Patient safety culture in primary care

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Patiëntveiligheidscultuur in de eerste lijn
(met een samenvatting in het Nederlands)

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CHAPTER 1

General introduction

"I am a solo practitioner, without assistant or other staff. Therefore, naturally there are hardly any adverse events as everything goes through me, delightfully."
(GP; argumentation not to participate in our study)

"As a GP, you should always ask yourself: is it safe enough for my staff to say what they want to say? You will not always be certain about that. Although we do try to. You see that people say things and dare to say stuff. Even things about which you think, well, amazing that you say that. I'm not sure I would dare to say that to my boss.
So, considering, it seems safe."
(GP, during interview one year after our intervention)

"I think that, since we had the workshop, we all improved, or at least things are set up. We already had a sort of reporting procedure. But due to the workshop, there came a sort of awareness in the whole team."
(Assistant, during interview one year after our intervention)

These citations, - one from the invitation reply form and two from post intervention interviews - give a wonderful glimpse of the versatile considerations regarding patient safety and culture in general practice. The importance of patient safety in the care of patients is naturally indisputable. Though, as a subject for policy and research, patient safety only gained momentum since the last two decades and, in primary care it has just gotten in the picture. Since 2008, patient safety in primary care has become a priority in Dutch health care policy. In order to start up and engage all different primary care professions in patient safety activities, the ministry of Health, Welfare and Sport launched a platform (Zorg voor Veilig; Care for Safety).[1] This platform facilitated regular meetings with professional associations in primary care to discuss the development of patient safety management and necessary tools. Patient safety culture improvement was recognized as an essential topic leading to the need for tools for improving culture in primary care practices. At that time, a Dutch questionnaire to assess patient safety culture had been validated only in general practice.[2] This thesis focuses on patient safety culture in primary care. In short, culture is described as 'the way we do things around here'.[3] Below, the concepts of patient safety and patient safety culture will be introduced. Also, the primary care setting will be described. Finally, the objectives and outline of this thesis are delineated.

PATIENT SAFETY

Several definitions of patient safety have been described. The Institute of Medicine (IOM) defines patient safety as the '*freedom from accidental injury*'. The World Health Organisation (WHO) speaks of '*prevention of errors and adverse effects to patients associated with health care*'.[4] A more elaborate definition was described by Wagner & van der Wal: '*The (almost) absence of (the risk of) patient harm (physical/mental) that is caused by not acting according to the professional standard of care providers and/or failure of the health system*'.[5] Safety science in itself is not a new concept, it originates from high-hazard industries such as the petrochemical industries. After the establishment of healthcare being a high-hazard industry as well, safety issues got more into focus. Particularly the IOM report 'To Err is Human' spurred to action and accelerated patient safety as a policy priority and research subject.[6] This report stated that approximately 44.000 people died in the United States as a result of medical errors. Subsequently, other countries conducted similar studies. In the Netherlands medical record studies were carried out in 2004, 2008 and 2011/12, the latter showing that 7.1% of patients encountered care related harm and 2.6% of those (968 patients) may have died of potential preventable harm.[7-9] Errors are suggested to be the result of both active and latent failures, meaning that an error is not only the result of a fallible person (mostly at the end of the chain), but also from errors occurring earlier in the process.[10] Woolf et al. called this 'a string of mistakes' also stating that most of the time, events are not isolated but the result of a sequence of mistakes.[11] Incident analysis, therefore, was even more important. Medical errors can be an important source of experiences and knowledge which can be used to improve patient safety. And although the shift from the personal blame approach to the system approach has been embraced and encouraged, still, there is a need for a non-punitive safety culture to get healthcare workers to report.

PRIMARY CARE AND PATIENT SAFETY

At first most of the patient safety research and policy recommendations were focused on hospitalised care. The last decade, this focus was broadened to include primary care as well. Primary care is a key part of healthcare and a strong primary care is associated with better healthcare outcomes.[12, 13] In the Netherlands the gatekeeper systems supports a strong primary care. More than 90 percent of healthcare is performed in primary care, emphasizing its importance and relevance.[14] In 2013, the number of GPs in the Netherlands was estimated at 11075.[15] Primary care is easily accessible and GPs serve as a gatekeeper for specialised care. Besides general practice, primary care consists of a broad array of different disciplines such as speech therapy, dental care, physiotherapy and midwifery. Unlike secondary care,

practices in primary care are relatively small. Practices can be single-handed or group practices, either mono- or multidisciplinary. Managerial and organisational tasks are mostly carried out by professionals themselves, sometimes supported by nurses or administrative assistants. An important difference between primary and secondary care is the type of care provided which might influence the kind of errors that could occur. Though, the risk of serious harm might seem smaller in primary care compared to incidents in hospitals, it is of significance to give attention to patient safety in primary care as well because of the large amount of patients contacts.[16] Several studies investigated the occurrence of adverse events in primary care settings. In Spain, 773 adverse events were identified in 48 practices.[17] Gaal et al. examined 1000 medical records in the Netherlands and found that in 2.5% of patient contacts an incident had occurred.[18] An equivalent record study in other Dutch primary care professions showed low percentages of harm: 0.8% in dental care practices, 2.5% in midwifery practices and 1.0% in paramedical practices.[19] Communication was stated to be one of the prominent causes for incidents.[11, 17, 18, 20-22]

PATIENT SAFETY CULTURE

The safety culture of an organization is described as: *''the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety and by confidence in the efficacy of preventive measures.''* (Advisory Committee on the Safety of Nuclear Installations).[23] In essence, culture is "the way we do things around here".[3] Sammer et al. performed a review on safety culture and classified culture properties into seven subcultures: leadership, teamwork, evidence-based, communication, learning, just, and patient-centered.[24] A constructive, open culture is seen as a facilitator in the success of implementations of safety interventions.[25, 26] Besides reporting the rates of adverse events and preventable deaths, the IOM report gave recommendations for improvement, including to develop a culture of safety. Likewise, the National Patient Safety Agency stated the creating of a positive safety culture as the first step in their '*Seven steps to patient safety*'.[27] In addition, a Dutch report by the former director of Shell in The Netherlands stated that it poses a safety risk when acknowledging mistakes is considered taboo.[28] An open safety culture is also suggested to be positive for healthcare outcomes.[29, 30]

CULTURE OR CLIMATE?

Measuring the prevailing culture is often one of the first steps undertaken when intending to improve patient safety and culture. The attempts to assess culture fuelled the debate whether one should speak of 'culture' or 'climate' when conducting a survey. To describe the distinction Guldenmund uses the framework by Schein[31] on organizational culture.[32] It distinguishes three levels: basic assumptions, espoused values and artefacts. The first level concerns the 'core' of the culture, these are the underlying convictions, and is equated with culture. The second level, the espoused values, are the manifestations of culture; the attitudes, which are compared with climate. Artefacts are any other manifestation of culture, such as clothes and symbols.

Guldenmund states that culture is explanatory to climate, *why* things are done in a certain way. From a methodological perspective, it is said that with a quantitative approach, i.e. questionnaires, only the superficial climate can be captured and, that longitudinal, qualitative methods, are necessary to examine culture.[33] The usability and relatively low cost, however, makes a survey an attractive instrument to assess patient safety culture. In the literature, both terms - climate and culture - are used interchangeably. In this thesis we will use the term culture because at the start of our patient safety research in primary care the term 'culture' was more commonly used. Though, we acknowledge that a survey will only tap into the espoused values, as called above 'climate'.

ASSESSING AND IMPROVING PATIENT SAFETY CULTURE

Data on the prevailing culture are not only useful as a starting point but also provide outcome measurements to be able to evaluate interventions.[34] Nieva and Sorra [23] state that the assessment of culture can be used to:

1. diagnose safety culture to identify areas for improvement and raise awareness about patient safety;
2. evaluate patient safety interventions or programs and track change over time;
3. conduct internal and external benchmarking;
4. fulfil directives or regulatory requirements.

Today, several instruments have been developed and validated for various healthcare settings.[3, 23, 35, 36] After a thorough literature review the Linneaus Euro-PC group identified two tools to be most useful for assessing safety culture in primary care settings[37]: the primary care version of the Manchester Patient Safety Framework (MaPSaF)[38, 39] and the Medical Office short version[40] or the Nursing Home version of the Agency for Healthcare Research and Quality (AHRQ) survey.[41]

The MaPSaF is both an assessment and a discussion tool based on typologies of organizational communication described by Westrum[38] and later expanded by Kirk et al.[42-44] It describes nine patient safety culture dimensions according to five increasing maturity stages: pathological, reactive, bureaucratic, proactive and generative, see Figure 1. Nine dimensions are described for primary care:

1. Overall commitment to quality;
2. Priority given to patient safety;
3. Perceptions of the causes of PSIs and their identification;
4. Investigating patient safety incidents;
5. Organisational learning following a patient safety incident;
6. Communication about safety issues;
7. Personnel management and safety issues;
8. Staff education and training about safety issues;
9. Team working around safety issues.

A practice may not only use it to identify the current state of affairs and to discuss strengths and weaknesses, but it is also a useful tool to learn about differences in perspectives between staff.[44] The latter is very important because during the subsequent discussions staff can elaborate on their viewpoints and get closer to each other.

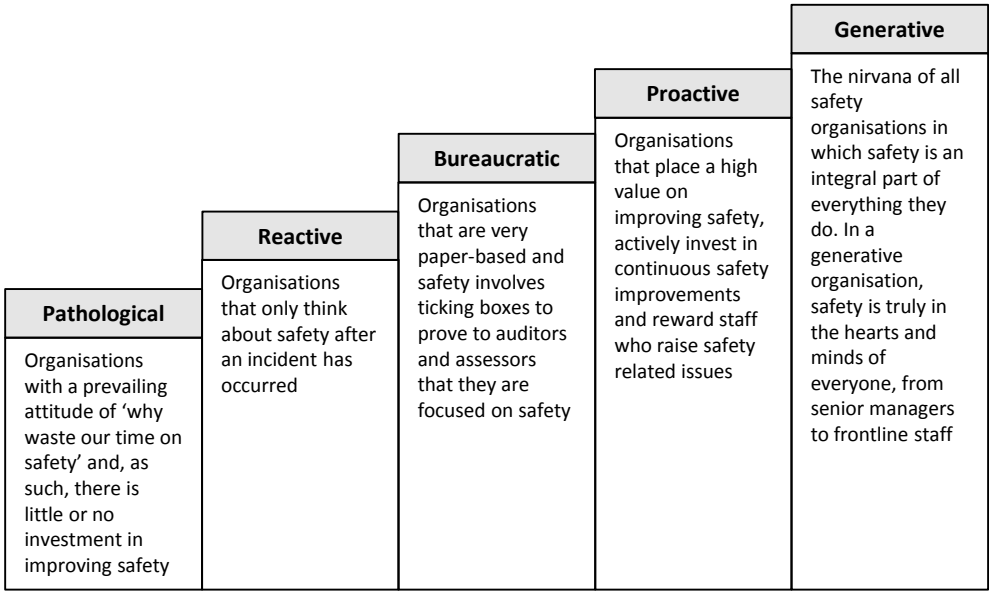

Figure 1. Culture ladder[42]

The series of AHRQ patient safety culture surveys started with the Hospital Survey on Patient Safety Culture (HSOPS) consisting of 12 dimensions: Teamwork across hospital units; teamwork within units; hospital handoffs and transitions; frequency of event reporting; non-punitive response to error; communication openness; feedback and communication about error; organisational learning – continuous improvement and supervisor/manager expectations and actions promoting patient safety; hospital management support for patient safety; staffing; overall perceptions of safety.[45] Smits et al. translated and validated the HSOPS into a version for Dutch hospitals.[46] This version was followed by the adaption of this questionnaire for general practice, the SCOPE (Systematisch Cultuur Onderzoek Patientveiligheid Eerstelijn).[2] SCOPE is an acronym for systematic culture inquiry on patient safety.

The SCOPE for general practice consists of 43 items divided over eight dimensions:

1. Handover and teamwork;
2. Support and fellowship;
3. Communication openness;
4. Feedback about and learning from error;
5. Intention to report events;
6. Adequate procedures and adequate staffing;
7. Overall perceptions of patient safety management;
8. Expectations and actions of managers.

In addition, two outcome questions are included on the assessment of a patient safety grade and frequency of error reporting.

In search for effective culture interventions two reviews found leadership walk rounds and broad programmes to have a positive effect on safety culture.[47, 48] Team training and communication were stated to be key in improvement efforts.[48] Improving patient safety culture is a complex intervention. Healthcare in itself is a complex organization as both practices and interventions cannot be fully standardized and succes, among others, depends on the context in which it is deployed. Singer and Vogus aptly described it as '*it is not a matter of taking a pill or flipping a switch*'.[49] The success of the intervention and direction of the results are highly dependent on the context.[50,51] Moreover, the failure to tailor complex interventions to the practice where it will be implemented limits its effectiveness.[52] Designing an intervention study using mixed-methods will provide insight in the success of the intervention and sheds light on how the intervention worked.

OBJECTIVE AND OUTLINE OF THE THESIS

The general objective of this thesis was to measure patient safety culture and to assess the effect of patient safety culture interventions in primary care. Figure 2 depicts the outline of the thesis and it shows an overview of the chapters and associated objectives.

Two studies were conducted. Part I of this thesis concerns patient safety culture assessment in Dutch primary care. The following research questions were addressed:

1. What is the validity of the patient safety culture questionnaire SCOPE-PC?
2. What is the prevailing patient safety culture in Dutch primary care professions and are there differences between professional groups?

Research question 1 concerned the validity and reliability of the patient safety culture questionnaire in all professions of primary care. The process of adapting the questionnaire to a generic multidisciplinary questionnaire is described in **chapter 2.** This questionnaire, SCOPE-PC, will add to available tools in primary care for patient safety activities. It will allow for the exploration and comparison of the prevailing culture in Dutch primary care professions. Research question 2, subsequently, regarded the prevailing culture in this setting and possible differences between professions. In **chapter 3** we present the perceptions of nine primary care profession groups on patient safety culture. Also, the differences between the professions are examined.

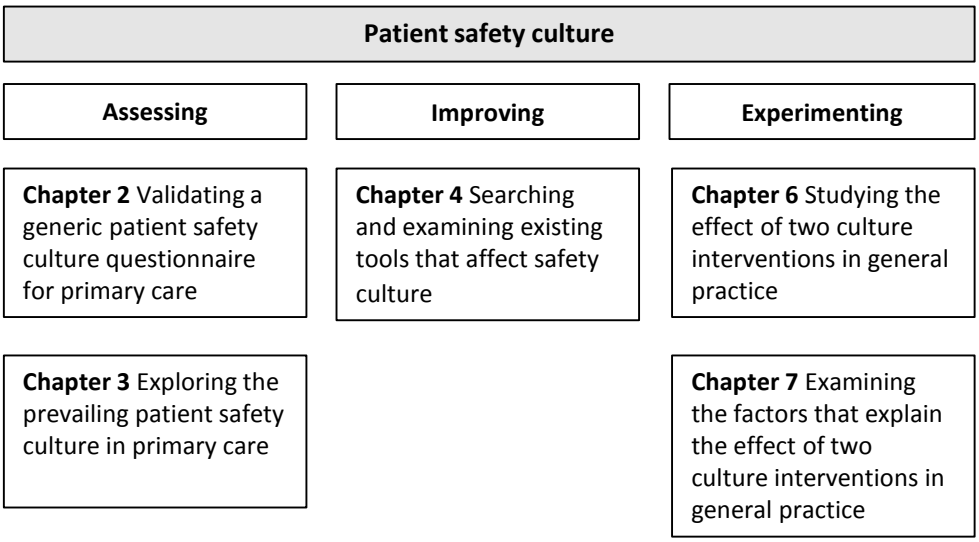

Figure 2. Outline of the thesis: chapters and objectives

Part II of this thesis concerns the SCOPE Intervention Study and focusses on improving patient safety culture in general practice. The majority of intervention tools and research are focused on secondary care. Consequently, little is known about how to create an open and positive culture in primary care practices. Therefore, the following research questions were addressed:

1. Which tools are available for patient safety culture improvement in the primary care setting and what is their effectiveness?
2. What is the effect of two culture interventions in general practice?
3. How can the effect of the two culture interventions be explained?

To learn about existing patient safety interventions in primary care (research question 3) and to choose our improvement strategy a systematic review was conducted which is presented in **chapter 4**. Together with the knowledge on assessment this was used to design a study to test two culture interventions in general practice. In **chapter 5** the study protocol of our trial on the effect of two patient safety culture interventions in general practice is reported. Here, both interventions are described in detail, i.e. a patient safety culture questionnaire (SCOPE) and a practice based workshop. Also, the methodology of the trial is elaborated on. Research question 4 regarded the effect of the interventions in daily practice. In **chapter 6**, the quantitative results of the trial, performed in thirty general practices are presented. The last research question concerned our understanding of the culture interventions. The qualitative results of the trial are described in **chapter 7.** The trial was conducted as a mixed-methods study using interviews to gain more insight in how the intervention worked in the different practices. In conclusion, we discuss our research and implications in the general discussion in **chapter 8**. **Chapter 9** summarises the thesis in English and Dutch.

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PART I

Patient safety culture in primary care

CHAPTER 2

Measuring safety culture in Dutch primary care: psychometric characteristics of the SCOPE-PC questionnaire

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ABSTRACT

Background

Patient safety has been a priority in primary healthcare in the last years. The prevailing culture is seen as an important condition for patient safety in practice and several tools to measure patient safety culture have therefore been developed. Although Dutch primary care consists of different professions, such as general practice, dental care, dietetics, physiotherapy and midwifery, a safety culture questionnaire was only available for general practices. The purpose of this study was to modify and validate this existing questionnaire to a generic questionnaire for all professions in Dutch primary care.

Methods

A validated Dutch questionnaire for general practices was modified to make it usable for all Dutch primary care professions. Subsequently, this questionnaire was administered to a random sample of 2400 practices from eleven primary care professions. The instrument's factor structure, reliability and validity were examined using confirmatory and explorative factor analyses.

Results

921 questionnaires were returned. Of these, 615 were eligible for factor analysis. The resulting SCOPE-PC questionnaire consisted of seven dimensions: 'open communication and learning from errors', 'handover and teamwork', 'adequate procedures and working conditions', 'patient safety management', 'support and fellowship', 'intention to report events' and 'organisational learning' with a total of 41 items. All dimensions had good reliability with Cronbach's alphas ranging from 0.70 – 0.90, and the questionnaire had a good construct validity.

Conclusions

The SCOPE-PC questionnaire has sound psychometric characteristics for use by the different professions in Dutch primary care to gain insight in their safety culture.

BACKGROUND

One of the main focuses in patient safety research is patient safety culture. A supportive patient safety culture is seen as an important condition for patient safety.[1] Patient safety culture refers to values, attitudes, norms, beliefs, practices, policies, and behaviours about safety issues in daily practice. In essence, culture is ''the way we do things around here''.[2] In a review, Sammer et al. identified seven subcultures of patient safety culture: leadership, teamwork, evidence based, communication, learning, just, and patient-centred.[3] Gaining insight in the prevailing safety culture is therefore seen as a first pivotal step towards an adequate patient safety system.[4] Various instruments have been developed to measure patient safety culture.[2,5-8] They help to identify weak areas in the perceived safety culture and thus enable designing tailored improvement strategies.

In recent years, increasing attention has been given to patient safety in primary care.[9-14] Primary care is directly accessible and consists of a broad array of professions, e.g. dental care, general practice, physiotherapy, midwifery, speech therapy. Despite this wide range of care, practices have many similarities in organisational structure. As most practices are small, managerial and organisational tasks -including safety improvement- are mostly done by the professionals themselves. Moreover, primary care professionals increasingly work together in broad healthcare centres, collaborating in disease management programmes and consulting one another in managing the care of individual patients.

Because of the increase in collaboration within primary care, developing a generic patient safety culture instrument was desirable. It will enable comparison between different primary care providers and in a later stage of safety management, may generate exchange of learning and improvement strategies. As a tool for patient safety culture already exists in the Netherlands: the SCOPE, it has been developed and validated for general practice only.[15] SCOPE is a Dutch acronym for systematic culture inquiry on patient safety. Other primary care professionals were already familiar with it, therefore, we choose to modify this tool into a generic questionnaire for all professions in primary care: the SCOPE-Primary Care (SCOPE-PC).

METHODS

First adjustment to the questionnaire

The Dutch SCOPE questionnaire for general practices, is a modification of the Dutch Hospital Survey on Patient Safety (HSOPS).[15,16]

This original SCOPE for general practice consists of eight dimensions:
1. Handover and teamwork (8 items);
2. Support and fellowship (5 items);
3. Communication openness (6 items);
4. Feedback about and learning from error (6 items);
5. Intention to report events (3 items);
6. Adequate procedures and adequate staffing (7 items);
7. Overall perceptions of patient safety management (4 items);
8. Expectations and actions of managers (4 items).

