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### **Engaging Patients as Vigilant Partners in Safety**

### **A Systematic Review**

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Several initiatives promote patient involvement in error prevention, but little is known about its feasibility and effectiveness. A systematic review was conducted on the evidence of patients' attitudes toward engagement in error prevention and the effectiveness of efforts to increase patient participation. Database searches yielded 3,840 candidate articles, of which 21 studies fulfilled the inclusion criteria. Patients share a positive attitude about engaging in their safety at a general level, but their intentions and actual behaviors vary considerably. Studies applied theories of planned behavior and indicate that self-efficacy, preventability of incidents, and effectiveness of actions seem to be central to patients' intention to engage in error prevention. Rigorous evaluations of major educational campaigns are lacking. Interventions embedded within clinical settings have been effective to some extent. Evidence suggests that involvement in safety may be successful if interventions promote complex behavioral change and are sensitively implemented in health care settings.

**Keywords:** patient safety; medical error; patient participation; patient involvement; systematic review

It is increasingly acknowledged that patients could make important contributions to their safety and the prevention of errors and adverse events (Davis, Jacklin, Sevdalis, & Vincent, 2007; Entwistle, 2007; Koutantji, Davis, Vincent, & Coulter, 2005; Vincent & Coulter, 2002;). Involvement of patients in the reporting of incidents and safety management has recently been recommended by the Council of Europe and the World Alliance for Patient Safety, and several organizations now provide educational materials that motivate patients to engage in their safety

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(Perneger, 2008; World Health Organization, 2008). For example, the "Speak Up" initiative of the Joint Commission presents several brochures for patients that include instructions on how to participate in the prevention of medication errors or nosocomial infections (Joint Commission, 2008). Safety actions commonly recommended to patients include traditional measures, such as ensuring proper transmission of information to and from providers, but more challenging behaviors are also advocated, such as asking staff whether they have washed their hands. The main character of advices is bidirectional communication—that is, asking questions and informing providers about experiences, occurrences, and observations. Patient advisories often suggest communicative actions that target both the prevention of errant processes and the interception of error before it reaches the patient or causes harm.

Patient safety campaigns are based on the assumption that patients at large are willing and able to participate and engage in their safety and that the recommended behaviors are finally effective in preventing medical errors. There are a number of reasons why patient involvement could be a feasible instrument, at least theoretically. As patients are the only individuals physically present during every treatment and consultation, they are a valuable resource and carry with them important contextualized information (Unruh & Pratt, 2006). In addition, many patients prefer to be involved in their care in general, and this may also apply to safety and quality-of-care issues (Davis et al., 2007). Patients are highly motivated to decrease the risk of harm and ensure good outcomes (Lyons, 2007). Finally, many safety problems occur at the final stage of the care process "at the bedside"—for example, medication administration errors or lack of hand hygiene—and have a relatively high potential for being observed by patients. While acceptability is a necessary precondition for effectiveness, educating patients about safety may also be justified on moral grounds, despite prospects for improvements in safety. Patients may expect information about ways to prevent errors, even though they would not take precautionary actions. Providing patients complete information and involving them in their care may not only serve as an important safeguard but also expresses providers' commitment to ensuring patients' safety and their respect for patients (Entwistle, 2007). Failing to meet such expectations would then have the potential to erode trust in providers.

While patients are indeed concerned about the safety of the care they receive and are able to identify and report adverse events (Agoritsas, Bovier, & Perneger, 2005; Schwappach, 2008; Weingart et al., 2005; Weingart et al., 2007) it is, however, not naturally given that such concerns for safety translate into willingness to engage for safety. Neither is it clear that the ability to identify and (anonymously) report errors enables patients to act in a timely and effective way to intercept these errors. There is evidence from critical incident reporting systems that at least some patients already observe and intercept errors during their hospital stay without being explicitly educated to do so (Frey et al., in press; Kuo, Phillips, Graham, & Hickner, 2008; Parnes et al., 2007). Patients who experience similar recurring procedures often attentively monitor treatments and actions, detect deviations from routines, and sometimes intervene to avoid harm (Hurst, 2001; Unruh & Pratt, 2006). For

example, patients recognize—mostly by accident—that wrong drugs or wrong doses of the right drug are being given or that devices such as infusion pumps malfunction (Muller, 2003; Schulmeister, 1999). It seems possible to tap into this potential by systematically educating patients about safety. However, the fact that there are sporadic instances of single patients intervening proactively does not imply that exposing entire patient populations to educational campaigns is a reasonable policy. This is so because large-scale efforts to engage patients as vigilant partners may come at considerable cost.

First, these efforts have the potential to erode trust and complicate relationships between health care staff and patients in multiple ways. Patients may feel that responsibility for safety is being shifted toward them in inappropriate ways (Entwistle & Quick, 2006). Patients may fear adverse consequences in case they fail to comply with the recommended actions. Trust may also be affected in case patients observe suboptimal care practices. Complications can occur if patients comply with recommendations but health care organizations are not prepared to respond to patients' activities in this regard. There may also be circumstances in which patients' engagement introduces additional risks—for example, in emergency situations. Involvement of patients could also lure professionals into a false sense of safety, and other safety barriers may be relaxed (Lyons, 2007). Large-scale interventions to educate patients may also increase inequalities between patients who do and those who do not engage in their safety—for example, between educational groups, between generations, or between groups with different communicative abilities, such as patients with a migrant background (Johnstone & Kanitsaki, 2006). Finally, patient involvement may simply be an inefficient use of resources, and there may be more cost-effective alternatives to increase safety.

If patients at large are unable or unwilling to engage in their safety, or if the interventions are ineffective, the economic and noneconomic costs associated with educational campaigns may be of concern. Thus, though the idea of involving patients in safety actions is convincing and its potential benefit is high, at least on theoretical grounds, the question remains whether patients at large are able and willing to be systematically involved in error prevention, which interventions are effective in enabling patients to engage in their safety, and whether the benefits outweigh the potential risks. The main aim of this review was to assess and summarize the current evidence related to patient participation in error prevention.

