ABSTRACT

Background Efforts to involve patients in patient safety continue to revolve around professionally derived notions of minimising clinical risk, yet evidence suggests that patients hold perspectives on patient safety that are distinct from clinicians and academics. This study aims to understand how hospital inpatients across three different specialties conceptualise patient safety and develop a conceptual model that reflects their perspectives.

Methods A qualitative semi-structured interview study was conducted with 24 inpatients across three clinical specialties (medicine for the elderly, elective surgery and maternity) at a large central London teaching hospital. An abbreviated form of constructivist grounded theory was employed to analyse interview transcripts. Constant comparative analysis and memo-writing using the clustering technique were used to develop a model of how patients conceptualise patient safety.

Results While some patients described patient safety using terms consistent with clinical/academic definitions, patients predominantly conceptualised patient safety in the context of what made them ‘feel safe’. Patients’ feelings of safety arose from a range of care experiences involving specific actors: hospital staff, the patient, their friends/family/carers, and the healthcare organisation. Four types of experiences contributed to how patients conceptualise safety: actions observed by patients; actions performed by patients themselves; and shared actions involving patients and other actors in their care.

Conclusions Our findings support the need for a patient safety paradigm that is meaningful to all stakeholders, incorporating what matters to patients to feel safe in hospital. Additional work should explore and test how the proposed conceptual model can be practically applied and implemented to incorporate the patient conceptualisation of patient safety into everyday clinical practice.

INTRODUCTION

Efforts to improve care quality frequently aim to address one or more specific domains: safety; effectiveness; patient experience/patient-centredness; timeliness; efficiency; equity, with interventions to improve safety traditionally focusing on minimising patient harm and learning from errors. Patient safety is commonly defined from a clinical risk paradigm, in terms of preventing errors and adverse events; clinicians and academics typically measure failures at
specific points in patient pathways, using quantifiable events and analysable processes to answer the question: ‘is care safe’?3,4

While there has been a tendency towards rejecting patients’ views on safe care as being too subjective,5 research demonstrates that patients are willing to provide feedback on their care to inform safety improvement.6–8 The past two decades have seen calls for patients to play more active roles in the safety of their care1,3,9,16 and studies have shown that patients hold positive attitudes about engaging in safety and are able to participate in safety behaviours.11,12 Although there are difficulties in measuring the impact of patient involvement on tangible safety outcomes,7,13 the 2019 National Health Service (NHS) Patient Safety Strategy and Patient Safety Learning’s Blueprint for Action share the view that patient engagement is key to improving safety.9,14

While patient engagement in patient safety is clearly paramount, a recent systematic review of reviews asserts that there are persistent barriers to effective patient and public involvement in patient safety, at both individual and organisational levels.15 Among these constraints, patients’ personal and sociodemographic characteristics, including age, illness and ethnicity, have traditionally been associated with lower opportunities for involvement. A persistent challenge in developing patient-derived definitions of safety is capturing the diversity of the patient voice, including the views of seldom heard groups.16

Where organisational processes are set up to collect patient feedback,17 healthcare systems have struggled to harness patients’ reports to drive risk reduction strategies in clinical settings.8,18 In a UK multicentre survey study exploring patients’ safety concerns,65% of 1165 patient reports were not classified by clinicians as safety incidents.8 This finding echoes previous work demonstrating that patients frequently report issues around ‘unsafe care’ that healthcare professionals would consider to be inconsequential.19 Patient-reported safety concerns include physical discomfort (eg, noise, light, food), lack of security (including fear of other patients), uncertainty (eg, about discharge), process failures (delays or omissions) and patient–provider interactions (eg, poor communication/lack of compassion).8,19–21

O’Hara and Isden highlighted ‘the fundamental paradox of considering the patient perspective within the current clinical risk paradigm’.3 Arguably, to achieve authentic partnerships with patients to drive improvements in the safety of healthcare, it is imperative to develop a more expansive view of patient safety that is meaningful to all stakeholders. To facilitate openness to the patient’s conceptualisation of safety, some researchers have chosen not to predefine or frame patient safety in terms of clinical risk. Despite recruiting from different patient groups and clinical specialties, these studies are consistent in their findings that patients conceptualise safety in terms of how their experiences of healthcare make them feel.22–26

