

Effectiveness of interventions designed to promote patient involvement to enhance safety: a systematic review

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ABSTRACT

Background There is growing international interest in involving patients in interventions to promote and support them in securing their own safety. This paper reports a systematic review of evaluations of the effectiveness of interventions that have been used with the explicit intention of promoting patient involvement in patient safety in healthcare.

Methods The authors searched Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, CENTRAL, CINAHL, EMBASE, HMIC, MEDLINE, MEDLINE in-process, PsycINFO and ASSIA to August 2008. We also searched databases of reports, conference proceedings, grey literature, ongoing research and relevant patient safety organisations, and hand-searched two journals. Meta-analysis of the data was not appropriate; therefore, studies were categorised according to how the interventions encouraged patients' actions to improve safety—informing the management plan, monitoring and ensuring safe delivery of treatment (by health professional and by self), making systems safer—and were critiqued in a narrative manner.

Findings The authors identified 14 individual experimental and quasiexperimental studies plus one systematic review. The majority of studies fell into the monitoring and ensuring safe delivery of treatment by self category and were all related to enhancing medication safety. Authors reported improved patient safety incident outcomes for the intervention groups compared with controls where the interventions aimed to encourage patient involvement in: (1) monitoring and ensuring safe delivery of treatment by self (self-management of anticoagulation, 'easy' read information leaflet, nurse-led education to promote self-medication in hospital, patient package insert using lay terminology); (2) informing the management plan/monitoring and ensuring safe delivery of treatment by self (individualised teaching plan by nurse, pharmacist counselling). It was not possible to draw any clear conclusions as to the effectiveness of the interventions (with the exception of one specific aspect of self-medication, that is, self-management of anticoagulation) due to concerns about the methodological quality of the studies.

Conclusions There is limited evidence for the effectiveness of interventions designed to promote patient involvement on patient safety incidents and in general is poor quality. Existing evidence is confined to the promotion of safe self-management of medication, most notably relating to the self-management of oral anticoagulants.

BACKGROUND

International estimates suggest that between 3% and 17% of hospital admissions result in an adverse event and that between 28% and 75% of them are preventable.¹ Strategies to reduce adverse events have focused mainly on the change of systems of care and professional behaviour. However, more recently, there has been growing international interest in the development and use of interventions to promote and support patients' (and their family members' or advocate) roles in securing their own safety in healthcare contexts.

The provision of safety-related advice, in the form of a 'tip sheet,' is the most common intervention currently used by healthcare providers that aim to encourage patients to contribute to their own safety. For instance, '20 tips to help prevent medical errors' (USA) and 'Ask About Your Medicines' (Croatia).^{2–3} Another method by which patients may contribute to improved safety (both their own and others), is through participation in reporting systems—for example, Meldpunt Medicijnen (DGV) in The Netherlands.⁴ Previous research suggests that while these interventions hold potential, there is scant information on their effectiveness.^{5–6}

The concept of patient involvement in healthcare is not unique to the area of patient safety. Indeed, there is a broad interest and literature base for patient involvement strategies in healthcare more generally; however, this paper reports the first systematic review of the research evidence on the effectiveness of interventions designed to promote patient involvement specifically to enhance safety, in a healthcare context.

OBJECTIVES

To identify, appraise and summarise evaluations of strategies or interventions which have been used with the explicit intention of promoting patients' (and/or their family members' or advocates') involvement in their care with a view to enhancing their own, or others' safety in a healthcare context.

METHODS

Eligibility and search strategy

We included all published and unpublished systematic reviews, experimental studies and quasiexperimental studies that evaluated any intervention which promoted or supported patients' involvement (and/or their family/representatives), in activities

relating to their healthcare with the explicit intention of enhancing patient safety. Experimental studies were defined as 'participants allocated to intervention or control groups by means of randomisation,' and quasiexperimental studies were defined as 'allocation to groups is under the control of the investigator but falls short of genuine randomisation.' We included any health service users or potential health service users in any healthcare context. Systematic reviews were included provided they were of a high quality and recently published. We excluded studies that promoted or supported patients in activities relating to their healthcare, but did not explicitly aim to enhance safety (for example, in-patient self-medication which aimed to improve pain control or, coaching and question prompts which aimed to improve clinical decision-making). Outcomes of interest were patient safety incidents such as adverse incidents, adverse events, near misses, medication error rates and infection rates.