### **New Contribution**

Despite the proliferation of educational campaigns to get patients involved in safety, to the author's knowledge, no systematic evaluation of the current evidence on this approach has been conducted yet. In our review, we were particularly interested in patients' and staff members' attitudes toward patients' proactive engagement in safety-related actions, their determinants, and the effectiveness of interventions aimed at fostering participation in safety. While many activities that

improve safety rely on patients' participation, for example, structured discharge education, we focus on nonindividualized interventions directed at non-diseasespecific patient populations that can be implemented proactively by patients, for example, recommendations to ask staff to wash their hands. The study thus covers activities, behaviors, attitudes, recommendations, and the target populations that are approached by the large educational safety campaigns. This review seeks to address whether patients are willing and able to act, how they can effectively be empowered to do so, and thus whether the benefits of this approach justify the potential risks and concerns associated with it. The results provide important information about the potential for involving patients in their safety, promising approaches, and future research needs.

### **Conceptual Framework**

Patients' engagement in safety can be seen as a special case of health-promoting behavior. Thus, theoretical approaches that explain individuals' engagement in such behaviors may also serve as a useful conceptual framework to understand patients' ability and willingness to participate in safety behaviors. The theory of planned behavior (TPB) has been successfully applied to a variety of health-promoting and prevention behaviors, for example, physical activity and exercise, safer sex, adherence to diet, and self-examination behavior (Ajzen & Manstead, 2007; Blanchard et al., 2009; Mausbach, Semple, Strathdee, & Patterson, 2009; McGilligan, McClenahan, & Adamson, 2009). According to the basic concept of TPB, attitudes toward a behavior, subjective norms, and perceived behavioral control are linked to intentions to perform a specific behavior (Fishbein & Ajzen, 1975; Figure 1). Attitudes toward the behavior, that is, the degree to which performing the behavior is positively or negatively valued—are assumed to be determined by accessible behavioral beliefs. Subjective norms, that is, perceived social pressure to show or not show the relevant behavior—are assumed to be determined by accessible normative beliefs. Perceived behavioral control, that is, patients' perceptions of their own ability to engage in the behavior—is assumed to be determined by accessible control beliefs. Intentions have been shown to be highly predictive of actual behavior for a number of behaviors and settings (Armitage & Conner, 2001; Godin & Kok, 1996). Transferred to patient involvement in safety, TPB would predict that a high subjective probability that participation positively affects safety—that is, patient preventability—is central to positive attitudes toward engagement. If patients hold normative beliefs that significant others (e.g., their family or maybe health care staff) expect them to engage in their safety, and share a high motivation to comply with these expectations, this would positively affect subjective norms and thereby intentions to participate. Finally, patients' perception of the presence of factors that would facilitate or impede engaging in safety, together with the subjective strength of these

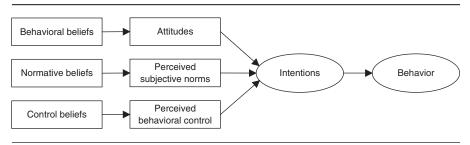


Figure 1 Conceptual Framework of the Theory of Planned Behavior

factors in affecting behavior, makes patients question their abilities to act as vigilant partners in safety. For example, patients may be less likely to engage if they perceive knowledge to be an important factor and they perceive their knowledge as insufficient. According to TPB, attitudes, subjective norms, perceived behavioral control, and its antecedent factors would explain patients' intentions to engage in their safety, and intentions would be predictive of actual behavior.

### Method

### **Data Sources and Searches**

The databases Embase, Pubmed, Cinahl, PsychInfo, ERIC, and the Cochrane Library were searched for relevant studies. The searches were conducted in October 2008 (Week 41). The references of retrieved articles were manually searched for further material. The search strategy consisted of MeSH terms (Medical Subject Headings) related to "adverse events" ["Iatrogenic Disease/prevention and control" or "Medical Errors/prevention and control" or "Medical Errors/adverse effects" or "Safety Management" or "Cross Infection/prevention and control" combined [AND] with MeSH terms related to "patient participation" ["Patient Education as Topic" or "Physician-Patient Relations" or "Nurse-Patient Relations" or "Patient Participation" or "Social Responsibility" or "Patient-Centered Care"] or the equivalent MeSH terms provided in the databases.

### **Study Selection**

Studies were included if they satisfied all of the following criteria:

- 1. They were in English, German, or French.
- 2. They were published between 1995 and 2008.

- 3. Empirical studies (qualitative or quantitative), commentaries, reviews, and theoretical analyses were excluded.
- 4. They investigated the participation of individual patients in safety-related actions or error prevention strategies, either by assessing attitudes or behaviors (e.g., surveying patients), or by evaluating interventions (e.g., educational material) aimed to promote proactive engagement of patients. Evaluative studies were included if they assessed the effects of nontailored recommendations directed at collectives of patients that can be put into practice by patients.

### **Data Extraction**

Study inclusion was determined in a two-step procedure. First, the bibliographic data and abstracts of retrieved studies were evaluated for concordance with formal inclusion rules by one reviewer (Items 1, 2, and 3 in the inclusion criteria). Studies that violated any criteria were discarded at this stage. These were mainly duplicate records and references to nonempirical studies, for example, letters, editorials, and abstracts. The remaining studies were selected for full-text retrieval and underwent critical appraisal. In the second step of the inclusion procedure, all full-texts were checked against Criteria 1 to 4. Studies were again excluded if they did not satisfy all criteria. A 20% random sample of studies that passed the first step was drawn. For this sample, concordance of two independent reviewers in the decision to include the study in the analysis was determined (Items 1 to 4). The main reasons for exclusion at this stage were that the publications did not present empirical data or did not cover the study objective. Typically, these were studies that investigated patient-provider communications in the aftermath of error. After initial review of full-texts, studies were classified according to content and study type in a second analysis. We formally extracted publication year, country of origin, type of publication, and type of study. The included studies are presented and discussed in detail.

### Results

The literature search initially identified 3,840 candidate articles, of which 110 were selected for full-text retrieval (Figure 2). The agreement of the two reviewers on inclusion/exclusion of studies was 100% in the 20% random sample (n = 24 studies). In all, 21 publications satisfied all criteria and are included in this review. These were 13 quantitative and qualitative survey studies and 8 evaluations of interventions (that may also have implemented surveys as an evaluative method; Table 1). The majority of studies originated in the United States or Canada (67%) followed by the United Kingdom (29%). A considerable increase in studies meeting the inclusion criteria during the past years can be observed. Many of the included studies are limited by methodological flaws, for example, the use of convenience samples and small sample sizes.

