you know, no-one’s learnt anything from it.” Patient

2.9 Litigation as a last resort

Pursuing litigation was often not financially motivated, or a decision taken lightly, but was considered an avenue people were forced down in hope to be finally heard, gain answers to their questions, and receive some recognition for what had happened and its impacts.

> “When I did, you know, seek legal advice, that wasn’t something that was a small decision, it was a massive decision. I just felt like it was the only way. I wanted to have a proper investigation and I just wanted them to take notice.” Patient

Some felt that outside of litigation, there was nobody with the power needed to help them piece together the puzzle. Others reflected on what was perceived unnecessary distress, having to go through the legal process, and that the organisation could have taken simple steps to avoid forcing them down that route.

> "If this was a mistake that had been immediately acknowledged and admitted to in the spirit of the Duty of Candour as it should be, this probably wouldn't have even been a clinical negligence claim. Don't get me wrong, we'd have been a bit p'ed off but we'd have got past it, you know, we recognize that, hey, we're all human." Relative

On gaining legal advice, some found the unhindered communication a refreshing contrast to a process that was seemingly out to question their realities, meaning it was the first time they felt heard.

> "That was the first time that somebody had just listened and then taken it all in… that validation just helps you." Relative

There was however, an acknowledgement that pursuing litigation required capital, both financially and mentally, to allow people to repeatedly revisit what happened, whilst also suffering potentially life changing consequences, or grieving. This sense of powerlessness led some to choose not to raise a legal claim.

> "At one stage I was so upset by the whole thing I felt like taking legal action but I was very aware that the NHS is a very large organization and, you know, that it was little me against them. I didn't feel like I wanted to take it on… I felt like I was in the boxing ring with my hands tied behind my back. And I felt desperate." Relative

Concerns were also raised for others who may be defeated by the process due to social inequity.

> "It discriminates against people who don't necessarily have the ability or the support around them to pursue it… or have the intelligence and have the drive to go through the compensation process." Patient

3 Discussion

The study aimed to explore the experiences of patients, families, staff and legal representatives affected by safety incidents over time, and the factors influencing decisions to litigate. In doing so, we found that patient safety incidents meant that patients and families went on a journey, including various stages of hope, disappointment and significant impact on their lives. Patients and families started investigation processes from a point of cautious hope, expecting the health service to want to listen and learn from what happened, as well as support them to heal. However, later, they came to realize that they lacked power, knowledge, and support to navigate the system, with risks of disproportionately affecting those most vulnerable. Some felt intentionally excluded, illuminated in awaited investigation reports. Overall, there was a sense that elusive "organizational needs" were prioritized above the needs of all affected. As a result, some felt forced to meet their needs elsewhere, such as pursuing litigation. Ultimately, emotional distress was experienced by everyone involved, yet processes neglected emotion, resulting in compounded harm. Our findings illuminated a parallel journey experienced by staff, who also faced a series of challenges and sometimes disappointments.

Just like healthcare staff, patients and families are emotional beings (45). The findings from this study highlight the undoubtable importance, impact and scale of emotional harm experienced by everyone affected, and failure to recognize and address such, contributing to compounded harm (46). Acknowledging that types of compounded harm center on emotion being imperative, as emotional harm is often ignored, or its importance minimized in favor of physical, and to some extent's financial reparation (7). As a result, we recommend that investigatory processes should be relational, centering the needs (including emotional) of patients, relatives and staff affected by safety incidents to avoid compounding harm (see Box 1). Innovative restorative approaches are being adopted in other nations such as New Zealand (47, 48). A separate, secondary analysis of this data also focusses specifically on the types of compounded harm experienced by patients and their families as a result of responsive processes—powerless, inconsequential, manipulated, abandoned, de-humanized, and disoriented (49) Designed in part, to support the emotional needs of patients and families, is also a role that is being increasingly established in the English healthcare system—the Patient Family Liaison Officer (PFLO) (Overton et al., In Prep), leaning from initiatives better established in policing. Nonetheless, research into such approaches remain in their infancy, and organizational readiness

BOX 1 Recommendations.

In light of the findings, we propose five recommendations:

1) Investigatory processes should be relational, centering the needs (including emotional) of patients, relatives and staff affected by safety incidents to avoid compounding harm.

2) The relational work carried out by investigators is both important and complex, and needs to be adequately resourced, valued, and recognized within policy and processes.

3) Patients, relatives and staff should have access to tailored information to aid their understanding of what investigation processes entail, how they can become meaningfully involved, and how they can effectively navigate the system in flexible ways.

4) Investigation processes should recognize and seek to reduce social inequities, providing tailored support to those who need it.

5) Policy and procedure directives at local and national level, as well as support from outside agencies (e.g., regulatory bodies) should be in alignment to overcome culturally engrained fears of litigation at all levels of the healthcare system.

for them is yet to be empirically explored within the context of the NHS.

Interestingly however, recognition of the centrality of emotion in investigatory processes is not new, with authors two decades ago suggesting a need to "go back to basics in healthcare" and dignify these very human experiences, with a human response (50). What our study does help to shed light on, is why what may seem both morally and logically the right thing to do (51), may be more complex to deliver in reality, than it appears from any individual perspective. To our knowledge, this represents the first UK-based study to examine the views of key stakeholders collectively—patients, their families, healthcare staff, investigators and legal staff, and over time. Our findings extend current literature by exploring both the convergence and divergence in the experiences of these important groups of people, with evidence of significant synergies, in particular between patients, relatives, and staff. Indeed, whilst traditional narratives of investigations might posit staff and patients and families as adversaries in investigations, we found compelling evidence that patients, relatives and staff often reported similarly feeling overwhelmed, excluded, ill-equipped, unsupported and uninformed. This contribution is significant, as current guidance and practical frameworks guiding involvement in investigations are often based on data from one perspective (19, 52), or developed within other healthcare economies (53–55).

In addition, an important finding of our research is that investigators felt their role was largely invisible and undervalued, leading to feeling isolated and at risk of burnout with limited knowledge, training and support. Investigators may shoulder unmanageable responsibility to navigate the balancing act of completing organizational priorities and sensitive discussion with those affected. As a result, we recommend that the relational work carried out by investigators is both important and complex, and needs to be adequately resourced, valued, and recognized within policy and processes (see Box 1). Implementing PFLO's may help to alleviate such pressure, or indeed, may shift or event amplify the pressure with heightened expectations. Further research is needed to determine the acceptability and feasibility of such role, including unintended consequences.

As well as the emotional harm, those affected also felt excluded from processes, and struggled to become meaningfully involved in a system that did not welcome them, support them or help them to understand. As a result, we recommend that patients, relatives and staff should have access to tailored information to aid their understanding of what investigation processes entail, how they can become meaningfully involved, and how they can effectively navigate the system in flexible ways (see Box 1). An important lens to look at these findings, is that of epistemic injustice (56), which has previously been explored by Kok et al. (57), within the context of incident investigations in Dutch health services. We recommend that investigation processes should recognize and seek to reduce social inequities, providing tailored support to those who need it. However, further research is needed to explore what that might look like, and whom might best benefit.

Perhaps even more complex to change it the wider cultural and systemic barriers to re-humanizing processes after harm are driven by organizational fear of litigation. Research from Bell et al. (58), found that patients and families who felt involved in transparent investigation processes were less likely to pursue litigation, whereas others felt the need to fight for progress, using methods such as threatening litigation. To help to overcome these issues, active compensation initiatives have been tested in an American healthcare economy, designed to reduce the burden on patients and families to seek financial recourse while suffering the impacts of what happened. This includes Communication Resolution Programmes (59–62) the Disclosure, Apology and Offer Model (58) and the Recognize, Respond and Resolve initiative (63). Nonetheless, this body of evidence suggests that culturally engrained fears of litigation remain difficult to overcome. Our findings support calls from PHSO (7) that if the healthcare system could be stripped of fear or litigation, and centered the needs of those effected, not only would people experience less compounded harm, but there would also be reduced litigation costs. Without that, there is a risk that no-one's needs are being met, in the pursuit of elusive organisational needs—such as learning, avoiding litigation and managing reputation. Integral to a reorientation of the system, we recommend that policy and procedure directives at local and national level, as well as support from outside agencies (e.g., regulatory bodies) should be in alignment to overcome culturally engrained fears of litigation at all levels of the healthcare system (see Box 1).

3.1 Limitations

There are three principal limitations to this study. First, the decision to include legal staff in the study was made part-way through, meaning that we did not recruit as many people bringing this perspective as we would have liked. To help to address this issue, we did however, involve the views of legal staff in the wider steering of the study and programme. Second, the self-selecting nature of participants perhaps attracted those with particularly negative experiences to take part. Third, while we did not specifically collect participant demographic information, we recognize from the findings that equity, diversity and inclusivity was perhaps an issue. Therefore, research is needed to capture experiences of those from a range of demographic groups, and in particular those who might be more vulnerable to patient safety incidents, to ensure the robustness of our findings and conclusions. Research better capturing experiences from those with protected characteristics, for example, would be important to ensure that findings are relevant across healthcare populations and include those potentially most vulnerable.

4 Conclusions

Current investigation processes fail to acknowledge and address the emotional harms that are experienced by those affected. As a result, patients and families are experiencing compounded harm and pursuing unnecessary litigation, staff are fearful, investigators are shouldering unmanageable responsibility, and the healthcare organization not visibly learning or improving. To avoid fear-driven processes compounding harm for those affected we propose five recommendations: (1) Investigatory processes should be relational, centering the needs (including emotional) of patients, relatives and staff affected by safety incidents to avoid compounding harm, (2) The relational work carried out by investigators is both important and complex, and needs to be adequately resourced, valued, and recognized within policy and processes, (3) Patients, relatives and staff should have access to tailored information to aid their understanding of what investigation processes entail, how they can become meaningfully involved, and how they can effectively navigate the system in flexible ways, (4) Investigation processes should recognize and see to reduce social inequities, providing tailored support to those who need it and (5) Policy and procedure directives at local and national level, as well as support from outside agencies (e.g., regulatory bodies) should be in alignment to overcome culturally engrained fears of litigation at all levels of the healthcare system.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Health and Care Research Wales. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

LR: Writing – original draft, Writing – review & editing. LS: Writing – review & editing. JW: Writing – review & editing. SM: Writing – review & editing. RS-E: Writing – review & editing. GL: Writing – review & editing. KL: Writing – review & editing. JO: Writing – original draft, Writing – review & editing.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article. This study was funded by the National Institute for Health and Care Research (NIHR) Health Services and Delivery Research Programme (18/10/02; ISRCTN14463242) and supported by the NIHR Yorkshire and Humber Patient Safety Research Collaboration (NIHR YH PSRC). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Acknowledgments

Decisions at each stage of the study were made in consultation with an active patient and family advisory group, a staff advisory group and a wider programme steering group. We thank all those interviewed for this study for so generously sharing their experiences and time with us.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 13 January 2025
DOI 10.3389/frhs.2024.1474195

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RECEIVED 01 August 2024
ACCEPTED 20 December 2024
PUBLISHED 13 January 2025

CITATION
Tran A, Blackall L, Hill MA and Gallagher W (2025) Engaging older adults in diagnostic safety: implementing a diagnostic communication note sheet in a primary care setting.
Front. Health Serv. 4:1474195.
doi: 10.3389/frhs.2024.1474195

Engaging older adults in diagnostic safety: implementing a diagnostic communication note sheet in a primary care setting

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Introduction: Adults over the age of 65 are at a higher risk for diagnostic errors due to a myriad of reasons. In primary care settings, a large contributor of diagnostic errors are breakdowns in information gathering and synthesis throughout the patient-provider encounter. Diagnostic communication interventions, such as the Agency for Healthcare Research and Quality's "Be the Expert on You" note sheet, may require adaptations to address older adults' unique needs.
Methods: We recruited and partnered with older adult patients ($n = 6$) in focus group sessions to understand their perspectives on diagnostic communication and the existing AHRQ note sheet. A two-page communication and clinic workflow tool was developed and implemented over a 6-month period using three Plan-Do-Check-Act cycles. Physicians, nurses, staff, and patients were surveyed.
Results: Most older adult patients ($n = 31$) found the tailored diagnostic communication note sheet to be easy-to-use, helpful for provider communication, and would recommend its use to other patients. Physicians and staff members were satisfied with the note sheet and described few challenges in using it in practice.
Discussion: Our findings contribute to the growing body of evidence around diagnostic safety interventions and patient engagement by demonstrating the feasibility and benefits of actively involving older adult patients in quality initiatives.

KEYWORDS

diagnostic safety, diagnostic communication, patient engagement, older adult, primary care, quality improvement

1 Introduction

Diagnostic errors—or the failures to establish an accurate and timely explanation of a patient's health problem(s) and/or communicate that explanation to the patient (1)—are common, costly, and pose risk for serious patient harm (2–4). Researchers estimate that 1 in 20 primary care patients in the United States (U.S.) experience a diagnostic error each year (3), and that most patients will experience a diagnostic error in their lifetime (1). In particular, older adults, typically described as individuals 65 and older, are vulnerable to preventable harms and deaths (5) and are at a higher risk of diagnostic errors due to a myriad of reasons. A systematic review of diagnostic errors in older adults found that diagnostic errors involving older adults were common and comprised both overdiagnosis and underdiagnosis; the presence of physical comorbidities was consistently associated with lower accuracy in diagnosing several prevalent and high disease-burden conditions in this population (6). The *Advancing Diagnostic Excellence for Older Adults Workshop* led by the National Academies of Sciences, Engineering, and Medicine (NASEM) described the importance of recognizing how diagnosis can become more difficult as medical complexity increases with age; this differentiation between ongoing or chronic disease trajectories vs. new, acute issues can complicate the diagnostic process (7). Ageist stereotypes may additionally perpetuate implicit biases towards older adults, and clinicians may mistake early symptoms of disease as subtle changes to physical and mental states that are part of the aging process (7–9).

Patient-facing strategies to engage patients in clearly communicating about their symptoms and experiences may be effective tools to reduce diagnostic errors. In 2021, the Agency for Healthcare Research and Quality (AHRQ) developed its *Toolkit for Engaging Patients to Improve Diagnostic Safety* to enhance communication and information sharing within the patient-provider encounter (10). The "Be the Expert on You" note sheet– a strategy aimed to help patients organize their medical stories and concerns in preparation for their health appointments—was the product of an extensive literature review of patient-facing materials to enhance communication, built off existing examples of patient-facing resources, and was based on the Subjective, Objective, Assessment, and Plan (SOAP) note communication template to support clinicians' existing cognitive models of diagnosis (11, 12).

Existing interventions for improving diagnostic safety may require additional efforts or considerations to engage older adults and address their unique needs. For example, several studies have found that older adults are less likely to feel comfortable speaking up about problems they've experienced (13), and those with low health literacy levels affect their ability to participate optimally in healthcare (14, 15). Older adult patients may require tailored or different interventions to address their unique needs in patient safety initiatives.

Evidence suggests that tailoring interventions to specific populations can lead to improvements in health equity and healthcare outcomes (16, 17). Interventions tailored for historically marginalized racial and ethnic populations, for example, have led to improvements in chronic disease management and overcoming barriers related to access to care and cultural competency (18, 19). Barriers to engaging older adults in research and quality improvement initiatives have been identified, including the lack of established relationships with researchers, exclusion from the intervention planning stages, varying preferences for engagement, and a lack of understanding of the benefits of participation (20, 21). Additionally, older adults may experience cognitive impairments and lack of support from medical providers when participating in quality improvement efforts, which can hinder their willingness to participate (21, 22). Older adults may also be more resistant to changes, emphasizing the need to provide reassurance about the benefits of new processes or interventions (23).

Several interventions aimed at enhancing communication specifically between older adult patients and their care providers have been developed, with many of these interventions are focused on shared decision-making (24) or advance care planning (e.g., SHARING Choices) (25). However, because these interventions generally focus on processes *after* a diagnosis has been made, they are limited in improving the information gathering and history-taking aspects of clinical care to inform a diagnosis. Further, while the "Be the Expert on You" note sheet is widely available and already being used by several health organizations and health provider groups across the U.S. to improve diagnostic safety, its use specifically for the older adult population has not yet been evaluated.