This review was conducted in conjunction with a broad-ranging review of strategies to promote patient involvement to enhance safety. Therefore, the search strategies were broad in nature in order to capture relevant records for each of the literature reviews. A range of free text terms and subject headings were used for both the patient involvement concept of the question and the patient safety element. Key terms for patient involvement included terms to describe 'patient' (eg, consumer, citizen, public, carer, care giver, user), terms to describe 'involvement' (eg, view, attitude, role, contribution, partner, engagement, opinion) and subject headings (consumer participation, patient education). Key terms for patient safety included risk, safe, mistake, error, near miss, adverse reporting and subject headings such as safety management, risk management, medical errors and medication errors. There were no language restrictions. We searched Cochrane Database of Systematic Reviews (CDSR) (Issue 3, 2008), Database of Abstracts of Reviews of Effects (DARE) (July 2008), CENTRAL (Issue 3, 2008), CINAHL (1982 to July 2008), EMBASE (1980 to Week 29 2008), HMC Health Management Information Consortium (July 2008), MEDLINE (1966 to July 2008), MEDLINE In-process & other non-indexed citations (July 2008), PsycINFO (1967 to July 2008), Applied Social Sciences Index and Abstracts (ASSIA) (1987 to July 2008) and NHS Economic Evaluations Database (NHS EED) (July 2008). We also searched databases of reports, conference proceedings, grey literature and ongoing research. We sought additional studies from: the websites of patient safety organisations, hand-searched two specialist patient safety journals and consulted topic specialists within the research team.

Selection of studies and data extraction

Two authors screened citations of titles and abstracts for potentially relevant papers. The inclusion criteria were then applied independently (based on the full paper) by two authors and data extracted according to predefined criteria. Disagreements were resolved by consultation with a third author. We assessed the methodological quality of all included studies. Systematic reviews were assessed according to the Quality of Reporting of Meta-analyses (QUOROM) statement.⁷ Experimental and quasiexperimental studies were assessed according to criteria recommended by the Centre for Reviews and Dissemination (CRD).⁸

Data analysis

After looking at the included studies in terms of participants, interventions and outcomes, it was not considered appropriate to undertake any formal pooling of data.

RESULTS

Results of the search

Over 22 000 references were retrieved by the searches (figure 1). Sixty-eight references were identified as potentially relevant. A total of 15 studies met the eligibility criteria. Four additional papers were identified as copublications that reported aspects of the same study. To date, one paper has not been received and awaits classification. The search did not identify any ongoing studies.

There were 14 individual studies with 8460 participants (although there were 17270 participants prior to post-randomisation exclusions) and one systematic review (included 16 RCTs) (table 1). The systematic review also included a review of non-randomised controlled studies and is not reported here because a number of the study designs did not fit the inclusion criteria for this review.

Design

Among the 14 individual studies included in the present review, 11 were an experimental design, and the remainder were quasiexperimental.^{9 11 22} The majority of the individual studies were conducted in the USA (n=9), plus one in Canada,¹⁸ one in Australia,⁹ one in Nepal,¹⁵ one in Belgium²¹ and one in the UK.¹⁴ The length of follow-up in these 14 individual trials ranged from immediately following the intervention^{15 16} up to 12 months.⁹ In the systematic review, the duration of the included studies varied from 2 months to 24 months.¹⁰

Setting

Among the individual studies included in the present review, eight took place in a hospital setting (five ward-based and three in outpatients), three in general practice clinics^{9 21 22} and three in other community settings.^{16 17 19}

Participants

The majority of individual studies in the present review included adult participants.^{11 14 15 19–23} Five studies included elderly participants.^{9 12 13 17 18} One study recruited parents of paediatric patients.¹⁶ The mean age of the participants varied from approximately 38 years to 80 years, and the proportion of male participants in the studies ranged from 12% to 55%. In the systematic review, the mean age of participants ranged from 42 to 75 years.¹⁰

