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Title: Feeling unsafe within the healthcare system: the patients' perspectives on contributory factors. An integrative review of the literature.

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Feeling unsafe within the healthcare system: the patients' perspectives on contributory factors. An Integrative Review of the literature.

Background

Feeling safe has been explained as an existential feeling of security that, if absent, leads to anxiety (Sandler and Sandler 1999). Definitions of feeling safe include factors as feeling secure and enjoying freedom from harm (Mollon 2014). There is recognition amongst healthcare professionals that patients normally feel anxious in the healthcare setting however, the assumption that feeling unsafe is merely the absence of feeling of safety is an easily made, but incorrect, assumption. Patients do not necessarily feel unsafe if errors occur (Schwappach 2010), neither do they necessarily feel safe if all is done to make some so. The recognition of safety as being both a psychological and physical perception is addressed in some, but not all, of the literature (Stenhouse 2013), and the recognition of the role of perceived threat as a subjective perception is not always recognised.

The original aim of this study was to conduct an integrative review to synthesise studies of patients' experience of feeling unsafe in healthcare settings. However, few studies were found and the review was broadened to include papers whose aim it was to consider feelings of safety but also uncovered incidental data on feeling unsafe. The review considered qualitative and quantitative studies that were conducted taking into account solely the patient perspective.

Research design

The design of the review uses Cooper's (1982) five-stage integrative review method modified by Whittemore and Knafl (2005) to produce a framework for integrative reviews. This framework allows for sufficient integrity to account for the diversity of study types in healthcare. The five stages involve; problem identification, data collection, evaluation of data, analysis and interpretation of data and presentation of results (Whittemore and Knafl 2005).

Problem identification

Problem identification was based on the recognition of the current debates within patient safety that predominantly view safety from the perspective of the clinician or organisation (Ocloo 2010). The absence of patient voices in the research literature is particularly pertinent in the current rhetoric of quality improvement and safety that pervades the NHS since the Francis Inquiry in 2013 (Francis 2013). The studies selected relate to patient feelings of safety, but in exploring feelings of safety, each study has something to say about what factors contributed to patients feeling unsafe. The broad evidence-based theory around this issue comes from qualitative and quantitative studies and therefore

in order to capture as much information as possible it is pertinent to consider studies employing both types of design. An integrative review therefore was chosen to identify and synthesise the variety of information presented via these studies (Souza 2010)

Data collection

A limit was placed on reviewing studies published since 2002. The rationale for this date limitation was the recognition of the impact and change in culture and patient safety practices that followed the publication of '*An Organisation With A Memory*' by Liam Donaldson in 2002. Although this publication did not change practice immediately, the impact upon the context of safety and learning from events was quickly evident. Information was retrieved using three electronic databases, Cinahl Plus, Medline and PsycARTICLES, between February 2016 and June 2016. Articles were systematically selected in stages as demonstrated in Fig 1. The final search terms, order of search and subject headings are demonstrated in Fig 1, which reflects the PRISM flow diagram (Moher et al 2009). Limiters were established that searched for articles published in English between 2002-2016. Academic journals were considered and duplicates were removed along with studies that failed to give primacy to the view and perspective of patients with regards to safety. Thirteen articles were selected and were subject to the next stage of the process. An additional hand search of reference lists from the selected articles was carried out and potential titles and their abstracts were explored for relevance. From this search a total of one additional article was identified. Fourteen articles were then subjected to the quality evaluation process.

Evaluation of data

Six descriptive criteria, modified and based on Bowling (2014) were used to consider the quality of the selected articles (Table 1). Following this evaluation process, no articles were excluded and therefore fourteen articles were taken to the next stage of the data analysis and interpretation.

Analysis and interpretation

Analysis commenced with all papers being read to gain a comprehensive overview of the content and the general direction of the study, method and findings. Each article was recorded, re-read and data extracted with the purpose of generating codes as per Braun and Clarke's (2012) approach to thematic analysis. This process is illustrated in Fig 2.