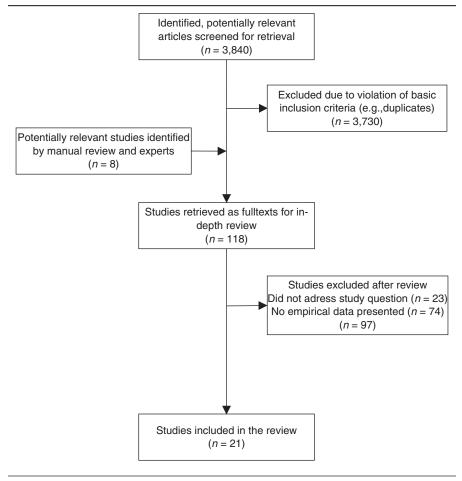


Figure 2 Flow Diagram for Search and Selection Processes

### Patients' Attitudes and Their Actual Safety-Related Behaviors

A total of 13 publications relating to 11 unique studies were identified that assessed patients' or the public's attitudes toward systematic engagement in safety or examined the relationship between attitudes, intentions to act, and actual behavior (Table 2). No study examined staff members' perspectives.

Survey studies suggest that, on a generalized level, patients and the public are receptive to and provide strong support for patients' active role in error prevention (Duncan, 2007; Duncanson & Pearson, 2005; McGuckin et al., 2006; Pearson &

Table 1 Details of Studies Included in the Review (n = 21)

Study Characteristic	Included Studies, $n$ (%)
Type of empirical study	
Evaluation of intervention	8 (38)
Assessment of attitudes/perceptions	13 (62)
Survey of patients/public	11 (52)
Survey of staff	
Qualitative study in patients	2 (10)
Study origin	
United States/Canada	14 (67)
United Kingdom	6 (29)
Continental Europe	1 (5)
Other	
Publication year	
1996-2000	1 (5)
2001-2004	7 (33)
2005-2008	13 (62)

Duncanson, 2006; Swift et al., 2001; Waterman et al., 2006). Waterman et al. (2006) report that a vast majority of surveyed patients agreed that patients could help prevent errors (91%) and that hospitals should educate patients about error prevention (98%). However, patients' attitudes toward engaging in specific, commonly recommended error prevention strategies vary considerably. Positive attitudes are more likely for actions that conform to traditional roles, for example, ensuring transmission of information from patients to providers—and less frequent for behaviors that are challenging and require questioning of medical authority (Davis et al., 2008; Swift et al., 2001; Waterman et al., 2006). Focus group discussions of the Agency for Healthcare Research and Quality's "20 Tips" campaign reveal that patients prefer messages with an unambiguous directive tone that clearly address what information should be provided, which issues to monitor, and which actions to take, when, how, and toward whom (Swift et al., 2001). Patients report a higher likelihood of intervening against nurses than against physicians, in particular if challenging interactions are involved (Davis et al., 2008; Duncan, 2007; Duncanson & Pearson, 2005; Swift et al., 2001). There is also some evidence that female, younger, highereducated patients, and those who experienced errors or intensive episodes of care are more likely to have a positive attitude toward involvement in error-prevention strategies, but these patterns are inconsistent (Davis et al., 2008; Duncan, 2007; Duncanson & Pearson, 2005; Swift et al., 2001; Waterman et al., 2006).

The survey conducted by Davis et al. (2008) also lends some support to the important role of staff in engaging patients in their safety. The survey assesses patients' willingness to ask staff safety-related questions and differentiates between

(text continues on p. 134)

(continued)

Table 2 Details of Studies That Assessed Attitudes Toward Patients' Engagement in Safety-Related Actions and/or Actual Behaviors (n=13)

Reference	Sample	Sample Size (Participants)	Methodology	Objectives	Main Findings
Abbate, Di, Marinelli, Random sample of and Angelillo patients hospitali (2008) at three randomly selected nonacad public acute care hospitals in Italy	Random sample of patients hospitalized at three randomly selected nonacademic public acute care hospitals in Italy	n = 450	Face-to-face interview using a standardized structured survey protocol	Patients' willingness to stop health care workers (hcw) who are not using gloves and a mask, and its predictors	Patients' willingness to stop The most important predictors for patients' willingness to (health care workers and early stop how were lack of gloves and a mask, and its predictors (OR = 0.17, $p < .001$ ), overestimation of the incidence of infections (OR = 3.12, $p = .006$ ), not having received information about infections (OR = 0.46, $p = .023$ ), a belief that how can infect patients (OR = $2.42$ , $p = .019$ ), not needing additional information about infections (OR = 0.39, $p = .014$ ), female gender (OR = $2.30$ , $p = .004$ ), female gender (OR = $2.30$ , $p = .006$ ), and higher education (OR = $1.51$ , $p = .009$ )
Anonymous (2001), Swiff, Koepke, Ferrer, and Miranda (2001)	Medicare beneficiaries in the United States	<i>n</i> = 72	Focus groups	Participants' attitudes toward self-protection and receptiveness to interaction with staff;	Safety messages that obtained the highest ranks from consumers were those that suggested concrete ways for

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Table 2	

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Reference	Sample	Sample Size (Participants)	Methodology	Objectives	Main Findings
				ranking of safety messages according to likelihood of taking action; interpretation of recommendations and how participants would implement them	information transmission between patients and providers and that specified which actions to take and how to implement them. The messages that ranked the lowest were those that recommended challenging actions or were perceived as unnecessary or too general. Message rankings provided by high- and low-education consumers were highly correlated
Davis, Koutantji, and Vincent (2008)	Convenience sample of patients who had undergone surgery in a U.K. innercity teaching hospital	n = 80	Face-to-face interview using the Patient Willingness to Ask Safety Questions Survey	Patients' willingness to ask health care staff factual and challenging safety questions, its predictors, and the effects of doctors' instructions on patients' willingness	Patients were more willing to ask doctors factual vs. challenging questions, nurses factual questions, doctors vs. nurses factual questions, nurses vs. doctors challenging questions, doctors challenging questions if instructed to, and nurses challenging questions if instructed to Female gender, higher education, and employment affected patients'

