Explaining the negative effects of patient participation in patient safety: an exploratory qualitative study in an academic tertiary healthcare centre in the Netherlands

Michael Van der Voorden, Kees Ahaus, Arie Franx

ABSTRACT

Objective Although previous studies largely emphasize the positive effects of patient participation in patient safety, negative effects have also been observed. This study focuses on bringing together the separate negative effects that have been previously reported in the literature. This study set out to uncover how these negative effects manifest themselves in practice within an obstetrics department.

Design An exploratory qualitative interview study with 16 in-depth semistructured interviews. The information contained in the interviews was deductively analysed.

Setting The study was conducted in one tertiary academic healthcare centre in the Netherlands.

Participants Patients (N=8) and professionals (N=8) from an obstetrics department.

Results The results of this study indicate that patient participation in patient safety comes in five different forms. Linked to these different forms, four negative effects of patient participation in patient safety were identified. These can be summarised as follows: patients’ confidence decreases, the patient–professional relationship can be negatively affected, more responsibility can be demanded of the patient than they wish to accept and the professional has to spend additional time on a patient.

Conclusion This study identifies and brings together four negative effects of patient participation in patient safety that have previously been individually identified elsewhere. In our interviews, there was a consensus among patients and professionals on five different forms of participation that would allow patients to positively participate in patient safety. Further studies should investigate ways to prevent and to mitigate the potential negative effects of patient participation.

INTRODUCTION

Patient safety is fundamental to excellent patient care and a critical component of healthcare quality management.1 2 Despite the longstanding principle of ‘do no harm’, unsafe medical care causes significant morbidity and mortality across the world.3 Unsafe practice mean that there are still many patients who suffer harm as a consequence of healthcare interventions.4 For this reason, many countries have prioritised patient safety and are actively working to build safer health systems.5 6 As part of this, there is a focus on improving the patient safety culture to enhance patient safety in hospitals.5 6

Patient participation is increasingly being prioritised internationally.7-9 Patient participation has become a starting point for quality of care and is frequently seen as an important instrument for improving care.10-12 For example, patient participation is seen as having led to increased efforts to measure patient experiences, which can then be used as input for improving or redesigning healthcare services.15-15

Further, there is increasing recognition and acceptance that patients should have a role because of their expertise.19

Involving patients in their own safety is an example of the wider concept of patient participation.16 Patient participation is advocated as a means of improving patient safety.17-19 Patient participation in, and views
on, patient safety are now considered valuable in the efficient identification of effective interventions that promote safe care.²⁰ Recent studies have shown that various forms of patient participation in patient safety, such as involvement in medication management, reduce the number of adverse events.²¹,²²

Despite the potentially major benefits of patient participation, several studies suggest that patient participation in patient safety can also have negative effects. First, asking patients to participate in improving their own safety can lead to anxiety issues.²³ This fear can arise when patients feel that they could be doing more to prevent harm.²⁴ Second, involving patients in their own safety can consume more of the healthcare professionals’ time, for example, when needing to respond when patients or their family express concerns.²⁵ Third, patients may be allocated more responsibility than their condition or ability allows them to cope with.²⁶ Fourth, a more open discussion about errors could harm the relationship between patient and professional and lower trust in the treatment²⁷–²⁹ and also decrease the patient’s confidence in the professional.³⁰,³¹

Notwithstanding these concerns, patients can bring experience and information that the professionals may lack. For this reason, a patient’s input is seen as crucial. There are different forms of patient participation and the benefits of these are widely emphasised and promoted. However, being aware of potential negative effects, especially when they relate to patient safety, is also very important. This study focuses on bringing together the negative effects that have been reported elsewhere in the literature. More specifically, this study seeks then to uncover how these negative effects manifest themselves in practice within an obstetrics department.

**METHODS**

**Study design**

Given that the aim of this research was to investigate forms of patient participation in patient safety and to clarify the negative effects that arise from these forms, an exploratory qualitative interview study was held in an obstetrics department. The views of both patients and professionals were obtained. The Standards for Reporting Qualitative Research checklist³² was used to demonstrate the transparency of all aspects of the qualitative research (see online supplemental Appendix A).