In this paper, we present the adaptation and implementation of this existing AHRQ tool in a quality improvement initiative aimed at improving diagnostic communication between older adult patients and physicians in a family medicine, primary care residency clinic that serves a diverse, underserved patient population. We sought to assess whether the note sheet was an effective and efficient way to improve diagnostic communication between older adult patients and physicians. Our project aims were to (i) review and modify the existing AHRQ "Be the Expert on You" note sheet in focus group sessions with recruited older adult patients; (ii) implement the modified note sheet in practice in 3 Plan-Do-Check-Act (PDCA) phases focused on patient engagement; and (iii) evaluate the impact of the revised note sheet on patient and physician satisfaction with diagnostic communication.

2 Materials and methods

2.1 Study design

This was a one-year quality improvement project with implementation occurring in three general phases. The study team consisted of a researcher to lead study design and planning, data collection and analysis, and evaluation; a research assistant to support patient recruitment, data collection, and data analysis; and a physician champion to lead physician and staff education and practice-wide implementation. To meaningfully involve patients and end users throughout the process, the three phases included (1) focus groups with recruited older adult patients to review and modify the note sheet, (2) training and engagement with physicians, nurses, and staff, and (3) implementing the note sheet with three PDCA cycles over a 6-month period. Institutional Review Board approval was obtained from MedStar Health Research Institute/Georgetown University prior to focus group recruitment and implementation.

2.2 Setting and participants

Focus group recruitment and project implementation occurred in a large family practice setting located in an urban area located in the

Southeastern U.S. The practice location consists of 7 attending physicians, 3 registered or licensed practical nurses, 4 medical assistants and 11 other practice staff members (e.g., front desk and administrative staff, and patient navigators). It additionally serves as a graduate medical education (GME) training site for 12 family medicine residents and serves a diverse population of patients (8,000 patient visits in 2022; 22% adults who are 65 years of age and older, 15% Hispanic, 68% Black or African American).

2.3 Phase 1: older adult patient focus groups to understand diagnostic communication and review AHRQ "Be the expert on you" note sheet

Patient recruitment involved the distribution of informational flyers, receipt of physician/staff referrals, and conduct of eligibility screening from daily patient appointment information from October 2022 to December 2022. Adults who were unable to provide verbal consent, non-English speakers, or those with suspected or documented impaired mental capacity were excluded. Patients were informed that they would be compensated with a $100 gift card for their complete participation in the project.

Four 60-minute focus group sessions with 6 recruited patient participants were conducted in January and February 2023. Focus groups were held in-person and at the practice location, depending on patients' preferences and communication needs. Patient focus groups were facilitated by the project lead (AT). Prior to the start of each focus group session, participants were informed about the purpose of the study, the procedures involved, and the voluntary nature of their participation. Verbal consent was obtained from all participants after a detailed explanation of the study's objectives and confidentiality measures. Participants were given the opportunity to ask questions, and their consent was documented by the study facilitator before the focus group began.

Focus group questions were designed to elicit feedback about patient experiences with the diagnostic process, perceptions of diagnostic communication, and on the note sheet's clarity, usability, and perceived value. Focus group questions included: "What does the term 'diagnostic error' mean to you?"; "How do doctors include you in the diagnostic process?"; "Which aspects of the note sheet were challenging for you to complete?"; "How do you think this note sheet could be improved so that you, or another patient, could use this more readily?"; and "What advice would you give a patient who was seeing this note sheet for the first time?" Patient focus group discussions were audio recorded, transcribed, and reviewed for accuracy by the research team. All transcripts were de-identified and summarized by key themes by two reviewers. Key themes were generated by a research assistant and the project lead separately, then reviewed and compared in research team meetings. These summarized themes were then presented to the focus group participants to confirm accuracy and seek additional feedback and clarification. Table 1 presents a summary of the modifications made to the existing AHRQ "Be the Expert on You" note sheet from feedback in patient focus groups. Given the minor changes made to the tool itself, we planned to administer only the modified tool to all patients, believing that the modified tool could meet the diagnostic communication needs of both older adults and the general adult population.

2.4 Phase 2: provider, nurse, and staff training for diagnostic communication and note sheet Use

A physician champion was responsible for leading implementation and was routinely updated on patient discussions and changes to the note sheet throughout the focus group phase. Because of the key roles that other patient-facing clinicians and staff members play in diagnostic safety efforts (1, 26), all practice physicians, nurses, and staff members (i.e., front desk, administrative, and patient navigation staff) received training from the physician champion about broad diagnostic safety concepts and the use of the note sheet in their new workflow. Physicians, nurses, and staff had not been previously familiar with the AHRQ note sheet or other diagnostic safety concepts. Training consisted of an introduction of the Toolkit Infographic and One-Page Handout for Staff Training (10) through in-service sessions and daily team huddles. In these sessions, clinicians and staff gave additional feedback on diagnostic safety concerns within the practice, explaining that patients occasionally failed to schedule follow-up appointments or complete care activities (e.g., laboratory tests, specialist referrals) which impacted the diagnostic process. They suggested adding a section to the note sheet to address clinical care needs prior to patient check-out to mitigate these concerns and better integrate the note sheet in the clinical workflow.

2.5 Phase 3: practice-wide intervention implementation in 3 phased PDCA cycles

This was the first diagnostic safety intervention to be implemented by physicians, nurses, and staff in this practice, and also the first time a communication tool was introduced to patients at this practice. Based on physician and practice leadership feedback, implementation of the modified "Be the Expert on You" note sheet in clinical practice occurred in three stages over the course of 6 months and included three iterative PDCA cycles to ensure that a continuous loop of workflow improvement effectively occurred (27). The PDCA cycle is a continuous loop of planning, doing, checking (or studying), and acting where testing of quality improvement measures occurs on a small scale before updating procedures and working practices (28).

We had initially planned for front desk staff to introduce the note sheet and allow patients to complete it while they were in the waiting room. However, after speaking with patients and care team members, we decided to have the note sheet introduced by nurses during the triage process. Patients expressed a desire to have the note sheet introduced by a health professional, citing the need to be encouraged to share their perspective in the

TABLE 1 Summary of modifications made to AHRQ's "Be the Expert on You" note sheet.

Change Made	Rationale
Add "pain" as an option for the question "why are you here today?"	Focus group members felt it was important to include, as it is a common motivation for them to seek care. Participant comments: P1: "That first time when the doctor comes in, it matters. They need to stick with you, asking, 'What can I do for you today? Are you in pain?' The only thing I would add is, 'Are you in pain? Where, and what is the level of your pain? It's important to me.'"
Replace "how does [a change in how you are feeling since your last visit] affect you?" with "how does [a change in how you are feeling] make you feel?"	Focus group members expressed concerns about being able to identify and describe appropriate effects of clinical changes to share with providers. They felt the modified language made it more inviting and comfortable for them to express their own perspectives. Participant comments: P4: "Is it more effective for me to fill it out from my perspective or is it more effective for me to fill it out from his [the provider's] perspective?".
Replace "what are you worried about" with "is there anything else going on?"	Focus group members felt that patients might not feel comfortable writing and admitting being "worried" about something. They felt patients should be encouraged to express their thoughts, as it could be a potentially important aspect of their health story that affects diagnosis. Participant comments: P3: "Very few people our age go volunteer anything. Nobody's going to admit 'What are you worried about?' or tell you 'I'm worried about depression.' It's a bit too direct, maybe soften it to 'What else is going on?'"
Added a note-taking space for patients to use during their appointment	Focus group members requested space on the note sheet to be able to take notes and organize their thoughts, and to refer back on. Participant comments: P6: "And if you want to make a note to yourself, you want to have a space about your impression or afterthought of your visit." P2: "I personally will put down what I discussed with the doctor. There should be some kind of comments area. 'Where is a spot if you want to put the doctor's comments down?' There should be space available for the remarks."
Added a checklist of diagnostic- and health-related tasks that need to be completed in the appointment (e.g., laboratory testing, vaccination, obtain specialty referral information, speak to clinical educator or social worker, get a work or school note)	Focus group members, staff, and physicians described the need for a checklist and plan of action to ensure that diagnostic-related tasks are completed. Participant comments: P5: "There's something missing, [there needs to be] the process for the front desk. The front desk needs to be able to look at this and see 'Okay, you need to reschedule an appointment'…too many times the doctor has left and I'm not clear on what to do."
Added information for front desk to make follow-up appointments (e.g., visit type, follow-up time period in weeks, provider type, double-booking allowed)	Physicians, nurses, and staff described the need for this information to be added to improve current clinic workflows.

context of diagnostic safety. Physicians and staff expressed the need for the note sheet to be included in the workflow in a way that accommodated concerns about high front desk staff turnover and clinic workflows.

We worked with our patient participants and physician champion to develop an adapted script from the One-Page Handout for Staff Training (10), intended for nurses to introduce the modified note sheet to patients. Nurses were provided with the script by physicians at the start of their workday, and used the script to verbally introduce the note sheet to all English-speaking adult patients after their vital signs and intake were completed. Patients were asked to fill out the note sheet while waiting to see the physician. Patients and physicians were instructed to review the note sheet together and use it to guide the health history communication. Patients were then offered the opportunity to have a scanned copy of the note sheet for their own records and asked to leave the completed note sheet in a box after checkout. All patients were invited to complete a post-appointment survey to provide feedback about using the note sheet during their appointments.

To gather feedback on the implementation process across multiple PDCA cycles, practice leadership suggested a phased approach. Initially, the physician champion piloted the modified note sheet with a designated group of patients and nursing staff over a two-week period. Feedback from the first PDCA cycle was then discussed in staff meetings, leading to minor revisions of the note sheet and workflow processes to address staff concerns and questions. These included adjustments to font size and wording, the addition of future appointment and testing reminders to the note sheet, modifications to checkout procedures, and improvements in the process of scanning and recording completed note sheets in patients' charts. The second PDCA cycle expanded the implementation to include six additional physicians and six nurses over a three-month period. Feedback from patients, physicians, nurses, and staff during this phase was reviewed and used to refine the implementation plan for the subsequent practice-wide rollout. Nurses confirmed that the script was appropriate and could be implemented within their workflows, and staff felt satisfied with the modifications to the patient checkout process and checklist of care activities provided by the diagnostic communication tool. In the final PDCA cycle, the modified note sheet was implemented across the entire practice, involving all physicians and staff over a three-month period.

2.6 Data collection

Surveys consisting of closed- and open-ended questions were developed by the study team to collect information about patients', physicians', and staff members' experiences with diagnostic communication throughout the project. No exclusion criteria were applied to patients during intervention implementation.

2.6.1 Physician, nurse, and staff surveys (pre- and post-)

To gain a better understanding of both physician and other healthcare team members' perspectives, surveys were distributed to all physicians and nurses and staff before and after implementation of the modified "Be the Expert on You" note sheet. A 5-point Likert scale was used to assess respondents' level of agreement with the following statements: "*My patients come to their appointments prepared*", "*My patients effectively communicate their health needs*", "*My patients share their health stories in an efficient manner*", "*My patients are helpful partners in the diagnostic process*", *and* "*My patients are organized with the important health information needed for me to make a diagnosis.*"

2.6.2 Patient surveys and note sheet utilization and completion rates

During the 6-month implementation period, surveys were distributed to gather insights on usability and satisfaction from the patient perspective. Responses remained anonymous and served as consent to participate in the project. Patients were asked to rate their level of agreement on a 5-point Likert scale to the following statements: "*The provider listened to me carefully during my visit*", "*The provider addressed my main concerns*", "*The 'Be the Expert on You' note sheet helped me to organized my thoughts*", "*The 'Be the Expert on You' note sheet helped my communication with my provider*", "*I am satisfied with this note sheet*", *and* "*I would recommend this note sheet to other patients.*" Open-ended questions were included to encourage patients to describe any perceived challenges and/or benefits of using the modified note sheet during their visit. Demographic information (e.g., age, gender, race/ethnicity) was also collected.

To improve survey completion rates, patients were offered the opportunity to participate in a raffle for a $100 gift card by including their name and contact information (email or phone) at the end of the survey.

3 Analysis

Survey responses were collected by the study team at each phase of implementation, recorded into an Excel spreadsheet, and stored in a cloud-based content management platform for analysis. Note sheet utilization rate (i.e., number of note sheets collected divided by numbers of patients seen) and average note sheet completion rates (i.e., percentage of note sheet that was completed by patients) were also evaluated. Descriptive statistics were completed to describe patient, physician, nurse and staff survey results. We employed means for continuous variables and frequencies and percentages for categorical variables. All analyses were conducted using STATA version 14.2 (29).

4 Results

4.1 Physician, nurse, and staff surveys (pre- and post-)

Fifteen physicians and 13 nurses and staff members responded to the pre-intervention survey; 12 physicians and 8 nurses and staff members responded to the post-intervention survey. We observed little change in the proportion of physicians who agreed with the statement, "my patients come to their appointments prepared" pre- and post- intervention; fewer staff agreed with the statement that patients came to appointments prepared after the note sheet intervention. Before implementing the "Be the Expert on You" note sheet, no physicians and only 1 nurse or staff member (3.6% of the total sample) agreed with the statement, "my patients are organized with the important health information needed for me to make a diagnosis"; after the intervention, 2 physicians and 3 nurses and staff members (25.0% of the total sample) agreed with this statement. Prior to the note sheet implementation, only 1 physician and 2 nurses and staff members (10.7% of the total sample) agreed with the statement, "patients share their health stories in an efficient manner"; after implementation, more than half of physicians and nurses and staff members (60.0% of the total sample) agreed with this statement. Additionally, after implementing the note sheet, more physicians and staff collectively agreed with the statement, "my patients effectively communicate their health needs" (75.0% vs. 42.9%). In the physician respondent subsample, 83.4% of physician respondents agreed with the statement, "my patients effectively communicate their health needs" after the note sheet implementation, compared to 33.3% of physician respondents before implementation. Table 2 presents the responses from our physician and nurse and staff subsamples.

4.2 Note sheet utilization and completion rates

We evaluated note sheet utilization and completion rates throughout the three phrases of the implementation period. A total of 143 patients completed at least one section of the "Be the Expert on You" note sheet. In the first phase of implementation (i.e., physician champion only), all 16 patients seen in clinic by the physician (100%) completed the note sheet in the 2-week period. In the second phase (i.e., 7 physicians), 39 of the 354 (11.0%) patients seen completed a note sheet in the 4-week period. During the 6-week implementation period occurring practice-wide, 88 of the 1,100 (8.0%) patients seen in clinic completed a note sheet.

Of those 143 patients who engaged with the note sheet in some capacity, 100 patients (69.9%) completed the note sheet in its entirety (i.e., completed each of the five questions). We found that all of these patients answered the first question ("Why are you here today?") and third question ("Have you seen anyone else about your health?"). The lowest percentage of patients

TABLE 2 Physician, nurses, and staff pre- and post-intervention responses.

Statement	Physician Responses, n (%) Pre-intervention, $n = 15$ Post-intervention, $n = 12$			Nurses and Staff Responses, n (%) Pre-intervention, $n = 13$ Post-intervention, $n = 8$		
	Strongly Agree or Agree	Neither Agree nor Disagree	Strongly Disagree or Disagree	Strongly Agree or Agree	Neither Agree nor Disagree	Strongly Disagree or Disagree
My patients come to their appointments prepared.	4 (26.7)	5 (33.3)	7 (40.0)	3 (23.1)	7 (46.2)	4 (30.8)
	4 (33.3)	3 (25.0)	5 (41.7)	0 (0)	4 (50.0)	4 (50.0)
My patients are organized with the health information needed for me to make a diagnosis.	0 (0)	7 (40.0)	3 (60.0)	1 (7.7)	7 (53.8)	5 (38.5)
	2 (16.7)	2 (33.3)	6 (50.0)	3 (37.5)	4 (50.0)	0 (0)[a]
My patients effectively communicate their health needs.	5 (33.3)	5 (33.3)	5 (33.3)	7 (53.8)	5 (38.5)	1 (7.7)
	10 (83.4)	2 (16.6)	0 (0)	5 (62.5)	2 (25.0)	1 (12.5)
My patients share their health stories in an efficient manner.	1 (6.7)	4 (26.7)	10 (66.6)	2 (15.4)	8 (61.5)	3 (23.1)
	5 (41.7)	3 (25.0)	4 (33.3)	7 (87.5)	1 (12.5)	0 (0)
My patients are helpful partners in the diagnostic process.	6 (40.0)	8 (53.3)	1 (6.7)	3 (23.1)	9 (69.2)	1 (7.7)
	6 (50.0)	6 (50.0)	5 (41.7)	3 (37.5)	5 (62.5)	0 (0)

Practice staff includes front desk and administrative staff, and patient navigators.