Fig 1. Search strategy and process used for Integrative literature review

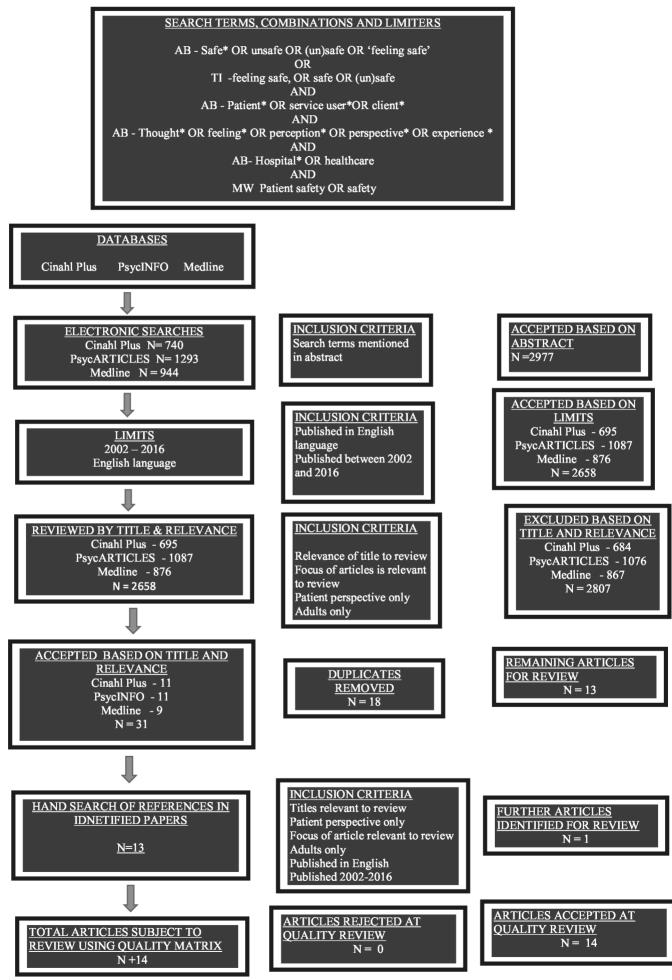


Table 1. Summary and quality appraisal for literature review

No	Title					Ouality ar	praisal criteria		
		Year	Country of origin	Aims & objective clearly described	Study design adequately described	Research methods appropriate	Explicit theoretical framework	Limitations presented	Implications discussed
1	Psychiatric wards: Places of safety? Journal of Psychiatric and Mental Health Nursing, 17, 124–130	2010	England	Yes	Yes	Yes	No	No	Yes
2	Older adults' perceptions of feeling safe in an intensive care unit. <i>Journal of Advanced Nursing</i> 67(12), 2649–2657.	20 11	USA	Yes	Yes	Yes	Yes	Yes	Yes
3	Patients' experiences of safety during haemodialysis treatment – a qualitative study. <i>Journal of Advanced Nursing</i> 71(10), 2374–2383	2015	Netherlands	Yes	Yes	Yes	Yes	Yes	Yes
4	Feeling safe during an inpatient hospitalization: a concept analysis. <i>Journal of Advanced</i> <i>Nursing</i> 70(8), 1727–1737.	2013	USA	Yes	Yes	Yes	Yes	Yes	Yes
5	Am I (un)safe here? Chemotherapy patients' perspectives towards engaging in their safety. <i>Quality</i> and Safety in Health Care 2010;19 1-6	2010	Switzerland	Yes	Yes	Yes	No	Yes	Yes
6	'Safe enough in here?': patients' expectations and experiences of feeling safe in an acute psychiatric inpatient ward. <i>Journal of Clinical</i> <i>Nursing</i> , 22, 3109–3119.	2012	Scotland	Yes	Yes	Yes	Yes	Yes	Yes
7	Patients' Perceptions of Care and Safety Within Psychiatric Settings. Psychological services 2007, Vol. 4, No. 3, 193–201	2007	USA	Yes	Yes	Yes	Yes	Yes	Yes
8	Factors promoting intensive care patients' perception of feeling safe: a systematic review. <i>International</i> <i>journal of nursing studies</i> , 51(2), pp.261-273.	2014	Netherlands	Yes	Yes	Yes	Yes	Yes	Yes
9	Am I safe here? improving patients' perceptions of safety in hospitals. Journal of nursing care quality, 21(1), pp.30-38.	2006	USA	Yes	Yes	Yes	No	Yes	Yes
10	Putting the 'patient' in patient safety: a qualitative study of consumer experiences. <i>Health Expectations</i> , 15(3), pp.327-336.	2012	USA	Yes	Yes	Yes	Yes	Yes	Yes
11	The experience of trauma resuscitation in the emergency department: themes from seven patients. <i>Journal of Emergency</i> <i>Nursing</i> , 30(3), pp.216-224.	2004	Canada	Yes	Yes	Yes	Yes	Yes	Yes
12	Patients' understandings and feelings of safety during hospitalization in Iran: A qualitative study. (2011) <i>Nursing & health</i> <i>sciences</i> , 13(4), pp.404-411.	2010	Iran	Yes	Yes	Yes	No	No	Yes
13	Older adults' perceptions of feeling safe in urban and rural acute care. Journal of Nursing Administration, $43(1)$, pp.30-36.	2013	USA	Yes	Yes	Yes	Yes	Yes	Yes
14	Safety as experienced by patients themselves: a Finnish survey of the most recent period of care. <i>Research in nursing &</i> <i>health</i> , 37(3), pp.194-203.	2014	Finland	Yes	Yes	Yes	Yes	Yes	Yes

