Title: Developing a Patient Measure of Safety (PMOS)

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Abstract

Background: Tools that proactively identify factors that contribute to accidents have been developed within high-risk industries. Although patients provide feedback on their experience of care in hospitals, there is no existing measure which asks patients to comment on the factors that contribute to patient safety incidents. The aim of the current study was to determine those contributory factors from the Yorkshire Contributory Factors Framework (YCFF) that patients are able to identify in a hospital setting and to use this information to develop a patient measure of safety (PMOS).

Methods: Thirty three qualitative interviews with a representative sample of patients from six units in a teaching hospital in the north of England were carried out. Patients were asked either to describe their most recent/current hospital experience (unstructured) or were asked to describe their experience in relation to specific contributory factors (structured). Responses were coded using the YCFF. Face validity of the PMOS was tested with 12 patients and 12 health professionals, using a "think aloud" approach, and appropriate revisions made. The research was supported by two patient representatives.

Results: Patients were able to comment on/identify 13 of the 20 contributory factors contained within the YCFF domains. They identified contributory factors relating to communication and individual factors more frequently, and contributory factors relating to team factors, and support from central functions less frequently. In addition, they identified one theme not included in the YCFF: dignity and respect. The draft PMOS showed acceptable face validity.

Discussion: Patients are able to identify factors which contribute to the safety of their care. The PMOS provides a way of systematically assessing these and has the potential to help health professionals and health care organisations understand, and identify, safety concerns from the patients' perspective, and in doing so make appropriate service improvements.

Introduction

The elicitation of feedback from patients about satisfaction with their care or their experience of care is relatively well established. Patient satisfaction surveys [1:2] are often criticized for producing mostly positive ratings from patients [3] which are not comparable with the lower levels of satisfaction revealed through interviews with the same patients [4:5]. More recently, measures of patient experience have been developed to capture data on specific aspects of health care processes and events [6:7:8]. While patient experience measures such as the widely used Picker Patient Experience Survey [7] ask some questions that are relevant to patient safety (for example, about medication side effects and communication with patients), to date, no tool has been developed that asks patients to provide feedback on the safety of their care, particularlyas a way of capturing information that can be used as a basis for improving safety at ward/unit level. There is growing evidence, however, that patients can be an important source of knowledge in reducing avoidable harm and improving health care [9, 10, 11].

Previous research has demonstrated that, while patients may be reluctant to directly challenge health care professionals [12], they are willing to engage in patient safety initiatives. This engagement includes providing feedback about their experiences of care via surveys, but also includes identifying factors that contribute to patient safety incidents [13]. A recent systematic review [14] generated a comprehensive taxonomy of the factors contributing to patient safety incidents, the Yorkshire Contributory Factors Framework (YCFF) (figure 1). These include factors such as physical environment, communication, leadership and teamwork. Using the YCFF as a starting point, this study aimed to explore the extent to which patients are able to provide feedback about the contributory factors represented in this framework.

Insert figure 1

A second aim was to develop indicators of each of these contributory factors in the form of questionnaire items and to test the face validity of this questionnaire (Patient Measure of Safety or PMOS) with staff and patients. These aims were achieved iteratively in two stages. Stage one involved a series of qualitative interviews with patients to identify which contributory factors they were able to identify, using the YCFF as a basis. These were used to

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inform the development of items for the PMOS. Stage two involved testing the PMOS with health professionals and patients using a "think aloud" [15] approach. A multidisciplinary panel of experts including policy makers, health professionals, academic researchers and patients informed the design of the study, and the patient panel aided the development of the questionnaire.

Methods

Participants

Patients in stage 1 (interviews) and both patients and health professionals in stage two (think-aloud) were recruited from six units (maternity, renal, physiotherapy outpatients, vascular surgery, ear, nose and throat, and cancer services) in an NHS trust in the north of England. These units were selected and purposive sampling used to ensure the views of a broad range of patients were elicited (for example, those with regular interaction with the health service (renal patients) and those with relatively short one-off stays (maternity), young and old, male and female and patients of different ethnic backgrounds. The data were collected by two researchers,one of whom was able to speak Mirpuri(a dialect spoken by three quarters of the Pakistani population in Bradford [16]).

