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Patient safety issues and concerns in Bhutan's healthcare system: a qualitative exploratory descriptive study

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Ethical approval: Ethical approvals were obtained from the Research Ethics Board of Health, Ministry of Health, Bhutan (REBH/Approval/2012/018) and the Deakin University Human Research Ethics Committee (DUHREC 2012-221) – *copies of approval letters can be provided on request*.

Patient safety issues and concerns in Bhutan's healthcare system: a qualitative exploratory descriptive study

Abstract

Objectives: To investigate what healthcare professionals perceived and experienced as key patient safety concerns in Bhutan's healthcare system.

Design: Qualitative exploratory descriptive inquiry.

Settings: Three different levels of hospitals, a training institute and the Ministry of Health, Bhutan.

Participants: In total, 140 healthcare professionals and managers.

Methods: Narrative data were collected via conversational in-depth interviews and Nominal Group Meetings. All data were subsequently analyzed using thematic analysis strategies.

Results: The data revealed that medication errors, healthcare associated infections, diagnostic errors, surgical errors and post-operative complications, laboratory/blood testing errors, falls, patient identification and communication errors, were perceived as common patient safety concerns. Human and system factors were identified as contributing to these concerns. Instituting clinical governance, developing and improving the physical infrastructure of hospitals, providing necessary human resources, ensuring staff receive patient safety education, and promoting 'good' communication and information systems were, in turn, all identified as processes and strategies critical to improving patient safety in the Bhutanese healthcare system.

Conclusion: Patient safety concerns described by participants in this study were commensurate with those identified in other low and middle-income countries. In order to redress these concerns, the findings of this study suggest that in the Bhutanese context patient safety needs to be conceptualised and prioritised.

Key words

Bhutan, patient safety, clinical governance, medical errors, quality assurance

Strengths and limitations of this study (summary)

- Creating a deeper awareness and understanding of the patient safety issues and concerns in the cultural context of Bhutan is the key strength of this study.
- The reliance on patient safety concepts, theories and practices that have been developed and applied in high-income resource-rich nations is the main limitation of this study.
- The large quantity of data generated required decisions about inclusion and exclusion of data, informed by consistency of the findings across the disparate participant groups, which may have resulted in the loss of some material.

Introduction

The World Health Organisation (WHO) has recognised patient safety as a global problem and positioned it as a worldwide endeavor, seeking to bring benefits to patients in countries rich and poor, developed and developing alike.[1] It is estimated that each year millions of patients worldwide suffer disabilities, injuries or death due to unsafe medical care, and that around 50% of these harmful outcomes are preventable.[2 3] The incidence and impact of preventable harmful events are particularly burdensome in developing and transitional-income countries.[2 3]

Despite patient safety being positioned by WHO as a global priority, improving patient safety outcomes in resource poor nations is challenging. One reason for this is a lack of reliable data to quantify the burden of unsafe patient care and, in turn, inform patient safety improvement

initiatives.[4] Another reason is that most current data on patient safety come from developed or high-income countries, where the healthcare contexts are different and where processes for improving patient safety outcomes cannot be readily transferred to other (less resourced) countries and their local healthcare settings.[5 6] Even so, it is estimated that rates of adverse events in low-income countries are higher than those of high-income countries. For example, the risk of healthcare associated infections in low-income countries is estimated to be 20 times higher than in high-income countries.[7] Similarly, research evidence suggests the prevalence of preventable surgical adverse event rates in low-income countries is five times more than in high-income countries.[8]

In Bhutan, patient safety issues are not well documented or known. To date there have been no published studies scoping either the nature or impact of patient safety concerns in Bhutan's healthcare system. Thus, at this time, as noted in the WHO *Global priorities for patient safety research*,[4] the main option for informing strategies aimed at improving patient safety in Bhutan is to scope stakeholders' perceptions and personal experiences of patient safety processes. It is anticipated that by undertaking preliminary scoping work a better understanding can be gained of the nature and extent of patient safety concerns in the Bhutanese context and what is required to redress these.

The aim of this study was to scope and describe what stakeholders (clinicians, health service managers, educators and policy makers) perceived and personally experienced as being the most common patient safety concerns in the Bhutanese healthcare system. The three research questions guiding the study were:

- What are healthcare professionals' and managers' knowledge, perceptions, understanding, and experiences of patient safety in Bhutan's hospitals?
- What factors do healthcare professionals and managers identify as most contributing to patient safety concerns in Bhutan's hospitals?
- What strategies do healthcare professionals and managers suggest are needed in order to address the patient safety issues and concerns they identified?

Methods

Study design

This study was undertaken as a naturalistic inquiry using a qualitative exploratory descriptive research approach.

Settings and participants

The study was conducted in three levels of hospital (district, regional referral and national referral), a training institute and the Ministry of Health in Bhutan. A sample of 94 participants (doctors, nurses, ward managers, senior managers and health assistants) was purposively recruited and interviewed. Of those interviewed, the majority (n=56) were male and the age range of participants was 23 to 60 years (mean 36.7 years). The majority of participants (n=33) had a diploma as their highest professional qualification, followed by master's degree (n=32), bachelor degree (n=23) and certificate (n=6). Length of service ranged from six months to 29 years (mean 12.7 years). Additionally, 46 healthcare professionals participated in Nominal Group Meetings (NGMs). Of those that participated in NGMs, the majority (n=24) were male and participants' age range was 24 to 50 years (mean 35.6 years). The majority of NGM participants (n=26) had a diploma as their highest professional qualification, followed by bachelor (n=9), master degree (n=9), and certificate

(n=2). Length of service of NGM participants ranged from six months to 22 years (mean 10.2 years).

Patient and public involvement

As the aim of this study was to scope and describe what healthcare professionals perceived and personally experienced as being the most common patient safety concerns in the Bhutanese healthcare system no patients were involved in this study.

Data collection procedure

Data were collected via in-depth interviews (n=94) and NGMs (n=5). Participants for in-depth interviews were invited through direct contact, flyers posted on staff noticeboards and invitation letters sent to participating wards/institutes. They were interviewed individually using broad semi-structured interview questions to elicit knowledge, perceptions, and experiences of patient safety in Bhutan. Participants for NGMs were nominated by their managers and the NGMs were conducted in different groups according to criterion based characteristics such as doctors, nurses and managers. To facilitate smooth NGMs, a nominal group task statement form, which specified the exploratory questions, was used to list the critical elements of the patient safety issues. Duration of individual interviews and NGMs ranged from 45 to 120 minutes.

Approval was received from the Research Ethics Board of Health, Ministry of Health, Bhutan (REBH/Approval/2012/018) and organisational consent was obtained from the five research sites from which participants were recruited and other materials were retrieved. Ethics approval was also obtained from the Human Research Ethics Committee of ([University

blinded]). All participants were informed about the nature and purpose of the study and provided verbal or written consent prior to interview or participation in a NGM.

Data analysis

Narrative data obtained from interviews and NGMs were analysed using the following steps: verbatim transcription of audio-recordings, active reading of transcripts, making notes on general themes, re-reading transcripts, comparing transcripts with key themes and concepts, making categories describing all aspects of the content, excluding unusable content or fillers, re-reading transcripts alongside the finally agreed list of categories, and making adjustments as necessary [9]. The data collected and analysed are reported and discussed in aggregate in this article - no additional data is available.

Results

This study revealed eight major patient safety concerns, possible factors contributing to them, and recommendations for strategies which could be used for addressing the concerns identified. The results are presented according to these areas.

Patient safety issues and concerns

Participants identified the following patient safety issues: medication/drug errors, healthcare associated infections, surgical errors and post-operative complications, diagnostic errors, laboratory/testing errors, injurious falls, communication errors, and patient identification errors (themes and supporting quotes are provided in Table 1).

Medication/drug errors: Medication error was the most common patient safety concern identified. Errors included administering wrong drugs to the wrong patient, administering

drugs that had passed their expiry date, giving the wrong drug dose, continuation of drugs for unjustified periods of time, and drug omissions (failure to administer prescribed drugs). 'Irrational' use of drugs was also described, manifested as prescribing of: large quantities of drugs; high drug doses that could not be justified or were outside recommended doses; and antibiotics to treat non-bacterial infections or viral conditions.

Healthcare Associated Infections (HAIs): Post-surgery wound infections and urinary tract infections (due to healthcare professionals not adhering to sterile technique during catheterisation) were the two main HAIs identified.

Surgical errors and post-operative complications: Notable among the surgical-related patient safety concerns were retention of foreign objects (e.g., gauze or instruments). In some instances, surgical errors resulted in mortality.

Diagnostic errors: Errors in diagnosis were perceived as common (e.g., wrongly diagnosing a patient as having tuberculosis, when they had cancer, and vice versa).

Laboratory/blood testing errors: Incompatible blood transfusion errors were reported. Common laboratory/blood testing errors included performing wrong or unnecessary blood investigations, and issuing wrong laboratory reports.

Fall injuries: This involves patients falling from beds and trolleys.

Communication errors: Communication errors, verbal abuse and/or rude behavior towards patients, and failure to communicate clearly to patients about their disease and treatment were identified.

Patient identification errors: The lack of a formal patient identification system was reported. This was considered particularly problematic since Bhutanese people often have the same or similar names. A major consequence of this was the risk and incidence of patients receiving the wrong treatment or procedure.

Table 1. Patient safety issues and concerns

Themes	**Participant statements**
Medication/drug errors	"I think the most common is errors in drug doses and medications. […] medication error includes errors in giving IV fluids like sometimes wrong IV fluids, wrong rate of administration – improper calculation of the drop rates" (Medical doctor). "[…] misuse of antibiotics – sometimes you continue antibiotics even for cough and cold where it is not required. They [doctors] use high dosage of different antibiotics for organisms that are not sensitive" (Medical doctor).
Healthcare Associated Infections (HAIs)	"Infection is definitely an issue. Previously where I used to work, […] in a small district hospital, usually patient with small surgery – minor surgery was getting post-surgery wound infection. Wound not healing faster" (Senior Manager).

	"We do come across hospital acquired infections – people especially with long term hospitalisation tend to get urinary tract infections. I don't know how people [healthcare providers] are handling the catheterisation process" (Medical doctor).
Surgical errors and post-operative complications	"We always hear from the operation theatre that some gauze pieces or some instrument has been left inside" (Nurse).
Diagnostic errors	"They [doctors] misdiagnose and then sometimes they give wrong medication which I have seen in one case that the patient really had adverse effect" (Nurse).
Laboratory/blood testing errors	"Sometimes there are few laboratory mistakes. I don't know whether it is the printing mistakes, sometimes we send two samples almost within 2 to 3 hours gap and the report come completely different. Maybe because staff are giving wrong sample for the other patient or is the printing mistake from the lab […]. We have cases like same patient having done the same investigations in few hours showed vast difference in the reading" (Nurse).
Fall injuries	"While patient is transferred in the trolley there was one incident where the patient went off the trolley. And then few times we have heard patient falling from the bed. So fall is common" (Ward Manager).
Communication errors	"Most of the time the misunderstanding that happens between the patient and the staff is due to lack of adequate communication. Many a times what we have done is for example probably not

	spend enough time on that part - explaining the diagnosis, where is the problem, what medicine you are prescribing, how you need to take that medicine, what are the side effects of the medicines, all these things, you know" (Senior Manager - NGM1). "I think one complaint we hear is that of verbal abuse by the health professionals to patients and their relatives" (Senior Manager).
Patient identification errors	"I think one pertinent one is for lack of patient identification marks. Our Bhutanese have similar names and then that can lead to, during procedures in rush hours, doing procedures in a wrong patient" (Medical doctor).

Factors contributing to patient safety concerns

Human (staff) and system factors were identified as the main contributing factors to patient safety concerns (themes and supporting quotes are presented in Table 2).

Human (staff) factors

Lack of patient safety competency: The most commonly cited factor contributing to patient safety concerns was healthcare professionals' lack of patient safety competencies, encompassing lack of knowledge of patient safety principles and processes, not having the necessary skills to practice safely, and not displaying the 'right' attitude.

Knowledge

Lack of knowledge about quality improvement and patient management processes was identified as a major contributing factor to patient safety concerns. Medication errors and HAIs were linked to healthcare professionals' lacking requisite knowledge about medicines/drugs and infection control.

