Patient Voices in Hospital Safety during the COVID-19 Pandemic

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Abstract
Hospitalized patients and their families may be reluctant to express safety concerns. We aimed to describe safety and quality concerns experienced by hospitalized patients and families and factors and outcomes surrounding decisions about voicing concerns, including those related to the COVID-19 pandemic. We conducted semi-structured interviews with 19 discharged inpatients or family members in a qualitative descriptive design. Some participants reported concern about staff competency or knowledge, communication and coordination, potential treatment errors, or care environment. Factors influencing feeling safe included healthcare team member characteristics, communication and coordination, and safe care expectations. Reasoning for voicing concerns often included personal characteristics. Reasons for not voicing concerns included feeling no action was needed or the concern was low priority. Outcomes for voicing a concern were categorized as resolved, disregarded, and unknown. These findings support the vital importance of open safety communication and trustworthy response to patients and family members who voice concerns.

Keywords
patient safety, hospitals, qualitative research

Introduction
Patient safety in hospitals is a serious public health issue (Lachman, 2019; The Lancet, 2019). Keeping patients free from preventable or accidental injuries caused by healthcare is an essential responsibility of hospitals and staff (Agency for Healthcare Research and Quality [AHRQ], n.d.; Slawomirski et al., 2017). A recent meta-analysis across 94 studies representing 590 million hospitalized patients found an increasing rate of 8.6 adverse events per 100 hospital admissions; approximately half of the adverse events were preventable (Sauro et al., 2021). Central to their own care, patients should partner with hospital staff to prevent adverse events and improve safety (The Lancet, 2019). However, literature indicates not only do many patients hesitate to speak up about safety, but also patients who do voice concerns may feel dismissed and unheard (Merner et al., 2019). When patients or family members do not feel heard, consequences include negative safety outcomes, increased risk, decreased trust, and future reluctance to voice concerns (Merner et al., 2019). Explorations of facilitators and barriers to expressing safety concerns are increasingly robust, but there is limited work focusing on patients’ and family’s perspectives of safety concerns being heard and the potential influence of patient/family characteristics. The onset of the COVID-19 pandemic also provides an opportunity to contextualize patient and family safety concerns during a period of altered visitor guidelines, workload, and workflow.

Voicing Safety Concerns
Creating and maintaining patient safety requires both organizational structure and individual action (Groves et al.,...
In addition to actions of individual healthcare workers, many patients want to be involved in safety through involvement in local efforts and providing feedback, with patient safety organizations promoting heightened patient engagement in safety (AHRQ, 2017; Khan et al., 2016; Lawton et al., 2017; O’Hara et al., 2017; The Joint Commission, 2017). Patients can detect risks clinicians may not, including problems with transitions and care delays, and feel harmed by disrespect, or even suffer fear without detection by the clinician (Armitage et al., 2018; De Brun et al., 2017; Harrison et al., 2015; O’Hara et al., 2018; Stern & Sarkar, 2018). However, identification of patient safety risks often relies on the reporting, documentation, and perspective of clinicians through adverse event reporting, chart reviews, and trigger tools (Harrison et al., 2015; Khan et al., 2017). There are few safety reporting mechanisms intended for patient use, so patients are commonly forced to use formal complaint processes or voice safety concerns directly to clinicians providing or supervising their care, a scenario awkward at best and deterring at worst (Terry et al., 2019).

Consequently, because nurses are the healthcare professionals most frequently at the bedside (AHRQ, 2019), nurses are likely to be the first to react to safety concerns voiced by patients or family members. In a recent grounded theory study conducted with bedside nurses, the authors found hospital safety requires nurses to be responsive to patient and family concerns through an evaluative process that functions on the interpersonal level (Groves, Bunch, Cannava, et al., 2021). Likewise, research with these nurses indicated they created space for open safety communication to both foster interpersonal trust and to maintain patient safety and patient sense of security (Groves, Bunch, Sabadosa, et al., 2021).

The problem is patients can be reluctant to express safety concerns to nurses or expressed safety concerns may be dismissed (De Brun et al., 2017; Merner et al., 2019; National Patient Safety Foundation’s Lucian Leape Institute, 2014; Terry et al., 2019). Though not all existing evidence is specific to nurses, it indicates hospitalized patients may be hesitant to voice concerns during their stay due to reasons relating to diminished power, limited healthcare knowledge, and potential negative response. Patients may be hesitant to bother busy staff, particularly if the patient worries the concern is minor (Entwistle et al., 2010). Patients may not want to challenge the expertise and/or authority of care providers (Hrisos & Thomson, 2013), may worry about being labeled “difficult,” (De Brun et al., 2017; Hrisos & Thomson, 2013) and be concerned about not being taken seriously (De Brun et al., 2017; Vaismoradi et al., 2015). Patients might even worry their care will suffer if they speak up (Hrisos & Thomson, 2013; National Patient Safety Foundation’s Lucian Leape Institute, 2014). The COVID-19 pandemic has altered the hospital environment and behaviors of those delivering and receiving care in ways that were not anticipated and are not fully understood, impacting quality and safety (Fleisher et al., 2022). Therefore, it is essential to understand how patients perceive nursing response to voicing their safety concerns, and if there are notable factors related to the ongoing public health crisis.