Other researchers have formalised patients’ and families/carers’ conceptualisations of safety into models or theories. Based on the reports of patients at the end of their lives, Collier et al’s model illustrates a conceptualisation of iatrogenic harm that extends beyond narrowly defined clinical risk parameters to include emotional, social and spiritual concerns, and ‘interpersonal’ safety based on meaningful interactions between patients and those involved in their care.27 Using constructivist grounded theory, Lyndon et al developed a preliminary conceptual model illustrating three overlapping domains in parents’ conceptualisations of safety in the neonatal intensive care unit (NICU), including physical safety (eg, safe practices around medication administration), developmental safety (how treatment might affect the infant’s development) and emotional safety (based on interpersonal relationships).24 Merner et al also applied constructivist grounded theory to derive a model of the complex social process surrounding carers’ contributions to patient safety in hospitals; the process involved three main concepts reflecting the level of intensity of ‘patient safety caring’: low (‘contributing without concern’), moderate (‘being proactive about safety’) and high (‘wrestling for control’).28

While helpful in bringing patient conceptualisations of safety to the fore, these models are based on the reports of carers, or of participants recruited from individual clinical specialties (palliative care, NICU). Additional work is needed to support and further extend previous research efforts to develop a new patient safety paradigm that incorporates broader patient perspectives. Therefore, the aim of the current study was to explore how hospital inpatients, recruited from three varying clinical specialties, conceptualise patient safety and develop a model to reflect this.

METHODS
Study design and setting
A qualitative semi-structured interview study was conducted with hospital inpatients from three different specialties: medicine for the elderly, elective surgery and maternity (postnatal ward), at a large, central London teaching hospital. Multiple specialties were included to support the transferability of our findings to a broader range of clinical contexts, and focused on patients with different levels of vulnerability, routes to admission and involvement in care.

Participant selection
Participants were recruited through purposive sampling to achieve diversity across gender, age and reason for hospital admission. Hospital inpatients aged > 18 years, were clinically stable, and had capacity to consent were identified by ward staff; potential
participants were approached, the study was explained and a participant information sheet was shared. Patients were given a minimum of 12 hours to decide if they wished to participate. There were no exclusions because of language (access to an interpreter was available, although not needed) and informed consent was completed prior to interviews taking place.

We aimed to recruit six to eight participants from each clinical specialty, as evidence suggests that thematic saturation is usually achieved between 6 and 12 interviews and a sample of this size can provide sufficient levels of information power for our research question.

Data collection
Recruitment and interviews were conducted by EB (Clinical PhD researcher), although participants were not known to EB in a clinical capacity, with interviews taking place face-to-face at a convenient location on/ near the wards. The topic guide, developed from a literature review focusing on patient/professional perceptions of patient safety, consisted of core, open-ended questions and subsequent prompts designed to elicit participants’ knowledge, understanding and experiences of patient safety (online supplemental appendix 1). It was further refined through discussion with the academic supervision team and after initial interviews. Interviews lasted an average of 31 min (range 14–90 min), were audio-recorded and professionally transcribed. The researcher (EB) took field notes summarising personal reflections, which were used to adapt the topic guide as the study progressed.

Analysis
The intention was to conduct an inductive thematic analysis to better understand how patients defined the term ‘patient safety’, with the potential to compare our findings with existing frameworks/theories of safety. After completing the interviews, however, it became clear that the term ‘patient safety’ held little meaning for our participants. Instead, patients gradually developed their conceptualisation of patient safety over the course of the interview, where questions focused on the social context and their experiences of safe (or unsafe) care.

In light of this, we considered whether another form of analysis might have been more suitable (eg, constructivist grounded theory or interpretative phenomenological analysis). As constructivist grounded theory focuses on exploring social processes, including the factors that influence, underpin and shape particular phenomena and had previously been used in two similar studies, we decided that this approach may be better suited to analyse our data.

As we had already conducted all of our interviews and had no opportunity to collect more data required for theoretical sampling (concurrent data collection and analysis and theoretical sampling are core tenets of grounded theory research), we opted for a ‘grounded theory-lite’ or ‘abbreviated’ approach. These approaches use grounded theory techniques in order to generate categories (and concepts), and to comprehend the relationship between the various categories (and concepts).