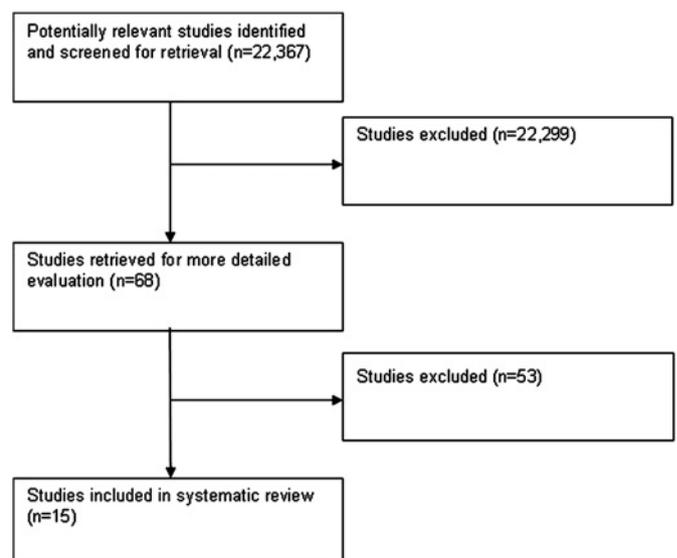


Figure 1 Flow chart of identification of relevant studies.

Table 1 Characteristics of included studies

Study	Design	Inclusion Criteria (patient characteristics)	Intervention	Control	Duration of study (days or months)	Mean age (years)	Sample size	
							Intervention	Control
Atkin <i>et al</i> , Australia ⁹	Quasi	Elderly patients attending GP clinic, taking at least three medications	Given Medication Record Card and asked to bring it to all medical consultations for updating; after each GP consultation visited by pharmacist; additionally asked to bring currently used medications to each GP consultation (reminder posted/telephoned)	Given Medication Record Card and asked by their doctor to bring it to all subsequent medical consultations for updating; after each GP consultation visited by pharmacist	12 months	Median 75	104	102
Connock <i>et al</i> , UK ¹⁰	Systematic review	RCTs where intervention was near-patient testing, patient self-testing or patient self-management of oral anticoagulant therapy versus a comparator of routine anticoagulation clinics	Self-testing (n=5) Self-management(n=9) Both (n=1)	Primary care/family doctor management (n=6) Specialised clinic (n=7) Both (n=2)	Range from 2 to >24 months	Range from 42 to 75	16 trials 2231	16 trials 2052
Fisher <i>et al</i> , USA ¹¹	Quasi	Out patients receiving a new prescription for oral antibiotics or tricyclic antidepressants	Patient-generated reports (via telephone) of adverse clinical events	Staff-generated reports	14 days	NR	2705	1109
Kennedy, USA ¹²	Experimental	Patients 70 years or over (English speaking) admitted from non-institutionalised setting to a medical-surgical unit and prescribed at least one medication at time of discharge	Home Medication Behaviour Programme: individualised teaching plan delivered by nurse prior to discharge	Usual care: staff nurse assessment	1 month	77/75	32	33
Kim and Grier, USA ¹³	Experimental	Elderly inpatients with a chronic disease requiring a prescription for a diuretic, antihypertensive or digitalis drug	Medication instruction (audiotape plus written) at 1. Normal pace 2. Slow pace	No medication instruction	1 day	77	15 + 15	15
Ley <i>et al</i> , UK ¹⁴	Experimental	Psychiatric outpatients requiring tranquilisers or antidepressant	Medication information leaflets which differed in reading level: 1. Easy 2. Moderate 3. Difficult	Normal procedure	NR	NR	40 + 40 + 40	40
McKellar and Rutland-Brown, Nepal ¹⁵	Experimental	Illiterate hospital outpatients prescribed at least one medication	Medication dose counselling from Community Medical Auxiliary On the Job Trainees	No intervention	Immediately following intervention	NR	50	50
McMahon <i>et al</i> , USA ¹⁶	Experimental	Parents attending health centre with children <4 years of age diagnosed as having otitis media and placed on an antibiotic suspension	Dosing instructions and demonstration plus: 1. Syringe 2. Syringe with correct dose marked	Dosing instruction only	Immediately following intervention	NR	30 + 30	30

