Title: Patients’ willingness and ability to participate actively in the reduction of clinical errors: A systematic literature review

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Corresponding Author: Dr. Carole Doherty,

Corresponding Author's Institution: University of Surrey

First Author: Carole Doherty, PhD

Order of Authors: Carole Doherty, PhD; Charitini Stavropoulou, PhD

Abstract: This systematic review identifies the factors that both support and deter patients from being willing and able to participate actively in reducing clinical errors. Specifically, we add to our understanding of the safety culture in healthcare by engaging with the call for more focus on the relational and subjective factors which enable patients’ participation (Iedema, Jorm & Lum, 2009; Ovretveit, 2009). A systematic search of six databases, ten journals and seven healthcare organisations' web sites resulted in the identification of 2714 studies of which 68 were included in the review. These studies investigated initiatives involving patients in safety or studies of patients' perspectives of being actively involved in the safety of their care. The factors explored varied considerably depending on the scope, setting and context of the study. Using thematic analysis we synthesized the data to build an explanation of why, when and how patients are likely to engage actively in helping to reduce clinical errors. The findings show that the main factors for engaging patients in their own safety can be summarised in four categories: illness; individual cognitive characteristics; the clinician-patient relationship; and organisational factors. We conclude that illness and patients' perceptions of their role and status as subordinate to that of clinicians are the most important barriers to their involvement in error reduction. In sum, patients' fear of being labelled 'difficult' and a consequent desire for clinicians' approbation may cause them to assume a passive role as a means of actively protecting their personal safety.
Research highlights

Illness and clinician-patient relationships are key to patients’ willingness and ability to engage with error reduction.

Age, gender and education are inconclusive factors.

Age may moderate the effect of illness on ability.

Contrary to policy assumptions, patients may actively protect their personal safety by assuming a passive role.

There is ‘design blindness’ in campaigns advising patients to speak up if they have concerns about their care.
Patients’ willingness and ability to participate actively in the reduction of clinical errors: A systematic literature review

Abstract

This systematic review identifies the factors that both support and deter patients from being willing and able to participate actively in reducing clinical errors. Specifically, we add to our understanding of the safety culture in healthcare by engaging with the call for more focus on the relational and subjective factors which enable patients’ participation (Iedema, Jorm & Lum, 2009; Ovretveit, 2009). A systematic search of six databases, ten journals and seven healthcare organisations’ web sites resulted in the identification of 2714 studies of which 68 were included in the review. These studies investigated initiatives involving patients in safety or studies of patients’ perspectives of being actively involved in the safety of their care. The factors explored varied considerably depending on the scope, setting and context of the study. Using thematic analysis we synthesized the data to build an explanation of why, when and how patients are likely to engage actively in helping to reduce clinical errors. The findings show that the main factors for engaging patients in their own safety can be summarised in four categories: illness; individual cognitive characteristics; the clinician-patient relationship; and organisational factors. We conclude that illness and patients’ perceptions of their role and status as subordinate to that of clinicians are the most important barriers to their involvement in error reduction. In sum, patients’ fear of being labelled ‘difficult’ and a consequent desire for clinicians’ approbation may cause them to assume a passive role as a means of actively protecting their personal safety.

Key words

Patient participation, clinical error, safety, systematic review
Introduction

This systematic review identifies the factors that both support and deter patients from being willing and able to participate actively in reducing the risk of clinical errors. There are important reasons for considering patients’ active participation in reducing the risk of error. Firstly, the extent of harmful events occurring in healthcare organisations is of international concern. Secondly, patients’ active participation is being encouraged as one way of reducing the problem. Thirdly, there is little evidence from patients themselves about their willingness or ability to be more involved. In this article we begin by providing the context for the policy recommendations. Then we describe our review methods. Following this, using thematic analysis, we synthesise the data to explore why, when and how patients are likely to participate in helping to reduce the potential for errors.

As the focal point of healthcare delivery, it is thought that patients can provide a unique perspective on the system and in doing so help to identify risks and solutions for reducing harm caused by clinical errors (DH, 2006; WHO, 2005). To this end, patients’ organisations have been promoting campaigns to encourage patients to: pay attention to the care they get; take nothing for granted; and not to be afraid to ask about safety or ‘speak up’ if they have questions or concerns about their care (JCAHO, 2011; WHO, 2004). Error victims have also been instrumental in campaigning for improvements in patient safety for example ‘Consumers Advancing Patient Safety’ in the USA and ‘Cure the NHS’ established by people who lost relatives or experienced poor care standards at the Mid-Staffordshire NHS Trust in England.

Peat et al. (2010) developed a framework describing three general courses of action by which patients can contribute to their safety. These include: 1) informing the management plan by
sharing information with clinicians and asking questions about treatment decisions 2) monitoring and ensuring safe delivery of treatment for example by self-administration of medication (SAM) 3) informing systems improvement for example by providing feedback on care quality.

