Improving Patient Safety Culture in Primary Care: A Systematic Review

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Background: Patient safety culture, described as shared values, attitudes and behavior of staff in a health-care organization, gained attention as a subject of study as it is believed to be related to the impact of patient safety improvements. However, in primary care, it is yet unknown, which effect interventions have on the safety culture.

Objectives: To review literature on the use of interventions that effect patient safety culture in primary care.

Methods: Searches were performed in PubMed, EMBASE, CINAHL, and PsychINFO on March 4, 2013. Terms defining safety culture were combined with terms identifying intervention and terms indicating primary care. Inclusion followed if the intervention effected patient safety culture, and effect measures were reported.

Results: The search yielded 214 articles from which two were eligible for inclusion. Both studies were heterogeneous in their interventions and outcome; we present a qualitative summary. One study described the implementation of an electronic medical record system in general practices as part of patient safety improvements. The other study facilitated 2 workshops for general practices, one on risk management and another on significant event audit. Results showed signs of improvement, but the level of evidence was low because of the design and methodological problems.

Conclusions: These studies in general practice provide a first understanding of improvement strategies and their effect in primary care. As the level of evidence was low, no clear preference can be determined. Further research is needed to help practices make an informed choice for an intervention.

Key Words: patient safety, safety culture, intervention, review, primary care

(*J Patient Saf* 2016;12: 152–158)

Patient safety has become a major topic in health-care research, and recently, its scope has been extended to primary care, as the role of primary care in health care increases in size and spending.[1,2] In The Netherlands, primary care covers a large part of healthcare: more than 90% of healthcare is delivered in primary care against only 4% of the total health-care costs.[3] Although incidents in primary care tend to be less harmful compared with incidents that occur in hospitals, the impact on overall safety in health care is at least similar because of the large number of patient contacts in primary care.[2,4]

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The authors disclose no conflict of interest.

Funding: the Dutch Ministry of Health, Welfare and Sport.

In primary care, patient safety research initially focused on studying taxonomy[5] and reporting systems.[6,7] These studies found that the majority of incidents can be categorized as process incidents including administrative failures. Other important categories were communication, knowledge, and skills. Gaal et al.[8] found patient safety incidents in 2.5% of patient contacts by reviewing general practice medical records, and communication was one of the reported causes. Another study in 48 primary care centers in Spain, identified 773 adverse events and stated that problems with communication and management were at the root of many of these events.[9] Reviewing 75 error reports, Woolf et al. found that 77% of the incidents were caused by a cascade of errors.[10] This shows that collaboration and communication are relevant issues to patient safety in primary care.

The way colleagues interact and collaborate in an organization is part of their culture. Safety culture is described as the shared values, attitudes, and behavior of all staff in health facilities in regard to giving safety priority over efficiency, improving care provider communication and collaboration, and creating a system that learns about and learns from errors and problems.[11] Furthermore, it is known that a safe and open culture is important for patient safety improvement.[12]

Studies on patient safety culture were mostly conducted in hospitals. A systematic review of patient safety improvement strategies indicated leadership walk rounds and multi-faced unit-based programs as having a positive impact on patient safety culture in hospitals.[13] Another review indicated multiple component strategies including team training, communication, and executive engagement in walk rounds to have the best evidence.[14] However, in both reviews, the level of evidence moderates firm conclusions on the effectiveness of patient safety culture in health care.

For primary care, however, it is not clear what the effect of patient safety interventions is on patient safety culture. It is not self-evident that patient safety culture strategies conducted in hospital care can be similarly applied in primary care or that they will have similar effects. The organizational structure differs as primary care practices have a smaller scale and are generally less hierarchical than hospitals. In addition, hospitals mainly provide therapeutic care, whereas primary care practices also care for preventive and diagnostic care, which may lead to different safety awareness and behavior. Therefore, we conducted a systematic review to assess the effectiveness of patient safety interventions on patient safety culture in primary care.

METHODS

Search

A literature search of papers describing an intervention with patient safety culture measurements in primary care was conducted in four databases: CINAHL, Embase, PubMed and PsycINFO. We combined terms defining safety culture such as *organizational culture*, *safety management*, *patient safety* with both terms identifying intervention, for example, *improvement*,

change, *effect,* and terms that indicated the setting of primary care. The PubMed search strategy is enclosed in Appendix 1. No restrictions were set regarding publication date. Language was restricted to English, Dutch, and German. In addition, we screened the Web pages of the Institute for Healthcare Improvement, the National Patient Safety Agency, and the Agency for Healthcare Research and Quality.[15–17] Also, the references of included articles were checked for relevant literature. The search strategy is conducted on March 4, 2013.