### Purpose of the Study

The purpose of this study was to identify patient and family member perceptions of safety and quality concerns during the COVID-19 pandemic, as well as factors and outcomes related to patients and family members feeling their safety and quality concerns are heard or not heard. Specific aims included the following: (1) Describe any safety and quality concerns experienced by patients and family members during hospitalization and (2) Describe factors and outcomes surrounding decisions to voice or not voice concerns.

The study used a qualitative descriptive design with directed content analysis of semi-structured interviews. Qualitative description is a method of qualitative content analysis that produces a “straight descriptive summary of the informational contents of the data organized in a way that best fits the data” (Sandelowski, 2000, p. 338). Because little is known about this topic from the patient perspective, this methodology allowed us to make sense of the participants’ experiences and describe it using their language, without restricting the results to a particular theory (Ayres, 2007; Sandelowski, 2000, 2010).

### Population and Participants

We recruited patients or family members from four adult and pediatric medical surgical units at a large US Midwest academic medical center serving urban and rural areas between the Summer of 2021 and Spring of 2022. Inclusion criteria included English-speaking patients or family members of patients with impending discharge from these units and ability to consent. We used three strategies to recruit participants. The first strategy involved delivering a flyer and exempt information sheet in packets patients received on admission. The second approach included a study team member visiting the unit to conduct enrollment in person. The final strategy included broadening the inclusion criteria to include those who might not consider their experiences as having the “worry or concern about your or a loved one’s care” initially described in the recruitment materials. This final strategy involved asking the potential participant if they would be willing to receive a phone call approximately 3–5 days after their anticipated discharge so we could explain the study in more detail. Those who agreed provided contact information and were contacted by phone, and if reached and interested in participating, were then scheduled for an interview. Each participant received compensation following the interview. In all, 19 patients and family members participated in the study.
Methods

Ethical Review

This study was deemed exempt by the University of Iowa Institutional Review Board (IRB), ID#202101472, and received a waiver of written consent; verbal consent was obtained after a review of an IRB-approved exempt information sheet.

Instruments

Demographic survey. Participants completed a demographic survey via telephone to collect data including whether they were a patient or family member and their age, gender, education level, household income level, sexual orientation, race, and ethnicity.

Semi-structured interview. Participants engaged in a semi-structured telephone interview of approximately 15–30 minutes designed to elicit what they identified as actual or potential safety concerns as well as factors and outcomes surrounding a decision to voice a safety or quality concern. An advisory panel consisting of experts representing lesbian, gay, bisexual, transgender, and queer (LGBTQ+), Black, Hispanic, low socioeconomic, and geriatric populations assisted with development and refinement of an interview guide. Immediately prior to the interview, participants were reminded they could skip any question they preferred not to answer and interviews were audio-recorded. All interviews began with asking whether they or their family member had felt unsafe or like they were not receiving the best care during their hospital stay. Based on findings from previous studies, we were purposefully broad and did not request only responses about “safety,” as patients may not have been sure if their concern met a specific definition of safety, or been able to isolate safety-specific events from their full experience of care (De Brum et al., 2017; O’Hara et al., 2018; Walton et al., 2017). For those who did have a concern, we used a series of probes to determine the (a) nature of the concern, (b) whether they voiced the concern, and (c) factors and outcomes surrounding that decision. For those who reported they did not have a concern, we used a modified series of probes to (a) determine what had made them feel safe, as well as (b) what they might have been worried about prior to the stay but did not actually experience, (c) if they thought they would have spoken up if there had been a concern, and (d) factors and outcomes they would have expected around that decision. If participants did reveal a concern during the interview after initially saying they had no concerns, we reverted back to the probes appropriate for having had a concern. At the end of the interview, all participants were invited to discuss what made them or their family member feel safe in the hospital. The full interview guide is available upon request to the corresponding author.

Procedures for Data Collection

Two experienced interviewers on the study team conducted the interviews. We digitally recorded interviews, a professional service transcribed them, and a study team member checked transcriptions for accuracy and redacted to ensure anonymity. Data were labeled with an ID code and stored on secure servers. Transcriptions were uploaded into the MAXQDA software program (VERBI Software, 2019) for analysis. Demographic data were entered into REDCap, an online survey and data management program.

Data Analysis

In the Spring of 2022, we paused recruitment due to a resurgence of COVID-19 infections and increased hospital staff workload. We began analysis at that time to assess whether we had reached data saturation. We constructed a preliminary codebook consisting of a priori major coding categories designed to capture the factors of interest, using a directed content analysis approach (Hsieh & Shannon, 2005). Examples of major coding categories related to aims included the following: (1) safety concerns, (2) factors influencing voicing or not voicing concerns, and (3) outcomes to voicing or not voicing concerns. The principal investigator coded the transcribed text of each interview using MAXQDA, locating codes related to the major coding categories. The principal investigator inspected all data for unanticipated codes, adding these to the codebook as they emerged. These decisions were tracked in MAXQDA to create an audit trail. To further ensure trustworthiness, when initial coding was complete, a second member of the study team reviewed the coding to assure all meaningful components were coded, and all codes were supported by the data (Draucker et al., 2007; Whittemore et al., 2001). Consensus on codes and categories were reached by these two study team members. A summary of the categories and codes were prepared for study team review and members agreed data saturation had been reached. Study team members then explored differences and commonalities among the codes and categories. To further support trustworthiness, the advisory panel provided insight into meaningful code interpretation.