Alternatively, expecting patients to take more responsibility for their safety may increase their fear and anxiety by taking them beyond what they perceive as their responsibilities as patients (Koutanji et al., 2005). Healthcare settings provide complex stimuli for patients which may lead to uncertainty about how to act. Expert knowledge gives power within the doctor-patient relationship to the doctor and the potential for patient exploitation and psychological dependency (Johnson, 1972). Patients’ willingness and ability to act is likely to be influenced by what they perceive as clinicians’ attitudes about what is acceptable and important in a patient’s role or because they do not believe they have the expert knowledge to question clinicians’ practice. The type of information available, the extent to which clinicians are prepared to provide information and doctors’ use of medical jargon can give patients the impression of reluctance to share decisions with them making them passive rather than active participants in their healthcare (Coulter & Ellins, 2006). Consequently patients may conform to what they perceive as acceptable behaviour. Other barriers to participation include language and cultural differences, low health literacy and physical factors such as hearing, speech or visual impairment and illness severity (Coulter & Ellins, 2006; Khan et al., 2004).

Importantly, encouraging patients’ involvement in error reduction may lower the wariness of staff (Lyons, 2007) and risk shifting responsibility to patients, deflecting attention away from healthcare systems and clinicians’ communication skills (Watt et al., 2009), reinforcing a culture where patients are seen and see themselves as part of the problem which is
counterproductive to improving safety (Esmail, 2006). This review seeks to address some of these complexities by synthesizing and analysing the literature in the context of patient safety in healthcare organisations.

**Methods**

**Search strategy**

Our search strategy was designed to find empirical data about actions that patients are willing and able to take to reduce the risk of medical error. We searched the literature according to methods outlined by Greenhalgh & Peacock (2005) for the synthesis of qualitative and quantitative data from numerous and dissimilar sources for the purpose of attending to broad policy questions. An initial set of articles (N= 19) thought by the researchers to be influential were obtained. We then hand searched the references of each article for titles and key words that included patient involvement in safety and citation tracked the titles, thereby identifying relevant journal articles that had subsequently cited those papers. Another key tool in the search process was the database search; we searched systematically for articles in MEDLINE, EMBASE, PsycINFO, ISI Web of Knowledge, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews and CINAHL. The search terms applied were: ‘patient* safety’; ‘patient involvement *safety’; ‘patients role * safety’; ‘patient participation’; ‘error * patient involvement’; ‘error * patient participation’ and ‘error prevention * patient’. In addition to the database searching, we hand searched 10 key healthcare, medical and nursing journals, over the same time period, including Social Science and Medicine, Quality and Safety in Health Care, BMJ, Health Expectations, International Journal of Nursing Studies, Journal of Advanced Nursing, Health Affairs, Archives of
Internal Medicine, JAMA, and Health Psychology. We also included in our search organisation based websites related to patient safety including Agency for Healthcare Research and Quality, Joint Commission on Accreditation of Healthcare Organisations/ International Centre for Patient Safety, National Patient Safety Agency (UK), National Patients Safety Foundation (USA), Picker Institute Europe, The Health Foundation and the WHO.

The search period was limited to 1999 to 2011 with exceptions made for important articles that pre-date this period. This period corresponds with an increase in interest in patient safety following the seminal report ‘To err is human’ (Kohn et al., 1999). Studies were limited to those published in English and Spanish, as these languages were represented on the research team, with no restrictions on the basis of country of origin or the context in which studies were undertaken.

We excluded data on actions that clinicians can take directed toward patients to increase their safety such as education programmes to increase compliance with treatment regimens or to improve overall health (or reduce disease side effects with respect to long term conditions like diabetes mellitus). Similarly articles that explored interventions directed at patients, such as education, information and instructions related to their safety, requiring patients’ passive involvement were also excluded. Articles about patients’ involvement in decision-making generally, case reports and literature reviews were excluded. Finally, comment or opinion about patients’ active participation in safety and studies involving the general population were excluded.
Firstly, we reviewed titles and key words and used these as our criteria for selecting abstracts. Then we reviewed the abstracts independently and then cross-referenced judgements on the papers. Duplicates were removed and complete articles obtained if the abstracts stated that the study was related to patient safety and that patients and/or carers were the primary research participants. Having agreed on the abstracts for inclusion, full papers were retrieved. Following this we read, reread, and discussed the papers again excluding those that did not meet our aims. We took a pragmatic approach in deciding not to exclude studies in terms of research quality. Only thirteen studies used a theoretical framework to support or explain the empirical findings. These included the Theory of Planned Behaviour, the Health Belief Model, status characteristics theory, role theory, safety culture and the role of the bio-medical model in decision making. Many of the studies had problems of design and reporting such as inadequate details of sampling or data analysis. We have made inferences from studies not specifically designed to investigate patients’ willingness and ability to participate actively in reducing the risk of clinical errors. Many of the studies relied on subjective measures of willingness to act. The methods used in the studies, as they relate to the themes which emerged from our synthesis are shown in Table 1.

