BMJ Open

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Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2015-008128
Article Type:	Research
Date Submitted by the Author:	06-Mar-2015
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Primary Subject Heading:	Qualitative research
Secondary Subject Heading:	General practice / Family practice
Keywords:	PRIMARY CARE, QUALITATIVE RESEARCH, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

Title: Monitoring patient safety in primary care. An exploratory study using in-depth semi-structured interviews.

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Key words: patient safety; primary health care; quality of care; monitoring; qualitative research; interviews

Word count: 3786

Number of tables, figures and boxes: 5

ABSTRACT

Objectives: To explore how information and data are used to monitor patient safety and quality of primary care by professionals working in, or supporting, primary health care.

Design: Qualitative study of semi-structured interviews with a directed content analysis of transcripts.

Setting: North-West London, UK.

Participants: Twenty-one individuals from various levels of the primary health care system were recruited, including general practitioners, practice nurses, practice managers, members of CCG governing bodies, and senior members of regional patient safety teams.

Main outcome measures: Perceptions of the facilitators and barriers to monitoring patient safety in primary care.

Results: Participants described being overwhelmed with complicated data which lacked any meaningful analyses about safety and quality. There was also a lack of clarity over which patient safety events are expected to be reported or monitored. Participants also reported uncertainty on whose responsibility it was to act on patient safety information or concerns. At the practice level, there was a range of disincentives for responding to and acting on safety issues and concerns, with few reported benefits. Participants made recommendations to improve future monitoring.

Conclusion: There is a need for clearer information in the form of specific guidelines, policies and procedures with regard to who monitors patient safety in primary care, what is monitored, and how it should be monitored.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study employed a multiprofessional participant group at various levels of the primary care system, providing a more realistic account of the complexities of monitoring patient safety in primary care.
- The interview topics were focused on current barriers and facilitators to monitoring patient safety which, combined with the use of a directed content analysis, allowed an in-depth exploration of what works and what does not work for patient safety monitoring in primary care.
- Participants offered detailed and specific recommendations to improving the use of data to monitoring patient safety in primary care.
- These findings may not be generalisable to other healthcare agencies and organisations involved in primary care that were not represented in this study.
- This study took place in North-West London and the results may not reflect the experiences of those working in other areas.

Word count (excluding figures and tables): 3786

Figures and Tables: 2 boxes and 3 tables

INTRODUCTION

It is estimated that between five and 80 threats to patient safety occur per 100,000 consultations in primary care (1), which translates as between 37 and 600 patient safety incidents occurring in UK primary care per day (2). Despite this, the nature and extent of harm in primary care are still not well understood (2, 3). Beyond the basic reporting and publishing of quality and safety outcome indicator data (4), it is also unclear how patient safety is monitored by primary care organisations, such as Clinical Commissioning Groups (CCGs), their member practices and local NHS England area teams.

One option is to use routinely collected data, given their availability and low cost. Smith et al. (5) have proposed the need for improved handling and analysis of these data to support commissioners' and patients' decision making (5). Furthermore, there have been calls for better developed methods of using the data held at GP practices to inform the quality and safety of care (6). Previous findings that GPs distrust some aspects of administrative and clinical data because they believe them to be manipulated (7) could have implications for how much attention is paid to such data in GP practices generally, as well as at the CCG governing body level. Additionally, practice staff typically may not have the time or expertise to reflect on the large amount of practice-level data to draw meaningful lessons about patient safety (8). Recent reports suggest that other forms of information, such as analyses from nationally reported significant event audits, serious incident reports and complaints, are handled with wide variation and poorly disseminated back to clinicians which can result in inaction regarding patient safety concerns (9, 10).There is a pressing need to explore how patient safety information of whatever origin is received, interpreted and acted on to improve the safety of healthcare.

Using the example of North-West London (NWL), this study uses informant interviews to explore how patient safety is currently monitored in primary care settings as well as identifying possible improvements to patient safety monitoring in the future. In this study, patient safety is defined as the *"reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum"* (11).

METHODS

Study design

This study consisted of in-depth semi-structured interviews, a format which we considered to be suited to exploratory aims of the study (12). An interview guide was used to ensure that some core

questions were asked of all participants, but also allowing flexibility to follow up novel information (13).

Participants and procedures

Twenty-one individuals participated in the study. Individuals working in GP practices and those supporting and monitoring the delivery of these services (CCG governing body members and members of the London region of the NHS England patient safety and quality teams) in NWL were eligible for interview. Initially, email invitations for study recruitment were distributed to members of the governing body of the eight NWL CCGs. Subsequently, snowballing was used to identify and access further relevant professionals. Snowball sampling is useful in cases where the sampling frame is unknown or diverse and traditional random sampling is implausible (14). A range of different perspectives on patient safety were sought for this study to allow for diverse accounts so as not to present one group's account as objective, known as *fair dealing* (15). Once data saturation was reached after 21 interviews, no further participants were recruited.

Data collection

Interviews took place between June and September 2014. Interviews ranged from 29 to 47 minutes and were audio-recorded. Interviews were conducted by one member of the research team who had previous experience interviewing healthcare staff. The interview guide was piloted on the first three participants, which resulted in minor changes to question wording and order. The final interview guide is included as Box 1. This study was deemed to be a service evaluation (16) and therefore did not require NHS Research Ethics Committee approval (17). Appropriate local research governance permissions were sought. Participants were given a study information sheet and gave informed consent.

Box 1 Interview guide

1. What does the phrase 'patient safety' mean to you?
2. Can you describe any ways of identifying cases where there have been medical errors or patients have been harmed by their care?
3. Are there any ways of sharing information about patient safety events or near misses with others who work in primary care?

   Prompts: Can you describe these?

   How often does this happen?
4. If there was a growing concern where the same patient safety adverse event was occurring in a particular area/practice/your practice, how would this usually be flagged up to you?
5. Are there any ways in which you think the data supporting patient safety in primary care could be improved?

   Prompt: do you think these analyses adequately represent trends in patient safety and quality of care?
6. With the information and feedback channels that exist, do you feel that primary care practices where there are safety issues are currently being identified with a good degree of accuracy?

   Prompts: Why/why not?

   How could this be done better?
7. In terms of monitoring patient safety in primary care, what makes this difficult for you?
8. Are there any things that would make it easier to monitor patient safety in primary care?