We made adjustments to this SCOPE through an iterative process. First, the research team revised the terminology of the questionnaire. Secondly, professionals from all primary care professions assessed the questionnaire individually clarity and applicability to their own setting. In total 27 professionals (1 midwife, 4 pharmacists, 1 physician, 2 dieticians, 2 physician assistants, 2 physiotherapists, 2 skin therapists, 2 general practitioners, 1 speech therapist, 2 dental hygienists, 2 exercise therapists, 2, dentists, 2 dentist assistants, 1 occupational therapist, 1 general practice nurse and 1 nurse working in an anticoagulation clinic) gave feedback by e-mail. Lastly, the research team reached consensus on the version to be used for the further validation process.
Adjustments were limited to a few changes of terminology, for example 'general practitioner' was changed to 'professional' and 'physician assistant' was changed to 'support staff'. None of the original patient safety culture items were deleted. Three questions were added for routing purposes, where if this question prompted a negative answer the respondent was not shown the other questions regarding this topic. One question was added: '*Are incident reports discussed in meetings on a structural basis? Structural means that it is a permanent feature on the agenda*'.
Besides patient safety culture questions the existing questions about patient safety characteristics of the practice were included: whether or not events were discussed in an informal way, the frequency of event reports filled in in the last 12 months and a patient safety grade for the total practice (answer categories: failing, poor, acceptable, good, excellent).
The final questionnaire consisted of 43 patient safety culture items (see Table 2). Items had to be answered using a five-point Likert scale ranging from strongly disagree (1) to strongly agree (5) or never (1) to always (5). On request of the individual professionals we added the option 'not applicable' to the questions about the practice organisation and collaboration. Background questions addressed demographics and work-related information, such as how long and in which profession the respondent had been working in this practice.

Data collection and respondents

Data collection for validation of the questionnaire took place from March until May 2011. An online system managed by the Dutch Practices Accreditation Organisation was used for collection and storage of the data.[17]

Eleven primary care professions participated: dental care, dental hygienist care, dietetics, exercise therapy, physiotherapy, occupational therapy, midwifery, anticoagulation clinics, general practice, skin therapy and speech therapy. A random sample of 200 members was drawn from the national databases of each professional association. These members were asked to participate and to invite colleagues from their own practice too. The key to sign in to the digital questionnaire was included in the invitation. It was emphasized that the questionnaire was to be filled out individually. In addition, practices were promised a feedback report regarding the patient safety culture of their practice.

The selection process differed for one of the professions: the physiotherapists were invited directly by their professional association. Because of this extra step, a lower response rate was expected. To anticipate on this, the sample for physiotherapists was doubled to 400. Once enrolled, the inclusion and the following steps were the same as for the other professions. All practices received a first invitation followed by two reminders with an interval of three weeks to all the contact persons. Invitations and reminders were preferably sent by e-mail but if not available by post.

Analyses

Preliminary analyses

As culture is a feature of a group, single-handed practices without employees were excluded from analyses. In addition, as it takes time to absorb the culture of an organisation, we excluded respondents with less than half a year experience in their current practice. Further, respondents with more than five missing values on the patient safety culture items were excluded. The answer category 'not applicable' was not counted as missing. Items that were negatively worded were recoded so that high scores always reflect a positive response. Subsequently, distributions of variables were examined to assess response variability and missing data. Inter-item correlations were studied, as well as Bartlett's test of sphericity and the Kaiser-Meyer-Olkin Measure of Sampling Adequacy (KMO) were performed to see whether a factor analysis could be performed. When Bartlett's test is significant ($p<0.001$) it indicates that the data are appropriate for factor analysis. For KMO a value near 1 indicates that patterns of correlations are relatively compact and factor analysis should yield distinct and reliable factors.[18] Regarding the rule of thumb of 10 respondents per patient safety culture item, at least 430 completed questionnaires were needed.[19]

Factor analyses

As we built on an existing questionnaire, a confirmatory factor analysis (CFA) was performed to investigate whether the structure of the original SCOPE for general practices could be confirmed for these data. The chi^2 and RMSEA were used as parameters for goodness of fit. A non-significant chi^2 means that the discrepancies between the hypothesized model and the empirical data are negligibly small and thus indicate a good fit. The RMSEA measures how well the empirical model approaches the theoretical model. A value of <0.05 is considered a close fit of the model, a value of <0.08 fair or a reasonable error of approximation, and values >0.1 are regarded as not acceptable.[20,21]

To examine whether a different structure would give a better fit to the data, an explorative factor analysis (principal component analysis, promax rotation) was performed. To determine how many factors should be retained the eigenvalues and the scree plot were examined. Also, the total explained variance was taken into account.

Reliability

Internal consistency of the factors was measured using Cronbach's alpha. A Cronbach's alpha of >0.60 indicates that different items measure the same concept.[18] A positive rating for internal consistency is met when Cronbach's alphas range between 0.70 and 0.95.[19] We also examined the deleted-item reliability coefficients.

Construct validity

For all respondents, sum scores were calculated by obtaining the mean score of all items within one dimension. One missing value per dimension was allowed. Subsequently, intercorrelations between dimensions were calculated with Pearson correlation coefficients. We expected that the various dimensions would correlate moderately as they cover an aspect of the same construct: patient safety culture. However, the correlations should not exceed 0.70 because this would mean that the dimensions are too similar and measure the same concept. Furthermore, correlations of the dimensions with the patient safety grade were computed. It was expected that all dimensions would have a positive correlation with the grade.

All Statistical analyses were conducted using SPSS 17.0 and Lisrel 8.8 for the CFA.[20]

Ethics statement

The Medical Research Ethics Committee of the University Medical Center Utrecht concluded that no WMO approval for this study was needed.

RESULTS

In total, 921 individual questionnaires were returned from 519 practices. 306 questionnaires were excluded for further analysis: 200 from single-handed practices, 11 from respondents with less than half a year experience at the particular practice and 94 with more than 5 missing values, resulting in 615 questionnaires eligible for the study. Bartlett's test was significant ($p<0.001$) and the KMO was 0.91 indicating that the data were appropriate for a factor analysis.

Table 1 gives a description of the study population by gender and age and response rate per profession. Overall, the age and gender distribution of the sample was representative for the Dutch professions population, where reference data were available (data not shown). However, in both dental care and general practice females were overrepresented.

Table 1: Study population by age and gender and response rate per profession

Professions	n	Response rate	Age Mean (SD)	% women
Exercise therapy practices	35	17.5%	42 (9.7)	97.1
Dental care practices	42	21%	42 (11.8)	67.5
Dental hygiene practices	14	7%	40 (10.1)	100
Dietetic practices	18	9%	41 (10.3)	100
Midwifery practices	123	61.5%	37 (10.3)	96.7
Occupational therapy practices	34	17%	41 (8.5)	93.5
Physiotherapy practices	147	36.8%	40 (12.2)	50.4
Anticoagulation clinics	95	47.5%	49 (9.1)	87.8
General practices	16	8%	48 (10.7)	50
Skin therapy practices	24	12%	35 (11.7)	100
Speech therapy practices	67	33.5%	37 (10)	100
Total	**615**	**25.6%**	**41 (11.4)**	**81.7**

Confirmatory factor analysis

A confirmatory factor analysis showed that the original factor structure did not fit well with the data (X^2=2855.56 df=832, $p<0.001$). The RMSEA was .06 (90% confidence interval: 0.06-0.07). Although some authors consider a value of 0.06 a fair fit, the cut-off point of <0.05 is usually used. Therefore, also an exploratory factor analysis was conducted to examine if a different structure would fit the data better.

Exploratory factor analysis

Exploratory factor analyses showed the best fit with seven dimensions: (1) open communication and learning from errors, (2) handover and teamwork, (3) adequate procedures and working conditions, (4) patient safety management, (5) support and fellowship, (6) intention to report events and (7) organisational learning. The original dimension 'communication openness' was divided in two dimensions: 'open communication and learning from error' and 'adequate procedures and working conditions'. Table 2 provides an overview of the seven dimensions, the number of items with their factor loading, mean score and standard deviation (SD) per dimension.

Two items did not have a satisfactory loading above 0.40 on any of the factors and one item loaded on two factors. Two of these items: '*Staff are afraid to raise questions if something does not seem right*' and '*Disciplines work together well to provide the best care for patients*' were deleted from the questionnaire, since the content of these items were covered to a great extent by other items. As the content of the item *'Professionals discuss errors that occurred with other disciplines'* was not covered by other items, and in view of the expected increase of interdisciplinary collaboration in the near future, it was retained as a separate item. A few items fell under a different dimensions than in the original SCOPE. The answer category 'not applicable' was retained for the question '*When one area in this practice gets really busy, others help out'* and questions regarding collaboration. The seven dimensions jointly explained 58.9% of variance.

Reliability and construct validity

The internal consistency was excellent with Cronbach's alphas ranging from 0.70 to 0.90 (see Table 2). Table 3 shows the mean dimension scores with the SD and correlations between the seven dimensions and the patient safety grade. Overall, the correlations between the dimensions were moderate to good. The highest correlations were between '*open communication and learning from error'* and '*patient safety management'* (r=0.61) and between 'a*dequate procedures and working conditions'* and '*handover and teamwork*' (r=0.57). '*intention to report events'* did not correlate with other dimensions (r= 0.11 - 0.18) except for *'open communication and learning from error'* (r=0.38). The correlation with the patient safety grade showed a similar pattern: for all dimensions there was a moderate to good positive correlation ranging from 0.34 to 0.55 except for 'Intention to report events' (r=0.21).

Table 2. Mean scores and factor loadings of the items of the SCOPE-PC questionnaire

Item	Description	Mean	SD	F1	F2	F3	F4	F5	F6	F7	α
1. Open communication and learning from error											
C1	We are given feedback about changes put into place based on event reports	3.95	1.27	0.84							
C2	Staff will freely speak up if they see something that may negatively affect patient care	4.53	0.65	0.59							
C3	We are informed about errors that happen in this practice	4.22	0.88	0.86							
C4	Staff feel free to question the decisions or actions of those with more authority	4.08	0.89	0.72							
C5	In this practice, we discuss ways to prevent errors from happening again	4.42	0.76	0.69							
C7	Professionals discuss errors that occurred with each other	4.30	0.78	0.73							
C9	We are given personal feedback about our own event reports	4.09	0.99	0.66							
B4n	My supervisor/manager overlooks patient safety problems that happen over and over	3.96	0.81	0.40							
2. Handover and teamwork											
F1n	Problems often occur in the exchange of information across disciplines in our practice	3.50	1.01		0.67						
F2n	The fact that patients are treated by different professionals in our practice is causing problems	4.12	0.71		0.77						
F3n	Disciplines in the practice that we co work with do not coordinate well with each other	3.88	0.90		0.85						

Table 2 continued

Item	Description	Mean	SD	F1	F2	F3	F4	F5	F6	F7	α
F4	There is a good exchange of information between professionals in this practice	4.30	0.76		0.52						
F5	There is a good exchange of information between supporting staff in this practice	4.21	0.72		0.45						
F7n	Things "fall between the cracks" when transferring patients between different disciplines in this practice	3.89	0.88		0.83						
F8n	Important patient care information is often lost because patients see different professionals	4.01	0.85		0.81						
3. Adequate procedures and working conditions											
A5n	It is just by chance that more serious mistakes don't happen around here	4.34	0.78			0.77					
A7n	We use more agency/temporary staff than is best for patient care	4.40	0.78			0.80					
A8n	Staff feel like their mistakes are held against them	4.23	0.80			0.54					
A10n	In this practice we work longer hours than is best for patient care	3.89	0.92			0.76					
A12n	When an event is reported, it feels like the person is being written up, not the problem	4.06	0.80			0.65					
A13n	We work in "crisis mode" trying to do too much, too quickly	3.80	0.95			0.59					
A14n	Staff worry that mistakes they make are kept in their personnel file	4.17	0.77			0.58					
A15n	We have patient safety problems in this practice	4.39	0.70			0.59					

Table 2 continued

Item	Description	Mean	SD	F1	F2	F3	F4	F5	F6	F7	α
B3n	Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts	4.02	0.84			0.43					
4. Patient safety management											
B1	My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures	3.32	0.96				0.71				
B2	My supervisor/manager seriously considers staff suggestions for improving patient safety	3.96	0.73				0.86				
B6	The actions of my supervisor/manager show that patient safety is top priority	3.76	0.88				0.90				
B7n	My supervisor/manager seems interested in patient safety only after an adverse event happens	4.09	0.74				0.43				
5. Support and followship											
A1	People support one another in this practice	4.56	0.62					0.90			
A2	We have enough staff to handle the workload	3.93	0.94					0.60			
A3	When a lot of work needs to be done quickly, we work together as a team to get the work done	4.18	0.75					0.85			
A4	In this practice, people treat each other with respect	4.51	0.63					0.92			
A11	When someone in this practice gets really busy, others help out	4.12	0.74					0.79			

Table 2 continued

Item	Description	Mean	SD	F1	F2	F3	F4	F5	F6	F7	α
Intention to report events											
D2	When a mistake is made, but is caught and corrected before affecting the patient, how often is this reported?	3.56	1.19						0.91		
D3	When a mistake is made, but has no potential to harm the patient, how often is this reported?	3.59	1.14						0.93		
D4	When a mistake is made that could harm the patient, but does not, how often is this reported?	4.01	1.04						0.90		
Organisational learning											
A6	We are actively doing things to improve patient safety	3.95	0.82							0.62	
A9	Mistakes have led to positive changes here	3.97	0.68							0.57	
A16	Our procedures and systems are good at preventing errors from happening	4.00	0.66							0.53	
Deleted items											
C6n	Staff are afraid to ask questions when something does not seem right										
F6	Disciplines work together well to provide the best care for patients										
Seperate item											
C8	Professionals discuss errors that occurred with other disciplines	3.55	1.08								

The letter 'n' in an item-code means that it concers an item in negative wording.

Table 3: Mean dimension scores, correlation with patient safety grade and intercorrelations of the seven dimensions

Dimensions	n	Mean (SD)	patient safety grade	1	2	3	4	5	6
1 Open communication and learning from error	588	4.22 (0.64)	0.44**						
2 Handover and teamwork	456	3.99 (0.62)	0.43**	0.50**					
3 Adequate procedures and working conditions	457	4.12 (0.54)	0.47**	0.53**	0.57**				
4 Patient safety management	294	3.81 (0.65)	0.55**	0.61**	0.53**	0.52**			
5 Support and fellowship	606	4.26 (0.60)	0.34**	0.40**	0.42**	0.46**	0.39**		
6 Intention to report events	590	3.72 (1.03)	0.21**	0.38**	0.11*	0.15**	0.17**	0.18**	
7 Organisational learning	609	3.97 (0.59)	0.42**	0.41**	0.38**	0.33**	0.49**	0.54**	0.20**

** Correlation is significant at the 0.01 level (2-tailed)

* Correlation is significant at the 0.05 level (2 tailed)

DISCUSSION

Main findings

Validation of the SCOPE-PC showed that the scale consisted of seven dimensions, slightly differing from the original SCOPE questionnaire with eight dimensions. The main difference was that the original dimension '*open communication'* in the current study was divided in two dimensions: '*open communication and learning from error*', and '*adequate procedures and working conditions'*. Internal consistency and construct validity were good.

Interpretation of findings

It is interesting to note the absence of a correlation between '*intention to report events*' and all other dimensions but one: '*open communication and learning from error*'. The absence of correlation between '*intention to report*' and most other dimensions may be explained by a difference in perspective. The questions about reporting relate to actual steps to be undertaken when an error occurs, they ask about one's personal intentions: What would

you *do* if? In contrast, questions regarding collaboration, support, the notion of abiding and employing the procedures about patient safety relate to how everybody *feels* or thinks of the atmosphere in their practice, and is concerned with how this is at the moment.
Another explanation for the absence of correlation could be the fact that reporting is still very uncommon in primary care. The dimension 'Intention to report events' does therefore not 'behave' the way the other dimensions do. Additionally, the fact that *'open communication and learning from error'* does correlate may indicate that this is an important precondition for reporting. Subsequently, one would expect that the coherence of all dimensions will become stronger as safety management activities become common practice.
The uneven distribution of the response rate in the eleven professions was striking. A partial explanation is that some professionals, like general practitioners, often receive requests to participate in a study and are therefore less likely to respond. Also, some general practitioners had already completed the original questionnaire during their accreditation process. The original questionnaire was already available for them. Furthermore, it is possible that the interest for patient safety differs between primary care professions. Despite these differences we considered all professions as one group; similarities in the targeted patient group, organisational structure and educational level of employees justify this.

Strengths and limitations

The strength of this questionnaire is that it serves all primary care professions with one generic questionnaire. This facilitates comparison in further research.
This study has some limitations. First, selection bias due to the fact that more innovative practices and practices that are more enthusiastic about the topic were probably more willing to participate, could not be excluded. Because data collection was done through a contact person, we may assume that personal drive and maybe even authority played a role in participation of individuals. However, for a psychometric study this is less important since the focus is on clustering of items.
Second, the response rate of 38.4% for individual questionnaires is not very high, yet it is not unusual for an open population study. The low response could be due to the fact that because of the organisational structure, primary care professionals have no overhead time for such activities. On top of this, data collection was hindered because the membership records of some groups were not up to date. In addition, we were not able to distinguish the single-handed practices beforehand. Still, with a total of 615 questionnaires the rule of thumb of a ratio of ten respondents per item is amply met with a ratio of 14:1.
Third, a general drawback of measuring culture with a survey is that it will not capture the heart of the current culture, for which a more sophisticated method is necessary.[23] Options given are participant observation, interviews and focus groups combined with attitudinal

surveys and established cultural assessment tools. Indeed, it would be interesting to combine the SCOPE-PC questionnaire with qualitative methods in a future study aiming at describing patient safety culture. However, for professionals themselves, as final users of the product, a survey has the advantage that it is feasible and easy to use.

Conclusions and implications

In conclusion, this study showed that the SCOPE-PC questionnaire for primary care has sound psychometric properties. The questionnaire is slightly different from the original SCOPE, but overall the main part of the factor structure is the same and only two items were deleted. In future, when sufficient data will be available, it would be interesting to perform cross-validation of the questionnaire. The use of the questionnaire will enable all professions in primary care to gain insight in their safety culture status and to take steps from there to improve patient safety in their practices. In our opinion, the next step in research is to explore the status and possible differences between professions in the Dutch primary care regarding patient safety culture.

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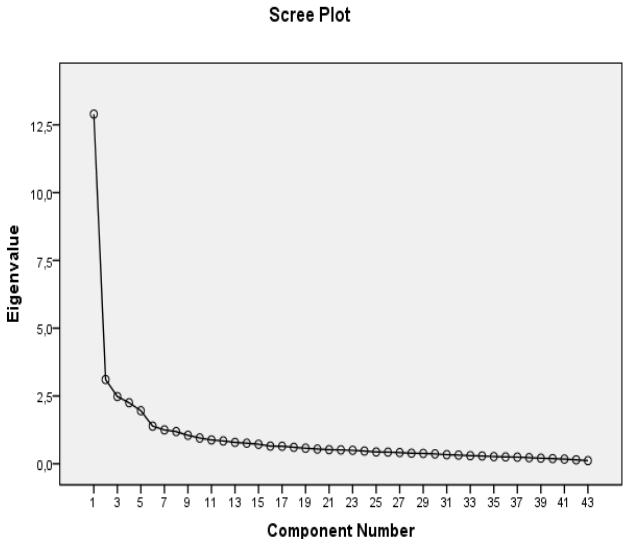
APPENDIX I Description confirmatory factor analysis (CFA)

A CFA provides a formal statistical test of how well the data fits the predisposed structure of factors. This fit is indicated by a X^2 score and goodness-of-fit indices. The CFA was performed in Lisrel version 8.8. Because CFA was performed on a data file with missing data, Lisrel automatically uses Full Information Maximum Likelihood estimation. This method makes maximal use of all data available from every respondent in the sample. When performing a confirmatory factor analysis with missing values, Lisrel only gives X^2 and the Root Mean Square Error of Approximation (RMSEA).

Interpretation of results

A non-significant X^2 means that the discrepancies between the hypothesized model and the empirical data are negligible small and thus indicate a good fit. However, the X^2 is sensitive to sample size and therefore little discrepancies can be statistical significant. The RMSEA measures how well the empirical model approaches the theoretical model. The assumption is that all models can only be an approximation and therefore a perfect fit cannot be obtained. A value of <0.05 is considered a close fit of the model, a value of <0.08 fair or a reasonable error of approximation, and values >0.1 are not acceptable.

APPENDIX II Scree plot



CHAPTER 3

Exploring patient safety culture in primary care

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ABSTRACT

Objective
To explore perceptions of safety culture in nine different types of primary care professions and to study possible differences.
Design
Cross-sectional survey.
Setting
Three hundred thirteen practices from nine types of primary care profession groups in the Netherlands.
Participants
Professional staff from primary care practices. Nine professions participated: dental care, dietetics, exercise therapy, physiotherapy, occupational therapy, midwifery, anticoagulation clinics, skin therapy and speech therapy.
Main Outcome Measure(s)
Perceptions of seven patient safety culture dimensions were measured: 'open communication and learning from error', 'handover and teamwork', 'adequate procedures and working conditions', 'patient safety management', 'support and fellowship', 'intention to report events' and 'organisational learning'. Dimension means per profession were presented and multilevel analyses was used to assess differences between professions. Also a so-called patient safety grade was self-reported.
Results
Five hundred and nineteen practices responded (response rate: 24%) of which 313 (625 individual questionnaires) were included for analysis. Overall, patient safety culture was perceived as being positive. Occupational therapy and anticoagulation therapy deviated most from other professions in a negative way, whereas physiotherapy deviated the most in a positive way. In addition, most professions graded their patient safety as positive (mean =4.03 on a 5-points scale).
Conclusions
This study showed that patient safety culture in Dutch primary care professions on average is perceived positively. Also, it revealed variety between professions, indicating that a customised approach per profession group might contribute to successful implementation of safety strategies.