Skills

Healthcare professionals' lack of patient assessment skills, for example, not checking vital signs, not taking a detailed patient history, or failure to review a patient's history, were perceived as contributing to errors such as wrong patient diagnoses and treatment.

Attitudes

The most prominent issue identified was a complacent attitude among healthcare professionals (e.g. taking 'shortcuts' and carelessness). Examples included healthcare professionals not applying knowledge, despite knowing about patient safety measures, and not apportioning sufficient importance to Standard Operating Protocols and guidelines.

System factors

Lack of resources: All categories of participants reported that shortage of staff (poor skill mix and staff-patient ratio) was the key contributing factor to diagnostic and medication errors. Also perceived to contribute to patient safety concerns was the lack of infrastructure. This included: a lack of rooms to isolate patients with infectious diseases, to store clinical items (e.g., sterilised packs), and to carry out procedures without disruption and contamination; lack of basic materials and equipment for infection control such as disinfectants, soaps, and wound dressing supplies; dusty hospital surroundings; and absence of adequate systems to

monitor hospital infection rates. Diagnostic errors were believed to be related to lack of adequate investigative resources (e.g., laboratory reagents) and lack of functional and reliable diagnostic equipment.

Lack of policies, guidelines and protocols on patient safety: As a consequence of the lack of policies, guidelines, standard protocols and checklists, there was perceived variation in the management of patients across different hospitals and/or wards, with treating specialists and nurses not agreeing on treatment matters.

Poor communication and collaboration: Healthcare professionals failing to communicate verbally and not clearly documenting patient care were reported to contribute to patient safety concerns. For example, continuation of medications for unreasonable periods of time was perceived to have resulted from poor communication between doctors and nurses. Lack of clear communication with and provision of information to patients about their disease and treatment was reported to lead to poor compliance with treatment.

Lack of teamwork and collaboration among hospital departments and clinicians were perceived to be particularly problematic. Internal conflicts and 'tribal fights' were reported, with stakeholders trying to blame and 'pull each other's legs' (which in Bhutan is taken to mean 'belittling'), disrupting workplace harmony, respect and cooperation. Participants described difficulty coordinating members of departments, due to lack of cooperation.

Lack of management support and governance: Some participants believed patient safety, as an agenda, had been overlooked by leaders and managers. Patient safety and risk

management have not yet permeated into the Bhutanese healthcare system, and management was perceived as not yet ready to accept change.

Poorly developed patient safety incident reporting: Incident reporting processes were reportedly poorly developed. For instance, robust systems did not exist to record and report incidents and it was perceived that as a result the majority of incidents went unreported.

Lack of patient education on patient safety: Participants contended that patients are not educated about infection control and are not aware of how to take care of their own body secretions (sputum, urine and blood), increasing the risk of cross infection. In addition, healthcare professionals' failure to inform and educate patients and the public about certain hospital functions and procedures, such as where to go in the event of emergencies and signs and symptoms of emergencies, were perceived to have contributed to patient mortality.

Table 2. Factors contributing to patient safety concerns

Themes	**Participant statements**
Human (staff) factors	
Lack of patient safety competency:	
• Knowledge	"Sometimes the medication errors usually happen because they [staff] aren't aware of the right method to be given. For example, there are some medications like [name of drugs withheld] which are really painful and it should not be given direct bolus, but it should rather be given as infusion. […] It so happens that they are given bolus and then we have to be facing a problem and solving it" (Nurse - NGM5).

• Skills	"One issue is - usually the patients are seen in […] OPD [Out-patient Department] and they are sent here [to the ward]. So they [clinicians] did not monitor the vital signs and then we had some incidents. […] [one patient] did not have vital signs monitored and did not have [Blood Pressure checked] - actually the patient was 'walking dead'. Then we had to manage here in the ward and then ultimately send to ICU" (Ward Manager).
• Attitudes	"It is the attitude [of healthcare providers] sometimes" (Ward Manager). "If I have to say, I think certain procedures are done by people who are not very cautious about taking precautions. For example, as a medical student we knew that we have to take lots of precaution even to insert a catheter but now I see that it is being done very casually. I don't think people are really taking care of the proper sterile techniques and all" (Medical doctor).
System factors	
Lack of resources	"Contribution for medication error maybe due to the shortage of nursing staff where while they are preparing the medicine, they have to go and attend the other critical cases, if any" (Senior Manager). "I think the most common patient safety issue is establishing diagnosis. I find it as a major issue because patients are not properly followed up and then adequate investigating facilities are

	not available and we lose patient in between" (Nurse).
Lack of policies, guidelines and protocols on patient safety	"One is the standard management of patient. That depends on individual specialists and individual doctors. A major crux of the thing is how to come to a proper diagnosis and what line of treatment. So, highly qualified specialists have their own line of management which some specialists don't agree" (Senior Manager).
Poor communication and collaboration	"When I talk about the patient safety one thing is that there is a gap in between doctors and nurses because they prescribe antibiotics and it goes more than 20 to 30 days. […] Doctors, when they prescribe the drugs in ward, most of the doctors they use [name of drugs withheld] which is a 3rd generation antibiotic and they do not write the specific days, like for this many days" (Nurse). "As of now we have a problem in getting all departments together to get a good care of the patient. For example, in the emergency we see lot of cases which need to be consulted with different departments – interdepartmental consultation. […] But at the moment it is very difficult to have an interdepartmental consultation" (Ward Manager).
Lack of management support and governance	"Patient safety in Bhutan, in my honest opinion, there isn't anything happening. We have some visiting professors and we have some health volunteers, they come in and they try to suggest and our staff, one or two maybe, try to take initiatives or people who have seen other hospital they think we need to do something. But it

	is ailing, because the system is not ready to accept anything. Right now, the health system is only considered about getting drugs and how many beds we can put and how many staff we can recruit but there is no check on how safe are the patients" (Nurse).
Poorly developed patient safety incident reporting	"I think that [incident reporting] is the weakest in the health system here. Keeping the data and then recording and reporting is very, very poor in the healthcare system- be it in National Referral Hospital or District Hospitals" (Medical doctor).
Lack of patient education on patient safety	"I think in the hospital settings when we talk about safety of the patient and the factors, basically patients were not educated on infection control so thereby they are not able to take care of their own secretions like sputum or urine or even blood. So that is one factor that we are likely to have infections" (Health Assistant).

Strategies to improve patient safety

Participants identified six strategies to improve patient safety: instituting governance for patient safety, development/improvement of physical infrastructure/environment, providing adequate resources, providing patient safety training and education, promoting communication and information systems, and changing the attitudes and behaviour of healthcare professionals (themes and supporting quotes are provided in Table 3).

Instituting governance for patient safety: Institution of patient safety governance was identified as an important strategy to improve patient safety processes and practices. Participants argued a hospital patient safety program with a committee structure (e.g., patient

safety, mortality, and clinical governance committees) reporting to the Ministry of Health would advance patient safety. To reduce risk of harm to patients, participants recommended implementation of robust policies, guidelines and protocols.

Development/improvement of physical infrastructure/environment: Participants highlighted the importance to patient safety of safe physical infrastructure and a safe environment. Safe infrastructure was characterised as strong buildings with adequate 'space'; good navigation systems (e.g., signage); an inbuilt oxygen system, ramps, electric elevators, a ventilation system and good natural lighting. A safe environment was characterised as promoting physical safety, such as providing patients with an orientation on admission and maintaining cleanliness. The provision of equipment, such as wheel chairs and beds with side rails, was also deemed to be core elements of patient safety.

Providing adequate resources: Having adequate resources – including skilled and educated healthcare professionals, functional equipment and a constant supply of drugs – was considered critical to patient safety. Access to reliable laboratory facilities was considered necessary to facilitate correct patient diagnoses, treatment and management.

Providing patient safety training and education for healthcare professionals: Healthcare professionals (including doctors) were perceived to have inadequate knowledge about the concept and practice of patient safety. Developing clear guidelines, protocols and programs to train and educate healthcare professionals about patient safety before they entered practice was considered essential to improving patient safety.

Promoting communication and information systems: Promoting communication and patient safety information systems was seen as important to patient safety. For participants, patient safety could be advanced by improving teamwork and interpersonal relationships among healthcare professionals, and by instituting mechanisms to monitor patient safety.

Changing the attitudes and behaviours of healthcare professionals: Changing healthcare professionals' attitudes was considered critical to improving patient safety processes. Provision of education on patient safety in pre-service courses, and throughout employment, was considered essential to shaping the attitudes of and promoting respectful behaviour among healthcare professionals.

Table 3. Strategies to improve patient safety

Themes	**Participant statements**
Instituting governance for patient safety	"One thing is to constitute committees, especially relevant committees like clinical governance committees. […] […] We have to have regular updates, discussions […] Certain bodies like quality control, mortality committee and clinical governance are very important" (Medical doctor).
Development/improvement of physical infrastructure/ environment	"[…] the infrastructure should be such that it promotes smooth flow of patients. Patients should not get confused. They should not get lost in a health facility. […] the infrastructure should be in a normal condition, for example, the air flow, the exposure to sun should be good, so that we use minimum advance technologies like heating system, cooling system […]" (Senior Manager).

	"[…] we need some trolleys, the oxygen and everything should be there and IV stands. We have the elevator here but it is not always working. So the patient sometimes gets locked inside the elevator. We need good electricity" (Ward Manager).
Providing adequate resources	"To improve patient safety in district hospital like ours, I think the first and foremost things we should have is enough staff. We should have enough equipment" (Nurse).
Providing patient safety training and education for healthcare professionals	"I think first and foremost most of the health workers don't have the concept of patient safety. Even doctors we are trained in different countries" (Medical doctor).
Promoting communication and information systems	"There should be proper communication between patient and the visitors and patient themselves, and also among healthcare workers because often a time there is a lot of miscommunication. This could ultimately pose a threat to patient safety" (Nurse).
Changing the attitudes and behaviours of healthcare professionals	"First and foremost is the notion that keeping patient safety is not the responsibility of the managers or the leaders. Every individual should take each and every service or an activity in line with patient safety. […] Patient safety has to be on our mind all the time" (Medical doctor). "It is not easy to change the attitude of people but maybe through our education system or through the training centre curriculum from day one till they leave the institute might have

	a role in changing the attitude and providing better safety to patient" (Senior Manager).

Discussion

The Bhutanese government has prioritised improving the quality of its healthcare services. However, achieving the improvements desired is proving to be difficult. A key reason for this relates to the levels of complexity involved in providing high quality services, which cannot be addressed without a well-structured dedicated program of patient safety. Arguably, one of the most striking findings of this study is the lack of a program or infrastructure for capturing quantifiable and independently verifiable data on patient safety outcomes. Despite this, the study participants identified problems and patient safety outcomes that were commensurate with those identified in other countries. The mainstream patient safety issues and contributing factors (human and system factors) identified in this study were commensurate with those found in the UK [10], US [11], Australia [12 13], Latin America [14], Thailand [15] and India [16-18]. Participants identified medication errors, HAIs, surgical errors and post-operative complications, diagnostic errors, laboratory/blood errors, fall injuries, information/communication errors and patient identification errors as key patient safety concerns in the Bhutanese healthcare system. Factors contributing to these concerns were perceived to include the system (latent failures) as well as human (staff) factors (slips, lapses and violations). Further, the strategies recommended by participants in this study are comparable to those tried and tested in other countries [19-21]. Participants recommended: instituting clinical governance, developing/improving physical infrastructure (including equipment), providing adequate human resources, providing patient safety education to

healthcare professionals and patients, and promoting communication and information systems.

In light of the findings of this study, patient safety interventions in the Bhutanese healthcare system may need to be targeted at several points in the hierarchy, starting with policy development, and extending to assessment and management of risk, and the implementation of processes for reducing the incidence and impact of preventable adverse events. Specifically, patient safety improvement efforts need to focus on organisational factors. Addressing the organisational factors identified in this study would help to improve the overall healthcare system safety culture, which is now widely recognised in the patient safety literature as being critical to reducing the incidence and impact of preventable adverse events [22-24].