We examined the demographic and qualitative data for patterns that could indicate association between participant characteristics and specific codes or categories. Finally, for demographic data, we calculated means and standard deviations (SDs) for continuous variables and frequencies and percentages for categorical variables.

Findings

Sample Demographics

In all, 19 participants completed interviews, with an average interview length of approximately 21 minutes. Of these, 10...
were patients from adult patient care units and 9 were parents of patients on pediatric units. There was a wide range of participant ages, with a mean of 52.21 years (SD: 20.88, range: 23–96 years). In all, 11 participants identified as men, and 8 participants identified as women. Participants reported their race/ethnicity as follows: 1 White Hispanic, 1 Black or African American, 1 Asian, and 16 White non-Hispanic. All participants indicated they spoke English at home. In total, 18 participants described their sexual orientation as straight (heterosexual), with one participant preferring not to say.

In terms of total education, one participant indicated a 10th-grade education, six indicated completing high school or equivalency credential, three had completed some college, seven graduated from college, one completed some graduate school, and one completed graduate school. There was a range of approximate yearly household incomes. Four participants each were in the categories of $25,000–49,000, and $50,000–$74,999 yearly household incomes. Three participants indicated a yearly household income of $75,000–99,999. One participant each were in the categories of $100,000–124,999, $150,000–174,999, $175,000–199,999, and $200,000 and over.

**Aim 1: Safety or Quality Concerns**

We aimed to describe any safety or quality concerns experienced by patients and family members during hospitalization. Of the 19 participants we interviewed, eight said they did not experience a quality or safety concern while they or their family member was in the hospital. Five participants said that they did experience a quality or safety concern. Interestingly, there were also six participants who initially said they did not experience a concern but went on to describe at least one event as a concern, worry, or problem later in the interview. In all, 11 total participants described concerns they experienced during a hospital stay, and 8 did not. In addition, we identified factors influencing a lack of concerns, meaning the participants offered explanations as to why they had no concerns, or what they would need to feel safe. The categories of codes related to Aim 1 can be seen in Table 1.

**Experienced concerns.** Participants expressed concerns falling into four categories: staff competence or knowledge, communication and coordination, potential treatment errors, and care environment. Some participants mentioned concerns related to staff competence or knowledge, including general nursing knowledge and competence, novice skills, and unfamiliarity with the patient. For example, one participant was concerned about the knowledge of a nurse, saying, “When I would ask her for certain things, I’d have to explain what they were because she just didn’t know what they were” (33-year-old woman [33/W] parent participant). Another participant was concerned that new physicians were unfamiliar with the previous stays of their child and wished physicians “could see exactly what they tried the last time, what he’s allergic to, what they shouldn’t be trying” (73/W patient). Communication and coordination were concerns of some participants, including lack of explanations, poor discharge and team coordination, poor physician communication, and possible bias. One participant explained, “Well, I understand that it’s hard for different teams to communicate and coordinate to each hospital and they had a lot to deal with, but doctors would just drop in and they would hit you with information and there wouldn’t be a follow-up” (69/M patient). Another concern experienced by some participants were treatment errors. It is notable that having a concern about an error did not necessarily mean that one occurred, as in this situation: Like I remember one night, one of the nurses. . . They always tell you, before they give it to you, what they’re giving you. So, I told her, I said, ‘I’ve not taken this medication before.’ And she said, ‘Well, let me look it up.’ She come back and she said it was ordered here and not [at the previous setting]. And I said, ‘Well, that’s what I would expect that it should be.’ But I said, ‘It would’ve been nice if somebody would’ve discussed it and said something to me about it.’ (78/M patient)

Other concerns participants experienced were related to the environment, including unclean rooms or public areas, unit design, and infection control related to COVID-19. As one participant put it, “the only thing I worried about was the COVID, of course” (46/M parent).

**Factors influencing a lack of concerns.** All but one participant was able to describe at least one thing that would make them feel safe in the hospital or contributed to their lack of concerns. These fell into three categories: characteristics of the healthcare team members, communication and coordination, and expectations of safe care.

