

Manuscript Number: SSM-D-11-02205R2

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

Article Type: Review

Keywords: Key words

Patient participation, clinical error, safety, systematic review

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

Manuscript Region of Origin:

**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.

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

**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

# 1 Patients' willingness and ability to participate actively in the reduction of clinical 2 errors: A systematic literature review 3

## 4 5 6 7 **Abstract**

8  
9 This systematic review identifies the factors that both support and deter patients from being  
10 willing and able to participate actively in reducing clinical errors. Specifically, we add to our  
11 understanding of the safety culture in healthcare by engaging with the call for more focus on  
12 the relational and subjective factors which enable patients' participation (Iedema, Jorm &  
13 Lum, 2009; Ovretveit, 2009). A systematic search of six databases, ten journals and seven  
14 healthcare organisations' web sites resulted in the identification of 2714 studies of which 68  
15 were included in the review. These studies investigated initiatives involving patients in safety  
16 or studies of patients' perspectives of being actively involved in the safety of their care. The  
17 factors explored varied considerably depending on the scope, setting and context of the study.  
18 Using thematic analysis we synthesized the data to build an explanation of why, when and  
19 how patients are likely to engage actively in helping to reduce clinical errors. *The findings*  
20 *show that the main factors for engaging patients in their own safety can be summarised in*  
21 *four categories: illness; individual cognitive characteristics; the clinician-patient*  
22 *relationship; and organisational factors. We conclude that illness and patients' perceptions*  
23 *of their role and status as subordinate to that of clinicians are the most important barriers to*  
24 *their involvement in error reduction. In sum, patients' fear of being labelled 'difficult' and a*  
25 *consequent desire for clinicians' approbation may cause them to assume a passive role as a*  
26 *means of actively protecting their personal safety.*  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55

## 56 **Key words**

57  
58 Patient participation, clinical error, safety, systematic review  
59  
60  
61  
62  
63  
64  
65

## Introduction

1  
2 This systematic review identifies the factors that both support and deter patients from being  
3  
4 willing and able to participate actively in reducing the risk of clinical errors. There are  
5  
6 important reasons for considering patients' active participation in reducing the risk of error.  
7  
8 Firstly, the extent of harmful events occurring in healthcare organisations is of international  
9  
10 concern. Secondly, patients' active participation is being encouraged as one way of reducing  
11  
12 the problem. Thirdly, there is little evidence from patients themselves about their willingness  
13  
14 or ability to be more involved. In this article we begin by providing the context for the policy  
15  
16 recommendations. Then we describe our review methods. Following this, using thematic  
17  
18 analysis, we synthesise the data to explore why, when and how patients are likely to  
19  
20 participate in helping to reduce the potential for errors.  
21  
22  
23  
24  
25  
26  
27  
28

29 As the focal point of healthcare delivery, it is thought that patients can provide a unique  
30  
31 perspective on the system and in doing so help to identify risks and solutions for reducing  
32  
33 harm caused by clinical errors (DH, 2006; WHO, 2005). To this end, patients' organisations  
34  
35 have been promoting campaigns to encourage patients to: pay attention to the care they get;  
36  
37 take nothing for granted; and not to be afraid to ask about safety or 'speak up' if they have  
38  
39 questions or concerns about their care (JCAHO, 2011; WHO, 2004). Error victims have also  
40  
41 been instrumental in campaigning for improvements in patient safety for example  
42  
43 'Consumers Advancing Patient Safety' in the USA and 'Cure the NHS' established by people  
44  
45 who lost relatives or experienced poor care standards at the Mid-Staffordshire NHS Trust in  
46  
47  
48  
49  
50  
51 England.

52  
53  
54  
55  
56 Peat et al. (2010) developed a framework describing three general courses of action by which  
57  
58 patients can contribute to their safety. These include: 1) informing the management plan by  
59  
60  
61  
62  
63  
64  
65

1 sharing information with clinicians and asking questions about treatment decisions 2)  
2 monitoring and ensuring safe delivery of treatment for example by self-administration of  
3 medication (SAM) 3) informing systems improvement for example by providing feedback on  
4 care quality.  
5  
6  
7  
8  
9

10  
11 Alternatively, expecting patients to take more responsibility for their safety may increase  
12 their fear and anxiety by taking them beyond what they perceive as their responsibilities as  
13 patients (Koutanji et al., 2005). Healthcare settings provide complex stimuli for patients  
14 which may lead to uncertainty about how to act. Expert knowledge gives power within the  
15 doctor-patient relationship to the doctor and the potential for patient exploitation and  
16 psychological dependency (Johnson, 1972). Patients' willingness and ability to act is likely to  
17 be influenced by what they perceive as clinicians' attitudes about what is acceptable and  
18 important in a patient's role or because they do not believe they have the expert knowledge to  
19 question clinicians' practice. The type of information available, the extent to which clinicians  
20 are prepared to provide information and doctors' use of medical jargon can give patients the  
21 impression of reluctance to share decisions with them making them passive rather than active  
22 participants in their healthcare (Coulter & Ellins, 2006). Consequently patients may conform  
23 to what they perceive as acceptable behaviour. Other barriers to participation include  
24 language and cultural differences, low health literacy and physical factors such as hearing,  
25 speech or visual impairment and illness severity (Coulter & Ellins, 2006; Khan et al., 2004).  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50

51 Importantly, encouraging patients' involvement in error reduction may lower the wariness of  
52 staff (Lyons, 2007) and risk shifting responsibility to patients, deflecting attention away from  
53 healthcare systems and clinicians' communication skills (Watt et al., 2009), reinforcing a  
54 culture where patients are seen and see themselves as part of the problem which is  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1 counterproductive to improving safety (Esmail, 2006). This review seeks to address some of  
2 these complexities by synthesizing and analysing the literature in the context of patient safety  
3 in healthcare organisations.  
4  
5  
6  
7  
8  
9

## 10 11 **Methods**

### 12 13 *Search strategy*

14  
15  
16  
17 Our search strategy was designed to find empirical data about actions that patients are willing  
18 and able to take to reduce the risk of medical error. We searched the literature according to  
19 methods outlined by Greenhalgh & Peacock (2005) for the synthesis of qualitative and  
20 quantitative data from numerous and dissimilar sources for the purpose of attending to broad  
21 policy questions. An initial set of articles (N= 19) thought by the researchers to be influential  
22 were obtained. We then hand searched the references of each article for titles and key words  
23 that included patient involvement in safety and citation tracked the titles, thereby identifying  
24 relevant journal articles that had subsequently cited those papers. Another key tool in the  
25 search process was the database search; we searched systematically for articles in MEDLINE,  
26 EMBASE, PsycINFO, ISI Web of Knowledge, Cochrane Central Register of Controlled  
27 Trials, Cochrane Database of Systematic Reviews and CINAHL. The search terms applied  
28 were: ‘patient\* safety’; ‘patient involvement \*safety’; ‘patients role \* safety’; ‘patient  
29 participation’; ‘error \* patient involvement’; ‘error \* patient participation’ and ‘error  
30 prevention \* patient’. In addition to the database searching, we hand searched 10 key  
31 healthcare, medical and nursing journals, over the same time period, including Social Science  
32 and Medicine, Quality and Safety in Health Care, BMJ, Health Expectations, International  
33 Journal of Nursing Studies, Journal of Advanced Nursing, Health Affairs, Archives of  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1 Internal Medicine, JAMA, and Health Psychology. We also included in our search  
2 organisation based websites related to patient safety including Agency for Healthcare  
3 Research and Quality, Joint Commission on Accreditation of Healthcare Organisations/  
4 International Centre for Patient Safety, National Patient Safety Agency (UK), National  
5 Patients Safety Foundation (USA), Picker Institute Europe, The Health Foundation and the  
6 WHO.  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16