One of the key recommendation made by participants in this study was to institute governance for patient safety: instituting patient safety monitoring committees and developing clear patient safety guidance documents. As suggested by this finding, a highly visible and functional patient safety committee/program within Bhutan's Ministry of Health and guidance documents are needed, in conjunction with secure and adequate funding to make significant improvements in patient safety. Such a safety program needs to include clear goals for safety; defining safety and risk management systems (including developing tools for identifying and analysing adverse events, and evaluating approaches taken to solve issues). Literature suggests that the institution of patient safety committees (including the establishment of national patient safety foundations and in-hospital patient safety committees) and patient safety guidance documents are imperative to enhancing patient safety in healthcare [25-27]. The essential functions that patient safety committees can serve

include: overseeing patient safety programs, developing expertise and managing resources [28-30]. Development of clear patient safety guidance documents could improve patient safety in the Bhutanese healthcare system by establishing minimum levels of performance, maintaining consistency or uniformity across multiple individuals and organisations, setting expectations about what is to be achieved and fostering a shared set of beliefs, attitudes and norms, and prevent variation in clinical practice [25 27 31-36]. Most importantly, development of adjunct guidance documents by the Bhutan Ministry of Health (with explicit process maps and decision trees detailing what healthcare professionals should do during the course of patient care) would help change the attitudes and behaviours of healthcare professionals.

As suggested by the findings of this study, development and/or improvement of physical infrastructure/environment (including equipment), providing adequate human resources, providing patient safety education to healthcare professionals and patients, and promoting communication and information systems, are also fundamental to improving patient safety. Research suggests that there is a positive relationship between these components and patient safety. For example, the lack of and/or poorly organised physical infrastructure or environment can have a significant impact on patient safety – including, for example, cross infection and falls [20 37-42]. The higher the ratio of qualified healthcare professionals to patients the better the patient safety outcomes - lower rates of medication errors and wound infections [43-50]. Patient safety education and training programs have been shown to increase healthcare professionals' ability to analyze and solve patient safety problems [51 52]. Promoting communication and information systems such as information technology or decision support systems such as computerised physician order entry, which are designed to assist healthcare professionals in applying new information to patient care through the analysis of patient specific variables, are believed to improve communication on all levels [53-56]. For instance,

computerised devices like Personal Digital Assistant, which provide useful and accurate clinical practice guidelines and an alert system have been found to be more efficient than their paper-based counterparts [57].

On the basis of the findings of this study, and in keeping with the immediate priorities for national action on matters of patient safety, the cornerstone for a comprehensive strategy to improve patient safety in the Bhutanese healthcare system involves (1) a national focus on patient safety; (2) leadership, research, tools and protocols to enhance the knowledge base about safety; (3) patient safety governance; and (4) patient safety education and training. In addition, based on the findings of the study, development of a program to address specific patient safety issues is recommended. This includes addressing medication safety, HAIs, surgical errors, diagnostic errors, laboratory/blood products, identification errors, falls injuries, and information and communication errors (including verbal abuse).

Strengths and limitations

A key strength of this study is the contribution it makes to a deeper awareness and understanding of the patient safety issues and concerns in the cultural context of Bhutan. Analysis of the data revealed the issues and concerns identified were commensurate with those experienced in other resource poor countries including the challenges of successfully addressing them. The main limitation of the study reported here is its reliance on patient safety concepts, theories and practices that have been developed and applied in high-income resource-rich nations. This, however, is also a strength of the study, since one of its aims was to explore the 'fit' or otherwise of such a frame in under-resourced and data-poor nations, and to make meaningful comparisons. On the basis of the comparisons made, establishing a foundation for informing a locally adapted program to address patient safety problems/issues

identified in Bhutan has been rendered possible. A second limitation of the study relates to the large amount of data generated. As previously reported [author blinded], decisions about inclusion and exclusion of data were informed by the consistency of findings across the disparate participant groups and the themes and/or issues that were pertinent to informing the patient safety concerns in the healthcare context of Bhutan. In this process it is possible that some material may have been lost.

Conclusion

This study pioneers the exploration of patient safety issues and concerns in Bhutan's healthcare system. The study has identified medication errors, HAIs, surgical errors and post-operative complications, diagnostic errors, laboratory/blood errors, fall injuries, communication errors and patient identification errors as key patient safety concerns. Factors contributing to these concerns were identified to include system as well as human factors. The strategies recommended by participants indicate that a system to mitigate risks caused by both human and system factors is required to improve patient safety in Bhutan's healthcare system.

Overall, this study has provided a basis upon which future research and patient safety improvement strategies can be identified and developed. An immediate strategy, based on the findings of this study, would be to conceptualise and position patient safety as a priority for Bhutan's healthcare system and its leaders. Interventions need to target several points in the hierarchy, starting from policy development and extending to assessment and management of risk, and to reducing the incidence and impact of disruptive behaviours. Additionally, the provision of patient safety training and education for healthcare professionals and patients is required. These strategies would help improve overall safety by preventing adverse events.

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Conflict of interest

The authors declare that there is no conflict of interest

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The first author conceived the study. Both authors designed the study and developed the study protocol. RP collected and analysed the data. The second author supervised data collection and data analysis. Both authors prepared and approved this paper.

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Patient safety issues and concerns in Bhutan's healthcare system: a qualitative exploratory descriptive study

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Ethical approval: Ethical approvals were obtained from the Research Ethics Board of Health, Ministry of Health, Bhutan (REBH/Approval/2012/018) and the Deakin University Human Research Ethics Committee (DUHREC 2012-221) – *copies of approval letters can be provided on request*.

Patient safety issues and concerns in Bhutan's healthcare system: a qualitative exploratory descriptive study

Abstract

Objectives: To investigate what healthcare professionals perceived and experienced as key patient safety concerns in Bhutan's healthcare system.

Design: Qualitative exploratory descriptive inquiry.

Settings: Three different levels of hospitals, a training institute and the Ministry of Health, Bhutan.

Participants: In total, 140 healthcare professionals and managers.

Methods: Narrative data were collected via conversational in-depth interviews and Nominal Group Meetings. All data were subsequently analyzed using thematic analysis strategies.

Results: The data revealed that medication errors, healthcare associated infections, diagnostic errors, surgical errors and post-operative complications, laboratory/blood testing errors, falls, patient identification and communication errors, were perceived as common patient safety concerns. Human and system factors were identified as contributing to these concerns. Instituting clinical governance, developing and improving the physical infrastructure of hospitals, providing necessary human resources, ensuring staff receive patient safety education, and promoting 'good' communication and information systems were, in turn, all identified as processes and strategies critical to improving patient safety in the Bhutanese healthcare system.

Conclusion: Patient safety concerns described by participants in this study were commensurate with those identified in other low and middle-income countries. In order to redress these concerns, the findings of this study suggest that in the Bhutanese context patient safety needs to be conceptualised and prioritised.

Key words

Bhutan, patient safety, clinical governance, medical errors, quality assurance

Strengths and limitations of this study (summary)

- Creating a deeper awareness and understanding of the patient safety issues and concerns in the cultural context of Bhutan is the key strength of this study.
- The reliance on patient safety concepts, theories and practices that have been developed and applied in high-income resource-rich nations is the main limitation of this study.
- The large quantity of data generated required decisions about inclusion and exclusion of data, informed by consistency of the findings across the disparate participant groups, which may have resulted in the loss of some material.

Introduction

The World Health Organisation (WHO) has recognised patient safety as a global problem and positioned it as a worldwide endeavor, seeking to bring benefits to patients in countries rich and poor, developed and developing alike.[1] It is estimated that each year millions of patients worldwide suffer disabilities, injuries or death due to unsafe medical care, and that around 50% of these harmful outcomes are preventable.[2 3] The incidence and impact of preventable harmful events are particularly burdensome in developing and transitional-income countries.[2 3]

Despite patient safety being positioned by WHO as a global priority, improving patient safety outcomes in resource poor nations is challenging. One reason for this is a lack of reliable data to quantify the burden of unsafe patient care and, in turn, inform patient safety improvement

initiatives.[4] Another reason is that most current data on patient safety come from developed or high-income countries, where the healthcare contexts are different and where processes for improving patient safety outcomes cannot be readily transferred to other (less resourced) countries and their local healthcare settings.[5 6] Even so, it is estimated that rates of adverse events in low-income countries are higher than those of high-income countries. For example, the risk of healthcare associated infections in low-income countries is estimated to be 20 times higher than in high-income countries.[7] Similarly, research evidence suggests the prevalence of preventable surgical adverse event rates in low-income countries is five times more than in high-income countries.[8]

Most adverse events have been found to be associated with human (staff) factors and system (organisational) factors.[9-11] Human (staff) factors include slips, lapses, violations and mistakes made by healthcare professionals (such as nurse, physicians, surgeons, pharmacists, anaesthetists) due to aberrant mental processes such as inattention, forgetfulness, carelessness, negligence, recklessness, poor motivation and lack of competency (knowledge, skills and attitude).[12-17] In medical and nursing literature, competency is classified according to knowledge, skills and attitudes.[17-22] Knowledge relates to healthcare professionals' ability to recognise and understand the potential patient safety features and/or strategies (i.e., correctly prescribing medication - right drug, for the right reasons). Skills relate to healthcare professionals' ability to perform clinical tasks correctly to reduce risk of harm to patients (i.e., the correct preparation and administration of injections, the prevention of cross infection, accurately checking vital signs, and taking a full patient history). Finally, attitudes relate to healthcare professionals' ability to value the patient safety prevention strategies and follow them (i.e., value own role in preventing errors by following standard protocols). System (organisational) factors relate to the conditions under which individuals work and can

be used to build defences to avert errors or mitigate their effects.[13] System (organisational) factors include effective patient safety and clinical governance, financial resources, educational system and hospital design.

In Bhutan, patient safety issues and concerns are not well documented or known. To date there have been no published studies scoping either the nature or impact of patient safety concerns in Bhutan's healthcare system. Thus, at this time, as noted in the WHO *Global priorities for patient safety research*,[4] the main option for informing strategies aimed at improving patient safety in Bhutan is to scope stakeholders' perceptions and personal experiences of patient safety processes. It is anticipated that by undertaking preliminary scoping work a better understanding can be gained of the nature and extent of patient safety concerns in the Bhutanese context and what is required to redress these.

The aim of this study was to scope and describe what stakeholders (clinicians, health service managers, educators and policy makers) perceived and personally experienced as being the most common patient safety concerns in the Bhutanese healthcare system. The three research questions guiding the study were:

- What are healthcare professionals' and managers' knowledge, perceptions, understanding, and experiences of patient safety in Bhutan's hospitals?
- What factors do healthcare professionals and managers identify as most contributing to patient safety concerns in Bhutan's hospitals?
- What strategies do healthcare professionals and managers suggest are needed in order to address the patient safety issues and concerns they identified?

Methods

Study design

This study was undertaken as a naturalistic inquiry using a Qualitative Exploratory Descriptive (QED) research approach. The QED research approach assists researchers to gain an understanding of the real world context as it is experienced by the participants – i.e., what is working and what is not working.[23] The approach enables the researcher to obtain a detailed account of the problem of concern and capture meaningful characteristics related to real life events.[24] Most importantly, QED research is appropriate in situations where the problem is not known or the problem is too complex to be captured by other methods (e.g., questionnaire survey).[23] QED research is considered to be a highly pragmatic approach that enables the answering of concrete and practical 'what' kinds of question,[23 25] such as those addressed in this study.

Settings and participants

The study was conducted in 2013 in three levels of hospital (district, regional referral and national referral), a training institute and the Ministry of Health in Bhutan[26]. A sample of 94 participants (doctors, nurses, ward managers, senior managers and health assistants) was purposively recruited and interviewed. Additionally, 46 healthcare professionals participated in Nominal Group Meetings (NGMs) (Table 1).

Table 1. Demographic characteristics of participants

Participant group	***Characteristic***		
In-depth interview participants	***Gender***	***N (%)***	
	Male	56 (59.6%)	
	Female	38 (40.4%)	
	Age	***Years***	***Mean (yrs)***
	Minimum	23	36.7
	Maximum	60	
	Professional qualification	***N (%)***	
	Certificate	6 (6%)	
	Diploma	33 (35%)	
	Bachelor	23 (25%)	
	Master	32 (34%)	
	Length of service	***Years***	***Mean (yrs)***
	Minimum	0.5	12.7
	Maximum	29	
Nominal Group Meeting participants	***Gender***	***N (%)***	
	Male	24 (52%)	
	Female	22 (47.8%)	
	Age	***Years***	***Mean (yrs)***
	Minimum	24	35.6
	Maximum	50	
	Professional qualification	***N (%)***	
	Certificate	2 (4.34%)	
	Diploma	26 (56.5%)	
	Bachelor	9 (19.6%)	
	Master	9 (19.6%)	
	Length of service	***Years***	***Mean (yrs)***
	Minimum	0.5	10.2
	Maximum	22	

Patient and public involvement

As the aim of this study was to scope and describe what healthcare professionals perceived and personally experienced as being the most common patient safety concerns in the Bhutanese healthcare system no patients were involved in this study.