Participants noted several characteristics of healthcare team members that influenced a lack of concerns or contributed to a feeling of safety, including having a good attitude, being confident, being timely, being “great,” being familiar with the patient, seeking knowledge, being part of a team, and being professional. One participant expressed this in terms of multiple healthcare team members:

The nurses that came in during the day, the evening nurses, they were just, everyone was really great. They were kind, thoughtful. We knew that they were busy, but when [the patient] needed

| Categories of experienced concerns | Factors influencing a lack of concerns |
|-----------------------------------|----------------------------------------|
| Staff competence or knowledge     | Characteristics of healthcare team members |
| Communication and coordination    | Communication and coordination          |
| Potential treatment errors        | Expectations of safe care               |
| Care environment                  |                                        |
something, they came and took care of whatever she needed and answered any questions we might’ve had. And I think we had a lady that came, two ladies, two different people came and cleaned twice I think, while we were there. And they were very sweet, and thoughtful, and considerate and asked if it was okay that they came in. We had a couple of nurses’ aides who were extremely thoughtful and helpful. And the people who brought food were very quick and quiet and respectful. (32/W parent)

Communication and coordination included attentiveness of healthcare team members, such as “Being responsive, being available. It’s like a lot of times I could hear them right outside of the room at the nursing station. So, I always knew there was somebody there if something happened” (26/M parent). Listening was an important aspect of communication and coordination as well:

They would come every morning and make their rounds. And the doctors would talk, ‘Well, here’s where we’re at and here’s what we think’s going on,’ and blah, blah, blah. And I’d say, ‘Well, this is kind of what I think.’ I would put my two cents’ worth in, and they would listen to me. (78/M patient)

Communication and coordination also included being informed and good communication from and among healthcare team members; examples were healthcare team members informing the patient or family member about care, being transparent, preparing the patient for admission, and providing physical and verbal reassurance, as well as team coordination and the patient or family having their own background in healthcare. Most commonly, the participants talked about being informed about their or the patient’s care, such as this participant:

I think that helps a lot because as a patient, most of the time you don’t know what you don’t know, so you don’t know what to ask. And so providing that level of, okay, just to set the stage that here’s the expectation management, this is what we’re going to do, and this is how we think it’s going to go. I think that’s very calming for patients and parents. (23/W patient)

Another participant explained both the importance of keeping him informed and team coordination:

They were very communicative about what they were doing, why they were doing it. So, I never felt like I was in the dark, they kept the routines. They did a good job of transferring between shifts, the knowledge and where we were at. So, I wasn't having to retell the story every day. (26/M parent)

Several participants expressed trust in the healthcare team members, which provided an expectation of safe care. Others referred back to a previous positive experience in the hospital or familiarity with the hospital environment as a basis for their expectation of safety. Some participants expressed a perceived limited risk due to their routine procedure or care in a high-quality environment; one participant described the environment as “cutting edge” (79/M patient). Another participant expressed trust this way:

And it’s just like, you go on an airplane, you got to trust your pilot or you won’t get on the plane. So, I trusted my doctors. I had an interview with him before all this happened. He seemed like he was a competent individual. I didn’t have any problem when I met him the first time. And he said he’s done hundreds and hundreds of these things. (63/M patient)

**Aim 2: Factors around and Outcomes for Voicing Concerns**

We also aimed to describe factors and outcomes surrounding decisions to voice concerns or not voice concerns. The categories of codes related to Aim 2 are shown in Table 2. In all, 11 participants provided reasons they did or would voice a concern to hospital staff. Those reasons included the following: their own personal characteristics, past experience with concerns, it being the only way to be sure something is done, expecting an appropriate response, staff being readily available, and the fact that the participants were paying for their care. Of these participants, most indicated that it was something about their personal characteristics that made them likely to voice a concern, such as a participant who said, “I’m pretty big on speaking up for my children’s wellbeing. And so if I feel like they’re not getting the proper care, or if I have a question, I will very much ask and speak up” (32/W parent). Two participants tied their willingness to voice a concern to their age, saying, “I’m old enough and getting grumpy enough that I’ll do that. Years ago, I probably wouldn't have said a thing” (63/M patient), and “No problem. I’m old and I guess fairly outspoken. I can talk about anything with the nurse. They had to help me pee and all that. It’s okay” (79/M patient).

Only six participants explained why they did *not* voice a concern to hospital staff, which largely appeared to vary based on the circumstance. Those reasons included feeling no action was needed, because it was resolving on its own. The categories of codes related to Aim 2 are shown in Table 2.
own or there being no apparent harm; feeling their concern was a low priority, because it seemed less important than other patients’ problems, they did not want to be a bother, or they wanted to stay out of the way; being unsure if they were “right”; being young; being physically or cognitively unable to do so; and wanting just to leave. As an example, based on her experience thus far, one participant said, “I didn’t feel like I needed to ask a million questions, they’re going to tell me the information that I need to know” (72/M patient). Another participant was conflicted in expressing a concern, as they described:

Yeah. I always wrestled with that. Because I thought that I did need something and it was important. And yet in context with perspective, what I needed really wasn’t so important. . . Most people there were in far worse shape than me and needed more attention, needed more care. So, I felt bad asking for much. (69/M patient)

Fourteen participants reported or suggested potential outcomes for voicing their concern. These could be categorized as resolved (completion of the requested task, finding the answer for their concern, and/or doing their best to respond however was appropriate), disregarded, and simply unknown. One participant provided the example:

So, they definitely do better, at least in my experience, at [this hospital] with actually listening to the parents - we know our babies and our kids best because we’re sitting in there with them for hours and hours. So, they actually listened to what I had to say and acted upon it. (47/W parent)

Another participant explained why they chose not to speak up shortly before discharge, “I guess I just figured since we were leaving that they would probably feel like, well, why worry about it because we’re not going to be there for long” (33/W parent).