**Inclusion criteria and participants**

The study was conducted at the obstetrics department of Erasmus Medical University Centre in Rotterdam, the Netherlands. Interviews were held with both patients and birth care professionals, to collect their subjective experiences of patient participation. Initially, 21 professionals and 32 patients were approached by email, phone or personally. Inclusion criteria for the patients were that the patient had been admitted to the obstetrics department at the time of the approach, were potentially willing to participate in an interview at least 3 weeks and at most 6 weeks after childbirth and had sufficient mastery of the Dutch language to fully participate. Inclusion criteria for the professionals were a position as a physician or clinical midwife, at least 6-month employment in the obstetrics department, and sufficient mastery of the Dutch language to fully participate. Of those approached, eight professionals and eight patients were interviewed (see table 1). A lack of time was the major given reason for the approached professionals not to participate in the study. For the patients, it was insufficient energy after childbirth to participate in the study. Given these reasons, we have no reason to conclude that the views of participants and the non-participants differed with regard to the research question. Further, since we continued to approach and interview participants alternating data collection and data analysis until we were no longer hearing anything new, we consider that data saturation was achieved.

**Data collection**

In-depth interviews were conducted between March 2020 and June 2020 by one researcher (MVdV), with the sample size extended until saturation was reached (after 16 interviews). Due to COVID-19 concerns, safety measures were observed and the interviews took place on the basis of the patients’ and professionals’ preferences. Nine interviews were conducted face to face and seven interviews by telephone. The interviews lasted on average 59 min (longest 101 min and shortest 43 min). The focus was on forms of individual patient participation. In these semistructured interviews, three areas were discussed: patient safety, patient participation in patient safety and the negative effects of patient participation in patient safety. These central themes were reflected in the interview topic guide, which were adapted to the context of both patient and professional respondents (see online supplemental Appendix B). There were no specific protocols and/or guidelines concerning patient participation

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**Table 1 Respondents’ characteristics**

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<th>Patients, N (%)</th>
<th>Professionals, N (%)</th>
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<td><strong>Gender</strong></td>
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<td>Scientific education</td>
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<tr>
<td><strong>Profession</strong></td>
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<tr>
<td>Gynaecologist</td>
<td>7 (87.5%)</td>
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<td>Clinical midwife</td>
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at the obstetrics department. The in-depth interviews gave us a sense of the local culture in this department. After the interviews, a member check was carried out by asking the respondents if there were factual inaccuracies in the transcripts. Twelve of the sixteen participants took part in this check, with the other four failing to respond despite several attempts. None of the participants indicated any factual inaccuracies and no changes were made.

Data analysis
The texts from the interviews were transcribed and analysed in ATLAS.ti, V.8 for Windows. ATLAS.ti is widely used as a tool to structure qualitative analysis. We opted for inductive analysis to investigate forms of patient participation in patient safety because no suitable validated scientific model was available. Several negative effects of patient participation in patient safety have already been reported in the literature and, based on these, categories were deductively assigned. First, codes based on the literature were linked to the text fragments and our initial themes. Each theme was given one or more codes and, in this way, this study recognises the significance and relevance of the existing literature. In addition, the study was open to new categories given our fresh approach and that we were curious how negative effects might manifest themselves in practice. However, no new negative effects emerged. In presenting the results, a table overview was generated for each category.

Patient and public involvement
Patients and the public were not involved in the design, conducting, reporting or dissemination plans of the research.

RESULTS
In this section, the most important findings will be detailed and substantiated using anonymise quotes.

Forms of patient participation in patient safety in an obstetrics department
In this subsection, the forms of participation where there was consensus between patients and professionals that they would encourage patients to participate more in their own safety are discussed.

Jointly coordinate birth plan
The interviewees stated that obstetric patients should ideally contribute to their birth plan to express their wishes and needs regarding the delivery, so that the obstetric patient can together with the professional of the obstetrics department see what is feasible. Most of the respondents in the interviews indicated that the joint coordination of the birth plan can increase the feeling of safety.

Act on signs and symptoms
Critical information on possible signs and symptoms that might indicate adverse outcomes would allow obstetric patients to alert their birth care professional to address any potential risks. Provided with this knowledge, obstetric patients feel less anxious if such symptoms actually occur. The professionals in the obstetrics department also become more alert to any issues.