Procedure

Ethical approval for this study was gained from a local Research Ethics Committee (ref: 09-H1302-115). The PMOS was developed in two stages. The process is described below.

Stage 1 – qualitative interviews

Qualitative interviews were used as the basis for identifying which contributory factor domains patients could identify, and for developing PMOS questionnaire items. The project steering group, consisting of a multidisciplinary panel of experts was consulted in the development of interview schedules. This panel recommended that whilst the YCFF [14] (figure 1) could be used to define the interview questions, some of the interviews should take

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a more unstructured approach to ensure that the views of the patients were fully represented and not constrained by an *a priori* framework. Thus, two approaches to interviewing were used: unstructured and structured. In the first case *(unstructured)* interviews (n=18) were based on a narrative approach [17] where participants were asked to describe their most recent/current hospital experience. These interviews were preceded by three pilot interviews. Participants were asked to describe their hospital experience with an emphasis on patient safety. However, during the pilot interviews it became clear that using the term patient safety (which was not familiar to many patients) appeared to discourage participants from engaging in the interview. Thus, it was decided to omit the phrase patient safety from any subsequent interviews, but for the interviewer to explore any experiences that related to patient safety (for example delays in waiting for medication, insufficient information given to patients regarding their condition/treatment/procedure, delays in treatment/procedures/operations, poor communication), should participants describe such experiences. In the case of the *structured* interviews the patient panel for the project were consulted and asked to select which of the contributory factors (contained within the YCFF) they felt that patients would definitely not be able to identify/comment on. Based on this assessment, patients were not asked to comment on safety culture, policy and procedures, external policy context, task characteristics and design of equipment and supplies. Active failures were also excluded from the structured interviews as the PMOS was designed to assess those factors contributing to error, but not the errors themselves. The structured interviews (n=15) asked patients, which of the remaining 13 factors (as active failures was excluded) they felt that they were able to comment on or were in a position to notice and/or make judgments about. They were encouraged to provide examples based on their own experience.

Patients (except those deemed too unwell by staff or those having undergone a general anaesthetic in the preceding 24 hours) were approached on the ward by the researcher who explained the study and gave them an information sheet. Willing participants were then consented. Where possible, interviews took place in the unit, often at the bedside. Some interviews were conducted elsewhere, for example in the hospital canteen or in the waiting room. Interviews ranged from 15 minutes (for the structured interviews) to two hours for the unstructured interviews. The interviews continued until no new themes emerged and theoretical saturation was achieved [18]. All interviews were recorded using a digital recorder and fully transcribed.

Stage Two – think aloud

The "think aloud" [15] process took place after the PMOS was produced. The purpose of this phase of the research was to test the face validity of the PMOS. Twenty-four "think aloud" interviews (12 patients and 12 health professionals) were conducted in the six units described above. Both patients and staff were asked to take part because both will be users of the survey, patients completing it and staff using this information to develop improvement strategies. Participants were asked to talk aloud about their thoughts and feelings as they read and decided how to respond to each question in the draft PMOS. Participants were also asked to comment on: 1) perceived barriers to completing the PMOS, 2) the timing of completion during the care pathway and 3) the questionnaire format. Minor revisions to the PMOS were made following the "think aloud" procedure.

Recruitment of the patients took place within the six units in the same way as for stage 1. The health professionals were identified using existing contacts within each of the areas. These think-aloud sessions were arranged via email or telephone and took place at a location chosen by the participants. They ranged from 10-30 minutes, all were digitally recorded and fully transcribed.