17 The search period was limited to 1999 to 2011 with exceptions made for important articles  
18 that pre-date this period. This period corresponds with an increase in interest in patient safety  
19 following the seminal report 'To err is human' (Kohn et al., 1999). Studies were limited to  
20 those published in English and Spanish, as these languages were represented on the research  
21 team, with no restrictions on the basis of country of origin or the context in which studies  
22 were undertaken.  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33

34 We excluded data on actions that clinicians can take directed toward patients to increase their  
35 safety such as education programmes to increase compliance with treatment regimens or to  
36 improve overall health (*or* reduce disease side effects with respect to long term conditions  
37 like diabetes mellitus). Similarly articles that explored interventions directed at patients, such  
38 as education, information and instructions related to their safety, requiring patients' *passive*  
39 involvement were also excluded. Articles about patients' involvement in decision-making  
40 generally, case reports and literature reviews were excluded. Finally, comment or opinion  
41 about patients' active participation in safety and studies involving the general population  
42 were excluded.  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

*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



1 of organising and summarising the findings from a diverse body of both qualitative and  
2 quantitative research (Dixon-Woods et al., 2005). Our emphasis was less on the quantitative  
3 analysis of data but aimed more on the searching out of any patterns in the data that might  
4 help build an explanation of why, when and how patients are likely to engage actively in  
5 helping to reduce errors. The process was iterative requiring rereading and discussion of the  
6 articles to further refine the categories and subcategories while seeking negative cases. The  
7 discussion and conclusion sections were the main sources used from the quantitative articles.  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18

## 19 **Results**

20 Overall, 139 abstracts of studies were identified (see Appendix A). During screening 63  
21 papers were excluded on the basis of the abstract because they did not fulfil the inclusion  
22 criteria or were duplications. A total of 95 articles were obtained for detailed review. An  
23 additional 27 articles were subsequently excluded; four were literature reviews, twelve  
24 reported on outcomes other than patients' willingness and ability to participate, three  
25 included educational interventions, one was a passive intervention, three were not empirical  
26 studies, two related to safety but not in the health context, one was the same study written for  
27 a different journal and another was a duplication. In total 68 papers were eligible for  
28 inclusion; these described the result of initiatives involving patients' in safety or studies of  
29 patients' perspectives of being actively involved in the safety of their care. *Table 2 provides a*  
30 *quantitative summary of the main themes which emerged from our synthesis of the data.*  
31 *Studies contributed to more than one factor and more than once within factors, for example*  
32 *within socio-demographic factors one study finds younger age as a facilitator of willingness*  
33 *and poor literacy as a barrier to ability; Appendix B provides further details of the articles*  
34 *reviewed.*  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1  
2  
3 **Insert Table 2 here**  
4  
5  
6

7 **Factors affecting patients' willingness and ability to participate**  
8

9 *Socio-demographic characteristics*  
10

11 Age was a common factor in a large number of studies. Older people were less likely to ask  
12 questions about hand washing or the purpose of their medication (Duncanson & Pearson  
13 2005; Waterman et al., 2006), were less willing to engage with SAM, if they had not  
14 experienced this before and preferred to assume a more passive role when invited to  
15 participate in the selection of performance indicators for a hospital in Italy (Deeks & Byatt,  
16 2000; Gagliardi et al., 2008). However, Watt et al. (2009) found that older study participants  
17 refuted a suggestion by others that older people would find asking questions more difficult.  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30

31  
32 Younger patients and those with busy working lives appeared to be over-represented in  
33 studies of self-management of oral anticoagulant therapy (OAT) (Cromheecke et al., 2000;  
34 Fitzmaurice et al., 2005; Gadisseur et al., 2003; Murray, et al., 2004). Alternatively,  
35 Menéndez-Jándula et al. (2005) found that old age and low education did not appear to be  
36 major obstacles to this. Cromheecke et al. (2000) found no correlation between age,  
37 education and therapeutic control. Khan et al. (2004) included only people over 65 years in  
38 their study and found that while some older people had difficulty with the technique, they  
39 improved with practice. Furthermore, older people preferred to attend the clinic as it provided  
40 an opportunity for social interaction suggesting that age may be a confounding variable.  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54

55 Women were found to be more willing to ask challenging questions of clinicians such as  
56 'have you washed your hands' (Abbate et al., 2008; Davis et al., 2008). Conversely, men  
57 appeared more willing to self-manage OAT (Cromheecke et al., 2000; Fitzmaurice et al.,  
58  
59  
60  
61  
62  
63  
64  
65

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

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 (Chromhecke 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

1 family members (Dowell et al., 2005; Lozowski et al., 1993). Indeed speaking up for a  
2 relative or another patient may be easier than speaking up on behalf of oneself (Watt et al.,  
3  
4  
5 2009).  
6  
7  
8  
9  
10

### 11 *Illness related factors*

12  
13  
14 Twenty-one studies reported various illness related factors such as confusion, general frailty,  
15 serious illness and depression that reduced patients' ability to participate actively in the  
16 reduction of error, often these factors resulted in people's exclusion from participation in the  
17 study. In studies of self-management of OAT the primary barriers to involvement were  
18 visual, hearing or motor impairment which restricted patients' ability to perform the required  
19 blood test competently (Cromheecke et al.,2000; Khan et al., 2004; Menéndez-Jándula et al.,  
20 2005). While confusion was an obstacle to SAM for elderly patients in a rehabilitation centre  
21 (Pereles et al., 1996). These findings suggest that one underlying cause of inability to be  
22 involved actively may be some age-related illnesses rather than age itself.  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40

### 41 *Cognitive factors*

42  
43 People who perceived a high risk of an error occurring were generally more willing to engage  
44 in protective behaviour such as: notifying staff of potential errors or asking them to comply  
45 with hand hygiene (Kovacs Burns, 2008; Schwappach & Wernli, 2010b); patients with  
46 MRSA were more likely to ask about hand washing than those without MRSA, patients  
47 without MRSA asked rarely or almost never (Luszczynska & Gunson, 2007); risk  
48 perceptions affected incident reporting among patients in psychiatric hospitals in London,  
49 where patients who perceived a threatening situation caused by other patients would often  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1 report it to staff (Quirk et al., 2005); patients with three or more drug allergies were more  
2 willing than patients without drug allergies to report preventable adverse events and near  
3 misses (Weingart et al., 2005); people who had personal experience of medication errors  
4 were likely to act to reduce the risk of similar errors (Nau & Erickson, 2005); and patients  
5 who kept their own records were often prompted to do so by the experience of a hospital  
6 losing a record of previous tests (Rassin et al., 2007). A common reason for unwillingness to  
7 ask staff about hand washing was individuals' conviction that staff hand hygiene did not pose  
8 an infection risk for them (Abbate et al., 2008); supporting Tarini (2009) that patients or their  
9 relatives who feel vulnerable are likely to be vigilant.  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23

24 Self-efficacy and positive attitudes towards preventability were also shown to increase  
25 willingness to act, for example by self-managing OAT (Hibbard et al., 2005; Schwappach &  
26 Wernli 2010c; Watt et al., 2009). Additionally, studies showed that the extent to which  
27 patients believed that their participation would prevent infections increased their intention to  
28 ask clinicians to wash their hands (Abbate et al., 2008; Longtin et al., 2009; Luszczynska &  
29 Gunson, 2007). Similarly, feeling more comfortable with error prevention increased  
30 willingness to act (Waterman et al., 2006). Extraversion was associated with patients'  
31 willingness to ask clinicians, including doctors, to wash their hands (Duncanson & Pearson,  
32 2005; Longtin et al., 2009). Having a family member in hospital in the last year and having  
33 read about medical errors increased perceptions of efficacy in being able to prevent medical  
34 errors. This was then significantly linked with a greater reported likelihood of engaging in  
35 preventative action (Hibbard et al., 2005). Lack of self-confidence reduced patients'  
36 willingness and ability to self-manage OAT (Menéndez-Jándula et al., 2005) in part this was  
37 because learning a new task was more difficult for people when in a stressful situation  
38 (Hovey et al., 2010). Longer duration of care in a cancer clinic increased the likelihood of  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1 patients reporting concerns about safety (Agoritsas et al., 2005; Weingart et al., 2007). Watt  
2 et al. (2009) found that patients were able to detect dispensing and prescribing errors in  
3 primary care but less able to do so in hospital, in part due to unfamiliarity of packaging.  
4 Perhaps as patients become more familiar and comfortable with their surroundings they  
5 believe they have greater control of their situation which increases their willingness to take an  
6 active role (Entwistle et al., 2010).  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16