Discussion

Although patient harm is measured at the system level, patients confront risk as individuals embedded within a care environment, while cared for by members of a healthcare team. An unforeseen risk or safety concern is first encountered and frequently first recognized at this interpersonal level of interaction. We therefore examined these potential interactions from the patient and family point of view, and we did so during a pandemic period where many hospitals have reported worsening quality metrics (Fleisher et al., 2022). Some participants reported being concerned about staff competency or knowledge, communication and coordination, potential treatment errors, or care environment. Somewhat unexpectedly, participants described a number of factors that instead made them more likely to feel safe, which included healthcare team member characteristics, communication and coordination, and expectations of safe care. Reasoning for voicing concerns frequently included a personal characteristic. Among reasons for not voicing concerns were feeling no action was needed or the concern was a low priority. Outcomes for voicing a concern could be categorized as resolved, disregarded, and unknown. These findings support previous work regarding the vital importance of open safety communication and a trustworthy response to patients and family members who voice concerns. Despite collecting these data during the COVID-19 pandemic, our findings are consistent with previous work related to feeling safe in the hospital, as well as our own work with nurses in the same institution.

In their concept analysis of feeling safe while hospitalized, Mollon (2014) listed four main categories of defining attributes: trust, cared for, presence, and knowledge. Our participants’ responses related to a lack of concerns and feeling safe closely align with Mollon’s categories. “Trust” is involved in expectations of safe care found in this study. “Presence” is related to the attentiveness described here in communication and coordination. The attribute of “knowledge” was included under characteristics of team members described by our participants. Finally, “cared for” also has overlap with characteristics of team members and communication and coordination in this study. It is also interesting to note that the concerns participants described experiencing did in fact reflect the absence of Mollon’s four defining attributes of feeling safe while hospitalized.

A previous study conducted by some of the authors at the same institution prior to the COVID-19 pandemic found nurses tried to create space for open safety communication with patients (Groves, Bunch, Sabadosa, et al., 2021). Nurses did this by taking steps to “anticipate safety concerns, invite safety discussion, be accessible, recognize verbal and non-verbal insecurity, react in a trustworthy way, share a plan, and follow up with patient and family” (p. 637). While these previous findings indicated nurses were aware of the importance of patients and family being able to communicate safety concerns, it was possible nurses over-estimated the comfort of patients and family with speaking up about safety. The findings of this study suggest that there are times that patients and family did not speak up for a variety of reasons. However, participants in this study also indicated that space was created in many cases for open safety communication as intended by the nurse participants in our 2021 study, via being informed (congruent with nurses’ intent to anticipate safety concerns and educate), the attentiveness of healthcare team members (congruent with nurses inviting open safety discussion), and expectations of safe care (congruent with nurses’ trustworthy reaction).

Perhaps the most interesting finding of this study was that patients and family did not always initially identify a concern that they experienced during the hospitalization, but then did describe one as the interview progressed. There are several possible explanations for this. First, the participant may not have seen that concern as relating to safety or the quality of
their care. Second, the participant may have minimized their concern or seen it as trivial or normal, and therefore not of note. Third, responsiveness to a concern may have essentially negated the concern by resolving it.

The concept of institutional trust, suggested in Mollon’s concept analysis of feeling safe, may provide a fourth explanation for a participant’s interpretation of having a concern. Mollon (2014) explains that patients may have an “inherent trust” in the healthcare system and in nurses, what Ozaras and Abaan (2018) described as institutional trust. For example, Carter (2009) describes institutional trust in the profession of nursing as founded in an assumption that nurses are “able and willing to use their power” to advance good (p. 403). Mollon (2014) suggests that when the behaviors of individuals are not as expected, that is when patients begin to feel unsafe and develop distrust. In other words, prior to entering the hospital, some patients may be predisposed to trust in the institution that they will be cared for while vulnerable and may only question that trust when they see evidence from individuals that it is misplaced. Ozaras and Abaan (2018) explain that interpersonal trust is among individuals and is focused on meeting individual needs, solutions to problems, and “being proficient and reliable in carrying out tasks” (p. 629). Thus, the participant may have been looking back at the overall experience of their stay, and if the concern was addressed appropriately (institutional trust was not violated), it did not rise to the level of coloring the entire stay and was not immediately recalled.

Finally, the most common reason participants gave for being comfortable speaking up about their concerns was related to their own personal characteristics, with participants describing themselves as “old enough,” “outspoken,” “blunt and open,” and “not afraid.” This may suggest that despite a presumable power imbalance between the participant and those providing care (Carter, 2009; Dinc & Gastmans, 2013; Ozaras & Abaan, 2018), many participants still felt they had sufficient power or trust in their healthcare team to speak up. Conversely, others saw themselves as too young and a “bother,” minimizing their own concerns as “low priority” compared to others.