Data Analysis

Stage 1 – Qualitative interviews

The interview transcripts were imported into NVivo eight and coded using content analysis [19]. As the aim was to develop a questionnaire based on the comprehensive YCFF, the 13 domains[1] identified as relevant for patients were used as a coding framework. Text relating to each of the contributory factors was identified, and frequency recorded. Any text that could not be coded using the YCFF was coded separately and new themes created. To begin, three members of the research team (SG, RL and ID) reviewed three of the transcripts each in order to ensure there was consensus in the interpretation of the factors within the YCFF. Following this, the remainder of the transcripts (n=30) were divided equally between two of the researchers (SG and ID), who used the above process to code the transcripts.

Stage Two – Think Aloud

The "think aloud" transcripts were imported into NVivo eight. Two of the researchers listened to the recordings and read through the transcripts (SG and ID) to identify and code comments made when completing the draft PMOS. In addition, both researchers collated the responses to the short questionnaire that took place following each "think aloud" session. These, together with the transcripts, informed any changes that were made to the PMOS questionnaire. The final PMOS was then tested for readability using the Flesch Reading Ease and Flesch-Kincaid Grade level.

<u>**Results**</u>

Participants –Stage 1

All participants approached for interview at both stages agreed to take part. This high uptake was due to patients who were too unwell or who did not have the capacity to complete the

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[1] Communication, individual factors, physical environment, scheduling and bed management, management of staff and staffing levels, staff workload, training and education, lines of responsibility, design of equipment and supplies, equipment and supplies, patient factors, supervision and leadership, team factors and support from central functions.

interview being filtered out by staff. In the stage 1 interviews, participants ranged from 18-83 years and included 14 male and 19 females (Table 1).

Table 1   Interview participants phases 1 and 2

	Phase 1 Unstructured interviews	Phase 1 Structured interviews	Total-phase 1	Phase 2 – Think Aloud		Total-phase 2
				Patient	Staff	
Total	**18**	**15**	**33**	**12**	**12**	**24**
Gender						
Male	10	4	14	7	1	8
Female	8	11	19	5	11	16
Age						
18-24	3	1	4	1	0	1
25-30	2	5	7	2	4	6
31-40	2	2	4	2	3	5
41-50	2	2	4	2	3	5
51-60	4	2	6	0	2	2
61-70	2	3	5	3	0	3
71-80	2	0	2	2	0	2
80+	1	0	1	0	0	0
Ethnicity						
White/British	9	10	19	10	11	21
Pakistani	7	3	10	2	1	3
Indian	1	0	1	0	0	0
White/Polish	0	2	2	0	0	0
Chinese	1	0	1	0	0	0
Unit						
Cancer Services	3	2	5	2	2	4
ENT	3	2	5	2	2	4
Maternity	3	3	6	2	2	4
Physiotherapy	3	2	5	2	2	4
Renal	3	3	6	2	2	4
Vascular	3	3	6	2	2	4

Stage 1 – Qualitative Interviews

Can patients identify contributory factors within the Yorkshire Contributory Factors Framework?

Table 2 shows the number of times patients highlighted a contributory factor domain and gives examples, in the form of interview excerpts, of the way in which patients talked about

these factors. As expected, none of the 5 domains excluded by the expert panel were identified during the qualitative interviews. All remaining 13 domains were identified by patients. Domains most frequently identified were 'communication' (identified 80 times) and 'individual factors' (in relation to both staff, for example stress, and patients, for example attitudes of carers, identified 62 times). Domains such as 'team factors' and 'support from central functions' were identified less frequently. Although the domain active failures wasexcluded from the structured interviews, participants did identify active failures during the unstructured interviews. There appeared to be no major differences in the nature of information collected using the structured and unstructured approach to the interviews. A further theme not captured within the Yorkshire Contributory Factors Framework was identified: dignity and respect. Little is known about the relationship between 'dignity and respect' and patient safety outcomes, but it is an important factor in patient's experience of their care, being associated with feeling comfortable, in control and valued [20]. Although not identified as a contributory factor within the literature, our patient panel members felt that patients who were not treated with dignity and respect may be reluctant to communicate important information about their well-being (including symptoms) to health professionals which might compromise their safety.