Insert Table 1 here

Thematic analysis

Our interpretative approach to evidence synthesis involved reading and rereading the studies firstly to identify the methods employed to support patients’ active participation. Next we hand searched each article for evidence of patients’ willingness and ability to be actively involved. We then used thematic analysis and constant comparison to investigate similarities and differences across studies (Pope et al., 2007). Thematic analysis is an appropriate method
of organising and summarising the findings from a diverse body of both qualitative and quantitative research (Dixon-Woods et al., 2005). Our emphasis was less on the quantitative analysis of data but aimed more on the searching out of any patterns in the data that might help build an explanation of why, when and how patients are likely to engage actively in helping to reduce errors. The process was iterative requiring rereading and discussion of the articles to further refine the categories and subcategories while seeking negative cases. The discussion and conclusion sections were the main sources used from the quantitative articles.

**Results**

Overall, 139 abstracts of studies were identified (see Appendix A). During screening 63 papers were excluded on the basis of the abstract because they did not fulfil the inclusion criteria or were duplications. A total of 95 articles were obtained for detailed review. An additional 27 articles were subsequently excluded; four were literature reviews, twelve reported on outcomes other than patients’ willingness and ability to participate, three included educational interventions, one was a passive intervention, three were not empirical studies, two related to safety but not in the health context, one was the same study written for a different journal and another was a duplication. In total 68 papers were eligible for inclusion; these described the result of initiatives involving patients’ in safety or studies of patients’ perspectives of being actively involved in the safety of their care. *Table 2 provides a quantitative summary of the main themes which emerged from our synthesis of the data.* Studies contributed to more than one factor and more than once within factors, for example within socio-demographic factors one study finds younger age as a facilitator of willingness and poor literacy as a barrier to ability; Appendix B provides further details of the articles reviewed.
Factors affecting patients’ willingness and ability to participate

Socio-demographic characteristics

Age was a common factor in a large number of studies. Older people were less likely to ask questions about hand washing or the purpose of their medication (Duncanson & Pearson 2005; Waterman et al., 2006), were less willing to engage with SAM, if they had not experienced this before and preferred to assume a more passive role when invited to participate in the selection of performance indicators for a hospital in Italy (Deeks & Byatt, 2000; Gagliardi et al., 2008). However, Watt et al. (2009) found that older study participants refuted a suggestion by others that older people would find asking questions more difficult.

Younger patients and those with busy working lives appeared to be over-represented in studies of self-management of oral anticoagulant therapy (OAT) (Cromheecke et al., 2000; Fitzmaurice et al., 2005; Gadisseur et al., 2003; Murray, et al., 2004). Alternatively, Menéndez-Jándula et al. (2005) found that old age and low education did not appear to be major obstacles to this. Cromheecke et al. (2000) found no correlation between age, education and therapeutic control. Khan et al. (2004) included only people over 65 years in their study and found that while some older people had difficulty with the technique, they improved with practice. Furthermore, older people preferred to attend the clinic as it provided an opportunity for social interaction suggesting that age may be a confounding variable.

Women were found to be more willing to ask challenging questions of clinicians such as ‘have you washed your hands’ (Abbate et al., 2008; Davis et al., 2008). Conversely, men appeared more willing to self-manage OAT (Cromheecke et al., 2000; Fitzmaurice et al., 2005; Gagliardi et al., 2008).
2005). Other studies found no association between gender and safety related attitudes (Burroughs et al., 2007; Deeks & Byatt, 2000; Hibbard et al., 2005; Schwappach, 2008).

Willingness to participate in error reduction strategies appeared to be associated with having higher education (Abbate et al., 2008; Davis et al., 2008; Dowell et al., 2005; Lozowski et al., 1993; Murray et al., 2004; Schwappach & Wernli 2010c). Other studies failed to confirm education as a factor increasing willingness and ability (Chromheecke et al., 2000; Menéndez-Jándula et al., 2005; Schwappach, 2008; Watt et al., 2009).

Many of the studies excluded patients who were unable to speak the native language, indicating that language is seen as a considerable barrier to ability to participate in error reduction activities. Ethnic minority groups were reported to ask fewer questions perhaps due to lack of ethnic concordance with their physicians and not race per se (Stepanikova, 2006).

Health literacy predicted better SAM in acute care among chronically ill Australian patients (Manias et al., 2004) and among ambulatory oncology patients in America (Weingart et al., 2009). Overall, despite a large number of studies investigating socio-demographic factors, the data in respect of age, gender and education were inconclusive to claim that socio-demographic characteristics were consistent factors predicting per se patients’ willingness or ability to engage with safety matters.

Nine studies commented on the involvement of relatives, three of these involved parents of children receiving intensive care. Overall, relatives appeared to play an important role with: SAM in the patients’ own home and in hospital (Manias, 2004; Phelan et al., 1996); self-management of OAT (Menéndez-Jándula, et al., 2005); and in the prevention of medication errors (Weingart et al., 2009). Relatives also had a role to play in ‘speaking up’ on behalf of
family members (Dowell et al., 2005; Lozowski et al., 1993). Indeed speaking up for a relative or another patient may be easier than speaking up on behalf of oneself (Watt et al., 2009).