In practical terms, our analysis followed the following steps: transcripts were coded by hand (by EB) in three stages (initial coding, focused coding, theoretical coding) using the constant comparison method. A second researcher (AM), a healthcare professional with experience in qualitative data analysis, initially coded 25% of the transcripts, with good concordance between the two researchers (EB and AM). Reflexivity was maintained by developing awareness of the ‘clinical lens’ through which the researchers approached the participants’ accounts, with careful reflection to ensure that findings emerging from the data were indeed the patient conceptualisation of safety.

Memo-writing using the clustering technique—a strategy like conceptual mapping that moves towards showing how ideas fit together—was employed during focused and theoretical coding, and during the development of the conceptual model. During focused coding, the most significant or frequent codes were used to organise the data into ‘conceptual categories’ (categories that summarise ideas, events or processes across the data). The relationships between the conceptual categories were then explored to generate theoretical categories. The final stage of analysis— theoretical sorting—considered the possible relationships between the theoretical categories and how they could be integrated into a conceptual model.

Reflexivity and rigour
The analytical stages of constructivist grounded theory were carefully followed. The origin of the data and codes was tracked throughout the analysis, second coding was employed and illustrative quotes are presented. The research team worked reflexively during the data collection and analysis, discussing and journaling their personal biases and clinical lenses and their potential impact on the research.

RESULTS
Patient characteristics
Table 1 presents the sample characteristics of the 24 patients who participated in the study.

The patient conceptualisation of patient safety
When asked to define patient safety, many patients indicated that the concept was unfamiliar. Although some referred to patient safety as a tangible objective state (‘I am safe’), patients more often described safety subjectively, in terms of their feelings and individual experiences, using statements such as ‘I feel safe when...’ and ‘[X] makes me feel safe’. Patients’
feelings of safety were evoked through their observations, interactions and encounters in hospital:

I sort of take it from my own experience in how I see things and experience it. (male, 80s, surgery)

Patients described a wide range of care experiences that contributed to their feelings of safety. Through coding and constant comparison, these experiences were organised into conceptual categories. Examination of the relationships between the conceptual categories identified the main factors influencing patients’ experiences: the organisation (hospital/NHS Trust); staff; patient; friends, family and carers. These conceptual and theoretical categories provide a thematic description of patients’ reports (figure 1) and are presented in the subsequent sections.

**Organisation**
The conceptual categories maintaining the environment; cleaning; and having protocols/plans for safety define how patients’ experiences of safety are shaped at the hospital/NHS Trust level. Patients reported observing these organisational-level processes and procedures, and they described feeling safe when they could see that the hospital environment was being looked after, maintained and cleaned:

Well just being on the ward and sort of feeling safety on the ward and feeling safe when you use the utilities and everything else. (female, 30s, maternity)

One patient acknowledged that he found it difficult to judge how much cleaning was appropriate, but the apparent lack of substantial cleaning made him feel unsafe:

The cleaning…I don’t see them going round. I feel the cleaning is cursory. But again, for all I know, that’s good enough because that’s all it needs. (male, 60s, surgery)

One patient acknowledged that he found it difficult to judge how much cleaning was appropriate, but the apparent lack of substantial cleaning made him feel unsafe:

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Some patients noticed the clinical audits displayed on boards in the ward; these contributed to one patient's feelings of safety because the checks were not 'obscured from the public' (female, 30s, maternity). Overall, it was important to patients that organisational processes and procedures were visible and observable to help them to feel safe.

Staff

Three conceptual categories titled *who is interacting with me*, *demonstrating qualities and skills*, and *performing clinical tasks* describe how patients' feelings of safety were intrinsically linked to having trust/confidence in hospital staff. As one patient articulated:

You buy into that person, you put all your faith into their ability to do their job. (female, 30s, maternity)

Patients’ observations with regard to the qualities and skills of hospital staff (‘observed actions’) shaped their feelings of safety. Patients described feeling safe when they knew they were seeing the appropriate specialty staff member for their specific problem:

It's different qualifications and different job roles innit [sic] really? (male, 30s, surgery)