Data analysis

Interview transcripts were subjected to a directed content analysis (18), in which some coding categories are predetermined in lines with the aims of the study (19, 20). These predefined categories were: the current methods of identifying patient safety events; perceived barriers and facilitators; and recommendations for the future. Each transcript was coded according to the manifest content (21) in line with these categories. Any other relevant statements were given new codes at this stage, which culminated in the final coding framework. The coded data were investigated for relationships which linked them. These became subthematic level data and

relationships between subthematic data became the overarching main themes. The final thematic framework was developed by one researcher and is included in Box 2.

Box 2 Thematic framework: Monitoring patient safety in primary care

(1) Access to information and data

a. The overwhelming number of performance measures

b. Variability in receiving patient data in the GP surgery

c. Access to (meaningful) analyses/data about safety

(2) Clarity of policies and guidelines

a. Operationalisation of patient safety and patient safety-related events

b. Local variation in policies and protocols

(3) Responsibility and action

a. Ownership of the issue

b. The lack of visible monitoring in primary care

c. Prioritising other pressures over safety and quality

d. Disincentives to report potentially serious incidents

e. Dependence on informal human vigilance and feedback

RESULTS

Twenty-one individuals participated in the study (Table 1). The three main themes are presented with data from the interview transcripts (with the participant identifier) to reflect the main points of interest.

Table 1 Interview participant characteristics

Identifier	Professional role/s	Gender	Job experience (in years)
CCG1	Clinician* with CCG governing body role	Male	24
GP1	GP	Male	1
CCG2	Clinician with CCG governing body role	Male	8
GP2	GP	Female	8
GP3	GP	Male	15
CSU1	Safety & Quality executive at NWL CSU	Female	8
CCG3	Clinician with CCG governing body role	Female	18
NHSE1	Safety/quality executive at NHS England	Female	1
GP4	GP	Female	13
NHSE2	Safety/quality executive at NHS England	Female	1
GP5	GP	Female	12
GP6	GP	Female	12
CCG5	Clinician with CCG governing body role	Male	20
CCG6	Clinician with CCG governing body role	Male	20
PM1	Practice manager	Female	16
GP7	GP	Male	25
CCG7	Safety/quality executive in CCG	Male	2
NHSE3	Safety/quality executive at NHS England	Female	1
CCG8	Clinician with CCG governing body role	Female	28
NHSE4	Safety/Quality executive at NHS England	Male	2
PM2	Practice manager	Female	6

*Clinicians – job experience denotes years worked after medical qualification; non-clinician - job experience denotes years worked in current role.
**Clinician denotes general practitioner, nurse or secondary care practitioner – exact profession is not specified as data would be identifiable.

Access to information and data

Participants reported an overwhelming number of performance measures, creating an ever-increasing workload for general practice staff. Typically, they did not believe that these performance measures reflected patient safety but were simply a mechanism for remuneration which sometimes conflicted with safety: "*You get fixated on depression because that's what you're being paid for… So*

you tend to ignore other mental health co-morbidities because depressions the one you're focusing on" (GP1). Importantly, individuals working in general practice reported that they did not know what type of harm they should be looking out for: *"If they set out really clearly, 'we believe that these five things would really improve patient safety and so we want you to report to us, every single medication error, every single needle stick injury…' whatever. We could then do that. I suppose that's the problem - It's just so wide at the moment in primary care that we're never really sure" (PM2)*.

GPs simultaneously spoke of too little information on the discharge summary or too much information *("… lots and lots of information about various tests that the patients have had but it's information that I actually don't have the expertise to interpret", CCG3).* Not knowing what occurs to patients after a referral to district nursing was a concern *("…referral to district nursing – it's like dropping it into a black hole. You don't know if the nurse has ever seen the patient or whether what you've asked to be done has been done", CCG3)*. Most primary care practitioners agreed that information sent from secondary care (e.g. outpatient letters and discharge letters) were more reliably delivered than in the past which had improved patient safety. There were, however, issues around receiving these letters in a format which was not compatible with the system holding the patient records in the practice. In these cases, the information needed to be manually entered into the patients record by practice staff which created a lot of opportunity for error: *"if there's ten or fifteen medications which is not uncommon with patients, that could be a really big problem… every possible error, from transcription error on names of medication or dosages, lengths of time that the patient's expected to be on the medication – be it permanent or short-term - loads of room for error on that"* (*GP7*).

Despite the outcomes indicators dataset, participants from NHS England reported that no core metrics were routinely analysed for safety monitoring *("it's very underdeveloped…The honest answer is we don't have a set of metrics that we look at", NHSE1)*. Instead, the accessible data were manually scanned for "*red flags which would then make you say 'actually we need to take a closer look'" (NHSE3)*. These data may be discussed at operational groups involving representatives from different agencies which met every one or two months, but these meetings were described as fixated on trying to get through the information collected through secondary care quality and safety indicators: *"We're trying to look at those. There's hundreds. There's literally about two hundred. Three hundred" (CCG7).*

Participants from management organisations (NHS England, CCG governing boards and the CSU) tended to report that safety data (such as serious incidents) and complaints were distributed across and within a number of organisations ("*It's distributed across NHS England: the revalidation team, the performance list team, the contract managing team, and so on.")* and recommended that this

information should be collated into one document shared between the agencies that have a responsibility to monitor safety.

Theme 2. Clarity of policies and guidelines

Across participants, there was no consensus on the meaning of the term 'patient safety' in relation to primary care. Most participants either couldn't explicitly define patient safety because the concept was considered vague or they described it as everything in the medical process: *"it could mean all sorts of things… So it's everything actually. Patient safety is everything we do*" (*GP5*). Additionally, it was not clear what constituted a serious incident, whether reporting was mandatory, and where to report them. Participants explained that serious harm and never events had an acute focus and that general practice was comparatively safer: "*you think 'well, compared to that, our risk is zero' so it feels like an overreaction to follow some of this process" (PM2)*. Different methods for reporting patient safety incidents (such as emailing or ringing up a local or national team at NHS England, completing an incident report form from NHS England, or anonymously reporting through the NRLS) appeared to result in confusion about which agency the information was received by and which of these methods satisfied mandatory reporting requirements, even amongst those at the CCG governing board level: *"I struggle when I ask the question to get any sense of the mechanisms by which general practitioners might report, or anybody in general practice might report, the mechanisms by which patients might report their concerns… I have no idea. And my suspicion would be that nobody has any idea." (CCG6).*

Some GPs reported having carried out informal safety monitoring evaluations or audits in the past. This type of monitoring was optional, variable and time-intensive: *"Looking at your prescribing rates compared to somebody else… so at the moment, GPs are having to do that by hand and that's why they might do it one year, skip it another year, because you're then doing lithium or you might be doing risperidone… or you might be looking at methotrexate and all the anti-tumour drugs that might be prescribed. So you're covering so many areas you do not have time to do every single one. If somebody could do that and just present the data…" (GP2)*. Recommended policies and practice seemed to exhibit variation, with individual practices able to develop their own policies on repeat prescribing, including the frequency of medication reviews for long-term medications and high-risk drugs. Multiple GPs mentioned that they needed more information about drug monitoring and greater uniformity of policies and procedures on: *"all the drugs that patients take where monitoring is recognised and recommended and then, what are the monitoring intervals and what are the*

ranges that are acceptable? And so… one could actually perhaps identify about 20 classes of drugs where monitoring is definitely useful" (CCG2).