Limitations

There were limitations to this study. Two limitations relate to the study design. First, like any qualitative study, there could be multiple possible interpretations of the data; we offset this limitation through coding checks and advisory board input. Second, while qualitative data collection methods are ideal for studying a poorly understood process, the generalizability of findings is limited, particularly with use of one study site. We attempted to offset this by using a large hospital with a multistate referral radius, adult and pediatric populations, and multiple diagnostic categories.

A third limitation is specific to the convenience sample. It is important to note most studies investigating the voicing of safety concerns by patients or families do not assess or report patient characteristics relevant to disparity populations, seldom identifying characteristics beyond age and gender. Thus, concerns specific to these populations are largely unknown. Previously, patients in outpatient settings have indicated experiencing discrimination on the basis of sexual orientation, race, age, insurance, and socioeconomic status through clinicians’ verbal and nonverbal communication style (Kates et al., 2018; Tajeu et al., 2015), suggesting health disparity populations are also likely to face barriers to expressing safety concerns in the inpatient setting. We were aware as we started recruitment that patients from disparity populations, particularly those who feel marginalized, might also be reluctant to participate. We attempted to address these issues through collection of demographics data, and advice from the advisory board regarding scripting and wording of recruitment materials. We achieved our goals in terms of diversity in age, gender, education, and yearly household income. However, our small convenience sample lacked diversity in the areas of race and ethnicity and sexual orientation. Recruitment challenges that contributed to this limitation included limited opportunities to recruit minorities based on population composition, restricted in-person recruitment at times due to COVID-19 mitigation measures and hospital staff workload concerns, and the focus on English-speaking populations in recruitment materials.

Finally, there is the possibly that there was a self-selection bias related to who sought care during the COVID-19 pandemic, and who was willing to be interviewed for a study. Those who sought care may very well reflect only a portion of the “usual” population in that they were willing to voice concerns and thus receive medical attention during a pandemic. Likewise, those willing to speak to someone conducting a research study may have also been more likely to voice concerns to hospital staff. Moreover, we cannot rule out that the unique context of the COVID-19 pandemic may have generated a sense of hypervigilance amongst participants, resulting in findings unique to the pandemic.

Application

Preventable patient harm in hospitals burdens the patient, their family members, and the healthcare system, improving patient safety is thus a moral responsibility (Slawomirski et al., 2017). Nurses are uniquely positioned to co-produce safety with patients by creating space for them to talk about safety and by responding appropriately (Groves, Bunch, Sabadosa, et al., 2021). This study provides insight into what makes patients feel safe while in the hospital as well as factors and outcomes surrounding decisions to voice concerns. While these data were collected during the COVID-19 pandemic when one might expect to find divergent findings, instead the findings support previous work in these areas, including the vital importance of open safety communication, particularly nurses’ openness and
trustworthy response to voicing of safety concerns by patients and family members. Reframing nurse–patient communication to normalize and encourage having questions is one specific way to apply these findings; for example, asking patients and family “What questions do you have?” rather than “Do you have any questions?” This study also suggests the continued importance of exploring aspects of institutional and interpersonal trust as important factors in both the voicing of patient and family safety concerns and the measurement of those concerns.

No system mechanisms exist to detect the impact of disparity characteristics on patient–clinician communication and speaking-up behaviors, nor can we assume hospital system safety interventions are equally effective for disparity populations. Further evidence is needed to design system processes to detect problems in patient communication about safety with particular emphasis on disparity populations. Future work might focus on settings with larger cohorts of LGBTQ+ and ethnic minority patients and use multilingual recruitment materials and interpreters.

Bell and Martinez (2019) suggest that every patient should have the ability to “stop the line” if they think something is wrong. Focusing on what makes patients feel safe and the factors that facilitate voicing any concern will allow nurses and other healthcare team members to make conscious efforts to invite open safety communication and respond appropriately. Healthcare teams must openly engage patients and families as full partners in safety and encourage them to use their voices. In turn, this will both co-produce safety in the moment as well as increase patient interpersonal and institutional trust and therefore continued likelihood to voice future concerns.

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Ethical Review
This study was deemed exempt research by the University of Iowa Institutional Review Board, ID# 202101472, and received a waiver of written consent; verbal consent was obtained after a review of IRB-approved exempt information sheet.