INTRODUCTION

The establishing of an open, constructive patient safety culture is believed to be important for improving patient safety. Culture refers to the shared values, attitudes, norms, beliefs, practices, policies, and behaviours about safety issues in daily practice.[1] Several safety culture surveys were developed to assess safety culture in healthcare.[1-4]

Until recently, patient safety research mostly addressed hospitalized care whilst a major part of health care is delivered in primary care settings. Although the risk for patient harm is lower in primary care, due to the high numbers of patient contacts absolute numbers seem significant.[5] Few studies have assessed patient safety culture in a primary care setting.[6-11] Some studies adapted and validated existing questionnaires developed for hospitals, others developed own questionnaires. Also, the Manchester Patient Safety Framework (MaPSaF), a discussion tool, was customized.[12,13]

In the Netherlands, primary care is easily accessible and for medical care it serves as a gatekeeper to hospital care. Most practices consist of staff members stemming from several different disciplines but practice sizes are relatively small. When primary care gained more attention in patient safety research, the Dutch hospital version of the HSOPS[14, 15] firstly was adapted for general practice.[16] Subsequently other primary care professional associations expressed their interest in this assessment tool and patient safety culture as a topic. The ambition of one questionnaire for all professions in primary care was voiced because primary care professions increasingly collaborate and work together in one health centre. A generic questionnaire would be in line with these developments and enhance exchange of lessons learned.

Following this need, the questionnaire for general practice was modified to a generic primary care version, the SCOPE-PC.[17] SCOPE is a Dutch acronym for systematic culture inquiry on patient safety in primary care. The aim of the current study was twofold: firstly, to explore primary care professionals perceptions of patient safety culture and, secondly, to examine whether there are differences between the primary care professions and in which area.

METHODS

Setting, participants and data collection

The SCOPE-PC was administered to practices in nine primary care profession groups from March until May 2011. Professions that participated were: dental care (which consists of both dentists and dental hygienists), dietetics, exercise therapy, physiotherapy, occupational therapy, midwifery, anticoagulation clinics, skin therapy and speech therapy. Anticoagulation clinics

monitor coagulation markers in patients' blood and ensure correct anticoagulant medication dosage. Skin therapy is professional care for the treatment of diseased or damaged skin. In primary care, teams are generally multidisciplinary. In this study we aimed to compare professions as whole teams. Therefore, within each profession we also included supporting staff, for instance healthcare assistants and nurses. We did not study individual professional disciplines. Per profession a random sample of 200 professionals was drawn from their national professional association member database. The research team invited professionals to participate and also to invite their colleagues at their practice location to complete an individual questionnaire. Only for physiotherapy, professionals were approached by the national physiotherapy association itself, in return asking them to contact the research team for an invitation and login keys. Anticipating on a lower response by this invitation procedure, a sample of 400 physiotherapists was drawn. Practices could participate if they consisted of at least two staff members and the questionnaire was to be completed by staff that worked at the practice location at least half a year. We chose to keep the minimum number of employees low so that also small practices could take part in our study. Primary care consists of many small practices and the sample would not be representative if these were excluded. The reasoning to set the limit at two was because also two people in one practice create a way of working and collaborating, in essence, a culture will therefore be present even in such a small quantity. For collection and storage of data an online system was used.[18]

Measurements

The SCOPE-PC questionnaire has been validated and showed sound properties with Cronbach alpha's ranging from 0.70-0.90.[17] It consists of 41 items divided over seven dimensions: 'open communication and learning from error'(1), 'handover and teamwork'(2), 'adequate procedures and working conditions'(3), 'patient safety management'(4), 'support and fellowship'(5), 'intention to report events'(6) and 'organisational learning'(7). Items were rated on a five-point Likert scale, ranging from 'strongly disagree' to 'strongly agree' or from 'never' to 'always'. In addition, in dimensions two, three and five some questions had the answer option 'not applicable'. Respondents were also asked to rate the level of patient safety in their own practice between 'poor' and 'excellent' (Patient Safety Grade, PSG).

Data analysis

Questionnaires from single-handed practices, from respondents working less than half a year at the practice or responses with more than 50% missing values in patient safety items were excluded from further analyses. Also, per dimension, respondents scoring "not applicable" on >50% of the items were excluded.

First, the average of the scaled items was computed per profession. Second, for each dimension a grand mean was calculated over all professions. While calculating the mean score, one missing item per dimension was allowed. When respondents indicated that there was no formal management layer in their practice, items concerning patient safety management were disregarded in the missing count (concerning items in dimension one, three and four).

To assess perceptions of patient safety culture we examined the mean scale scores of the seven dimensions per profession group and the PSG. A score of four or higher represents a positive attitude. Next, to examine whether professions differed from each other we compared the mean of each profession to the grand mean of the dimension using multilevel analyses in order to adjust for clustering of respondents in practices. A linear mixed model with a random intercept was used for the analyses. To interpret differences and their relevance we adhered to the size of a difference of a half standard deviation (SD).[19] All statistical analyses were conducted using SPSS 20.0.

RESULTS

In total, 906 individual questionnaires were returned from 519 practices, the response rate was 23.6%. From these, 281 questionnaires were excluded from analysis: 200 from single-handed practices (mainly exercise therapy, speech therapy and dietetics), 11 from respondents with less than half a year experience and 70 respondents with >50% missing values in the patient safety culture items. This resulted in a total of 625 questionnaires (313 practices) eligible for analysis (see Figure 1). The distribution varied over the seven dimensions due to the fact that some respondents had >50% of the dimension items answered with not applicable. The low number of subjects in dimension four resulted from the majority of respondents not having formal management and therefore not able to answer the items in this dimension.

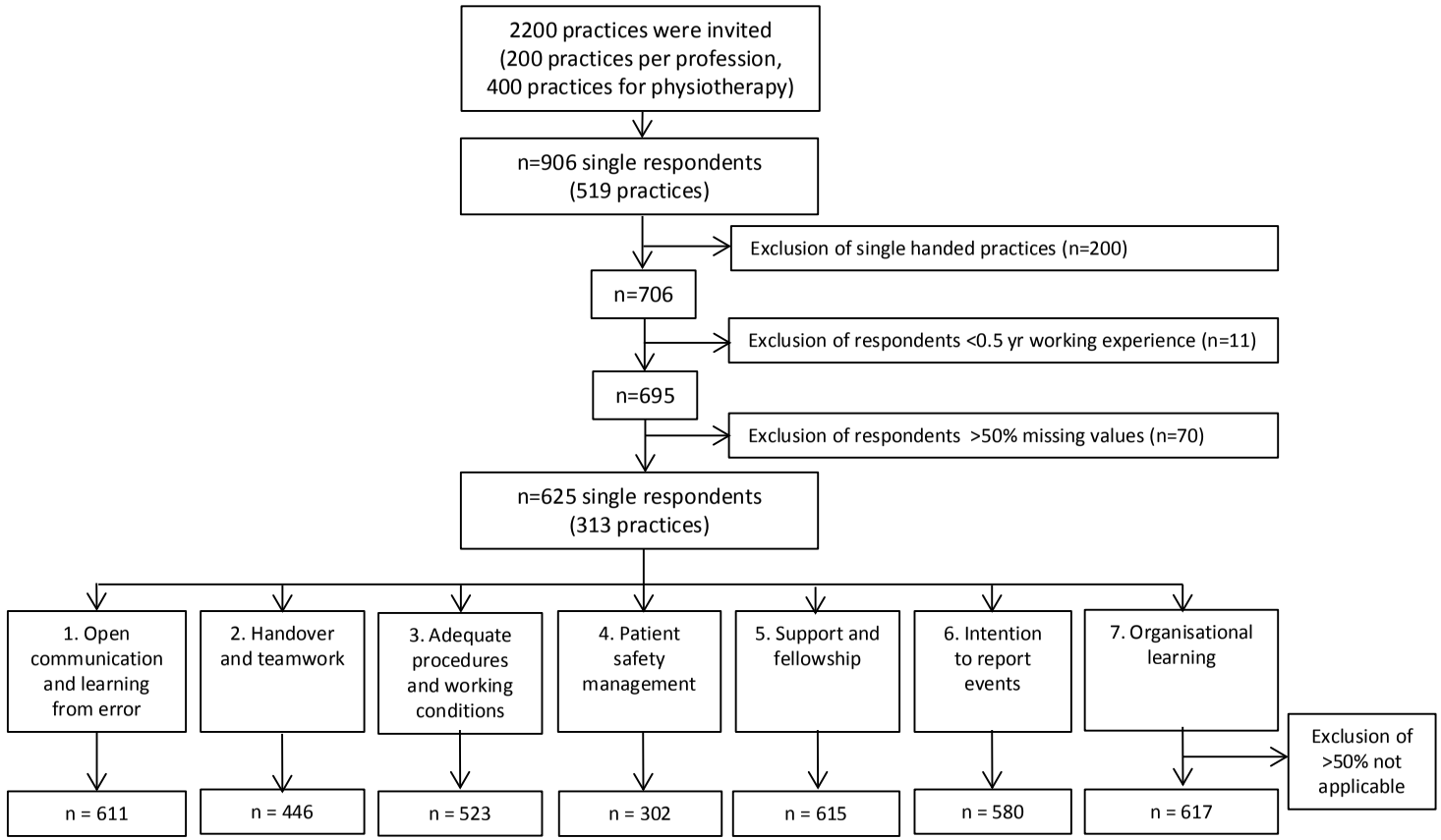

Figure 1. Flowchart of numbers and exclusions of study population and distribution over the seven dimensions

Respondents characteristics

Table 1 shows characteristics of the participating practices sorted by profession. The largest groups to respond were physiotherapists (n=150), midwives(n=125) and anticoagulation clinics (n=99). The smallest numbers of respondents were for dietetics (n=19) and skin therapy (n=26). The high percentage of female respondents stands out (82,6%), only in physiotherapy practices the percentage of male and female employees were equal. With regard to practice size, skin therapy, exercise therapy and speech therapy practices were small, whilst anticoagulation clinics were large. Working experience was shortest in skin therapy, anticoagulation clinics and midwifery practices and longest in exercise therapy.

Patient safety culture

The mean dimension scores, SD and PSG are presented in Table 2. At the bottom of Table 2 the grand mean of each dimension is presented. In general, primary care professions perceived dimensions positively. There were two dimensions that scored below four: (6) 'intention to report events' scored the lowest (3.73) and (4) 'patient safety management' (3.79). The highest dimension scores were for (1)'open communication and learning from error' (4.25) and (5)'support and fellowship' (4.26). Dimension (6) 'Intention to report events' showed the largest variation within the profession groups itself. In addition, the PSG was rated positively (four or higher) with a mean of 4.03 (range 3.62 – 4.16). Two professions, occupational therapy (3.62) and anticoagulation therapy (3.83), scored below four on the PSG.

Differences between professions

When comparing each profession to the grand mean, in general, deviations were small. Differences larger than half a standard deviation are underlined in Table 3. Two professions showed only negative deviations from the overall mean: occupational therapy and dietetics. These professions also had the largest deviations overall. In addition, anticoagulation therapy also perceived safety culture more negatively on most dimensions when compared to the other professions. In contrast, physiotherapy was the only profession that showed solely positive deviations on all dimensions. However, none of these differences were larger than half a SD. Dental care deviated slightly positive on all dimensions but (1) 'open communication', where they deviated negatively. With regard to the dimensions, largest deviations were found for (6) 'intention to report events' which showed two large negative deviations, 0.84 (occupational therapy) and 0.63 (dietetics) respectively.

Table 1 Characteristics of respondents and practices

	Dietetics	Physiotherapy	Dental care	Skin therapy	Exercise therapy	Occupational therapy	Anticoagulation therapy	Midwifery	Speech therapy
Respondents (n)	19	150	61	26	36	39	99	125	70
Practices (n)	13	52	46	22	27	28	14	70	41
Professionals per practice									
2-4	5	13	15	18	21	14	0	34	35
5-9	2	18	14	3	4	10	0	32	6
10-14	1	13	5	1	1	0	4	4	0
≥15	5	5	12	0	1	4	10	0	0
Age of respondents* median (range)	43 (24-56)	37.5 (22-64)	42 (24-63)	29 (25-63)	44 (25-58)	43 (27-56)	50 (24-63)	35 (22-61)	37 (22-61)
Gender (% women)*	100	50.3	75.9	100	97.1	93.8	87.8	96.8	100
Working experience in years median (range)	17 (1.5-30)	11.5 (0-40)	13 (0.5-40)	5 (2.5-25)	20 (3-33)	16 (1-35)	7 (0.5-36)	8 (0.5-40)	13 (1-38)

* The distribution of age and gender is representative for Dutch primary care professionals.

Table 2 Mean scores per dimension and PSG, presented by profession

	1 Open communication and learning from error (mean, SD)	2 Handover and teamwork (mean, SD)	3 Adequate procedures and working conditions (mean, SD)	4 Patient safety management (mean, SD)	5 Support and fellowship (mean, SD)	6 Intention to report events (mean, SD)	7 Organisational learning (mean, SD)	Patient safety grade (mean, SD)
Number of respondents	611	446	523	302	615	580	617	605
Dietetics	4.00 (0.67)	3.78 (0.28)	4.06 (0.39)	3.86 (0.28)	4.23 (0.37)	3.24 (1.22)	3.98 (0.45)	4.00 (0.77)
Physiotherapy	4.20 (0.56)	4.11 (0.49)	4.22 (0.49)	3.93 (0.59)	4.29 (0.49)	3.72 (0.81)	4.07 (0.52)	4.12 (0.64)
Dental care	4.13 (0.66)	4.03 (0.56)	4.20 (0.42)	4.05 (0.61)	4.34 (0.42)	3.92 (1.03)	4.03 (0.50)	4.16 (0.73)
Skin therapy	4.28 (0.58)	3.86 (0.23)	4.20 (0.26)	3.95 (0.62)	4.50 (0.35)	3.67 (0.86)	3.92 (0.57)	4.12 (0.53)
Exercise therapy	4.38 (0.33)	3.98 (0.31)	4.40 (0.57)	4.27 (0.31)	4.13 (0.23)	3.55 (0.51)	3.67 (0.33)	4.14 (0.49)
Occupational therapy	3.57 (0.51)	3.74 (0.33)	3.90 (0.37)	3.55 (0.71)	3.96 (0.40)	2.84 (1.02)	3.55 (0.35)	3.62 (0.74)
Anticoagulation therapy	3.90 (0.54)	3.38 (0.72)	3.68 (0.63)	3.69 (0.54)	3.86 (0.56)	3.76 (0.84)	3.99 (0.43)	3.83 (0.56)
Midwifery	4.44 (0.43)	4.09 (0.55)	4.01 (0.65)	4.02 (0.77)	4.07 (0.93)	4.02 (0.93)	3.82 (0.97)	4.08 (0.52)
Speech therapy	4.35 (0.64)	4.08 (0.23)	4.23 (0.24)	4.00 (0.23)	4.39 (0.27)	3.79 (0.75)	3.88 (0.38)	4.05 (0.59)
Grand mean (SD)	4.25 (0.59)	3.99 (0.62)	4.14 (0.54)	3.79 (0.65)	4.26 (0.56)	3.73 (1.01)	3.98 (0.58)	4.03 (0.62)

Table 3: Deviations from the grand mean presented by profession

	1 Open communication and learning from error	2 Handover and team-work	3 Adequate procedures and working conditions	4 Patient safety manage-ment	5 Support and fellowship	6 Intention to report events	7 Organizational learning
Dietetics (n=19)	-0.35*	-0.21	-0.05	-0.19	-0.03	-0.63*	-0.34*
Physiotherapy (n=150)	0.08	0.22**	0.16*	0.13	0.12*	0.08	0.11
Dental care (n=61)	-0.26**	0.04	0.08	0.05	-0.03	0.19	0.11
Skin therapy (n=26)	0.17	-0.05	0.25*	0.17	0.31**	-0.02	0.10
Exercise therapy (n=36)	0.17	0.10	0.28*	0.52	0.30**	0.13	-0.01
Occupational therapy (n=39)	-0.43**	-0.18	-0.16	-0.39*	-0.13	-0.84**	-0.37**
Anticoagulation therapy (n=99)	-0.25*	-0.57**	-0.35**	-0.23	-0.27**	0.10	0.08
Midwifery (n=125)	0.22**	0.13	-0.03	0.14	0.03	0.06	0.00
Speech therapy (n=70)	-0.05	0.18	0.17*	0.07	0.04	-0.22	-0.20*

Multilevel analyses of professions in relation to the grand mean of the SCOPE-PC dimensions, adjusted for clustering in practices. Differences larger than half a standard deviation are underlined.

* $p<0.05$

** $p<0.01$

DISCUSSION

In exploring perceptions of patient safety culture in nine Dutch primary care professions, we found that all professions perceived safety culture fairly positive and graded patient safety in their practice as very well. Differences in perception of patient safety between the professional groups were small.

Comparison with literature

Real comparison with other studies on perceived safety culture in primary care was difficult because of heterogeneity both in the applied questionnaires and the reporting of outcomes. In addition, almost all were focused on family practice, only one study reported separately

on the results of midwifery.[9] Compared to these results it seemed that the midwives in our study perceived safety culture more positively. In a previous study conducted in family practices in the Netherlands, using a slightly different version of the SCOPE-PC questionnaire, means of the eight dimensions ranged between 3.8 and 4.1.[20] This corresponds with our results and indicates that primary care professionals, although not exposed as much as general practitioners to the concept of patient safety yet, still experience patient safety quite similarly. Other studies also found generally positive results in family practice.[7, 8] In our study the intention to report was perceived the least positive of all dimensions. This is in line with other studies that found similarly low scores on the frequency of events reported[9] and error management.[7]

Strengths and limitations

The strength of this study is that we have gained insight in patient safety culture in several primary care professions that have not been examined before. Also, we used one generic questionnaire to assess perceptions of patient safety culture in all professions. Hereby, we could not only describe the current state of affairs but also make comparisons. A limitation was the low response of 24%. Also, the responses varied across the professions. Various causes may have contributed to the low response. Firstly, not all national professional associations were able to provide up to date addresses of professionals nor could they specify whether practices were single handed. This led to loss of participants. Secondly, there was a selective non-response as the low response mainly occurred in particular professions: dietetics, skin therapy, exercise therapy and occupational therapy. These professions may perceive their practice as less likely to provoke harm and therefore were less inclined to participate in our study. Thirdly, because we initially contacted one professional, and in turn asked them to involve their colleagues, the degree of interest and position of this contact person might have determined participation of the whole practice. In line with this, some professions mainly consist of single handed or small practices. By asking all staff to complete the questionnaire, in some professions this inherently will lead to less questionnaires because practices are smaller. In hindsight, taking into account the populations of different professions could have contributed to a larger response rate and more individual questionnaires.

The low response rate constrains the generalizability of our results. In addition, we cannot exclude that the responders were somewhat more positive about patient safety. However, there is no reason to believe that selection was different for the different professions and therefore did not affect the comparisons between them.

Also, there was a considerable amount of questionnaires that had missing values, which might limit the strength of the study. However, we checked whether this might have caused

differences in outcome by imputing the mean dimension scores when <50% of dimension items were missing. Original and imputed mean dimension scores and results of the multilevel analyses gave only minor differences and none of relevance to the conclusions. We chose to compare profession scores with a grand mean per dimension as comparing nine professions with each other led to uninterpretable results because of the amount of comparisons.

Interpretation of the results

Notable was the dimension 'intention to report' as it was perceived both the least positive but also varied the most within the profession groups itself. This finding reflects the early stage of development of incident reporting as part of safety management in primary care. Nationally and within professions incident reporting procedures and forms have been developed. Whilst these tools are easily available, actual incident reporting has not landed in daily practice yet. We see incident reporting as an important and logic tool in dealing with the potential occurrence of incidents, however, not all professionals may share this view. Implementation and adherence is dependent on personal motives and context.[21] Therefore, it could be that on the one hand practices are just gradually starting to implement patient safety initiatives. In this process some practices are forerunners and some lag behind which could explain the variation and possibly, in a few years incident reporting will be more common in daily primary care practice. On the other hand, we should also consider the possibility that incident reporting is of less relevance in some professions because of the nature of the work. For example, occupational therapy which scored lowest, rarely experiences an incident and, those that do occur are mostly without significant harm.

From the literature it is known that leadership is an important precondition for sustainable patient safety implementation.[22,23] The relatively lower scores on 'patient safety management' might reflect the structure of the organisations in primary care that are generally small and mostly do not have a clear hierarchy. Often there is no formal supervisor in these practices, but professionals sharing the same responsibilities. Another plausible argument could be that patient safety is relatively new and therefore is not managed explicitly.

Promising is the finding that 'open communication and learning from error' was perceived positively by all professions, because it is an important condition for patient safety culture. Three professions showed negative deviations on this dimension, i.e. occupational therapists, dieticians and dentists. While the first two professions perceived their culture more negatively overall, we considered the result of dental care on this dimension as more striking. Whereas overall dental staff perceived most patient safety culture aspects as

positive as the other professions, in open communication they seem to deviate negatively from their primary care peers. This may indicate that open communication is a sensitive subject in dental care that requires specific attention when targeting patient safety issues in this profession.