**Illness related factors**

Twenty-one studies reported various illness related factors such as confusion, general frailty, serious illness and depression that reduced patients’ ability to participate actively in the reduction of error, often these factors resulted in people’s exclusion from participation in the study. In studies of self-management of OAT the primary barriers to involvement were visual, hearing or motor impairment which restricted patients’ ability to perform the required blood test competently (Cromheecke et al., 2000; Khan et al., 2004; Menéndez-Jándula et al., 2005). While confusion was an obstacle to SAM for elderly patients in a rehabilitation centre (Pereles et al., 1996). These findings suggest that one underlying cause of inability to be involved actively may be some age-related illnesses rather than age itself.

**Cognitive factors**

People who perceived a high risk of an error occurring were generally more willing to engage in protective behaviour such as: notifying staff of potential errors or asking them to comply with hand hygiene (Kovacs Burns, 2008; Schwappach & Wernli, 2010b); patients with MRSA were more likely to ask about hand washing than those without MRSA, patients without MRSA asked rarely or almost never (Luszczynska & Gunson, 2007); risk perceptions affected incident reporting among patients in psychiatric hospitals in London, where patients who perceived a threatening situation caused by other patients would often
report it to staff (Quirk et al., 2005); patients with three or more drug allergies were more willing than patients without drug allergies to report preventable adverse events and near misses (Weingart et al., 2005); people who had personal experience of medication errors were likely to act to reduce the risk of similar errors (Nau & Erickson, 2005); and patients who kept their own records were often prompted to do so by the experience of a hospital losing a record of previous tests (Rassin et al., 2007). A common reason for unwillingness to ask staff about hand washing was individuals’ conviction that staff hand hygiene did not pose an infection risk for them (Abbate et al., 2008); supporting Tarini (2009) that patients or their relatives who feel vulnerable are likely to be vigilant.

Self-efficacy and positive attitudes towards preventability were also shown to increase willingness to act, for example by self-managing OAT (Hibbard et al., 2005; Schwappach & Wernli 2010c; Watt et al., 2009). Additionally, studies showed that the extent to which patients believed that their participation would prevent infections increased their intention to ask clinicians to wash their hands (Abbate et al., 2008; Longtin et al., 2009; Luszczynska & Gunson, 2007). Similarly, feeling more comfortable with error prevention increased willingness to act (Waterman et al., 2006). Extraversion was associated with patients’ willingness to ask clinicians, including doctors, to wash their hands (Duncanson & Pearson, 2005; Longtin et al., 2009). Having a family member in hospital in the last year and having read about medical errors increased perceptions of efficacy in being able to prevent medical errors. This was then significantly linked with a greater reported likelihood of engaging in preventative action (Hibbart et al., 2005). Lack of self-confidence reduced patients’ willingness and ability to self-manage OAT (Menéndez-Jándula et al., 2005) in part this was because learning a new task was more difficult for people when in a stressful situation (Hovey et al., 2010). Longer duration of care in a cancer clinic increased the likelihood of
patients reporting concerns about safety (Agoritsas et al., 2005; Weingart et al., 2007). Watt et al. (2009) found that patients were able to detect dispensing and prescribing errors in primary care but less able to do so in hospital, in part due to unfamiliarity of packaging. Perhaps as patients become more familiar and comfortable with their surroundings they believe they have greater control of their situation which increases their willingness to take an active role (Entwistle et al., 2010).

In contrast, if patients’ perceived their role to be that of passive recipient of medical expertise they were unwilling to engage actively with their safety for example by self-management of their condition or by challenge clinicians about their practice (Burnett et al., 2010; Entwistle, 2005; Forsyth, 2000; Hibbard, et al., 2005; Longtin et al., 2009; Manias et al., 2004; Schwappach & Wernli, 2010a). One study found that patients did not read medication instructions (Brown et al., 2006) and others found that patients were reluctant to mark their body to indicate the site of surgery (DiGiovanni et al., 2003; Waterman, 2006) suggesting a submissive attitude towards safety.

**Clinician-patient relationships**

An emergent theme was that a poor relationship with their clinicians made patients less willing and able to engage in error reduction (Kuzel, et al., 2004; Watt et al., 2009). Problems of miscommunication between the two parties both verbal (Britten et al. 2000; Brown et al., 2006) and non-verbal, such as no eye contact with nurses (Bolster & Manias, 2010) made patients reluctant to ask questions or challenge clinicians. Patients who were not asked about prior knowledge of medications were less willing to ask questions (Bolster & Manias, 2010). Parents of children being treated for cancer who were less satisfied with the emotional support they received from clinicians reported intervening more often to prevent or correct an
error (Lozowski et al., 1993). Perceived lack of support may have reduced parents’ trust in clinicians.