## Table 2 (continued)

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Reference	Sample	Sample Size (Participants)	Methodology	Objectives	Main Findings
Duncan (2007)	Stratified convenience sample of methicillin-resistant Staphylococcus aureus (MRSA) and non-MRSA patients sampled randomly among in-patients of an acute hospital in the United Kingdom	n = 109	Semistructured survey	Patients' attitudes and anxiety toward participation in a program to ask health care staff to wash their hands; ratings of supportive measures that would make it easier to ask staff	willingness to ask questions for some but not all constellations. Patients on average felt confident in participating in the program. A smaller number of admissions and less information about MRSA available at admission were correlated with feeling anxious about participation. Staff wearing badges (72%), posters on wards (55%), and seeing other patients ask questions
					(54%) would make it easier for patients to ask questions
Hibbard, Peters, Slovic, and Tusler (2005)	Convenience sample of university staff in the United States	n = 195	Self-administered questionnaire	Individuals' evaluations of effectiveness of recommended safety actions (measured on a 6-point Likert scale with 6 = very effective), their anticipated behaviors (6-point likert scale with 6 = very likely) and selfefficacy; analysis of causal pathways that may lead to taking preventive action	Effectiveness ratings ranged between 5.3 and 3.5 and were highest for longstanding traditional recommendations and lowest for challenging, new, and unfamiliar actions (mean of all items: 4.8). Ratings of likelihood of taking the preventive action ranged between 1.7 and 5.5 (mean: 3.8). Self-efficacy

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Reference	Sample	Sample Size (Participants)	Methodology	Objectives	Main Findings
Luszczynska and	Individuals who	n = 171	Mail survey	Patients' behaviors,	was related to the likelihood of taking action, in particular unfamiliar actions. Belief in the effectiveness of actions and self-efficacy together explained 26% of the variance in the likelihood of taking action
Gunson (2007)	approached the Patients Association and MRSA support groups in the United Kingdom			intentions, attitudes, subjective norms, and perceived behavioral control with regard to asking health care staff about hand washing	unrelated to intentions to ask questions. Attitudes were predictive of intentions only in older patients with MRSA. Perceived behavioral control was the best predictor of intentions and behaviors for all patient groups, except older patients without MRSA. The variables in the study explained more variance in intentions than in behavior. The fraction of variance explained was twice as high for intentions and behaviors in younger patients (approximately 50% of variance) compared with older patients without MRSA

Table 2 (continued)

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Reference	Sample	(Participants)	Methodology	Objectives	Main Findings
McGuckin, Waterman, Random digit dialing and Shubin (2006) probability sample U.S. households	Random digit dialing probability sample of U.S. households	n = 1,008	Telephone survey	Consumers' attitudes toward asking hew to wash their hands	80% of responders said they would ask their hew to wash their hands if the hew explained the importance of this
Nau and Erickson (2005)	Stratified random sample of employees (faculty and staff) and retirees of a U.S. university	n = 920	Mail survey	Individuals' engagement in medication-safety-related behaviors and its predictors	Medication safety behaviors were common: 88% of respondents reported checking their name on the label, 94% reported checking the name of the medication on the label, and 81% reported checking the directions on the label. Only 24% reported counting or measuring the medication, and 27% reported talking to the pharmacist about the medication
Duncanson and Pearson (2005), Pearson and Duncanson (2006)	Sample of surgical in-patients who were due to be discharged from an acute care hospital in the United Kingdom	n = 150	Two in-hospital self-administered surveys	Patients' attitudes toward participation in a campaign to improve staff compliance with hand washing; factors influencing the likelihood of patients	79% of patients agreed that patients should be involved in helping staff improve their hand hygiene. Patients with high extraversion scores were more likely to agree. Patients were more likely to

### Table 2 (continued)

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Reference	Sample	Sample Size (Participants)	Methodology	Objectives	Main Findings
Peters, Slovic, Hibbard, and Tusler (2006)	Convenience sample of university staff	n = 195	Experimental design with two versions of a self-administered survey randomized to participants	asking staff to wash their hands (e.g., personality traits) and measures that could facilitate asking staff to wash their hands take precautionary actions to prevent medical errors in relation to worry and risk perceptions	likely to ask nurses than to ask doctors. Staff wearing badges, posters on wards, and seeing other patients asking staff were regarded the most encouraging ideas by patients. 17% of patients reported that they would be concerned that asking staff would affect their relationship with them, leading to discrimination Dread, patient preventability, negative reactivity, age, and not being a White male increased worry about medical errors. Individuals who believed that patients who could prevent errors were more likely to intend to take preventive action ( $\beta = .27$ , $p < .05$ ). Greater worry increased the likelihood of taking strategic actions ( $\beta = .44$ , $p < .01$ ) and the likelihood of preventive effort while in hospital ( $\beta = .39$ , $p < .01$ ). Worry was a better predictor of intentions than risk perceptions

### Table 2 (continued)

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Reference	Sample	Sample Size (Participants)	Methodology	Objectives	Main Findings
Waterman et al. (2006) Random sample of patients discharg their homes from Midwest hospital (United States)	Random sample of patients discharged to their homes from 11 Midwest hospitals (United States)	n = 2,078	Telephone interviews within 10 days of discharge	Patients' comfort with recommended error prevention behaviors, their actual behaviors, and predictors of taking error prevention actions	91% of patients agreed that they could help prevent errors, and 98% agreed that hospitals should educate patients about error prevention. Patients' level of comfort varied greatly across the seven error prevention strategies. 91% felt comfortable with asking about the purpose of a medication, and 46% with asking staff whether they washed their hands. The fraction that reported safetyrelated behavior during hospitalization varied between 85% (asked general medical questions) and 5% (asked staff about hand washing). Patients who felt comfortable were 2 to 6 times more likely to take the specific actions

factual and challenging questions, asking doctors versus nurses, and asking staff challenging questions under the hypothetical condition that patients had been instructed to do so by doctors (Davis et al., 2008). Responders had higher anticipated willingness to ask doctors and nurses factual versus challenging questions, to ask doctors versus nurses factual questions, and to ask nurses versus doctors challenging questions. Patients were also more willing to ask doctors and nurses challenging questions if instructed to by a doctor. While this study provides preliminary evidence on the importance of staff support, the design is vulnerable to social and cognitive biases. As the factors assessed in the study are integrated in a single-version instrument, patients' responses may be contaminated by overestimation, focusing, or halo effects. Experimental factorial designs in which the factors, for example, "instruction by staff," are randomly allocated to patients would be useful to eliminate these effects. The relevance of instruction by staff may also help explain the relatively high fraction of U.S. citizens (80%) who "would ask their health care worker to wash or sanitize his or her hands, if the health care worker explained the importance of this to them" (McGuckin et al., 2006). Motivation by staff is inherent in the question posed, and the results need to be interpreted accordingly.