The initial codes were specifically around the issues of what factors that had emerged as contributing to patients feeling unsafe. Most studies looked at what made patients feel safe rather than unsafe, and so the search for codes that indicated feelings of being unsafe was not always explicitly connected to the themes identified in the specific articles. Where authors indicated specific incidences of what made patients feel unsafe, this was extracted as a code. Where authors identified factors that contributed to making patients feel safe it was not automatically assumed that an absence of these factors indicates that patients felt unsafe. Therefore, these factors were not extracted as data. Once these codes were attached to each particular feature, themes were identified and mapped onto a matrix to identify similarities, overlaps and clusters. The fourteen articles identified were from studies carried out in a range of settings across six different countries.

Presentation of results

The analysis was conducted by the lead author and were presented as a thematic analysis. A thematic analysis is an inductive approach that allows for extraction of the data based on the content and broad themes that emerge from the data itself (Braun and Clarke 2014. A thematic indicative approach was taken in this case to preference the patient voice, in line with the critical theory underpinnings of this study. The analysis was enhanced by the additional support of two doctoral supervisors who provided guidance in relation to procedures. From the data collected, seven themes were identified and PRISM guidelines were used to guide reporting of these themes (Moher et al 2009).

Description of studies reviewed

All articles were published between 2004 and 2015 and participants in all studies were all aged over 18. Nine studies were qualitative and three quantitative. One paper was a systematic review looking at both qualitative and quantitative data on perceptions of feeling safe in ITU, considering 11 studies published between 1950 and 2012 (Wassenaar et al 2014), and one was a concept analysis that referenced 31 articles published between 1999 to 2012 (Mollon 2014). The range of clinical settings, participants and geographical locations are set out in Fig 3. Of the ten qualitative studies, semi-structured interviews were used in seven studies (Jones et al 2009, Lasiter et al. 2013, O'Brian et al 2004, Schwappach et al. 2009, Vaismoradi et al. 2011, Rathert et al. 2011, Lasiter 2011), with the remaining two qualitative studies utilising unstructured interviews (Lovink et al 2015, Stenhouse 2013). The range of clinical settings, participants and geographical settings, participants and geographical settings, participants and geographical settings, participants and geographical settings utilising unstructured interviews (Lovink et al 2015, Stenhouse 2013). The range of clinical settings, participants and geographical locations in the quantitative studies are set out in Fig 3.