Access to information was positively associated with patients’ ability and willingness to get involved with their own safety (Forsyth et al., 2010; Hurst, 2001; Unruh & Pratt, 2007). Information can increase self-efficacy and risk perceptions thereby increasing intention to act (Schwappach & Wernli 2010a), perhaps by giving patients an understanding of what they can do (Smythe, 2010). Clinicians’ ability to communicate with patients is important in this respect. Patients’ ability to act is compromised by a poor understanding of drug dosages, clinicians’ failure to assess patients’ information needs and receiving conflicting or inadequate information about their treatment (Bolster & Manias, 2010; Britten et al., 2000; Entwistle et al., 2010; Hovey et al., 2010). Other obstacles of willingness to act were worrying about being labelled a “difficult” patient (Entwistle et al., 2005, 2010; Hurst, 2001; NPSA, 2004), fear of embarrassment and negative or judgemental reactions from clinicians (Ballinger & Payne, 2002; Brown et al., 2006; Burnett et al., 2010; Davis et al., 2008) including having their concerns dismissed, ignored, not believed or taken seriously and clinicians disagreeing with them without explaining why (Britten et al., 2000; Entwistle et al., 2010; Kovacs Burns, 2008; Ocloo 2010; Schwappach, 2008; Smythe, 2010).

Clinicians enabled patients’ more active engagement by encouraging or instructing patients to ask questions or to participate in specific actions (Bernstein et al., 2004; Davis et al., 2008; Entwistle et al., 2010) and by demonstrating that they were willing to listen (Dowell et al., 2005). One study found that patients considered engaging with their own safety had the indirect benefit of strengthening their relationship with nurses (Schwappach & Wernli, 2010a). Simple visual reminders, encouraging patients to ask questions or tell clinicians to
wash their hands such as leaflets, posters and “it’s okay to ask” stickers increased patients’ willingness to do so (Duncan, 2007; Duncanson & Pearson, 2005; Lent et al., 2009; NPSA, 2004; Quinn, 2003).

The hierarchical, elitist and paternalistic culture of the medical profession was often a barrier to patients’ willingness to engage with their safety (Davis et al., 2008; Ocloo, 2010; Weingart et al., 2009). It was seen as inappropriate to challenge clinicians (Ballinger & Payne, 2000); some patients were fearful of questioning medical authority (Schwappach, 2008; Smythe, 2010) while others were afraid of being rude to or offending the doctor (Brown et al., 2006; Davis, et al., 2008; Randle et al., 2006; Schwappach & Wernli, 2010b; Waterman et al., 2006; Quinn, 2003). Other studies demonstrated patients’ perceptions of doctors’ as holding an elite position in the healthcare context for example patients were more willing to ask nurses than doctors to wash their hands (McGuckin et al., 1999, 2001; NPSA, 2004) and might ask challenging questions of the nurses while they left factual questions for the doctors (Davis et al., 2008). One study found that unwillingness to SAM by some patients was related to a concern that nurses would be blamed should patients make an error (Manias et al., 2004).

Organisational aspects

A common finding was that a busy setting was a strong barrier in preventing patients’ active involvement in safety. When patients perceived that clinicians’ time was constrained due to work pressure or staff shortages they were wary of engaging in error prevention behaviours (Bolster & Manias, 2010; Entwistle et al., 2010; Hurst, 2001; Schwappach & Wernli, 2010c). Other organisational constraints were lack of continuity of care and isolation in a side room for reasons of infection control (Hurst, 2001; Stelfox et al., 2003; Unruh & Pratt, 2007). Liberal visiting hours in a paediatric intensive care unit enabled parents to report more errors;
although parents in this context could also cause errors such as disconnecting tubes inadvertently (Frey et al., 2009). The review found evidence that patients were generally willing and able to report formally incidents such as drug complications and medication errors as this did not require the overt questioning of clinicians (Jarernsiripornkul et al., 2002, 2003; van den Bemt et al., 1999; Waterman et al., 2006; Weingart et al., 2004). However, an important barrier is that generally patients were not made aware of the incident reporting system (Frey et al., 2009; Watt et al., 2009).

**Discussion**

*Overall, we found no compelling evidence that age, gender or education affect directly patients’ willingness or ability to engage with their own safety. This contrasts with what is known about the prevalence of low health literacy and health inequalities among lower socioeconomic groups and older people (Coulter & Ellins, 2006). This contradiction should be a focus for further research.* While the studies we reviewed found that older age was a barrier to safety related behaviour, our synthesis suggests that age is probably a confounding factor. Commonly people who were able were willing (Weingart et al., 2004). Important barriers affecting ability are illness, which is often aged related, and ability to communicate in the native language. Patients come to the clinical encounter carrying their own experiences, and they have a number of cognitive characteristics that affect their willingness to participate in their own safety. These include patients’ beliefs about their self-efficacy in respect of the extent to which they can prevent and control errors and their attitude about the risk of an error occurring. As our synthesis demonstrates, the role of patients’ attitudes and beliefs should not be underestimated as these perceptions create obstacles in the environment that patients themselves have to manage.
The review also shows that the relationship between patients and clinicians is particularly important in predicting patients’ safety-related attitudes and behaviours. Studies demonstrate that patients’ deferential attitudes towards clinicians are a barrier for patients’ active engagement in helping to reduce clinical errors. The main issue identified was the power of the medical profession which has been often discussed in the literature (Vincent & Coulter, 2002). Many of the studies found that patients did not challenge clinicians because they felt that it was not their role to do so. Patients were also more likely to challenge nurses than doctors, indicating that they are sensitive to the occupational hierarchy in healthcare organisations.