[a] Missing a survey response for this item.

(80.4%) responded to the last question of the note sheet, "Is there anything else going on?"

4.3 Older adult patient surveys and feedback

We received 120 patient survey responses, with 31 surveys from patients 65 years of age or older (21.7%). Survey participants were predominantly women (71.7%) and Black or African American (81.7%) (see Table 3).

A majority of older adult patients who responded to survey questions ($n = 31$) agreed or strongly agreed that the "Be the Expert on You" note sheet helped them to organize their thoughts (71.0%) and helped their communication with their physician (77.4%). Most older adult patients reported being satisfied with the note sheet (80.6%) and would recommend the note sheet to other patients (77.4%). More than three-quarters of older adult patients who used the note sheet felt their provider listened to them carefully during their visit (77.5%) and addressed their main concerns (80.6%). The responses from the older adult subsample, as well as from the broader patient sample, are presented in Table 4. With the exception of the item regarding recommending the note sheet to other patients, we found that the responses to all other items were similar between the older adult subsample and the full patient sample, with differences within 10%.

We asked all patients to describe any challenges utilizing the note sheet and to identify ways that the note sheet helped them with their health visit. Of the 35 free-text comments received related to challenges using the note sheet, 30 patients (85.7%) responded "none" or "n/a". One patient reported they had "nothing to write on" and that a clipboard might be helpful; two patients reported lost information or information-related challenges. The remaining two comments described appointment details rather than the note sheet itself.

TABLE 3 Patient survey demographics ($n = 120$).

Variable	n (%)
Age (in years)	
21 or younger	7 (5.8)
22–34	11 (9.2)
35–44	19 (15.8)
45–54	20 (16.7)
55–64	26 (21.7)
65–74	26 (21.7)
75 and older	5 (4.2)
Missing	6 (5.0)
Gender	
Man	28 (23.3)
Woman	86 (71.7)
Missing	6 (5.0)
Race	
American Indian or Alaska Native	0 (0.0)
Asian or Pacific Islander	2 (1.7)
Black or African American	98 (81.7)
Other or multiple	6 (5.0)
White	5 (4.2)
Missing	9 (7.5)

Thirty-two patients responded to the question about how the note sheet helped with their health visit. Several patients ($n = 6$) stated the note sheet helped them focus, for example: "It helped me stay focused on what is ailing me and tell the doctor without rambling." Other patients stated that the note sheet helped them communicate better ($n = 4$) and helped to prepare or get organized prior to meeting with the physician ($n = 4$): "It helped me think out what I needed to ask my physician." A few patients ($n = 3$) expressed that the note sheet helped the physician with the diagnosis, "It allowed the doctor to immediately identify my issues," and one patient wrote that the note sheet "Shows that the staff is concerned about its patients."

TABLE 4 Older adult ($n = 31$) and all patient ($n = 120$) responses.

Question	Older adult responses, *n* (%) All patient responses, *n* (%)					
	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree	Missing
The “Be the Expert on You” note sheet helped me to organize my thoughts.	14 (45.2)	8 (25.8)	4 (12.9)	0 (0)	3 (9.7)	2 (6.5)
	60 (50.0)	34 (28.3)	12 (10.0)	0 (0)	10 (8.3)	4 (3.3)
The “Be the Expert on You” note sheet helped my communication with my provider.	15 (48.4)	9 (29.0)	3 (9.7)	0 (0)	2 (6.5)	2 (6.5)
	64 (53.3)	29 (24.2)	14 (11.7)	0 (0)	9 (7.5)	4 (3.3)
The provider listened to me carefully during my visit.	22 (71.0)	2 (6.5)	3 (9.7)	0 (0)	2 (6.5)	2 (6.5)
	88 (73.3)	17 (14.2)	3 (2.5)	0 (0)	9 (7.5)	3 (2.5)
The provider addressed my main concerns.	20 (64.5)	5 (16.1)	1 (3.2)	0 (0)	2 (6.5)	3 (9.7)
	87 (72.5)	17 (14.2)	2 (1.7)	0 (0	9 (7.5)	5 (4.2)
I am satisfied with this note sheet.	17 (54.8)	8 (25.8)	2 (6.5)	0 (0)	3 (9.7)	1 (3.2)
	68 (56.7)	30 (25.0)	9 (7.5)	0 (0)	10 (8.3)	3 (2.5)
I would recommend this note sheet to other patients.	20 (64.5)	4 (12.9)	2 (6.5)	0 (0)	4 (12.9)	1 (3.2)
	71 (59.2)	28 (23.3)	6 (5.0)	0 (0)	12 (10.0)	3 (2.5)

5 Discussion

Quality improvement can benefit from early and meaningful integration of patients and families in all aspects of the process. While definitions of patient engagement vary widely, strategies that foster a partnership and shared leadership between healthcare providers and patients are generally considered the highest level of engagement. These strategies have the potential to yield better, more patient-centered outcomes (30). However, codesigning with patients is a strategy that is often absent or undefined in the existing literature, and particularly with input from patients of different ethnic backgrounds, age groups, and disability statuses (31). In our study, patient focus groups provided a meaningful opportunity for research and clinical teams to introduce diagnostic safety topics to older adult patients and engage them in codesigning strategies to improve diagnostic communication. As older adult patients are often underrepresented in patient safety and quality initiatives, they may require additional support and accommodations for meaningful involvement in codesign. Our experience highlighted the desire of older adult patients to be informed and encouraged to take on active roles in their own medical care, and demonstrates the positive outcomes of a relatively simple, low-cost intervention on older adult patient satisfaction and communication effectiveness.

In response to feedback from patient focus group sessions, several changes were made to the original note sheet wording and structure to improve older adult engagement and uptake. Older adult patients described the need for the note sheet to be introduced by a healthcare team member to understand their roles and be encouraged to participate in diagnostic safety initiatives. Patients who used the note sheet generally found it easy to use, helpful for communicating with their physicians, and would recommend its use to other patients. Patients described few challenges or concerns about using the note sheet.

Physicians, nurses, and staff members were generally satisfied with the note sheet, described few challenges to using it in practice, and agreed favorably about its use in improving information gathering and diagnostic communication. Somewhat unexpectedly, in our post-survey, we noted that no nurses and staff agreed with the statement that patients came prepared to their appointments. This lack of agreement may have been due to our decision for nurses to introduce and provide the note sheet to patients immediately prior to the physician encounter (during the triage process), rather than sharing the note sheet with patients prior to their appointment altogether. Alternatively, this finding may also represent an increased awareness of the role of patients in the diagnostic process and thus, an increase in expectations for patients to prepare and share their health stories more effectively.

Despite increased research and attention on patient engagement interventions, few studies have assessed the outcomes and impacts of various patient engagement interventions on quality outcomes (32), and particularly diagnostic quality. To our knowledge, this is the first study to determine the appropriateness of a diagnostic communication tool for older adults and to evaluate the uptake of AHRQ’s “Be the Expert on You” note sheet in a primary care setting. We found uptake of the note sheet across all patients to be less than 10%; however, our implementation occurred in tiered phases and was implemented practice-wide for only 3 months to accommodate the overall one-year project time constraint. The proportion of completed note sheets to patients seen in clinic seems low; however, we observed a consistent and promising increase of completed note sheets over the short time period and positive feedback from patients, physicians, and staff. It is worth noting that implementation occurred despite several competing practice priorities and responses to the COVID-19 pandemic (e.g., high front desk staff turnover, building reconstruction, and blocked patient rooms), was relatively simple and required minimal workflow changes or additional resources, and that physicians and staff expressed an interest in continuing its use after our project period. Future efforts utilizing this tool should consider research studies that evaluate the uptake of the note sheet across longer implementation periods, deploy study designs that include comparison groups and/or can better ascertain the relationship between the intervention and diagnostic outcomes, and develop ways to accurately embed and/or track the patient note sheet across workflows and using electronic health record or technologies.

We found that nearly all patients who used the note sheet felt that their physicians listened to them carefully and addressed their main concerns, with more than 70% strongly agreeing with these statements. However, we were unable to compare this finding with the response rates of patients not utilizing the note sheet and there is a lack of comparable data around the “Be the Expert on You” note sheet and other diagnostic communication interventions in the existing literature. Future studies can build on our preliminary findings to examine whether the “Be the Expert on You” note sheet improves not only diagnostic communication but also patients’ general experiences around communication in care appointments. Tailoring interventions to patients’ preferences is necessary, particularly for historically marginalized patient groups, to ensure satisfactory experiences and help physicians to be more attuned to specific cultural and micro-cultural factors during medical encounters (33). Employing a patient co-design approach to adapt existing communication interventions may be an effective and relatively simple way to improve patients’ communication experiences with their primary care physicians. Further research is needed to test the relationship between patients using the note sheet and their perceptions of being listened to and having their concerns addressed, particularly among ethnic minority and historically disadvantaged groups.

Our study has several strengths. Although the AHRQ “Be the Expert on You” note sheet was developed with patient partners and from patient input, additional changes and considerations were needed to make this more appropriate for our older adult population. Second, it demonstrates the feasibility of recruiting and engaging patient partners and implementing an intervention with several PDCA cycles as a one-year quality improvement initiative to achieve end user buy-in and engagement.

Despite these strengths, the results should be interpreted in light of a number of limitations. Because our study was conducted in one family practice, the generalizability of our findings is limited. Because this was intended to be a quality improvement initiative, we focused on implementation and did not have a comparison group available or evaluate diagnostic outcomes such as reported errors, time to diagnosis, or diagnostic accuracy. The small physician and staff sample size (both less than 20) limited our ability to perform nonparametric statistical tests to compare survey responses before and after the note sheet implementation. We did not have information available on non-respondents and therefore were unable to examine patient-level factors likely to contribute to engagement and the extent or impact of response bias. Finally, and despite recruitment efforts to include them, caregivers and family members of older adult patients were not involved in our focus groups. Caregivers are critical historians and messengers about any acute changes in older adults’ symptoms, and there are few formal channels for caregivers to share information that could be essential to improving diagnosis. Future research considering the roles of caregivers and ways to better involve them in patient-facing interventions to improve diagnostic quality and other quality initiatives are needed.

Data availability statement

The datasets presented in this article are not readily available because with patient focus group transcripts, the small group size could compromise participant confidentiality and the proprietary nature of the information. De-identified excerpts relevant to the study's conclusions are available from the authors upon reasonable request, subject to ethical approval and confidentiality agreements.

Ethics statement

The studies involving humans were approved by Georgetown-MedStar Institutional Review Board (IRB). The studies were conducted in accordance with the local legislation and institutional requirements. The ethical committee/IRB waived the requirement of written informed consent for participant from the participants because verbal consent was obtained, audio recordings of focus group sessions were only used for transcription purposes, did not contain protected health information (PHI), and were de-identified. The Georgetown-MedStar IRB approved a partial waiver of HIPAA authorization in accordance with regulatory requirements and study screening procedures. Participants’ PHI was not collected as part of the patient surveys or during note sheet implementation.

Author contributions

AT: Conceptualization, Funding acquisition, Methodology, Investigation, Project administration, Data curation, Writing – original draft, Writing – review & editing. LB: Project administration, Data curation, Writing – original draft, Writing – review & editing. MH: Conceptualization, Funding acquisition, Methodology, Writing – original draft, Writing – review & editing. WG: Conceptualization, Investigation, Project administration, Resources, Writing – review & editing.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article. The study was supported by grant #590 (Dr. Tran) from the Society to Improve Diagnosis in Medicine DxQI Seed Grant Program. The funders had no role in the study design; in the collection, analysis; and interpretation of the data; in the

writing of the report; and in the decision to submit the paper for publication.

Acknowledgments

We would like to express our sincere gratitude to the patients who participated in focus groups and were involved throughout the duration of the project. Your expertise, dedication, and collaboration were invaluable in ensuring the success of this work. We additionally appreciate the physicians, nurses, and staff at the practice site for their support throughout the research process and their commitment to improving patient care.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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frontiers | Frontiers in Health Services

TYPE Perspective
PUBLISHED 28 February 2025
DOI 10.3389/frhs.2025.1472738

OPEN ACCESS

EDITED BY
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RECEIVED 29 July 2024
ACCEPTED 27 January 2025
PUBLISHED 28 February 2025

CITATION
Wailling J, Cameron G, Stolarek I, Turner S, Bleakley B, O'Connor N, Harwood C, Power M, Turner K, Kooijman A, Oelke ND, Gustafson D, Robson R, Anderson Wallace M, Drennan G, Hughes J, O'Hara JK, Swanepoel F and LeMaster CH (2025) Restorative initiatives: emerging insights from design, implementation and collaboration in five countries.
Front. Health Serv. 5:1472738.
doi: 10.3389/frhs.2025.1472738

Restorative initiatives: emerging insights from design, implementation and collaboration in five countries

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Introduction: Restorative systems are human centred and distinguished by an emphasis on relational principles and practices. Emerging evidence indicates that a restorative approach holds promise to mitigate and respond to harm in the complex health environment. Advocates are collaborating with clinicians and institutions to develop restorative responses to adverse events.

Method: This paper shares the insights of an international network who have been collaborating to nurture the development of restorative policy and practice in five countries since 2019 (Aotearoa New Zealand, Australia [New South Wales & Queensland]; Canada [British Columbia], England and the United States [California]). Our work is at varying stages of maturity and incorporates co-designing, implementing, and evaluating restorative responses to adverse events.

Results & discussion: The viewpoint provides an overview of the core principles, emerging evidence, and shares our collective reflections about the constraining and enabling factors to development. We recognise that we cannot speak to the breadth of work underway worldwide. Our hope is that by drawing on our experiences, we can offer some thoughts about what a restorative lens offers the future of patient and family involvement in patient safety, whilst providing the opportunity for transparent critique of work to date.

KEYWORDS

patient safety, restorative responses, compounded harm, restorative justice, restorative approaches, restorative practice, healthcare harm, adverse events

Introduction

The restorative approach is conceptualised as a broader social movement that holds promise to nurture potentially transformative, more accountable, healing systems that are dynamic and responsive to communities (1, 2). Given the focus on equity and community involvement, perhaps it is unsurprising that advocates are increasingly partnering with clinicians, academics, Indigenous leaders and policy makers to promote the rapid adoption of restorative initiatives intended to mitigate and respond to healthcare harm (conflict, complaints and adverse events). Our vantage point, as an international collaborative, who come together with a shared purpose, provides a broad network and diverse lenses to draw from whilst supporting and promoting development during a period of rapid growth. We recognise that we cannot speak to the breadth of work underway worldwide.

Drawing on our unique and collective experiences of developing restorative initiatives in five countries, (Aotearoa New Zealand [NZ], Australia [New South Wales & Queensland]; Canada [British Columbia], England and the United States [California]) this paper explores the key factors constraining or enabling development. We are mindful that our own experiences are influenced by the interplay between country specific structures, worldviews and cultural norms and that the complex adaptive nature of healthcare delivery presents context specific challenges. To date, our work has been focussed on the application of restorative principles and practices to *proactively* co-design patient safety initiatives and/or *reactively* respond to harm. Implicit is a requirement for institutions to ensure Indigenous practices and the voices of priority populations and those with lived experience are upheld and have a place.