Patients' attitudes also need to be interpreted in light of responders' (or lack of) experiences of situations in which the safety behavior could have been performed. The hypothetical nature of attitude surveys may lure patients into anticipation of proactive behavior and downsizing of the serious difficulties of taking action. The study by Abbate et al. (2008), who surveyed patients on whether they would stop providers who are not wearing gloves, a relatively confronting behavior, supports this hypothesis. Patients were most likely to be willing to intervene if they had never been exposed to a health care worker who did not wear gloves and a mask (odds ratio [OR] = 0.17, confidence interval [CI] = 0.09-0.31) and if they overestimated the incidence of hospital-acquired infections (OR = 3.12, CI = 1.39-7.01). This indicates patients' overestimation of their own behavior and points to the important link between attitudes, intentions, and actual behavior. Prior experiences may be linked to self-efficacy or control beliefs.

### Attitudes, Intention to Act, and Actual Behavior

Considering these limitations, it is not surprising that patients' positive attitudes toward engaging in their safety commonly do not reflect their actual behaviors. Indeed, TPB suggests that attitudes are not sufficient in explaining intentions or even behaviors. Waterman et al. (2006) report substantial disagreement between patients' level of comfort with specific actions and their actual behavior, in particular for actions that require patients to adopt unfamiliar behavior. For example, 71% of patients reported feeling comfortable with helping health care professionals to mark a surgical site, but only 17% reported that behavior. Feeling comfortable with error prevention strategies was the strongest predictor for performing the behavior.

Patients who felt very comfortable with asking staff whether they had washed their hands were 6 times more likely to have taken this action during their hospitalization (OR = 6.3, CI = 1.4-28.2).

Recently, Luszczynska and Gunson (2007) applied the theory of planned behavior to model the complex relationship between intentions and error prevention behaviors. The authors used structural equation modeling to investigate patients' infection-protective behaviors, intentions, attitudes, subjective norms, behavioral control, and knowledge as predictors for patients' asking medical staff to wash their hands. Intention and perceived behavioral control were significantly associated with each other and with asking staff to wash their hands. Subjective norms (i.e., whether patients felt their peers would approve of their asking staff to wash their hands) were unrelated to intentions to intervene. Attitudes toward hand washing were significantly related to intentions only in older subjects with methicillinresistant Staphylococcus aureus (MRSA). Perceived behavioral control (i.e., whether patients felt that asking would be possible for them) was strongly related to intention to ask. Intention to ask was significantly related to behavior, except in older patients without MRSA. In younger patients with MRSA, perceived behavioral control not only influenced intention to ask but also directly affected behavior. Beliefs about ability to control one's own behavior were the most important predictor for both intention to ask and behavior.

Hibbard et al. (2005) extend this evidence on the relation between control beliefs and intention to act from participation in hand hygiene prevention strategies to a series of safety recommendations. Ratings of effectiveness of various safety messages, the likelihood of taking these actions, and perceived self-efficacy, that is, how efficacious one feels in preventing errors, were assessed. Self-reported likelihood of taking action was highest for longstanding recommendations (e.g., making sure all your doctors know about every prescription medicine you are taking), lower for newer recommendations (e.g., choosing a hospital that has a computer system for tracking each patient's medication), and lowest for challenging actions (e.g., confirming whether you are getting the right medication and dose). However, several new recommendations were deemed effective in error prevention. An individual's perceived self-efficacy was strongly related to the likelihood of taking preventive actions. Self-efficacy is a particularly strong predictor of taking preventive actions that are unfamiliar and require questioning medical authority. Whether they had read about medical errors in the past and the number of nights a family member stayed in hospital correlated significantly with responders' self-efficacy.

It was also observed that responders' self-efficacy significantly increased during the study simply by working through medical error scenarios and responding to the survey. This suggests that self-efficacy, and thus the likelihood of participating in error prevention, can be manipulated by exposure to specific information about errors. A path analyses confirmed that higher self-efficacy and perceived effectiveness of preventive actions are two distinct, uncorrelated patterns that additively increase participation in error prevention. Those subjects who had high self-efficacy and also perceived the actions as effective were 50% more likely to engage in preventive actions as compared with those low on both dimensions. Thus, interventions to engage patients in participation of error prevention will have maximal impact if they address both paths, self-efficacy and control beliefs.

Indeed, perceived worry, that is, emotional responses to medical error, seems to be a better predictor for patients' engagement in preventive behaviors than cognitive factors such as risk perception. Recently, the relationship between risk perceptions, worry, and intention to act to prevent medical errors was investigated under experimental design conditions (Peters et al., 2006). Responders rated 20 medical error scenarios on different measures of dread, patient preventability, worry, and risk likelihood. A preventive action index and a strategic action index were constructed and estimated. The former is a summary measure that averages responses to 14 items. In these items, respondents were asked to rate the likelihood of taking the specific action. The strategic action index averages responses to three behavioral intention items. In addition, participants responded to a "government regulation" item and several items related to their reactivity to negative events. Measures of worry were strongly correlated with the prevention action index, the strategic action index, and the government regulation index. In a structural equation model, worry was predicted by higher age, not being a White male, higher negative reactivity, higher dread, and higher perceptions of preventability by patients. Greater worry predicted higher scores on the strategic action index, that is, reporting behavioral intentions to respond to information regarding medical errors prior to hospitalization; higher scores on the preventive action index, that is, a higher likelihood of taking preventive actions during hospitalization; and support for governmental regulation. The prevention action index was also directly affected by perceived preventability. These results show that worry and increased perception of preventability play a central role in engaging patients in their safety. Preventability affected the likelihood of preventive behavior on two paths, through its direct effects on taking preventive action and indirectly through increased worry.

The role of worry may also explain why experiences of error increase the likelihood of taking preventive actions. In a medication safety survey, responders with personal experiences of medication errors or who knew someone who had encountered such errors were more likely to be worried and more likely to engage in prevention behaviors (Nau & Erickson, 2005). Still, the observation that individuals' worry seems to strongly influence engagement in preventive actions bears heavy ethical and practical implications. Manipulations of worry to engage patients in their safety need to be sensitively counterbalanced with other important dimensions of the patient-provider encounter, such as trust and accountability.