Data collection procedure

Data were collected via in-depth interviews (n=94) and NGMs (n=5). Participants for in-depth interviews were invited through direct contact, flyers posted on staff noticeboards and invitation letters sent to participating wards/institutes. They were interviewed individually using broad semi-structured interview questions to elicit knowledge, perceptions, and experiences of patient safety in Bhutan. Participants for NGMs were nominated by their managers and the NGMs were conducted in different groups according to criterion based characteristics such as doctors, nurses and managers. To facilitate smooth NGMs, a nominal group task statement form, which specified the exploratory questions, was used to list the critical elements of the patient safety issues. Duration of individual interviews and NGMs ranged from 45 to 120 minutes.

Approval was received from the Research Ethics Board of Health, Ministry of Health, Bhutan (REBH/Approval/2012/018) and organisational consent was obtained from the five research sites from which participants were recruited and other materials were retrieved. Ethics approval was also obtained from the Human Research Ethics Committee of Deakin University. All participants were informed about the nature and purpose of the study and provided verbal or written consent prior to interview or participation in a NGM.

Data analysis

Narrative data obtained from interviews and NGMs were analysed using the following steps: verbatim transcription of audio-recordings, active reading of transcripts, making notes on general themes, re-reading transcripts, comparing transcripts with key themes and concepts, making categories describing all aspects of the content, excluding unusable content or fillers, re-reading transcripts alongside the finally agreed list of categories, and making adjustments as necessary [27]. The data collected and analysed are reported and discussed in aggregate in this article - no additional data is available.

Results

This study revealed eight major patient safety concerns, possible factors contributing to them, and recommendations for strategies which could be used for addressing the concerns identified. The results are presented according to these areas.

Patient safety issues and concerns

Participants identified the following patient safety issues: medication/drug errors, healthcare associated infections, surgical errors and post-operative complications, diagnostic errors, laboratory/testing errors, injurious falls, communication errors, and patient identification errors (themes and supporting quotes are provided in Table 2).

Medication/drug errors: Medication error was the most common patient safety concern identified. Errors included administering wrong drugs to the wrong patient, administering drugs that had passed their expiry date, giving the wrong drug dose, continuation of drugs for unjustified periods of time, and drug omissions (failure to administer prescribed drugs). 'Irrational' use of drugs was also described, manifested as prescribing of: large quantities of

drugs; high drug doses that could not be justified or were outside recommended doses; and antibiotics to treat non-bacterial infections or viral conditions.

Healthcare Associated Infections (HAIs): Post-surgery wound infections and urinary tract infections (due to healthcare professionals not adhering to sterile technique during catheterisation) were the two main HAIs identified.

Surgical errors and post-operative complications: Notable among the surgical-related patient safety concerns were retention of foreign objects (e.g., gauze or instruments). In some instances, surgical errors resulted in mortality.

Diagnostic errors: Errors in diagnosis were perceived as common (e.g., wrongly diagnosing a patient as having tuberculosis, when they had cancer, and vice versa).

Laboratory/blood testing errors: Incompatible blood transfusion errors were reported. Common laboratory/blood testing errors included performing wrong or unnecessary blood investigations, and issuing wrong laboratory reports.

Fall injuries: This involves patients falling from beds and trolleys.

Communication errors: Communication errors, verbal abuse and/or rude behavior towards patients, and failure to communicate clearly to patients about their disease and treatment were identified.

Patient identification errors: The lack of a formal patient identification system was reported. This was considered particularly problematic since Bhutanese people often have the same or similar names. A major consequence of this was the risk and incidence of patients receiving the wrong treatment or procedure.

Table 2. Patient safety issues and concerns

Themes	**Participant statements**
Medication/drug errors	"I think the most common is errors in drug doses and medications. […] medication error includes errors in giving IV fluids like sometimes wrong IV fluids, wrong rate of administration – improper calculation of the drop rates" (Medical doctor). "[…] misuse of antibiotics – sometimes you continue antibiotics even for cough and cold where it is not required. They [doctors] use high dosage of different antibiotics for organisms that are not sensitive" (Medical doctor).
Healthcare Associated Infections (HAIs)	"Infection is definitely an issue. Previously where I used to work, […] in a small district hospital, usually patient with small surgery – minor surgery was getting post-surgery wound infection. Wound not healing faster" (Senior Manager). "We do come across hospital acquired infections – people especially with long term hospitalisation tend to get urinary tract infections. I don't know how people [healthcare providers] are handling the catheterisation process" (Medical doctor).

Surgical errors and post-operative complications	"We always hear from the operation theatre that some gauze pieces or some instrument has been left inside" (Nurse).
Diagnostic errors	"They [doctors] misdiagnose and then sometimes they give wrong medication which I have seen in one case that the patient really had adverse effect" (Nurse).
Laboratory/blood testing errors	"Sometimes there are few laboratory mistakes. I don't know whether it is the printing mistakes, sometimes we send two samples almost within 2 to 3 hours gap and the report come completely different. Maybe because staff are giving wrong sample for the other patient or is the printing mistake from the lab […]. We have cases like same patient having done the same investigations in few hours showed vast difference in the reading" (Nurse).
Fall injuries	"While patient is transferred in the trolley there was one incident where the patient went off the trolley. And then few times we have heard patient falling from the bed. So fall is common" (Ward Manager).
Communication errors	"Most of the time the misunderstanding that happens between the patient and the staff is due to lack of adequate communication. Many a times what we have done is for example probably not spend enough time on that part - explaining the diagnosis, where is the problem, what medicine you are prescribing, how you need to take that medicine, what are the side effects of the medicines, all these things, you know" (Senior Manager - NGM1).

	"I think one complaint we hear is that of verbal abuse by the health professionals to patients and their relatives" (Senior Manager).
Patient identification errors	"I think one pertinent one is for lack of patient identification marks. Our Bhutanese have similar names and then that can lead to, during procedures in rush hours, doing procedures in a wrong patient" (Medical doctor).

Factors contributing to patient safety concerns

Human (staff) and system factors were identified as the main contributing factors to patient safety concerns (themes and supporting quotes are presented in Table 3).

Human (staff) factors

Lack of patient safety competency: The most commonly cited factor contributing to patient safety concerns was healthcare professionals' lack of patient safety competencies, encompassing lack of knowledge of patient safety principles and processes, not having the necessary skills to practice safely, and not displaying the 'right' attitude.

Knowledge

Lack of knowledge about quality improvement and patient management processes was identified as a major contributing factor to patient safety concerns. Medication errors and HAIs were linked to healthcare professionals' lacking requisite knowledge about medicines/drugs and infection control.

Skills

Healthcare professionals' lack of patient assessment skills, for example, not checking vital signs, not taking a detailed patient history, or failure to review a patient's history, were perceived as contributing to errors such as wrong patient diagnoses and treatment.

Attitudes

The most prominent issue identified was a complacent attitude among healthcare professionals (e.g. taking 'shortcuts' and carelessness). Examples included healthcare professionals not applying knowledge, despite knowing about patient safety measures, and not apportioning sufficient importance to Standard Operating Protocols and guidelines.

System (organizational) factors

Lack of resources: All categories of participants reported that shortage of staff (poor skill mix and staff-patient ratio) was the key contributing factor to diagnostic and medication errors. Also perceived to contribute to patient safety concerns was the lack of infrastructure. This included: a lack of rooms to isolate patients with infectious diseases, to store clinical items (e.g., sterilised packs), and to carry out procedures without disruption and contamination; lack of basic materials and equipment for infection control such as disinfectants, soaps, and wound dressing supplies; dusty hospital surroundings; and absence of adequate systems to monitor hospital infection rates. Diagnostic errors were believed to be related to lack of adequate investigative resources (e.g., laboratory reagents) and lack of functional and reliable diagnostic equipment.

Lack of policies, guidelines and protocols on patient safety: As a consequence of the lack of policies, guidelines, standard protocols and checklists, there was perceived variation in the management of patients across different hospitals and/or wards, with treating specialists and nurses not agreeing on treatment matters.

Poor communication and collaboration: Healthcare professionals failing to communicate verbally and not clearly documenting patient care were reported to contribute to patient safety concerns. For example, continuation of medications for unreasonable periods of time was perceived to have resulted from poor communication between doctors and nurses. Lack of clear communication with and provision of information to patients about their disease and treatment was reported to lead to poor compliance with treatment.

Lack of teamwork and collaboration among hospital departments and clinicians were perceived to be particularly problematic. Internal conflicts and 'tribal fights' were reported, with stakeholders trying to blame and 'pull each other's legs' (which in Bhutan is taken to mean 'belittling'), disrupting workplace harmony, respect and cooperation. Participants described difficulty coordinating members of departments, due to lack of cooperation.

Lack of management support and governance: Some participants believed patient safety, as an agenda, had been overlooked by leaders and managers. Patient safety and risk management have not yet permeated into the Bhutanese healthcare system, and management was perceived as not yet ready to accept change.

Poorly developed patient safety incident reporting: Incident reporting processes were reportedly poorly developed. For instance, robust systems did not exist to record and report incidents and it was perceived that as a result the majority of incidents went unreported.

Lack of patient education on patient safety: Participants contended that patients are not educated about infection control and are not aware of how to take care of their own body secretions (sputum, urine and blood), increasing the risk of cross infection. In addition, healthcare professionals' failure to inform and educate patients and the public about certain hospital functions and procedures, such as where to go in the event of emergencies and signs and symptoms of emergencies, were perceived to have contributed to patient mortality.

Table 3. Factors contributing to patient safety concerns

Themes	**Participant statements**
Human (staff) factors	
Lack of patient safety competency:	
• Knowledge	"Sometimes the medication errors usually happen because they [staff] aren't aware of the right method to be given. For example, there are some medications like [name of drugs withheld] which are really painful and it should not be given direct bolus, but it should rather be given as infusion. […] It so happens that they are given bolus and then we have to be facing a problem and solving it" (Nurse - NGM5).
• Skills	"One issue is - usually the patients are seen in […] OPD [Out-patient Department] and they are sent here [to the ward]. So they [clinicians] did not monitor the vital signs and then we had some

	incidents. […] [one patient] did not have vital signs monitored and did not have [Blood Pressure checked] - actually the patient was 'walking dead'. Then we had to manage here in the ward and then ultimately send to ICU" (Ward Manager).
• Attitudes	"It is the attitude [of healthcare providers] sometimes" (Ward Manager). "If I have to say, I think certain procedures are done by people who are not very cautious about taking precautions. For example, as a medical student we knew that we have to take lots of precaution even to insert a catheter but now I see that it is being done very casually. I don't think people are really taking care of the proper sterile techniques and all" (Medical doctor).
System (organizational) factors	
Lack of resources	"Contribution for medication error maybe due to the shortage of nursing staff where while they are preparing the medicine, they have to go and attend the other critical cases, if any" (Senior Manager). "I think the most common patient safety issue is establishing diagnosis. I find it as a major issue because patients are not properly followed up and then adequate investigating facilities are not available and we lose patient in between" (Nurse).
Lack of policies, guidelines and	"One is the standard management of patient. That depends on individual specialists and individual doctors. A major crux of the

protocols on patient safety	thing is how to come to a proper diagnosis and what line of treatment. So, highly qualified specialists have their own line of management which some specialists don't agree" (Senior Manager).
Poor communication and collaboration	"When I talk about the patient safety one thing is that there is a gap in between doctors and nurses because they prescribe antibiotics and it goes more than 20 to 30 days. […] Doctors, when they prescribe the drugs in ward, most of the doctors they use [name of drugs withheld] which is a 3rd generation antibiotic and they do not write the specific days, like for this many days" (Nurse). "As of now we have a problem in getting all departments together to get a good care of the patient. For example, in the emergency we see lot of cases which need to be consulted with different departments – interdepartmental consultation. […] But at the moment it is very difficult to have an interdepartmental consultation" (Ward Manager).
Lack of management support and governance	"Patient safety in Bhutan, in my honest opinion, there isn't anything happening. We have some visiting professors and we have some health volunteers, they come in and they try to suggest and our staff, one or two maybe, try to take initiatives or people who have seen other hospital they think we need to do something. But it is ailing, because the system is not ready to accept anything. Right now, the health system is only considered about getting drugs and how many beds we can put and how many staff we can recruit but

	there is no check on how safe are the patients" (Nurse).
Poorly developed patient safety incident reporting	"I think that [incident reporting] is the weakest in the health system here. Keeping the data and then recording and reporting is very, very poor in the healthcare system- be it in National Referral Hospital or District Hospitals" (Medical doctor).
Lack of patient education on patient safety	"I think in the hospital settings when we talk about safety of the patient and the factors, basically patients were not educated on infection control so thereby they are not able to take care of their own secretions like sputum or urine or even blood. So that is one factor that we are likely to have infections" (Health Assistant).