Theme 3. Responsibility and action

At the management level, there were conflicting responses about whose responsibility it was to monitor patient safety in primary care. CCG governing body members generally reported that monitoring safety was outside of their remit and lay with NHS England, whereas participants from NHS England saw themselves as part of collaborative effort with CCG governing bodies and the practice networks. There was the mention of the fact that the CCGs do *"have this vague responsibility for quality [improvement] in general practice, whatever that's supposed to mean" (CCG3)*. The reported lack of clarity around what is expected for monitoring patient safety was sometimes attributed to NHS England having too few resources ("*underresourced and understaffed*", CCG3) to undertake effective patient safety monitoring combined with the restrictions of having to enforce a legal contract with GPs that was vague and underspecified in the area of patient safety *("not fit for purpose", CCG8).* Participants from NHS England and the CCG governing bodies also reported conflicting responses about who monitors patient safety in urgent care centres and for out-of-hours services, with some GPs stating that it appeared that nobody was monitoring these services: "*And urgent care centres are making huge amounts of money but the quality of care – who's questioning that? … Do we have any data on the safety of prescribing or drug errors or prescribing errors in urgent care centres, is anyone looking at that – even out of hours?" (GP6)*.

Participants from CCG governing bodies and NHS England spoke at length about how GP practices managed their incidents locally and made use of networks or peer groups (of 6 to 11 practices meeting monthly) to check up on each other and share information. In actual practice it appeared that the network meetings were more often used to make sense of recent changes to policies or procedures instead of discussing patient safety. Additionally, likeminded poor performers (typically regarded to be smaller practices) may seek work together to avoid detection, referred to interviews as *"collusion" (CCG8)*. Participants tended to report that they had local knowledge about which practices were and were not safe, with some identifying single-handed or two-handed practices as where the focus of patient safety monitoring should lie: *"There's a pattern of poor performance in men, over 50, who trained abroad, who didn't train in the UK, and who are single handed, small, very small practice and probably have got poor premises. They're high indicators of underperformance… the trouble is the trained abroad stuff, is politically very sensitive" (NHSE4).*

Participants who were primary care practitioners frequently described the difficulty of managing time pressures on an average work day. GPs reported not having the time to fill in incident report forms or conduct safety audits: "*although there are areas where we are asked to collect data, we're just so busy and so stretched that we don't really do it. So for example, we hold the minor surgery service and in theory we try to run an audit of, or we try to keep a record of if there's post-operative infections. But actually to do that properly, it's really difficult, so we don't do it properly" (CCG2).* Many GPs explained that it was difficult to be safe in a ten to fifteen minute appointment in which patients often bought multiple serious health and social concerns to the same appointment due to having access to care issues: *"But I think primary care's really dangerous right now to be honest. I am getting quite near to the feeling that I don't want to carry on doing it." (CCG2).*

For a number of reasons, the recommended protocol for dealing with a potentially serious incident was not always followed: *"so what I should be doing is logging it on that, sending it off to them. To be honest, almost never happens" (CCG3)*. Other than lack of time, reasons for this included fear of blame, organisational repercussions as well as fear personal repercussions which were amplified if the potentially serious incidents involved a senior GP. Importantly, multiple GPs reported the belief that NHS England would not or could not act on the evidence, which was a deterrent to reporting incidents: "*I don't believe that they [NHS England] have enough power to do what they need to do – they need to have really hard evidence… It's almost as if you have to prove that somebody's not performing or prescribing is terrible and the onus is on that GP and so on top of your normal workload, and for the fear of being isolated and victimised, who's going to do that? It's easier to walk away from it" (GP6).* The failure to report incidents outside of the practice was attributed to a number of factors, including workplace culture: *"There's a culture that the mistakes are there… but they're in tolerable limits; they're within acceptable limits even though in fact if one was to have the hard evidence and comparative with what's going on on a national basis, you might find that you are a complete outlier." (GP7)*.

Summary

Across the group, participants were able to describe their perceptions about the barriers to using data to monitor safety in primary care at various levels of the primary care system (Table 2) as well as outline recommendations designed to improve the use of data to monitor patient safety (Table 3).

Table 2 Perceived barriers to using data to monitor safety

Perceived barriers
Lack of information about district nursing activity delivered to patients' GP
Lack established regional/national protocols regarding monitoring of repeat prescribing or high-risk drugs
Information received from hospitals is too basic or too complex for GP
Lack of examples of serious harm or never events that are applicable to primary care settings for which to monitor
Limitations to involvement of salaried and locum doctors with QOF data
Too many inappropriate pop-up warnings on GP clinical systems
Limited and unreliable data on serious incidents
Lack of specifically allocated time to look at practice-held data or QOF statistics on patient safety
Local practice network meetings designed for some patient safety peer monitoring used for other purposes
Organisation holding safety data may not have power to investigate patient safety threats
Majority of time at operational group meetings dedicated to hospital patient safety monitoring
Lack of safety metrics routinely analysed at NHS England (London region)
Limited access to existing safety data as it is divided in terms of the organisations that hold it and within departments in these organisations