Co-treatment
The professionals of the obstetrics department indicated that they want to stimulate patient access to and participation in the patient file so that obstetric patients can act on the information recorded and have a better insight into possible unintended deviations. Both patients and professionals stated that, through this, obstetric patients can become more involved during their hospitalisation and become more of a co-owner of the information in the file and also act as a co-practitioner in the care process.

Medication check
The obstetric professionals argued that medication errors in prescribing and dispensing medication are not that uncommon, and that a check on the medication overview involving the professional and the obstetric patient in combination with the packaging information is seen as a priority. Obstetric patients indicated that they would like to assist in checking whether the correct medication at the correct dosage is present in the intravenous drip.

Patient’s own input in the time-out procedure
By time out procedure, we refer to the surgical team’s short pause, just before an incision, to confirm that they are about to perform the correct procedure on the correct patient. Obstetric professionals indicated that it is important to check at least the name and date of birth of the patient before childbirth. Both sets of respondents argued that, in order to increase the input of obstetric patients, it is important that obstetric patients actively attract the attention of the professionals.

Negative effects of patient participation in patient safety
The four negative effects of patient participation identified are summarised in table 2 and then discussed in more detail below.

Patients’ confidence decreases
Anxiety
Obstetric patients indicated that the discovery of medication errors and greater transparency over medication errors can cause anxiety. Most of the respondents stated that, if errors are made several times, obstetric patients become more anxious, and this leads to a decrease in confidence. Moreover, the respondents argued that this can also make obstetric patients anxious when they do not have a medical background because they cannot understand everything.

Most of the patients would say, I had to get paracetamol and now you are giving me antibiotics. They...
Table 2 Negative effects of patient participation in patient safety

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<th>Negative effects</th>
<th>Causes</th>
<th>Identified by</th>
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<td>Patients’ confidence decreases</td>
<td>Anxiety</td>
<td>Patients/professionals</td>
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<tr>
<td>The patient–professional relationship can be negatively affected</td>
<td>Negotiations with the patient about the treatment Unwanted insight Patient and professional cannot bridge the gap in their wishes regarding treatment</td>
<td>Patients/professionals Patients/professionals Patients/professionals</td>
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<td>More responsibility can be demanded of the patient than they wish to accept</td>
<td>Professionals hand over a lot of responsibility Patients experience considerable responsibility</td>
<td>Patients/professionals Patients/professionals</td>
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<tr>
<td>The professional has to spend additional time on a patient</td>
<td>Additional questions from the patient Overdiagnosis</td>
<td>Patients/professionals Professionals</td>
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then wonder if that is true. And then, as a healthcare provider you say sorry and that it is how it goes. If they notice in the record that they have been given the wrong medication three times, they will be more anxious. Then they will also start to think, things always go wrong here. And then it could just lead to less trust in us. (professional 2, 48 years old)

You do not need an explanation for a paracetamol. But iron tablets do have some side-effects that you do not know about. You can also have some serious side effects from magnesium tablets. If I had known that in advance, I wouldn’t have been shocked anymore. Then I would have thought, okay, it feels to me like I have a really bad fever. My body felt like I was on fire and afterwards it turned out to be from the magnesium. I read that on Google. It made me very anxious at the time because I didn’t hear it there and I could not understand it myself. (patient 2)

The patient–professional relationship can be negatively affected

Negotiations with the patient about the treatment

If obstetric patients read things in their patient file that they find difficult to understand, the relationship between patient and professional can be affected. When obstetric patients start to consult the patient file, it is possible that they raise more points for discussion. This can also happen if obstetric patients participate in the time-out procedure. The obstetric professionals reported that it sometimes feels as if they have to continually negotiate treatment with an obstetric patient since patients are encouraged to express their needs, and participate in both the keeping of the electronic patient file through co-treatment and in the time-out procedure through making their own input.