However, as our analysis indicates, at the interpersonal level clinicians have an important influence on patients’ willingness and ability to participate in error reduction. Our review found that when clinicians encourage patients’ involvement in safety then patients are generally willing to participate. This result supports the need for more effective patient clinician collaboration on safety issues (Entwistle et al., 2010). Other barriers to involvement include lack of clear written or verbal information explaining illness and treatment. *Clinicians have an important role to play in addressing these communication barriers in the clinician-patient relationship.*

Busy hospital settings discourage patients from engaging in error reduction behaviour. This is of concern because a busy ward is probably the time when patients are at greater risk. Indeed, the conditions that nurture the failures of foresight which eventually lead to error are rarely found at the individual level of analysis (Turner, 1976). To focus on the actions of individuals is to promote a culture of blame which is counterproductive to safety (Reason, 1998). The culture of safety within any organisation arises from the associated folkways, mores and
codes of practice, namely the set of commonly accepted ways of doing things. It follows that it is readjustment of accepted cultural norms that will lead to reduction of errors (Turner, 1976). In the context of healthcare there is a gap between ‘espoused theories’ (Agryris & Schon, 1996), what clinicians intend or believe they do (no harm) and their ‘theory-in-use’, or actual behaviour (to err is human). Policies encouraging patients’ greater involvement are intended to bring these gaps to the attention of clinicians. Thus programmes designed to encourage patients to ask may fail when the espoused theory -‘it’s okay to ask’- meets patients’ theory-in-use -‘doctor knows best’. Certainly, the theories-in-use that underlie practice have developed in part to enable the normalisation of unsafe practices as a way for clinicians to cope with competing demands (Dixon-Woods et al., 2009), behaviour with which patients may collude.

Our analysis demonstrates that illness and patients’ perceptions of their role and status as subordinate to that of clinicians were the most important barriers to their involvement in error reduction. Usually it is health, not healthcare, that is of value to patients. In itself, healthcare generally is negative and undesirable; people put themselves under the control of clinicians in anticipation of positive health outcomes because they have to. Implicit in this is patients’ need to trust clinicians as they are in a situation of vulnerability, where there is task uncertainty and ambiguity in intended outcomes. These conditions create ‘design blindness’ (Friedman, 2001: 164) that is a dislocation between policy planning and implementation. In the context of patient safety the power and individualism of the medical profession has been cited as part of the problem (Collins et al., 2009), therefore deference to clinicians appears to be outmoded. Policy that tells patients ‘don’t be afraid to ask’ while well intentioned, is blind to some of the possible underlying reasons why patients assume deferential behaviour in the clinical setting. Rather than perceiving active involvement in safety as protecting themselves
from error, patients express concerns about being labelled “difficult” and clinicians responding negatively or defensively to being questioned; consequently patients may be actively protecting their personal safety by assuming a relatively passive role.

Policy and practice implications

In essence a policy of encouraging patients’ to be more involved in reducing medical errors requires a ‘demystification’ of clinicians’ claim to knowledge (Schon, 2007: 289) in the sense that it is opened up to inquiry. Our analysis builds on Peat et al.’s (2010) approach for appraising interventions to support patients’ involvement in safety and demonstrates that there are simple actions that clinicians can take in this respect. These include: actively listening to and taking seriously patients’ concerns; providing a clear explanation when concerns or views differ from those of the patient; appearing to have the time to talk by making eye contact and other non-verbal behaviours such as sitting by the patient’s bed; and, if acceptable to the patient, involving relatives in their care. Reassuring patients that it is okay to ask by using posters or information leaflets helps to reinforce this message. Forty-nine of the studies we reviewed involved hospital patients and those attending hospital out-patient departments; explanatory analysis of specific contexts would further assist policy makers to determine what works for whom and in what circumstances. Finally, by attending to the patients’ perspective this article has demonstrated the importance of the clinician-patient relationship for patients to participate actively in reducing clinical errors. Further exploration of the clinicians’ attitudes towards patients’ engagement in safety would aide our understanding on how to effect more profound cultural change.