Background

Two decades ago, the patient safety movement was established with the intention of preventing harm from adverse events. The World Health Organisation defines patient safety as:

> “the absence of preventable harm to a patient and reduction of risk of unnecessary harm associated with health care to an acceptable minimum” (3).

The definition is underpinned by ethical biomedical decision-making which aims to balance beneficence (performing an act that benefits someone) and non-maleficence (the obligation not to intentionally inflict harm). The implication is that someone must determine which harm is *preventable* or *unnecessary,* and what risks are *acceptable* (or not) (4). In the aftermath of an adverse event, directly affected individuals - clinicians, patients or families - are usually excluded from these decisions. Context specific medico-legal or safety infrastructure, and its enactment, contributes to subtle or potentially devastating impacts (5). The severity and nature of the harm, and what to do about it, is defined by an investigator enacting specific legal or safety procedures. Using evidence-based approaches to learn and improve system safety is essential, but the quality and efficacy of investigative approaches, especially those which do not involve safety expertise, is critiqued (6, 7). Legal systems also do not reliably produce justice (8). For example, Section 51 of the Evidence Act 1996 in BC Canada affords protections, through legal privilege, to members of committees who investigate adverse events, who cannot be forced to testify, answer questions or produce documents. Whereas, harmed patients and family members are not provided with similar protections, included in reviews, nor are they given access to the committee report (9).

A fundamental premise for restorative justice is that when a ‘conflict’ (e.g., an adverse event) becomes the property of an institution or profession, specific frameworks and practices determine whose voice is credible (10). The resulting response discounts emotion and steals the ability of affected individuals to decide how harm might be addressed, what they need, and who should support their journey. The character of the response is adversarial, dictating how individuals are allowed to interact with each other, what issues they should be engaged with, and who is in charge (11). There is growing evidence that failing to account for the emotionally distressing and potentially traumatising nature of adverse events dehumanises directly affected individuals, and contributes to compounded harm (4, 12, 13). Compounded harm is fast emerging as an urgent public health issue, which has negative impacts on clinicians, patients and families, investigators and the wider community (4, 14). The following definition was developed over a five-year period, using a range of methods, in Aotearoa NZ.

Compounded harm emerges from institutional or interpersonal responses to healthcare harm. It is associated with one or more relational or structural violations that inhibit human agency and deny individuals or communities access to the relational resources they need to make sense of, and heal from, a harmful experience in a safe environment (e.g., dignity, mutuality, care); or the structural rights citizens expect (e.g., informed consent, safe healthcare).

When relational or structural rights are violated, compounded harm can evolve and intensify over time, contributing to individual or collective dehumanisation, injustice, interpersonal violence, mental distress, trauma, post-traumatic stress syndrome (PTSS), unjustified blame (of oneself and others), shame, stigmatisation, moral injury, mistrust, inequity, social isolation or suicide. Ultimately, compounded harm can negatively impact how individuals or communities view themselves, or the world around them, eroding their ability to be free of harm in the future

[Wailling (4). p. 237].

Improving mental health is a global priority and requires consideration of how health system processes can promote, erode, or negatively impact well-being (15). The phenomenon is under researched, but emerging work provides insights into the key features, which may be related to country specific frameworks [e.g., (4, 9, 12, 16)]. This paper explores the development of restorative responses as a key strategy to mitigate compounded harm and promote dignity, wellbeing and trust. A restorative response is a set of relational philosophy, principles and practices that can be applied to prevent, mitigate, or respond to healthcare harm and may be used interchangeably with the term restorative approach.

Restorative principles and practices

Restorative philosophy appreciates that humans are inherently relational beings, and that relationships can heal and harm us (17). A discussion of the rich and diverse roots is beyond the scope of this paper, which attempts to surface key challenges in patient safety, where it has more recently been combined with safety science (11, 18). Different terms are used in our respective countries, often interchangeably, to describe approaches underpinned by restorative principles and goals.

A restorative approach may be broadly conceived as a set of relational principles that finds expression in common practices that promote human agency, dignity, respect, voluntariness, responsibility, equity and safety. In the complex health environment, a restorative initiative appreciates the holistic, responsive and dynamic human contribution to safety and wellbeing. The restorative triangle (Figure 1) serves as a visual reminder as to how human relationships contribute, and how relational "slack"[1] influences system resilience capacity. Ideally, restorative systems focus their efforts on *proactively* promoting safety through strong relationships, anticipating that harm is inevitable in a complex system, and less time in a *reactive* state responding to harm. Developing relational capacity nurtures conditions in which individuals feel more able to have difficult conversations and resolve conflict. Doing so means that when harm inevitably occurs, it is understood as an event worthy of learning and a human experience that creates needs and obligations (4).

A restorative response involves listening to understand what happened, the impacts and needs involved, and clarifying the responsibilities for repair (20). NZ research concludes that the following principles are important considerations in complex health systems (4, 21).

1. **Acknowledge the harm and involve the affected community.** Systemic and individual risks are transparently communicated. When harm occurs, it is approached as an event to be managed and a human experience. The affected community is informed about the potential outcomes and impacts of involvement and can choose to participate in ways that matter to them. Dynamic lived and living experience is validated and responded to.
2. **Respond to the human impacts and needs involved.** Directly affected individuals can access a range of trauma informed supports within (e.g. skilled facilitation, emotional support) or outside of a procedural response (e.g. peer support, psychologist). Directly affected individuals can safely share what happened (or might happen), with the people of their choosing in a manner of their choosing, and their contributions are viewed as a credible source of evidence.
3. **Clarify obligations.** Listen to understand diverse individual and institutional needs associated with healing, learning and improvement and clarify obligations. Honestly communicate if and how risks can be mitigated.
4. **Take responsibility for harm and repair.** Responsibility is taken for: the human impacts (e.g., compensation); systemic issues (e.g., the design of embedded systems); latent conditions; and ensuring actions for repair and risk mitigation are realised. Potential solutions are co-created and account for the diverse perspectives involved.

A common myth is that a restorative response requires a face-to-face meeting, in alignment with the restorative justice conferences used in criminal settings. Whereas healthcare research identifies that offering a range of trauma-informed documentary and dialogical options is valued by harmed patients and families (21). Both can accommodate the use of art, poetry, or other forms of storytelling and stand in contrast to the investigative "interview" or "statement". Dialogical practices associated with restorative practice encompass a continuum of affective questions and statements, facilitated meetings and Circle practices. Circles involve a structured and intentional conversation in which people, sitting in a circle, respond sequentially to questions posed by the facilitator. Community building Circles create foundations that nurture wellbeing, safety, connection and trust by encouraging collaboration, equitable decision making and cognitive diversity (22).

Emerging evidence for the use of restorative approaches

In health systems, restorative initiatives have found roots in communities with lived experience of inequity in all its forms and settings where the relational contribution to safety and well-

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[1] Slack refers to *"available spare resources, of any sort, which can be called on in times of need"* (19).

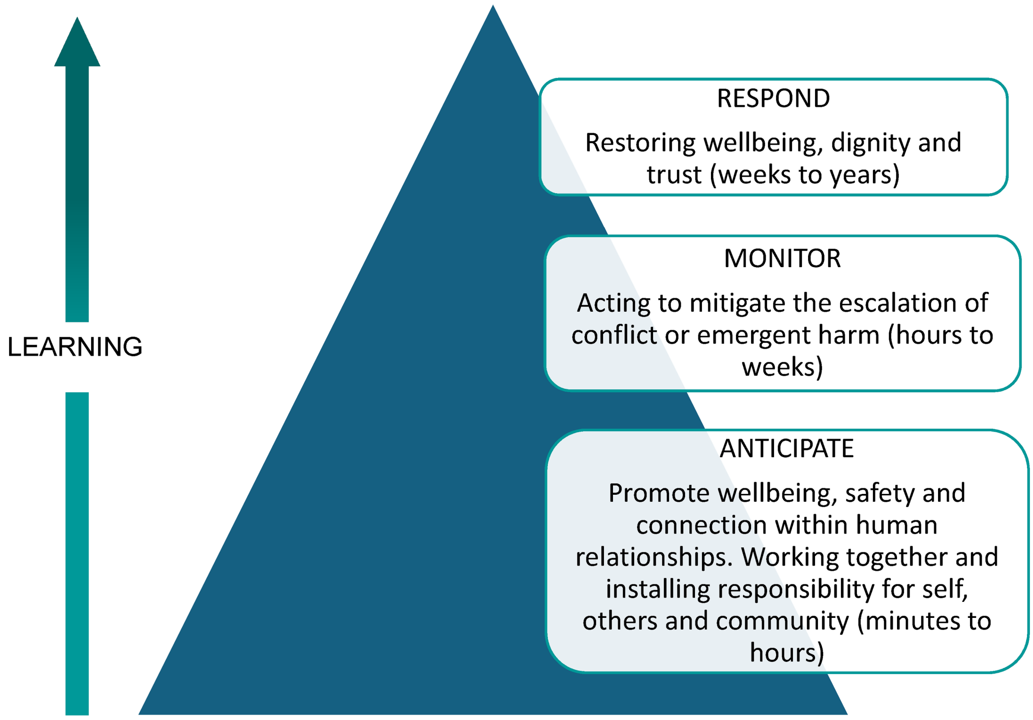

FIGURE 1
The restorative triangle. Adapted with permission from "Restorative inquiry: A resilient response to systemic harm?" by Jo Wailling, 2021.

being is incorporated in cultural norms, worldviews, or everyday practices. The key areas of development underway are mental health, women's health, and paediatrics. It is notable that in all of our countries, harmed patients and families, and advocacy organisations are amplifying lived experience voices to inform a community driven approach [e.g., (5, 23)]. In Canada and NZ, initiatives were developed in the aftermath of government inquiries that highlighted health system racism, bias or inequity (24, 25). In these settings, policy development is occurring in partnership with Indigenous communities. In NZ, the sovereignty of Māori over the rights and practices of hohou te rongo (peace-making) as a distinct Indigenous restorative approach is protected by Te Tiriti o Waitangi (The Treaty of Waitangi).

Restorative efforts are focussing on co-designing, implementing or evaluating restorative responses to adverse events or identifying enabling conditions. Table 1 provides an overview of policy and practice initiatives in our countries, and the evidence supporting development. Australian and NZ adverse event policies and restorative guides focus on supporting healing, learning and improvement equitably (42–44). NZ has the most established national approach, being co-designed with a diverse range of stakeholders in the aftermath of a Ministry of Health inquiry (22). As well as providing information about surgical mesh harm and what to do about it, the restorative inquiry identified that compounded harm was widespread and contributed to mental distress, PTSS and suicidal ideation. A descriptive evaluation determined that the restorative response met most participants psychological and procedural needs, captured information crucial for learning, and recommended embedment within systems that mitigate and respond to harm (21).

The NZ approach has been informed by Indigenous worldviews and Western research that identifies the relational contribution to safety (see Table 1). To mitigate the risk of marginalising voices or communities, co-design has been shaped within a collaborative framework that is guiding development (44). The expectation to offer restorative responses (restorative practices or hohou te rongo) is embedded within the Adverse Events Policy 2023 and Health and Disability Standards 2022 (42, 45). Section 17(d) of the Mental Health Bill 2024 includes the expectation that hui whaiora (wellbeing meetings) "support restorative practice to uphold the mana (power and authority) of all parties following the use of coercive practices". Capability building has been underway for two years, initially focussing on workers in mental health settings.

In Australia, mental health has been at the forefront of development, with New South Wales piloting the approach under the umbrella of a *restorative just and learning culture* (RJLC) (43). A development in safety culture thinking, RJLC encourages organisational justice, and 'forward looking' accountability, rather than blaming individual clinicians (18). In Queensland, the approach gained traction as part of a Zero Suicide framework at Gold Coast Hospital (46). Their healing, learning, and improving model includes a peer response for clinicians, demonstrated benefits to a range of stakeholders, and enhanced the quality of

TABLE 1 Examples of restorative initiatives in our five health systems.

Location	Terms	Practice enablers	Policy enablers	Research/evaluation
Aotearoa New Zealand	Restorative systems, restorative practices, restorative responses, restorative approach. Hohou te rongo (distinct form of peace-making from the Māori worldview)	Ministry of Health restorative response to surgical mesh harm National Collaborative for Restorative Initiatives in Health uses restorative practices to co-create the approach supported by interdependent government agencies. Mental health team capability building sponsored by the Health Quality Safety Commission Māori communities' (iwi, hapū, whānau) have sovereignty over the distinct but complementary approach of hohou te rongo.	Requirement for restorative responses to be offered in the national adverse events policy, Health and Disability Standards and Mental Health Bill. National restorative health system framework is guiding principles led development Unique legislation supports no fault no blame legislation alongside a Code of Consumer Rights Te Tiriti o Waitangi protects Indigenous knowledge and practice	• A descriptive evaluation of the surgical mesh inquiry concludes that restorative responses should be woven into the embedded system (21) • A realist evaluation of restorative responses in NZ develops a testable definition of compounded harm and eight middle range theories about what works, for whom and in what contexts (4) • A qualitative study concludes that the unique legislation does not mitigate compounded harm for clinicians, advocating for a restorative response to consumer complaints (26). • A study applying social network analysis and qualitative interviews concludes that safety leadership is a responsive relational process (27) • Kaupapa Māori research concludes that adverse event responses contribute to intergenerational trauma and that a culturally responsive practice is required ensuring that each person has their own culture, values and beliefs acknowledged and supported when harm has occurred (28).
Australia (Queensland & New South Wales)	Restorative Just and Learning Culture (RJLC) restorative practice	Queensland state Coroner supports the benefits of using RJLC in coronial matters In NSW, restorative leadership forums raise awareness and build connection Mental health team capability building sponsored by the Clinical Excellence Commission Metro North Mental Health—The Prince Charles Hospital, Queensland uses restorative practices in everyday work	RJLC is incorporated into the NSW safety culture guidance and organisational adverse event policy in Metro North Hospitals Queensland Apology/open disclosure legislation	• A comparative survey and audit evaluation of RJLC initiative concludes improved staff experience, stakeholder involvement and recommendations following suicide (29) • An independent evaluation of a restorative practice model in a secure mental health rehabilitation unit demonstrates efficacy of proactive and reactive approaches (30)
Canada British Columbia	Restorative approach, restorative practice	BC Restorative Circle and Ministry of Health guiding development Restorative leadership forum to raise awareness and build connection Health Quality BC created principles to develop Indigenous patient feedback process	Advocacy to "modernise" a major structural barrier (Section 51 of the Evidence Act)	A scoping review and environmental scan identifies relevant initiatives (8) A co-developed formal research programme includes a feasibility study (31)
England	Learn Together, Restorative justice, restorative just culture, restorative responses, restorative practice, restorative learning	Executive and board commitment in some NHS trusts, and from the Office of the Patient Safety Commissioner Specific organisations advocate context specific approaches to a range of restorative employment and patient safety issues (e.g., Mersey Care, Harmed Patients Alliance, South London & the Maudsley NHS Trust) Restorative Justice Council hosts a Restorative Practitioners in Mental Health Network, with quarterly meetings and annual conference (inaugurated 2016). South London & the Maudsley NHS Trust employ a full-time restorative justice practitioner responsive to patient safety incidents Seven mental health trusts train multi-disciplinary cohorts of staff in restorative conferencing	Learn Together co-developed five principles that encourage restorative learning. The principles inform adverse event policy in participating health organisations and the national Patient Safety Incident Response Framework Royal College of Psychiatry Forensic Mental Health Quality Network Standards for in-patient services include a requirement to enable access to restorative justice for victims, patients and mental health staff (32) South London & the Maudsley NHS Trust made available NHS approved job descriptions to enable the employment of restorative practitioners at three different grades	• Learn Together is founded on a broad programme of participatory research that includes qualitative interviews, ethnography and documentary analysis. It developed guidance relating to how learning responses can incorporate restorative principles to mitigate compounded harm (33). • An independent evaluation of RJLC demonstrated human and economic benefits in a large mental health organisation (34) • A clinical psychology doctoral qualitative evaluation of restorative justice in mental health identifies enablers and inhibitors of up-take of restorative justice (35). • Case series in forensic mental health (36–38)

(*Continued*)

TABLE 1 Continued

Location	Terms	Practice enablers	Policy enablers	Research/evaluation
United States (California)	Not widespread	Unknown Potential to develop into existing Communication and Resolution Programmes	Apology legislation in some states	• A qualitative study involving interviews of 40 patients, family and staff about their experience of CRP programmes recommends that restorative competency is developed (39). • Findings from an exploratory sequential mixed methods study were integrated into a revised version of the "social discipline window" (40) to develop the "restorative accountability' model which promotes high accountability for institutional citizenship and high support through restorative, non-punitive leadership in academic healthcare institutions (41).

recommendations (29, 47). A mixed methods evaluation of a restorative practice initiative that balanced proactive and reactive elements in a secure adult community mental health service concluded that the model was beneficial for worker and client relationships. Evaluation participants almost unanimously indicated that there was no downside to introducing restorative practices, identifying that most of the benefits were gained from alignment with the mental health recovery model and everyday use of the proactive elements (30).