Table 3 Recommendations for improving data to monitor safety

Recommendations
For hospital information, clearly outline changes to patient medical and/or medication status and clearly outline action plan for GP follow up and monitoring
Share copy of district nursing care plan with GP
Hospital information should have READ-codes applied to avoid error during information transfer
Provide data on missed appointments in other parts of healthcare system to patient's GP, especially required for those at high risk (e.g. frail, elderly)
Collate all patient safety and quality information (including complaints) in one source document which is shared within and between organisations that have a duty to monitor patient safety.
Provide spreadsheet feedback charts (colour coded: red, amber, green) on prescribing rates data relating to safety (e.g. non-formulary drugs, drugs with boxed warnings)
Provide list of five to ten patient defined safety events for practices to identify, clinically code in the patient record, and monitor
Supply rapid discharge summaries from hospital for other serious illnesses (e.g. meningitis, sepsis or lower respiratory tract infections)
Identify all drugs in which monitoring is recognised; provide a list of the recommended monitoring intervals and acceptable ranges
Need for computerised automatic safety monitoring audits for known risks (e.g. unsafe combination of drugs, long-term use of short-term medication)
Provide a one-page outline on what a patient safety event is, how and where it should be reported for practices to display in waiting rooms
Provide a safety reporting system for suspected problems which need further investigation
Provide a safety reporting system which all primary care practice staff have access to
Up-to-date (live) patient care record shared between all the patient's NHS healthcare providers

DISCUSSION

This qualitative study used interviews to explore how patient safety is monitored in primary care settings in North-West London. The findings showed that patient safety and patient safety events, such as serious incidents, appear ill-defined in primary care, and therefore it is unclear on the ground what is to be monitored. Given the acute focus of serious harm and serious incidents, the need to monitor patient safety in primary care appeared to be less urgent. There was an absence of policies and protocols outlining which aspects of care or treatment need monitoring for patient safety by whom and how often. In the absence of formal guidance and policies, it appeared that monitoring was perceived to be voluntary and conducted ad hoc, based on time and resource constraints as more urgent tasks took priority over the peer-reviewing the safety of local practices or one's own practice. At the management level, the information about patient safety was divided between, and within, various organisations, and there appeared to an absence of clear and explicit monitoring strategies and ownership of the issue. Overall, this lack of coherence on patient safety in primary care presents an obstacle towards transitioning to a culture in which safety is the main priority for the NHS (22). This study indicates that the focus on safety may require: (1) a detailed operationalisation of core concepts relating to safety in primary care; (2) explicit guidance for the monitoring, detection and reporting of safety concerns is needed for when events fall outside of well-defined acceptable parameters; and (3) clear dissemination of this information is needed for all primary care staff (administrative, managerial, clinical, etc). Going forward, this study also indicates that participants working in primary care settings are able to describe the areas of guidance, information and data that are needed to improve their capacity to monitor patient safety. As a starting point, this study has put forward participants' recommendations for improving safety monitoring in primary care with the intention for this to be an avenue for future work.

Strengths and weaknesses

A major strength of this study was that it incorporated a multiprofessional participant group at different levels of the healthcare system, resulting in a realistic case study account of the complexities of monitoring patient safety in the local NHS context. This is demonstrated by the stark differences amongst perceptions of monitoring at different levels of the local healthcare system even when individuals were describing the success of same monitoring strategy. As a local evaluation study, the involvement of national bodies such as the CQC was outside the remit of the present work. The CQC has recently undergone significant changes to its primary care services team and undertaken a national consultation on monitoring in GP practices which concluded after the

closure of this study (23). There is now room to explore the influence of these national changes on the local context. This study used snowball sampling to access key contacts in the local primary care system but due to the use of this method the extent the individuals selected are representative of any wider group is unknown. Snowball sampling can result in oversampling similar members of the population (14); however, attempts to address this were made by trying to access participants from a variety of organisations and in different professional roles. Additionally, the present study was conducted in a local primary care system and therefore may not be generalisable to areas other than NWL. The coding and thematic framework was developed by one researcher and so offers room for the replication and development of these themes and subthemes in other studies.

Comparison with other studies

Recent work has identified the failure to define quality in general practice (24) and, in a similar vein, the present study adds that this may extend to *safety* as well as *serious incidents* in primary care. This lack of shared understanding regarding concepts central to safe care stands in stark contrast to creating an NHS in safety is front and centre (22). This results of this study also support the recent report describing a wide range of disincentives to identify and report safety concerns which has led to a fear of speaking out about these issues (25). A number of participants raised concerns about the perceived failure to monitor out-of-hours care and urgent care centres. These findings are consistent with a recent parliamentary committee report that describes how monitoring these services has not been a priority for NHS England or the CCGs (26). This study found that there does not appear to be a systematic analysis of the vast dataset collected on individual practices or a clear sense of who has the responsibility to act on these data at the management levels. Therefore, the findings of this study support general conclusions from past work that there has been a long history of poor analysis of quality and safety data in primary care (27, 28). The present study also indicated that other work demands are being prioritised over patient safety. It serves to support the growing evidence that the increasing pressures and responsibilities put on GPs and primary care staff are limiting their ability to deal with issues related to patient safety (29-31). Whilst supporting other studies, these findings demonstrate trends that conflict with recent statements explaining that the NHS must transition to a culture in which safety is the main priority (22).

Implications for clinicians and policymakers

There were recommendations that the meaning of patient safety and serious incidents as they relate to primary care should be explicitly outlined, available in a succinct format, and any reports concerning primary care patient safety should be accompanied by clear action points in relation to the implications of the report for practice policies. Amid the confusion regarding protocols and procedures for reporting serious harm at practice level, and even amongst those working in agencies with a responsibility to monitor harm (NHS England, CSU, CCG governing bodies), there is an opportunity for developing and disseminating brief standardised guidance regarding how, and to whom, serious incidents in primary care are reported. This study also highlighted a host of participant-derived recommendations designed to improve safety which have clear implications for practice and improving patient safety in primary care.

Funding: This paper represents independent research supported by the National Institute for Health Research (NIHR) Imperial Patient Safety Translational Research Centre (grant number: P40490). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

Competing interests: None declared

Ethical approval: This study was deemed to be a service evaluation, and did not require NHS Research Ethics Committee approval. Appropriate local research governance permissions were sought.

Acknowledgements: The authors wish to thank the individuals who participated in the study. The authors are grateful for the funding and support from the NIHR.

Contributorship: PA and AB secured the funding. PA conceived the study idea. RS wrote the study protocol and recruited participants. RS collected and analysed the data and wrote the initial draft of the paper. RS, PA and AB revised the paper and approved the final version.

Guarantor: RS

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BMJ Open

Monitoring patient safety in primary care. An exploratory study using in depth semi-structured interviews.