Implications and conclusions

This study showed that primary care professionals in the Netherlands are rather positive in their opinion of their patient safety culture. In addition, our study indicated differences between professions which may demand a tailored approach of patient safety management per profession. However, given the low response rate we cannot draw firm conclusions nor specifically inform on directions of improvement strategies. Primary care is a key factor in the whole healthcare system. Not only a large proportion of health care is provided in this setting, it also contributes to healthcare outcomes.[24, 25] Furthermore, primary care professionals increasingly collaborate facing the challenge of the aging population and more complex care. In this view it is of importance to gain more insight in patient safety and improvement strategies in these settings. Having said this, our study was an important first step in examining perceptions of different professions. Hopefully this leads to more attention and research in this area of healthcare. We believe it is necessary to conduct further research, desirably with mixed methods to further explore attitudes towards patient safety and identify specific needs for improvements.

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PART II

Patient safety culture interventions in general practice

CHAPTER 4

Improving patient safety culture in primary care: a systematic review

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ABSTRACT

Background

Patient safety culture, described as shared values, attitudes and behaviour of staff in a healthcare 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 the 4th of March 2013. Terms defining safety culture were combined with terms identifying intervention and terms indicating primary care. Inclusion followed if the intervention affected 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 two 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 due to the design and methodological problems.

Conclusion

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.

INTRODUCTION

Patient safety has become a major topic in healthcare research and recently its scope has been extended to primary care, as the role of primary care in healthcare 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 four percent of the total healthcare costs.[3] Although incidents in primary care tend to be less harmful compared to incidents that occur in hospitals, the impact on overall safety in healthcare is at least similar due to the large number of patient contacts in primary care.[2,4]

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 categorised 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 percent of patient contacts by reviewing general practice medical records and communication was one of the reported causes. Another study in 48 primary care centres 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 percent 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 organisation is part of their culture. Safety culture is described as the shared values, attitudes and behaviour 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 programmes 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 healthcare.

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 organisational 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 behaviour. Therefore, we conducted a systematic review to assess the effectiveness of patient safety interventions on patient safety culture in primary care.

METHOD

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 'organisational 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 webpages 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 was conducted on the 4th of March 2013.

Eligibility and quality assessment

Studies were eligible for inclusion if they met three inclusion criteria. First, the research had to be conducted in primary care. Second, a patient safety intervention affecting 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 five 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 one author (NV) followed by abstract and full-text screening by two authors (NV; ML). Results were compared and discussed between both authors. In case of disagreement a third author (DZ) was consulted. Data was 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 (Figure 1). After initial screening, eighteen 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.

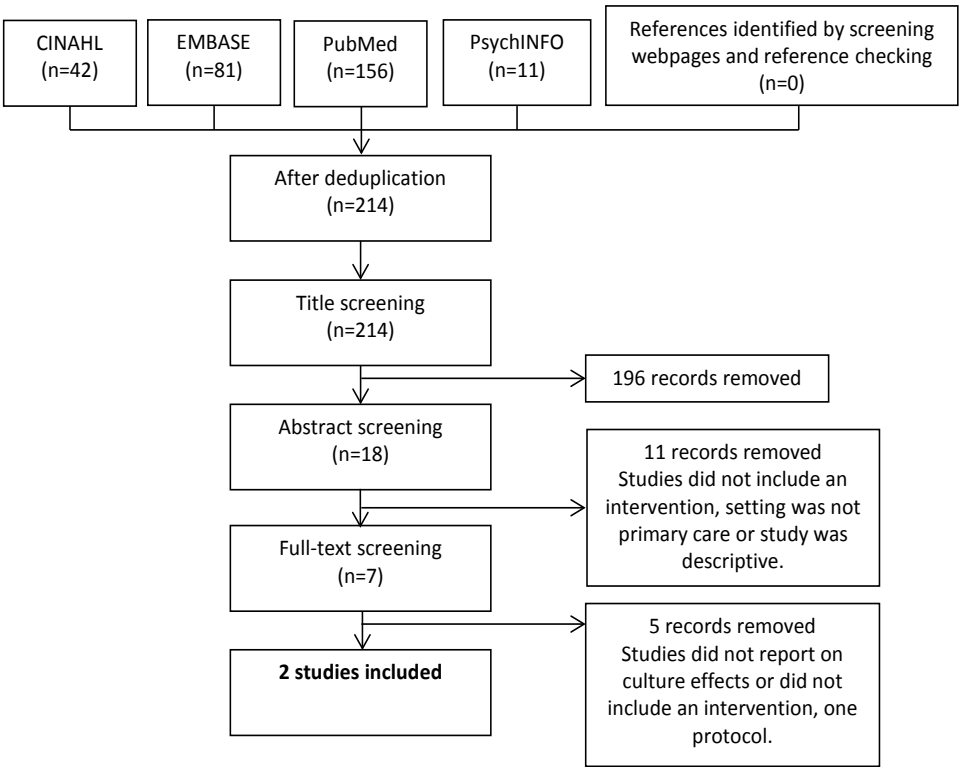

Figure 1: Flowchart search results

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 three years.[21] Wallace et al. used a pre-post design with an implementation time of eight months.[22] Both studies did not use a control group.

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 due to growing of the provider group

[*] Two practices ceased to exist or amalgamated by T2

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 on-going 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 two 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 the most important safety issues specific for their practice. Five of seven 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. Respondents reported time constraints as the most significant concern, followed by communication problems.

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 - Practice-specific needs assessment	Implementation of an electronic medical record system.	Changes in percentages for SAQ dimensions at T1,T2 and T3: 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: - having the right skills, - being supported by structures and policies, - having staff who believed their practice has an open learning culture. *Secondary objective:* Evaluation of the contribution of the RM initiatives to the development of RM competence and learning culture.	- RM audit questionnaire - Learning organization Culture Questionnaire (LCQ) with 4 domains: - creativity - communication - climate - change	- Medical Defence Union RM workshops (single day) - Facilitation of significant event analysis (SEA) (2 hours) - Own development activities including Quality Team Development.	RM competence score showed an overall significant improvement at practice level. 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.

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 two 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 by 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 eight dimensions: 'personal innovation', 'open communication', 'personal blame for errors', 'error awareness', 'team problem-solving', 'task information', 'supportive climate', and 'practice development', distributed over four 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 twenty-four 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 was '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 three 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. Following the GRADE approach they are therefore graded as 'low' on the level of evidence rating. Though, 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.

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. 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.
	Reporting	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.
	Other	There was no distinction made between the three initiatives in the analysis and reporting.

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 due to 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 twenty practices from which data was available for both T1 and T2 were included. Also, in the analyses all three initiatives, the RM workshop, the SEA workshop and own activities were analysed together: no results were given for separate groups.

DISCUSSION

In our search for primary care studies that implemented patient safety strategies which affect patient safety culture we found two 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 behaviour and its relation to a learning culture, in which aspects of a safe culture are 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 two 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 websites of the IHI, NPSA and AHRQ it may be that we missed publications in grey 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 due to 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 standardised. Such complex interventions are inherently conducted in existing systems and therefore raises 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 organisation 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.

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 walk rounds, multi-faceted unit-based programmes, teamwork and communication to have a positive effect on patient safety culture.[13,14] Due to organisational 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 walk rounds will be more difficult to apply in primary care, as the small primary care practices often lack a clear hierarchical organisational 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's 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 I 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 II 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

CHAPTER 5

Cluster randomized, controlled trial on patient safety improvement in general practice: a study protocol

Published as:

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BMC Family Practice 2013, **14**:127

ABSTRACT

Background

An open, constructive safety culture is key in healthcare since it is seen as a main condition for patient safety. Studies have examined culture improvement strategies in hospitals. In primary care, however, not much is known about effective strategies to improve the safety culture yet. The purpose of this study is to examine the effect of two patient safety culture interventions: a patient safety culture questionnaire solely, the SCOPE, or the SCOPE questionnaire combined with a patient safety workshop. The purpose of this paper is to describe the rationale and design of this trial.

Methods/design

The SCOPE Intervention Study is a cluster randomized, three-armed controlled trial, that will be conducted in 30 general practices in the Netherlands. Ten practices in the first intervention arm will complete the SCOPE questionnaire and are expected to draw and implement their own improvement initiatives based on a computerised feedback report. In the second intervention arm, staff of the ten practices also will be asked to complete the SCOPE questionnaire and in addition will be given a complementary workshop. This workshop is theoretical and interactive, educating staff and facilitating discussion, leading to a practice specific action plan for patient safety improvement. The results of the SCOPE questionnaire are incorporated in the workshop. The ten practices in the control arm continue care as usual. Baseline and follow-up measurements will be conducted with an implementation period of one year. The primary outcome will include the number of incidents reported and secondary several quality and safety indicators and the patient safety culture. Moreover, interviews will be conducted at follow-up to evaluate the implementation process of the intervention.

Discussion

Results of this study will give insight in the effect of administering a culture questionnaire or the questionnaire with a complementary workshop. This knowledge will aid implementation of patient safety tools and future research. Attention has been given to the strengths and limitations of the study.

Trial registration: Netherlands Trial Register: NTR3277.

BACKGROUND

A main condition for patient safety is an open constructive safety culture. Patient safety culture is described as the values, attitudes, norms, beliefs, practices, policies, and behaviours regarding safety issues in daily practice.[1] One of the main recommendations in the Institute of Medicine report 'to Err is Human' was to support a safety culture. The National Patient Safety Agency in the UK also recognizes the importance of an open culture. In their developed "Seven steps to patient safety for primary care" the first step is to "build a safety culture".[2] In a report about safety in healthcare in the Netherlands, the former director of Shell, called an environment where acknowledging mistakes is taboo, one of the main causes of safety-risks.[3] Nonmedical industries have been working on safety for much longer and showed that an open culture on error ameliorates business performance.[4,5] Reports suggest a similar role of safety culture in healthcare.[6,7]

In hospital care, team training and communication, executive walkrounds and Comprehensive Unit-Based Safety Program (CUSP) are well received interventions to improve patient safety culture that have been studied. Although positive effects were reported, the level of evidence moderates firm conclusions on the effectiveness of patient safety culture in healthcare.[8,9] Despite the fact that a large part of healthcare is delivered in primary care where practice organisations are becoming larger scaled and more complex, leading to increasing importance of patient safety issues, the effectiveness of such improvement strategies in primary care is underexposed.Often, the first step to initiate patient safety culture improvements is to measure the current state of affairs. We have developed and validated a patient safety culture questionnaire for general practice: the SCOPE.[10] During this former study we observed that this culture questionnaire raised awareness and stimulated some professionals to change their practice. The conducting of a survey can be perceived as a measurement tool and also as a vehicle for communication. It is stated that the actual administration of a survey operates as an intervention. The survey affects people's perceptions and sends messages to employees about the importance of the topic it addresses.[11] Also, feedback of patient safety culture surveys, combined with benchmark data are found highly informative.[12] Others observed a possible intervention effect of conducting a culture questionnaire.[9,13,14] However, it is not clear what the magnitude and the sustainability of the application of a single questionnaire is. It appears that professionals find it difficult to shape actual improvement in practice.[15] We expect that the effect of a single questionnaire could only be temporarily, and subsequently, that the raised awareness will fade away and thus will not lead to actual safety culture improvements. Sexton et. al developed a tool to discuss results of a culture questionnaire as they state that without such a tool it would be

unlikely that spontaneous discussions lead to meaningful improvements in cultures, given the relative novelty of safety culture and its complexity.[16] This corresponds to the reasoning that "the process of reporting results is perhaps most important in determining a survey's effectiveness as a cultural change tool".[11] Hence, a more practical and comprehensive intervention seems needed for obtaining profound and lasting results. Following this, we develop a complementary workshop to the SCOPE questionnaire, based on the Manchester Patient Safety Framework (MaPSaF).[17] The MaPSaF is developed by the NHS specifically for primary care. The tool aims at helping primary care practices to assess the current level of maturity (pathological, reactive, bureaucratic, proactive, generative) of their approach to patient safety. The tool's output serves as a basis for discussions on how to improve the practices' patient safety. Our approach resembles the CUSP, an eight step programme to improve safety culture, used in hospitals.[18] The first step is to measure the culture, followed by the science of safety, identification of safety concerns by staff, adopting of a unit by senior executives, implementation of improvements, analysing and documentation of efforts, sharing of results and last, reassessment of culture.

Objectives

The first objective of this study is to examine the effect of two interventions on patient safety behaviour and patient safety culture in general practice: the SCOPE questionnaire solely, and the SCOPE questionnaire combined with a safety culture workshop. We conduct a three armed trial instead of a two-armed trial. The purpose of the 'questionnaire only' arm is twofold. Firstly, to assess whether administering a culture questionnaire with only a feedback report has an effect on patient safety behaviour and culture, compared to the control arm. Secondly, to be able to adjust for the possible intervention effect of the questionnaire in the workshop arm. Our second objective is to evaluate the implementation process of both interventions. Designing, implementing and evaluating a patient safety culture intervention is complex. The direction of results will largely depend on the context.[19-22] Therefore, evenly important as the possible effect of the interventions is the process evaluation.

METHODS/DESIGN

Design and setting

The SCOPE Intervention Study is a cluster randomized, three-armed controlled trial complemented with a qualitative study. The study will be conducted in thirty general practices in the Netherlands. Practices selection and randomization All general practices (n = 350) in Utrecht area received an invitation to participate in the study. Practices that consist of at least three employees of whom at least one GP can participate in the study. In addition,

the SCOPE questionnaire should not have been completed in the past two years. Stratified randomization will be used to allocate the practices in the three trial arms (see Figure 1). Stratification is based on practice size and whether a practice is accredited on the Dutch GP Practice Accreditation system[23], as we expect these parameters to possibly confound the effects on patient safety culture. The randomisation will be performed by the Data Management Unit of the Julius Center, independent of the research team. Because of the nature of the intervention blinding is not feasible.

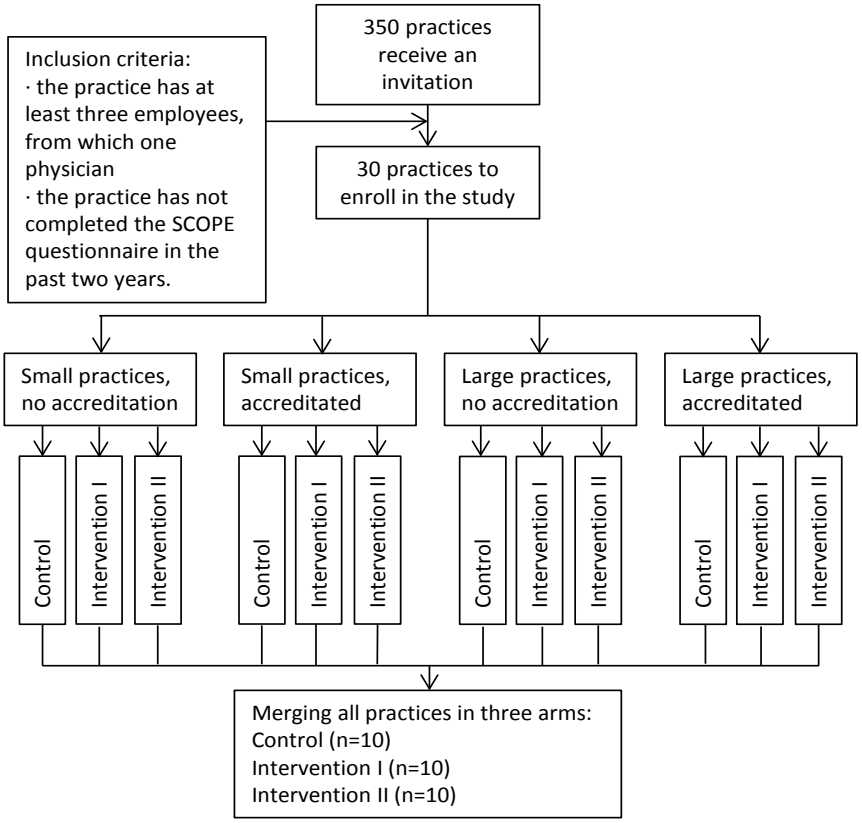

Figure 1. Flowchart randomisation

Procedure

In Figure 2 an overview is given of the intervention procedure and timeframe. Practices in the control arm continue work as usual. All practices are asked to complete a baseline and follow-up questionnaire. At follow-up we administer the SCOPE questionnaire to all participating practices and we will carry out interviews.

Intervention arm I

Practices allocated to intervention I receive access to the online SCOPE questionnaire and simultaneously receive a key to download their results in a feedback report. Also, it is communicated that they are expected to anticipate on these results themselves. After one week a reminder is sent. Additionally, one month after the reminder an email is sent reminding the practice of the feedback report and to inform them about the continuation of the study. We interfere as little as possible in this research arm trying to mimic the normal course of events, when a practice would choose for itself to use the SCOPE questionnaire as improvement strategy.

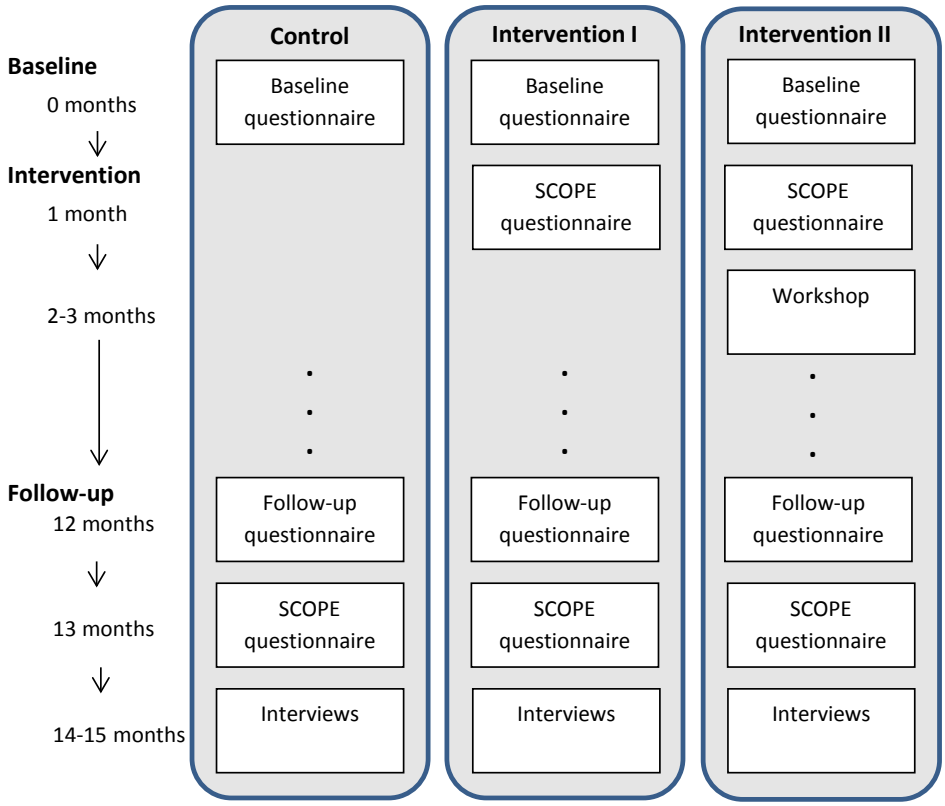

Figure 2 Flowchart of study procedure

Intervention arm II

The practices in intervention II also receive access to the questionnaire. However, these practices do not receive the key to download their results. Instead, they will be given a patient safety workshop at their practice location. The feedback on the results of their questionnaire is embedded in this workshop. The complete feedback report is handed out at the end of the workshop.

Interventions

The intervention consists of the SCOPE questionnaire solely (intervention I) or the SCOPE combined with a patient safety workshop (intervention II). We chose the SCOPE questionnaire and the workshop for both practical and theoretical reasons. The European Linneaus project recommends the AHRQ safety culture questionnaire, from which the SCOPE has been derived, and the MaPSaF for primary care.[17,24] The SCOPE questionnaire and the Dutch translation of the MaPSaF were both readily available and translated in Dutch. In addition, the tools combine well together as the dimensions largely correspond with each other, facilitating the alignment of the workshop complementary to the questionnaire.

SCOPE questionnaire

The SCOPE questionnaire is a culture questionnaire for general practices. The SCOPE is derived from the HSOPS and validated in Dutch general practice,[10,25,26] Cronbach's alpha ranged between 0.64 - 0.85. The questionnaire consists of 43 items divided over eight dimensions:

1. Handover and teamwork (8 items);
2. Support and fellowship (5 items);
3. Communication openness (6 items);
4. Feedback about and learning from error (6 items);
5. Intention to report events (3 items);
6. Adequate procedures and adequate staffing (7 items);
7. Overall perceptions of patient safety management (4 items);
8. Expectations and actions of managers (4 items).

Items are answered using a five point scale varying from 'strongly disagree' to 'strongly agree' or 'never' to 'always'. In addition, respondents are asked to grade the patient safety culture in their practice. Also, questions on demographics such as gender, age and years of working experience are included. All staff of each practice are asked to complete this questionnaire. For data collection and storage an online system will be used, managed by the Dutch GP Practices Accreditation Organisation.[23]

SCOPE feedback report

Results of the completed questionnaires are presented in a computerized feedback report. In this report it is presented how often the questionnaire is completed and by which disciplines. Per dimension the percentage positive scores (four or five on the five point-scale) are calculated. When this is 75 percent or higher it is perceived as a "strong" dimension. When this percentage is lower than 50 percent it is perceived as a "weak" dimension and, when scored in between it is "neutral". The eight dimensions, the percentage positive scores and their classification are presented in a table. Subsequently, all complete dimensions with all questions are reported. Per question the average practice score is reported and compared with an overall benchmark mean that is calculated from data of all practices that have completed the SCOPE questionnaire in 2008 (n = 506-587). When a question scores more than fifteen percent lower than this mean it is depicted red and when higher green. By this, practices can inform themselves on their performance being average, below or above, as compared to the benchmark average. The last page of the report gives general suggestions to improve the patient safety in practice. Suggestions are not fully worked out, but address some issues and refer to more reading material and organizations that can be consulted, if desired. The feedback report is downloaded from the same webpage as where the questionnaires are completed.