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References
Agency for Healthcare Research and Quality. (2017). Patient engagement and safety. https://psnet.ahrq.gov/primers/primer/17/patient-engagement-and-safety
Agency for Healthcare Research and Quality. (2019). Nursing and patient safety. https://psnet.ahrq.gov/primers/primer/22/nursing-and-patient-safety
Agency for Healthcare Research and Quality. (n.d.). Patient safety. https://psnet.ahrq.gov/glossary?%5B0%5D=term%3AP
Armitage, G., Moore, S., Reynolds, C., Laloe, P. A., Coulson, C., McEachan, R., Lawton, R., Watt, I., Wright, J., & O’Hara, J. (2018). Patient-reported safety incidents as a new source of patient safety data: An exploratory comparative study in an acute hospital in England. Journal of Health Services Research and Policy, 23(1), 36–43. https://doi.org/10.1177/1355819617727563
Ayres, L. (2007). Qualitative research proposals-part II: Conceptual models and methodological options. Journal of Wound, Ostomy & Continence Nursing, 34(2), 131–133.
Bell, S. K., & Martinez, W. (2019). Every patient should be enabled to stop the line. BMJ Quality & Safety, 28(3), 172–176. https://doi.org/10.1136/bmjqs-2018-008714
Carter, M. A. (2009). Trust, power, and vulnerability: A discourse on helping in nursing. Nursing Clinics of North America, 44(4), 393–405. https://doi.org/10.1016/j.cnur.2009.07.012
De Brun, A., Heavey, E., Waring, J., Dawson, P., & Scott, J. (2017). PReSaFe: A model of barriers and facilitators to patients providing feedback on experiences of safety. Health Expectations, 20(4), 771–778. https://doi.org/10.1111/hex.12516
Dinc, L., & Gastmans, C. (2013). Trust in nurse-patient relationships: A literature review. Nursing Ethics, 20(5), 501–516. https://doi.org/10.1177/0969733012468463
Drucker, C. B., Martzolf, D. S., Ross, R., & Rusk, T. B. (2007). Theoretical sampling and category development in grounded theory. Qualitative Health Research, 17(8), 1137–1148. https://doi.org/10.1177/104973307308450
Entwistle, V. A., McCaughan, D., Watt, I. S., Birks, Y., Hall, J., Peat, M., Williams, B., & Wright, J. (2010). Speaking up about safety concerns: Multi-setting qualitative study of patients’ views and experiences. Qualitative and Safety in Health Care, 19(6), e33. https://doi.org/10.1136/qhc.2009.039743
Fleisher, L. A., Schreiber, M., Cardo, D., & Srinivasan, A. (2022). Health care safety during the pandemic and beyond—building a system that ensures resilience. New England Journal of Medicine, 387(6), 609–611. https://doi.org/10.1056/NEJMp2118285
Groves, P. S., Bunch, J. L., Cannava, K. E., Sabadosa, K. A., & Williams, J. K. (2021). Nurse sensemaking for responding to patient and family safety concerns. *Nursing Research, 70*(8), 106–113. https://doi.org/10.1097/NRN.0000000000000487

Groves, P. S., Bunch, J. L., Sabadosa, K. A., Cannava, K. E., & Williams, J. K. (2021). A grounded theory of creating space for open safety communication between hospitalized patients and nurses. *Nursing Outlook, 69*, 632–640. https://doi.org/10.1016/j.outlook.2021.01.005

Groves, P. S., Meisenbach, R. J., & Scott-Cawiezell, J. (2011). Keeping patients safe in healthcare organizations: A structuration theory of safety culture. *Journal of Advanced Nursing, 67*, 1846–1855. https://doi.org/10.1111/j.1365-2648.2011.05619.x

Harrison, R., Walton, M., Manias, E., Smith-Merry, J., Kelly, P., Iedema, R., & Robinson, L. (2015). The missing evidence: A systematic review of patients’ experiences of adverse events in health care. *International Journal for Quality in Health Care, 27*(6), 424–442. https://doi.org/10.1093/ijqhc/mnz075

Hrisos, S., & Thomson, R. (2013). Seeing it from both sides: Do approaches to involving patients in improving their safety risk damaging the trust between patients and healthcare professionals? An interview study. *PloS One, 8*(11), e80759. https://doi.org/10.1371/journal.pone.0080759

Hsieh, H., & Shannon, S. E. (2005). Three approaches to qualitative content analysis. *Qualitative Health Research, 15*(9), 1277–1288. https://doi.org/10.1177/1049732305276687

Kates, J., Ranji, U., Beamesderfer, A., Salganicoff, A., & Dawson, L. (2018). Health and access to care and coverage for lesbian, gay, bisexual, and transgender (LGBT) individuals in the U.S. https://www.kff.org/disparities-policy/issue-brief/health-and-access-to-care-and-coverage-for-lesbian-gay-bisexual-and-transgender-individuals-in-the-us/

Khan, A., Coffey, M., Litterer, K. P., Baird, J. D., Furtak, S. L., Garcia, B. M., Ashland, M. A., Calaman, S., Kuzma, N. C., O’Toole, J. K., Patel, A., Rosenbluth, G., Destino, L. A., Everhart, J. L., Good, B. P., Hepps, J. H., Dalal, A. K., Lipsitz, S. R., & Yoon, C. S. . . . Patient and Family Centered I-PASS Study Group. (2017). Families as partners in hospital error and adverse event surveillance. *JAMA Pediatrics, 171*(4), 372–381. https://doi.org/10.1001/jamapediatrics.2016.4812

Khan, A., Furtak, S. L., Melvin, P., Rogers, J. E., Schuster, M. A., & Landrigan, C. P. (2016). Parent-reported errors and adverse events in hospitalized children. *JAMA Pediatrics, 170*(4), e154608. https://doi.org/10.1001/jamapediatrics.2015.4608

Lachman, P. (2019). New challenges for patient safety. *International Journal for Quality in Healthcare, 31*(2), 73–74. https://doi.org/10.1093/ijqhc/mzz010