The Patient Safety Incident Response Framework in England is based on a programme of participatory research with harmed patients and families that included interviews, ethnography and documentary analysis (12, 14, 48). The 'Learn Together' programme incorporates five principles that support a systems based approach to 'restorative learning' (49). In British Columbia, a research programme is underway to investigate feasibility and inform contextually relevant, evidence based restorative approaches (50). In the US, an interdisciplinary network is raising awareness about the requirement to enable 'restorative competency' within Communication and Resolution Programmes. Academic institutions in the US and Canada have also applied restorative principles and practices to address workplace harms in medical, nursing and dental settings (41, 51).

What is enabling development?

In our unique and collective journeys, several key factors are enabling the development of restorative potential within our distinctive contexts. Interdisciplinary collaboratives, co-facilitated by individuals with restorative knowledge and skills, have guided development in NZ and BC (44, 52). Indigenous worldview, leadership and voice is ensured and has been integral to advancement. Indigenous communities have many approaches to addressing harm, which can differ by place, be dynamic (shift and change over time), and hold competing perspectives. In the US a similar network connects Western restorative expertise with safety scientists. Opportunities that connect and explore structural and relational interdependencies between institutions, those with lived experience of the system, and communities is essential to build a mutual understanding about what works (or not). Developing relational infrastructure (i.e., collaboratives) is pivotal to ameliorate adversarial relationships and enables the co-creation of systems, key concepts (e.g., safety, harm, justice, responsibility), and supports those involved in the emotional work of change.

Mental health is proving to be a fertile area for policy and practice development and conditions may be conducive for numerous reasons. Firstly, priority populations are overrepresented and there is a strong focus on social justice. Mental health teams work within an interdisciplinary model, have transferable skills, and are familiar with trauma informed dialogical therapies which have some alignment with restorative practices (4, 30). In mental health settings, lived experience is increasingly viewed as a credible form of evidence that has been structuralised into peer worker roles in the UK (53), Australia and NZ. Furthermore, restorative justice is embedded in disciplines used to navigating complex legal and safety matters e.g., Forensics (54). Importantly, most adverse events are suicides, can affect over a hundred people, and thus require a community response (55). Existing suicide postvention services afford a structural opportunity to incorporate restorative principles.

An important first step in a restorative response is to acknowledge that harm has occurred, affects the community providing and receiving care in different ways, and creates unique needs and obligations. Doing so creates opportunities to shape holistic responses and attend to the range of physical, psychosocial, cultural and other needs involved, whilst also learning to improve system safety. It is more challenging to offer a restorative response in the context of adversarial systems, when responses privilege the rights or wishes of institutions or providers, focus on minimising reputational or liability exposure, or are inequitable (9). However, restorative potential can be enabled, and compounded harm mitigated, if approaches explicitly acknowledge and respond to the human experience of harm and participants can make an informed choice about the potential benefits and risks of stepping into procedural responses (4).

Adverse event policy and practice that explicitly acknowledges the complex human experience; enacts an equitable focus on healing, learning and improvement; and expects a range of diverse outcomes is advantageous [e.g., (42–44, 46)]. In Australia and the US, apology protections enable restorative dialogue during open communication and resolution practices (39, 56). An influential institute in England recently proposed that no fault no blame legislation may be advantageous (57). It is important to note that tax payer funded compensation and consumer protections have supported restorative potential in NZ, but can also generate compounded harm if the needs of harmed patients and families are minimised or dismissed (4, 58).

Use of restorative inquiry as a triage tool supports a focus on who is affected and the impacts, needs and obligations involved from the outset of an investigation (29). Furthermore, restorative practices are proving useful tools to enable shared understandings, equitable and safe conditions, honest (often courageous) conversations or the restoration of dignity and trust (21, 30). Early adopters should be aware that restorative responses can result in compounded harm when efficiency is prioritised over quality.

Discussion

Investment in collaboration and coproduction is a policy enabler for patient safety (59). Restorative responsibility infers broad professional and moral obligations and requires an examination of the voices and contexts that shape how patient safety is defined, responded to, and how system design influences the patient and family experience (4). The rapid adoption or commercialisation of restorative initiatives in healthcare, without a deeper commitment to involving patients and communities might not result in the hoped for and hypothesised change. Marder (60) suggests that the institutionalisation of restorative justice often leads to (re) interpretation, meaning the approach is applied in ways that reflect highly embedded institutional and systemic cultures and practices, that focus on doing things that benefit one party at the expense of another, thus creating inequalities and harms that initially inspired its use. Research examining the prevalence and characteristics of compounded harm, and the human and financial impacts, is essential to raise awareness of the impact of embedded system design.

The term ‘priority population’ reflects a policy and strategy approach that affected communities may reject or view as a label imposed up them by the State. Many of our countries were colonised and the unique harms and needs of Indigenous peoples, and the implications for responsive systems, must be determined by these communities. Western restorative justice can compound intergenerational trauma for Indigenous communities or result in a shift away from its emancipatory and transformative intent (61). Therefore, Indigenous knowledge and practices must be protected rather than being assimilated into Western concepts (62).

To date, RJLC implementation has been overly focussed on institutional goals and supporting clinicians, whilst neglecting to provide the same options to harmed patients and families. An unintended consequence of popularising Wu's ’second victim’ terminology, and excluding voices, is the development of a hierarchy of victimhood that can amplify adversarial conditions [e.g., (63)]. If the goal is to develop restorative potential, these inequities must be addressed, and culturally safe and responsive systems co-designed. Policy that acknowledges patients and families as victim-survivors, rather than a source of evidence, may enable the development of responsive services, ideally independent from investigative matters, and provide access to confidential supports. Evaluation criteria should be co-created with affected communities.

The challenges presented by structural independencies are immense. Culturally safe, trauma informed navigation or support services or harmed patient pathways may offer a way forward (23, 44). In the aftermath of a death, Wailling (4) proposes a further step, in which interdependent institutions collaborate to discharge unique responsibilities within one procedure that is co-designed with the family. Co-design should be used as a tool that distributes power and facilitates cultural responsiveness (64). Research should focus on identifying how responses and their participants might best achieve different ambitions associated with healing, learning and improvement. Given the sociocultural, epistemic and moral issues involved, those concerned with learning to improve system safety may wish to use or extend models that explicitly incorporate these factors [e.g., (65)]; support collective sensemaking [e.g., (66)]; use decolonising methodologies (64); or aggregate and act on the overwhelming amount of recommendations already available [e.g., (7)].

Another potential approach is responsive regulation, which has been utilised in the aged care sector in Australia for some time (67). Responsive regulation is grounded in restorative justice and practice. It involves listening to multiple stakeholders and making a deliberate and responsive choice from a pyramid of regulatory strategies, which are less interventionist and coercive at the bottom of the triangle, and move towards more punitive sanctions (68). Leading safety scholars, suggest responsive regulation may also act as a potential strategy for health system resilience (69). The potential contribution should be explored.

Conclusion

Restorative approaches are grounded in relational philosophy, principles and practices. Being new to health systems they offer a way to promote wellbeing, dignity and trust and emphasise an equitable focus on healing, learning and improvement. Mitigating the risk of compounded harm from structural and relational violations is essential to promote and maintain human wellbeing. It is possible to enable restorative potential within the context of embedded legislation and policy, but these structures and adversarial practices can constrain development or contribute to compounded harm. Policy makers, practitioners and advocates may wish to invest in development of restorative initiatives in mental, women's and Indigenous health settings which are providing fertile ground to co-design and explore utility. Doing so may also discharge responsibilities to priority populations and requires a human centred collaborative approach that is inclusive of the affected community.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material. Further inquiries can be directed to the corresponding author.

Author contributions

JW: Writing – original draft, Writing – review & editing. GC: Writing – review & editing. IS: Writing – review & editing. ST: Writing – review & editing. BB: Writing – review & editing. NO: Writing – review & editing. CH: Writing – review & editing. MP: Writing – review & editing. KT: Writing – review & editing. AK: Writing – review & editing. NO: Writing – review & editing. DG: Writing – review & editing. RR: Writing – review & editing. MA: Writing – review & editing. GD: Writing – review & editing. JH: Writing – review & editing. JO: Writing – review & editing. FS: Writing – review & editing. CL: Writing – review & editing.

Funding

The author(s) declare that no financial support was received for the research, authorship, and/or publication of this article.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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frontiers | Frontiers in Health Services

TYPE Original Research
PUBLISHED 23 April 2025
DOI 10.3389/frhs.2025.1474699

OPEN ACCESS

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RECEIVED 02 August 2024
ACCEPTED 26 March 2025
PUBLISHED 23 April 2025

CITATION
Kazi S, Littlejohn R, Smith KM, Busog D-N, Blumenthal J, Mathur S, McGill Z, DeBold D, Hettinger AZ and Miller KE (2025) Extending care beyond the clinic: integrating patient-reported outcomes in chronic pain management through human factors engineering.
Front. Health Serv. 5:1474699.
doi: 10.3389/frhs.2025.1474699

Extending care beyond the clinic: integrating patient-reported outcomes in chronic pain management through human factors engineering

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Objectives: Tapering prescription opioid pain medication through evidence-based guidelines can help in combating the opioid epidemic. Integrating clinical decision support (CDS) into the clinical workflow of tapering can help in translating guidelines to formulate and implement a tapering plan that manages pain symptoms while minimizing withdrawal, and optimally engages with the patient. The purpose of our project was to develop patient- and clinician-facing CDS in the area of chronic pain management in one integrated application (app) called Tapering And Patient Reporting outcomes for Chronic Pain Management (TAPR-CPM) App.

Methods: We leveraged human factors methodologies and a user-centered design (UCD) approach through guideline review, stakeholder interviews, ethnographic workflow analysis, process mapping, design workshops, and usability testing. Participants included patients with chronic noncancer pain, their family members, pain management physicians, primary care physicians, and health IT developers who focus on patient- and provider-facing technologies.

Results: Based on interview findings and workflow analysis, the provider-facing app had five sections: Patient Context, Taper Settings, Create Taper Plan, Withdrawal and Non-opioid Pain Plan, and Summary Dashboard. The patient-facing app had three sections: Maintaining a Pain Journal, Sharing Pain Scores with Provider, and Connecting to Resources about Opioid Tapering.

Conclusions: This project leveraged a multi-method approach based in human factors and UCD to develop the TAPR-CPM app. Engaging with a diverse set of stakeholders including patients, caregivers, primary care providers, pain specialists, and health information technology developers was critical to develop a user-friendly experience with accessible technology to support patient engagement and provider decision-making.

KEYWORDS

human factors engineering (HFE), chronic pain, opioid tapering, user-center design, patient-reported outcomes

1 Introduction

Chronic pain treatment and management requires innovative patient engagement and healthcare system strategies to inform decision making for both patients and clinicians. Chronic pain is a multidimensional health condition defined as pain persisting or recurring for more than three to six months (1). While the true prevalence of Americans living with chronic pain is difficult to define, as of 2021, an estimated 20.9% of US adults experienced chronic pain, translating to 51.6 million people and 6.9% (17.1 million) experienced high-impact chronic pain (i.e., pain that results in substantial restriction to daily activities) (2). Chronic pain complaints are the second most common reason for outpatient primary care visits (3). Pharmacological management of pain—including opioid analgesics—is often a first line of defense for many clinicians (4). Despite inadequate evidence of long-term benefit, 3%–4% of US adults report long-term use of opioid medications (5). Given the prevalence of opioid prescriptions more broadly, the treatment and clinical management of chronic pain is among the most vexing challenges currently facing primary care providers (PCPs) (6).

Prescription opioid pain medication overuse, misuse, and abuse have been significant contributing factors in the opioid epidemic. Healthcare systems are moving towards optimizing pain therapy through opioid-dose reductions, (i.e., opioid tapering). However, implementing opioid tapering is exacerbated by sociotechnical challenges including a limited number of pain specialist physicians and patient pessimism about non-opioid treatments for pain and fear of opioid withdrawal (7, 8). Although PCPs provide much of the healthcare systems chronic pain management, they report a number of challenges: minimal training in pain treatment and management, a lack of resources to support opioid tapering decisions, practical time constraints to address optimization of pain therapy in a routine visit, and maintaining the provider-patient relationship through challenging communications characterized by highlighting the importance of tapering and managing patient fears of being abandoned by providers during the taper (9–12). The science of human factors engineering and user-centered design can help address these unique challenges faced by providers and patients to design user-friendly solutions to support opioid tapering for chronic pain management.

One potential solution is the use of clinical decision support (CDS) to enhance health-related decisions, action, and outcomes. CDS strategies enabled by modern health information technology (health IT) offer more targeted opportunities to provide information when, where, and how it is needed to optimize patient and care decisions, actions, and partnerships. CDS also provides the opportunity to capture patient perceptions about outcomes meaningful to them such as level of functioning with pain, quality of life, and satisfaction with the care team and treatment, i.e., patient-reported outcomes (PROs) (13–16). Given the dangers of opioid medications as first-line treatment for chronic pain, the need for such measures is especially imperative. Consequently, national guidelines and experts have called for the assessment of pain-related functioning in addition to pain intensity to determine whether patients are benefitting sufficiently to merit the use of opioid treatment or whether lower doses of medication and/or nonpharmacological treatment options should be prioritized (17–19). Despite the recognition of the potential benefits of using functional pain-related PROs, their systematic use in everyday clinical care is rare.

Designing a CDS system tailored for patients undergoing opioid tapering for chronic pain necessitates a rigorous human factors engineering approach. This methodology is crucial as it emphasizes the integration of human capabilities, limitations, and preferences into the system's design and development. By focusing on human factors science encompassing the concepts of cognitive processes, usability, and user-centered design principles, the CDS can effectively support patients in navigating the complex and often challenging opioid tapering process (20). Understanding user needs and behaviors ensures that the system enhances patient engagement, promotes adherence to tapering protocols, and ultimately improves clinical outcomes while minimizing the risk of opioid misuse or relapse (21, 22). Thus, applying human factors engineering to the design is essential for creating a supportive, intuitive, and safe tool that optimally serves patients.

The objective of this paper is to describe the user-centered design (UCD) approach involved in developing and informing the implementation of a CDS system for chronic pain management with two components: patient-facing CDS and clinician-facing CDS in one integrated application (app) called: Tapering And Patient Reporting outcomes for Chronic Pain Management (TAPR-CPM) App. Our approach tackled technological and design components of health IT architecture while understanding end-user needs (e.g., patients and clinicians), workflow, and data integration. We describe a "codesign" approach whereby we engaged true end users in the development of the TAPR-CPM app. This approach is grounded in the concept of co-production (23–25) informed by empirically validated models supporting patient and clinician behavior change (26) and effective approaches for translating evidence into practice.