Eligibility and Quality Assessment

Studies were eligible for inclusion if they met 3 inclusion criteria. First, the research had to be conducted in primary care. Second, a patient safety intervention effecting culture had to be described. And third, the effect on patient safety culture had to be reported. There were no requirements regarding the design of the study, provided that there had to be more than one measurement. Opinion papers, editorials, reviews, interviews and comments were excluded. For assessment of the study quality we examined the quality of reporting, using 5 criteria for qualitative research used in previous intervention research, and potential bias by using "the risk of bias tool" from the Cochrane Collaboration, see Table 3.[18,19] In addition, the GRADE approach from the Cochrane Collaboration was used to assess the level of evidence ranging from high to very low.[20]

Selection Process and Data Extraction

The title screening was conducted by 1 author (N.V.) followed by abstract and full-text screening by 2 authors (N.V. and M.L.). Results were compared and discussed between both authors. In case of disagreement, a third author (D.Z.) was consulted. Data were extracted on intervention characteristics, defined as aims, measurement tools, intervention description, and effect on culture. We also extracted data on study characteristics, defined as country, design, and participants. For the extraction of data, a beforehand composed form was used.

RESULTS

In total, 214 references were retrieved from the database search (Fig. 1). After initial screening, 18 articles were selected for full text screening. No references were added after searching the bibliographies of included studies. A list of excluded articles is enclosed in Appendix 2. Two studies[21,22] met our inclusion criteria, as these were both observational and reported on different interventions with heterogeneous outcomes, no meta-analysis was done.

Both studies were conducted in general practice. Table 1 shows their study characteristics. The study of McGuire et al. used a follow-up design with a total follow-up time of 3 years.[21] Wallace et al. used a pre-post design with an implementation time of 8 months.[22] Both studies did not use a control group.

Table 2 shows details on the intervention and effect measurements. McGuire et al. described the implementation of an electronic medical record (EMR) system.[21] This was part of ongoing quality and safety improvement efforts. Additional efforts were made to facilitate the EMR implementation such as identification of "change champions," development of committees to support implementation, reduction of work schedules during the first 2 weeks, and on site "super-user" support. Immediately prior to go-live, staff attended a training session. The effect of the intervention was assessed with the Safety Attitudes Questionnaire (SAQ)[23] directly after implementation and repeated after 1.5 and 2.5 years. Also, practices were asked to indicate

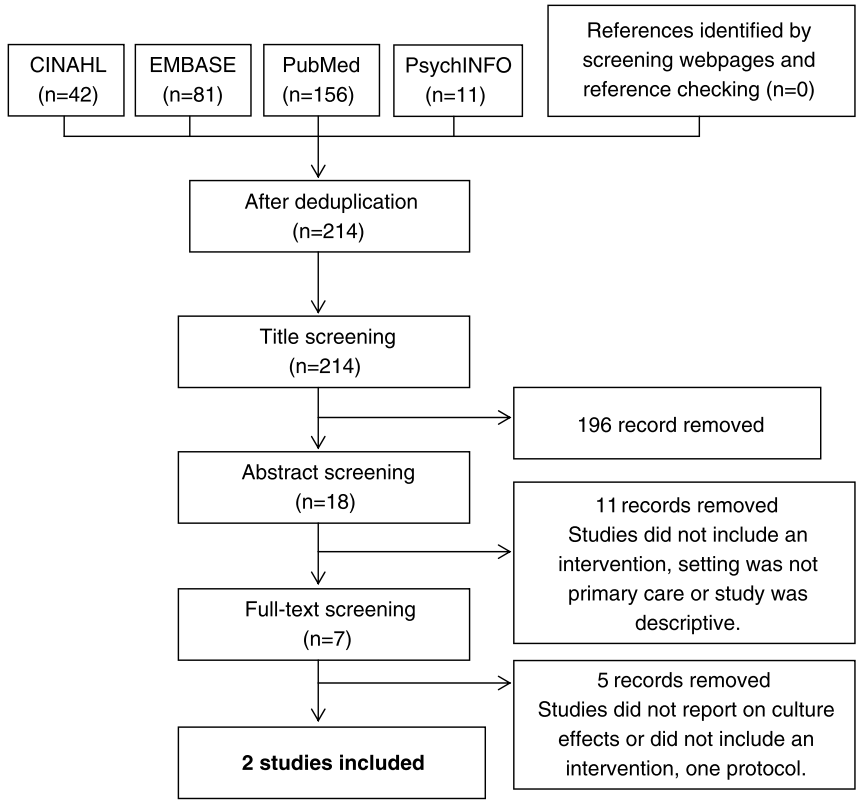

FIGURE 1. Flowchart search results.