A trend that I, and also my colleagues, experience is that patient participation in some cases sometimes gives rise to constant negotiation, which is about what treatment they should or shouldn’t have. That’s something that I think has been increasing in recent years. It is something I notice myself suffering from, that if the patient expresses it in such a way, I cannot provide good care. This is the opposite of what I would like, and what I think is medically justified. (professional 1, 54 years old)

Unwanted insight

Patient involvement with the patient file creates greater transparency for obstetric patients, but they may then see things they would rather not have seen. Obstetric patients especially find things linked to mental wellbeing uncomfortable to read and that the content can be too painful. This can affect their relationship with the professionals at the time. In response to the reality that obstetric patients can read everything, the professionals will sometimes deliberately withhold things or write them down in a coded form. The obstetric professionals indicated that they do not always get the full picture from the obstetric patients and that some information must first be cross-checked with other professionals in the department before it is included in the file.

Patient and professional cannot bridge the gap in their wishes regarding treatment

With obstetric patients participating in their birth plan, the professional respondents indicated that sometimes obstetric patients have unrealistic wishes, and ones that are medically irresponsible. As such, an obstetric patient’s wishes cannot always be met.

The intention behind the birth plan is that it improves the communication between me and the patient. The time investment that is required for this and the number of conversations you have, still take a lot of the professional’s time, and that also means that it doesn’t always work out. So, there are definitely examples of patients where the individual birth plan has given rise to different and unrealistic expectations, and that in some cases it is also difficult to manage. However, even in the most extreme case, ignoring the wishes and context of a patient is also outdated. (professional 6, 62 years old)
More responsibility can be demanded of the patient than they wish to accept

Professionals hand over a lot of responsibility

Obstetric patients, given the initiative to give them a role in providing an extra control over medication, may identify errors. After identifying such errors, patients may have continuing doubts and bad feelings when taking their medication. The obstetric professionals had warned about placing too much responsibility on their patients and believed that medication checks should remain a medical responsibility. In addition, home monitoring places considerable responsibilities on the obstetric patients, something they are normally not used to. Respondents on both sides argued that many obstetric patients are not ready to take on this responsibility when it is given to them.

Patients experience considerable responsibility

The majority of the obstetric patients interviewed indicated that they do want to participate in safety, but they do not want to bear too much responsibility. In the context of checking their medication, obstetric patients argue that this should be an extra check—in addition to the nurse’s check. The respondents indicated that obstetric patients do not always want to bear this responsibility.

I would not want to take full responsibility for doing a medication check. The reason for this is that I am not medically trained. There may just be another name [for the same medication] that I am not aware of. I have experienced this before with my dad that two names have been mixed up, and that caused considerable damage. As far as I am concerned, two medical people should look at it anyway to prevent mistakes. I would then like to contribute to patient safety by doing a third and final check. (patient 1)

The professional has to spend additional time on a patient

Additional questions from the patient

Both patients and professionals indicated that transparency provides obstetric patients with greater insight, and that this can lead to more questions from them. It was reported that patient participation in medication checks, and their involvement in the electronic patient file and the birth plan, resulted in more questions from them to the professionals.

I think there should be a part in the electronic patient file that remains between the nurses and the doctors. And that part is what you should not share in the file, and you do not need to because the patient does not have to read everything literally. If everything is there, then I would also want to know everything, and that will only lead to many more questions. (patient 6)

Overdiagnosis

The professionals in the obstetric department mentioned that overdiagnosis is a risk and stems from the patient participation initiative that encourages them, in the event of signs and symptoms, to raise these with the professionals. The professionals reported that obstetric patients do indeed report signs and symptoms, and that this can lead to overdiagnosis and overtreatment because of the limited knowledge of obstetric patients regarding potential complications.

It should be a simple conversation about the three main symptoms that they should never ignore and directly raise the alarm. And this conversation should not be overshadowed by a lot of other symptoms, because the risks for the professional are that we then test for all kinds of things because we have alerted the patient. In addition, the patient does not even really know about it. Overall, we will probably not find very many relevant things and the costs will increase. (professional 7, 45 years old)

DISCUSSION AND CONCLUSION

Although various studies have shown individual negative effects of patient participation in patient safety, this study is the first to bring these together and our empirical study, based in the practice of obstetrics, has given added insights to these negative effects.

Discussion

Based on the results of previous studies, the expectation is that patient participation in patient safety will generally have positive effects. However, a literature search identified four negative effects of patient participation in patient safety identified in different studies. This study brought together these negative effects and sought further explanation.