At times, it was important to patients’ feelings of safety that they received the input of a senior clinician—those ‘at top level’ (female, 80s, elderly medicine). Patients described deferring to the opinions and skills of consultants:

I just asked the person who was going to do it [the epidural], ‘Have you done many of these?’ and she said, ‘Well I’m not a consultant but I have done many.’ And I said, ‘I’m really sorry but if you don’t mind a consultant doing it, I’m just very afraid of the epidural’. (female, 30s, maternity)

The availability of staff was important for patients’ feelings of safety. While patients were content with less contact with doctors, patients across all three specialties felt that nurses (or midwives) should be constantly visible or accessible. Other members of the wider multidisciplinary team were not mentioned. Patients were reassured by staff presence, but they also felt safe when they observed hospital staff to be altruistic, interested and motivated:

[working] not just to get paid, because they love work. (female, 80s, surgery)

Patients observed how staff performed clinical tasks and procedures. One patient felt unsafe when he saw that a staff member could not perform a procedure that he thought the staff member should be able to do:

One of the nurses couldn’t put the IV in, that’s a qualified staff nurse. (male, 30s, surgery)

The care/treatment that patients directly received from staff (‘received actions’) also influenced how safe patients felt. For example, patients knew that it was possible to receive the wrong medication—one patient described feeling frightened believing that a nurse had...
failed to follow the correct medication administration process:

I’ll tell you what makes me feel unsafe. They have tubes here [pointing to neck]. One night, one of the nurses put medicine in the wrong tube. She nearly frightened me to death. (female, 70s, surgery)

Of note, patients’ satisfaction with staff–patient interactions was central to their feelings of safety; there were few references to interprofessional interactions. When patients received care or treatment, their feelings of safety could be influenced by how staff treated them (‘depends on the way they treat you really, isn’t it?’ (male, 80s, elderly medicine)) and the quality of the interaction (‘how the people talk to you’ (male, 80s, elderly medicine)). As one patient explained, feelings of safety arose when staff communicated effectively:

It’s the contact that you have with the professionals, it’s the way they interact with you, it’s putting your mind at ease, having patience with questions, answering them and then following up on them, and feeling as though, you know, you are being listened to. (female, 30s, maternity)

Patients also felt safe when their interactions with staff were emotionally and psychologically supportive:

They ask like how you’re feeling or what you’re going through and try to understand, they can suggest things to make certain things better. This to me is part of your patient safety even though it’s not branded as it. (female, 20s, surgery)

One patient described the way in which a nurse washed him—without compassion or concern for his dignity:

The way that she had asked me, not saying ‘Good morning,’ or anything, you understand? Pushing me. I watch out and with this thing she poured the cold water all over the body and ‘Turn here, turn here.’ I’m naked. (male, 80s, elderly medicine)

Overall, patients believed that every staff member had a responsibility towards patient safety, ‘it has to be in the minds of all levels, no matter what it is that you do’ (female, 30s, maternity). The quality of staff–patient interaction influenced both physical and psychological aspects of care, and both were important in shaping how safe patients felt.

Patient

Patients’ actions for safety are described by four conceptual categories: keeping an eye on and checking care; reporting concerns; taking responsibility; following advice, rules and regulations. A minority of patients chose to assume a passive role in hospital: ‘you just let go, you let things happen to you’ (female, 90s, elderly medicine). They felt they had no control over the processes that were important for their feelings of safety (for example, clinical tasks or cleaning) and that they lacked the expertise or knowledge about healthcare and hospitals to contribute to safety:

I don’t know if I really have the medical expertise...
I guess I could be in a position to suggest something they do to make you feel like it’s more safe but I’m ... yeah I don’t think I know enough about hospitals to make suggestions on them. (female, 30s, maternity)

However, most patients wanted to assume an active role in contributing to safety (patients’ ‘performed actions’). Some patients believed that it was important to report safety concerns:

I’d have to say something […] otherwise nobody will learn, so I should say something. (female, 30s, maternity)

Other patients believed that it was important to ‘do what I am told’ (female, 80s, elderly medicine) and ‘follow the rules and regulations’ (male, 80s, surgery). Certain patient actions were ‘shared’ with other actors in their care. Like health professionals, patients participated in their own safety by actively checking their medications and monitoring their care:

I think you can’t just sit by and let things happen. You’ve got to be aware of what’s going on around you… Being observant, and processes, and what’s going on, and what’s happening, and what people are doing. (male, 70s, surgery)

(Male, 70s, Surgery) Patients also felt that an important part of feeling safe was acting on the advice of hospital staff and taking shared responsibility for recovery; this included using walking aids (‘my stick, to use it and to use it properly’ (male, 80s, elderly medicine)) and looking after themselves:

It’s sort of generally like looking after yourself as well as making sure you are getting up and about if they want you to and keeping clean and things like that. (female, 40s, surgery)

Overall, most patients felt safe when they were able to play an active role in their own care.