17 In contrast, if patients' perceived their role to be that of passive recipient of medical expertise  
18 they were unwilling to engage actively with their safety for example by self-management of  
19 their condition or by challenge clinicians about their practice (Burnett et al., 2010; Entwistle,  
20 2005; Forsyth, 2000; Hibbard, et al., 2005; Longtin et al., 2009; Manias et al., 2004;  
21 Schwappach & Wernli, 2010a). One study found that patients did not read medication  
22 instructions (Brown et al., 2006) and others found that patients were reluctant to mark their  
23 body to indicate the site of surgery (DiGiovanni et al., 2003; Waterman, 2006) suggesting a  
24 submissive attitude towards safety.  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39

#### 40 *Clinician-patient relationships*

41 An emergent theme was that a poor relationship with their clinicians made patients less  
42 willing and able to engage in error reduction (Kuzel, et al., 2004; Watt et al., 2009). Problems  
43 of miscommunication between the two parties both verbal (Britten et al. 2000; Brown et al.,  
44 2006) and non-verbal, such as no eye contact with nurses (Bolster & Manias, 2010) made  
45 patients reluctant to ask questions or challenge clinicians. Patients who were not asked about  
46 prior knowledge of medications were less willing to ask questions (Bolster & Manias, 2010).  
47 Parents of children being treated for cancer who were less satisfied with the emotional  
48 support they received from clinicians reported intervening more often to prevent or correct an  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1 error (Lozowski et al., 1993). Perceived lack of support may have reduced parents' trust in  
2 clinicians.  
3  
4  
5  
6

7 Access to information was positively associated with patients' ability and willingness to get  
8 involved with their own safety (Forsyth et al., 2010; Hurst, 2001; Unruh & Pratt, 2007).  
9 Information can increase self-efficacy and risk perceptions thereby increasing intention to act  
10 (Schwappach & Wernli 2010a), perhaps by giving patients an understanding of what they can  
11 do (Smythe, 2010). Clinicians' ability to communicate with patients is important in this  
12 respect. Patients' ability to act is compromised by a poor understanding of drug dosages,  
13 clinicians' failure to assess patients' information needs and receiving conflicting or  
14 inadequate information about their treatment (Bolster & Manias, 2010; Britten et al., 2000;  
15 Entwistle et al., 2010; Hovey et al., 2010). Other obstacles of willingness to act were  
16 worrying about being labelled a "difficult" patient (Entwistle et al., 2005, 2010; Hurst, 2001;  
17 NPSA, 2004), fear of embarrassment and negative or judgemental reactions from clinicians  
18 (Ballinger & Payne, 2002; Brown et al., 2006; Burnett et al., 2010; Davis et al., 2008)  
19 including having their concerns dismissed, ignored, not believed or taken seriously and  
20 clinicians disagreeing with them without explaining why (Britten et al., 2000; Entwistle et al.,  
21 2010; Kovacs Burns, 2008; Ocloo 2010; Schwappach, 2008; Smythe, 2010).  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45

46 Clinicians enabled patients' more active engagement by encouraging or instructing patients to  
47 ask questions or to participate in specific actions (Bernstein et al., 2004; Davis et al., 2008;  
48 Entwistle et al., 2010) and by demonstrating that they were willing to listen (Dowell et al.,  
49 2005). One study found that patients considered engaging with their own safety had the  
50 indirect benefit of strengthening their relationship with nurses (Schwappach & Wernli,  
51 2010a). Simple visual reminders, encouraging patients to ask questions or tell clinicians to  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1 wash their hands such as leaflets, posters and “it’s okay to ask” stickers increased patients’  
2 willingness to do so (Duncan, 2007; Duncanson & Pearson, 2005; Lent et al., 2009; NPSA,  
3 2004; Quinn, 2003).  
4  
5  
6  
7  
8

9 The hierarchical, elitist and paternalistic culture of the medical profession was often a barrier  
10 to patients’ willingness to engage with their safety (Davis et al., 2008; Ocloo, 2010; Weingart  
11 et al., 2009). It was seen as inappropriate to challenge clinicians (Ballinger & Payne, 2000);  
12 some patients were fearful of questioning medical authority (Schwappach, 2008; Smythe,  
13 2010) while others were afraid of being rude to or offending the doctor (Brown et al., 2006;  
14 Davis, et al., 2008; Randle et al., 2006; Schwappach & Wernli, 2010b; Waterman et al.,  
15 2006; Quinn, 2003). Other studies demonstrated patients’ perceptions of doctors’ as holding  
16 an elite position in the healthcare context for example patients were more willing to ask  
17 nurses than doctors to wash their hands (McGuckin et al., 1999, 2001; NPSA, 2004) and  
18 might ask challenging questions of the nurses while they left factual questions for the doctors  
19 (Davis et al., 2008). One study found that unwillingness to SAM by some patients was related  
20 to a concern that nurses would be blamed should patients make an error (Manias et al., 2004).  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40

#### 41 *Organisational aspects*

42 A common finding was that a busy setting was a strong barrier in preventing patients’ active  
43 involvement in safety. When patients perceived that clinicians’ time was constrained due to  
44 work pressure or staff shortages they were wary of engaging in error prevention behaviours  
45 (Bolster & Manias, 2010; Entwistle et al., 2010; Hurst, 2001; Schwappach & Wernli, 2010c).  
46  
47 Other organisational constraints were lack of continuity of care and isolation in a side room  
48 for reasons of infection control (Hurst, 2001; Stelfox et al., 2003; Unruh & Pratt, 2007).  
49  
50 Liberal visiting hours in a paediatric intensive care unit enabled parents to report more errors;  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65



1 although parents in this context could also cause errors such as disconnecting tubes  
2 inadvertently (Frey et al., 2009). The review found evidence that patients were generally  
3 willing and able to report formally incidents such as drug complications and medication  
4 errors as this did not require the overt questioning of clinicians (Jarensiripornkul et al., 2002,  
5 2003; van den Bemt et al., 1999; Waterman et al., 2006; Weingart et al., 2004). However, an  
6 important barrier is that generally patients were not made aware of the incident reporting  
7 system (Frey et al., 2009; Watt et al., 2009).  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19