Continued

Table 1 Continued

Study	Design	Inclusion Criteria (patient characteristics)	Intervention	Control	Duration of study (days or months)	Mean age (years)	Sample size	
							Intervention	Control
Neafsey <i>et al</i> , USA ¹⁷	Experimental	Elderly people attending senior centre and able to perform activities of daily living, answer six of 10 items on the Short Portable mental Status Questionnaire, have a reading comprehension score of at least grade 6, be living independently and have visual acuity of at least 20/100 with corrective lenses	Personal Education Programme about potential drug interactions delivered by interactive computer program plus medication information booklet, or booklet only	NR	28 days	74	33 + 33	32
Perelles <i>et al</i> , Canada ¹⁸	Experimental	Elderly hospital inpatients with plan to return to community living	Self-medication programme; three-stage programme where patient is given increasing responsibility for administration of medications	Standard care, medications administered by nursing staff	40 days	80	51	56
Punekar, USA ¹⁹	Experimental	Member of drug benefit plan with at least one prescription filled in the 3 months	Brochure containing tips about medication and list of questions to ask healthcare professional, plus wallet card containing list of questions to ask healthcare professional and space for patients to record personal medical data	NR	42 days	NR	744	735
Schnipper <i>et al</i> , USA ²⁰	Experimental	English speaking inpatients on general medicine wards who were being discharged home	Pharmacist counselling about medication at discharge and follow-up telephone call	Usual care: routine review of medication by ward-based pharmacist	30 days	58	92	84
Van Haecht <i>et al</i> , Belgium ^{21,t}	Experimental	Patients attending GP with acute locomotor injury requiring non-steroidal anti-inflammatory drugs	Patient package insert using explicit headings, lay terminology and simple syntax	Traditional insert	7 days	38	161	156
Varkey <i>et al</i> , USA ²²	Quasi	Adults visiting primary care clinic	Multifaceted intervention for patient and provider; patient-level interventions: posted reminder to bring all medications to clinic visit and verification/correction of medication list in electronic medical record	Usual care: medication history obtained from patient by provider and documented in electronic medical record	NR	50/54	53	57
Weingart <i>et al</i> , USA ²³	Experimental	Adult medical inpatients	Given copy of current medication list with glossary of common medical terms (updated every 3 days) plus one page education guide to medication safety	One page education guide to medication safety	1053 patient-days at risk	58/62	107	102

NR, not reported.

Interventions

To gain a better understanding of the interventions included in this review, three broad routes by which patients' actions might contribute to safety were identified. The categorisations were originally developed (and described in further detail) for a broad-ranging review of patient involvement in safety,²⁴ which was undertaken in conjunction with this systematic review. The categorisations were:

1. informing the management plan: helping to ensure the appropriate treatment plan is formulated (eg, patients make sure that healthcare professionals have information about any of their allergies or adverse reactions to medication);
2. monitoring and ensuring safe delivery of treatment: helping to ensure the management plan is correctly implemented by: (a) helping to ensure safe delivery of planned treatment by health professionals (eg, checking that the correct dose of chemotherapy medication is administered at the right time); and (b) helping to ensure safe delivery of treatment by self (eg, patient self management of anticoagulation treatment);
3. making systems safer: helping ensure that current and future healthcare systems are safe (eg, patients acting as patient representatives on a hospital safety committee).

These are not completely mutually exclusive. For example, patient use of a treatment diary could be categorised as informing the management plan if the intention was that patients complete and update the diary with information about themselves. In addition, the diary could also be categorised as supporting monitoring and ensuring safe delivery of treatment if it contained general information for warning signs and symptoms to look out for and list routine tests that should be carried out.

Indirectly, all interventions could contribute to making systems safer, but for the purpose of this review, only those which explicitly set out to involve patients in ways that would have impacts on patient safety beyond the scope of their own care have been categorised as such.

The interventions employed in the 14 studies and one systematic review were all related to the use of medications and were classified as follows:

1. Eight individual studies and the systematic review reported on interventions that encouraged patients in monitoring and ensuring safe delivery of treatment.^{10 13–16 18 19 21 23} In one study, the intervention was concerned with helping to ensure safe delivery of planned treatment by health professionals.²³ The remainder were helping to ensure safe delivery of treatment by self.
2. In two studies, the interventions were classified as 'informing the management plan.'^{9 22}
3. In three studies, the interventions were classified as 'informing the management plan combined with monitoring and ensuring safe delivery of treatment (by self).'^{12 17 20}
4. In one study, the intervention was classified as 'informing the management plan combined with making systems safer.'¹¹

Outcomes

Seven of the 14 individual studies plus the systematic review reported at least one outcome related to patient safety incidents.^{10–12 14 18 20 21 23} These included death, medication errors, adverse drug events and reactions, close-call drug errors and patient reporting of adverse clinical events.

Methodological quality of included studies

Overall, the methodological quality of the majority of the included individual studies was poor. For example, none of the 11 experimental studies provided details regarding concealment

of allocation, and only four (of the experimental and quasi-experimental) studies provided details of blinded outcome assessment. The quality of the systematic review and meta-analysis of self-management of anticoagulation was good, addressing all the items on the QUOROM checklist.