Strategies to improve patient safety

Participants identified six strategies to improve patient safety: instituting governance for patient safety, development/improvement of physical infrastructure/environment, providing adequate resources, providing patient safety training and education, promoting communication and information systems, and changing the attitudes and behaviour of healthcare professionals (themes and supporting quotes are provided in Table 4).

Instituting governance for patient safety: Institution of patient safety governance was identified as an important strategy to improve patient safety processes and practices. Participants argued a hospital patient safety program with a committee structure (e.g., patient safety, mortality, and clinical governance committees) reporting to the Ministry of Health would advance patient safety. To reduce risk of harm to patients, participants recommended implementation of robust policies, guidelines and protocols.

Development/improvement of physical infrastructure/environment: Participants highlighted the importance to patient safety of safe physical infrastructure and a safe environment. Safe infrastructure was characterised as strong buildings with adequate 'space'; good navigation systems (e.g., signage); an inbuilt oxygen system, ramps, electric elevators, a ventilation system and good natural lighting. A safe environment was characterised as promoting physical safety, such as providing patients with an orientation on admission and maintaining cleanliness. The provision of equipment, such as wheel chairs and beds with side rails, was also deemed to be core elements of patient safety.

Providing adequate resources: Having adequate resources – including skilled and educated healthcare professionals, functional equipment and a constant supply of drugs – was considered critical to patient safety. Access to reliable laboratory facilities was considered necessary to facilitate correct patient diagnoses, treatment and management.

Providing patient safety training and education for healthcare professionals: Healthcare professionals (including doctors) were perceived to have inadequate knowledge about the concept and practice of patient safety. Developing clear guidelines, protocols and programs to

train and educate healthcare professionals about patient safety before they entered practice was considered essential to improving patient safety.

Promoting communication and information systems: Promoting communication and patient safety information systems was seen as important to patient safety. For participants, patient safety could be advanced by improving teamwork and interpersonal relationships among healthcare professionals, and by instituting mechanisms to monitor patient safety.

Changing the attitudes and behaviours of healthcare professionals: Changing healthcare professionals' attitudes was considered critical to improving patient safety processes. Provision of education on patient safety in pre-service courses, and throughout employment, was considered essential to shaping the attitudes of and promoting respectful behaviour among healthcare professionals.

Table 4. Strategies to improve patient safety

Themes	**Participant statements**
Instituting governance for patient safety	"One thing is to constitute committees, especially relevant committees like clinical governance committees. […] […] We have to have regular updates, discussions […] Certain bodies like quality control, mortality committee and clinical governance are very important" (Medical doctor).
Development/improvement of physical infrastructure/ environment	"[…] the infrastructure should be such that it promotes smooth flow of patients. Patients should not get confused. They should not get lost in a health facility. […] the infrastructure should be in a normal condition, for example, the air flow, the exposure to

	sun should be good, so that we use minimum advance technologies like heating system, cooling system […]" (Senior Manager). "[…] we need some trolleys, the oxygen and everything should be there and IV stands. We have the elevator here but it is not always working. So the patient sometimes gets locked inside the elevator. We need good electricity" (Ward Manager).
Providing adequate resources	"To improve patient safety in district hospital like ours, I think the first and foremost things we should have is enough staff. We should have enough equipment" (Nurse).
Providing patient safety training and education for healthcare professionals	"I think first and foremost most of the health workers don't have the concept of patient safety. Even doctors we are trained in different countries" (Medical doctor).
Promoting communication and information systems	"There should be proper communication between patient and the visitors and patient themselves, and also among healthcare workers because often a time there is a lot of miscommunication. This could ultimately pose a threat to patient safety" (Nurse).
Changing the attitudes and behaviours of healthcare professionals	"First and foremost is the notion that keeping patient safety is not the responsibility of the managers or the leaders. Every individual should take each and every service or an activity in line with patient safety. […] Patient safety has to be on our mind all the time" (Medical doctor).

	"It is not easy to change the attitude of people but maybe through our education system or through the training centre curriculum from day one till they leave the institute might have a role in changing the attitude and providing better safety to patient" (Senior Manager).

Discussion

The Bhutanese government has prioritised improving the quality of its healthcare services. However, achieving the improvements desired is proving to be difficult. A key reason for this relates to the levels of complexity involved in providing high quality services, which cannot be addressed without a well-structured dedicated program of patient safety. Arguably, one of the most striking findings of this study is the lack of a program or infrastructure for capturing quantifiable and independently verifiable data on patient safety outcomes. Despite this, the study participants identified problems and patient safety outcomes that were commensurate with those identified in other countries. The mainstream patient safety issues and contributing factors (human and system factors) identified in this study were commensurate with those found in the UK,[28] US,[29] Australia,[30] [31] Latin America,[32] Thailand[33] and India.[34-36] Participants identified medication errors, HAIs, surgical errors and post-operative complications, diagnostic errors, laboratory/blood errors, fall injuries, information/communication errors and patient identification errors as key patient safety concerns in the Bhutanese healthcare system. Factors contributing to these concerns were perceived to include the system (latent failures) as well as human (staff) factors (slips, lapses and violations). Further, the strategies recommended by participants in this study are comparable to those tried and tested in other countries.[37-39] Participants recommended:

instituting clinical governance, developing/improving physical infrastructure (including equipment), providing adequate human resources, providing patient safety education to healthcare professionals and patients, and promoting communication and information systems.

In light of the findings of this study, patient safety interventions in the Bhutanese healthcare system may need to be targeted at several points in the hierarchy, starting with policy development, and extending to assessment and management of risk, and the implementation of processes for reducing the incidence and impact of preventable adverse events. Specifically, patient safety improvement efforts need to focus on system/organisational factors. Addressing the system/organisational factors identified in this study would help to improve the overall healthcare system safety culture, which is now widely recognised in the patient safety literature as being critical to reducing the incidence and impact of preventable adverse events.[40-42]

One of the key recommendation made by participants in this study was to institute governance for patient safety: instituting patient safety monitoring committees and developing clear patient safety guidance documents. As suggested by this finding, a highly visible and functional patient safety committee/program within Bhutan's Ministry of Health and guidance documents are needed, in conjunction with secure and adequate funding to make significant improvements in patient safety. Such a safety program needs to include clear goals for safety; defining safety and risk management systems (including developing tools for identifying and analysing adverse events, and evaluating approaches taken to solve issues). Literature suggests that the institution of patient safety committees (including the establishment of national patient safety foundations and in-hospital patient safety

committees) and patient safety guidance documents are imperative to enhancing patient safety in healthcare.[43-45] The essential functions that patient safety committees can serve include: overseeing patient safety programs, developing expertise and managing resources.[46-48] Development of clear patient safety guidance documents could improve patient safety in the Bhutanese healthcare system by establishing minimum levels of performance, maintaining consistency or uniformity across multiple individuals and organisations, setting expectations about what is to be achieved and fostering a shared set of beliefs, attitudes and norms, and prevent variation in clinical practice.[43 45 49-54] Most importantly, development of adjunct guidance documents by the Bhutan Ministry of Health (with explicit process maps and decision trees detailing what healthcare professionals should do during the course of patient care) would help change the attitudes and behaviours of healthcare professionals.

As suggested by the findings of this study, development and/or improvement of physical infrastructure/environment (including equipment), providing adequate human resources, providing patient safety education to healthcare professionals and patients, and promoting communication and information systems, are also fundamental to improving patient safety. Research suggests that there is a positive relationship between these components and patient safety. For example, the lack of and/or poorly organised physical infrastructure or environment can have a significant impact on patient safety – including, for example, cross infection and falls.[38 55-60] The higher the ratio of qualified healthcare professionals to patients the better the patient safety outcomes - lower rates of medication errors and wound infections.[61-68] Patient safety education and training programs have been shown to increase healthcare professionals' ability to analyze and solve patient safety problems.[69 70] Promoting communication and information systems such as information technology or decision support systems such as computerised physician order entry, which are designed to assist healthcare

professionals in applying new information to patient care through the analysis of patient specific variables, are believed to improve communication on all levels.[71-74] For instance, computerised devices like Personal Digital Assistant, which provide useful and accurate clinical practice guidelines and an alert system have been found to be more efficient than their paper-based counterparts.[75]

On the basis of the findings of this study, and in keeping with the immediate priorities for national action on matters of patient safety, the cornerstone for a comprehensive strategy to improve patient safety in the Bhutanese healthcare system involves (1) a national focus on patient safety; (2) leadership, tools and protocols to enhance the knowledge base about safety; (3) patient safety governance; and (4) patient safety education and training.

National focus on patient safety

A national focus on patient safety entails setting national standards for patient safety; developing a strategic framework for patient safety; establishing a national patient safety program; instituting a national patient safety governance committee; establishing well trained and supported patient safety consultation teams (groups with specific responsibility for patient safety); and developing national policies on patient safety (service policy to establish resource allocation; practice policy that depicts minimum level of safety management and treatments; governance policy; sentinel event policy which provides clear guidance on appropriate responses to such situations; educational policy; and patient/staff abuse policy).

Leadership for patient safety

Leadership to promote patient safety involves launching patient safety initiatives in hospitals; allocating a budget for patient safety initiatives and ensuring they are adequately resourced;

initiating change management programs to build support for patient safety by the leaders of various health programs; developing research agendas (to understand the nature and extent of patient safety concerns; implement effective strategies to improve patient safety; and conduct research focused on teaching and learning of patient safety concerns and solutions); and establishing measures of performance (e.g., developing and disseminating tools for identifying and analysing patient safety concerns and evaluating correction measures).

Patient safety governance

Governance for patient safety requires development of a patient safety framework and policy; developing and implementing practice standards and guidelines for clinical practices and procedures; developing and implementing clinical bundles, pathways and protocols related to specific medical conditions and practices; developing and implementing checklists for different clinical practices, procedures and technologies/equipment; improving existing quality assurance processes; and developing clear job descriptions.

Patient safety training and education

Continuing patient safety training and education should be provided to all categories of healthcare staff (including cleaners and ward aides/assistants). This involves developing educational curricula on patient safety in institutes, universities and hospitals (for all categories of healthcare professionals undertaking certificate, diploma, higher degrees, and continuing medical education); developing and implementing standard protocols and guidelines for supervision and monitoring of students and junior clinicians; promoting dissemination of information on best practices; and providing healthcare professionals with training in risk management.

In addition, development of a program to identify and address specific patient safety issues is recommended. This includes addressing medication safety, surgical errors, diagnostic errors, laboratory/blood products, identification errors, HAIs and falls injuries by adopting six key methods of data collection and measurement, encompassing: patient outcome measurements (mortality and morbidity statistics); auditing of clinical practice, resource use and program activities; measurement of patient satisfaction; systematic reporting and monitoring of patient safety data; and patient safety research. These processes help in detecting and monitoring a broad range of medical errors and solutions.[50 76-79] Strategies to address specific patient safety issues include, for example, patient identification by bracelet, correct labelling of medicines, implementation of unit-dose systems for medications, policies for blood transfusion and implementation of guidelines and/or protocols for the prevention of wrong patient, wrong site and wrong surgical procedure.