## 20 **Discussion**

21  
22 *Overall, we found no compelling evidence that age, gender or education affect directly*  
23 *patients' willingness or ability to engage with their own safety. This contrasts with what is*  
24 *known about the prevalence of low health literacy and health inequalities among lower*  
25 *socioeconomic groups and older people (Coulter & Ellins, 2006). This contradiction should*  
26 *be a focus for further research. While the studies we reviewed found that older age was a*  
27 *barrier to safety related behaviour, our synthesis suggests that age is probably a confounding*  
28 *factor. Commonly people who were able were willing (Weingart et al., 2004). Important*  
29 *barriers affecting ability are illness, which is often aged related, and ability to communicate*  
30 *in the native language. Patients come to the clinical encounter carrying their own*  
31 *experiences, and they have a number of cognitive characteristics that affect their willingness*  
32 *to participate in their own safety. These include patients' beliefs about their self-efficacy in*  
33 *respect of the extent to which they can prevent and control errors and their attitude about the*  
34 *risk of an error occurring. As our synthesis demonstrates, the role of patients' attitudes and*  
35 *beliefs should not be underestimated as these perceptions create obstacles in the environment*  
36 *that patients themselves have to manage.*  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1 The review also shows that the relationship between patients and clinicians is particularly  
2 important in predicting patients' safety-related attitudes and behaviours. Studies demonstrate  
3 that patients' deferential attitudes towards clinicians are a barrier for patients' active  
4 engagement in helping to reduce clinical errors. The main issue identified was the power of  
5 the medical profession which has been often discussed in the literature (Vincent & Coulter,  
6 2002). Many of the studies found that patients did not challenge clinicians because they felt  
7 that it was not their role to do so. Patients were also more likely to challenge nurses than  
8 doctors, indicating that they are sensitive to the occupational hierarchy in healthcare  
9 organisations.  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23

24 However, as our analysis indicates, at the interpersonal level clinicians have an important  
25 influence on patients' willingness and ability to participate in error reduction. Our review  
26 found that when clinicians encourage patients' involvement in safety then patients are  
27 generally willing to participate. This result supports the need for more effective patient  
28 clinician collaboration on safety issues (Entwistle et al., 2010). Other barriers to involvement  
29 include lack of clear written or verbal information explaining illness and treatment.  
30  
31 *Clinicians have an important role to play in addressing these communication barriers in the*  
32 *clinician-patient relationship.*  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45

46 Busy hospital settings discourage patients from engaging in error reduction behaviour. This is  
47 of concern because a busy ward is probably the time when patients are at greater risk. Indeed,  
48 the conditions that nurture the failures of foresight which eventually lead to error are rarely  
49 found at the individual level of analysis (Turner, 1976). To focus on the actions of individuals  
50 is to promote a culture of blame which is counterproductive to safety (Reason, 1998). The  
51 culture of safety within any organisation arises from the associated folkways, mores and  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1 codes of practice, namely the set of commonly accepted ways of doing things. It follows that  
2 it is readjustment of accepted cultural norms that will lead to reduction of errors (Turner,  
3 1976). In the context of healthcare there is a gap between ‘espoused theories’ (Agryris &  
4 Schon, 1996), what clinicians intend or believe they do (no harm) and their ‘theory-in-use’,  
5 or actual behaviour (to err is human). Policies encouraging patients’ greater involvement are  
6 intended to bring these gaps to the attention of clinicians. Thus programmes designed to  
7 encourage patients to ask may fail when the espoused theory -‘it’s okay to ask’- meets  
8 patients’ theory-in-use -‘doctor knows best’. Certainly, the theories-in-use that underlie  
9 practice have developed in part to enable the normalisation of unsafe practices as a way for  
10 clinicians to cope with competing demands (Dixon-Woods et al., 2009), behaviour with  
11 which patients may collude.  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29

30 Our analysis demonstrates that illness and patients’ perceptions of their role and status as  
31 subordinate to that of clinicians were the most important barriers to their involvement in error  
32 reduction. Usually it is health, not healthcare, that is of value to patients. In itself, healthcare  
33 generally is negative and undesirable; people put themselves under the control of clinicians in  
34 anticipation of positive health outcomes because they *have* to. Implicit in this is patients’  
35 need to trust clinicians as they are in a situation of vulnerability, where there is task  
36 uncertainty and ambiguity in intended outcomes. These conditions create ‘design blindness’  
37 (Friedman, 2001: 164) that is a dislocation between policy planning and implementation. In  
38 the context of patient safety the power and individualism of the medical profession has been  
39 cited as part of the problem (Collins et al., 2009), therefore deference to clinicians appears to  
40 be outmoded. Policy that tells patients ‘don’t be afraid to ask’ while well intentioned, is blind  
41 to some of the possible underlying reasons why patients assume deferential behaviour in the  
42 clinical setting. Rather than perceiving active involvement in safety as protecting themselves  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1 from error, patients express concerns about being labelled “difficult” and clinicians  
2 responding negatively or defensively to being questioned; consequently patients may be  
3  
4  
5 *actively protecting* their personal safety by assuming a relatively *passive* role.  
6  
7  
8

9  
10 *Policy and practice implications*

11  
12 In essence a policy of encouraging patients’ to be more involved in reducing medical errors  
13 requires a ‘demystification’ of clinicians’ claim to knowledge (Schon, 2007: 289) in the sense  
14 that it is opened up to inquiry. Our analysis builds on Peat et al.’s (2010) approach for  
15 appraising interventions to support patients’ involvement in safety and demonstrates that  
16 there are simple actions that clinicians can take in this respect. These include: actively  
17 listening to and taking seriously patients’ concerns; providing a clear explanation when  
18 concerns or views differ from those of the patient; appearing to have the time to talk by  
19 making eye contact and other non-verbal behaviours such as sitting by the patient’s bed; and,  
20 if acceptable to the patient, involving relatives in their care. Reassuring patients that it is okay  
21 to ask by using posters or information leaflets helps to reinforce this message. Forty-nine of  
22 the studies we reviewed involved hospital patients and those attending hospital out-patient  
23 departments; explanatory analysis of specific contexts would further assist policy makers to  
24 determine what works for whom and in what circumstances. Finally, by attending to the  
25 patients’ perspective this article has demonstrated the importance of the clinician-patient  
26 relationship for patients to participate actively in reducing clinical errors. Further exploration  
27 of the clinicians’ attitudes towards patients’ engagement in safety would aide our  
28 understanding on how to effect more profound cultural change.  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55

56 **Appendices A & B**

57  
58 Supplementary data associated with this article can be found, in the online version  
59  
60  
61  
62  
63  
64  
65

## References

1  
2  
3  
4  
5 Abbate, R., Di Giuseppe, G., Marinelli, P., Angelillo, I.F., & the Collaborative Working  
6  
7 Group (2008) Patients' knowledge, attitudes, and behavior toward hospital-associated  
8  
9 infections in Italy. *American Journal of Infection Control*, 36, 39-47.  
10

11  
12  
13  
14 Agoritsas, T., Bovier, P.A., & Perneger T.V. (2005) Patient Reports of Undesirable Events  
15  
16 During Hospitalization. *Journal of General Internal Medicine*, 20, 922–928.  
17  
18  
19  
20

21  
22 Argyris, C., & Schon, D. A. (1996). *Organizational learning II: Theory, method, and*  
23  
24 *practice*. Reading, MA: Addison Wesley  
25  
26  
27

28  
29 Ballinger, C., & Payne, S. (2000) Falling from grace or into expert hands? Alternative  
30  
31 accounts about falling in older people. *British Journal of Occupational Therapy*, 63(12),  
32  
33 573–579.  
34  
35  
36

37  
38  
39 Ballinger, C., & Payne, S. (2002) The construction of the risk of falling among and by older  
40  
41 people. *Ageing and Society*, 22(3), 305-324.  
42  
43  
44

45  
46 Bernstein, M., Potvin, D., & Martin, D.K. (2004) A qualitative study of attitudes toward error  
47  
48 in patients facing brain tumour surgery. *Canadian Journal of Neurological Sciences*, 31, 208-  
49  
50 212.  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1 Bolster, D., & Manias, E. (2010) Person-centred interactions between nurses and patients  
2 during medication activities in an acute hospital setting: Qualitative observation and  
3 interview study. *International Journal of Nursing Studies*, 47,154-165.  
4  
5  
6  
7

8  
9 Britten, N., Stevenson, F.A., Barry, C.A., Barber, N., & Bradley C.P. (2000)  
10 Misunderstandings in prescribing decisions in general practice: qualitative study. *BMJ*  
11 (*Clinical Research Ed.*), 320(7233), 484-488.  
12  
13  
14  
15  
16