First, it was found that the confidence of obstetric patients can decrease as a result of their participation in patient safety. Knowing that there is a risk of medical errors may cause anxiety and a decrease in trust. This is in line with a study that revealed that the participation of patients in improving their own safety can lead to anxiety issues.23 Another study similarly shows that fully opening up all information to patients at bedside handovers can lead to anxiety.34

Second, we found that patient participation in their own safety can negatively affect the relationship between the obstetric patient and the professional from the obstetrics department. This is mainly because making all the information in the patient file available to the obstetric patients can result in the professionals having to continuously renegotiate treatment. It is also possible that a patient and a professional cannot bridge the gap between the wishes of the patient and the professionals received need for treatment. These are fresh insights extending earlier studies.27–29

Third, in the obstetrics department investigated, the patients were given a lot of responsibility regarding patient safety and they were aware of this responsibility. While one study has argued that patients are now expected to take responsibility for their own safety,35 a
more recent study considered that patients could only function as a safety buffer (often the final one) alongside professionals.²⁶ In addition, it is argued that, while it may be easy for professionals to say that patients should bear the responsibility for their own safety, professionals always remain responsible for the care they provide. As such, the responsibility for patient safety can be unfairly assigned to patients.²⁶ Our study found that patients are willing to perform a final check. As such, it could be said that patients should take on the responsibility, but we also saw that obstetric patients were not ready to take on full responsibility. Consequently, a balance needs to be found between patients and professionals, and here is where shared decision-making should come into play. Further, because patients’ preferences are often misunderstood, professional training should be organised for professionals so that they can make a better diagnosis based on a patient’s preferences.³⁶

Fourth, the obstetric professionals indicated that patient participation in patient safety consumes more of their time as it leads to additional questions from patients leading to more requests for diagnostic tests. This is at odds with an earlier observation in the literature that patient participation is regarded as an efficient way to find effective interventions to promote safe care.²⁰ Our view is that the role of patients is inevitably increasing and, presently, this is not balanced with the time that professionals have to invest in this. More questions from patients and subsequent overdiagnosis, unnecessary testing and treatment can cause harm to patients. However, if there is time to develop strong relationships with patients, engage in shared decision-making and, take the time to fully educate them about risks and benefits, patients often prefer to avoid excessive testing and treatment.³⁷ A different perspective seen in the literature reasons that, patient participation in patient safety investigations can lead to greater recognition of errors and their correction, but will indeed absorb more of a professional’s time.²⁷ It has also been argued that, if a professional cannot find enough time to be involved in patient participation processes, the patient is less likely to participate or view it as a positive experience. Another reason identified in the literature for professionals not making the time for patient participation is simply because professionals do not want to encourage patient participation.³⁸–⁴⁰ A reason offered is that it is not always clear why the patient’s perspective is important.⁴¹ If this is not clear, there may be no incentive for the professional to let the patients participate. If professionals see the process as taking more of their time due to what they consider an excess of questions and requests for further diagnostics, this could have a negative effect leading them to try and spend less time on patient participation. Further studies should investigate the impact of time on patient participation in more detail.

The negative effects reported in this study are found on both the patient and the professional levels. This study also shows that there are negative effects on the institutional level and identifies the following: cost considerations, legal implications and policies, and culture. If patients discover errors, appropriate medical and mental support may have to be immediately arranged, adding to costs. Further, patient participation can lead to organizational liabilities in the event of errors. Overall, institutional policies and operating procedures will define the level of patient participation.²⁵

**Strengths and limitations**

The strengths of this study include viewing on patient participation from a fresh perspective, namely the possible negative effects of patient participation in patient safety, and particularly in the context of obstetrics. Another strength of the current study is that it included the perspectives of both patients and professionals. As a result, this is a more comprehensive study on patient participation than many earlier ones and brought both perspectives together. Nevertheless, our study has some limitations. First, giving the small sample size, there may be a selection bias in both patient and professional samples. However, small, non-representative samples are considered acceptable for qualitative studies provided one strives for maximum variation within the sample. Further, although a single case study provides in-depth findings, it imposes limitations on the extent of external validity. The reason for this is that there may well be different procedures and cultures within other obstetrics departments. In addition, there are different types of patient groups and practices within other care specialties that might lead to different findings.