All these domains, with the exception of 'active failures' (deemed to be an outcome rather than a contributory factor) were used as a basis for the PMOS.

Table 2 – Frequency of Contributory Factors domains identified, and number of PMOS items developed.

Domain	Definition	Times domain identified	Illustrative quotes from interviews
Communication	Effectiveness of the exchange and sharing of information between staff, patients, groups, departments and services	80	No. I don't think they really understand anyway. But they don't talk. We were saying this before, I have got five or six different people, and they don't communicate between them, and a lot of the time that would help. (*White British female, 30, physiotherapy*)
Individual factors/patient factors	Individual factors refer to characteristics of the person delivering care that may contribute in some way to active failures. Examples of such factors include inexperience, stress, personality, attitudes.	62	The nurses, they can be quite arrogant and they got no manners. They don't know how to talk to patients, really. (*Pakistani female, 22, ENT*)

Domain	Definition	Times domain identified	Illustrative quotes from interviews
Physical environment	Features of the physical environment that help or hinder safe practice	25	If your blood pressure drops they need to be able to lay you flat and there isn't enough room to move your chair down. (*White British male, 64, renal*)

Domain	Definition	Times domain identified	Illustrative quotes from interviews
Scheduling and bed management	Adequate scheduling to manage patient throughput minimising delays and excessive workload	25	All I can say to start off with is I've had five operations on my leg and I've had 13 cancellations. Now we're being not always getting into the hospital because some of the cancellations were, I would have to be …… at the weekend and then ring up Monday morning expecting to come in and then said no there's no bed you can't come in ring up next Monday morning but don't stop taking your medication. *(White male, 60, ENT)*
Management of staff and staffing levels /Staff workload	The appropriate management and allocation of staff to ensure adequate skill mix and staffing levels for the volume of work Level of activity and pressures on time during a shift	21	'Cause they're dealing with other patients. There's like six rooms with four in them, dealing with twenty eight patients… They're understaffed. *(White male, 47, renal).*
Dignity and Respect	Associated with patients feeling comfortable, in control and valued	13	This one lady she has had a line on her chest over here and a few times they have not put the curtain around and you know they just dealt with her. I have looked over and closed my eyes and I have thought to myself that this is just not done. *(Pakistani male, 39, renal)*
Training and education	Access to correct, timely and appropriate training both specific (for example Task related) and general (for example Organisation related)	13	When you get the trainees, they sometimes don't seem to know what they are doing, it's a worry really. *(White male, 45, Renal)*

Domain	Definition	Times domain identified	Illustrative quotes from interviews
Lines of responsibility	Existence of clear lines of responsibility clarifying accountability of staff members	12	They'll just shake your hand and say 'hello I'm doctor so and so' or whatever, but you don't know who they're working for or why they're there, they just keep coming in to see you, you think why has he come to see you, and who's that, they don't exactly say why they're there, that's it really! *(White British Female, 54, cancer services).*
Equipment and supplies	Availability and functioning of equipment and supplies	10	One of the things – just on today's experience, one of the things is about the hand gel, when I came in today I noticed that the first obvious hand gel on that side was empty (*White British female, 34, ENT*)
Supervision and leadership	The availability and quality of direct and local supervision and leadership	10	They don't know the machines – they have to go get some help, but what I'm saying is I think it's unfair on them, and they start getting a bit stressed do you know what I mean? I haven't seen it for a while, it's when we had a batch of young nurses in which they are all pretty much fine now, but at that time I just thought it was wrong and unfair on them to be left without an experienced member of staff that did know the machines *(White British female, renal).*
Team factors	Any factor related to the working of different professionals within a group which they may be able to change to improve patient safety	8	[Partner] Wasn't there before when you had the two consultants, one was asking for …. and the other one was ignoring it, things like that, Katherine's had. Two specialities clashing. *(White female, 28, physiotherapy).*
Support from central	Availability and adequacy of central	8	Yeah the practical side was good, the only downside I would say that's let this particular ward down and the patients is the

functions	services in support the functioning of wards/ units		pharmacy. When you come for appointments you can be 2 hours waiting for the drugs to come up from the pharmacy and that's annoying for the staff, for the patients because your waiting around for 2 hours before you get your treatment, which is probably a couple of hours anyway! And it's quite annoying! So you just sit in the waiting area. *(White British Female, 54, cancer services).*