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2015-008128.R1
Article Type:	Research
Date Submitted by the Author:	21-May-2015
Complete List of Authors:	Samra, Rajvinder; Imperial College London, Department of Primary Care and Public Health Bottle, Alex; Imperial College London, Department of Primary Care and Public Health Aylin, Paul; Imperial College London, Department of Primary Care and Public Health
Primary Subject Heading:	Qualitative research
Secondary Subject Heading:	General practice / Family practice
Keywords:	PRIMARY CARE, QUALITATIVE RESEARCH, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

Title: Monitoring patient safety in primary care. An exploratory study using in-depth semi-structured interviews.

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Key words: patient safety; primary health care; quality of care; monitoring; qualitative research; interviews

Word count: 2988

Number of tables, figures and boxes: 5

ABSTRACT

Objectives: To explore how information and data are used to monitor patient safety and quality of primary care by professionals working in, or supporting, primary health care.

Design: Qualitative study of semi-structured interviews with a directed content analysis of transcripts.

Setting: North-West London, UK.

Participants: Twenty-one individuals from various levels of the primary health care system were recruited, including general practitioners, practice nurses, practice managers, members of CCG governing bodies, and senior members of regional patient safety teams.

Results: Participants described being overwhelmed with complicated data which lacked any meaningful analyses about safety and quality. There was also a lack of clarity over which patient safety events are expected to be reported or monitored. Participants also reported uncertainty on whose responsibility it was to act on patient safety information or concerns. At the practice level, there was a range of disincentives for responding to and acting on safety issues and concerns, with few reported benefits. Participants made recommendations to improve future monitoring.

Conclusion: There is a need for clearer information in the form of specific guidelines, policies and procedures with regard to who monitors patient safety in primary care, what is monitored, and how it should be monitored.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study employed a multiprofessional participant group at various levels of the primary care system, providing a more realistic account of the complexities of monitoring patient safety in primary care.
- The interview topics were focused on current barriers and facilitators to monitoring patient safety which, combined with the use of a directed content analysis, allowed an in-depth exploration of what works and what does not work for patient safety monitoring in primary care.
- Participants offered detailed and specific recommendations to improving the use of data to monitoring patient safety in primary care.
- These findings may not be generalisable to other healthcare agencies and organisations involved in primary care that were not represented in this study.
- This study took place in North-West London and the results may not reflect the experiences of those working in other areas.

INTRODUCTION

It is estimated between 37 and 600 patient safety incidents occurring in UK primary care per day (1). Despite this, the nature and extent of harm in primary care are still not well understood (1, 2). Beyond the basic reporting and publishing of quality and safety outcome indicator data (3), it is also unclear how primary care organisations, such as Clinical Commissioning Groups (CCGs), their member practices and local NHS England area teams collaborate to monitor patient safety. Past primary care patient safety research often has a tightly focused area of enquiry such as general practice computer systems or e-prescribing (4-6), incident reporting (7), and safety culture (8, 9). However, primary care is diverse, complex and collaborative (10), and a less top-down approach has been recommended (11). Additionally, studies that indicate ways to improve patient safety systems (4), tend to assume that provision of an improved system is sufficient for its uptake which is not necessarily the case (6, 12), especially given the unprecedented time and resource demands on UK primary care staff (13, 14). There exists an opportunity to consult primary care staff for a realistic picture of whether, and how, they collaborate to monitor patient safety. Drawing on the tradition of qualitative enquiry into patient safety (4, 6), this study uses informant interviews in North-West London (NWL) to explore how patient safety is currently monitored in primary care settings. Patient safety is defined as the *"reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum"* (15).

METHODS

Study design

This study used in-depth semi-structured interviews which were suited to exploratory aims of the study (16). An interview guide was used to ensure that some core questions were asked of all participants, but also allowing flexibility to follow up novel information (17).

Participants and procedures

Twenty-one individuals participated in the study. Individuals working in GP practices and those supporting and monitoring the delivery of these services (CCG governing body members and the NHS England regional patient safety and quality teams) in NWL were eligible for the study. Email invitations were distributed to members of the governing bodies of the eight NWL CCGs. Snowballing was employed through the use of email lists to CCG-member GP practices which allowed for identification and access to further relevant professionals. This method is useful when

the sampling frame is unknown and traditional random sampling is implausible (18). Once data saturation was reached after 21 interviews (19), no further participants were recruited.

Data collection

Interviews took place between June and September 2014 in a private office at the participants' workplace. Interviews ranged from 29 to 47 minutes and were audio-recorded. Interviews were conducted by one member of the research team (RS) who had previous training in interviewing healthcare staff and holds a PhD in applied psychology. Participants were informed that RS was a research associate and did not hold any clinical or management roles in any healthcare organisations. The interview guide was piloted on the first three participants. For all interviews, participants were asked to first provide their own description of patient safety, and then instructed to consider patient safety as relating to when a patient has been harmed or injured as a result of their care or lack of care. An interview guide is included (Box 1). This study was a service evaluation (20) and therefore did not require NHS Research Ethics Committee approval (21), but local research governance permissions were sought. Participants were given a study information sheet and gave informed consent.

Box 1 Interview guide

1. What does the phrase 'patient safety' mean to you?
2. Can you describe any ways of identifying cases where there have been medical errors or patients have been harmed by their care?
3. Are there any ways of sharing information about patient safety events or near misses with others who work in primary care?

   Prompts: Can you describe these?

   How often does this happen?
4. If there was a growing concern where the same patient safety adverse event was occurring in a particular area/practice/your practice, how would this usually be flagged up to you?
5. Are there any ways in which you think the data supporting patient safety in primary care could be improved?

   Prompt: do you think these analyses adequately represent trends in patient safety and quality of care?
6. With the information and feedback channels that exist, do you feel that primary care practices where there are safety issues are currently being identified with a good degree of accuracy?

   Prompts: Why/why not?

   How could this be done better?
7. In terms of monitoring patient safety in primary care, what makes this difficult for you?
8. Are there any things that would make it easier to monitor patient safety in primary care?

Data analysis

Interview transcripts were subjected to a directed content analysis (22), a form of thematic analysis in which some coding categories are predetermined in lines with the aims of the study (23, 24). These predefined categories were: the current methods of identifying patient safety events; perceived barriers and facilitators; and recommendations for the future. Transcripts were coded by one member of the research team (RS). Any other relevant statements were given new codes at this stage, which culminated in the final coding framework. The coded data were investigated for relationships which linked them. These became subthematic level data and relationships between

subthematic data became the overarching main themes. The final thematic framework (Box 2) was developed by one researcher.