Strengths and limitations

A key strength of this study is the contribution it makes to a deeper awareness and understanding of the patient safety issues and concerns in the cultural context of Bhutan. Analysis of the data revealed the issues and concerns identified were commensurate with those experienced in other resource poor countries including the challenges of successfully addressing them. The main limitation of the study reported here is its reliance on patient safety concepts, theories and practices that have been developed and applied in high-income resource-rich nations. This, however, is also a strength of the study, since one of its aims was to explore the 'fit' or otherwise of such a frame in under-resourced and data-poor nations, and to make meaningful comparisons. On the basis of the comparisons made, establishing a foundation for informing a locally adapted program to address patient safety problems/issues identified in Bhutan has been rendered possible. A second limitation of the study relates to

the large amount of data generated. As previously reported [26], decisions about inclusion and exclusion of data were informed by the consistency of findings across the disparate participant groups and the themes and/or issues that were pertinent to informing the patient safety concerns in the healthcare context of Bhutan. In this process it is possible that some material may have been lost.

Conclusion

This study pioneers the exploration of patient safety issues and concerns in Bhutan's healthcare system. The study has identified medication errors, HAIs, surgical errors and post-operative complications, diagnostic errors, laboratory/blood errors, fall injuries, communication errors and patient identification errors as key patient safety concerns. Factors contributing to these concerns were identified to include system as well as human factors. The strategies recommended by participants indicate that a system to mitigate risks caused by both human and system factors is required to improve patient safety in Bhutan's healthcare system.

Overall, this study has provided a basis upon which future research and patient safety improvement strategies can be identified and developed. An immediate strategy, based on the findings of this study, would be to conceptualise and position patient safety as a priority for Bhutan's healthcare system and its leaders. Interventions need to target several points in the hierarchy, starting from policy development and extending to assessment and management of risk, and to reducing the incidence and impact of disruptive behaviours. Additionally, the provision of patient safety training and education for healthcare professionals and patients is required. These strategies would help improve overall safety by preventing adverse events.

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Conflict of interest

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Authors' contribution:

The first author conceived the study. Both authors designed the study and developed the study protocol. RP collected and analysed the data. The second author supervised data collection and data analysis. Both authors prepared and approved this paper.

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Patient safety issues and concerns in Bhutan's healthcare system: a qualitative exploratory descriptive study

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Patient safety issues and concerns in Bhutan's healthcare system: a qualitative exploratory descriptive study

Abstract

Objectives: To investigate what healthcare professionals perceived and experienced as key patient safety concerns in Bhutan's healthcare system.

Design: Qualitative exploratory descriptive inquiry.

Settings: Three different levels of hospitals, a training institute and the Ministry of Health, Bhutan.

Participants: In total, 140 healthcare professionals and managers.

Methods: Narrative data were collected via conversational in-depth interviews and Nominal Group Meetings. All data were subsequently analyzed using thematic analysis strategies.

Results: The data revealed that medication errors, healthcare associated infections, diagnostic errors, surgical errors and post-operative complications, laboratory/blood testing errors, falls, patient identification and communication errors, were perceived as common patient safety concerns. Human and system factors were identified as contributing to these concerns. Instituting clinical governance, developing and improving the physical infrastructure of hospitals, providing necessary human resources, ensuring staff receive patient safety education, and promoting 'good' communication and information systems were, in turn, all identified as processes and strategies critical to improving patient safety in the Bhutanese healthcare system.

Conclusion: Patient safety concerns described by participants in this study were commensurate with those identified in other low and middle-income countries. In order to redress these concerns, the findings of this study suggest that in the Bhutanese context patient safety needs to be conceptualised and prioritised.

Key words

Bhutan, patient safety, clinical governance, medical errors, quality assurance

Strengths and limitations of this study (summary)

- A strength of this study is the qualitative exploratory descriptive approach used, a pragmatic approach which enabled capture of participants' experiences of the real world context.
- The detailed account of the problem and the capture of meaningful characteristics related to real life events is a strength of the study.
- A further strength of the study is the inclusion of health professionals from a range of disciplinary backgrounds across three levels of hospitals.
- Reliance on patient safety concepts, theories and practices that have been developed and applied in high-income resource-rich nations is the main limitation of this study.
- The large quantity of data generated required decisions about inclusion and exclusion of data, which may have resulted in the loss of some material.

Introduction

The World Health Organisation (WHO) has recognised patient safety as a global problem and positioned it as a worldwide endeavor, seeking to bring benefits to patients in countries rich and poor, developed and developing alike.[1] It is estimated that each year millions of patients worldwide suffer disabilities, injuries or death due to unsafe medical care, and that around 50% of these harmful outcomes are preventable.[2 3] The incidence and impact of preventable harmful events are particularly burdensome in developing and transitional-income countries.[2 3]

Despite patient safety being positioned by WHO as a global priority, improving patient safety outcomes in resource poor nations is challenging. One reason for this is a lack of reliable data to quantify the burden of unsafe patient care and, in turn, inform patient safety improvement initiatives.[4] Another reason is that most current data on patient safety come from developed or high-income countries, where the healthcare contexts are different and where processes for improving patient safety outcomes cannot be readily transferred to other (less resourced) countries and their local healthcare settings.[5 6] Even so, it is estimated that rates of adverse events in low-income countries are higher than those of high-income countries. For example, the risk of healthcare associated infections in low-income countries is estimated to be 20 times higher than in high-income countries.[7] Similarly, research evidence suggests the prevalence of preventable surgical adverse event rates in low-income countries is five times more than in high-income countries.[8]

Most adverse events have been found to be associated with human (staff) factors and system (organisational) factors.[9-11] Human (staff) factors include slips, lapses, violations and mistakes made by healthcare professionals (such as nurse, physicians, surgeons, pharmacists, anaesthetists) due to aberrant mental processes such as inattention, forgetfulness, carelessness, negligence, recklessness, poor motivation and lack of competency (knowledge, skills and attitude).[12-17] In medical and nursing literature, competency is classified according to knowledge, skills and attitudes.[17-22] Knowledge relates to healthcare professionals' ability to recognise and understand the potential patient safety features and/or strategies (i.e., correctly prescribing medication - right drug, for the right reasons). Skills relate to healthcare professionals' ability to perform clinical tasks correctly to reduce risk of harm to patients (i.e., the correct preparation and administration of injections, the prevention of cross infection, accurately checking vital signs, and taking a full patient history). Finally, attitudes

relate to healthcare professionals' ability to value the patient safety prevention strategies and follow them (i.e., value own role in preventing errors by following standard protocols). System (organisational) factors relate to the conditions under which individuals work and can be used to build defences to avert errors or mitigate their effects.[13] System (organisational) factors include effective patient safety and clinical governance, financial resources, educational system and hospital design.

In Bhutan, patient safety issues and concerns are not well documented or known. To date there have been no published studies scoping either the nature or impact of patient safety concerns in Bhutan's healthcare system. Thus, at this time, as noted in the WHO *Global priorities for patient safety research*,[4] the main option for informing strategies aimed at improving patient safety in Bhutan is to scope stakeholders' perceptions and personal experiences of patient safety processes. It is anticipated that by undertaking preliminary scoping work a better understanding can be gained of the nature and extent of patient safety concerns in the Bhutanese context and what is required to redress these.

The aim of this study was to scope and describe what stakeholders (clinicians, health service managers, educators and policy makers) perceived and personally experienced as being the most common patient safety concerns in the Bhutanese healthcare system. The three research questions guiding the study were:

- What are healthcare professionals' and managers' knowledge, perceptions, understanding, and experiences of patient safety in Bhutan's hospitals?
- What factors do healthcare professionals and managers identify as most contributing to patient safety concerns in Bhutan's hospitals?

- What strategies do healthcare professionals and managers suggest are needed in order to address the patient safety issues and concerns they identified?

Methods

Study design

This study was undertaken as a naturalistic inquiry using a Qualitative Exploratory Descriptive (QED) research approach. The QED research approach assists researchers to gain an understanding of the real world context as it is experienced by the participants – i.e., what is working and what is not working.[23] The approach enables the researcher to obtain a detailed account of the problem of concern and capture meaningful characteristics related to real life events.[24] Most importantly, QED research is appropriate in situations where the problem is not known or the problem is too complex to be captured by other methods (e.g., questionnaire survey).[23] QED research is considered to be a highly pragmatic approach that enables the answering of concrete and practical 'what' kinds of question,[23 25] such as those addressed in this study.

Settings and participants

The study was conducted in 2013 in three levels of hospital (district, regional referral and national referral), a training institute and the Ministry of Health in Bhutan[26]. A sample of 94 participants (doctors, nurses, ward managers, senior managers and health assistants) was purposively recruited and interviewed. Additionally, 46 healthcare professionals participated in Nominal Group Meetings (NGMs) (Table 1).

Table 1. Demographic characteristics of participants

Participant group	*Characteristic*		
In-depth interview participants	***Gender***	***N (%)***	
	Male	56 (59.6%)	
	Female	38 (40.4%)	
	Age	***Years***	***Mean (yrs)***
	Minimum	23	36.7
	Maximum	60	
	Professional qualification	***N (%)***	
	Certificate	6 (6%)	
	Diploma	33 (35%)	
	Bachelor	23 (25%)	
	Master	32 (34%)	
	Length of service	***Years***	***Mean (yrs)***
	Minimum	0.5	12.7
	Maximum	29	
Nominal Group Meeting participants	***Gender***	***N (%)***	
	Male	24 (52%)	
	Female	22 (47.8%)	
	Age	***Years***	***Mean (yrs)***
	Minimum	24	35.6
	Maximum	50	
	Professional qualification	***N (%)***	
	Certificate	2 (4.34%)	
	Diploma	26 (56.5%)	
	Bachelor	9 (19.6%)	
	Master	9 (19.6%)	
	Length of service	***Years***	***Mean (yrs)***
	Minimum	0.5	10.2
	Maximum	22	

Patient and public involvement

As the aim of this study was to scope and describe what healthcare professionals perceived and personally experienced as being the most common patient safety concerns in the Bhutanese healthcare system no patients were involved in this study.

Data collection procedure

Data were collected via in-depth interviews (n=94) and NGMs (n=5). Participants for in-depth interviews were invited through direct contact, flyers posted on staff noticeboards and invitation letters sent to participating wards/institutes. They were interviewed individually using broad semi-structured interview questions to elicit knowledge, perceptions, and experiences of patient safety in Bhutan. Participants for NGMs were nominated by their managers and the NGMs were conducted in different groups according to criterion based characteristics such as doctors, nurses and managers. To facilitate smooth NGMs, a nominal group task statement form, which specified the exploratory questions, was used to list the critical elements of the patient safety issues. Duration of individual interviews and NGMs ranged from 45 to 120 minutes.

Approval was received from the Research Ethics Board of Health, Ministry of Health, Bhutan (REBH/Approval/2012/018) and organisational consent was obtained from the five research sites from which participants were recruited and other materials were retrieved. Ethics approval was also obtained from the Human Research Ethics Committee of Deakin University. All participants were informed about the nature and purpose of the study and provided verbal or written consent prior to interview or participation in a NGM.

Data analysis

Narrative data obtained from interviews and NGMs were analysed using the following steps: verbatim transcription of audio-recordings, active reading of transcripts, making notes on general themes, re-reading transcripts, comparing transcripts with key themes and concepts, making categories describing all aspects of the content, excluding unusable content or fillers, re-reading transcripts alongside the finally agreed list of categories, and making adjustments as necessary [27]. The data collected and analysed are reported and discussed in aggregate in this article - no additional data is available.

Results

This study revealed eight major patient safety concerns, possible factors contributing to them, and recommendations for strategies which could be used for addressing the concerns identified. The results are presented according to these areas.

Patient safety issues and concerns

Participants identified the following patient safety issues: medication/drug errors, healthcare associated infections, surgical errors and post-operative complications, diagnostic errors, laboratory/testing errors, injurious falls, communication errors, and patient identification errors (themes and supporting quotes are provided in Table 2).

Medication/drug errors: Medication error was the most common patient safety concern identified. Errors included administering wrong drugs to the wrong patient, administering drugs that had passed their expiry date, giving the wrong drug dose, continuation of drugs for unjustified periods of time, and drug omissions (failure to administer prescribed drugs). 'Irrational' use of drugs was also described, manifested as prescribing of: large quantities of

drugs; high drug doses that could not be justified or were outside recommended doses; and antibiotics to treat non-bacterial infections or viral conditions.