**Conclusions**

In advance, it was expected that patient participation in patient safety would generally have positive effects. However, a literature search identified four negative effects of patient participation in patient safety identified in different studies. This study brought together these negative findings and sought further explanation, by interviewing both patients and professionals, in the context of an obstetrics department, about their experiences and ideas. The interviews with patients and professionals revealed further evidence for these negative effects. Future studies could investigate ways to prevent or at least mitigate the negative effects of patients participating in patient safety. Adopting measures to remove the negative effects is necessary to promote patient safety through patient participation.

**Practical implications**

It is important to continue to encourage patient participation. However, because we know from this study that there are also negative effects, in addition to the positive ones, it is important to look for ways to deal with these. To allow obstetric patients to participate in patient safety, it is necessary to create moments where they can participate. To enable this, it is important that professionals are given enough time and professional training by their organisation to enable them to appropriately respond to patients’ participatory inputs.

**Acknowledgements** The authors would like to thank the obstetrics department of Erasmus University Medical Centre and the individual patients and professionals of the department for making this study possible.


29 Donaldson MS, Corrigan JM, Kohn LT. To err is human: building a safer health system, 2000.


38 Kamzan AD, Ng E. When less is more: the role of overdiagnosis and overtreatment in patient safety. Adv Pediatr 2021;68:21–35.


Standards for Reporting Qualitative Research (SRQR)*

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

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<td><strong>Title</strong> - 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</td>
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<tr>
<td><strong>Abstract</strong> - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions</td>
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<td><strong>Purpose or research question</strong> - Purpose of the study and specific objectives or questions</td>
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<td><strong>Researcher characteristics and reflexivity</strong> - 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</td>
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<td><strong>Context</strong> - Setting/site and salient contextual factors; rationale**</td>
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<td><strong>Sampling strategy</strong> - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**</td>
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<td><strong>Data collection methods</strong> - 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**</td>
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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

Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)

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

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

Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale

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

Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings

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

Limitations - Trustworthiness and limitations of findings

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed

Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting

*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:
O’Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Academic Medicine, Vol. 89, No. 9 / Sept 2014*
DOI: 10.1097/ACM.0000000000000388
Appendix B, online supplementary material, topic guide

Professionals

Patient safety
What do you understand by patient safety?
Could you provide a case/example(s) of this to help clarify your understanding?
How does the department pay attention to patient safety?

Patient participation in patient safety
What do you understand by patient participation?
Could you illustrate a case/example(s) of this to help clarify your understanding?
Which possibilities do you see for your patients to contribute to their own safety?
What would this look like in practice?

Negative effects of patient participation in patient safety
Do you, in practice, see ‘the confidence of patients’ decreasing’ as negative effect of patient participation in patient safety? If so, what cause(s) of this negative effect can you illustrate?
Do you, in practice, see ‘the patient-professional relationship can be negatively affected’ as negative effect of patient participation in patient safety? If so, what cause(s) of this negative effect can you illustrate?
Do you, in practice, see ‘more responsibility can be demanded of the patient than they wish to accept’? If so, what cause(s) of this negative effect can you illustrate?
Do you, in practice, see ‘the professional has to spend additional time on a patient’ as negative effect of patient participation in patient safety? If so, what cause(s) of this negative effect can you illustrate?
How do these negative effects show themselves in practice?

Patients

Patient safety
What do you understand by patient safety?
Could you provide a case/example(s) of this to help clarify your understanding?
How does the department pay attention to patient safety?

Patient participation in patient safety
What do you understand by patient participation?
Could you illustrate a case/example(s) of this to help clarify your understanding?
Which possibilities do you see for yourself to contribute to your own safety?
What would this look like in practice?

Negative effects of patient participation in patient safety
How do you think ‘the confidence of patients’ could decrease given the way patients participate in patient safety?
How do you think ‘the patient-professional relationship’ could be negatively affected given the way
patients participate in patient safety?
How do you think ‘more responsibility can be demanded of the patient than they wish to accept’ given the way patients participate in patient safety?
How do you think ‘the professional has to spend additional time on a patient’ given the way patients participate in patient safety?