17  
18  
19 Brown, M., Frost, R., Ko, Y., & Woosley, R. (2006) Diagramming patients' views of root  
20 causes of adverse drug events in ambulatory care: an online tool for planning education and  
21 research. *Patient Education & Counseling*, 62(3), 302-315.  
22  
23  
24  
25  
26

27  
28  
29 Burnett, E., Lee, K., Rushmer, R., Ellis, M., Noble, M., & Davey, P. (2010) Healthcare-  
30 associated infection and the patient experience: a qualitative study using patient interviews.  
31 *Journal of Hospital Infection*, 74, 42-47.  
32  
33  
34  
35  
36

37  
38  
39 Burroughs, T.E., Waterman, A.D., Gallagher, T.H., Jeffe, D.B., Claiborne Dunagan, W.,  
40 Garbutt, J., Cohen, M.M., Cira, J., & Fraser, V. (2007) Patients' Concerns about medical  
41 errors during hospitalization. *Journal on Quality and Patient Safety*, 33, 5-14.  
42  
43  
44  
45  
46

47  
48 Collins, M E., Block S. D., Arnold R. M., & Christakis, N. A. (2009) On the prospects for a  
49 blame-free medical culture. *Social Science & Medicine*, 69,1287–1290  
50  
51  
52  
53

54  
55 Cromheecke, M.E., Levi, M., Colly, L.P., de Mol, B.J.M., Prins, M.H., Hutten, B.A., Mak,  
56 R., Keyzers, K.C.J., & Büller, HR. (2000) Oral anticoagulation self-management and  
57  
58  
59  
60  
61

1 management by a specialist anticoagulation clinic: a randomised cross-over comparison.  
2 *Lancet*, 356, 97–102.  
3

4  
5  
6  
7 Coulter, A., & Ellins, J. (2006) *Patient-focused interventions: A review of the evidence*.  
8  
9 London: Picker Institute Europe.  
10

11  
12  
13  
14 Davis, R.E., Koutanji, M., & Vincent, C.A. (2008) How willing are patients to question  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

healthcare staff on issues related to the quality and safety of their healthcare? An exploratory study. *Quality and Safety in Health Care*, 17, 90-96.

Deeks, P.A., & Byatt, K. (2000) Are patients who self-administer their medicines in hospital more satisfied with their care? *Journal of Advanced Nursing*, 31(2), 395-400.

Department of Health (2006) *Safety first: a report for patients, clinicians and healthcare managers*. HMSO: London.

DiGiovanni, C.W., Kang, L., & Manuel, J. (2003) Patient Compliance in Avoiding Wrong-Site Surgery. *The Journal of Bone and Joint Surgery*, 85, 815-819.

Dixon-Woods, M., Agarwal, S., Jones, D., Young, B. & Sutton A. (2005) Synthesising qualitative and quantitative evidence: a review of possible methods. *Journal of Health Services Research and Policy*, 10, 45-53.

1 Dixon-Woods M., Suokas A., Pitchforth, E., & Tarrant C (2009) An ethnographic study of  
2 classifying and accounting for risk at the sharp end of medical wards. *Social Science &*  
3  
4  
5 *Medicine*, 69, 362–369  
6

7  
8  
9  
10 Dowell, D., Manwell, L.B., Maguire, A., An, P.G., Paluch, L., Felix, K., & Williams, E.  
11  
12 (2005) Urban Outpatient Views on Quality and Safety in Primary Care. *Healthcare*  
13  
14 *Quarterly*, 8(2), Suppl. 2-8  
15  
16

17  
18  
19 Duncan, C. (2007) An exploratory study of patient’s feelings about asking healthcare  
20  
21 professionals to wash their hands. *Journal of Renal Care*, 33(1), 30-34.  
22  
23

24  
25  
26 Duncanson, V., & Pearson, L.S. (2005) A study of the factors affecting the likelihood of  
27  
28 patients participating in a campaign to improve staff hand hygiene. *British Journal of*  
29  
30 *Infection Control*, 6(4), 26-30.  
31  
32

33  
34  
35  
36 Entwistle, V.A., Mello, M.M., & Brennan, T.A. (2005) Advising patients about patient  
37  
38 safety: current initiatives risk shifting responsibility. *Joint Commission Journal of Quality &*  
39  
40 *Patient Safety*, 31, 483-494.  
41  
42

43  
44  
45  
46 Entwistle, V.A., McCaughan, D., Watt, I.S., Birks, Y., Hall, J., Peat, M., Williams, B., &  
47  
48 Wright, J. (2010) Speaking up about safety concerns: multi-setting qualitative study of  
49  
50 patients' views and experiences. *Quality and Safety in Health Care*, 19 (6), 1-7.  
51  
52

53  
54  
55  
56 Esmail, A. (2006) Clinical perspectives on patient safety Chapter 1 in K Walshe & R Boaden  
57  
58 (eds.) *Patient Safety: research into practice*. Open University Press.  
59  
60



1 Fitzmaurice, D.A., Murray, E.T., McCahon, D., Holder, R., Raftery, J.P., Hussain, S.,  
2 Sandhar, H., & Hobbs, F.D.R. (2005) Self management of oral anticoagulation: randomised  
3 trial. *BMJ*, 331(7524), 1057.  
4  
5  
6

7  
8  
9 Fitzmaurice, D.A., Murray, E.T., Gee, K.M., Allan, T.F., & Hobbs, F.D.R. (2002) A  
10 randomised controlled trial of patient self-management of oral anticoagulation treatment  
11 compared with primary care management. *Journal of Clinical Pathology*, 55, 845-849.  
12  
13  
14

15  
16  
17  
18 Forsyth, R., Maddock, C.A., Iedema, R.A., & Lessere, M. (2010) Patient perceptions of  
19 carrying their own health information: approaches towards responsibility and playing an  
20 active role in their own health – implications for a patient-held health file. *Health*  
21 *Expectations*, 13(4), 416-26.  
22  
23  
24

25  
26  
27  
28 Frey, B., Ersch, J., Bernet, V., Baenziger, O., Enderli, L., & Doell, C. (2009) Involvement of  
29 parents in critical incidents in a neonatal–paediatric intensive care unit. *Quality and Safety in*  
30 *Health Care*, 18, 446-449.  
31  
32  
33

34  
35  
36  
37 Friedman V.J. (2001) Designed Blindness: An Action Science Perspective on Program  
38 Theory Evaluation. *American Journal of Evaluation*, 22(2), 161–181  
39  
40

41  
42  
43  
44 Gadisseur, A.P.A., Breukink-Engbers, W.G.M., van der Meer, F.J.M., van den Besselaar,  
45 Sturk, A.M.H., & Rosendaal, F.R. (2003) Comparison of the quality of oral anticoagulant  
46 therapy through patient self-management and management by specialized anticoagulation  
47 clinics in the Netherlands. *Archives of Internal Medicine*, 163, 2639-2646.  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

Gagliardi, A.R., Lemieux-Charles, L., Brown, A.D., Sullivan, T., & Goel, V. (2008) Barriers to patient involvement in health service planning and evaluation: an exploratory study. *Patient education and counselling*, 70(2), 234-241.

Greenhalgh, T., & Peacock, R. (2005) Effectiveness and efficiency of search methods in systematic reviews of complex evidence: audit of primary sources. *BMJ*, 331, 1064-1065.

Hibbard, J.H., Peters, E., Slovic, P., & Tusler, M. (2005) Can Patients Be Part of the Solution? Views on Their Role in Preventing Medical Errors. *Medical Care Research and Review*, 62, 601-616.

Hovey, R.B., Morch, A., Nettleton, S., Robin, E., Bullis, D., Findlay, A., & Massfeller, H. (2010) Partners in our care: patient safety from a patient perspective. *Quality and Safety in Health Care*, 19, 1-4.