Lawton, R., O’Hara, J. K., Sheard, L., Armitage, G., Cocks, K., Buckley, H., Corbacho, B., Reynolds, C., Marsh, C., Moore, S., Watt, I., & Wright, J. (2017). Can patient involvement improve patient safety? A cluster randomised control trial of the patient reporting and action for a safe environment (PRASE) intervention. *BMJ Quality & Safety, 26*(8), 622–631. https://doi.org/10.1136/bmjqs-2016-005570

Mernier, B., Hill, S., & Taylor, M. (2019). “I’m trying to stop things before they happen”: Carers’ contributions to patient safety in hospitals. *Qualitative Health Research, 29*(10), 1508–1518. https://doi.org/10.1177/1049732319841021

Mollon, D. (2014). Feeling safe during an inpatient hospitalization: A concept analysis. *Journal of Advanced Nursing, 70*(8), 1727–1737. https://doi.org/10.1111/jan.12348

National Patient Safety Foundation’s Lucian Leape Institute. (2014). *Safety is personal: Partnering with patients and families for the safest care*. Author. http://www.ihi.org/resources/Pages/Publications/Safety-Is-Personal-Partnering-with-Patients-and-Families-for-the-Safest-Care.aspx

O’Hara, J. K., Armitage, G., Reynolds, C., Coulson, C., Thorp, L., Din, I., Watt, I., & Wright, J. (2017). How might health services capture patient-reported safety concerns in a hospital setting? An exploratory pilot study of three mechanisms. *BMJ Quality & Safety, 26*(1), 42–53. https://doi.org/10.1136/bmjqs-2015-004260

O’Hara, J. K., Reynolds, C., Moore, S., Armitage, G., Sheard, L., Marsh, C., Watt, I., Wright, J., & Lawton, R. (2018). What can patients tell us about the quality and safety of hospital care? Findings from a UK multicentre survey study. *BMJ Quality & Safety, 27*(9), 673–682. https://doi.org/10.1136/bmjqs-2017-006974

Ozgur, G., & Abaan, S. (2018). Investigation of the trust status of the nurse-patient relationship. *Nursing Ethics, 25*(5), 628–639. https://doi.org/10.1097/NNE.0000000000000889

Sandelowski, M. (2000). Focus on research methods. Whatever happened to qualitative description? *Research in Nursing and Health, 23*(4), 334–340. https://doi.org/10.1002/1098-240x(200008)23:4<334::aid-nur9>3.0.co;2-g

Sandelowski, M. (2010). What’s in a name? Qualitative description revisited. *Research in Nursing and Health, 33*(1), 77–84. https://doi.org/10.1002/nur.20362

Sauro, K. M., Machan, M., Whalen-Browne, L., Owen, V., Wu, G., & Stelfox, H. T. (2021). Evolving factors in hospital safety: A systematic review and meta-analysis of hospital adverse events. *Journal of Patient Safety, 17*(8), e1285–e1295. https://doi.org/10.1097/pts.0000000000000889

Slawomirski, L., Auraen, A., & Klazinga, N. (2017). *The economics of patient safety: Strengthening a value-based approach to reducing patient harm at national level*. Organisation for Economic Co-operation and Development (OECD). https://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf

Stern, R. J., & Sarkar, U. (2018). *Patient engagement in safety: Annual perspective 2017*. https://psnet.ahrq.gov/perspective/patient-engagement-safety

Tajeu, G. S., Cherriington, A. L., Andreae, L., Prince, C., Holt, C. L., & Halanych, J. H. (2015). “We’ll get you to when we get to you”: Exploring potential contributions of health care staff behaviors to patient perceptions of discrimination and satisfaction. *American Journal of Public Health, 105*(10), 2076–2082. https://doi.org/10.2105/AJPH.2015.302721

Terry, D., Kim, J. A., Gilbert, J., Jang, S., & Nguyen, H. (2019). “Thank you for listening”: An exploratory study regarding the lived experience and perception of medical errors among those who receive care. *International Journal of Health Services, 42*, 292–302. https://doi.org/10.1177/0020716119889306

The Joint Commission. (2017). *Speak up initiatives*. https://www.jointcommission.org/speakup.aspx

The Lancet. (2019). Patient safety: Too little, but not too late. *The Lancet, 394*, 895. https://doi.org/10.1016/S0140-6736(19)32080-X
Vaismoradi, M., Jordan, S., & Kangasniemi, M. (2015). Patient participation in patient safety and nursing input – a systematic review. *Journal of Clinical Nursing, 24*(5–6), 627–639. https://doi.org/10.1111/jocn.12664

VERBI Software. (2019). *MAXQDA 2019* [Computer software]. VERBI Software. https://www.maxqda.com

Walton, M. M., Harrison, R., Kelly, P., Smith-Merry, J., Manias, E., Jorm, C., & Iedema, R. (2017). Patients’ reports of adverse events: A data linkage study of Australian adults aged 45 years and over. *BMJ Quality & Safety, 26*, 743–750. https://doi.org/10.1136/bmjqs-2016-006339

Whittemore, R., Chase, S. K., & Mandle, C. L. (2001). Validity in qualitative research. *Qualitative Health Research, 11*(4), 522–537. https://doi.org/10.1177/104973201129119299

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