In summary, self-efficacy, behavioral control beliefs, the preventability of incidents by patients and the perceived effectiveness of actions seem to be the key forces in engaging patients in their safety, moderated by sociodemographic characteristics. Figure 3 summarizes these results on structural relations reported in the reviewed

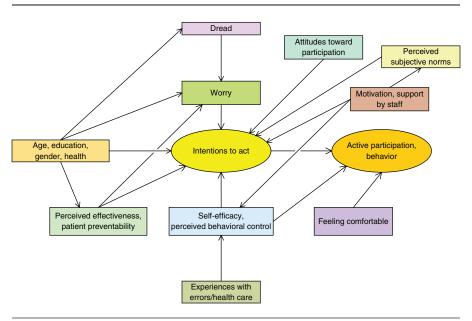


Figure 3 Structural Model of Intention to Act and **Engagement in Safety-Related Behaviors** 

studies. It should be noted though that this model integrates evidence on factors that have not all been assessed within a single study. The figure thus does not replicate the observed quantitative relations but provides a conceptual model of the relevant factors and the latent structures that seem to affect intentions and the actual behavior of taking preventive safety actions. It is also important to acknowledge that the reported models assume specified causal relationships that follow a particular direction. Though it seems plausible that, for example, intentions affect behavior, not vice versa, there are associations for which these causalities are less clear.

### **Evaluations of Interventions to Engage Patients in Safety-Related Actions**

Overall, 8 studies were identified that evaluated interventions to engage patients in proactive safety-related behavior. The variety of interventions is considerable, and the evaluative objectives assessed represent the entire continuum from development process, awareness, attitudes, and behaviors to their effects on the incidence of safety-related events or proxies thereof (Table 3). Evidence on the effects of widely

(text continues on p. 143)

Table 3 Details of Studies That Evaluated Interventions to Engage Patients in Safety-Related Actions (n=8)

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Reference	Intervention	Setting	Evaluative Method	Evaluation Objective	Main Findings
Anthony et al. (2003)	Lehigh Valley Hospital and The video was presented Health Network to a convenience educational patient safety sample of patients in video that addresses six ambulatory surgical topics (treatment plan, areas at a 800-bed U.S medication safety, falls, community hospital surgical site and to local students identification, hand and is presented eight washing, and discharge times per day on the planning) and outlines hospital education strategies that patients hospital education strategies that patients channel, accessible may employ or from any television in observations they should a patient's room make to improve patient		Anonymous self- administered survey distributed to convenience samples of patients who watched the video (n = 217 responders) Anonymous self- administered survey distributed to convenience samples of students (n = 288 responders)	Participants' self- perceived changes in comfort in talking to healthcare workers about questions and concerns before and after viewing the video, their self-rated knowledge before and after the video, and ratings of the six sections of the video; all items measured on a 5-point Likert scale	Only patient survey Mean ex-post ratings of knowledge $(3.9)$ before vs. 4.5 after the video, $p < .001$ ) and level of comfort with talking to staff $(4.1)$ before vs. 4.5 after the video, $p < .001$ ) increased slightly. Over the six major sections of the video, the mean helpfulness rating was 4.3 (range $4.2.4.3$ )
DiGiovanni, Kang, and Manuel (2003)	$ m P_I$	Observational study in an Observation of patients' outpatient elective foot-and-ankle clinic in limb marking by two raters (circulating nurse and operating physician) (n = 100 consecutive patients).	Observation of patients' correct preoperative limb marking by two raters (circulating nurse and operating physician) ( <i>n</i> = 100 consecutive patients).	Patients' complete or partial compliance with preoperative limb-marking instructions	59% of patients were fully and 4% were partially compliant. 37% made no mark. Patients who had had a previous related surgery were more likely to be noncompliant

### Table 3 (continued)

Reference	Intervention	Setting	Evaluative Method	Evaluation Objective	Main Findings
Entwistle, Mello, and Brennan (2005)	Five written patient advisories disseminated by high-profile U.S. patient safety organizations	Advisories were analyzed for content and the process of their development	Advisories were analyzed Thematic content analysis Involvement of patients for content and the of written material in the development process of their 40 semistructured face- process development to-face/telephone Evidence base of interviews with key recommendations informants, including Information on the role consumer advocates of providers for and informants ensuring safety involved in the Practical support to development and implement distribution of recommended actions advisories Clear statements on responsibility for safety	Involvement of patients in the development process Evidence base of recommendations Information on the role of providers for ensuring safety Practical support to implement recommended actions Clear statements on responsibility for safety	Lack of patient involvement in developing advisories Lack of formal evaluation prior to large-scale dissemination. Lack of information in dimensions regarded as important. Some messages suggest an inappropriate shift in responsibility. Lack of practical support to carry out recommendations.
Kutty and Weil (2006)	The "Your health care—be Observational study 10 involved" campaign months after the consists of five general campaign had been safety recommendations launched using severadirected toward patients not clearly described and was launched in convenience samples Ontario (Canada). The elements of the campaign included brochures, posters, brochure folders, and a	Observational study 10 months after the campaign that been launched using several not clearly described convenience samples	Three focus groups with providers $(1 \times)$ and patients $(2 \times)$ ( $n =$ unknown) Stakeholder satisfaction survey distributed via e-mail to directors of patient safety, risk management, and quality and patient relations of	Three focus groups with Awareness and impact of Providers evaluated the patients $(1\times)$ and the recommendations initiative positive in patients $(2\times)$ ( $n=$ from patients' and reminding staff about unknown) and identification of campaign to be well survey distributed improvement accepted by staff. via e-mail to directors Use and effectiveness of Length and layout of of patient safety, the campaign and materials were risk management, specific elements of the considered problemat and quality and campaign, and the for cost-efficient patient relations of strategies	the health care setting and message reinforcement by staff Providers evaluated the initiative positive in reminding staff about safety and reported the campaign to be well accepted by staff.  Length and layout of materials were considered problematic for cost-efficient hospital reproduction