A total of seven themes emerged in the review. These were; information and communication, loss of control, staff presence, interpersonal care, patients vulnerable emotional and physical state, being taken seriously, and the perception of staff experience.

Information and communication. In 11 studies, it was identified that lack of information and communication contributed to patients feeling unsafe (Stenhouse 2013, Wassenaar et al. 2014, Lovink

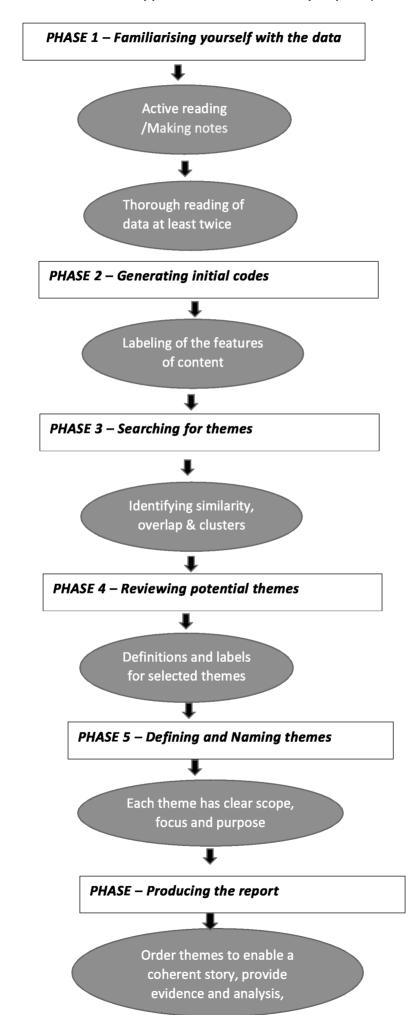


Fig 2. Braun and Clarke's Six Phase approach to thematic analysis (2012).

et al. 2015, Schwappach et al. 2010, O'Brian et al 2004, Mollon 2014, Wolosin 2006, Rathert et al. 2011, Vaismoradi et al. 2011, Lasiter 2011, Sahlstrom 2014). However, only one of these studies had explicitly recognised this as an actual category of 'communication and health information' (Rathert et al 2011). Aspects of information and communication were frequently cited as part of other broader categories such as 'not being forgotten' (Vaismoradi et al 2011), 'devices safety' (Sahlstrom et al 2014), 'presence of the nurse' (Lovink et al 2015) and other similar categories were established as factors in the data. Examples of poor information exchange were cited by patients and ranged from lack of communication about specific aspects of care such as not being told about crucial medication changes (Sahlstrom et al 2014), to being told that a care plan was not yet in place or more general principles of communication (Vaismoradi et al 2011). A general perception of a lack of quality assessment, planning or implementation of care is presumed by patients to contribute to their feelings of being unsafe.

Loss of control. Six studies explored the feeling of lack of autonomy, personal agency or ability to control one's own environment (Lasiter 2011, Wassenaar et al. 2014, Schwappach et al. 2010, O'Brian et al. 2004, Lovink et al. 2015 and Wolosin 2006). However, two studies make mention of a particularly interesting response. The participants, patients in one ITU setting, talk about the loss of their vocal abilities as being something that specifically makes them feel unsafe (Wassenaar et al 2014). The physical or psychological ability to tell staff if something was wrong was seen as a significant factor in contributing to patients feeling unsafe. Additionally, patients in a dialysis unit identify concern about being able to leave the unit quickly in the event of a fire (Lovink et al 2015). Patients trusted that the nurses would be able to facilitate the rapid exit, but did worry about this as something that made them feel less safe. This loss of ability to 'fight or flight' has not been indicated as a factor in any of the studies and would certainly warrant further consideration and research.