Friends, family or carers

The actions of friends, family or carers were represented by two conceptual categories: being an advocate and being a source of support. Patients explained that friends, family and carers could act as advocates by validating patient concerns and supporting them to report issues with their care:

If it’s only yourself you might think you’re imagining it or something, you know. (female, 80s, elderly medicine)

In this way, friends, family and carers undertook ‘shared actions’ with patients to help them to feel safe. In some cases, patients relied on friends, family or carers to report concerns when they did not feel able to do so themselves:
He [my husband] is very capable of dealing with it in a way I am not. I get embarrassed and this, that and the other so he takes over and deals with it. (female, 70s, surgery)

In addition, most patients felt that friends, family and carers provided physical comfort that contributed to their feelings of safety:

They sort of look after you, so they make sure you’re feeling comfortable and things like that and bring you in bits if you need it. (female, 40s, surgery)

However, one patient noted that her partner’s support was limited by his lack of knowledge:

I know he didn’t know much–I kind of didn’t believe him. (female, 30s, maternity)

Overall, patients felt that friends, family or carers contributed to feelings of safety through by being advocates and sources of support.

DISCUSSION

This study aimed to understand how hospital inpatients across three clinical specialties conceptualise patient safety, thereby contributing to a more expansive patient safety paradigm that values the patient perspective. Patient safety was conceptualised by patients both objectively and subjectively. The objective components of ‘being safe’ paralleled academic definitions of patient safety; however, these were not at the forefront of participants’ minds and were elicited predominantly through prompting and direct questioning.

Consistent with previous research, patients in this study discussed safety in the context of what made them ‘feel safe’. However, by moving beyond thematic description of patients’ reports to the generation of a conceptual model, this study provides important insights into how patients conceptualise safety including the ‘actors’ and ‘actions’ that influence how patients experience hospital care. Patients’ feelings of safety arose from a range of experiences involving specific actors in their care: the organisation, staff, the patient, and their friends, family, or carers. Four types of patient experiences were identified: actions observed by patients; actions received by patients; actions performed by patients themselves; and shared actions involving patients and other actors in their care.

The concept of ‘feeling safe’ has been explored in other studies. A grounded theory study of intensive care unit patients developed a model of the psychosocial needs of patients around a core category of feeling safe. This work was extended to create a theoretical model which described feeling safe as arising from...
processes, actions and interactions. While a subsequent concept analysis sought to understand patient safety from the patient perspective and define the critical attributes of feeling safe, the study lacked empirical referents for the concept of feeling safe by defining it a priori. Our study moves beyond this, using transparent methods to derive the patient conceptualisation of safety without presupposition.

While care quality has traditionally been defined using several ‘domains’ including safety and patient experience, our study has shown that for patients, safety and experience are intrinsically linked. There has been a tendency to reject patient experience as too subjective and unrelated to “real” clinical work of measuring and delivering patient safety and clinical effectiveness, despite evidence that patients’ experiences may provide new information supporting patient safety and clinical effectiveness. Our study adds to this growing body of evidence on the key relationship between safety and experience, highlighting that clinical practice must broaden its understanding of what patient safety is and incorporate the more expansive conceptualisation of patients.

Our study indicates that patients monitor certain aspects of hospital care, including staff undertaking clinical procedures and observing organisational-level processes, such as cleaning. The findings of this study and others demonstrate that, through their observations, patients provide valuable insights into safety that could complement existing patient safety measurements. Importantly, our study highlights that patients do not necessarily express safety concerns using the language of the clinical risk paradigm. Efforts to capture patients’ views around safety should enable patients to articulate their views of safety in the context of their feelings and individual care experiences; these mechanisms do exist but are not widely implemented. The Friends and Family Test is a feedback mechanism in the NHS but this tool has been underused for quality and safety improvement because of the resources required to extract useful insights from free-text comments. Innovative digital technologies can automate the process of analysing unstructured patient feedback, and could potentially be used to translate patients’ experiences into meaningful insights to support quality and safety improvement.