### Table 3 (continued)

Reference	Intervention	Setting	Evaluative Method	Evaluation Objective	Main Findings
	brief DVD for use during in-hospital TV. Materials were sent to hospitals together with supportive materials for hospital administrators and communicators, electronic and print media, and partnering		Ontario hospitals (n = unknown) Anonymous self- administered patient survey distributed to patients in ambulatory waiting rooms or prior to discharge over a 2-day period at six	Patients' awareness of the campaign and its potential impact	Hospitals used various methods to promote the campaign internally (staff meetings, hospital newsletters, etc.). 66% of stakeholders rated the campaign as "somewhat or very effective"
	groups		hospitals $(n = 108)$		17% of patients had heard about the campaign. Booklets (48%) and posters (48%) were the most prevalent sources of information. 7 out of 15 patients reported they had changed communication with staff as a result of having the new
McGuckin et al. (1999)	"Partners in your care" program to increase staff hand hygiene that involved a single patient instruction by a health educator, a patient brochure and supportive materials that encourage patients to ask staff	Prospective controlled 6-week intervention/ control study in four community hospitals in South Jersey (two general medical-surgical wards per hospital) with hospitals serving as their own control	Assessment of soap usage by staff per bed-day ( $n = 441$ patients enrolled) Telephone interview with patients after discharge ( $n = 276$ responders)	Changes in soap usage of staff Patient compliance with the program: implementation of recommendation by patients, comfort of patients, and responses of experienced staff	On average, soap usage increased by 34% between control and intervention periods ( <i>p</i> = .021) 81% of patients read the brochure. 57% asked staff whether they had washed their hands.

# Table 3 (continued)

		I apric 3	rable 3 (continued)		
Reference	Intervention	Setting	Evaluative Method	Evaluation Objective	Main Findings
	"Did you wash your hands?"				Among these, 90% asked a nurse, and 32% asked a doctor. 68% felt comfortable with asking, and 81% received a positive
McGuckin et al. (2001)	"Partners in your care" program to increase staff hand hygiene that involved staff information, a single patient instruction by an infection control nurse, a patient brochure, and supportive materials that encourage patients to ask staff, "Did you wash your hands?"	Prospective controlled 6-week intervention/ control study on two wards in an National Health Service trust with wards serving as their own control	Assessment of soap usage by staff per bed-day $(n = 39)$ patients enrolled) Telephone interview with patients after discharge $(n = 24)$ responders)	Changes in soap/gel/ paper towel usage of staff Patient compliance with the program: implementation of recommendation by patients, their level of comfort, and responses of experienced staff	response response and control, by 50% between baseline and control, by 50% between baseline and intervention ( $p < .05$ ), and by 10% between control and intervention periods 96% of patients read the brochure, and 38% asked staff. Among these, all patients asked a nurse, and 35% asked a doctor. 62% felt comfortable asking, and 78% received a
McGuckin, Taylor, Martin, Porten, and Salcido (2004)	McGuckin, Taylor, "Partners in your care" Martin, Porten, program to increase and Salcido staff hand hygiene that involved staff information, a single patient instruction by an	Prospective 6-week preand postintervention study with a 3-month follow-up in a 24-bed in-patient rehabilitation unit of an acute care	A T	sessment of soap/ Changes in soap/ sanitizer usage by staff sanitizer usage of staff per resident-day ( $n = 35$ Patient compliance with patients enrolled) the program: He program: Hephone interview implementation of with patients after recommendation by	positive response The overall increase in all phases was $56\%$ $(p < .001)$ $95\%$ of patients read the brochure, and $79\%$ asked staff.

Table 3 (continued)

		radic 3	rable 3 (commuted)		
Reference	Intervention	Setting	Evaluative Method	Evaluation Objective	Main Findings
Weingart et al. (2004)	undergraduate student, a patient brochure, a patient information video and supportive materials that encourage patients to ask staff "Did you wash/sanitize your hands?" Patient partnership intervention that included a consumer guide to medication safety (control) and copies of current medication lists (intervention) updated every 3 days to prevent adverse drug events	hospital in the United States Prospective randomized controlled trial conducted at a 40-bed general medicine unit at a U.S. teaching hospital	discharge ( <i>n</i> = 19 responders)  Incidence of adverse drug events and close calls identified using chart review and incident reports Self-administered written questionnaire of patients at discharge, follow-up by mail and telephone in nonresponders ( <i>n</i> = 173)  Anonymous written questionnaire survey of nurses working on the study unit ( <i>n</i> = 17)	patients, their level of comfort, and responses of asked a nurse, and responses of accomfortable asking, and 67% received a positive response drug events and close drug events and close control patients or and whether they 20% of nurses reported were informed about medication and its side effects by staff preventing medication on to patients, perceived or control patients in patients asked more preventing medication and its side effects by staff prevented because preventing medication workload and relation to patients, perceived and relation to patients, perceived would make care safe intervention.	Among these, 93% asked a nurse, and 40% asked a doctor. 73% were comfortable asking, and 67% received a positive response No statistically significant differences in adverse event rate (8.4 vs. 2.9, <i>p</i> = .12, close-call rate (7.5 vs. 9.8, <i>p</i> = .57), severity, and preventability No statistically significant differences in patients' experiences in patients' experiences in patients reported that one to five medication errors were prevented because patients intervened. 23% reported that postients asked more questions, and 47% reported that providing patients medication safety information would make care safer

distributed safety recommendations is scarce and suffers from methodological rigor. A retrospective analysis of the *processes* of development and the *contents* of five leading patient advisories by means of content analysis and interviews with key informants suggests that, though well-intended, advisories are not based on patients' perspectives toward involvement in error prevention and suffer from lack of cultural and practical integration into the health care setting (Entwistle et al., 2005). Entwistle et al. (2005) frequently identified missing information and rationales in several key dimensions and note that many advisories provide little practical support for patients. Materials were usually not formally tested or evaluated before wide publication. Informants also raised doubts that the way the advisories are disseminated would cultivate message reinforcement or support by health care staff. Two smaller evaluations report the effects of a large patient education campaign and a patient safety video. Awareness and behavioral response to the disseminated material was generally low among patients (Kutty & Weil, 2006). The video resulted in slight increases in ex post ratings of self-reported knowledge and comfort with talking to staff about safety concerns (Anthony et al., 2003).

The results of more precise interventions embedded in clinical contexts have yielded more positive results. These evaluations investigated patient participation in surgical site marking, patients' engagement in staff hand washing, and the effects of provision of drug information on the incidence of adverse drug events.