Workshop

The workshop is based on the Dutch translation of the MaPSaF.[27] The MaPSaF is a matrix of nine dimensions in which for each dimension all five maturity stages (pathological, reactive, bureaucratic, proactive, generative) of patient safety are described. We add items on theory on patient safety, human factors engineering and safety culture (Figure 3). The workshops are organized at each practice location to make it easier for staff to attend. It requires three and a half hour and at least 75% of the staff should be present. The workshops are given by both an educational scientist who also is a GP and one of the researchers (NV). We intentionally chose for one of the trainers to be an outsider of the research project as well as to be a GP. The first feature allows for questioning and interpreting independently of the research project. The second feature, the trainer being a GP, may allow more rapidly gaining a certain level of understanding and trust among the participants because of being familiar with the GPs practice and context. We believe that the content of the workshop will be better conveyed when explained by a GP. In addition, as the dialogues can contain intimate content, for example when discussing an incident or flaws in communication between staff, a GP as trainer may be easier to confide in and can also display more understanding of the situation. The researcher attending the workshop gives the opportunity to observe and gather research data. Being part of the research setting is linked with intimate knowledge of

the situation, which is essential to develop an understanding 'from within'.
The workshop is both theoretical and interactive, facilitating discussion among practice staff about their own safety culture.

Workshop programme

- Introduction to patient safety
  - Discussing patient safety terminology
  - Data on number of incidents internationally and nationally
- Human factor engineering
  - Why do people make mistakes
  - Interactive examples
  - System approach
- Classify organization according to the MaPSaF vignettes on two dimensions (individually)
  - Each respondent classified the maturity of their practice for two dimensions without consultation
- Patient safety culture
  - Theory on patient safety culture
- Feedback on SCOPE questionnaire
  - Discussion about results
- Dialogue about own patient safety culture based on vignettes
  - Vignettes are discussed in pairs (trying to align with each other)
  - Vignettes are discussed with all staff
- Brainstorm on possible improvement actions
- Drafting of practice improvement action plan
- Evaluation & take home message

Figure 3. Workshop programme

In consecutive order we cover an introduction to patient safety, including discussion about terminology and international and national data about patient safety incident numbers. Followed by theory and interactive examples of human factor engineering and a systems approach to error. Subsequently, we ask all staff to classify the maturity stage, following the MaPSaF matrix, on two vignettes. A vignette is an A4-paper with one dimension worked out in five descriptions of this patient safety theme according to the five stadia. Staff are asked to choose the description that resembles their own daily practice the most. Per workshop we discuss two dimensions: the dimensions that scores the lowest on the SCOPE questionnaire. To be sure the same vignettes will be used for the same SCOPE dimension we made a compatibility table of the SCOPE dimensions and the MaPSaF dimensions (Table 1). The first two SCOPE dimensions have the same MaPSaF dimension. When these are the weakest dimensions, we will use the three weakest SCOPE dimensions in order to have two

different vignettes to discuss. The two vignettes in each practice will be different dependent on their SCOPE results. After scoring these vignettes we introduce theory on culture as an important aspect of patient safety. Subsequently, we show the practice results on their SCOPE questionnaires at dimension levels and ask whether these are recognized and discuss these. Next, we will ask to discuss the MaPSaF vignettes in pairs and subsequently in the whole group. During the workshop we facilitate discussion about the patient safety culture of the practice using the results of the SCOPE, the vignettes and other themes that emerge, leading to a brainstorm of possible improvements. At the end of the workshop the staff will draw a practice specific improvement plan. The workshop ends with an evaluation and a round with take home messages from everyone.

Table 1 Compatibility table of SCOPE questionnaire and MaPSaF dimensions

SCOPE[10]	**MaPSaF**[27]
Handover and teamwork	Teamwork
Support and fellowship	Teamwork
Communication openness	Communication about patient safety
Feedback and learning from error	Learning from errors and achievement of improvement
Intention to report events	Registration and evaluation of errors
Adequate procedures and adequate staffing	Personnel management and safety issues *(Resources)*
Overall perceptions of patients safety management	Priority given to patient safety *(Staff education and training aimed at patient safety)*
Expectations and actions of managers	Errors and responsibility for patient safety

Pretesting workshop

The workshop has been piloted during a training day in six general practices. The aim of this pilot was twofold, first to evaluate the workshop and to be able to customize possible improvements. Second, to give the trainers a chance to get acquainted to the programme. The workshop was well received, main adjustments were to print out a format for the action plan to take home and to print out the feedback report and handing them out directly after the workshop instead of e-mailing them afterwards.

Facultative workshops after ending the study

During the recruiting of the practices, we will communicate that a facultative workshop will be offered for all practices allocated to the control and intervention I arm after ending the study. Hereby, we aim to prevent selective drop-out of practices in the control and intervention I arm.

Measurements

a. Patient safety behaviour

The primary endpoint is the number of incident reports reported by staff in the practice. This endpoint is chosen as incident reporting gives an indication of the patient safety behaviour and culture in the practice. We hypothesize that an increase of reported incidents corresponds to an open patient safety culture. Secondary endpoints are the presence of quality and safety indicators in the previous year such as 'the presence of a procedure for complaints', 'how often safety was on the agenda and/or discussed during team meetings', 'whether a safety management policy was present' and 'whether safety was subject of staff education'. These outcomes are measured using a practice questionnaire at baseline and follow-up in all study arms.

b. Patient safety culture

As stated in the introduction, a culture questionnaire may have an effect on patient safety culture. Therefore, we deploy the SCOPE questionnaire as an intervention. However, as the SCOPE questionnaire will also provide information about the prevailing culture simultaneously, we do not refrain from interpreting and using this data for analyses. Practices in the intervention arms will complete the questionnaire at the beginning of the study as a (part of the) intervention and at follow-up as a measurement tool. The practices in the control arm will only complete the SCOPE questionnaire at follow-up as measurement tool. As such, data on the development of culture will be available for the intervention groups and differences between groups will be available at follow-up.

c. Process evaluation

Besides the effect of the intervention we want to examine the implementation process. As a complex intervention is dependent on contextual factors we want to study these in depth to be able to address facilitators and barriers of the intervention. Therefore, we conduct interviews with the physicians and other staff of the practice. Interviews are conducted by a semi-structured format using a topic list. Topics will examine the patient safety behaviour and culture. First the actual activities are assessed in reference to the research arm where the practice is allocated. Subsequently, patient safety themes that come up during the interview are scrutinized. For example, practices in intervention II will be questioned on their follow-up of the action plan that has been drawn during the workshop. Which activities are implemented and to which level? How did they approach this activity, and what were barriers and facilitators? Practices in the control arm will be questioned on how they perceive patient safety and on what they actually do in their practice around this theme.

Interviews are held in an iterative design, by two interviewers. Every week the interviewers will discuss their data briefly to evaluate and, if necessary, to adjust the topic list accordingly.[28]

Statistical power

The power calculation for the effect of the interventions on patient safety behaviour is based on the primary outcome, incident reporting, and resulted in a power of 0.90. The following assumptions are used: 30 practices divided in three equal groups; an improvement of reported incidents in a year (from 50[13] to 70 (intervention I) to 100 (intervention II) incidents per practice, standard deviation of 30 and an alpha of 0.05.

Ethical approval

The Medical Research Ethics Committee of the University Medical Center Utrecht concluded that the Medical Research Involving Human Subjects Acts does not apply.

Implementation of study results

The results of the SCOPE Intervention Study will result in a self-employable product with a guideline that can be used by professionals in primary care to improve their patient safety and culture. To transfer the knowledge acquired during this study among general practitioners we will organize a meeting with representatives of the primary care professional associations other than of general practice. Here, we will present our results and discus possible adjustments of the tool and possible additional information needed to shape the workshop so that these professions in primary care, such as physiotherapy and midwifery, can use this tool as well.

Data analysis

To analyse the number of reported incidents we will use a poisson regression, if necessary, the analysis will be adjusted for over- or underdispersion.[29] Baseline characteristics such as number of incidents, size of the practice and accreditation will be included as confounders. Where possible we will adjust for baseline measurement of patient safety culture. We will describe patient safety behaviour measured by complaints, meetings and other quality and safety indicators and compare baseline with follow-up. The development of patient safety culture in the two intervention groups and differences in culture between the three arms at follow-up will be analysed by mean scores of the dimension using mixed linear models. All analyses will be corrected for clustering within practices. If necessary a multiple imputation technique will be used for missing data. Data collected from staff during the interviews will be transcribed and analysed with thematic content analysis using software NVivo to code and analyse the data.[30]

DISCUSSION

The purpose of this paper is to outline the rationale and design of the SCOPE Intervention Study. This study will provide insight in the effect of conducting a safety culture questionnaire with a feedback report, on patient safety behaviour and culture in general practice. In addition, this study will reveal whether a complementary workshop to a patient safety culture questionnaire adds to the effect on safety behaviour in general practice. Lastly, interviews will shed a light on the implementation process of the interventions.

This study has several strengths. The SCOPE Intervention Study is one of the first studies that examines the effect of an intervention in primary care on patient safety behaviour and culture. Moreover, the design, a controlled trial, will provide more trustworthy results than previous studies which were observational. Another strength is that the second part of the design is qualitative and will shed light on the implementation process of the interventions. By conducting interviews with practice staff we will gain a deeper understanding on how the interventions work. Several limitations have to be considered also. Firstly, we ask practices to voluntary participate in our study. This may lead to selection bias. For instance, it is likely that the most motivated practices will decide to participate. However, in daily practice forerunners will also be the first to implement patient safety improvements. By studying the effects and implementation of such interventions we hope to facilitate broader implementation. Secondly, we realise that the number of incidents as outcome is ambiguous as both increasing and decreasing numbers could indicate an improvement in patient safety culture and behaviour. However, we believe that reporting incidents is a good measurement of the change in patient safety. Especially in an organisation where patient safety initiatives are relatively new and the number of incident reports are likely to raise before they will lessen.[31] As reporting is still very uncommon in general practice, we will consider an increase of reported incidents as an indicator of an ameliorating safety culture. Increased rates will indicate the starting of safe reporting and raised awareness. Lastly, interventions in this study are complex and may have a diffuse effect. This may be difficult to measure quantitatively. Therefore, we designed a study with mixed methods to understand the potential effect. The strength is that results will reflect daily practice and approximates the effect to be attained when this intervention would be employed on a large scale.

This study will contribute to the body of knowledge concerning the effect of patient safety interventions in general practice. This knowledge will enhance implementation of patient safety tools in general practice and other primary care professions.

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CHAPTER 6

A cluster randomized trial on the effects of patient safety culture interventions in general practice

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Submitted

ABSTRACT

Background

Having a constructive safety culture is essential for successful implementation of patient safety improvements. Because it was unclear how to improve culture in general practice we facilitated two culture tools for general practices.

Aim

To assess the effect of two patient safety culture interventions on safety culture.

Design and setting

A cluster randomised trial was conducted in a mixed method study, studying the effect of administering a patient safety culture questionnaire (intervention I), the questionnaire complemented with a practice-based workshop (intervention II) and no intervention (control) in thirty general practices in the Netherlands.

Method

The primary outcome, the number of incidents reported, was measured with a questionnaire at baseline and a year after. Secondary outcomes were quality and safety indicators and safety culture. Generalized linear models were used for analysis.

Results

The number of incidents increased in both intervention groups, to 81 and 214 in intervention I and II respectively. Adjusted for baseline number of incidents, practice size and accreditation status the study showed that practices that additionally participated in the workshop reported 40 times more incidents compared to the control group. Practices that only completed the questionnaire reported 5 times more incidents. There were no statistically significant differences in staff's perception of patient safety culture at follow-up between the three study groups.

Conclusions

Educating staff and facilitating discussion about patient safety culture in their own practice leads to increased reporting of incidents. It is beneficial to invest in a team-wise effort to improve patient safety.

Trial registry number: Netherlands Trial Register: NTR3277.

INTRODUCTION

At the very start of patient safety research the Institute of Medicine stated that "healthcare organizations must develop a culture of safety to focus on improving the reliability and safety of care for patients".[1] Originated from organizational culture, safety culture is described as the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization's health and safety management.[2]

In the Netherlands, patient safety policy in general practice is now being developed and among others there is a clear need for effective intervention tools on safety culture. Two reviews examining culture improvement strategies in hospitals showed broad multipart interventions and walk rounds with engaged leaders to be most successful.[3, 4] Although a large part of healthcare is delivered in primary care, a review resulted in only few studies on interventions affecting its culture.[5]

Surveys, initially developed to measure existing culture,[6-10] have been observed to possibly affect aspects of safety culture.[3, 11, 12] Administering a survey draws attention to the topic, influencing staff and as such can be considered an intervention.[13, 14] The advantage of a survey is the usability and relatively low cost, however, when considering it as a safety culture intervention, it is questionable whether it is strong enough to accomplish sustained changes on its own. Indeed, the effectiveness of a survey as change tool is determined by the process of digesting and reporting the data.[13]

In addition, educational activities, like workshops, showed positive results on risk management and safety culture.[15, 16] The Manchester Patient Safety Framework (MaPSaF) is a discussion tool for assessing and improving the maturity of safety culture in primary care settings[17] that is increasingly being used.[18-20]

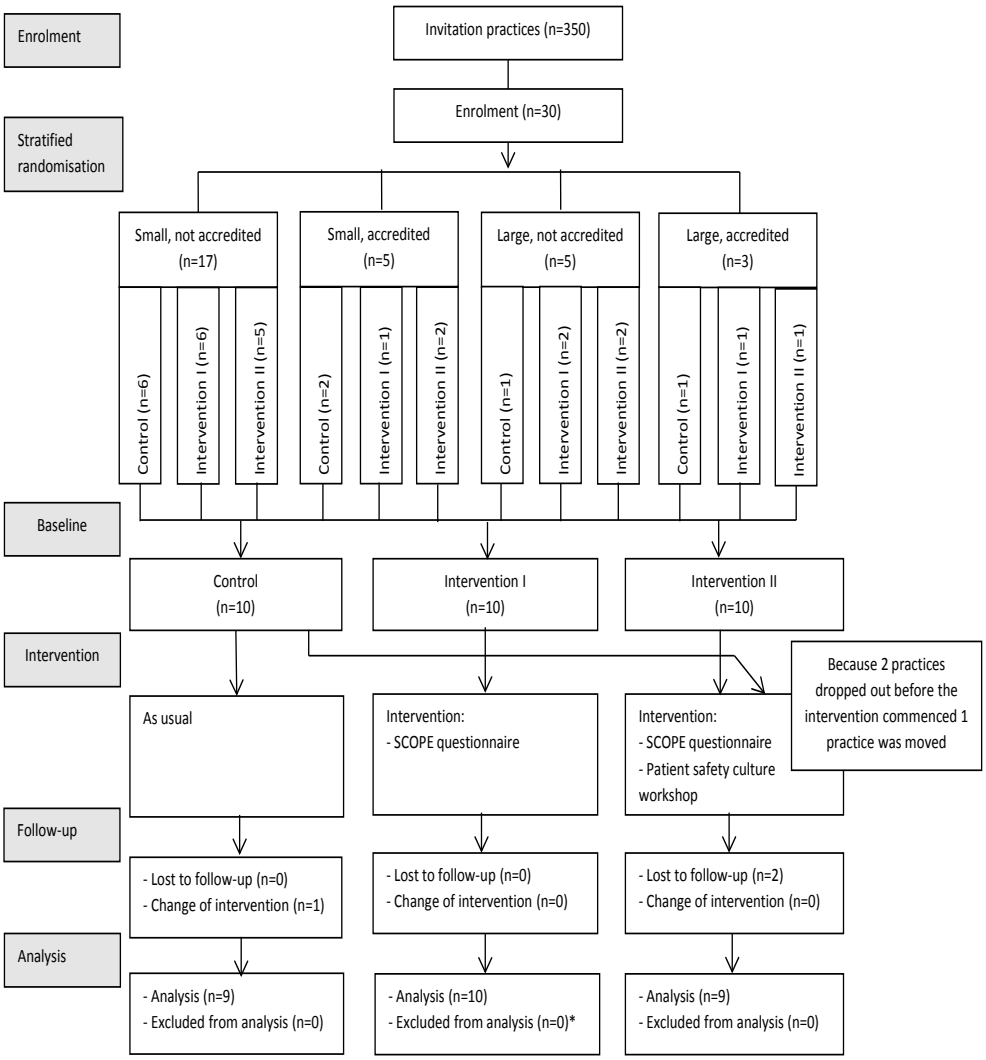
The objective of our study was to assess the effect of administering a culture questionnaire with digital feedback or the questionnaire combined with a practice-based workshop including their feedback in general practice. We hypothesized that both interventions would lead to improved patient safety culture relative to the control practices, and that practices receiving the workshop would improve the most.

METHOD

Design and participants

We conducted a three-armed cluster randomised trial, in a mixed methods study. In this paper quantitative results will be presented. Randomisation was stratified based on practice size (small: < 8 employees, large: ≥ 8 employees), and accreditation status (Figure 1). The

minimisation technique was used taking into account the strata, performed by the data management department independent of the research team. The practices were enrolled and contacted by the first author (NV). Details of the study protocol were described previously.[21] Due to the nature of the interventions blinding was not possible.



* None of the practices were excluded in the analysis of the primary outcome; 1 practice in intervention I was excluded in the analyses of the SCOPE questionnaires.

Figure 1. Enrolment and randomisation

Interventions

Three interventions were studied. The administering of and feedback on a patient safety culture questionnaire, the administering of the questionnaire complemented with a patient safety workshop and no intervention.

I. Patient safety culture questionnaire

The SCOPE questionnaire, translated and adapted originally from the Hospital Survey on Patient Safety Culture (HSOPS)[22] specifically for Dutch general practices[23] was used as intervention tool. Practices simultaneously received a login for the SCOPE questionnaire and a key to download their results in a report. Practices were reminded twice to complete the questionnaire and to download their report. An online system was used for collection of the SCOPE data.[24]

II. Practice based patient safety workshop

The workshop, led by an independent GP trainer, provided education on the concept of patient safety and culture, terminology and human factor engineering and was held at the practice location. Discussion about the own culture was facilitated using their own SCOPE results and Dutch translations of MaPSaF[17] focusing on two SCOPE dimensions that scored lowest. A brainstorm of possible improvements resulted in an action plan. Attendance of 75% staff was required. To study the course of the workshop one of the authors (NV) attended and kept observations. Also, participants were asked to complete an evaluation form.

Outcome measurements

Primary outcome

The primary outcome was the number of reported incidents per practice at follow-up, measured with a questionnaire at baseline and one year hereafter. Actual reporting is a prominent feature of a generative safety culture.[25] Because reporting is just in its infancy in general practice[26, 27], we hypothesized that an increase of reports would reflect a 'pattern of behaviour'[2] congruent to improvement of patient safety culture. Hence, we considered the number of incidents reported as a proxy of actual patient safety culture.

Secondary outcome

Patient safety culture was additionally operationalized by quality and safety indicators (e.g. the presence of complaints procedure, patient safety being an agenda item of team meetings, see Appendix I).

Patient safety culture was measured at all practices at follow-up using the SCOPE questionnaire, consisting of 43 items distributed over eight dimensions (Table 3). SCOPE has sound psychometric properties: Cronbach's alpha's: 0.64 - 0.85.[23] Two outcome questions were included: 'Looking back at the past 12 months, how many incidents reports did you fill-out' and 'How would you grade the patient safety in your practice' (PSG) (five-point scale from 'failing' to 'excellent').

Sample size and practice recruitment

The sample size was calculated based on the primary outcome, numbers of incident reports, showing thirty practices were needed. Based on previous research[11] we assumed an increase from 50 to 70 (intervention I) and 100 (intervention II), respectively, with a standard deviation of 30. Practices (n=350) were invited (February/March 2012) per mail. The first 30 practices that fulfilled inclusion criteria, ≥3 employees and not having completed the culture questionnaire before, were enrolled and allocated to the three research groups (n=10).

Analysis

The number of incidents was analysed per practice with a generalized linear model based on a negative binomial distribution. Intervention, number of reports at baseline, accreditation status and practice size were included in the model. The model using a Poisson distribution showed large overdispersion and minor violations of the assumptions of homoscedasticity and normally distributed residuals. Therefore, we used the negative binomial distribution, hereby deviating from the protocol.[21]

The quality and safety indicators were compared before and after using descriptives. SCOPE questionnaires with >50% missing items were excluded. Multiple imputation (10 imputations) was performed on item level.[28] Culture items were imputed and used as predictors while gender, discipline and age were used as predictors only. Because formal management items could not be answered by everybody, these were not imputed. Therefore, when calculating the mean scores of dimension 7 and 8 one missing was allowed. Percentages positive scores were calculated per dimension. As described in the HSOPS manual, we adhered to the cut off value of >75% positive scores to indicate practices' strengths and by ≤50% positive scores for weak dimensions.[29] For two measurements in the same practice a 5% change was considered meaningful.[30] To analyse differences at follow up we calculated mean dimension scores and performed generalized linear mixed analysis. Intervention type, practice size and accreditation status were included in the model. All analyses were conducted in SPSS 20.0.