TABLE 1. Study Characteristics

Study	Country	Design	Participants; Response Rate
McGuire et al. 2013[21]	USA	Follow-up Control group: no Implementation time: 3 years	18 practices participated*, response rate per measurement point: T1: 83.7% (103 of 123) T2: 85.3% (122 of 143) T3: 78.5% (142 of 181)
Wallace et al. 2007[22]	UK	Pre-post Control group: no Implementation time: 8 months	Risk management data, response rate per measurement point: Pre: 57% (43 from 75 practices) Post: 33% (24 from 73 practices)† Learning organization Culture Questionnaire: Pre: 45 practices. Respondents: 41% (184/450) Post: 36 practices. Respondents: 56%(125/225)

* Respondents increased from 103 to 142 because of growing of the provider group.

† Two practices ceased to exist or amalgamated by T2.

the most important safety issues specific for their practice. Five of 7 domains of the SAQ, "job satisfaction," "perceptions of executive management," "local management," "safety climate," and "teamwork climate,", showed significant improvements between T1 and T3. 'Working condition' significantly improved between T2 and T3 (Table 2). Respondents reported time constraints as the most significant concern, followed by communication problems. A majority responded positively when asked whether implementation of the EMR enhanced their ability to provide safe care to patients.

Wallace et al. studied the effect of own patient safety initiatives and 2 workshops, a risk management (RM) workshop and a significant event audit (SEA)[24] workshop, respectively.[22] The RM workshop included a practice self-assessment questionnaire and feedback against other training sites, use of protocols for patient group directions and chaperones, and a lecture on how to conduct a SEA. The second workshop consisted of the lecture on SEA solely. Effects were measured using a RM competence score covering "the scope of risk management activity," "staff involvement," "documentation of RM activities," "accessibility of RM records," "existence of specific written policies and an audit program." In addition, the learning organization culture questionnaire (LCQ) was completed by practice staff. This survey measured 8 dimensions: "personal innovation," "open communication," "personal blame for errors," "error awareness," "team problem solving," "task information," "supportive climate," and "practice development," distributed over 4 domains.

Seventy-five practices were invited to participate either in the workshop of preference (RM: n = 40, SEA: n = 2) or in both (n = 9). There were 24 practices that chose not to participate in one of the workshops as they undertook their own development activities. Practices that responded at T1 and T2 were included in the analysis (n = 20). The authors reported an overall significant improvement of the RM competence score. Three competences improved: there was a widening of the scope of RM activities, more staff were involved, and activities were increasingly documented in formal systems. Spent time was indicated as main disadvantage of RM. The gains reported by most of the practices were "better learning from events," "fewer complaints," and "a better atmosphere." Results from the LCQ were used to examine the association with the RM competence. At baseline, 3 subscales showed a positive relation with RM competence scores. At follow-up "task information" was positive, and "practice development" was negative correlated.

Quality Appraisal

Both studies used an observational design without a control group. After the GRADE approach, they are therefore graded as "low" on the level of evidence rating. Although an observational design could be upgraded to a "moderate" level of evidence when the study is methodologically sound and yields large, consistent and precise estimates of the intervention effect.[20]

We appraised the publications on methodological quality according to quality of reporting and potential risk of bias (Table 3). As these studies did not use a control group, performance and detection bias were not applicable. Quality of reporting was good in McGuire et al. Potential bias was possible as there was no adjustment for possible within-person correlations and because of simultaneous implementation of other interventions. The study of Wallace et al. had some limitations regarding the reporting of the sample and the significance and value of the assessed risk management competency scales. Bias could occur because of selection, attrition, and reporting, as there were half as many practices at T2 than at T1, and measurements of the LCQ were not reported. Furthermore, the reporting of results was limited. In addition, only the 20 practices from which data were available for both T1 and T2 were included. Also, in the analyses, all 3 initiatives, the RM workshop, the SEA workshop, and own activities were analyzed together: no results were given for separate groups.