Appendices A & B

Supplementary data associated with this article can be found, in the online version
References


management by a specialist anticoagulation clinic: a randomised cross-over comparison.


http://www.youtube.com/user/TheJointCommission


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<th>Method</th>
<th>Self-administered questionnaires</th>
<th>Structured interviews</th>
<th>Qualitative interviews</th>
<th>Nonparticipant observation</th>
<th>Randomized trials</th>
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Table 2. Numbers of Studies Identifying Facilitators and Barriers to Willingness and Ability (Studies Can Include More Than One Factor)

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<th>Facilitators of ability</th>
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<td>-</td>
<td>-</td>
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</tr>
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<td>10</td>
<td></td>
<td>-</td>
<td>23</td>
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<tr>
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<td>26</td>
<td>1</td>
<td>9</td>
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<tr>
<td>Organisational</td>
<td>-</td>
<td>3</td>
<td>1</td>
<td>6</td>
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Ref: SSM-D-11-02205R1
Manuscript Title: Patients' willingness and ability to participate actively in the reduction of clinical errors: A systematic literature review Social Science & Medicine

24th January 2012

Dear Dr Davis,

Thank you and the reviewers for their further comments on our paper. We have attempted to respond to remaining reviewer comments one-by-one, showing where changes have been made. Our responses to reviewers are given below; within the text we have used italics to highlight where we have made changes.

We hope that you will find merit in this revision and we look forward to hearing from you in due course.

Yours sincerely,

Dr Carole Doherty.

Senior Editor:

2. Can you make it clear what the substantive conclusions are that you can draw from your very extensive and systematic literature review? These need to feature in some way in your abstract and in your research highlights.

We have altered the abstracts as follows:

‘... The findings show that the main factors for engaging patients in their own safety can be summarised in four categories: illness; individual cognitive characteristics; the clinician-patient relationship; and organisational factors. We conclude that illness and patients’ perceptions of their role and status as subordinate to that of clinicians are the most important barriers to their involvement in error reduction. In sum, patients’ fear of being labelled ‘difficult’ and a consequent desire for clinicians’ approbation may cause them to assume a passive role as a means of actively protecting their personal safety.’

We have altered the research highlights to read:

Illness and clinician-patient relationships are key to patients’ willingness and ability to engage with error reduction

Age, gender and education are inconclusive factors

Age may moderate the effect of illness on ability
Contrary to policy assumptions, patients may actively protect their personal safety by assuming a passive role.

There is ‘design blindness’ in campaigns advising patients to speak up if they have concerns about their care.

3. Would it be possible to provide some summary table of your very extensive list of papers in Appendix A? You have what looks like a helpful framework and annotation, and it would be possible to quantify this and show how many of the different articles reviewed featured on your criteria and classifications (e.g. methodological, substantive). At present that solid intellectual work is rather lost since it is relegated to that appendix (which it has to be, for reasons of space and reader "fatigue"), and it must be possible to summarise at least some of that work in a tabular form in the main body of the text.

We have attempted to address this comment and that of reviewer 3 concerning the methods with the inclusion of two tables. Table 1 lists the factors that emerged from our synthesis by the methods used in each of the respective studies. In table 2 we have attempted to provide a quantitative summary of the themes which emerged from what is primarily a qualitative synthesis of the data.

4. Could you cut your reference list down to those that are cited in text? The full list should appear in your web-accessible file, say, following your extensive initial tabulation. The reference list at the end of the paper that will be published should be limited to those that are cited in text. However, the reader can be directed to the full list. This should free up space elsewhere for spending a bit more time summarising your appendix, outlining your substantive findings (and responding to comments). The reference list at the end of the paper contains all the reference that are cited in the text and all of the articles used in our review are referenced in the text. We have reduced some of the additional background references and judiciously reduced the number of times some of the review articles are referenced thus there are no additional references.

5. Keep under 8,000 words.

By pruning of references and parsimonious use of words we have contained the word count to 7759 words.

Reviewer #1: The authors have clearly attempted to address all of the reviewers’ concerns, and the manuscript has improved as a result.

I was unable to see Appendices A and B in the revised submission, and I think few readers will have sufficient interest and time to review additional online resources. The appending of information about the data extraction process does not help explain the selection of findings for presentation or the interpretation/synthesis presented in the paper. The details that are appended about individual studies may be useful, depending on what information has been extracted and how accurate it is.
The main text of the findings sections appears less ad hoc now, and is probably generally acceptable, although the difficulty of justifying the basis/strengths of claims summarised from particular studies remains.

Two tables have been added: Table 1 shows the range of methods used in the studies; and Table 2 is a quantitative summary of the themes which emerged from our synthesis of the studies.

One of the changes that the authors highlight several times in their letter describing their responses to the reviews is problematic in a couple of respects. The Peat et al (2010) framework is now appropriately mentioned in the Introduction (pdf p5/53). However, this framework was based on a literature review, the findings of which should, according to the authors' protocol, have been excluded from their systematic review. The statement in the findings section on pdf p10/53 that "Peat et al. (2010) found that ability to be involved actively was dependent on socio-economic and cognitive skills" therefore seems out of place. I would recommend removing it and replacing it with an accurate summary from a study that did meet the review eligibility criteria and that analysed willingness/ability to participate on socioeconomic and/or educational lines. (I also note that I think the summary statement as written is rather misleading. The Peat et al paper focused primarily on the different ways in which patients' or family members' actions might contribute to their safety and concluded an overview of all of these with a comment that "All of the above behaviours to a greater or lesser degree require patients and their representatives to be well informed. The capacity to do this varies across individuals and has been found to be affected by achieved educational level, income, cognitive skills and cultural differences which may affect patients' health beliefs and their ability to fully utilise health services" (p21-22).