Staff presence. Jones et al (2010), Stenhouse (2013), Lasiter (2011), Lovink et al. (2015), Mollon (2014) and Rathert et al (2011), all identified that lack of staff availability, including visibility, presence-physically and psychologically, and perceptions of being 'short staffed', all added to patients feeling less safe (Rathert et al 2011). Lack of physical presence was perceived as being significant (Mollon 2014, Lasiter 2011), as was the lack of engagement with patients described as a lack of psychological or physical presence (Mollon 2014). The presence of staff was linked with the ability to summon help through various means, or with the ability of staff to check on patients, notice deterioration, monitor technology or other adjuncts to care, and to respond appropriately. The lack of staff presence was linked to an inability to summon care (Lasiter 2010), to be left alone, forgotten (Vaismoradi et al 2011) or ignored (Stenhouse 2013).

Interpersonal care. Five studies indicated that impersonal care made patients feel less safe (Wassenaar et al 2014, O'Brian et al. 2004, Mollon 2014, Wolosin 2006, Vaismoradi et al. 2011). Participants included factors such as nurses not taking note of the detail of care, patients feeling that

staff were not interested in them and their specific needs, and being treated as just one of many. Again, this theme links in to the personal engagement of staff with patients that is connected to the perceived ability of the nurse to understand what the individual patient needs.

Patients vulnerable, emotional and physical state. This theme encompasses factors such as when patients felt vulnerable, (O'Brian 2004, Wassenaar et al 2014), very seriously ill (Lovink et al 2015), or when they relied on specific equipment (Lovink et al 2015, Lasiter 2011). One of the studies (Sahlstrom 2014) indicated that patients reliant on medical devices felt unsafe when device alarms sounded, not understanding if this was a serious occurrence or what to do if a nurse did not respond in a timely way. Being vulnerable was discussed in depth by Sahlstrom (2014) and was said to be linked to a loss of control, dependency on others, and feeling helpless.

Not being taken seriously. In five studies, this factor emerged as being significant in contributing to patients feeling unsafe (Wassenaar et al 2014, Wolosin 2006, Rathert et al. 2011, Vaismoradi et al. 2011, Lasiter 2011). It seems that the perceived inability of staff to take concerns seriously and be dismissive of these, contributes to feelings of not being listened to. This linked to fears that if something goes wrong, for example patients indicate that that they feel unwell, then their experience as an early warning of deterioration or error is not responded to by staff.

Patient perception of lack of staff experience, knowledge, proactivity and interest. Stenhouse (2013), Lasiter (2011), Lovink et al. (2015) and Mollon (2014), all found this as a theme within their studies and participants mentioned this as a contributory factor to feeling unsafe. This theme was often about the inability of staff to convey their competence to patients. Patients who perceived that staff were unsure, preoccupied, or under confident were clear about the fact that this contributed to feeling unsafe in their care.

Discussion.

This review presents a synthesis of factors extracted from studies that did not explicitly look at feeling unsafe, but focused on the issue of feeling safe. In discussing safety, and what contributed to patients feeling safe, there were inevitable discussions about what made patients feel unsafe. It is the explicit references to these factors that shaped the coding and the development of themes for this study. The rationale for this approach is that there is simply a paucity of studies that explicitly look at the factors that contribute to patients feeling unsafe. Superficially, the themes identified seem straightforward. However, two further overarching categories allow for additional theoretical consideration of the patient experience. These categories encompass the following and were seen by patients as a high risk or threat to safety:

1. Perceived availability of helpers and willing engagement in helping when needed - inability to summon help due to lack of staff (staff presence), understanding of personal need (the perception of staff experience, impersonal care, being taken seriously), and patients'

understanding of risk (information communication). Generally, this group of themes are not safety issues as relating to unsafe practice. While the themes are not best practice, they fall in the category of service quality deficits - systems and processes not working properly, poor quality and ineffective care rather than care that is overtly unsafe. However, patients perceived this lack of quality to be much more than merely poor quality, but to be unsafe. Some themes lend themselves to the recognition that activities such as poor communication can and do contribute to a culture of unsafe care. This is recognised by some studies and is acknowledged as being a rationale for improving quality.

2. Inability to summon help due to patient vulnerability - such as the loss of voice, inability to move, or not knowing who to engage the help (loss of control, patients vulnerable, emotional and physical state).