DISCUSSION

In our search for primary care studies that implemented patient safety strategies that affect patient safety culture, we found 2 studies, both conducted in general practice. McGuire et al. implemented an electronic medical record and measured improvement on safety climate and teamwork climate with the SAQ.[21] Wallace et al. assessed the effect of organizational initiatives; participation in a workshops on risk management (RM) or significant event analysis (SEA) or own activities.[22] It showed increased risk management activities on clinical or administrative issues. A learning culture seemed positive for the risk competence score, although the size and content of this relation remained unclear. Overall, both publications approached both their interventions as well as the evaluation of effect differently. Whereas the study of McGuire et al. applied a culture questionnaire, Wallace et al. more directly assessed patient safety behavior and its relation to a learning culture, in which aspects of a safe culture are

TABLE 2. Intervention Characteristics

Study	Aim	Measurement Tools	Intervention Description	Effect on Culture
McGuire et al. 2012[21]	Improving safety and evaluating changes in perceptions of safety among the primary care provider group after EMR implementation.	- Safety Attitudes Questionnaire	Implementation of an electronic medical record system.	Changes in percentages for SAQ dimensions at T1, T2, and T3:
		- Practice-specific needs assessment		Job satisfaction: 74.1 78.2 86.2 Perceptions of executive management: 59.1 66.7 72.6 Perceptions of local management: 76.2 84.6 86.0 Safety climate: 76.4 84.2 87.8 Stress recognition: 68.4 75.6 74.8 Teamwork climate: 77.4 85.5 88.9 Working conditions: 74.3 74.2 84.9 Agreement to question: "Our electronic medical record has improved our ability to provide safe patient care": T2: 77.9% / T3: 85.4%
Wallace, L.M. et al. 2007[22]	To establish that practices were prepared to engage in risk management (RM) through:	- RM audit questionnaire	Medical Defense Union RM workshops (single day)	RM competence score showed an overall significant improvement at practice level.
	- having the right skills, - being supported by structures and policies, - having staff who believed their practice has an open learning culture.	- Learning organization Culture Questionnaire (LCQ) with 4 domains: - creativity - communication - climate - change	Facilitation of significant event analysis (SEA) (2 hours) Own development activities including Quality Team Development.	At T1, there was no association found between the levels of competence and culture. At T2, "task information" was significant ($P < 0.01$) in a positive direction, and "practice development" was significant ($P < 0.009$) in a negative direction.
	Secondary objective: Evaluation of the contribution of the RM initiatives to the development of RM competence land earning culture.			

incorporated. These varied approaches align with observations that patient safety culture is a very versatile concept.[13,25]

Strengths and Limitations

This review revealed only 2 studies. This may be due to the strict application of the inclusion criteria because we searched for intervention studies that both assessed and reported on the cultural effect. Although we additionally searched Web sites of the IHI, NPSA, and AHRQ, it may be that we missed publications in gray literature outside the mainstream. In addition, it could be that studies have been conducted on the improvement of patient safety culture in primary care but were not published.

We cannot draw any firm conclusions as the level of evidence of both studies was low. This is largely because of the observational design but also because of the likelihood of bias. On the other hand, it is very difficult to rule out all influences as in a pragmatic study the research environment cannot be standardized. Such complex interventions are inherently conducted in existing systems and therefore raise the question of attribution of the effect to the intervention.[26] However, the strength of such observational studies is that they are less intrusive in the usual course of affairs which is beneficial to the validity of the study results.[27]

The validity may be enhanced by combining with a qualitative study, so called triangulation in a mixed method.[28] This could, for example, shed light on what respondents themselves designate as most effective aspects for their organization and why they perceive these as such. To some extent, Wallace et al. have done this by describing the disadvantages and advantages of the intervention that were reported by practice managers.

TABLE 3. Quality Appraisal

Study		Quality Appraisal
McGuire et al. 2013[21]		**Quality of reporting:**
	Aims clearly reported	+
	Adequate description of context	+
	Adequate description of sample and methods of recruiting	+
	Adequate description of data collection	+
	Adequate description of data analysis	+
		Potential risk of bias:
	Selection	−
	Attrition	−
	Reporting	−
	Other	There was no baseline measurement.
		No adjustment for possible within-person correlations (80% of respondents were similar in T1 and T3)
		Other interventions (communication training, management processes and educational interventions) were simultaneously present.
Wallace et al. 2007[22]		**Quality of reporting:**
	Aims clearly reported	+
	Adequate description of context	+
	Adequate description of sample and methods of recruiting	+/− Unclear which practices and corresponding demographics are included in the analysis.
	Adequate description of data collection	+
	Adequate description of data analysis	+/− Unclear what the significance and value of differences of the competency scales are.
		Potential risk of bias:
	Selection	Possible bias due to asking practices to volunteer. Practice that declined the workshops were already undertaking their own development activities.
	Attrition	There was selective drop-out of practices (from 43 to 24 for RM data) who chose not to participate anymore due to own initiatives or priorities. Response rate was very low and for follow-up these were halved for the RM data. It was reported that a check for sample bias was done.
	Reporting	Results on the scales of the LCQ are not reported and it was not reported which domains of the LCQ correlate with RM at baseline.
	Other	RM competence score at T2 was derived from audit of only the practice manager.
		Only practices that delivered data at both T1 and T2 were included in analysis.
		There was no distinction made between the three initiatives in the analysis and reporting.