Healthcare Associated Infections (HAIs): Post-surgery wound infections and urinary tract infections (due to healthcare professionals not adhering to sterile technique during catheterisation) were the two main HAIs identified.

Surgical errors and post-operative complications: Notable among the surgical-related patient safety concerns were retention of foreign objects (e.g., gauze or instruments). In some instances, surgical errors resulted in mortality.

Diagnostic errors: Errors in diagnosis were perceived as common (e.g., wrongly diagnosing a patient as having tuberculosis, when they had cancer, and vice versa).

Laboratory/blood testing errors: Incompatible blood transfusion errors were reported. Common laboratory/blood testing errors included performing wrong or unnecessary blood investigations, and issuing wrong laboratory reports.

Fall injuries: This involves patients falling from beds and trolleys.

Communication errors: Communication errors, verbal abuse and/or rude behavior towards patients, and failure to communicate clearly to patients about their disease and treatment were identified.

Patient identification errors: The lack of a formal patient identification system was reported. This was considered particularly problematic since Bhutanese people often have the same or similar names. A major consequence of this was the risk and incidence of patients receiving the wrong treatment or procedure.

Table 2. Patient safety issues and concerns

Themes	**Participant statements**
Medication/drug errors	"I think the most common is errors in drug doses and medications. […] medication error includes errors in giving IV fluids like sometimes wrong IV fluids, wrong rate of administration – improper calculation of the drop rates" (Medical doctor). "[…] misuse of antibiotics – sometimes you continue antibiotics even for cough and cold where it is not required. They [doctors] use high dosage of different antibiotics for organisms that are not sensitive" (Medical doctor).
Healthcare Associated Infections (HAIs)	"Infection is definitely an issue. Previously where I used to work, […] in a small district hospital, usually patient with small surgery – minor surgery was getting post-surgery wound infection. Wound not healing faster" (Senior Manager). "We do come across hospital acquired infections – people especially with long term hospitalisation tend to get urinary tract infections. I don't know how people [healthcare providers] are handling the catheterisation process" (Medical doctor).

Surgical errors and post-operative complications	"We always hear from the operation theatre that some gauze pieces or some instrument has been left inside" (Nurse).
Diagnostic errors	"They [doctors] misdiagnose and then sometimes they give wrong medication which I have seen in one case that the patient really had adverse effect" (Nurse).
Laboratory/blood testing errors	"Sometimes there are few laboratory mistakes. I don't know whether it is the printing mistakes, sometimes we send two samples almost within 2 to 3 hours gap and the report come completely different. Maybe because staff are giving wrong sample for the other patient or is the printing mistake from the lab […]. We have cases like same patient having done the same investigations in few hours showed vast difference in the reading" (Nurse).
Fall injuries	"While patient is transferred in the trolley there was one incident where the patient went off the trolley. And then few times we have heard patient falling from the bed. So fall is common" (Ward Manager).
Communication errors	"Most of the time the misunderstanding that happens between the patient and the staff is due to lack of adequate communication. Many a times what we have done is for example probably not spend enough time on that part - explaining the diagnosis, where is the problem, what medicine you are prescribing, how you need to take that medicine, what are the side effects of the medicines, all these things, you know" (Senior Manager - NGM1).

	"I think one complaint we hear is that of verbal abuse by the health professionals to patients and their relatives" (Senior Manager).
Patient identification errors	"I think one pertinent one is for lack of patient identification marks. Our Bhutanese have similar names and then that can lead to, during procedures in rush hours, doing procedures in a wrong patient" (Medical doctor).

Factors contributing to patient safety concerns

Human (staff) and system factors were identified as the main contributing factors to patient safety concerns (themes and supporting quotes are presented in Table 3).

Human (staff) factors

Lack of patient safety competency: The most commonly cited factor contributing to patient safety concerns was healthcare professionals' lack of patient safety competencies, encompassing lack of knowledge of patient safety principles and processes, not having the necessary skills to practice safely, and not displaying the 'right' attitude.

Knowledge

Lack of knowledge about quality improvement and patient management processes was identified as a major contributing factor to patient safety concerns. Medication errors and HAIs were linked to healthcare professionals' lacking requisite knowledge about medicines/drugs and infection control.

Skills

Healthcare professionals' lack of patient assessment skills, for example, not checking vital signs, not taking a detailed patient history, or failure to review a patient's history, were perceived as contributing to errors such as wrong patient diagnoses and treatment.

Attitudes

The most prominent issue identified was a complacent attitude among healthcare professionals (e.g. taking 'shortcuts' and carelessness). Examples included healthcare professionals not applying knowledge, despite knowing about patient safety measures, and not apportioning sufficient importance to Standard Operating Protocols and guidelines.

System (organizational) factors

Lack of resources: All categories of participants reported that shortage of staff (poor skill mix and staff-patient ratio) was the key contributing factor to diagnostic and medication errors. Also perceived to contribute to patient safety concerns was the lack of infrastructure. This included: a lack of rooms to isolate patients with infectious diseases, to store clinical items (e.g., sterilised packs), and to carry out procedures without disruption and contamination; lack of basic materials and equipment for infection control such as disinfectants, soaps, and wound dressing supplies; dusty hospital surroundings; and absence of adequate systems to monitor hospital infection rates. Diagnostic errors were believed to be related to lack of adequate investigative resources (e.g., laboratory reagents) and lack of functional and reliable diagnostic equipment.

Lack of policies, guidelines and protocols on patient safety: As a consequence of the lack of policies, guidelines, standard protocols and checklists, there was perceived variation in the management of patients across different hospitals and/or wards, with treating specialists and nurses not agreeing on treatment matters.

Poor communication and collaboration: Healthcare professionals failing to communicate verbally and not clearly documenting patient care were reported to contribute to patient safety concerns. For example, continuation of medications for unreasonable periods of time was perceived to have resulted from poor communication between doctors and nurses. Lack of clear communication with and provision of information to patients about their disease and treatment was reported to lead to poor compliance with treatment.

Lack of teamwork and collaboration among hospital departments and clinicians were perceived to be particularly problematic. Internal conflicts and 'tribal fights' were reported, with stakeholders trying to blame and 'pull each other's legs' (which in Bhutan is taken to mean 'belittling'), disrupting workplace harmony, respect and cooperation. Participants described difficulty coordinating members of departments, due to lack of cooperation.

Lack of management support and governance: Some participants believed patient safety, as an agenda, had been overlooked by leaders and managers. Patient safety and risk management have not yet permeated into the Bhutanese healthcare system, and management was perceived as not yet ready to accept change.

Poorly developed patient safety incident reporting: Incident reporting processes were reportedly poorly developed. For instance, robust systems did not exist to record and report incidents and it was perceived that as a result the majority of incidents went unreported.

Lack of patient education on patient safety: Participants contended that patients are not educated about infection control and are not aware of how to take care of their own body secretions (sputum, urine and blood), increasing the risk of cross infection. In addition, healthcare professionals' failure to inform and educate patients and the public about certain hospital functions and procedures, such as where to go in the event of emergencies and signs and symptoms of emergencies, were perceived to have contributed to patient mortality.

Table 3. Factors contributing to patient safety concerns

Themes	**Participant statements**
Human (staff) factors	
Lack of patient safety competency:	
• Knowledge	"Sometimes the medication errors usually happen because they [staff] aren't aware of the right method to be given. For example, there are some medications like [name of drugs withheld] which are really painful and it should not be given direct bolus, but it should rather be given as infusion. […] It so happens that they are given bolus and then we have to be facing a problem and solving it" (Nurse - NGM5).
• Skills	"One issue is - usually the patients are seen in […] OPD [Out-patient Department] and they are sent here [to the ward]. So they [clinicians] did not monitor the vital signs and then we had some

	incidents. […] [one patient] did not have vital signs monitored and did not have [Blood Pressure checked] - actually the patient was 'walking dead'. Then we had to manage here in the ward and then ultimately send to ICU" (Ward Manager).
• Attitudes	"It is the attitude [of healthcare providers] sometimes" (Ward Manager). "If I have to say, I think certain procedures are done by people who are not very cautious about taking precautions. For example, as a medical student we knew that we have to take lots of precaution even to insert a catheter but now I see that it is being done very casually. I don't think people are really taking care of the proper sterile techniques and all" (Medical doctor).
System (organizational) factors	
Lack of resources	"Contribution for medication error maybe due to the shortage of nursing staff where while they are preparing the medicine, they have to go and attend the other critical cases, if any" (Senior Manager). "I think the most common patient safety issue is establishing diagnosis. I find it as a major issue because patients are not properly followed up and then adequate investigating facilities are not available and we lose patient in between" (Nurse).
Lack of policies, guidelines and	"One is the standard management of patient. That depends on individual specialists and individual doctors. A major crux of the

protocols on patient safety	thing is how to come to a proper diagnosis and what line of treatment. So, highly qualified specialists have their own line of management which some specialists don't agree" (Senior Manager).
Poor communication and collaboration	"When I talk about the patient safety one thing is that there is a gap in between doctors and nurses because they prescribe antibiotics and it goes more than 20 to 30 days. […] Doctors, when they prescribe the drugs in ward, most of the doctors they use [name of drugs withheld] which is a 3rd generation antibiotic and they do not write the specific days, like for this many days" (Nurse). "As of now we have a problem in getting all departments together to get a good care of the patient. For example, in the emergency we see lot of cases which need to be consulted with different departments – interdepartmental consultation. […] But at the moment it is very difficult to have an interdepartmental consultation" (Ward Manager).
Lack of management support and governance	"Patient safety in Bhutan, in my honest opinion, there isn't anything happening. We have some visiting professors and we have some health volunteers, they come in and they try to suggest and our staff, one or two maybe, try to take initiatives or people who have seen other hospital they think we need to do something. But it is ailing, because the system is not ready to accept anything. Right now, the health system is only considered about getting drugs and how many beds we can put and how many staff we can recruit but

	there is no check on how safe are the patients" (Nurse).
Poorly developed patient safety incident reporting	"I think that [incident reporting] is the weakest in the health system here. Keeping the data and then recording and reporting is very, very poor in the healthcare system- be it in National Referral Hospital or District Hospitals" (Medical doctor).
Lack of patient education on patient safety	"I think in the hospital settings when we talk about safety of the patient and the factors, basically patients were not educated on infection control so thereby they are not able to take care of their own secretions like sputum or urine or even blood. So that is one factor that we are likely to have infections" (Health Assistant).

Strategies to improve patient safety

Participants identified six strategies to improve patient safety: instituting governance for patient safety, development/improvement of physical infrastructure/environment, providing adequate resources, providing patient safety training and education, promoting communication and information systems, and changing the attitudes and behaviour of healthcare professionals (themes and supporting quotes are provided in Table 4).

Instituting governance for patient safety: Institution of patient safety governance was identified as an important strategy to improve patient safety processes and practices. Participants argued a hospital patient safety program with a committee structure (e.g., patient safety, mortality, and clinical governance committees) reporting to the Ministry of Health would advance patient safety. To reduce risk of harm to patients, participants recommended implementation of robust policies, guidelines and protocols.

Development/improvement of physical infrastructure/environment: Participants highlighted the importance to patient safety of safe physical infrastructure and a safe environment. Safe infrastructure was characterised as strong buildings with adequate 'space'; good navigation systems (e.g., signage); an inbuilt oxygen system, ramps, electric elevators, a ventilation system and good natural lighting. A safe environment was characterised as promoting physical safety, such as providing patients with an orientation on admission and maintaining cleanliness. The provision of equipment, such as wheel chairs and beds with side rails, was also deemed to be core elements of patient safety.

Providing adequate resources: Having adequate resources – including skilled and educated healthcare professionals, functional equipment and a constant supply of drugs – was considered critical to patient safety. Access to reliable laboratory facilities was considered necessary to facilitate correct patient diagnoses, treatment and management.

Providing patient safety training and education for healthcare professionals: Healthcare professionals (including doctors) were perceived to have inadequate knowledge about the concept and practice of patient safety. Developing clear guidelines, protocols and programs to train and educate healthcare professionals about patient safety before they entered practice was considered essential to improving patient safety.

Promoting communication and information systems: Promoting communication and patient safety information systems was seen as important to patient safety. For participants, patient safety could be advanced by improving teamwork and interpersonal relationships among healthcare professionals, and by instituting mechanisms to monitor patient safety.