Effects of interventions

In the two studies where the intervention aimed to involve patients by their 'informing the management plan,' no patient safety incident outcomes were reported. In the study categorised as 'monitoring and ensuring safe delivery of treatment by health professional' and also in the study categorised as 'informing the management plan/making systems safer,' there were no differences in outcomes between the intervention and control groups. In the category informing the management plan/monitoring and ensuring safe delivery of treatment by self, two studies reported favourable outcomes for the intervention group compared with the control (one study in this category did not report any patient safety incident outcomes). In the eight studies where the interventions aimed to involve patients in 'monitoring and ensuring safe delivery of treatment by self,' four of them reported patient safety incident outcomes and in the main describe improved outcomes for the intervention groups compared with controls (table 2).

DISCUSSION

This review identified evidence of safety benefit for patient involvement in one specific aspect of self-medication but little evidence of effectiveness in other aspects of healthcare.

The majority of studies fell into the monitoring and ensuring safe delivery of treatment by self category, and the interventions were all related to enhancing medication safety. Only half of the included studies evaluated at least one outcome related to patient safety incidents. Of those that did evaluate patient safety incidents, authors reported improved outcomes for the intervention groups compared with controls where the interventions aimed to encourage patient involvement in:

1. monitoring and ensuring safe delivery of treatment by self (self-management of anticoagulation, 'easy' read information leaflet, self-medication in hospital, patient package insert using lay terminology);
2. informing the management plan/monitoring and ensuring safe delivery of treatment (individualised teaching plan by nurse, pharmacist counselling).

However, it was not possible to draw any clear conclusions as to the effectiveness of the interventions (with the exception of one specific aspect of self-medication, ie, self-management of anticoagulation) due to concerns about the methodological quality of the studies.

The evidence identified in our review does not sufficiently address all potential areas of patient involvement in patient safety. For instance, the included studies and interventions were all pertaining to patient involvement to ensure medication safety, especially by promoting safe self-medication. We found no robust evaluations of efforts to involve patients in other areas of healthcare and only one evaluation encouraging patients to monitor professionally delivered healthcare. In particular, there are no evaluations of the many 'advisories' offering 'hints and tips' to patients about how to ensure they stay safe when using healthcare services, and no high-profile initiatives such as the patient empowerment element of the UK-based 'Clean your hands' campaign (although ongoing work by the NPSA aims to provide 'evidence of robust evaluation' in the future).²⁵

Table 2 Effect of interventions on patient safety incident outcomes

Intervention	Patient safety incident outcomes		
	Favours intervention	No difference	Favours control
Informing the management plan			
Medication Record Card/bring all meds/visit by pharmacist ⁹	NR	NR	NR
Reminder to bring meds/verification of med list ²²	NR	NR	NR
Monitoring and ensuring safe delivery of treatment by self			
Self-management of anticoagulation ¹⁰	Reduction in death; reduction in thromboembolic events	Major bleeding	NR
Medication instruction at normal or slow place ¹³	NR	NR	NR
'Easy' read information leaflet ¹⁴	Decrease in medication errors	NR	NR
Medication dose counselling ¹⁵	NR	NR	NR
Dosing instruction/syringe with dose marked ¹⁶	NR	NR	NR
Nurse intervention to promote self-administration of medication in hospital ¹⁸	Decrease in medication errors	NR	NR
Medication tips brochure/wallet card ¹⁹	NR	NR	NR
Patient package insert ²¹	Increase in patient reporting of adverse drug reactions	NR	NR
Monitoring and ensuring safe delivery of treatment by health professional			
List of current medication/one page medication consumer guide ²³	NR	Adverse drug events; close-call drug errors	NR
Informing the management plan/monitoring and ensuring safe delivery of treatment			
Individualised teaching plan by nurse ¹²	Reduction in medication errors	NR	NR
Personal education plan via interactive computer ¹⁷	NR	NR	NR
Pharmacist counselling ²⁰	Reduction in preventable adverse drug events; reduction in total adverse drug events	NR	NR
Informing the management plan/making systems safer			
Patient-initiated reporting system ¹¹	NR	Adverse clinical event reporting	NR

Informing the management plan: helping to ensure that appropriate treatment plan is formulated; Making systems safer: helping ensure that current and future healthcare systems are safe; Monitoring and ensuring safe delivery of treatment: helping to ensure the management plan is correctly implemented; NR, none reported; Patient safety outcomes: for example, adverse incidents, adverse events, near misses, medication error rates, infection rates.