Box 2 Thematic framework: Monitoring patient safety in primary care

(1) Access to information and data

a. The overwhelming number of performance measures

b. Variability in receiving patient data in the GP surgery

c. Access to (meaningful) analyses/data about safety

(2) Clarity of policies and guidelines

a. Operationalisation of patient safety and patient safety-related events

b. Local variation in policies and protocols

(3) Responsibility and action

a. Ownership of the issue

b. The lack of visible monitoring in primary care

c. Prioritising other pressures over safety and quality

d. Disincentives to report potentially serious incidents

e. Dependence on informal human vigilance and feedback

RESULTS

Twenty-one individuals participated in the study (Table 1). The three main themes are presented with data from the interview transcripts (with the participant identifier) to reflect the main points of interest.

Table 1 Interview participant characteristics

Identifier	Professional role/s	Gender	Job experience (in years)
CCG1	Clinician* with CCG governing body role	Male	24
GP1	GP	Male	1
CCG2	Clinician with CCG governing body role	Male	8
GP2	GP	Female	8
GP3	GP	Male	15
CSU1	Safety & Quality executive at NWL CSU	Female	8
CCG3	Clinician with CCG governing body role	Female	18
NHSE1	Safety/quality executive at NHS England	Female	1
GP4	GP	Female	13
NHSE2	Safety/quality executive at NHS England	Female	1
GP5	GP	Female	12
GP6	GP	Female	12
CCG5	Clinician with CCG governing body role	Male	20
CCG6	Clinician with CCG governing body role	Male	20
PM1	Practice manager	Female	16
GP7	GP	Male	25
CCG7	Safety/quality executive in CCG	Male	2
NHSE3	Safety/quality executive at NHS England	Female	1
CCG8	Clinician with CCG governing body role	Female	28
NHSE4	Safety/Quality executive at NHS England	Male	2
PM2	Practice manager	Female	6

*Clinicians – job experience denotes years worked after medical qualification; non-clinician - job experience denotes years worked in current role.
**Clinician denotes general practitioner, nurse or secondary care practitioner – exact profession is not specified as data would be identifiable.

Access to information and data

Participants reported an overwhelming number of performance measures, which did not reflect patient safety but were considered a mechanism for remuneration: "*You get fixated on depression because that's what you're being paid for… So you tend to ignore other mental health co-morbidities because depressions the one you're focusing on*" *(GP1)*. Individuals working in general practice reported not knowing which harms they should be evaluating to monitor safety: *"If they set out really clearly, 'we believe that these five things would really improve patient safety and so we want*

you to report to us, every single medication error, every single needle stick injury'… We could then do that. I suppose that's the problem, it's just so wide at the moment in primary care that we're never really sure" (PM2).

GPs simultaneously spoke of too little and too much information on discharge summaries *("… lots and lots of information about various tests that the patients have had but it's information that I actually don't have the expertise to interpret", CCG3).* Not knowing what occurs to patients after a referral to district nursing was a concern *("…referral to district nursing – it's like dropping it into a black hole. You don't know if the nurse has ever seen the patient or whether what you've asked to be done has been done", CCG3)*. There were issues around receiving letters/communication in a format incompatible with the system holding the patient records in the practice, in which case pertinent information was manually entered into the patient's record by practice staff which created a lot of opportunity for error: *"if there's ten or fifteen medications which is not uncommon with patients, that could be a really big problem… every possible error, from transcription error on names of medication or dosages, lengths of time that the patient's expected to be on the medication – be it permanent or short-term - loads of room for error on that"* (*GP7*).

Participants from NHS England reported that no core metrics were routinely analysed for safety monitoring *("it's very underdeveloped…The honest answer is we don't have a set of metrics that we look at", NHSE1)*. Instead, the accessible data were manually scanned for red flags. These data may be discussed at operational group meetings every one or two months, but these meetings were described as fixated on trying to get through the information collected through secondary care quality and safety indicators: *"We're trying to look at those. There's hundreds. There's literally about two hundred. Three hundred" (CCG7).* Participants from management organisations (NHS England, CCG governing boards and the CSU) tended to report that safety data (such as serious incidents) and complaints were distributed across and within a number of organisations ("*It's distributed across NHS England: the revalidation team, the performance list team, the contract managing team, and so on.")* with recommendations to collate this information in the future.

Theme 2. Clarity of policies and guidelines

Across participants, there was no consensus on the meaning of the term 'patient safety' in relation to primary care because the concept was considered vague or they described it as everything in the medical process: *"it could mean all sorts of things… So it's everything actually. Patient safety is everything we do*" (*GP5*). Additionally, it was not clear what constituted a serious incident, whether reporting was mandatory, and where to report them. Participants explained that serious harm and

never events had an acute focus and that general practice was comparatively safer: "*you think 'well, compared to that, our risk is zero' so it feels like an overreaction to follow some of this process" (PM2)*. Different methods for reporting patient safety incidents (such as emailing or ringing up a local or national team at NHS England, completing an incident report form from NHS England, or anonymously reporting through the NRLS) appeared to result in confusion about which agency the information was received by and which of these methods satisfied mandatory reporting requirements, even amongst those at the CCG governing board level: *"I struggle when I ask the question to get any sense of the mechanisms by which general practitioners might report, or anybody in general practice might report, the mechanisms by which patients might report their concerns… I have no idea. And my suspicion would be that nobody has any idea." (CCG6).*

Some GPs reported having carried out informal safety monitoring evaluations or audits in the past. This type of monitoring was optional, variable and time-intensive: *"Looking at your prescribing rates compared to somebody else… GPs are having to do that by hand and that's why they might do it one year, skip it another year … you might be looking at methotrexate and all the anti-tumour drugs that might be prescribed. So you're covering so many areas you do not have time to do every single one. If somebody could do that and just present the data…" (GP2)*. Multiple GPs mentioned that they needed more guidance about which drugs to monitor and the frequency of medication reviews (especially for long-term medications and high-risk drugs) for repeat prescribing. Specifically they were interested in: *"all the drugs that patients take where monitoring is recognised and recommended and then, what are the monitoring intervals and what are the ranges that are acceptable?" (CCG2).*

Theme 3. Responsibility and action

At the management level, there were conflicting responses about whose responsibility it was to monitor patient safety in primary care. CCG governing body members generally reported that monitoring safety was outside of their remit and lay with NHS England, whereas participants from NHS England saw themselves as part of collaborative effort with CCG governing bodies and the practice networks. There was the mention of the fact that the CCGs do *"have this vague responsibility for quality [improvement] in general practice, whatever that's supposed to mean" (CCG3)*. Participants from NHS England and the CCG governing bodies also reported conflicting responses about who monitors patient safety in urgent care centres and for out-of-hours services, with some GPs stating that it appeared that nobody was monitoring these services: "*And urgent care centres are making huge amounts of money but the quality of care – who's questioning that? … Do*

we have any data on the safety of prescribing or drug errors or prescribing errors in urgent care centres, is anyone looking at that – even out of hours?" (GP6).