Hurst, I. (2001) Vigilant Watching Over: Mothers' Actions to Safeguard Their Premature Babies in the Newborn Intensive Care Nursery. *Journal of Perinatal and Neonatal Nursing*, 15(3), 39-57.

Iedema, R., Jorm C., & Lum, M. (2009) Affect is central to patient safety: The horror stories of young anaesthetists. *Social Science & Medicine*, 69(12),1750-1756

Jarernsiripornkul, N., Krska, J., Capps, P.A.G., Richards, R.M.E., & Lee, A. (2002) Patient reporting of potential adverse drug reactions: a methodological study. *British Journal of Clinical Pharmacology*, 53(3), 318-325.

1 Jarernsiripornkul, N., Krska, J., Richards, R.M.E., & Capps, P.A.G. (2003) Patient reporting  
2 of adverse drug reactions: useful information for pain management? *European Journal of*  
3 *Pain*,7(3), 219-24.  
4  
5  
6  
7  
8

9 JCAHO (2011) Speak Up Initiatives. The Joint Commission website.

10 <http://www.youtube.com/user/TheJointCommission>  
11  
12  
13  
14  
15

16 Johnson T.J. (1972) *Professions and Power*. MacMillan Press: London.  
17  
18  
19  
20  
21

22 Khan, T.I., Kamali, F., Kesteven, P., Avery, P., & Wynne, H. (2004) The value of education  
23 and self-monitoring in the management of warfarin therapy in older patients with unstable  
24 control of anticoagulation. *British Journal of Haematology*, 126, 557–564.  
25  
26  
27  
28  
29  
30

31 Kohn, L.T., Corrigan, J., & Donaldson, M.S. (1999) *To Err is Human: Building a Safer*  
32 *Health System*. Washington, DC: National Academies Press.  
33  
34  
35  
36  
37  
38

39 Kovacs Burns, K. (2008). Canadian patient safety champions: collaborating on improving  
40 patient safety. *Healthcare Quarterly*, 11, 95-100.  
41  
42  
43  
44  
45

46 Koutanji, M., Davis, R., Vincent, C., & Coulter, A. (2005) The patients' role in patient safety:  
47 engaging patients, their representatives, and health professionals. *Clinical Risk*, 11(3), 99-  
48 104.  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1 Kuzel, A.J, Woolf, S.H., Gilchrist, V.J., Engel, J.D., LaVeist, T.A. Vincent, C., & Frankel,  
2 R.M. (2004) Patient reports of preventable problems and harms in primary health care.  
3  
4 *Annals of Family Medicine*, 2(4), 333-340.  
5  
6  
7

8  
9 Lent, V., Eckstein, E.C., Cameron, A.S., Budavich, R., Eckstein, B.C., & Donskey, C.J.  
10 (2009) Evaluation of patient participation in a patient empowerment initiative to improve  
11 hand hygiene practices in a Veterans Affairs medical center. *American Journal of Infection*  
12 *Control*, 37(2), 117-120.  
13  
14  
15  
16  
17  
18

19  
20  
21 Longtin, Y., Sax, H., Allegranzi, B., Hugonnet, S., & Pillet, D. (2009) Patients' Beliefs and  
22 Perceptions of Their Participation to Increase Healthcare Worker Compliance with Hand  
23 Hygiene. *Infection Control and Hospital Epidemiology*, 30, 830-839.  
24  
25  
26  
27  
28

29  
30  
31 Lozowski, S., Chesler, M. A., & Chesney, B.K. (1993) Parental intervention in the medical  
32 care of children with cancer. *Journal of Psychosocial Oncology*, 11(3), 63-88.  
33  
34  
35  
36

37  
38  
39 Luszczynska, A., & Gunson, K.S.E. (2007) Predictors of asking medical personnel about  
40 handwashing: The moderating role of patients' age and MRSA infection status. *Patient*  
41 *Education and Counselling*, 68(1), 79-85.  
42  
43  
44  
45  
46

47  
48  
49 Lyons, M. (2007) Should patients have a role in patient safety? A safety engineering view.  
50 *Quality & Safety in Health Care*, 16, 140-42.  
51  
52  
53

54  
55  
56 Manias, E., Beanland, C., Riley, R., & Baker, L. (2004) Self-administration of medication in  
57 hospital: patients' perspectives. *Journal of Advanced Nursing*, 46(2), 194-203  
58  
59  
60  
61

1 McGuckin, M., Waterman, R., Porten, L., Bello, S., Caruso, M., Juzaitis, B., Krug, E., Mazer,  
2 S., & Ostrawski, S. (1999) Patient education model for increasing handwashing compliance.  
3  
4  
5 *American Journal of Infection Control*, 27(4), 309-314.  
6

7  
8  
9 McGuckin, M., Waterman, R., Storr, J., Bowler, ICJW., Ashby, M., Topley, K., & Porten, L.  
10  
11 (2001) Evaluation of a patient-empowering hand hygiene programme in the UK. *Journal of*  
12  
13 *Hospital Infection*, 48, 222–227.  
14  
15

16  
17  
18  
19 Menéndez-Jándula, B., Souto, J.C. Oliver, A., Montserrat, I., Quintana, M., Gich, I., Bonfill,  
20  
21 X., & Fontcuberta, J. (2005) Comparing Self-Management of Oral Anticoagulant Therapy  
22  
23 with Clinic Management. *Annals of Internal Medicine*, 142, 1-10.  
24  
25

26  
27  
28  
29 Murray, E., Fitzmaurice, D., McCahon, D., Fuller, C., & Sandhur, H. (2004) Training for  
30  
31 patients in a randomised controlled trial of self-management of warfarin treatment. *BMJ*, 328,  
32  
33 437–8.  
34  
35

36  
37  
38  
39 National Patient Safety Agency (2004) Achieving our aims: Evaluating the results of the pilot  
40  
41 Cleanyourhands campaign. [www.npsa.nhs.uk](http://www.npsa.nhs.uk).  
42  
43

44  
45  
46 Nau, D. P., & Erickson, S.R. (2005) Medication safety: patients' experiences, beliefs, and  
47  
48 behaviors. *Journal of the American Pharmacists Association*, 45(4), 452-7.  
49  
50

51  
52  
53 Ocloo, J.E. (2010) Harmed patients gaining voice: challenging dominant perspectives in the  
54  
55 construction of medical harm and patient safety reforms. *Social Science & Medicine*, 7(3),  
56  
57 510-516.  
58  
59

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

Ovretveit, J. (2009) The contribution of new social science research to patient safety. *Social Science & Medicine*, 69(12),1780-1783.

Peat M., Entwistle, V., Hall, J., Birks, Y., Golder, S., on behalf of the PIPS Group (2010) Scoping review and approach to appraisal of interventions intended to involve patients in patient safety. *Journal of Health Services Research and Policy*, 15(1),17-25.

Pereles, L., Romonko, L., Murzyn, T., Hogan, D., Silvius, J, Stokes, E., Lond, S., & Fung, T. (1996) Evaluation of a self-medication program. *Journal of the American Geriatrics Society*, 44(2), 161-165.

Phelan, G., Kramer, E.J., Grieco, A.J., & Glassman, K.S. (1996) Self-administration of medication by patients and family members during hospitalization. *Patient Education & Counseling*, 27(1), 103-12.

Pope, C., Mays, N., & Popay, J. (2007) *Synthesizing Qualitative and Quantitative Health Evidence*. Maidenhead: Open University/McGraw-Hill.

Quirk, A., Lelliott, P., & Seale S. (2005) Risk management by patients on psychiatric wards in London: An ethnographic study. *Health, Risk & Society*, 7(1), 85-91.

Quinn, C. (2003) Infusion devices: understanding the patient perspective to avoid errors. *Professional Nurse*, 19(2), 79-83.