Our study found that patients felt safe when they observed the ward environment being cleaned and maintained. An NHS inpatient survey conducted at the height of the COVID-19 pandemic similarly found that patients who remembered observing infection control measures (ie, the wards being cleaned and staff washing their hands/wearing personal protective equipment) were more likely to report feeling safe in hospital. Policymakers favour transparent reporting of quality and safety measures, and as such, NHS organisations stipulate that the results of specific safety checks and audits (eg, falls/rates of hospital-acquired infections) are publicly displayed in hospital wards. However, a qualitative study comparing these ward-level performance reports to patients’ own priorities found that patients had little need to view measures of past quality/safety performance. Moreover, patients’ own experiences of care took precedence over any other safety measure. This important distinction is well supported by our findings, which determined that direct care experiences are the cornerstone of how patients conceptualise safety.

Our study showed that the actions of hospital staff play a pivotal role in evoking patients’ feelings of safety. While existing evidence demonstrates that certain clinical work-force variables are associated with patient outcomes, a notable finding of our study was that patients’ feelings of safety are strongly influenced by the quality of patient–provider interactions and the relational aspects of care. Communication failure in healthcare has long been recognised as a major determinant of patient harm. Patients, however, commonly consider communication problems to be safety issues, even when they do not lead to adverse outcomes. Our findings clarify why this is the case: patients conceptualise safety as ‘feeling safe’ (rather than ‘being safe’) and the quality of interaction between patients and their care providers plays an important role in contributing to patients’ feelings of safety. Thus, our findings support the view that safe communication is not simply about the accurate exchange of information—it also necessitates situational awareness, engagement, and reflection to meet the social, emotional, and cultural needs of individual patients.

Strengths and limitations

Across the three different clinical specialties, we included patients who are often excluded from research (ie, older patients, non-native English speakers). However, this study was conducted at a single NHS site and excluded patients who were clinically unstable or lacking capacity to consent to study participation. Although we recruited patients from diverse ethnic groups, it will be important to extend this work to develop our understanding around how patients from minority ethnic groups conceptualise safety to enhance efforts to address health inequalities.

Of note, specialty-specific differences are not presented here but were explored as part of wider analyses (for example, issues specific to the care of the newborn in the maternity cohort, or issues relating to falls and mobility in the medicine for the elderly cohort); additionally, the cohort is surgically biased (as we had surgical patients and women who had elective/emergency caesarean sections). However, after returning to our data to review if and/or how this may impact on our conceptual model, we found that a small number of differences in experience lie only at the coding level, and as these are beneath the
theoretical and conceptual category levels, they did not influence our conceptual model. They may have an impact on the practical application of the model (ie, knowing which specific processes were important for feeling safe) but would not change the model itself.

The use of an abbreviated form of constructivist grounded theory has limitations in that we could not return to data collection to conduct theoretical sampling with a view of achieving saturation. For this reason, we have presented our findings as a conceptual model (rather than a full theory), consistent with Charmaz’s earlier writings. Engaging with these processes would have allowed us to further explore points of interest that arose while analysing the data, such as the role and impact of (1) the wider multidisciplinary team, (2) the quality of staff interaction and communication, and (3) social isolation. This could form the basis of future work.

CONCLUSION

The findings of this study emphasise the need for healthcare professionals, organisations and policymakers to expand their ideas about patient safety: to consider the importance—not just of ‘being safe’—but also of ‘feeling safe.’ Although it is imperative that the patient safety agenda continues to drive efforts to minimise the risk of patient harm, there is a real need to develop a new paradigm meaningful to all stakeholders—this must include a deep understanding of what matters to patients to feel safe in hospital. Future work should seek to test the conceptual model developed here more widely, before going on to explore how it can be practically applied and implemented across the sector to incorporate the patient conceptualisation of safety into everyday clinical practice.

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