Changing the attitudes and behaviours of healthcare professionals: Changing healthcare professionals' attitudes was considered critical to improving patient safety processes. Provision of education on patient safety in pre-service courses, and throughout employment, was considered essential to shaping the attitudes of and promoting respectful behaviour among healthcare professionals.

Table 4. Strategies to improve patient safety

Themes	**Participant statements**
Instituting governance for patient safety	"One thing is to constitute committees, especially relevant committees like clinical governance committees. […] […] We have to have regular updates, discussions […] Certain bodies like quality control, mortality committee and clinical governance are very important" (Medical doctor).
Development/improvement of physical infrastructure/ environment	"[…] the infrastructure should be such that it promotes smooth flow of patients. Patients should not get confused. They should not get lost in a health facility. […] the infrastructure should be in a normal condition, for example, the air flow, the exposure to sun should be good, so that we use minimum advance technologies like heating system, cooling system […]" (Senior Manager). "[…] we need some trolleys, the oxygen and everything should be there and IV stands. We have the elevator here but it is not always working. So the patient sometimes gets locked inside

	the elevator. We need good electricity" (Ward Manager).
Providing adequate resources	"To improve patient safety in district hospital like ours, I think the first and foremost things we should have is enough staff. We should have enough equipment" (Nurse).
Providing patient safety training and education for healthcare professionals	"I think first and foremost most of the health workers don't have the concept of patient safety. Even doctors we are trained in different countries" (Medical doctor).
Promoting communication and information systems	"There should be proper communication between patient and the visitors and patient themselves, and also among healthcare workers because often a time there is a lot of miscommunication. This could ultimately pose a threat to patient safety" (Nurse).
Changing the attitudes and behaviours of healthcare professionals	"First and foremost is the notion that keeping patient safety is not the responsibility of the managers or the leaders. Every individual should take each and every service or an activity in line with patient safety. […] Patient safety has to be on our mind all the time" (Medical doctor). "It is not easy to change the attitude of people but maybe through our education system or through the training centre curriculum from day one till they leave the institute might have a role in changing the attitude and providing better safety to patient" (Senior Manager).

Discussion

The Bhutanese government has prioritised improving the quality of its healthcare services. However, achieving the improvements desired is proving to be difficult. A key reason for this relates to the levels of complexity involved in providing high quality services, which cannot be addressed without a well-structured dedicated program of patient safety. Arguably, one of the most striking findings of this study is the lack of a program or infrastructure for capturing quantifiable and independently verifiable data on patient safety outcomes. Despite this, the study participants identified problems and patient safety outcomes that were commensurate with those identified in other countries. The mainstream patient safety issues and contributing factors (human and system factors) identified in this study were commensurate with those found in the UK,[28] US,[29] Australia,[30] [31] Latin America,[32] Thailand[33] and India.[34-36] Participants identified medication errors, HAIs, surgical errors and post-operative complications, diagnostic errors, laboratory/blood errors, fall injuries, information/communication errors and patient identification errors as key patient safety concerns in the Bhutanese healthcare system. Factors contributing to these concerns were perceived to include the system (latent failures) as well as human (staff) factors (slips, lapses and violations). Further, the strategies recommended by participants in this study are comparable to those tried and tested in other countries.[37-39] Participants recommended: instituting clinical governance, developing/improving physical infrastructure (including equipment), providing adequate human resources, providing patient safety education to healthcare professionals and patients, and promoting communication and information systems.

In light of the findings of this study, patient safety interventions in the Bhutanese healthcare system may need to be targeted at several points in the hierarchy, starting with policy

development, and extending to assessment and management of risk, and the implementation of processes for reducing the incidence and impact of preventable adverse events. Specifically, patient safety improvement efforts need to focus on system/organisational factors. Addressing the system/organisational factors identified in this study would help to improve the overall healthcare system safety culture, which is now widely recognised in the patient safety literature as being critical to reducing the incidence and impact of preventable adverse events.[40-42]

One of the key recommendation made by participants in this study was to institute governance for patient safety: instituting patient safety monitoring committees and developing clear patient safety guidance documents. As suggested by this finding, a highly visible and functional patient safety committee/program within Bhutan's Ministry of Health and guidance documents are needed, in conjunction with secure and adequate funding to make significant improvements in patient safety. Such a safety program needs to include clear goals for safety; defining safety and risk management systems (including developing tools for identifying and analysing adverse events, and evaluating approaches taken to solve issues). Literature suggests that the institution of patient safety committees (including the establishment of national patient safety foundations and in-hospital patient safety committees) and patient safety guidance documents are imperative to enhancing patient safety in healthcare.[43-45] The essential functions that patient safety committees can serve include: overseeing patient safety programs, developing expertise and managing resources.[46-48] Development of clear patient safety guidance documents could improve patient safety in the Bhutanese healthcare system by establishing minimum levels of performance, maintaining consistency or uniformity across multiple individuals and organisations, setting expectations about what is to be achieved and fostering a shared set of beliefs, attitudes and

norms, and prevent variation in clinical practice.[43 45 49-54] Most importantly, development of adjunct guidance documents by the Bhutan Ministry of Health (with explicit process maps and decision trees detailing what healthcare professionals should do during the course of patient care) would help change the attitudes and behaviours of healthcare professionals.

As suggested by the findings of this study, development and/or improvement of physical infrastructure/environment (including equipment), providing adequate human resources, providing patient safety education to healthcare professionals and patients, and promoting communication and information systems, are also fundamental to improving patient safety. Research suggests that there is a positive relationship between these components and patient safety. For example, the lack of and/or poorly organised physical infrastructure or environment can have a significant impact on patient safety – including, for example, cross infection and falls.[38 55-60] The higher the ratio of qualified healthcare professionals to patients the better the patient safety outcomes - lower rates of medication errors and wound infections.[61-68] Patient safety education and training programs have been shown to increase healthcare professionals' ability to analyze and solve patient safety problems.[69 70] Promoting communication and information systems such as information technology or decision support systems such as computerised physician order entry, which are designed to assist healthcare professionals in applying new information to patient care through the analysis of patient specific variables, are believed to improve communication on all levels.[71-74] For instance, computerised devices like Personal Digital Assistant, which provide useful and accurate clinical practice guidelines and an alert system have been found to be more efficient than their paper-based counterparts.[75]

On the basis of the findings of this study, and in keeping with the immediate priorities for national action on matters of patient safety, the cornerstone for a comprehensive strategy to improve patient safety in the Bhutanese healthcare system involves (1) a national focus on patient safety; (2) leadership, tools and protocols to enhance the knowledge base about safety; (3) patient safety governance; and (4) patient safety education and training.

National focus on patient safety

A national focus on patient safety entails setting national standards for patient safety; developing a strategic framework for patient safety; establishing a national patient safety program; instituting a national patient safety governance committee; establishing well trained and supported patient safety consultation teams (groups with specific responsibility for patient safety); and developing national policies on patient safety (service policy to establish resource allocation; practice policy that depicts minimum level of safety management and treatments; governance policy; sentinel event policy which provides clear guidance on appropriate responses to such situations; educational policy; and patient/staff abuse policy). As recommended by the World Health Organisation,[76] patient safety policy and strategy should be aligned with existing national priorities.

Leadership for patient safety

Leadership to promote patient safety involves launching patient safety initiatives in hospitals; allocating a budget for patient safety initiatives and ensuring they are adequately resourced; initiating change management programs to build support for patient safety by the leaders of various health programs; developing research agendas (to understand the nature and extent of patient safety concerns; implement effective strategies to improve patient safety; and conduct research focused on teaching and learning of patient safety concerns and solutions); and

establishing measures of performance (e.g., developing and disseminating tools for identifying and analysing patient safety concerns and evaluating correction measures).

Patient safety governance

Governance for patient safety requires development of a patient safety framework and policy; developing and implementing practice standards and guidelines for clinical practices and procedures; developing and implementing clinical bundles, pathways and protocols related to specific medical conditions and practices; developing and implementing checklists for different clinical practices, procedures and technologies/equipment; improving existing quality assurance processes; and developing clear job descriptions.

Patient safety training and education

Continuing patient safety training and education should be provided to all categories of healthcare staff (including cleaners and ward aides/assistants). This involves developing educational curricula on patient safety in institutes, universities and hospitals (for all categories of healthcare professionals undertaking certificate, diploma, higher degrees, and continuing medical education); developing and implementing standard protocols and guidelines for supervision and monitoring of students and junior clinicians; promoting dissemination of information on best practices; and providing healthcare professionals with training in risk management.

In addition, development of a program to identify and address specific patient safety issues is recommended. The mechanisms to assure, monitor and continually improve patient safety and quality of care must be built into the foundations of the health system.[77] This includes addressing medication safety, surgical errors, diagnostic errors, laboratory/blood products,

identification errors, HAIs and falls injuries by adopting six key methods of data collection and measurement, encompassing: patient outcome measurements (mortality and morbidity statistics); auditing of clinical practice, resource use and program activities; measurement of patient satisfaction; systematic reporting and monitoring of patient safety data; and patient safety research. These processes help in detecting and monitoring a broad range of medical errors and solutions.[50 78-81] Strategies to address specific patient safety issues include, for example, patient identification by bracelet, correct labelling of medicines, implementation of unit-dose systems for medications, policies for blood transfusion and implementation of guidelines and/or protocols for the prevention of wrong patient, wrong site and wrong surgical procedure.

Strengths and limitations

A key strength of this study is the contribution it makes to a deeper awareness and understanding of the patient safety issues and concerns in the cultural context of Bhutan. Analysis of the data revealed the issues and concerns identified were commensurate with those experienced in other resource poor countries including the challenges of successfully addressing them. The main limitation of the study reported here is its reliance on patient safety concepts, theories and practices that have been developed and applied in high-income resource-rich nations. This, however, is also a strength of the study, since one of its aims was to explore the 'fit' or otherwise of such a frame in under-resourced and data-poor nations, and to make meaningful comparisons. On the basis of the comparisons made, establishing a foundation for informing a locally adapted program to address patient safety problems/issues identified in Bhutan has been rendered possible. A second limitation of the study relates to the large amount of data generated. As previously reported [26], decisions about inclusion and exclusion of data were informed by the consistency of findings across the disparate

participant groups and the themes and/or issues that were pertinent to informing the patient safety concerns in the healthcare context of Bhutan. In this process it is possible that some material may have been lost.

Conclusion

This study pioneers the exploration of patient safety issues and concerns in Bhutan's healthcare system. The study has identified medication errors, HAIs, surgical errors and post-operative complications, diagnostic errors, laboratory/blood errors, fall injuries, communication errors and patient identification errors as key patient safety concerns. Factors contributing to these concerns were identified to include system as well as human factors. The strategies recommended by participants indicate that a system to mitigate risks caused by both human and system factors is required to improve patient safety in Bhutan's healthcare system.

Overall, this study has provided a basis upon which future research and patient safety improvement strategies can be identified and developed. An immediate strategy, based on the findings of this study, would be to conceptualise and position patient safety as a priority for Bhutan's healthcare system and its leaders. Interventions need to target several points in the hierarchy, starting from policy development and extending to assessment and management of risk, and to reducing the incidence and impact of disruptive behaviours. Additionally, the provision of patient safety training and education for healthcare professionals and patients is required. These strategies would help improve overall safety by preventing adverse events.

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Conflict of interest

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Authors' contribution:

The first author conceived the study. Both authors designed the study and developed the study protocol. RP collected and analysed the data. The second author (AH) supervised data collection and data analysis. Both authors prepared and approved this paper.

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Standards for Reporting Qualitative Research (SRQR)*

http://www.equator-network.org/reporting-guidelines/srqr/

	Page/line no(s).
Title and abstract	
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	1 and 3
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	3
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	4 - 6
Purpose or research question - Purpose of the study and specific objectives or questions	6 - 7
Methods	
Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	7 - 10
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	1 - 10
Context - Setting/site and salient contextual factors; rationale**	7 - 8
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	7 - 8
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	9
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	9

Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	9
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	7 - 8
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	10
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	10
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	10

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	10 - 23
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	10 - 23

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	24 - 29
Limitations - Trustworthiness and limitations of findings	29 - 30

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	31
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	31

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Reference:

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