Evidence in the present review was also limited in the type of participants and reported outcomes. Participants were primarily English-speaking, literate adults and elderly patients. Targeting elderly patients to improve medication safety would seem to be a reasonable strategy, since they are a group where comorbidity and poly-pharmacy are more common. However, it is important that patients' ability to be involved in ensuring their own safety is evaluated in other particularly vulnerable groups such as those with communication difficulties and those with low health literacy or understanding.

Although all the studies were couched in a 'patient safety frame,' only half evaluated at least one outcome directly related to patient safety incidents. One possible reason for this is that patient safety events are relatively rare and may be difficult to capture in conventional evaluations of interventions. Recent thinking in this area advocates a more individualised approach to patient safety research design: 'one size does not fit all.'^{26 27} The choice of research methods should suit the nature of the intervention to be evaluated; in particular, researchers should consider the use of a range of outcome measures including surrogate end points alongside patient outcomes.

The development of the interventions in the review is also of concern. None of the studies reported any patient involvement or consultation in the development of the intervention prior to evaluation. Since the success of these interventions depends

entirely on their uptake by patients, their views and preferences should be taken into account prior to implementation and evaluation. In addition, there was a clear lack of theoretical basis with no consideration of the intended mechanisms of the interventions (how they will work) or where they will affect the 'causal chain' (where they will work) to improve safety.

This review identified evidence of safety benefit for patient involvement in one specific aspect of self-medication; however, Connock *et al* highlight a number of caveats to take into account. First, the observed reduction in complications and deaths may be attributable to explanations other than self-management itself, including other components of the interventions (eg, patient education or training) and systematic or chance errors. Second, there is a lack of evidence about whether patient education or training alone is sufficient to reduce the risk of complications and death. Finally, the reductions in complications and deaths by patient self-management were mainly observed in trials conducted outside the UK, although this was derived from a post hoc subgroup analysis and 'should be interpreted with great caution.'¹⁰

The present review has a number of potential limitations. First, while the search for this review was comprehensive, there is nevertheless the possibility that studies (both published and unpublished) have been missed. Second, two authors did not independently screen citations of titles and abstracts (although they were validated by a random sample check).

Third, to be included in this review, studies had to be couched in a 'patient safety frame,' explicitly stating that their aim was to improve safety. Many similar interventions that involve patients may, indirectly, also impact on safety. However, any studies of these that were not reported as evaluations of safety-promoting activities may not have been identified by our search strategy and would not have fulfilled our inclusion criteria. For instance, we are aware of a body of literature pertaining to interventions that involve patients with the aim of enhancing medication adherence. A recent Cochrane review of this literature selected RCTs that reported an intervention to improve medication adherence and treatment outcome.²⁸ The review included a total of 93 interventions, of which many were very similar to those identified in our review. For example, more instruction or counselling for patients, involving patients in self-monitoring of blood pressure, dose-dispensing units and posted communications to patients. The findings from the Cochrane review suggest that 'the literature concerning interventions to improve adherence with medications remains surprisingly weak' with little evidence that medication adherence can be improved consistently and lead to improvements in treatment outcomes.

Finally, this review focussed on effectiveness of the interventions. We did not attempt to summarise the 'process' of patient involvement in patient safety; however, we recognise that this is an important consideration in evaluations of patient-involvement strategies. A scoping review of interventions intended to involve patients in patient safety, which was conducted in conjunction with this systematic review, found that patients have, largely, not been involved in the development of interventions, and little is known about their willingness and ability to adopt recommended patient-safety-promoting behaviours.²⁴ Building on the findings of that review, we developed an approach to the appraisal of interventions which encourages attention to the mechanisms by which patients might contribute to their safety, the conditions under which their contributions are likely to be successful and the extent to which these interventions are likely to ensure those conditions are filled in particular contexts. Incorporating this type of appraisal and qualitative observations (of patients' views and attitudes) within evaluations of interventions can assist in illuminating the processes whereby patients may be involved in enhancing safety.

CONCLUSIONS

There is a major international movement to increase patient involvement with a view to enhancing patient safety. However, there is scarce evidence of benefit. This review identified evidence of safety benefit for patient involvement in one specific aspect of self-medication, but little evidence of effectiveness in other aspects of healthcare. Future research should focus on areas other than medication safety. Those undertaking future research should carefully consider what is the most appropriate research design for the intervention or strategy to be evaluated. In particular, what outcomes should be measured and the inclusion of qualitative methods to complement and illuminate the assessment of patient-involvement strategies.

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