Developing the items for inclusion in the draft PMOS

The interview transcripts (both structured and unstructured) were used to develop the individual items for each domain. For some domains, particularly those which patients referred to less in the interviews, only a small number of questionnaire items were necessary to adequately represent the codes (for example, training was represented by two items). For other domains, such as communication, which was a broad category, more items were necessary to reflect the assigned codes. Forty two questionnaire items were developed in total. A mixture of positive and negative items were included in order to avoid acquiescence response set bias (the tendency to give the same response to questions where the direction of wording is the same [21]), and items were designed to be responded to using a Likert scale. Two pairs of domains, "management of staff and staffing levels" and "staff workload", and "patient factors" and "individual factors" were merged based on data from the interviews which suggested that patients did not distinguish between these domains. One item was also included in the questionnaire, under the heading of "dignity and respect" to capture this aspect of the safety of care.

Consulting with the research team and patient panel

The items in the draft PMOS were developed and revised based on discussions with both the research team (consisting of psychologists, social scientists and clinicians) and the patient panel for the project to maximize content validity [22]. A small number of changes were suggested by both groups[2]. This resulted in a draft version of the PMOS to be used in stage 2, the "think aloud" process.

Stage 2 – Think Aloud

All those involved in the "think aloud" process (n=24) felt that, on the whole, patients would be interested and willing to complete the PMOS. Participants identified some potential barriers to completion of the PMOS, such as eyesight, language and age (i.e. elderly patients finding it a challenge).

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[2] These included changes to the format (i.e. more space to write comments), size and font of the text.

During the "think aloud", the majority (n=20) of participants were able to complete the questionnaire within 15 minutes and were able to both understand and respond to the items. The same participants also stated that they were satisfied with the length of the PMOS. Only a small number expressed concerns with understanding or found it difficult to respond to questions (appendix 1).

There were three key areas of concern that arose during the "think aloud" process. First, negative statements appeared to present a problem for a small number of participants (n=5). Second, some participants (n=2) were unfamiliar with terminology used within the questionnaire (for example, care plan). Finally, some patients found it difficult to answer questions that they had no experience or knowledge of, but were often able to use the "not applicable" option if this was the case. These issues were discussed and addressed in consultation with the patient panel, and where necessary, revisions to items were made.

Finalising the PMOS

Following the "think aloud" process and consultation with the patient panel, some changes were made to the draft PMOS, including the format (i.e. more space between questions and space to comment after each) and changes to some of the wording used in the questionnaire (for example, care plan was changed to plan of care). Once the changes to the draft PMOS had been made, this resulted in the main outcome of this study, the PMOS (appendix 2). This was then tested for readability using the Flesch Reading Ease (65.7%, i.e. easily understandable by 13to 15-year-old students) and Flesch-Kincaid Grade level (6.9, i.e. indicates that the text is expected to be understandable by an average student in the 6th grade) tests.