Participants from CCG governing bodies and NHS England spoke at length about how GP practices managed their incidents locally and made use of networks or peer groups (of 6 to 11 practices meeting monthly) to check up on each other and share information. However, participants working in GP practices reported using these meetings to make sense of recent changes to policies instead of discussing patient safety. Additionally, likeminded poor performers may seek work together to avoid detection, referred to interviews as *"collusion" (CCG8)*. Almost all participants reported that they had local knowledge about which practices were and were not safe and that the focus of patient safety monitoring should be on these types of practices, with some identifying single-handed or two-handed practices as a cause for concern: *"There's a pattern of poor performance in men, over 50, who trained abroad, who didn't train in the UK, and who are single handed, small, very small practice and probably have got poor premises. They're high indicators of underperformance… the trouble is the trained abroad stuff, is politically very sensitive" (NHSE4).*

Participants who worked in practices frequently described the difficulty of managing time pressures on an average work day. GPs reported not having the time to fill in incident report forms or conduct safety audits: "*although there are areas where we are asked to collect data, we're just so busy and so stretched that we don't really do it… we hold the minor surgery service and in theory we try to run an audit of, or we try to keep a record of if there's post-operative infections. But actually to do that properly, it's really difficult, so we don't do it properly" (CCG2).* Many GPs explained that it was difficult to be safe in a ten to fifteen minute appointment in which patients often bought multiple serious health and social concerns to the same appointment due to having access to care issues: *"But I think primary care's really dangerous right now to be honest. I am getting quite near to the feeling that I don't want to carry on doing it." (CCG2).*

For a number of reasons, the recommended protocol for dealing with a potentially serious incident was not always followed: *"so what I should be doing is logging it on that, sending it off to them. To be honest, almost never happens" (CCG3)*. Other than lack of time, participants' feared blame, organisational and personal repercussions that were amplified if the potentially serious incidents involved a senior GP. Multiple GPs reported the belief that NHS England would not or could not act on the evidence, and that this deterred them: because "*the onus is on that GP and so on top of your normal workload, and for the fear of being isolated and victimised, who's going to do that? It's easier to walk away from it" (GP6).* The failure to report incidents outside of the practice was attributed to a number of factors, including a workplace culture that mistakes were deemed to be *"within*

acceptable limits even though in fact if one was to have the hard evidence and comparative with what's going on on a national basis, you might find that you are a complete outlier" (GP7).

Summary

Participants' reports of the barriers to monitoring patient safety in primary care are outlined in Table 2 and their recommendations for the future are provided in Table 3.

Table 2 Perceived barriers to using data to monitor safety

Perceived barriers
Lack of information about district nursing activity delivered to patients' GP
Lack established regional/national protocols regarding monitoring of repeat prescribing or high-risk drugs
Information received from hospitals is too basic or too complex for GP
Lack of examples of serious harm or never events that are applicable to primary care settings for which to monitor
Limitations to involvement of salaried and locum doctors with QOF data
Too many inappropriate pop-up warnings on GP clinical systems
Limited and unreliable data on serious incidents
Lack of specifically allocated time to look at practice-held data or QOF statistics on patient safety
Local practice network meetings designed for some patient safety peer monitoring used for other purposes
Organisation holding safety data may not have power to investigate patient safety threats
Majority of time at operational group meetings dedicated to hospital patient safety monitoring
Lack of safety metrics routinely analysed at NHS England (London region)
Limited access to existing safety data as it is divided in terms of the organisations that hold it and within departments in these organisations

Table 3 Recommendations for improving data to monitor safety

Recommendations
For hospital information, clearly outline changes to patient medical and/or medication status and clearly outline action plan for GP follow up and monitoring
Share copy of district nursing care plan with GP
Hospital information should have READ-codes applied to avoid error during information transfer
Provide data on missed appointments in other parts of healthcare system to patient's GP, especially required for those at high risk (e.g. frail, elderly)
Collate all patient safety and quality information (including complaints) in one source document which is shared within and between organisations that have a duty to monitor patient safety.
Provide spreadsheet feedback charts (colour coded: red, amber, green) on prescribing rates data relating to safety (e.g. non-formulary drugs, drugs with boxed warnings)
Provide list of five to ten patient defined safety events for practices to identify, clinically code in the patient record, and monitor
Supply rapid discharge summaries from hospital for other serious illnesses (e.g. meningitis, sepsis or lower respiratory tract infections)
Identify all drugs in which monitoring is recognised; provide a list of the recommended monitoring intervals and acceptable ranges
Need for computerised automatic safety monitoring audits for known risks (e.g. unsafe combination of drugs, long-term use of short-term medication)
Provide a one-page outline on what a patient safety event is, how and where it should be reported for practices to display in waiting rooms
Provide a safety reporting system for suspected problems which need further investigation
Provide a safety reporting system which all primary care practice staff have access to
Up-to-date (live) patient care record shared between all the patient's NHS healthcare providers

DISCUSSION

This study's findings demonstrate that patient safety and patient safety events, such as serious incidents, appear ill-defined in primary care, and therefore it is unclear on the ground what is to be monitored. Patient safety monitoring was perceived to be voluntary, with time and resource constraints dictating that other tasks frequently took priority over safety monitoring. At the management level, the information about patient safety was divided between, and within, various organisations. There was an absence of clear and explicit monitoring strategies and ownership of the issue. This study indicates that there may be a need to establish a clear focus on patient safety in primary care, which requires: (a) a detailed operationalisation of core concepts relating to safety in primary care; (b) explicit guidance for the monitoring, detection and reporting of safety concerns is needed for when events fall outside of well-defined acceptable parameters; and (c) clear dissemination of this information is needed for all primary care staff (administrative, managerial, clinical, etc) with action points. These findings indicate the need to make the patient safety agenda (25) more explicit in primary care.