2 Methods

2.1 Study population and design

We leveraged human factors methodologies and a UCD approach through guideline review, stakeholder interviews, ethnographic workflow analysis, process mapping, design workshops, and usability testing. Stakeholder feedback was elicited at several stages throughout the knowledge discovery and pre-implementation design phases of app development to capture the needs of the intended end users, i.e., patients with chronic pain, pain management physicians, and PCPs. The study was approved by the MedStar Health Research Institute Institutional Review Board.

Data collection efforts purposefully sampled a heterogenous sample of participants. Participants included patients with chronic noncancer pain, their family members, pain management physicians, primary care physicians, and health IT developers who focus on patient- and provider-facing technologies. Some participants contributed to a single activity; others participated in multiple activities.

2.2 Data collection instruments and procedures

2.2.1 Guideline review

We reviewed guidelines and best practices on tapering opioids for chronic noncancer pain to inform the CDS. The search strategy for guidelines relevant on opioid tapering was decided in conjunction with clinical subject matter experts (SME), including pain management specialists, psychiatrists, and primary care physicians. Federal guidelines (e.g., from the Veterans Affairs/ U.S. Department of Defense, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services) and peer-reviewed literature on opioid tapering were reviewed by physicians for alignment with knowledge and practices about tapering, guidance specificity and clarity, and gaps and discrepancies between the guidelines (27–31). Concurrently, we conducted a task analysis to organize the key tasks performed by physicians during the process of opioid tapering, and analyzed which key tasks and decisions were supported by the guidelines. We validated the task analysis with clinical SMEs, including pain management specialists, psychiatrists, and primary care physicians.

2.2.2 Semi-Structured interview

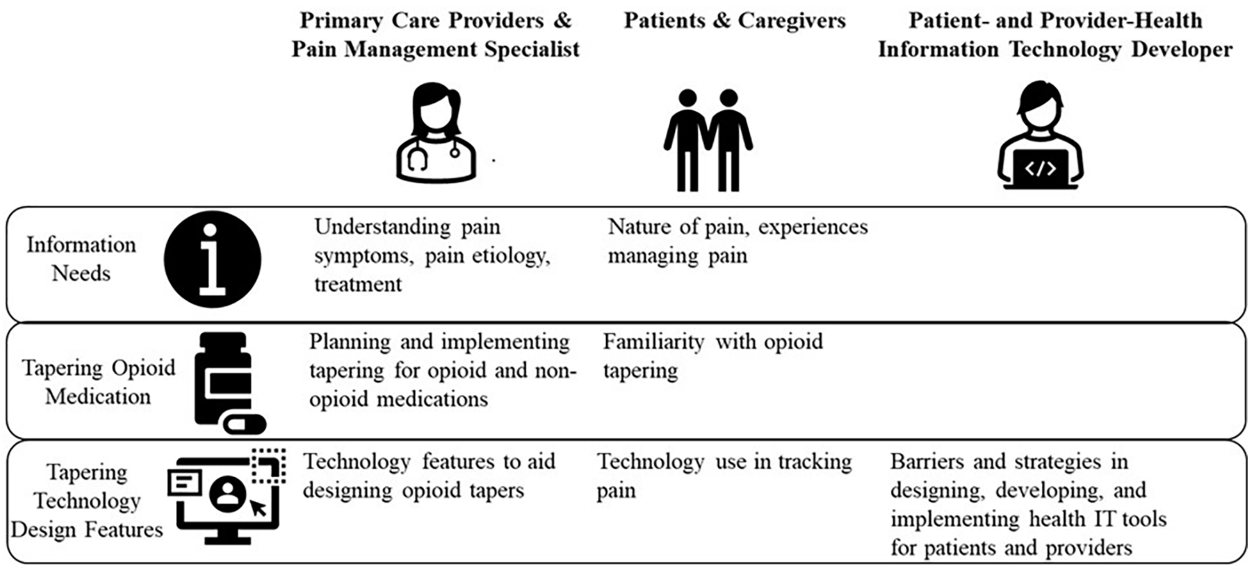
We developed five interview guides, one each for patients with chronic pain and their caregivers, PCPs, pain specialist providers, patient-facing health IT developers, and provider-facing health IT developers. Figure 1 lists the interview topics for each participant group. Remote interviews, lasting no more than an hour, were conducted by interviewers skilled in human factors or implementation science. Interviews were audio recorded, de-identified, and transcribed for analysis.

2.2.3 Workflow analysis

The goal of the workflow analysis was to understand how the CDS tools will function under realistic care setting conditions (e.g., variable workflows, high stress tasks, frequent missing data, interruptive environments) and the effectiveness and usefulness of tapering guideline recommendations. The workflow for tapering opioid medication was constructed by collating findings from interviews, guideline review, and electronic health record (EHR) data (e.g., details around the specific medication type, dose, and frequency). Workflow maps detailed cognitive tasks involved in implementing opioid guidelines [e.g., calculating the desired oral morphine milligram equivalent (MME)] for each tapering period and visualizations to guide prescribing patterns and patient-provider communication. The workflow maps were presented to SMEs for input to inform app design for usability testing.

2.2.4 Design workshops and usability testing

Interview findings and workflow analysis were used to inform wireframes (i.e., two-dimensional illustrations of an app interface) for the patient- and provider-facing app through design workshops with a multidisciplinary team comprising clinical SMEs, human factors engineers, and informaticians. Participants brainstormed the content, design of app sections, and specific items for both apps. Prototypes were revised and finalized through several



	Primary Care Providers & Pain Management Specialist	Patients & Caregivers	Patient- and Provider-Health Information Technology Developer
Information Needs	Understanding pain symptoms, pain etiology, treatment	Nature of pain, experiences managing pain	
Tapering Opioid Medication	Planning and implementing tapering for opioid and non-opioid medications	Familiarity with opioid tapering	
Tapering Technology Design Features	Technology features to aid designing opioid tapers	Technology use in tracking pain	Barriers and strategies in designing, developing, and implementing health IT tools for patients and providers

FIGURE 1
Interview topics for healthcare providers, patients, caregivers, and patient- and provider-facing health information technology developers.

rounds of design sessions and formally evaluated through two rounds of usability testing. In Round 1, usability testing participants were allowed to freely explore the interface; iterative changes were made to address points of difficulty or confusion. Round 2 usability testing asked participants to perform specific tasks. Final changes to the interfaces addressed outstanding issues and points of confusion. A trained usability specialist conducted each session after completing a full verbal consent process with the participant. The usability specialist was able to give the participant navigation abilities, allowing them the ability to click through the app prototype. For the provider-facing app, use cases were designed with simulated patient data to simulate differing complexity levels in terms of opioid medication type (long- vs. short-acting opioids), patient history, and desired tapering speed (standard, slower than usual, faster than usual). For the patient-facing app, patients were asked to explore all components of the app but were not asked to enter their personal data into the app. For both provider and patient usability testing, sessions were one-on-one, conducted remotely, and lasted for approximately an hour.

2.3 Analysis

Sociotechnical systems theory was applied to summarize findings from all primary (i.e., interviews, usability testing) and secondary (guidelines review, workflow analysis) methods to understand systems barriers and facilitators in addition to specific design components. A sociotechnical system's perspective provides insights into external and internal organization systems influences (e.g., social, technical, environmental factors). Raw data from primary data collection methods (interview transcripts and usability sessions) were analyzed using the grounded theory approach to enable prioritizing participant narratives in guiding key findings to shape app design (32). Data were analyzed by identifying common themes across patient and provider groups. Focused coding was used to organize and synthesize the initial data. Once the data were coded, analysis was completed to determine the most prominent themes in the context of the interview questions and goals of the questions.

3 Results

Table 1 shows the details about participants at different stages of the design.

3.1 Provider-facing app

Based on guideline review and the workflow analysis, we identified three main tapering tasks for providers: identifying candidates appropriate for opioid tapering, implementing the tapering plan, and monitoring the safety of tapering. Provider interviews and input from SMEs showed that identifying tapering candidates was not challenging compared to the latter two tasks.

PCP 1: "*Let me put it to you this way. I am aware of the CDC mme (morphine milligram equivalent). I have this (patient I was)*

TABLE 1 Demographics of stakeholders across five activities including guideline review, interviews, design workshops, usability testing, and workflow analysis.

Method	Stakeholder type	*n*	Demographics
Guideline Review	Healthcare providers	6	Medical specialties: Pain management, palliative care, primary care
Interviews	Healthcare providers (Primary care)	4	Gender: Female ($n = 4$) Education: MD ($n = 3$); PharmD ($n = 1$)
	Healthcare providers (Pain management)	4	Gender: Male ($n = 4$) Education: MD ($n = 4$) Experience: 13–21 years
	Patients with chronic noncancer pain	4	Gender: Male ($n = 3$); Female ($n = 1$) Age: 58–76 years old; mean 68.1 Race: Caucasian ($n = 3$); African American ($n = 1$) Education: High school to advanced degree
	Caregivers of patients	4	Gender: Female ($n = 4$) Age: 50–76 years, mean 66.5 years Race: Caucasian ($n = 3$); African American ($n = 1$) Education: High school to advanced degree
	Patient-facing health IT developers	4	Experience: 2–6 years health IT experience
	Provider-facing health IT developers	4	Experience: 3–10 years health IT experience
Design Workshops	Research team (clinical and non-clinical members)	N/A	Specialties: Human factors, emergency medicine, health IT developers, implementation scientists, nursing, patient advocates
Patient Usability Testing	Patients with chronic pain	5	Gender: Female ($n = 5$) Age: 45–64 years Race: Caucasian ($n = 4$); African American ($n = 1$) Education: High school to advanced degree
Provider Usability Testing	Healthcare providers	10	Education: MD ($n = 9$); PharmD ($n = 1$) Experience: 4–16 years, mean = 10.4 years Specialties: Pharmacist ($n = 1$), Primary care ($n = 8$), pain management ($n = 1$)
Workflow Analysis	Research team (clinical and non-clinical members)	N/A	Specialties: Human factors, emergency medicine, pain management, health IT developers, implementation scientists, nursing, patient advocates

telling you about that I'm (tapering) in the next few weeks (who) is going to be unpleasant (and is on) about three times that (of the CDC mme). There's other people that are nowhere near that number, and they need to be tapered. So I would say, no (I don't think there is a specific number of mmes that is a trigger for opioid tapering)".

Further, PCPs had low familiarity with information to plan a taper, detailed steps outlined in opioid tapering guidelines about recommended speeds of tapering, dosage reductions, and implementing supportive therapies to manage withdrawal and pain.

Interviewer: *"So generally, if a patient tells you, "I'm ready to taper my opioids", what do you generally do with that patient?"*

PCP 3: *"I don't think a lot of people know exactly how to taper … what percentage to go down by over what amount of time. I think that even more people have no idea of what withdrawal medicines to use. So … because now I've read the (CDC) guidelines that you sent me, I'm like, "Oh, well, now I know what to do". But … before I read that, depending on if they were only on short acting (medication) like Oxycodone … say they were taking like, five of Oxy four times a day. I might see if I could … get a couple of those to be half a pill, or, you know, be like, "Okay … take it three times a day, and then at night, just take half a pill*".

On the other hand, pain specialist providers reported extensive experience setting boundaries and expectations with patients prior to beginning opioid therapy and in implementing and monitoring the impact of opioid tapering on patients' physical functioning (e.g., pain intensity and interference with activities of daily living) and mental health (e.g., depression) through PRO measures. Based on information needs elicited from interviews and the workflow analysis, we decided to focus the provider-facing app to support PCPs in formulating and executing a tapering plan and monitoring its impact on patients.

Through design workshops and usability testing, we prioritized three main goals for the provider-facing app: (1) operationalize technical guidelines for prescribing and tapering opioids for chronic pain to address information gaps about tapering speed and dose, (2) better monitor functional pain and opioid use through PROs that include depression measures and incorporate a range of alternative strategies for pain management, and (3) visualize patient data. We synthesized these findings to create five sections in the provider-facing app: Patient Context, Taper Settings, Create Taper Plan, Withdrawal and Non-opioid Pain Plan, and Summary Dashboard. The Provider Summary Dashboard is created after interaction with the first four sections of the TAPR-CPM app (Figure 2). The sections of the TAPR-CPM app are discussed below.

3.1.1 Patient context

Interviews with PCPs revealed a need for integrated information pertinent to understanding the patient's relevant opioid medication management history.

PCP 2: "*…The app would enable reviewing the prescription drug monitoring program (PDMP) there as opposed to having clicked in and clicking out. Maybe it could also connect to the patient's pain contract and also the most recent drug screen? So that we have one tab to go to to review everything to meet our requirements. So, we've reviewed the PDMP. We reviewed the last pain contract. "Oh, look. It's been over a year. We should probably redo that today". And "Oh, they haven't had a random urine screen in six months. We're going to do that today as well*".

PCP 4: *"A dedicated section for, When was this person last referred to physical therapy or orthopedic?" Maybe the date… Put those pain management notes in one section. And then maybe, their musculoskeletal MRIs or CTs in one place, because then you could quickly see, "Okay, when's the last time we did look at this person's neck or low back, or what have you?"*

Based on these findings, we designed the Patient Context section to provide an overview of pertinent patient clinical data summary including, laboratory testing, medication lists and integration of the PDMP.

3.1.2 Opioid tapering medication plan

Interviews with PCPs showed they desired support with creating a tapering schedule based on morphine milligram equivalents of all the medications that patient was on.

PCP 2: "*Maybe, (what will) be helpful is what they're currently on in, like morphine equivalents. That would be easy if it automatically calculated what's in their med list and what their daily … morphine equivalents are. And then … you could put in what their decreased dose was and see how much they're decreasing every day. That would be nice. Or even to convert between one medicine to another one. So, if you're going to be going from a long acting (opioid medication) to a short acting (opioid medication), to help convert your (morphine milligram) equivalent there. That would be very helpful*".

In addition, providers also asked for help in generating a tapering schedule that providers could implement.

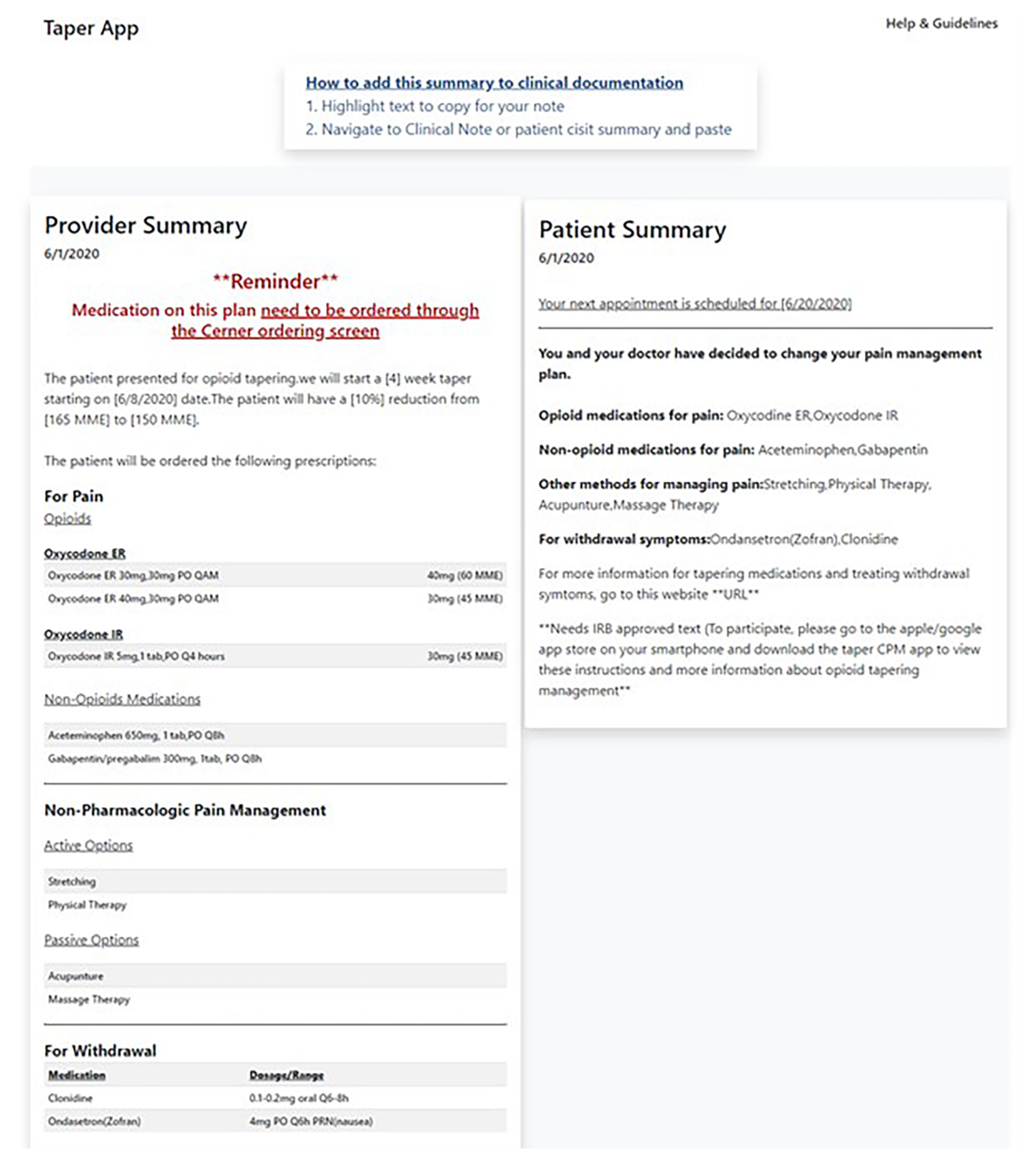
PCP 1: *"I think it would be great if it generated an actual (tapering) schedule. So somehow you put in what the patient's on, and hit a button, and this thing generates a schedule*".