Discussion

The current study is innovative, not only in that it clarifies the types of contributory factors that patients can identify in hospital settings, but it also details the development of the first healthcare questionnaire to assess safety from the perspective of the users of healthcare:

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patients. The fact that patients identified and described contributory factors from 13 domains of the YCFF also provides evidence of the face validity of this framework. Patients were best able to identify contributory factor domains inherent in 'local working conditions' (for example, communication, availability of equipment) as these are often issues that a patient can explicitly observe whilst on a ward. Those contributory factors at a moremore upstream, organisational, level (for example, six of the 20 original domains) appear to represent factors that patients do not recognise as impacting directly on their safety or, even more generally, on their hospital experience (for example, policy context or design of equipment). Being outside the scope of experience for most patients, these factors were not measured within the PMOS. However, a similar questionnaire could be designed for staff which included items to tap these more upstream contributory factors. In addition, the study identified one further area which patients felt was strongly linked to safety in hospital settings: 'dignity and respect', therefore confirming that patients are able to give a more holistic view of issues relating to their safety. Future work using the PMOS will allow the relationship between 'dignity and respect' and the other contributory factors to be investigated.

The PMOS is designed to be a useful diagnostic tool which, when used at a ward level, has the potential to allow health professionals to proactively identify areas of strength and weakness, and intervene to prevent errors occurring. To date, patients have had minimal opportunity to input into traditional incident-reporting and risk procedures for managing safety despite being able to offer valuable feedback (for example, 13 and 23). In addition, unlike other patient reported outcome measures [7] patients have played a more central role in its development, both as research participants and part of the research team. With the increasing emphasis on patient reported outcome measures both in the UK [24] and USA [25], the PMOS provides a useful and timely addition to current tools which focus on safety culture [26]. The PMOS is part of a larger programme of work [27] which will explore the use of the tool, combined with patient incident reporting, as a mechanism for improving safety within wards.

The potential role of patients in promoting patient safety has been emphasised [28-32], particularly for those patients who have on-going treatment and may be better placed to identify errors or lapses as they become more knowledgeable and familiar with the details of their care [30]. PMOS is a specific example of how this role can be realized and how patients have the potential to provide valuable quality and safety improvement data at a micro-level.

It is clear from this study that patients could identify contributory factors within the hospital setting with ease. In fact, all patients identified at least ten different factor domains. It is hoped that by providing a mechanism for this information to be systematically gathered, the PMOS will provide a useful source of information which service providers can use to aid organisational learning. Indeed, the PMOS could be seen as an adjunct to other patient safety tools, such as incident reporting systems. Current information on quality and safety comes predominantly from incident reporting systems that rely on health care professionals to report, and suffer from high levels of underreporting [33].

Limitations

The development of the PMOS was based on the YCFF, which, in turn,was based on a review of studies conducted almost exclusively with health care professionals. This means there is a danger that PMOS may not truly reflect the views of patients if patients tend to identify different contributory factors. However, taking an unstructured approach to half of the qualitative interviews meant we were not constrained by this a priori structure. It is worth noting that, aside from the 'dignity and respect' domain, all contributory factors patients identified mapped onto the YCFF model.

In addition, the PMOS contains only those domains from the YCFF that patients were able to comment on, which means that five of the domains within the YCFF are not represented. Although a major strength of the PMOS is that it allows identification of contributory factors from a patients' perspective, it must be recognised that it does not capture all possible contributory factors. It must therefore be used in conjunction with other tools, such as staff safety culture surveys and Failure Modes Effects Analysis (FMEA) [34], to explore upstream organizational failures.

PMOS may not represent the views of the general population internationally because despite being developed with a diverse ethnic population, the sample was drawn from a single hospital in the north of England. However, future work will explore the utility of the PMOS with a larger number of patients across a number of NHS trusts within England.

Conclusion

Patients are in a very good position to observe the safety of their care and that of others on the same ward/unit and are able to respond to items in the PMOS that areindicative of the safe organisation of their care. In this study we have developed a patient measure of safety that patients can complete during their hospital stay. The next step in this research programme is to test the reliability and validity of the questionnaire and to develop an intervention based on data that are produced to help staff improve patient safety on their wards [27].

Contributorship Statement

SG, RL and RM developed the draft and final versions of the PMOS. SG and ID conducted all the qualitative interviews. SG, RL and ID were involved in the analysis of the qualitative interviews. All authors contributed to draft versions of the manuscript. All authors read and approved the final manuscript.

Competing interests

There are no competing interests.

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