RESULTS

Participants

After randomisation, two practices discontinued because of time-issues. Therefore one control practice was moved to intervention II (this was the first practice allocated to the control group). Table 1 gives an overview of practices and respondents characteristics.

Table 1 Practices and respondents characteristics

	Control (n=9)	**Intervention I** (n=10)	**Intervention II** (n=9)
Age* (m, sd)	44.6 (9.9)	44.3 (12.4)	41.08 (10.7)
Female gender* (percentage)	81.3	92.6	85.0
Composition of staff (n, %)	**n=67**	**n=87**	**n=81**
GPs	35.8	35.6	33.3
Assistants	38.2	41.4	38.3
Nurses	17.7	19.5	27.2
Other	7.5	3.4	1.2
Years in current practice* (m,sd)	7.1 (6.3)	9.0 (8.6)	8.3 (6.2)
Accreditation status baseline			
Yes	2	2	3
Accreditation status follow-up			
yes	3	3	4
Working on	1	5	2
Formal reporting system Baseline (y)	2	2	4
Formal reporting system Follow-up (y)	2	4	8

*Based on data of the SCOPE questionnaires at follow-up.

Number of incidents

Intervention I showed an increase of 66 incident reports (15 to 82), intervention II an increase of 144 (70 to 224) and the control group a decrease from 18 to 4 (Figure 2). Appendix II shows the distribution of incident reports, reporting procedure and accreditation status at baseline and follow-up per practice. In intervention I there was one outlier with 57 reported incidents at follow-up. An employee of this practice participated in a workshop on incident reporting outside our study. An intention to treat analysis showed that intervention II resulted in 42 times more reports than the control group, and intervention I reported 5 times as much when adjusted for baseline reports, accreditation status and practice size (Table 2). Without the outlier mentioned earlier the effect of intervention I became non-

significant. The outcome question on number of reports in the SCOPE questionnaire showed the same trend of increasing reports in intervention II and I, respectively (Appendix III).

Quality and safety management

Some indicators showed meaningful changes. Having a formal reporting system remained the same in the control group, but doubled in both intervention groups (I: 2 to 4; II: 4 to 8). In intervention II more practices analysed incidents systematically (2 to 7), had an orientation procedure for new employees (3 to 6) and patient safety was an agenda item of practices' meetings more often (2 to 8). During the study accreditation status of some practices changed (control: 2 to 3, I: 2 to 3, II: 3 to 4). Particularly in intervention I practices (n=5) reported at follow-up that they were working towards accreditation.

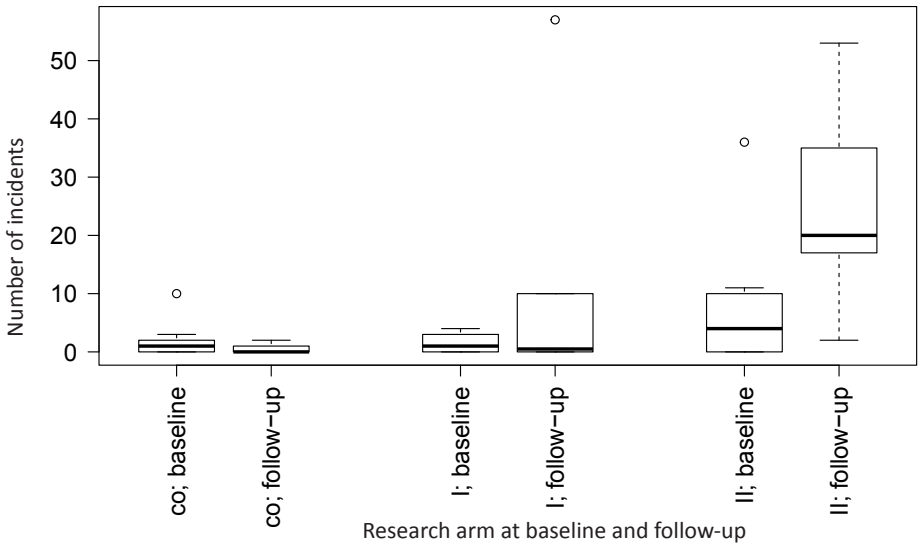


Figure 2. Number of incidents by intervention at baseline and follow-up

Patient safety culture

As part of the intervention, 134 questionnaires were completed at baseline and 183 at follow-up. One practice was excluded from analysis because only one questionnaire was completed at both measurement moments. We included 131 and 166 questionnaires, respectively as 2 baseline and 14 follow-up questionnaires had <50% of safety items completed. A missing analyses showed 2.6% missing items at baseline and 3% at follow-up.

Percentages positive scores ranged between 63 and 86 at follow-up (Table 3).

Table 2 Effect of interventions on number of incidents at follow-up

Parameter	Rate ratio[1] (95% C.I.)	p	Rate ratio[2] (95% C.I.)	p	Rate ratio[3] (95% C.I.)	p
Intention to treat analysis with all 28 practices						
Intervention I	18.45 (4.79-71.06)	**< 0.001**	14.72 (3.72-58.20)	**< 0.001**	5.45 (1.17-25.49)	**0.031**
Intervention II	56.00 (14.47-216.71)	**< 0.001**	45.47 (11.56-178.93)	**< 0.001**	41.72 (9.81-177.50)	**< 0.001**
Number of incidents at baseline (ln)	-	-	1.66 (1.02-2.70)	**0.040**	1.78 (1.02-3.10)	**0.044**
Accredited at baseline (y)	-	-	-	-	0.28 (0.08-1.03)	0.056
Practice size in employees	-	-	-	-	1.22 (1.06-1.41)	**0.005**
Analysis without outlier in intervention I						
Intervention I	6.25 (1.54-25.42)	**0.010**	6.11 (1.49-25.00)	**0.012**	4.12 (0.92-18.44)	**0.064**
Intervention II	56.00 (14.47-216.71)	**< 0.001**	46.50 (11.86-182.22)	**< 0.001**	40.15 (9.88-163.10)	**< 0.001**
Number of incidents at baseline (ln)	-	-	1.37 (0.87-2.17)	0.175	1.46 (0.87-2.46)	0.151
Accredited at baseline (y)	-	-	-	-	0.52 (0.14-1.92)	0.327
Practice size in employees	-	-	-	-	1.15 (0.99-1.33)	0.070

1. Univariable analysis
2. Corrected for baseline number of incidents (ln)
3. Corrected for baseline number of incidents (ln), accreditation status and practice size.

Several dimensions showed room for improvement (<75%), however, none were below 50%. In intervention I six dimensions improved ≥5%, in intervention II three dimensions did. One dimension 'support and fellowship' decreased in intervention I. With regard to the PSG, both intervention groups showed rather low scores at baseline. This increased with 8% and 30% for intervention I and II, respectively. Multilevel analyses showed no differences between groups at follow-up (Appendix IV).

Course of the workshop in Intervention II

All, but one practice met the minimal attendance, ranging from 4 to 10 caretakers (total 66). Workshops proceeded in a pleasant atmosphere and we observed increasing willingness to share opinions and experiences as the workshop progressed. Assigned maturity stages of their own safety culture varied between the first four stages (pathological, reactive, bureaucratic, proactive). All but one practice drew an action plan, predominantly about introducing or activating a reporting procedure. Evaluation forms showed that, though some staff was sceptic at start, responses after the workshop were fairly enthusiastic.

DISCUSSION

Summary

Aiming at contributing to the knowledge of culture interventions in general practice we found that administering a culture questionnaire solely or integrated in a workshop both increased reporting incidents. However, the effect was much larger in practices receiving the workshop. Also, these practices were more active in analysing incidents and discussing the subject during team meetings. These changes in handling incidents indicate patient safety culture improvement at the practices' shop floor after a team-wise safety culture intervention. Yet, safety culture measurements did not show large improvements nor differences between the groups after one year of follow-up.

Strengths and limitations

Our study is one of the first trials on culture improvement in general practice. Also, to our knowledge it is the first trial that studied the possible effect of a questionnaire and indeed found some effect. However, closer examination revealed that the increase of reporting in this group largely occurred in three practices, of which one had participated in a workshop outside the current study. Excluding this practice resulted in a non-significant effect. In the practices that received the workshop the increase in incident reports was found in almost all practices, indicating that the effect was not due to particular practices. Notably, also practices that scored high at baseline showed improvement in Intervention II.

Table 3. SCOPE dimension means, sd and percentage positive scores for the control and both intervention groups

Dimensions (scale 1-5)	**Control (follow-up)** m (sd) % positive	**Intervention I (baseline)** m (sd) % positive	**Intervention I (follow up)** m (sd) % positive	**Intervention II (baseline)** m (sd) % positive	**Intervention II (follow-up)** m (sd) % positive
1 Handover and teamwork	3.72 (0.46) 69.6%	3.58 (0.67) **63.4%**	3.77 (0.49) **74.8%**	3.72 (0.48) 71.8	3.80 (0.37) 74.8%
2 Support and fellowship	4.05 (0.50) 85.3%	3.94 (0.55) 82.4%	3.86 (0.73) 75.8%	3.99 (0.49) 82.8%	4.13 (0.55) 83.7%
3 Communication openness	4.16 (0.51) 85.6%	3.91 (0.70) **73.6%**	4.06 (0.49) **80.9%**	4.13 (0.57) 81.3%	4.22 (0.43) 85.6%
4 Feedback about and learning from error	3.95 (0.84) 69.8%	3.94 (0.86) **69.8%**	4.04 (0.65) **75.6%**	3.91 (0.77) **69.5%**	4.15 (0.61) **75.0%**
5 Intention to report events	3.84 (0.88) 62.6%	3.76 (1.00) **62.7%**	3.90 (0.89) **68.9%**	3.84 (0.93) 64.7%	3.99 (0.71) 68.2%
6 Adequate procedures and adequate staffing	3.83 (0.49) 72.5%	3.73 (0.56) **70.1%**	3.96 (0.45) **80.4%**	3.91 (0.54) 75.2%	3.92 (0.54) 77.9%
7 Overall perceptions of patient safety management	3.66 (0.67) 65.5%	3.65 (0.62) **64.0%**	3.75 (0.57) **69.2%**	3.63 (0.63) **61.5%**	3.94 (0.54) **84.7%**
8 Expectations and actions of managers	3.71 (0.63) 69.9%	3.68 (0.61) 66.5%	3.78 (0.54) 72.2%	3.67 (0.59) **70.2%**	3.84 (0.50) **75.9%**
Patient safety grade	3.63 (0.64) 58.3%	3.57 (0.83) **61.0%**	3.65 (0.75) **69.1%**	3.57 (0.79) **54.9%**	3.84 (0.49) **85.2%**

Percentages depicted in bold show differences ≥5%.

This study has some limitations. Firstly, during the study quality improvement initiatives emerged, particularly in the questionnaire only group. Five practices appeared to be working on the Dutch practice accreditation system (NHG Praktijk Accreditering®), which requires an incident reporting system. Further examination showed that the number of incident reports remained the same before and after the intervention indicating that the

accreditation process for these five practices did not change their reporting behaviour. However, for future studies it would be advisable to include only fully accredited practices to avoid this potential confounder.

Secondly, the absence of changes in culture measurements may be due to underpowering because the sample size calculation was based on the number of incidents, a practice feature. The culture questionnaires, however, were conducted at caregiver level, which resulted in clustered data requiring higher numbers of participants for measuring a potential significant effect. Also, we were not able to match individual questionnaires before and after.

Comparison with existing literature

The MaPSaF, when used in hospitalized setting, showed improvement in culture measurements over a five year follow up.[31] We did not find such improvement in our study. Interestingly, using the MaPSaF in general practice Hoffmann et al. found effects on incident reporting and not on self-reported culture improvement similar to our study.[32] This lack of effect on culture measurements may be explained either by the short intervention time of one year or by the insufficient sensitivity of a survey for measuring perceptions of safety culture.[33] Our workshop was an adapted version of the MaPSaF tool. An important asset of the MaPSaF tool is stimulating participants to self-reflect on daily work within their team.[18] Team effort seems crucial for patient safety.[34-37] However, as the MaPSaF is extensive, we integrated the SCOPE results in the workshop, both focusing the discussion and tailoring it to the participating practice. Hereby, the workshop became comprehensive and manageable. Furthermore, we added an educational part on safety science to the workshop. Education is perceived important in quality improvement[38] and as the most important factor to improve patient safety in primary care.[39] The aim was to educate staff on safety science providing them with a sense of urgency concerning safety in general practice in order to instigate change. In addition, it supported participants' understanding of the systems approach, ensuring a safe atmosphere to discuss culture. With these consecutive elements we built the workshop on the experiential learning principles of Kolb e.g. concrete experience, reflection, conceptualization and experimentation.[40] The subsequent order of the elements of education and presentation of own practice results (what?), team based reflection on own practice data (so what?) and team based development of action plan (now what?) is in line with this experience-based learning cycle that mostly fits professionals because it explicitly connects daily practice with the learning. Moreover, the workshop resulted in an action plan made up by all staff, thus matching their practice with team based commitment, increasing the feasibility of actual implementation.[41] We belief that this format has added to the workshop's impact found in our study.

Implications for practice

Applying a culture survey is a convenient way to enhance staff involvement in patient safety culture improvements. However, discussing the results together as a team when embedded in a workshop appeared to be more effective. For future research it is worthwhile to study the sustainability of the results found and the need for repeated interventions. An additional challenge hereby is to determine whether practices that changed their behaviour concerning patient safety issues deliver better care than practices that do not invest in patient safety culture change.

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APPENDIX I

Quality and safety management questions

The following questions were included in the quality and safety form conducted at baseline and follow-up.

Incident reporting

1. How many incidents from your practice are known from 2011/2012? (primary outcome)
2. In which way became these known by you?
3. If your practice has a formal reporting system, since when was this used?

4a. How many of these incidents have you analysed?

4b. Which method was used?

5. How many of these incidents caused harm to patients?
6. Of these incidents, how many were, to your opinion, possible avoidable?
7. Did you proactively searched for incidents in your practice? (for example by file studies, audits, reporting weeks)

8a. Were there improvement actions implemented in response to (reported) incidents?

8b. If yes, did these improvement actions lead to the desired results?

Complaints procedure

1. How many complaints were received the past year (both from employees and patients)?
2. Does your practice have an internal coordinator for complaints?
3. Is there a formal procedure for handling of complaints?

Team meetings

1. Was the subject patient safety on the agenda for planned team meetings the past year (2011/2012)?
2. If yes, please specify dates on which patient safety was on the agenda.
3. Was patient safety during these team meetings actually discussed?
4. Have there been team meetings in 2011/2012 where patient safety was not on the agenda but was discussed?
5. Could you describe in catchwords the content of the discussed subject? (or sent minutes)

6a. Were action points/improvement plans formulated during these mee tings? If yes, could you describe these in catchwords.

6b. If yes, were these action points/improvement plans actually implemented and evaluated? Which were and which were not? If no, why not?

Training

1. Was the subject "patient safety" subject of training the past year?
2. Which training was this?
3. Was this training for the whole practice or individual?
4. Did you notice the learned being implemented in practice? If no, why not?

Safety management

1. Does your practice have a patients safety management plan or other wise described safety management policy?

2a. Is this practice safety plan deployed the last year?

2b. If not, why not/which subparts were not?

Quality management

1. Does your practice have a protocols book?
2. Do you participate regularly in pharmacotherapeutic consultations?
3. Do you have a procedure/method for controlling the content of the GP emergency bag? (inclusive medication)
4. Does your practice have an introduction procedure for new employees?
5. Does your practice have an emergency telephone?
6. Have you ever conducted a patient safety satisfaction survey?
7. Does your practice use "ZorgDomein" (This is a referring aid for physicians)
8. Does your practice have a procedure to check repeat prescriptions?
9. When was the last time the equipment in the practice was calibrated?
10. Did you implement a quality improvement project last years?

APPENDIX II

Distribution of incident reports, presence of reporting procedure and accreditation status at baseline and follow-up

Interven-tion	# incidents baseline	# incidents follow-up	Formal reporting procedure baseline	Formal reporting procedure follow-up	Accreditation status baseline	Accreditation status follow-up
control	2	2	yes	yes	no	yes
control	2	0	no	-	no	no
control	0	0	no	no	no	no
control	0	0	no	yes	yes	yes
control	0	0	no	no	yes	yes
control	3	1	yes	-	no	in progress
control	1	1	no	no	no	no
control	10	0	no	no	no	no
control	0	0	no	no	no	no
SCOPE	0	0	no	no	no	in progress
SCOPE	3	4	yes	yes	no	in progress
SCOPE	0	0	no	no	no	in progress
SCOPE	1	1	no	no	no	in progress
SCOPE	0	0	no	-	no	in progress
SCOPE	3	10	yes	yes	yes	yes
SCOPE	4	57	no	yes	no	yes
SCOPE	0	0	no	yes	yes	yes
SCOPE	1	10	no	no	no	no
SCOPE	3	0	no	no	no	no
workshop	0	5	no	yes	no	in progress
workshop	5	20	yes	yes	yes	yes
workshop	10	20	yes	yes	yes	yes
workshop	0	20	no	yes	no	no
workshop	36	53	yes	yes	no	yes
workshop	11	35	yes	yes	yes	yes
workshop	4	17	no	yes	no	no
workshop	0	52	no	yes	no	no
workshop	4	2	no	no	no	in progress

APPENDIX III

Self-reported number of incident forms (outcome question included in the SCOPE questionnaire)

		Baseline		Follow-up	
Intervention		Frequency	Percentage	Frequency	Percentage
Control*	none			40	83.3
	1 to 2			3	6.3
	3 to 5			4	8.3
	6 to 10			-	-
	11 to 20			-	-
	>20			1	2.1
SCOPE	none	49	84.5	34	61.8
	1 to 2	7	12.1	7	12.7
	3 to 5	1	1.7	4	7.3
	6 to 10	1	1.7	6	10.9
	11 to 20	-	-	4	7.3
	>20	-	-	-	-
SCOPE + workshop	none	56	77.8	21	35.0
	1 to 2	9	12.5	11	18.3
	3 to 5	7	9.7	17	28.3
	6 to 10	-	-	9	15.0
	11 to 20	-	-	2	3.3
	>20	-	-	-	-

*This question was included in the SCOPE questionnaire. This questionnaire was deployed as an intervention and therefore baseline data was not available for practices in the control group.

APPENDIX IV

Effect of interventions on SCOPE safety culture dimensions after one year of follow-up

	Regression coefficient (95% C.I.)#	p	Regression coefficient (95% C.I.)*	p
1. Handover and teamwork				
Intervention I	0.031 (-0.20-0.27)	0.796	0.072 (-0.15-0.30)	0.531
Intervention II	0.087 (-0.14-0.31)	0.449	0.123 (-0.09-0.34)	0.254
Accredited (y)			-0.039 (-0.25-0.17)	0.716
Practice size			-0.024 (-0.05-0.00)	0.069
2. Support and fellowship				
Intervention I	-0.216 (-0.52-0.09)	0.164	-0.224 (-0.54-0.09)	0.160
Intervention II	0.065 (-0.24-0.37)	0.674	0.076 (-0.23-0.38)	0.625
Accredited (y)			-0.201 (-0.50-0.10)	0.193
Practice size			-0.002 (-0.04-0.03)	0.089
3. Communication openness				
Intervention I	-0.170 (-0.46-0.35)	0.245	-0.144 (-0.43-0.14)	0.323
Intervention II	0.064 (-0.22-0.35)	0.660	0.102 (-0.18-0.38)	0.479
Accredited (y)			-0.113 (-0.39-0.16)	0.425
Practice size			-0.019 (-0.05-0.02)	0.279
4. Feedback about and learning from error				
Intervention I	-0.024 (-0.41-0.36)	0.902	0.030 (-0.32-0.38)	0.866
Intervention II	0.102 (-0.28-0.48)	0.602	0.177 (-0.16-0.52)	0.308
Accredited (y)			-0.317 (-0.65-0.02)	0.064
Practice size			-0.028 (-0.07-0.01)	0.177
5. Intention to report events				
Intervention I	0.051 (-0.35-0.45)	0.800	0.064 (-0.34-0.45)	0.746
Intervention II	0.148 (-0.24-0.54)	0.455	0.168 (-0.20-0.54)	0.368
Accredited (y)			-0.327 (-0.66-0.00)	0.053
Practice size			-0.015 (-0.06-0.03)	0.712
6. Adequate procedures and adequate staffing				
Intervention I	0.075 (-0.26-0.41)	0.663	0.083 (-0.27-0.44)	0.459
Intervention II	0.123 (-0.21-0.46)	0.474	0.135 (-0.22-0.49)	0.459
Accredited (y)			-0.002 (-0.35-0.35)	0.992
Practice size			-0.001 (-0.05-0.04)	0.766

7. Overall perceptions of patient safety management				
Intervention I	0.017 (-0.33-0.37)	0.922	0.024 (-0.34-0.39)	0.895
Intervention II	0.218 (-0.13-0.57)	0.211	0.237 (-0.12-0.60)	0.189
Accredited (y)			-0.122 (-0.48-0.23)	0.486
Practice size			-0.007 (-0.05-0.04)	0.736
8. Expectations and actions of managers				
Intervention I	0.001 (-0.37-0.37)	0.997	0.015 (-0.38-0.41)	0.936
Intervention II	0.133 (-0.24-0.50)	0.468	0.156 (-0.24-0.55)	0.418
Accredited (y)			-0.050 (-0.44-0.34)	0.791
Practice size			-0.011 (-0.06-0.04)	0.633
PSG				
Intervention I	-0.035 (-0.48-0.42)	0.875	-0.008 (-0.44-0.42)	0.970
Intervention II	0.161 (-0.29-0.61)	0.463	0.224 (-0.20-0.65)	0.287
Accredited (y)			-0.344 (-0.76-0.08)	0.103
Practice size			-0.022 (-0.07-0.03)	0.386

Univariate analyses

* Corrected for accreditation status and practice size

CHAPTER 7

How does it work? An interview study on culture interventions in general practice

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Submitted

ABSTRACT

Background

When improving patient safety a positive safety culture is key. As little is known on improving patient safety culture in primary care we examined whether administering a culture questionnaire with or without a complementary workshop could be used as interventions for improving safety culture.