Based on these findings, the Opioid Tapering Medication Plan section is designed to support choosing the tapering plan in a stepwise fashion. It presents providers with the patient's current list of opioids and aids in selecting the initial tapering plan and calculating the oral MMEs. It also broadly presents options for tapering speeds (standard, slower than usual, and faster than usual tapers) as a starting point. Our workflow analysis found that MME calculation was a cognitively complex task with high potential for miscalculation error; therefore, we decided to automate MME calculation.

3.1.3 Create taper plan

This section of the app enables specifying details about the tapering plan selected in the previous screen. Providers wanted the option to manually input varying tapering speeds and compare tapering plans with different speeds.

PCP 3: "*I'm just imagining it in my head, if there was almost an option to change the percent to go down by per month or week, so that I could see what the different … sort of see what that (i.e., different plans) would look like*".



How to add this summary to clinical documentation
1. Highlight text to copy for your note
2. Navigate to Clinical Note or patient cisit summary and paste

Provider Summary
6/1/2020

Reminder
Medication on this plan need to be ordered through the Cerner ordering screen

The patient presented for opioid tapering.we will start a [4] week taper starting on [6/8/2020] date.The patient will have a [10%] reduction from [165 MME] to [150 MME].

The patient will be ordered the following prescriptions:

For Pain
Opioids

Oxycodone ER

Oxycodone ER 30mg,30mg PO QAM	40mg (60 MME)
Oxycodone ER 40mg,30mg PO QAM	30mg (45 MME)

Oxycodone IR

Oxycodone IR 5mg,1 tab,PO Q4 hours	30mg (45 MME)

Non-Opioids Medications

Aceteminophen 650mg, 1 tab,PO Q8h
Gabapentin/pregabalim 300mg, 1tab, PO Q8h

Non-Pharmacologic Pain Management
Active Options

Stretching
Physical Therapy

Passive Options

Acupunture
Massage Therapy

For Withdrawal

Medication	Dosage/Range
Clonidine	0.1-0.2mg oral Q6-8h
Ondasetron(Zofran)	4mg PO Q6h PRN(nausea)

Patient Summary
6/1/2020

Your next appointment is scheduled for [6/20/2020]

You and your doctor have decided to change your pain management plan.

Opioid medications for pain: Oxycodine ER,Oxycodone IR

Non-opioid medications for pain: Aceteminophen,Gabapentin

Other methods for managing pain: Stretching,Physical Therapy, Acupunture,Massage Therapy

For withdrawal symptoms: Ondansetron(Zofran),Clonidine

For more information for tapering medications and treating withdrawal symtoms, go to this website **URL**

Needs IRB approved text (To participate, please go to the apple/google app store on your smartphone and download the taper CPM app to view these instructions and more information about opioid tapering management

FIGURE 2
The TAPR-CPM provider summary allows providers a final check of the tapering plan and associated medications after using the app and provides flexibility for the providers to incorporate the findings into the EHR as it aligns with their workflow.

Our workflow analysis revealed that dose modification involved multiple steps which could result in high cognitive workload and potential for error if providers had to perform these calculations in conjunction with choosing the tapering speed. Therefore, to avoid overwhelming providers with multiple decision points on a single screen, we chose to separate these two tasks. The app first asks providers to choose the tapering speed. Then, the Create Taper Plan section enables providers to modify specific details about the opioid medications (e.g., long- vs. short-acting, dose, frequency) to reach the target oral MME dose for the upcoming taper period corresponding to the desired tapering speed chosen on the previous section.

3.1.4 Withdrawal and non-opioid pain plan

Many providers mentioned proactively managing expectations about pain and treating withdrawal symptoms with a goal of minimizing the impact of experiencing withdrawal on patients' lives:

PCP 1: *"So, I usually say at the outset, you know, "We're gonna learn to manage your pain. We're not gonna make it away. There's no manage magic bullet here. It's all about function." Is that (pain) also related to withdrawal symptoms? And … that's a big part of this game, is having people know about withdrawal. Withdrawal is incredibly … painful, and it's just … so uncomfortable. And so, a lot of people, they just live in fear of withdrawing. Which I understand, if they're taking their meds, right? They can go to work, they can take care of their kids, yeah, but if they go and start having all that stuff (experiencing withdrawal symptoms), they're out, they can't live their lives*".

PCP 3: "*…Having … a good outline of those (withdrawal medications) is really helpful*".

Provider and patient interviews helped us generate many sources of non-opioid and non-pharmaceutical therapies to manage pain (e.g., physical activities such as yoga, stretching, physical therapy; non-traditional treatments such as acupuncture, massage therapies).

PCP 1: "*I absolutely suggest yoga. I suggest weight loss programs, if I think that's part of it*".

Pain Specialist 3: "*Some combination of medications, physical therapy, psychological therapies … I'll recommend alternatives sometimes, like acupuncture, chiropractic, different modalities, injections*".

Guideline review and SME inputs helped identify non-opioid therapies to manage pain (e.g., non-steroidal anti-inflammatory drugs) and monitor their appropriateness through relevant lab results (e.g., liver and/or kidney dysfunction), and medication to manage withdrawal symptoms from long-term opioid therapy.

PCP 3: "*I tend to lean pretty heavily on physical therapy, NSAIDs and ice and heat and stretching and all that stuff*".

Based on these findings, the Withdrawal and Non-Opioid Pain Plan section serves as a checklist of options to proactively treat withdrawal and integrate the patient's medication list and laboratory testing that may impact the selection of certain medications. Our goal was to facilitate clinician decision making and prevent the clinician from having an error of omission by forgetting to treat the patient's pain or waiting for the patient to go into withdrawal before prescribing appropriate medications. All providers appreciated the holistic approach to opioid tapering that concurrently addressed withdrawal symptoms and ongoing pain experienced during opioid tapering.

3.1.5 Summary dashboard

This section ensures that clinicians can conduct a final review, catch any potential errors, discuss and share the opioid tapering plan with the patient before finalizing it, and integrate reports into the EHR.

3.1.6 PRO data

Provider interviews revealed the importance of evaluating the impact of pain medication on pain levels and the patient's functioning.

PCP 3: "*I usually ask them, "How's your pain been since I last saw you? Would you say that it's worse, better, about the same?" But I usually ask them then to describe the pain again to me, and depending on the type of pain, like things like headaches, I'll usually help them quantify, like, "How many days a week did you have the pain? How long did it last for?" And then ask them if they've identified any, triggers or things that have helped*".

We used to these findings to design the PRO Data section. After the initial visit, the PRO section provides a visualization of PROs following the initial tapering period and app use, patient journal data to provide additional context around the patient's experience, and a dedicated screen for medication plan to add structure for creating the next taper interval. As a result of patient interaction with the patient-facing app, subsequent clinical encounters could leverage this data to inform decisions to optimize the tapering process.

3.2 Patient-facing app

Based on interviews, we identified that patients and their caregivers perform substantial work to track details about their pain and to communicate that information to providers.

Patient 3: "*We use the calendar to track the day, the pain level, what meds we take, and our activity*".

Patients also mentioned the mental toll of tapering in terms of its impact of their functioning.

Patient 2: "*After first starting that lower dose that I felt horrible. I missed a lot of work, actually. So it has a huge impact on your ability to function … because my body was so used to it. And whatever that part of the brain is that it's the feeling of the drugs was saying, "Hey, you're not giving me what I really want." And it took a lot of mentally fighting that off to say, "No, what I really want is to go down (reduce opioid dosage)*".

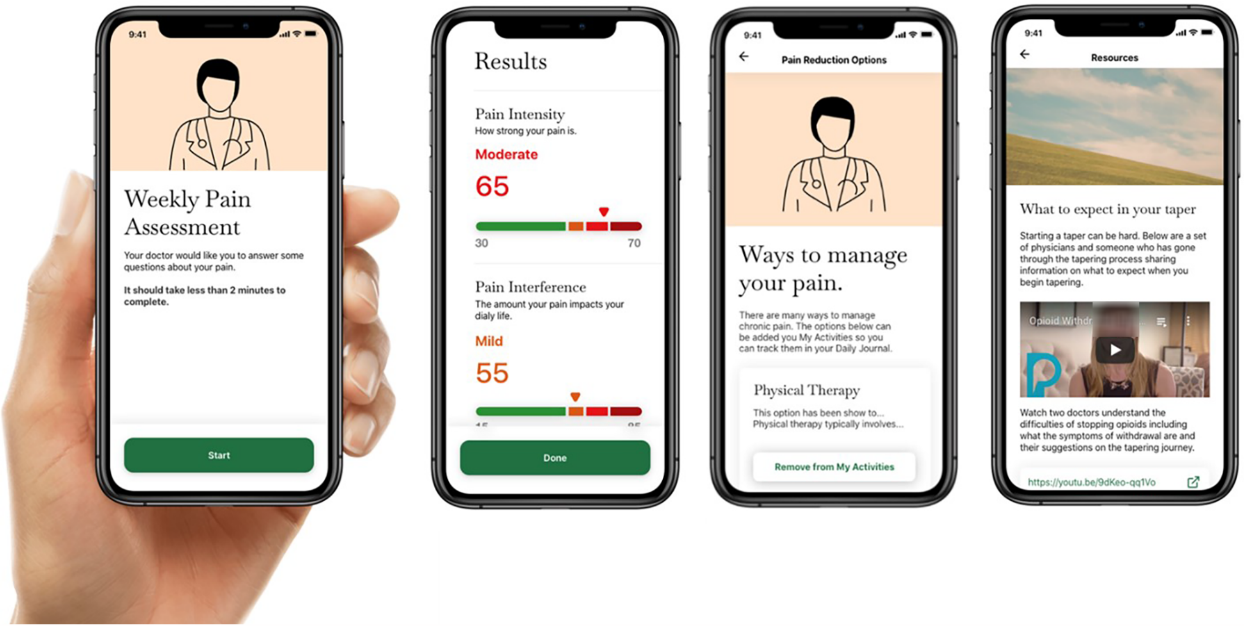
All patients actively engaged with their providers to discuss pain, set goals, and current treatment options through a variety of methods (e.g., phone, patient portal, email).

Patient 3: "*If it hurt, I took something. If it didn't hurt, I didn't take it. You know, it wasn't like I have to have this (substance such as alcohol, nicotine) to function, and never got into that. Still haven't and my doctor and I have worked pretty hard over the years to make sure that [further increase of opioid dosage] didn't happen*"

Patients prioritized clear communication across multiple members of their care team (e.g., primary care physician, pain management specialist).

Patient 1: "*If I experience paralyzing pain, I call the doctor, and he will explain things to me about the pains and everything*".

Communication was particularly important during an active taper to manage the patient's experiences and unexpected physical and mental effects of the taper. Therefore, through design workshops, we prioritized three main goals for the patient-facing app: (1) tracking information about pain symptoms, (2) sharing relevant information with providers, and (3) getting connected to resources to better understand the tapering journey. We synthesized these findings to create three sections in the patient-facing app: Maintaining a Pain Journal, Sharing Pain Scores with Provider, and Connecting to Resources about Opioid Tapering (see Figure 3).



Weekly Pain Assessment

Your doctor would like you to answer some questions about your pain.

It should take less than 2 minutes to complete.

Pain Intensity
How strong your pain is.
Moderate
65
30 70

Pain Interference
The amount your pain impacts your dialy life.
Mild
55

Ways to manage your pain.

There are many ways to manage chronic pain. The options below can be added you My Activities so you can track them in your Daily Journal.

Physical Therapy
This option has been show to... Physical therapy typically involves...

What to expect in your taper

Starting a taper can be hard. Below are a set of physicians and someone who has gone through the tapering process sharing information on what to expect when you begin tapering.

Watch two doctors understand the difficulties of stopping opioids including what the symptoms of withdrawal are and their suggestions on the tapering journey.

FIGURE 3
Screenshots of the patient-facing TAPR-CPM app illustrate different components including weekly pain assessments, taper plan monitoring and progress, and education resources.

3.2.1 Maintaining a pain journal

Many patients highlighted how pain levels vary over time, sometimes in response to chronic conditions, emphasizing the value of a journal to track daily changes and identify patterns over time.

Patient 2: "*Something in the app to track pain daily where it would ask: "What's your pain level now? What have you been doing?" So that you can see that my pain level has grown by doing these certain things, my pain level has decreased by doing other certain things*".

Patient 3: "*I got Lyme disease and everything changed. We've been dealing with that nerve pain ever since. It's really trying to get back to that "before" state, or somewhere closer to that. You never expect to go 100% back but you'd like to be able to do some of the things you did*".

Provider interviews also revealed potential positive impacts of pain tracking on patients.

Pain Specialist 3: "*There's probably a lot of potential there … to allow the patient to be tracking their progress also. So, seeing a trend line for their morphine equivalents and their pain numbers, especially if they're both going in a good direction, could be really interesting … some kind of … patient reassurances*".

Based on these findings, we designed the "Maintaining a Pain Journal" section to enable patients to track their daily record of pain localization on a visualization of the body map tool, and understanding the pattern of their pain symptoms over time, and track daily mood through emoji sets, as well as daily activities.

3.2.2 Sharing pain scores with provider

Patients discussed the importance of sharing contextual factors influencing medication usage or pain levels.

Patient 2: "*If one of the (transdermal) patches had actually fallen off … it just would let them know that's why there was an uptick in the oxycodone*".

Therefore, we designed the Sharing Pain Scores with Provider section to enable patients to record their pain intensity and pain interference scores on a pre-set day each week (e.g., Monday), share their pain scores and symptoms with their physician, and review their scores with the physician at their next visit.

3.2.3 Connecting to resources about opioid tapering

Providers and patients revealed several resources that could help patients during the taper process, including anticipating withdrawal symptoms, and information to help with tapering doses.