We agree with the reviewer’s comments and have removed the sentence: "Peat et al. (2010) found that ability to be involved actively was dependent on socio-economic and cognitive skills".

Minor points:

All the double speech marks around newly inserted text need to be removed.

These have been removed.

Pdf p7/53 The first sentence is hard to follow. Did you first review titles and keywords, and select abstracts to review on the basis of those?

This has been altered to read:
‘Firstly we reviewed titles and key words and used these as our criteria for selecting abstracts’.

PDF p11/35 "Many of the studies excluded patients who were unable to speak the native language, indicating that language is a considerable barrier.” Perhaps better "indicates that language is seen as a considerable barrier."

We have altered the sentence to read ‘is seen’.
Reviewer #2: Social Science & Medicine - Manuscript number : SSM-D-11-02205R1
Title: Patients willingness and ability to participate actively in the reduction of clinical errors: A systematic literature review

This revised version of the paper again provides a very interesting read in which the authors of the paper have very thoroughly and succinctly taken on board the various comments from the reviewers which much improves the paper.

My only remaining comments are as follows:

1) The conclusion on page 15, line 33, states 'we found no compelling evidence that socio-demographic factors affect directly patients' willingness or ability to engage with their own safety'.

I think this conclusion does rather contrast with a much wider literature on the impact of health inequalities on participation. I therefore think it would be useful to refer to this in some way and to make the case for more research on PPI in patient safety to look more closely at this area (one example that could be referred to here is the Coulter and Ellins study on patient focused interventions which refers strongly to issues of health literacy and lack of access of disadvantaged groups as a barrier to participation. The authors do also show in their summary table under factors influencing ability to participate, that educ level, literacy and social disadvantage are socio demographic factors that may need to be looked at more closely.

We agree with this comment and have altered the text to read as follows:
‘Overall, despite a large number of studies investigating socio-demographic factors, the data in respect of age, gender and education were inconclusive to claim that socio-demographic characteristics were consistent factors predicting per se patients’ willingness or ability to engage with safety matters.’

In addition we have moved this sentence to the last full paragraph of p9.

In the Discussion section we have now stated:

‘Overall, we found no compelling evidence that age, gender or education affect directly patients’ willingness or ability to engage with their own safety. This contrasts with what is known about the prevalence of low health literacy and health inequalities among lower socioeconomic groups and older people (Coulter & Ellins, 2006). This contradiction should be a focus for further research’.

2) On page 16, line 46, I wondered if it might be more accurate given the overall conclusions about problems of power in the clinician-patient relationship to rephrase/replace the sentence starting with 'In short and finishing with resolved', to read after 'illness and treatment': 'Clinicians have an important role to play in addressing these barriers of communication in the clinician-patient relationship.

We agree with this comment and have altered the text to read:
‘Clinicians have an important role to play in addressing these communication barriers in the clinician-patient relationship’.
Lastly I did find the reference to the small number of studies using a theoretical framework to support or explain the empirical findings important and useful in the previous version of the paper. This is because theories about user involvement have been extremely important in explaining lack of involvement and how to address this in other parts of the public services outside of health and its omission in healthcare is therefore significant. This may be useful to refer to, although I appreciate the issue of word length and it should not be a barrier to publishing what is a very interesting paper.

In the last paragraph of the search strategy section we have included two sentences which state:

‘Only thirteen studies used a theoretical framework to support or explain the empirical findings. These included the Theory of Planned Behaviour, the Health Belief Model, status characteristics theory, role theory, safety culture and the role of the bio-medical model in decision making’.

Reviewer #3: The authors were very responsive to the reviewers' comments. The online appendices (A in particular) are helpful in demonstrating that the authors used a reasonably structured approach to their analysis. The paper is well written and conceived and will make a contribution to the field.

Methodologically, I still have concerns about the degree to which the articles were selected in as structured and systematic a way as one would prefer. The authors could do more to critically assess the relative quality of the various studies. These are limitations that likely go beyond the authors' ability to address, and that may be inherent in the research literature itself. And while these considerations detract from the paper, its merits far outweigh these concerns.

We believe that it would be inappropriate to attempt to assess the relative quality of the various studies for the reasons that we have stated in the text: Many of the studies had problems of design and reporting such as inadequate details of sampling or data analysis; We have made inferences from studies not specifically designed to investigate patients’ willingness and ability to participate actively in reducing the risk of clinical errors; and many of the studies relied on subjective measures of willingness to act.

However, to provide readers with more details of the type of methods used in the studies we have included a table, Table 1, which shows the methods used in the studies as they relate to the themes which emerged from our synthesis.