Comparison With Existing Literature

Up to now, no review on patient safety interventions affecting culture was conducted with a specific focus on primary care. In hospital setting, however, reviews showed leadership walkrounds, multi-faceted unit-based programs, teamwork, and communication to have a positive effect on patient safety culture.[13,14] Because of organizational differences and size of the practices, it is not clear whether these strategies are applicable or have a similar effect in primary care. The study by McGuire et al. did use a broad approach by embedding the intervention in facilitating activities such as training and installing committees. The intervention was not a stand alone: it was accompanied by communication, educational, and managerial interventions. Leadership walkrounds will be more difficult to apply in primary care, as the small primary care practices often lack a clear hierarchical organizational structure. However, audits or peer reviews by colleagues from other practices may have similar beneficial effects. A tool to assess and discuss patient safety culture is the Manchester Patient Safety Framework (MaPSaF).[29] This framework was modified for use in New Zealand general practice. During this qualitative study, MaPSaF was observed to be a helpful discussion tool which stimulated learning and enhanced communication.[30]

Implications for Research and Practice

In conclusion, this review indicates effect of interventions on patient safety culture in primary care, but the size and external validity of the measured changes are unclear. Furthermore, the range of interventions on patient safety culture in primary care is limited compared to secondary care. In conclusion, it is not evident which intervention would help practices most to improve their patient safety culture. Hence, practices should choose an intervention close to their momentary needs of improvement and evaluate frequently to assess whether the intervention leads to the

desired effect.[31] To support this choice, more research is needed to assess the effect of interventions on safety culture in primary care practice. Studying facilitators and barriers aimed at clarifying the mechanisms that underlie the dynamics of a patient safety culture interventions would add to patient safety improvement in primary care.

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APPENDIX 1. Search strategy PubMed

((health care evaluation mechanisms[mesh]) OR (intervention*[tiab]) OR (improv*[tiab]) OR (chang*[tiab]) OR (effect*[tiab])) AND ((((((((((((((((((((((("General Practice, Dental"[Mesh])) OR (dental care[Mesh])) OR (dental care[tiab])) OR ("Dental Hygienists"[MeSH])) OR ("Dental Hygienists"[tiab])) OR ("Dietetics"[Mesh])) OR ("Dietetics"[tiab])) OR ("Exercise Therapy"[Mesh])) OR ("Exercise Therapy"[tiab])) OR ("Physical Therapy Specialty"[Mesh])) OR (physical therapy[tiab])) OR (occupational therapy[MeSH Terms])) OR (occupational therapy[tiab])) OR ("Midwifery"[Mesh])) OR ("Midwifery"[tiab])) OR ("General Practice, Dental"[Mesh])) OR (skin therapy[tiab])) OR ("Speech Therapy"[Mesh])) OR ("Speech Therapy"[tiab])) OR ("Family Practice"[Mesh])) OR ("Family Practice"[tiab])) OR (general practice[tiab]) OR (primary care[tiab]) OR ("Primary Health Care"[Mesh])) AND (((((organizational culture[mesh]) OR (organizational culture[tiab]) OR (organisational culture[tiab] OR (organizational climate[tiab])))) AND (safety[tiab])) OR ((safety management[mesh]) AND (culture[tiab] OR (climate[tiab])))) OR ((patient safety[mesh]) AND (culture[tiab] OR (climate[tiab])))) OR ((culture[tiab] OR (climate[tiab])) AND (safety[tiab]))))

APPENDIX 2. Excluded Articles

Study	Reason for exclusion
Bowie (2010)	No intervention
Evans (2012)	No intervention
Gehring (2012)	Descriptive study
Gonzalez (2011)	Study protocol
Jacobs (2012)	No report of culture effects
Linzer (2005)	No intervention
Masotti (2009)	No intervention
McKeon (2009)	No report of culture effect, subject was nurse training
Milligan (2007)	Descriptive study
Palinkas (2011)	No intervention
Singh(2006)	No intervention
Singh(2009)	No intervention
Smith (2004)	No intervention
Sorokin (2011)	No intervention
Terol (2008)	No intervention
Tham (2011)	Setting was pediatric hospital