Patient 2: "*Seeing a psychologist or someone like that…adding that person in to be able to talk to and have them give you alternate suggestions (on how to manage pain without opioids). A discussion board where you could post to your success, like, "Hey, this worked for me." Or, "I had this side effect."*"

PCP 3: "*I think patients tend to do better if … they're fully aware of what to expect. And so, I can go through like, "Oh, these are the symptoms of withdrawal". But, you know, if I had a way to be more specific … usually, like, "X many hours from your last dose is when you're going to start feeling bad. Here's usually how it starts … things will probably be worse at this point, and then things should start to* *get better”. If a patient has…a very clear understanding of the trajectory, like, “Oh, 48 hours is when I'm going to feel the worst. Things should be turning around. I can power through a little bit.”*

Patient 3: “*For me, because I like keeping track of when I can do things just so I can have my own information. Like the fact that when you're sick like this, when you have chronic pain, looking back at what you can do on certain times is like a reminder. Like “Wait a minute, I've experienced this before. When was that?” Go back through the notes. “Okay, this is what I was able to do that time. Let me try and do that”. Because you forget that sometimes you're able to push through it and do certain things*”.

Therefore the Connecting to Resources about Opioid Tapering section was designed to provide resources to support patients throughout the tapering journey. These resources include understanding what to expect during an opioid taper in terms of dose reductions and its effect on pain and other symptoms, ways of managing pain and other symptoms during a taper, experiences of other people with opioid tapering, and social support resources that can be accessed to aid during the tapering journey.

3.3 Workflow analysis

Patient and provider workflows for tapering opioids in primary care settings were created for four high-level tasks: pre-taper; initial visit; home experience, and follow-up visit. Table 2 shows sub-tasks under each higher-level task. The

TABLE 2 Overall tapering workflow organized by activities of the patient, provider, TAPR-CPM app, and EHR workflow across the four stages of pre-taper, initial taper visit, activities that occur outside of the clinic visit (“home”), and follow-up visit.

		Taper setting			
		Pre-taper	Initial taper visit	Home	Follow-up visit
Stakeholder workflow	Patient	• Self-assess willingness to taper • Self-educate (opioids, tapering) • Educate provider on history (medical, social) • Commit to shared decision making with the provider	• Update history (medical, social) with provider • Participate in plan development (opioid tapering, withdrawal symptoms management, non-opioid pain management) • Commit to open communication regarding taper success/challenges • Reconfirm commitment to shared decision making with provider	• Explore the app (features, resources, data) • Review prescribed plan development (opioid tapering, withdrawal symptoms management, non-opioid pain management) • Continue commitment to open communication regarding taper success/challenges	• Update history (medical, social) with provider • Participant in plan modification (opioid tapering, withdrawal symptoms management, non-opioid pain management) • Continue commitment to open communication regarding taper success/challenges • Continue commitment to shared decision making with provider
	Provider	• Assess taper candidacy • Educate patient (opioids, tapering) • Ensure open dialogue with patients about options for tapering	• Review patient history • Educate patient [e.g., through patient-reported outcome measurement information system (PROMIS), risks] • Self-educate (tapering guidelines) Obtain patients opioid history • Create/prescribe/document plans (opioid tapering, withdrawal symptoms management, non-opioid pain management) • Reconfirm commitment to patient/provider relationship		• Review patients updated history • Review patients data (from app and patients verbal updates) • Update/prescribe/document plans (opioid tapering, withdrawal symptoms management, non-opioid pain management) • Continue commitment to patient/provider relationship
	Tool		• Provide education and resource links • Calculate taper • Document and save entered information • Generate summary documentation • Generate data visualizations	• Provide education and resource links • Calculate taper • Document and save entered information • Generate summary documentation • Generate data visualizations	• Provide education and resource links • Calculate taper • Document and save entered information • Generate summary documentation • Generate data visualizations
	EHR	• Clinical documents, medication, and Prescription Drug Monitoring Program [Chesapeake Regional Information System for Patients, or CRISP] data	• Clinical documents, medication, and CRISP data		• Clinical documents, medication, and CRISP data

workflow analyses identified several gaps between the ideal vs. actual workflows (i.e., work as imagined vs. work as performed). Providers must often go to different places on the EHR to assess the patient's candidacy for taper, gather information to plan the taper, and review effectiveness of the taper. Several findings from provider interviews re-surfaced in workflow assessments: there tends to be a lack of support for operationalizing evidence-based guidelines at the point of care, resulting in sub-optimal taper plans, which fail to consider recommended taper parameters and holistic management of withdrawal and pain symptoms. There is also a relative lack of standardized patient-friendly resources to engage patients during opioid tapers and educate patients about what to expect during opioid tapers. We designed our apps to address many of these challenges.

3.4 Technical specifications

During the course of the design and implementation of the apps, several key design decisions were made based on our user-centered design approach. We included patient portal authentication and designed a "lite" version of the app to test pain tracking and optimize EHR workflow. The "lite" version solution was designed for sites that could not accommodate an embedded FHIR app within their EHR. This version used a "hubless" application model (lack of data hub) that was connected to the EHR and easily accessible without requiring the provider to leave their current workflow. The elimination of the data hub requirement reduced the technical requirements of the application and expedited implementation.

3.4.1 Authentication of patient portal

Based on feedback from providers and health IT developers, the research team decided early in the design process to leverage the health system's patient portal for authentication and secure data transfer. The use of the patient portal allows the patient to use a single set of credentials and reduce maintenance of a redundant authentication strategy. Patient portal authentication does add complexity for the patient if they do not already have a portal account or do not have their login credentials easily accessible.

3.4.2 "Lite" app version for chronic pain tracking

A second design decision led to a streamlined "lite" version of the app created to focus on pain tracking. The initial implementation of the patient and provider app provided two-way communication between the provider and patient, and the creation of opioid tapering plans. Clinicians at later stages in the project requested streamlined approaches to help track patients' pain experience before opioid tapering was initiated as well as a focus on tapering calculations before providing two-way communication.

3.4.3 Optimizing for EHR workflow

Different EHRs provide clinicians the ability to document via different pathways and in different locations. Guided by best practices in human factors engineering, we decided that the content created by the provider app should be optimized to the individual EHR to make sure it matches the provider's workflow in terms of size of text recommendations and formatting. For example, copying and pasting large amounts of text into small text entry boxes may reduce the opportunity for the clinician to make modifications of the plan that is placed in the patient's chart.

3.4.4 Design for safety

The clinical team provided input on the medications and dosing that would be appropriate for tapering opioids. For example, the app was limited to medications where conversion factors were readily available with a maximum number of opioids set to two (including only one long-acting opioid). Safety guardrails prevented tapering in patients with more complex medical histories or patients that may have duplicate or out of date prescriptions in their record. Implementation teams may decide to expand or reduce the number and types of opioids allowed for tapering based on local prescribing practices.

4 Discussion

A human factors engineering, user-centered design approach elicits feedback from stakeholders and provides an opportunity to collaborate and co-design with representative end users as sessions support creative thinking and the generation of ideas and solutions (33). This research identified design features for the TAPR-CPM app and facilitators and barriers for implementation of CDS to streamline the delivery of care. The design of the provider-facing app supported organization of EHR data that is likely to reduce the need to "hunt and gather" (i.e., identifying and reviewing multiple individual tabs including medications, patient history, and diagnoses). Designing a solution that incorporates individual components into a single app can allow providers to assess candidacy, plan a taper, and assess the efficacy of a taper. Providing support to operationalize tapering guidelines at the point of care, a need elicited through PCP interviews, can encourage evidence-based medicine by supporting the workflow of modifying the taper plan. The design of the patient-facing app can support shared decision making through patient-provider feedback (e.g., reporting taper effects, resources related to chronic pain) and encourage patient engagement by providing educational resources and an education plan (e.g., resources related to tapering, what to expect, when to contact your provider). Collectively, the design promises to facilitate an effective patient-provider partnership during the opioid taper. Lastly, TAPR-CPM app facilitates a holistic approach to tapering that includes integration of standard patient-reported outcome measures for patients to report pain symptoms between appointments.

Successful adoption of CDS requires careful consideration of the knowledge driving the alert system (technical integration) and also requires application of human factors principles to understand the system (20, 34). There is substantial value in clinical, operational, and technical understanding and validation of newly developed CDS in the stages that occur prior to public release. Stakeholder interviews ensured input from end users and perspective of developers experienced in creating patient- and clinician-facing technologies was incorporated into the ultimate design. A comprehensive evaluation of current state guideline implementation with considerations of EHR use, clinical decision-making, and shared decision-making was used to support development of the implementation strategy. Workflow analysis was used to evaluate the current state of primary care clinician-patient interaction using an ethnographic approach to develop site-specific process maps that identified the overall processes and specific elements for CDS implementation. Usability testing included a formative evaluation of preference and performance to assess usability before going live and to allow time for iterative changes. The application of these methods ensured inclusion of stakeholder feedback, considerations of workflow, and review of adherence to design principles.

Specifically, many existing CDS tools for chronic pain management focus exclusively on either the clinician or patient side of the equation (35). TAPR-CPM is distinct in its integration of both patient-facing and clinician-facing components into one application, allowing for a more cohesive approach to managing chronic pain. Unlike other initiatives that focus primarily on static educational content or decision aids for clinicians, TAPR-CPM incorporates dynamic features informed by co-design with end users. This approach has been seen in recent studies co-design pain management programs with patients, underscoring the importance of involving end users throughout the design process (36, 37). This ensures that the app aligns with real-world workflows and addresses both technological integration challenges and behavioral factors affecting patient and clinician engagement. Additionally, the app builds on validated behavior change models, which is less commonly emphasized in comparable tools.

Opioid prescribing is a complex process that has additional considerations when reducing patients' prescriptions, and is not completely solved by the TAPR-CPM app. The goal of the CDS tool is to support clinical decision-making at the point of care, leveraging the clinical expertise of the provider and the perspective of the patient. Therefore, integrated components of the solution like creating the taper plan (i.e., calculating doses corresponding to tapering speed) only partially address the tapering discussion. The technical solution does not directly support ongoing patient fear of withdrawal or abandonment, challenges that can only be addressed by improved patient-provider communication (10). Consistent with interview findings about desired support during the process of tapering rather than identifying patients appropriate for tapering, the app does not evaluate individual patients' risk or suggests patients that should be considered for enrollment

The patient-facing app was limited in its functionality given the need to strike a careful balance in providing medication information but not medical advice. The clinical teams expressed concern about the need to modify and respond to patient-generated data in real-time which presented workflow and legal challenges. Therefore, patient facing materials included disclaimers on the intention of the TAPR-CPM app. Because of technical and protocol limitations, the app was not designed to write back directly to the EHR, but instead leveraged a data hub to collect provider generated data, primarily the opioid tapering plan. Writing into the EHR is a long-standing challenge, particularly in medication prescribing Fast Healthcare Interoperability Resources (FHIR) applications which unintentionally bypass EHR vendor medication safeguards. FHIR specifies standards for exchange of health data between technical systems in healthcare (38). Addressing this functionality was outside the scope of this project.

Our work also demonstrated the feasibility of designing a "lite" version of the app, which requires fewer technical resources and minimizes dependence on complex healthcare system interoperability. This streamlined version could be particularly suitable for deployment in lower-resource settings or healthcare systems facing significant interoperability challenges. However, while the technical feasibility of the lite version was established, it was not tested with patients or providers. Future research should explore patient and provider perspectives on the lite version to assess its effectiveness in supporting opioid tapering, identify any unique barriers or facilitators in its use, and determine whether the simplified approach can achieve comparable outcomes to the fully integrated app. Such studies will be essential to refine the lite version and expand its applicability across diverse healthcare settings.

Our goal was to design the app iteratively with significant stakeholder engagement and feedback at many timepoints, but often the feedback was conflicting or introduced privacy, policy, or legal challenges. For example, patient stakeholders requested ongoing screening through the app for depression, but the app was not designed to alert a provider to a medical emergency and would introduce both technical (alerting) and legal liability issues. Family members and caregivers of patients suggested the ability for a secondary log-in to see the patient's app input in order to support their medical and emotional needs which would introduce privacy challenges. We considered every stakeholders' feedback to guide app design and functionality but had to balance practical challenges for the TAPR-CPM app implementation.

Our research also revealed healthcare system challenges that could impact the successful adoption of the app. One notable barrier is the complexity of patient portal authentication, which may hinder access for patients unfamiliar with digital tools or those experiencing technological barriers. Additionally, ensuring consistent technical support and addressing variable digital literacy levels across patient populations are critical for widespread adoption. To address these challenges, future implementation efforts should prioritize proactive enrollment strategies, such as assisting patients with portal registration during clinical visits and offering automatic enrollment with immediate access upon sign-up. Simplifying authentication processes and providing tailored support could reduce delays, improve usability, and promote equitable engagement.

5 Conclusions and next steps

The TAPR-CPM app was developed through a human factors, user-centered design approach. Methodologies like stakeholder interviews with patients, caregivers, providers, and developers; an ethnographic approach for workflow analysis and process mapping; design workshops with PCPs and pain specialists; and usability testing support the design and development of to develop a user-friendly experience with highly accessible technology that met stakeholder workflow and decision-making needs. Our next steps include wider scale implementation of the apps in a large healthcare system by engaging with healthcare providers and patients with chronic noncancer pain.

Data availability statement

The qualitative datasets presented in this article (i.e., interview transcripts) are not readily available to protect the privacy of participants and comply with IRB regulations about protections for human subjects research participants. Requests to access the datasets should be directed to kristen.e.miller@medstar.net.

Ethics statement

The studies involving humans were approved by MedStar Health Research Institute. The studies were conducted in accordance with the local legislation and institutional requirements. The ethics committee/institutional review board waived the requirement of written informed consent for participation from the participants because the research qualifies as exempt and posing minimal risk to participants.

Author contributions

SK: Investigation, Methodology, Formal analysis, Writing – original draft, Writing – review & editing. RL: Investigation, Formal analysis, Project administration, Visualization, Writing – original draft, Writing – review & editing. KS: Investigation, Writing – original draft, Writing – review & editing. D-NB: Investigation, Formal analysis, Writing – original draft, Writing – review & editing. JB: Data curation, Writing – original draft, Writing – review & editing. SM: Data curation, Writing – original draft, Writing – review & editing. ZM: Software, Visualization, Writing – original draft, Writing – review & editing. DB: Software, Visualization, Writing – original draft, Writing – review & editing. AH: Conceptualization, Funding acquisition, Formal analysis, Data curation, Visualization, Supervision, Writing – original draft, Writing – review & editing. KM: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Visualization, Writing – original draft, Writing – review & editing.

Funding

The author(s) declare that financial support was received for the research and/or publication of this article. This work was supported by the Agency for Healthcare Research and Quality (contract number: HHSP233201500022I). The views expressed here are solely those of the authors and do not necessarily reflect the official positions of the U.S. Department of Health and Human Services or the Agency for Healthcare Research and Quality.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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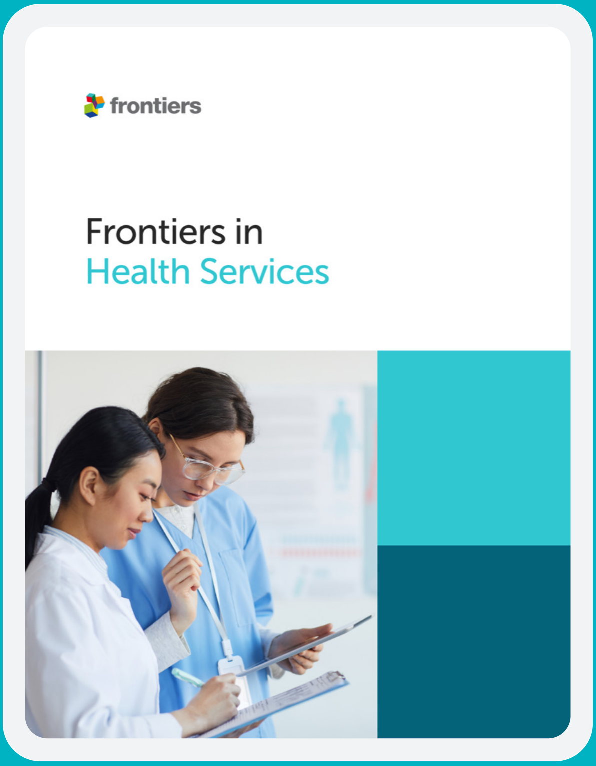

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