Patients' compliance with preoperative instructions to mark the surgical site for the prevention of wrong-site surgery was investigated by Di Giovanni, Kang, and Manuel (2003). Patients were advised to mark the extremity not to be operated on as part of general preoperative instructions before elective surgery. Compliance with limb marking was assessed preoperatively. Full compliance was recorded if patients marked the correct site in the requested style. If patients marked a different location or used a different style (e.g., color) for marking, or if patients also marked the correct site, they were considered partially compliant. Noncompliance was recorded if patients made no mark. A total of 63% of patients presented with marking, of whom 4% were considered partially compliant and 59% fully compliant. In bivariate analyses, age, gender, employment, and a number of health- and procedure-related variables were not associated with compliance. However, patients with previous related surgery were less likely to be compliant as compared with those with no prior related surgery (OR = 0.38, CI = 0.16-0.87, p = .023).

The effects of patient participation to increase staff hand washing are reported in three studies with slightly different designs and settings but involving the same intervention (McGuckin et al., 1999; McGuckin et al., 2001; McGuckin et al., 2004). The intervention consists of staff information, personal patient education, brochures, and prompting aids. As a core element of the program, patients were instructed to ask health care workers who had direct contact with them whether they had washed their hands. Changes in soap/sanitizer usage between control and intervention periods as a proxy measure for hand hygiene practice were monitored, and patients were surveyed about their compliance. Estimated over all three surveys and weighted for sample size, the majority of patients read the brochure (83%), and half of the patients reported to have asked staff to wash their hands (57%). Of those, 91% asked a nurse, but only 33% asked a doctor. A total of 69% of patients felt comfortable asking, and 80% received a positive response from staff. Soap usage significantly increased by 34%, 50%, and 56% between the control and intervention periods in the three studies. Results show that the change in hand-washing practices occurred irrespective of initial soap usage, and in one study, the change in soap usage from the preprogram to control period was 37%, indicating that staff changed their behavior before the intervention was installed. This suggests that the effects were partly due to changes in perceived subjective norms, that is, changes in staff expectations, rather than patients actually intervening. Subjective behavioral norms, that is, the perception that patients expect hand washing and the intention to comply with these expectations, have been shown to be highly influential for hand washing (Sax, Uckay, Richet, Allegranzi, & Pittet, 2007).

Only one study investigated the effects of a medication safety intervention on adverse drug events and close calls, that is, true events, rather than proxies (Weingart et al., 2004). In a prospective randomized controlled trial, hospitalized patients either received drug safety information (control) or individual medication cards that listed their current medications, updated every 3 days (intervention). There were no significant differences between the control and intervention groups in rates of adverse drugs events, close calls, serious preventable adverse drugs events, and serious nonintercepted close calls. Patients' awareness of medication mistakes, experiences of drug-related problems, and ratings of medication safety and quality of care in hospital also did not differ between the groups. Several limitations need to be considered in interpreting the results. For example, the educational materials were not pretested with patients, and the control group also received drug safety information, which may have diluted the effects of the intervention. Patients were also not instructed by staff on how to respond to the educational material in terms of behavior.

### Discussion

Recommendations that advise patients to actively engage in their safety have obtained considerable attention and are broadly propagated. Patients share a positive attitude about engaging in their safety and support educational campaigns at a general level, but their level of comfort and intentions to act vary considerably with specific actions. None of the large educational campaigns directed toward patients have been evaluated thoroughly, and results of the smaller evaluations are flawed by methodological shortcomings, in particular uncontrolled designs and small sample sizes. Commonly, patients have not been consulted in the development of recommendations, and several aspects of these campaigns suggest that the materials do not fully exhaust their potential. Despite the proliferation of these programs, there is yet relatively little evidence on their success in affecting behavior change (Rucker, 2003). Empirical research confirms the framework of the theory of planned behavior and indicates that self-efficacy, behavioral control beliefs, the preventability of incidents, and the perceived effectiveness of actions seem to be central to patients' intentions to engage in their safety and subsequent behavior (Ajzen & Manstead, 2007; Fishbein & Ajzen, 1975). It is unfortunate that patient safety messages have not yet adopted and translated these findings. Interventions that are implemented within clinical settings have been effective to some extent. Clinical context may have a positive impact on control beliefs, perceived behavioral control, or both. However, there is a paucity of research into patients' reasons for noncompliance, their perceptions of interventions, and the potential negative consequences of their engaging in their safety, such as a decrease in trust.

This review also has some limitations that need to be considered. First, we restricted the search protocol to MeSH terms. While we did comprehensive searches in the relevant databases, a risk that not all relevant studies were identified remains. Second, we limited our review to nontailored interventions that can be proactively put into practice by patients. For example, we did not include studies of individualized safety messages (Weingart et al., 2008) or the involvement of patients in adverse event reporting (Pereles, Romonko, Murzyn, & Hogan, 1996; Wasson, MacKenzie, & Hall, 2007), but some of these studies may provide results indirectly relevant to the current analysis. Third, our study may have been conducted prematurely, as many of the large-scale campaigns have been released in the recent past and evaluations may be underway (Byrd & Thompson, 2008). However, given that several of the campaigns are disseminated on a large, nationwide level, one would expect prior evaluations of the materials in single regions or institutions.

The reviewed studies also suggest that staff seem to play an important role in engaging patients, but the evidence is yet insufficient to draw concrete conclusions. The observation that patients are more willing to ask staff challenging questions if they were instructed to by doctors indicates that the same perception of medical authority that hinders patients from performing challenging behaviors may be supportive in instructing patients (Davis et al., 2008). Further studies are needed to examine whether the observed changes in intention occur by altering patients' perceived subjective norms or by simply embedding unfamiliar behavior within the same expectations attributed to authorities. Recent research among oncology patients and staff indeed demonstrated that both processes play a major role. Oncology nurses intuitively choose among a set of strategies, role models, and patterns of language to get patients engaged and switch between participative and authoritative models of education (Schwappach, Hochreutener, & Wernli, in press). Similarly, patients' motivations to comply with staff instructions for involvement in safety vary considerably (Schwappach & Wernli, in press). The results of this review

suggest that the involvement of patients in safety may be successful if initiatives are based on patients' perspectives, if they promote complex behavioral change, and if their implementation is accompanied by serious efforts for cultural and normative change in health care institutions that place patients and their safety at the center of health care, and support staff to provide care in a trustful environment without trying to shift responsibility.

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