There was a sense that if patients were not in control of what had happened to them, then staff would take control of care, be an advocate championing the needs of patients. Factors that made staff less available, less interested or informed about individual patients contributed to patients feeling less confident that this would happen and less safe. Significantly, there was little discussion that indicated patients were concerned with errors, even those who had experienced an error in care previously (Schwappach et al 2010). Errors were mentioned as something that patients were aware of and worried about on occasions, but there was recognition that where the subject of errors was discussed an absence of errors did not mean the patients always felt safe.

The concept of perceived threat or risk posed by lack of availability of help and inability to summon help fits well with the model of vulnerability developed by Judith Spiers (2000). Spiers identifies the concept of perceived risk and personal experience as contributing to feeling vulnerable and that personal and environmental factors influence the degree of vulnerability. In relation to the two broad categories suggested in this paper, patients perceive the possible lack of availability of helpers and the inability of themselves to summon help as a significant risk and this risk is suggested as a contributory factor to their feeling unsafe. In an environment where patients may not feel they can employ the normal responses associated with risk or threat; raising the alarm, summoning help, or using their 'fight or flight 'response, the recognition of potential threats becomes very frightening. This inability to respond in the usual way to a threat promotes a feeling of helplessness that is suggested as a significant factor in what makes patients feel unsafe. Within the studies, patients said that the contributing factors were predominantly around the recognition of poor quality. The manner in which these quality deficits were articulated by patients meant that many researchers focused on the explicit nature of the factor rather than considering the broad nature of patient safety and quality. Therefore, deeper questions about what it was about each factor that specifically impacted upon safety seems to be lacking. The assumption, for example, that nurse availability is an important aspect of patients feeling safe, and that when nurses were not available patients felt less safe, has been identified as a factor in a number of studies. However, what is it about nurses' presence that promotes feelings of

safety. This is not pursued well in any of the studies. Reviewing several studies together enhances understanding each factor. Additionally, this synthesis has allowed factors to be grouped together as suggested in this study into two broad factors that give a different perspective to the view that these factors are merely service deficits. Rathert et al (2011), in her study, does recognise that patients equated safety with good quality service and when interviewed, patients cited lapses in quality as 'unsafe events' (p 328). Other studies did not make that link, even though factors raised by patients were very similar to those raised in Rathert's study.

In summary, the seven themes identified are in fact quality deficits rather than practice that might be deemed by professionals as unsafe. Errors, while recognised as being worrying for patients do not necessarily make patients feel more unsafe, neither does the absence of errors make patients feel safe. The themes identified can be put broadly into two groups that indicate that patients feel vulnerable and often helpless to some degree, predominantly because they perceive a lack of available individuals to engage in the task of helping them should they need help, and an inability to ask for help if it were needed. As patients' cannot always help themselves, eliciting help from others is a key part of the response to threat to physical and psychological integrity in the face of not being able to run or defend themselves - the fight or flight response.

Limitations of this study

This study looked at the literature around feeling unsafe within the healthcare system. Factors have been extracted from studies that did not explicitly look at feelings around being unsafe, but focused on feeling safe. In discussing safety there are inevitable discussions about what made patients feel unsafe. It is the explicit reference to these factors that shape the development of the themes for the study. This in itself is a limitation.

Conclusion

Responses to threat are both psychological and physiological and can contribute to the poor recovery of patients in clinical settings, resulting in longer recovery times and less positive health outcomes. Patients do not just feel unsafe when an error occurs, but also where service quality is noticeably poor and a recognition of a lack of quality is perceived as an indication of potential threat. It is that may contribute to patients feeling unsafe within the healthcare setting. Often simple things can be done to reduce the unsafe feelings patients have by improving quality as much as reduction of errors, and by ensuring that patients have strategies to summon help or ways of indicating distress that are acknowledged by staff. This improvement in quality would not just be a response to the quality agenda within healthcare setting, but should also be part of the patient's experience of safety.

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