Aim

To gain insight into how two interventions affected patient safety culture in everyday practice.

Design and setting

An interview study nested in a cluster randomized trial was conducted in Dutch general practice.

Method

Interviews were conducted at practice locations (n=27). We spoke with 24 GPs and 24 practice nurses. The theory of Communities of Practice — in particular its concepts of a *domain*, a *community* and a *practice* — was used to interpret our findings by examining which elements were or were not present in the participating practices.

Results

We found that communal awareness of the problem was only raised after getting together and discussing patient safety. The combination of a questionnaire and workshop enhanced interaction of team members and nourished team-feelings. Also, this shared experience helped them to understand and develop tools and language for daily practice.

Conclusions

In order for patient safety culture to improve, the safety culture questionnaire accompanied with a practice workshop was more successful. Initial discussion and negotiation of shared goals during the workshop fuelled feelings of coherence and belonging to a community that wishes to learn about enhancing patient safety. Team meetings and day to day interactions enhanced further liaison and sharing, making patient safety a common and conscious goal.

INTRODUCTION

A constructive safety culture is important for patient safety improvement efforts.[1] Safety culture reflects the values, competencies and behaviour that determine the commitment to, and the proficiency of an organization's safety management.[2]

Patient safety is a prominent issue in primary care as well.[3] In 2008 a national collaboration project was launched aiming to engage Dutch primary care professions in patient safety.[4] And we developed a safety culture questionnaire applicable for all primary care professions.[5] Previous research indicated raised awareness and possible intervention effects of culture surveys.[6, 7] A questionnaire can be deployed as an intervention as results can be reflected and acted upon.[8] However, it is unlikely that a questionnaire alone leads to meaningful improvements.[9-13]

We conducted a randomised trial studying two culture interventions: (1) administering a safety culture questionnaire and (2) the questionnaire combined with a practice based workshop, compared to a control group.[14] We found that the combination of a questionnaire with a workshop led to an increased number of reported incidents. In contrast, the stand-alone questionnaire was significantly less effective.[15] In this paper, we aim to explain these differences in effect using a qualitative approach.

Theoretical framework

The theory of Communities of Practice (CoP) was used to interpret the interviews and explain the differences in intervention effect. A CoP is described as a set of people who "share a concern, a set of problems or a passion about a topic, and who deepen their knowledge and expertise in this area by interacting on an ongoing basis".[16] Central to learning is exchanging experiences and reflecting upon everyday practice. Since the concept was introduced in 1991 by Lave and Wenger[17] and further elaborated on by Wenger in 1998[18], it is picked up as a tool for quality improvement, problem-solving and innovation. Three dimensions need to be present in order to be a CoP; *a joint enterprise* (the domain), *mutual engagement* (the community) and *a shared repertoire* (the practice).[18-21] The interest that members share defines the domain, in our study this was patient safety. By sharing information and engaging in activities and discussions, members build relationships that enable them to learn from each other, thereby establishing a community.[19,22] This mutual engagement, refers to the level of communication and interaction with each other. By interrelating, the members are motivated to give meaning to and negotiate about their practices. Members of a CoP develop "a shared repertoire of resources: experiences, stories, tools, ways of addressing recurring problems".[19]

SCOPE Intervention Study, the trial and intervention components

Details of the SCOPE Intervention Study design and its findings have been reported elsewhere.[14, 15] The first intervention was administering a patient safety culture questionnaire, the SCOPE questionnaire[22], further referred to as SCOPE group (Figure 1). The contact person in each practice could download the results of the survey.

Intervention I: A safety culture questionnaire

- The contact person received a letter informing a) the allocation of their practice in the three research arms and b) the request to fill-out the SCOPE with their whole practice
- Details of login procedures were given directly in this letter
- The feedback report could be downloaded by the contact person
- A reminder to complete the questionnaire and download the report was sent after 1 week and 1 month

SCOPE Questionnaire

- 43 culture items (five-point scales), 2 outcome questions
- Demographic variables
- 15-20 min to complete

Feedback report

- Oversight of the eight dimensions and percentages positive scores
- Mean score of the practice per item compared to a benchmark score
- Tips for improvement and further information
- The contact person was responsible for disseminating the report

Figure 1. Description of intervention I

The second intervention consisted of the SCOPE questionnaire complemented with a workshop, further referred to as workshop group (Figure 2). Instead of downloading their results, these were presented during the workshop and used for discussion.

METHOD

Design and participants

Interviews were conducted by NV and MvM between May and July 2013 in all participating practices, one practice (control group) refused to do interviews. We spoke with 24 general practitioners and 24 practice nurses (Table 1). Because interviews in the control group revealed no change in patient safety activities, we only described results from the intervention practices (36 interviews). In addition to the interviews, NV observed during the workshops and staff was asked to complete an evaluation form afterwards.

Intervention II: A practice-based patient safety workshop

- At practice location
- ≥ 75% of staff was required to attend
- 3,5 hours
- SCOPE questionnaire was completed a few weeks before the workshop

Workshop elements

- Education on safety science/human factor engineering/culture (systems approach)
- Filling-out and discussing two MaPSaF vignettes[23]
- Presentation and discussing the SCOPE results
- Guided discussion on own culture and possible improvement
- Drawing of an action plan to improve patient safety (culture)

Figure 2. Description of intervention II

Data collection and analysis

To direct the interviews we used a topic list. This addressed opinions on the prevailing patient safety and culture and actual implementation of tools following their particular intervention. In the control practices we additionally asked whether their focus on patient safety was influenced by governance, insurance agencies or otherwise. All interviews were audiotaped with consent from the interviewee, transcribed verbatim and transcripts were presented to the interviewees for approval. Analysis of data was performed using NVivo software for qualitative data for coding.[24] Prior to coding important themes were discussed within the research team to develop a coding template which focussed on safety culture, behaviour and activities attributable to the intervention.[25] After initial coding, the CoP theory was used to analyse and interpret our findings.

RESULTS

The interviews showed the necessity of a joint follow-up of the questionnaire. When explicitly asked at the end of the interviews, all interviewees of the workshop group stated that their results would not have been achieved had they only completed the questionnaire. Moreover, the SCOPE practices felt that results would have been different had they participated in the workshop. Below we explained why the workshop was regarded as necessary to intervene in the patient safety culture.

Table 1 Characteristics of participants per intervention group

	SCOPE group (10 practices)	Workshop group (9 practices)
GPs	8	8
Practice nurses	10	10
Female gender %	77.8	66.7
GPs	50	37.5
Practice nurses	100	90
Age (m, sd)	43.4 (9.7)	40.7 (14.1)
GPs	46.0 (8.8)	48.6 (9.4)
Practice nurses	41.4 (10.3)	33.4 (13.9)
Hours per week in practice	33.6 (15.8)	34.2 (10.7)
GP	39.6 (19.9)	35.8 (14.7)
Practice nurses	27.6 (7.4)	32.9 (6.6)
Qualified since (years)	15.2 (9.6)	13.1 (10.2)
GP	14.3 (9.0)	16.7 (8.9)
Practice nurses	16.0 (10.5)	10.3 (11.0)
Working in practice (years)	8.9 (7.1)	9.7 (6.8)
GP	10.3 (9.1)	12.5 (7.0)
Practice nurses	7.8 (5.3)	7.5 (6.0)
Duration interview (minutes)	38.9 (16.8)	34.2 (11.4)
GP	42.2 (10.2)	38.6 (7.1)
Practice nurses	36.4 (20.7)	30.7 (13.2)

Joint enterprise

In our study the problem and thereby the possible identity of the CoP concerned patient safety. The workshop showed to contribute to the awareness for patient safety in two ways. Firstly, getting together and spending time on the topic sends the message of the subject being important. Secondly, the workshop changed their view on patient safety. Discussing international and national data about iatrogenic harm amazed and sometimes even shocked the caregivers, creating a sense of urgency. The interviewees expressed how the workshop changed their perception of the problem.

[Talking about what was done about patient safety after the workshop]
"Anyway, we now have all become very alert. […] in any case, we all had our minds on the job after the workshop. […] You really were facing the facts."

Practice nurse, workshop group(20)

One of the assignments during the workshop illustrated the process of reaching agreement on their own culture and the gaps. When assigning maturity stages to the MaPSaF vignettes we noticed that the individually chosen stages were almost always relatively high and during the process of discussing in pairs and subsequently the whole team negotiation of the best fit arose and the stages chosen became lower.
Contrary, in the SCOPE practices patient safety mostly was not perceived to be an urgent problem. Interviewees often stated that no action was undertaken because patient safety was seen as adequate. It seemed that no risk-awareness for safety problems was generated by the questionnaire.

Interviewer: "Do you think that the questionnaire had an impact on your practice?"
Interviewee: "I don't think so. Since things are already going well. "

Practice nurse, SCOPE group (8)

Interviewee: "Until now, not one complaint and not one incident. That is perhaps also the reason that until now, we haven't put anything on paper."
Interviewer: "Ok, are there no incidents or aren't they noticed?"
Interviewee: "Yes… that could be. So, it is not reported as such … maybe also because it is not noticed."

GP, SCOPE group (9)

Mutual engagement

The key element in a community is learning from each other and discussing experiences, i.e. knowledge sharing. Workshop participants stated that the workshop was experienced very positive also nourishing the team-feeling and mutual trust. The workshop initiated discussions about patient safety (activities) during the day and during team meetings, for instance by asking each other to write an incident report.

Interviewee: "Yes. I think that, since we had the workshop, we all improved, or at least things are set up. We already had a sort of reporting procedure. But due to the workshop, there came a sort of awareness in the whole team. "
[…]

Interviewer: "And what would you see as your success factor, why did it work so well for you?"
Interviewee: "I do think the organization, thus, the workshop we had. Getting aware of reporting incidents and the explanation on that, what the pros and cons are so to speak, to discuss that among each other. As a result, we have started a reporting week. We started reporting more. We give feedback during work-meetings. I mean during general meetings, the practice assistants meetings, the nurses meetings. Allowing discussing it together, become aware and learn about it. So I think that are major steps we made, making it successful."

Practice nurse, workshop group (5)

Interviewer: "Suppose that you only filled out the questionnaire. Would the effect have been similar?"
Interviewee: "No, because in a certain way you have to be shown the facts and be made more aware of the problem. And that is certainly what happened in this intervention [the workshop], it more did get to us. So, that also the fear for reporting, that culture and the usefulness of reporting was more clear than if we had not done it [the workshop]. I think that, if I had only had the SCOPE questionnaire for the employees… nothing would have been achieved regarding the reporting week. So, in that respect it has a clear effect and added value to for the whole team… and its progression and improvement."

GP, workshop group (5)

In the SCOPE group such impetus for change in daily practice lacked. The feedback report bearing the results and benchmark (580 practices from previous research[26]) known to be an incentive for improvement[27], was mostly not read or, if read by the contact person, only shared once with colleagues.

"Interviewer: Last year you have had a report with feedback. So, than you get a summary of the whole practice results compared to other practices in the Netherlands. Do you remember that you have received it [the report]. Or that you have seen it?"
Interviewee: [silence] "That doesn't ring a bell."
Interviewee: "Or discussed during the team-meeting?"
Interviewee: "No, oh no, that would.. no, than I would have [remembered]… No, I dare not say."

Practice nurse, SCOPE group (13)

Though, there were two interviewees from different SCOPE practices that stated that the SCOPE spurred them to thinking about the topic. One practice grabbed the opportunity to put patient safety on the agenda. In this case the strong and weak points of the results were discussed within the team and this made clear that there was no incident reporting procedure. They decided that a nurse would participate in a course about incident reporting (outside the study as they were in the questionnaire only group) and implemented this in their practice. Hereby, the interaction and learning from each other was clearly established, as was the enthusiasm.

Interviewee: "It [SCOPE] has certainly given a boost, because discussing, openly, the things that don't go well… That is something that clearly comes from the SCOPE, and that you emphasize that again. […] It is a guide to discuss things and further elaborate on, ok, how are we going to improve this further?"

GP, Intervention I (21)

In the other practice the contact person read the report but did not share it within the team. The subject remained the responsibility of this one nurse. She stated that her awareness upon the topic was raised and that this was indirectly the case for the other staff as she broached it. However, no mutual relations were established in the sense of team interaction about patient safety.

Interviewer: "Do you think that the results of the questionnaire raised awareness? Did it foster your reflective thinking?"
Interviewee: "Yes, it did . The rest [of the team] indirectly. Because I bring it up. Somebody has to take the lead. And that is what we are missing here, also due to the situation, that nobody takes it on. If I only put it on the desk of the practice assistants, nothing will be done. I really have to bring it up and then maybe something will be done with it."

Practice nurse, SCOPE group (26)

In addition the workshop was perceived as a shared experience. Participants experienced the success of the workshop to a large extent to be the 'communality', a team moment to focus on patient safety. According an interviewee, the team often referred in particular to the workshop when patient safety was discussed.

Interviewer: "Ok, and how did that go? [the workshop]? Or do you discuss these things more often together? [incidents]."
Interviewee: "Eh, well not really. We do not… Yes, you know, you all do the workshop together and so it is easier to refer to it like 'gosh, how was that again, do you remember?' So than, yes, it makes it easier to come back to it when you did it together so to say."

Practice nurse, workshop group (6)

Unlike these workshop practices, the SCOPE practices expressed precisely the opposite, missing this 'getting-together'. It was stated by several interviewees that they missed the attention that was given to the workshop practices claiming that would have made a great difference. An 'event' was thought to be key in involving staff and to make the subject tangible.

[Talking about the lack of change following the SCOPE, what would be needed]
"Well, maybe such a workshop it will make us all more involved. It would probably help. Now it stays all a bit theoretical [having only the SCOPE results]."

GP, SCOPE group (2)

In some SCOPE practices the questionnaire even became perceived as an exercise to the fulfilment of the research obligations. From the interviews we learned that a few practices even thought of themselves as a non-intervention practice.

"I hoped I would not be in the control group, but in the intervention group that was to work systematically [on the topic during the intervention], but we weren't, unfortunate…"

GP, SCOPE group (9)

Shared repertoire

The workshop and subsequent interactions around the topic contributed to the alignment of terminology. We started the workshop by asking participants what they thought common definitions meant, which showed differences between staff. By discussing these terms the team made them their own and negotiated a mutual understanding of the terms.

Also, interviews showed that without an action plan, nothing happened. We asked the workshop group if they thought the results would be the same when they would only had completed the questionnaire. They claimed that the questionnaire solely would not have done enough, they needed this joint meeting to convert the message into action. An action plan conveys commitment to change and, more important, how to address it. This

point was also demonstrated by two practices, one in each intervention group. Only one practice in the workshop group did not realize an action plan and only one practice in the SCOPE group was able to discuss the matter and draw joint activities. Interviews indicated that only the practices that did commonly agree on activities showed improvements. The workshop helped the conversation and enhanced ideas for improvement and subsequent implementation. The interviews in the SCOPE practices showed the conversion of ideas and results to activities to be a bottleneck.

Interviewer: Can you explain this, what was the reason for it? [talking about already having a reporting procedure but only after the workshop there was more attention for reporting]
Interviewee: Well, just the importance of it I guess, that due to such a workshop... Yes, and it is more in your system. So you can so to say put flesh on the bones.

Practice nurse, workshop group (20)

[Talking about what you pick-up on the subject and what you want to do in practice]
"You are right that if you read something, if you read articles on the subject, it makes you more aware. But implementing it in daily practice is something else and that is where it often falters."

GP, SCOPE group (29)

Lastly, the start-up of activities in turn, also helped to reinforce the actual repertoire and community. Workshop practices started to implement or revive an incident reporting procedure. As this is an ongoing or a repetitive tool it also strengthened the interaction around the subject of patient safety. Some practices installed reporting committees, forms were downloaded or created and reporting weeks were organised. Interviewees told they pointed out to each other to write a report after an incident had happened. Reports were discussed during the day and during team meetings. This invigorative process again conveyed the message of importance and also created a learning effect. In other words, the shared repertoire of terms and tools in itself added to establishing knowledge sharing and interaction.

DISCUSSION

Summary

We examined how administering a patient safety culture questionnaire solely or combined with a workshop affected patient safety culture in general practice. Trial data showed that incident reporting increased significantly in the workshop group, compared to the control and SCOPE group. The latter showed some increase, but the effect was not significant

when discarding an outlier. We used the concept of Communities of Practice – and its key concepts of joint enterprise, mutual engagement, shared repertoire – to explain the differences between the two interventions.

Due to the workshop, risk-awareness arose. In addition, it contributed to team feelings regarding patient safety and helped to align terminology and negotiate subsequent activities. Patient safety was more often discussed and the atmosphere was more open to discuss incidents. In the practices in the SCOPE group, contrary, the questionnaire did raise some awareness, but s did not lead to actual changes. Almost none of our contact persons in this group had read the report with their findings and only once they were discussed with the remainder of the team. Our study, therefore, showed that a workshop is a valuable addition to a questionnaire to improve patient safety culture.

Strengths and limitations

This qualitative study has been conducted alongside an RCT. By studying observations and perceptions of participants the trial results are supported and better understood. In addition, we believe the intervention itself to be a strength. Though a workshop itself is a one-time event our study showed that it can be used to set the focus on patient safety and to set behavioural change in motion. Moreover, with one workshop the whole team can be reached. The advantage of one team meeting, reaching all disciplines in one time, enables the intervention to be unifying. This reduces the risk of 'in-silo' behaviour which interferes with collaboration negatively.[28] Limitations of this study could be the recall bias of the interviewees. The interviews were held a year after the intervention and most of the interviewees found it hard to remember details of the workshop or the action plan they drafted.

Comparison with existing literature

Through the years, patient safety culture questionnaires were developed, modified and validated in primary care, adding to an evidence-based means of assessing culture in practice.[29-34] A survey as change instrument is comprehensible, usable and affordable for practices. Though, Sexton et al. stated it to be unlikely that questionnaire results and spontaneous discussion would lead to meaningful improvements and developed a discussion tool.[11] Analogous, an assessment and discussion tool, the Manchester Patient Safety Framework, was found to be a meaningful instrument in primary care.[35, 36] In addition, there have been numerous improvement approaches based on team wise efforts such as CRM, TeamSTEPPS and variable safety workshops that showed promising results.[37-41] A successful team that strives for a clear common goal and that regularly discusses how to achieve this is seen as valuable in improvement programmes.[42] In the current study we

found that combining the assessment and the team wise approach has added value. This is in line with reviews showing the multifaceted or multi component interventions to be most successful in improving patient safety culture.[6, 43]

Implications for research and practice

Our findings exposed the interaction between targeting safety culture and implementing a structure simultaneously, as these reinforced each other.[44] A generative culture is needed to raise risk-awareness. Also it is a prerequisite for conducting activities that require openness and trust, such as reporting.[45] In turn, incident reporting is a recurrent activity, which leads to regularly discussing safety issues each time reports are analysed. These discussions contribute to openness and trust.[46,47] In our study, indeed, interviewees indicated that discussions around reports helped them to remain aware of incidents and to address each other around safety issues during daily practice. In this way, safety management was embedded in everyday work. The structure with recurrent features provided improvement of safety culture, and vice versa. A frequently heard, almost unanimous response during the interviews in the SCOPE practices was that it certainly would have made a difference when more serious attention, as was done with the workshop, was paid to the subject. For future research, therefore, it would be interesting to conduct a likewise trial in a stepped wedge design. Yet, we can confidently encourage general practitioners to invest time in a team wise event in their practice to effectively put patient safety on the map in primary care.

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CHAPTER 8

General discussion

The aim of this thesis was to measure patient safety culture and to assess the effect of safety culture interventions in primary care. Assessment of patient safety culture can be used for positioning and tailoring (improvement) activities and evaluation. For this, a valid and reliable tool was needed. We validated a generic questionnaire to assess patient safety culture in primary care professions and subsequently examined the prevailing culture. In addition to measurement, we intended to add knowledge on how to improve patient safety culture in primary care. Therefore, a trial was conducted incorporating two interventions: the administering of a patient safety culture questionnaire solely or combined with a practice based workshop. Five research questions were formulated:

1. What is the validity of the patient safety culture questionnaire SCOPE-PC?
2. What is the prevailing patient safety culture in Dutch primary care proefessions and are there differences between professional groups?
3. Which tools are available for patient safety culture improvement in the primary care setting and what is their effectiveness?
4. What is the effect of two culture interventions in general practice?
5. How can the effect of the two culture interventions be explained?

The trial focussed on question 4 and 5 was conducted in the general practice setting, but was made transferable to other primary care practices.