Randle, J., Clarke, M., & Storr, J. (2006) Hand hygiene compliance in healthcare workers. *Journal of Hospital Infection*, 64, 205-209.

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

Rassin, M., Zilcha, L., Berger, M., & Silner, D. (2007) Personal medical documents management-How patients perceive, keep and manage their medical documents: A qualitative study. *International Journal of Nursing Studies*, 44(6), 862-868.

Reason, J. (1998) Achieving a safe culture: Theory and practice. *Work & Stress*, 12(3),293-306.

Schon D.A. (2007) the Reflective Practitioner. Ashgate Publishing Ltd.

Schwappach, D.L.B. (2008) "Against the silence": Development and first results of a patient survey to assess experiences of safety-related events in hospital. *BMC Health Services Research*, 8,59.

Schwappach, D.L.B., & Wernli, M. (2010a) Am I (un)safe here? Chemotherapy patients' perspectives towards engaging in their safety. *Quality and Safety in Health Care*, 19, 1-6.

Schwappach, D.L.B., & Wernli, M. (2010b) Chemotherapy Patients' Perceptions of Drug Administration Safety. *Journal of Clinical Oncology*, 28(17), 2896-2901.

Schwappach, D.L.B., & Wernli, M. (2010c) Barriers and facilitators to chemotherapy patients' engagement in medical error prevention. *Annals of Oncology*, 21(8), 424-30.

Smythe, E. (2010) Safety is an interpretive act: A hermeneutic analysis of care in childbirth. *International Journal of Nursing Studies*, 47(12), 1474-1482.

1 Stelfox, H.T., Bates, D.W., & Redelmeier, D.A. (2003) Safety of patients isolated for  
2 infection control. *JAMA*, 290, 1899-1905  
3

4  
5  
6  
7 Stepanikova, I. (2006) Patient–physician racial and ethnic concordance and perceived  
8 medical errors. *Social Science and Medicine*, 63(12), 3060-3066  
9

10  
11  
12  
13  
14 Tarini, B.A., Lozano, P., & Christakis, D.A. (2009) Afraid in the hospital: Parental concern  
15 for errors during a child’s hospitalization. *Journal of Hospital Medicine*, 4(9), 521-527  
16  
17  
18  
19

20  
21  
22 Turner B. A. (1976) The Organizational and Interorganizational Development of Disasters.  
23  
24 *Administrative Science Quarterly*, 21, 378-397  
25

26  
27  
28  
29 Unruh, K.T., & Pratt, W. (2007) Patients as actors: The patient’s role in detecting, preventing,  
30 and recovering from medical errors. *International Journal of Medical Informatics*, 76 S,  
31 S236–S244.  
32  
33  
34  
35

36  
37  
38  
39 van den Bemt P.M.L.A., Egberst, A.C.G., Lenderink, A.W., Verzijl, J.M, Simons, K.A., van  
40 der Pol, W.S.C.J.M., & Leukfens, H.G.M (1999) Adverse drug events in hospitalized  
41 patients: a comparison of doctors, nurses and patients as a source of reports. *European*  
42  
43  
44  
45  
46 *Journal Clinical Pharmacology*, 55,155–8.  
47  
48  
49

50  
51 Vincent, C.A., & Coulter, A., (2002) Patient safety: what about the patient? *Quality and*  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65



1 Waterman, A.D., Gallagher, T.H., Garbutt, J., Waterman B.M., Fraser, V., & Burroughs, T.E.  
2 (2006) BRIEF REPORT: Hospitalized Patients' Attitudes About and Participation in Error  
3 Prevention. *Journal of General Internal Medicine*, 21, 367–370.  
4  
5  
6  
7  
8

9 Watt, I. S., Birks, Y., Entwistle, V., Gilbody, S., Hall, J., Mansell, P., McCaughan, D., Peat,  
10 M., Sheldon, T., Williams, B., & Wright, J. (2009) A review of strategies to promote patient  
11 involvement, a study to explore patient's views and attitudes and a pilot study to evaluate the  
12 acceptability of selected patient involvement strategies. *Patient Safety Research Programme*  
13 *PS/034*. University of York.  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23

24 Weingart, S.N., Pagovich, O., Sands, D.Z., Li, J.M., Aronson, M.D., Davis, R.B., Bates,  
25 D.W., & Phillips, R.S. (2005) What Can Hospitalized Patients Tell Us About Adverse  
26 Events? Learning from Patient-Reported. *Incidents Journal of General Internal Medicine*, 20,  
27 830–836.  
28  
29  
30  
31  
32  
33  
34  
35

36 Weingart, S.N., Toth, M., Eneman, J., Aronson, M.D., Sands, D.Z., Ship, A.N., Davis, R.B.,  
37 & Phillips, R.S. (2004) Lessons from a patient partnership intervention to prevent adverse  
38 drug events. *International Journal for Quality in Health Care*, 16(6), 499–507.  
39  
40  
41  
42  
43  
44  
45

46 Weingart, S. N., Price, J., Duncombe, D., Connor, M., Sommer, K., Conley, K., Bierer, B.E.,  
47 & Ponte, P.R. (2007) Patient-reported safety and quality of care in outpatient oncology. *Joint*  
48 *Commission Journal On Quality And Patient Safety*, 33(2), 83-94.  
49  
50  
51  
52  
53  
54  
55

56 Weingart, S.N., Simchowicz, B., Eng, T.K., Morway, L., Spencer, J., Zhu, J., Clearly, C.,  
57 Korman-Parra, J., & Horvath, K. (2009) The You CAN Campaign: Teamwork Training for  
58  
59  
60  
61  
62  
63  
64  
65

1 Patients and Families in Ambulatory Oncology. *The Joint Commission Journal on Quality*  
2 *and Patient Safety*, 35(2), 63-71.  
3  
4  
5

6  
7 WHO (2004) *World Alliance for Patient Safety; Forward Programme 2004*. Geneva: World  
8  
9 Health Organization, 2004.  
10

11  
12  
13  
14 WHO (2005) *World Alliance for Patient Safety; Forward Programme 2005*. Geneva: World  
15  
16 Health Organization, 2005.  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

**Table 1. Number of Factors Identified By Methods (Studies Can Use More Than One Method)**

Method	Self-administered questionnaires	Structured interviews	Qualitative interviews	Nonparticipant observation	Randomized trials	Focus groups	Document analysis
<b>Factors</b>							
Socio-demographic	10	3	11	0	7	2	1
Illness	5	0	9	1	7	1	0
Cognitive	9	0	7	0	1	0	1
C-P relationship	12	1	25	4	0	4	0
Organisational	2	0	7	2	0	1	1

**Table 2. Numbers of Studies Identifying Facilitators and Barriers to Willingness and Ability (Studies Can Include More Than One Factor)**

<b>Factors</b>	<b>Facilitators of willingness</b>	<b>Barriers to willingness</b>	<b>Facilitators of ability</b>	<b>Barriers to ability</b>	<b>Total</b>
Socio-demographic	8	4	-	15	<b>27</b>
Illness related	-	-	-	23	<b>23</b>
Cognitive	13	10	-	-	<b>23</b>
Clinician-patient	7	26	1	9	<b>43</b>
Organisational	-	3	1	6	<b>10</b>

**Electronic Supplementary Material (online publication only)**

**[Click here to download Electronic Supplementary Material \(online publication only\): Appendix A.docx](#)**

**Electronic Supplementary Material (online publication only)**

**[Click here to download Electronic Supplementary Material \(online publication only\): Summary table Appendix B.doc](#)**

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

**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**

24<sup>th</sup> 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

1 Contrary to policy assumptions, patients may *actively protect* their personal safety by  
2 assuming a *passive* role  
3

4 There is 'design blindness' in campaigns advising patients to speak up if they have  
5 concerns about their care  
6  
7  
8