Strengths and weaknesses

This study incorporated a multiprofessional participant group at different levels of the local healthcare system, resulting in a realistic case study account of the complexities of monitoring patient safety. As a local evaluation study, the involvement of national bodies such as the CQC was outside the remit of the present work. The CQC has recently undergone significant changes to its primary care services team and undertaken a national consultation on monitoring in GP practices which concluded after the closure of this study (26). This study used snowball sampling which can result in oversampling similar members of the population (18); but attempts were made to access participants in range of organisations and professional roles. The present study was conducted in a local primary care system and may not be generalisable to areas other than NWL. The coding and thematic framework was developed by one researcher and so offers room for the replication and development of these themes in future work.

Comparison with other studies

Recent work has identified the failure to define quality in general practice (27) and, in a similar vein, the present study adds that this may extend to *safety* as well as *serious incidents* in primary care. This lack of shared understanding regarding concepts central to safe care stands in stark contrast to

creating an NHS in safety is front and centre (25). Concerns were raised about the failure to monitor out-of-hours care and urgent care centres, which is consistent with reports that monitoring these services has not been a priority for NHS England or the CCGs (28). This study found that there does not appear to be a systematic analysis of the vast dataset collected on individual practices or a clear sense of who has the responsibility to act on these data at the management levels. Therefore, the findings of this study support general conclusions from past work that there has been a long history of poor analysis of quality and safety data in primary care (29, 30). The present study also supports the growing evidence that the increasing pressures and responsibilities put on GPs and primary care staff are limiting their ability to deal with issues related to patient safety (13, 14, 31).

Implications for clinicians and policymakers

An operationalisation of *patient safety* and *serious incidents* specifically addressing primary care should be explicitly outlined, and available in a succinct format. Primary care patient safety reports should be accompanied by clear action points for GP practices. The development and dissemination of brief standardised guidance regarding how, and to whom, serious incidents in primary care are reported is recommended. Participants provided recommendations for improved monitoring of safety, which have clear implications for practice and policy.

Contributorship: PA and AB secured the funding. PA conceived the study idea. RS wrote the study protocol and recruited participants. RS collected and analysed the data and wrote the initial draft of the paper. RS, PA and AB revised the paper and approved the final version.

Competing interests: None declared

Funding: This paper represents independent research supported by the National Institute for Health Research (NIHR) Imperial Patient Safety Translational Research Centre (grant number: RDPSC 79560). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

Data sharing: No additional data available.

Ethical approval: This study was deemed to be a service evaluation, and did not require NHS Research Ethics Committee approval. Appropriate local research governance permissions were sought.

Acknowledgements: The authors wish to thank the individuals who participated in the study. The authors are grateful for the funding and support from the NIHR.

Guarantor: RS

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Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Submission to BMJ Open

Title: Monitoring patient safety in primary care. An exploratory study using in depth semi-structured interviews

Authors: Rajvinder Samra, Alex Bottle, Paul Aylin

No	Item	Guide questions/description	Response
Domain 1: Research team and reflexivity			
Personal Characteristics			
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?	Rajvinder Samra conducted all interviews
2.	Credentials	What were the researcher's credentials? *E.g. PhD, MD*	BSc Psychology, MSc Occupational Psychology, PhD Applied Psychology
3.	Occupation	What was their occupation at the time of the study?	She was a research associate at Imperial College London
4.	Gender	Was the researcher male or female?	Female
5.	Experience and training	What experience or training did the researcher have?	RS had conducted over 50 interviews with medical healthcare professionals as part of her PhD study. She received training in interview techniques and qualitative analysis as part of her PhD and her primary PhD supervisor was a qualitative researcher.
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	RS did not personally know, nor had she met any of the participants prior to the study commencement.
7.	Participant knowledge of the	What did the participants know about the researcher? e.g.	Participants were told that RS was a

No	Item	Guide questions/description	Response
	interviewer	*personal goals, reasons for doing the research*	research associate in the department of primary care and public health at imperial college and she was exploring issues around patient safety and quality of care in primary care.
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic*	Participants were also told that RS had a psychological background and did not have a medical background, and did not work for the NHS.
Domain 2: study design			
Theoretical framework			
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*	We used a direct content analysis, which is based on content analysis (see reference 18: Hsieh H-F, Shannon SE. Three approaches to qualitative content analysis. Qualitative Health Research. 2005;15(9):1277-88.)
Participant selection			
10.	Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball*	Participants were recruited through snowball sampling.
11.	Method of approach	How were participants approached? e.g. *face-to-face, telephone, mail, email*	Participants were approached via email.
12.	Sample size	How many participants were in the study?	21
13.	Non-participation	How many people refused to participate or dropped out? Reasons?	We are not aware of anyone who refused or dropped out (after consenting).
Setting			
14.	Setting of data collection	Where was the data collected? e.g. *home, clinic, workplace*	Participants' workplace
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	No.

No	Item	Guide questions/description	Response
16.	Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date*	Participants' professional role, gender and job experience are provided in Table 1 of the manuscript
Data collection			
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	The interview guide is provided in Box 1 of the manuscript. It was pilot tested on other research staff, and following this, it was piloted on the first three participants to ensure the wording was easy to understand and the questions and question order were logical.
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?	A digital Dictaphone was used to record the interviews
20.	Field notes	Were field notes made during and/or after the interview or focus group?	No.
21.	Duration	What was the duration of the interviews or focus group?	Interviews ranged from 29 to 47 minutes.
22.	Data saturation	Was data saturation discussed?	Yes. Data collection ended when saturation was reached.
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No. Transcripts were checked for accuracy by Rajvinder to ensure it was consistent with the audio-recording
Domain 3: analysis and findingsz			
Data analysis			
24.	Number of data coders	How many data coders coded the data?	One
25.	Description of the coding tree	Did authors provide a description of the coding tree?	Yes, the some of the predefined codes were described (as it was a directed content analysis). These included: the

No	Item	Guide questions/description	Response
			current methods of identifying patient safety events; perceived barriers and facilitators; and recommendations for the future
26.	Derivation of themes	Were themes identified in advance or derived from the data?	Some codes were identified in advance but the themes were derived from the data
27.	Software	What software, if applicable, was used to manage the data?	Data was sorted using Microsoft excel
28.	Participant checking	Did participants provide feedback on the findings?	No.
Reporting			
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. *participant number*	Yes
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31.	Clarity of major themes	Were major themes clearly presented in the findings?	Yes, see Box 2 for major and minor themes. The findings are presented at the level of the major themes and these headings were used.
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes, the minor themes are included in Box 2 and included in the findings to the extent that the word count permitted and where the minor themes were deemed to be informative and interesting to the reader.