9 3. Would it be possible to provide some summary table of your very extensive list of  
10 papers in Appendix A? You have what looks like a helpful framework and annotation, and it  
11 would be possible to quantify this and show how many of the different articles reviewed  
12 featured on your criteria and classifications (e.g. methodological, substantive). At present that  
13 solid intellectual work is rather lost since it is relegated to that appendix (which it has to be,  
14 for reasons of space and reader "fatigue"), and it must be possible to summarise at least some  
15 of that work in a tabular form in the main body of the text.  
16  
17  
18

19 We have attempted to address this comment and that of reviewer 3 concerning the  
20 methods with the inclusion of two tables. Table 1 lists the factors that emerged from  
21 our synthesis by the methods used in each of the respective studies. In table 2 we have  
22 attempted to provide a quantitative summary of the themes which emerged from what  
23 is primarily a qualitative synthesis of the data.  
24  
25

26 4. Could you cut your reference list down to those that are cited in text? The full list  
27 should appear in your web-accessible file, say, following your extensive initial tabulation.  
28 The reference list at the end of the paper that will be published should be limited to those that  
29 are cited in text. However, the reader can be directed to the full list. This should free up space  
30 elsewhere for spending a bit more time summarising your appendix, outlining your  
31 substantive findings (and responding to comments).  
32  
33  
34

35 The reference list at the end of the paper contains all the reference that are cited in the  
36 text and all of the articles used in our review are referenced in the text. We have  
37 reduced some of the additional background references and judiciously reduced the  
38 number of times some of the review articles are referenced thus there are no  
39 additional references.  
40  
41

42 5. Keep under 8,000 words.  
43

44 By pruning of references and parsimonious use of words we have contained the word  
45 count to 7759 words.  
46  
47  
48

49 Reviewer #1: The authors have clearly attempted to address all of the reviewers' concerns,  
50 and the manuscript has improved as a result.  
51  
52

53 I was unable to see Appendices A and B in the revised submission, and I think few readers  
54 will have sufficient interest and time to review additional online resources. The appending of  
55 information about the data extraction process does not help explain the selection of findings  
56 for presentation or the interpretation/synthesis presented in the paper. The details that are  
57 appended about individual studies may be useful, depending on what information has been  
58 extracted and how accurate it is.  
59  
60  
61  
62  
63  
64  
65



1 The main text of the findings sections appears less ad hoc now, and is probably generally  
2 acceptable, although the difficulty of justifying the basis/strengths of claims summarised  
3 from particular studies remains.

4  
5 Two tables have been added: Table 1 shows the range of methods used in the studies;  
6 and Table 2 is a quantitative summary of the themes which emerged from our  
7 synthesis of the studies.  
8

9  
10 One of the changes that the authors highlight several times in their letter describing their  
11 responses to the reviews is problematic in a couple of respects. The Peat et al (2010)  
12 framework is now appropriately mentioned in the Introduction (pdf p5/53). However, this  
13 fraework was based on a literature review, the findings of which should, according to the  
14 authors' protocol, have been excluded from their systematic review. The statement in the  
15 findings section on pdf p10/53 that "Peat et al. (2010) found that ability to be involved  
16 actively was dependent on socio-economic and cognitive skills" therefore seems out of place.  
17 I would recommend removing it and replacing it with an accurate summary from a study that  
18 did meet the review eligibility criteria and that analysed willingness/ability to participate on  
19 socioeconomic and/or educational lines. (I also note that I think the summary statement as  
20 written is rather misleading. The Peat et al paper focused primarily on the different ways in  
21 which patients' or family members' actions might contribute to their safety and concluded an  
22 overview of all of these with a comment that "All of the above behaviours to a greater or  
23 lesser degree require patients and their representatives to be well informed. The capacity to  
24 do this varies across individuals and has been found to be affected by achieved educational  
25 level, income, cognitive skills and cultural differences which may affect patients' health  
26 beliefs and their ability to fully utilise health services" (p21-22).  
27  
28  
29  
30

31 We agree with the reviewer's comments and have removed the sentence: "Peat et al.  
32 (2010) found that ability to be involved actively was dependent on socio-economic  
33 and cognitive skills".  
34  
35

36 Minor points:

37  
38 All the double speech marks around newly inserted text need to be removed.

39  
40  
41 These have been removed.  
42

43 Pdf p7/53 The first sentence is hard to follow. Did you first review titles and keywords, and  
44 select abstracts to review on the basis of those?  
45  
46

47 This has been altered to read:  
48 'Firstly we reviewed titles and key words and used these as our criteria for selecting  
49 abstracts'.  
50

51  
52 PDF p11/35 "Many of the studies excluded patients who were unable to speak the native  
53 language, indicating that language is a considerable barrier." Perhaps better " . indicating that  
54 language is seen as a considerable barrier."  
55

56  
57 We have altered the sentence to read 'is seen'.  
58  
59  
60  
61  
62  
63  
64  
65

1 Reviewer #2: Social Science & Medicine - Manuscript number : SSM-D-11-02205R1  
2 Title: Patients willingness and ability to participate actively in the reduction of clinical errors:  
3 A systematic literature review  
4

5 This revised version of the paper again provides a very interesting read in which the authors  
6 of the paper have very thoroughly and succinctly taken on board the various comments from  
7 the reviewers which much improves the paper.  
8

9 My only remaining comments are as follows:  
10

11 1) The conclusion on page 15, line 33, states 'we found no compelling evidence that  
12 socio-demographic factors affect directly patients' willingness or ability to engage with their  
13 own safety'.  
14

15 I think this conclusion does rather contrast with a much wider literature on the impact of  
16 health inequalities on participation. I therefore think it would be useful to refer to this in some  
17 way and to make the case for more research on PPI in patient safety to look more closely at  
18 this area (one example that could be referred to here is the Coulter and Ellins study on patient  
19 focused interventions which refers strongly to issues of health literacy and lack of access of  
20 disadvantaged groups as a barrier to participation. The authors do also show in their summary  
21 table under factors influencing ability to participate, that educ level, literacy and social  
22 disadvantage are socio demographic factors that may need to be looked at more closely.  
23  
24

25 We agree with this comment and have altered the text to read as follows:

26 'Overall, despite a large number of studies investigating socio-demographic factors,  
27 the data in respect of age, gender and education were inconclusive to claim that socio-  
28 demographic characteristics were consistent factors predicting per se patients'  
29 willingness or ability to engage with safety matters.'  
30  
31

32 In addition we have moved this sentence to the last full paragraph of p9.  
33  
34

35 In the Discussion section we have now stated:  
36

37 'Overall, we found no compelling evidence that age, gender or education affect  
38 directly patients' willingness or ability to engage with their own safety. This contrasts  
39 with what is known about the prevalence of low health literacy and health inequalities  
40 among lower socioeconomic groups and older people (Coulter & Ellins, 2006). This  
41 contradiction should be a focus for further research'.  
42  
43  
44

45 2) On page 16, line 46, I wondered if it might be more accurate given the overall  
46 conclusions about problems of power in the clinician-patient relationship to rephrase/replace  
47 the sentence starting with 'In short and finishing with resolved', to read after 'illness and  
48 treatment': 'Clinicians have an important role to play in addressing these barriers of  
49 communication in the clinician-patient relationship.'  
50  
51

52 We agree with this comment and have altered the text to read:  
53

54 'Clinicians have an important role to play in addressing these communication barriers  
55 in the clinician-patient relationship'.  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65

1  
2  
3  
4  
5  
6  
7  
8  
9  
3) 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.

10  
11  
12  
In the last paragraph of the search strategy section we have included two sentences which state:

13  
14  
15  
16  
17  
18  
19  
‘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’.

20  
21  
22  
23  
24  
25  
26  
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.

27  
28  
29  
30  
31  
32  
33  
34  
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.

35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
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.

45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65  
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.