MAIN FINDINGS

The patient safety culture questionnaire – SCOPE-PC –
Validation of the SCOPE-PC questionnaire showed excellent internal consistency and good construct validity. Seven dimensions were found: '*open communication and learning from error'* (8 items); '*handover and teamwork'* (7 items); '*adequate procedures and working conditions'* (9 items); '*patient safety management'* (5 items); '*support and fellowship'* (5 items); '*intention to report events'* (3 items); '*organisational learning'* (3 items).

Prevailing culture in Dutch primary care
Exploring patient safety culture in nine types of Dutch primary care professions (dental care, dietetics, exercise therapy, physiotherapy, occupational therapy, midwifery, anticoagulation clinics, skin therapy and speech therapy) showed that perceptions were positive, as were their grades on patient safety in their practice. '*Intention to report events'* scored lowest of all dimensions. Moreover, this dimension showed the largest variation in culture within the professional groups itself. Differences between professions were small.

Tools affecting patient safety culture

A systematic literature review showed a lack of research regarding interventions affecting patient safety culture in the area of primary care. Two studies were found. One study described the implementation of an electronic medical record system and the other study reported on the effect of two workshops. Both studies were performed in general practice.

Studying two culture interventions in general practice

The SCOPE Intervention Study was designed as a cluster randomized trial where practices were allocated to either the control group or one of the two intervention groups: (I) the administering of a patient safety culture questionnaire or (II) the same questionnaire complemented with a practice based patient safety workshop. Practices in the first intervention group (the questionnaire) were to download their results themselves whereas practices in the second intervention group (workshop) were given their results during the workshop. The workshop was designed to educate and facilitate discussion i.e. using vignettes of the Manchester Patient Safety Framework (MaPSaF). A mixed-methods design was chosen to both allow for quantitative effect measuring as well as in-depth qualitative evaluation.

The effect of two culture interventions in general practice

Combining the patient safety culture questionnaire with a practice-based workshop showed larger effect in terms of increased number of incident reports compared to the questionnaire solely or the control practices. In addition, the workshop practices analysed incidents more systematically and the topic was more often on the agenda of practice meetings. Although these changes in behaviour concerning patient safety issues strongly suggested safety culture changes in the workshop practices, no intervention effect was found on the safety culture dimensions of the SCOPE questionnaire.

Understanding the implementation of two culture interventions

The interviews supported the quantitative findings of our trial study. Analysis showed that the components of a 'community of practice' (CoP) regarding patient safety were more present in the practices that received the workshop. These practices showed a shared understanding of the patient safety concept, increased interaction on the topic and shared terminology and tools. Contrary, all practices except one that had completed the questionnaire solely, showed no shared problem definition, minimal patient safety activities, scarce dialogue and difficulty in applying tools.

METHODOLOGICAL REFLECTIONS

The SCOPE questionnaire as measuring instrument

In the first part of this thesis the SCOPE questionnaire was used to measure patient safety culture. Without getting entirely entangled in the clinimetric debate on the measurement of culture a few words are in order. First, there is the issue whether it is possible to capture the concept 'culture' with a questionnaire. It is known that a survey is not a perfect instrument as it will only provide a snapshot, the surface of culture.[1] Marshall et al. described this problem as 'the inability to capture the heart of culture'.[2] They suggested to use participant observation, interviews and focus groups combined with attitudinal surveys and established cultural assessment tools. Still, the use of a questionnaire is one of the most convenient and efficient ways to collect information on a subject. It can be done at relatively low cost and it is easy deployable. Moreover, with regard to the delicate subject on hand it should not be overseen that in contrast to more observational methods, a questionnaire can be completed anonymously. In addition, a survey can be used to get the views of a relatively large population at once, for example a hospital ward or, in primary care, a whole health care centre.

Second, when used for evaluation purposes, features regarding responsiveness and interpretability are important.[3] Responsiveness is described as the ability to detect change over time and interpretability refers to how well we can assign a qualitative judgement to the quantitative results found. Measures that can be applied are the Minimal Detectable Change, which shows the change larger than the measurement error, also called the 'real change',[4] and the Minimal Important Change (MIC), which is the amount of change that is considered important or beneficial. These criteria are not yet established for patient safety culture questionnaires. The current best alternative is to use a well validated questionnaire and predefine meaningful changes for a study. Because culture questionnaires are frequently used for monitoring or evaluation purposes, for the future, it is recommendable to study and determine the characteristics of culture measurement more thoroughly. Awaiting these further studies, we, in our study, used an adaptation of the well-developed and widely used HSOPS questionnaire (Hospital Survey on Patient Safety Culture)[5-9] and adhered to the guideline of this questionnaire.[10]

In our trial we found no significant differences in the dimensions of patient safety culture survey between the three research groups at follow-up nor did we find any significant improvements before and after the intervention in the intervention practices. Firstly, it could be that there were indeed no actual differences or changes in culture in the participating practices. Secondly, as it is not formally studied yet, it is possible that the SCOPE questionnaire

is not sensitive enough to detect changes. Thirdly, it may also very well be that the time after the intervention till the measurement (1 year) was too short to measure changes. Culture changes generally are slow processes.[11] A study that measured safety culture by a similar questionnaire five years after an intervention programme did find improvements on their measurement scale (HSOPS).[12] Lastly, it may be that staff filled-out the SCOPE questionnaire too optimistic in the first round. We found that risk-awareness was less present in practices that did not participate in the workshops, which suggests that practices without education and discussion are too optimistic about their own culture. Moreover, it is possible that staff was more critical on their culture after the workshop. A similar phenomenon was found in the study by Hoffmann et al. who conducted an intervention study also using the MaPSaF.[13] Presumably, all these factors influenced our findings, however, it is most likely that the short time frame in particular contributed to the a lack of effect found at the SCOPE questionnaire.

Qualitative study

In the second part of the thesis we consciously chose a mixed method approach, applying qualitative methods during our trial. Qualitative research focuses on 'why' and 'how' allowing for more profound understanding of the findings as it can discuss perspectives, experiences and contexts.[14] Despite these important contributions, qualitative research is not commonly conducted as part of RCTs.[15] We intended to explore factors that would hinder or contribute to the success of changing safety culture in the practices and to explain found differences in effectiveness between groups. Interestingly, where the culture questionnaire results failed to show significant improvements on culture dimensions, the increase in incident reports as well as data from the interviews suggested otherwise. These latter indicated that the culture was more open after the workshops. Though most interviewees of all three research groups stated that their culture was fine before the intervention, at follow up, interviewees that had the workshop intervention stated that discussing patient safety as well as discussing incidents was easier than before.

Nonetheless, when asking the professionals more in detail about how this worked in daily practice, we encountered that many interviewees had difficulties remembering the workshop in detail and more particularly the action plan they drew. This hindered in depth exploration of the interviewees' perceived changes. Apparently, these kind of qualitative observations have to balance between the risk of recall bias and influencing trial results when observations are performed during or closely after interventions.

PATIENT SAFETY CUTLURE IN PRIMARY CARE: RISK-AWERENESS IS KEY

The validation study and subsequent examination of the prevailing culture in nine primary care professions gave a first impression of patient safety culture in primary care. Patient safety research in primary care is emerging but until now mostly focussing on general practice and midwifery. Our exploration of safety culture in other professions incites some considerations that may add to further directing practice and research. Examination of the SCOPE dimensions showed that culture is perceived highly positive by the primary care professions. At the same time, the SCOPE dimension '*intention to report'* scored the lowest compared to the other dimensions, and moreover, it showed the largest variations in opinions of professionals within the profession groups itself.[16]

We believe three issues are relevant to elaborate on here: possible overestimation of the level of the own safety culture, underestimation of possible risks and number of incidents in the own profession and possible essential differences between primary care professions regarding the relevance of patient safety thinking.

Firstly, the intervention study showed that the workshop contributed highly to a sense of urgency. Participants stated that the numbers of adverse events presented in the educational part of the workshop 'opened their eyes'. In other words, their risk-awareness enhanced. Although this study was conducted in general practice, it is likely that also in the other professions the initial risk-awareness, i.e. without additional education, is low and that safety culture is overestimated.

Second, examining the dimension 'intention to report' we found on the one hand, incident reporting not being common yet. But on the other hand, incidents and reporting did seem to play an important role in the concept of patient safety. Participants in our validation study were enabled to give open comments at the end of the questionnaire. These remarks indicated that having incidents or not was connected to how patient safety was perceived. More specifically, it was often stated that because they perceived that no incidents occurred, they felt that patient safety was fine in their practice and not an issue that had to be improved; "*I would surely discuss patient safety if there were incidents"*. There is not much research on the occurrence of incidents in primary care professions other than in general practice. One study indeed reported only low percentages: 0.8% in dental care, 2,5% in midwifery and 1.0% in paramedical practices based on 1000 patient medical records.[17] So, although incidents are perceived less likely, they do occur. Therefore, it is likely that primary care professions are not sufficiently aware of potential risks in their practice.

Thirdly, remarks were made about the relevance of the subject patient safety to their practice or profession: "*I do not see much risk with respect to patient safety"* (speech therapy), "*My profession is not very risky"* (employee anticoagulation care), which supports

the assumption of lack of risk-awareness. Similar findings were reported in a study on the meaning of patient safety in primary care, stating that professionals do care about patient safety but they do not recognize any safety problems in the current approach of their work.[18] Adding to this, there was a fairly low response rate in our study (38%) which could indicate a lack of interest in the subject. Primary care consists of a broad array of professions and though they share many similarities such as the educational level, structure of the practice and patient population, with respect to medical orientation of the care provided there are gradations. It is quite conceivable that professions with a less medical orientation, such as speech therapy, dietetics, skin therapy and occupational therapy are less inclined to see adverse events or other safety issues in their practice than their colleagues from midwifery, dental care and general practice where incidents generally may cause actual harm. Hence, primary care professions may deservedly have different levels of risk awareness.

Taking this all together, for future research and practice it is important to firstly search for a dialogue with each of the professions. Above raised questions should be addressed to investigate to which extent overestimation of the culture and underestimation of risks exist. Single-handed practices should be included in this dialogue because these are a large part of primary care. Also, professions evidently differ from each other concerning risk of patient harm. These differences should be taken into consideration when addressing patient safety (culture) in a particular profession. Still, educating professionals remains an important first step as otherwise potential risks are not assessed. Quality circles, described as "small groups of 6 to 12 professionals from a similar background who meet at regular intervals to discuss and review their clinical practice"[19] could provide a platform to discuss these risks and tailor safety interventions.

A SAFETY CUTLURE QUESTIONNAIRE AS INTERVENTION?

A central issue in the intervention study was the question whether a safety questionnaire can be deployed as a culture intervention to change perspective and eventually behaviour. In fact, Dixon-Woods et al. in their evaluation of the Michigan study referred to Heisenberg's uncertainty principle that states that measurement cannot be performed without influencing the system being measured. In case of this Michigan study, disclosure of data to other IC's also boosted action.[20] Morello et al. in their review of safety culture interventions in hospitals posited the same question.[21] And, during the validation of the SCOPE questionnaire our research group also found that it raised awareness.[22] Remarks during the SCOPE-PC validation similarly showed that questionnaire items in theory could contribute to changes in practice, for example:

- *'We would have to make a protocol we think now and secure its inclusion in the weekly meetings, good point. Thank you for this' (occupational therapist)*
- *'Do you have an example of a reporting procedure? It cannot hurt to have one' (occupational therapist)*
- *'We report to each other, not formally but during a meeting, though it is no fixed feature. By this questionnaire I get the idea to do so. Thanks for that!' (midwife)*

Theoretically, a survey could be a suitable and effective instrument for change. Though, measurement is only one thing, additional important steps are feeding back the results and involvement of employees in planning and action. Five steps are distinguished in a well-designed survey process:

1. Measuring and assessing;
2. Understand issues (what the survey is really telling us);
3. Prioritizing the issues most importantly;
4. Plan actions (who is accountable?);
5. Implement plans and follow-through.[23]

Culture change is a complicated process, among others because culture concerns the identity of its members. By involving staff, awareness can be raised and through discussion they will become more open to new ideas and become motivated to search for solutions. As Wagner et al. stated: "The process of reporting the results is perhaps most important in determining a survey's effectiveness as a cultural change tool. It is the process that is used to understand and act on the results which turns data into actionable information."[24] Pringle et al. found that using a questionnaire in patient safety improvement efforts helped to adjust regional patient safety initiatives to specific needs. Moreover, 60% of the participating hospitals used the survey to address their patient safety culture.[25] In our interview study we found that precisely the feedback and discussion part was lacking in the SCOPE group, nullifying the effect of the questionnaire. When asked, interviewees stated that they missed 'getting-together' and additional attention given to the subject. Contrary, interviewees from the workshop group stated explicitly that the intervention would not have been as successful without the workshop. From research on implementation of evidence based practice or guideline adherence it is already known that it is laborious to convert new knowledge and procedures into real practice.[26-28] When these new ideas and procedures are only made available but no additional activity is conducted, it will not be adopted by most professionals. In our study we found that when the above described steps were addressed during a workshop where staff had room for discussion, it helped to convey the message to the caregivers and subsequently led to behavioural change. During the

workshop, besides education, results of the SCOPE were presented and discussed whether they were recognizable (step 2). Together, the staff brainstormed on possible improvements that could be made (step 3) and at the end of the workshop an action plan was made (step 4). Moreover, we found that after the workshop these practices implemented the activities they chose for their action plan (step 5). The workshop helped these practices to digest their results and convert their thoughts and ideas for improvement into concrete action.

CULTURE AND STRUCTURE

So far, there was no clear approach for improving patient safety culture in primary care. Our study showed that a patient safety culture questionnaire combined with a patient safety workshop enhanced the risk-awareness and spurred dialogue upon the subject. Interestingly, all practices chose incident reporting as their activity to improve patient safety in their practice. Incident reporting can be perceived as the most practical step to start improving patient safety, as the goals are clear and the anticipated results are understandable. In fact, it is conceivable that choosing this particular activity in their action plan contributed to the success of the intervention. As incident reporting is not a one-time event, but a cyclic process, it provides a structure for patient safety behaviour in everyday practice. Analogous to any 'plan, do, check, act' cycle awareness is raised each time an incident is addressed, also motivating staff when they perceive their reports were useful. To understand error but also to improve safety, interventions should target system, culture and technology simultaneously.[29] Approaching culture and structure simultaneously has a reinforcing effect on each other. By providing a structure, like incident reporting, culture is positively affected. And vice versa, by enhancing a positive culture during discussions of incidents, barriers can be broken down. From the perspective of diffusion of innovation, incident reporting as a safety intervention fulfils the criteria proposed to be successfully implemented (perceived benefit of the change, compatibility with the culture, manageable complexity).[30] It is plausible, as culture and structure reinforces each other, that a positive culture will mature during the pursue of safety activities and implementing safety structures, like incident reporting. Nevertheless, it will still be crucial to foster an open and positive culture by discussing underlying values and building trust.[31] Our trial showed that the team-effort helped to emphasize both the importance of safety and having a positive culture. Just talking is not sufficient. Both culture and structure need to be addressed for managing safety.

SAFETY MANAGEMENT SYSTEM

Is implementing a safety management system attainable to provide a solid structure for primary care? In 2004, the president director of Shell in The Netherlands, wrote recommendations to improve hospital safety.[32] The first recommendation was to install certified safety management systems. These systems were to constitute of three components: a risk inventory, incident analysis and a management system to plan and monitor improvement actions. A risk inventory calls for a proactive approach to walk through processes in order to address potential safety risks adequately. Contrary to incident analysis, this inventory is undertaken while an incident has not yet occurred. The idea is to predict where problems could occur in order to optimise the safety of the process. Several tools are available to support this process analysis. The Healthcare Failure Mode and Effect Analysis (HFMEA) is probably the best known tool.[33] This tool was translated in Dutch and adapted to SAFER (Scenario Analyse van Faalwijzen, Effecten en Risico's).[34] In addition, the platform for patient safety in primary care (ZorgvoorVeilig) has developed and provided a risk scan to recognize and address patient safety issues in practice.[35] For incident analysis two methods are mostly applied in The Netherlands. The SIRE (Systematische Incident Reconstructie en Evaluatie) method[36] and the PRISMA (Prevention and Recovery Information System for Monitoring and Analysis).[37] Both components, the proactive inventory and the incident analysis, are well suitable to be used by professionals in the primary care setting. The third component requires a safety management system comparable to quality management systems which is needed to manage the safety processes. Emphasis should be placed on both planning and implementing as well as evaluating and making adjustments in order to let the system be more than a bureaucratic thing. A generative safety culture overarching all components is key condition for such safety management systems.[32, 38]

CERTIFICATION AND ACCREDITATION

Certification and accreditation may be helpful to achieve and maintain safety management systems in primary care practices. It is available for all primary care professions and incorporates safety management. General practice has a professional accreditation system which requires a formal incident reporting procedure.[39] Stichting HKZ (Foundation for Harmonisation of Quality of Care) provides two options for other primary care professions. Firstly, a patient safety management certification scheme that focuses explicitly on patient safety management. This scheme includes all three mentioned components.[40] Secondly, there is a certification scheme that is designed specifically for small(er) organisations. This scheme addresses a quality management system, and also includes above described safety

components.[41] Participants in our interview study indicated that patient safety management was perceived as 'something extra' that had to be done. This was also found in other professions.[18] Certification or accreditation can well be used to secure safety elements into daily policy and practice. Moreover, the recurrent aspect of these elements contribute to the frequency of discussing the topic which enhances the liveliness and incorporates a safety view by caregivers. In addition, a safety management system contributes to the sustainability of safety improvements and allows for evaluation and learning.

EXTERNAL INCENTIVES?

As argued earlier, implementing innovations and involving professionals in this process is very laborious. Is external pressure needed? External pressure could be used to oblige practices to implement certain safety components, such as incident reporting, in their practice. This could be enforced by certification or accreditation and subsequently by demands of insurance companies. We believe that external pressure can certainly be very helpful to get practices started. For some practices this is needed to cross the threshold and just start. Once started they often experience the benefits themselves which may boost motivation and finally contribute to a constructive safety culture. Moreover, regulation enables the possibilities for compensations similar to the funding practices receive from insurance companies when meeting targets of quality indicators of care.

Of course, regulating safety management in such a manner will only be helpful when it is focused on the whole process. Having an incident reporting system is not enough, incidents should be reported and analysed too. Otherwise, it will only create paperwork and a burden for caregivers. Evidently, this is the drawback of external versus internal incentives. When activities are only implemented because they are obligatory there will never be real commitment. Particularly in matters of culture, commitment and a real team-effort are needed. Lastly, safety management should not be confined to the own profession. Primary care professions are increasingly collaborating in the care of patients, for example in disease management. By building in safety components such as incident reporting, prospective risk analysis and explicit focus on a constructive culture, professions that lag behind can be towed along by other professions that are forerunners. Other studies used intermediate meetings to allow for professionals to share thoughts and ideas. Moreover, it is known that comparisons help practices to initiate change.[20, 42] Integrated healthcare chains or other collaborative care structures offer great chances for a patient safety dialogue among primary care professions. Hence, safety management initiatives within the current healthcare chains of chronic diseases will create new opportunities to share lessons on quality and safety as well as on multidisciplinary collaboration.

SHIFTING PERSPECTIVES AND THE IMPORTANCE OF CULTURE

Through incident reporting a practice can learn from their mistakes and anticipate by adjusting procedures. The notion of proactive risk analysis is also based on the principle to search for potential risks and incorporate barriers. These approaches assume a practically linear relationship between risk management and safety. However, healthcare cannot be fully standardized in procedures and policy, it consists of complex systems. Safety research and management, therefore, should not only focus on incidents and risks but also on all the things that go right. Mesman proposed "a research perspective that focuses on the presence of safety and explores its texture". She calls it 'exnovation', referring to "the attempt to foreground what is already present".[43] It is stated that this will not only offer new understanding of the vigour of healthcare, but also perspectives on caregivers' competencies and inventiveness. Based on similar motives, Hollnagel et al. described a necessary shift from a 'Safety One"- to a "Safety Two"-perspective.[44, 45] Safety One is "a state where as few things as possible go wrong", where incident analysis can be used to identify causes and contributing factors, and risk assessment to determine their likelihood. The Safety One state focuses on eliminating these causes and improving safety barriers, a so called 'find and fix' (reactive) approach. However, it assumes that systems are decomposable and that systems function bimodal (successful or unsuccessful). But, healthcare does not always fulfil these assumptions and another approach is needed (too). Instead, Hollnagel et al. describe Safety Two as "as much things as possible go right". It is about the system's ability to succeed under varying conditions as is applicable to healthcare. Safety management should be more proactive, 'we need to know how they go right' and should invest in examining theoretical foundations, underlying mechanisms and their manifestations.

Regarding safety culture, the resilient (i.e. Safety Two) instead of reliable (i.e. Safety One) approach calls for a high level of safety culture where adequate risk-awareness is crucial. The Safety Two view naturally aligns with daily handling uncertainties as health professionals do.[46] In this view, good safety management leaves room for proactive handling degrading situations. It assumes that health care is not suitable to be fully standardized, but in fact it needs to be resilient. Moreover, sometimes it is even better to decide not to follow the protocol. However, while primary caregivers generally are used to handle uncertainties, they are not infallible nor always aware of risks in daily routine proceedings. Indeed, both approaches should be considered as complementary. And a debate should be started on which part of daily primary care practice should be handled in a Safety One way and which part needs a Safety Two approach. For balancing both approaches , safety management should encourage a learning attitude, open communication, understanding of human error and possible preventive measures and knowledge on potential risks in primary care

practice. Hence, the shifting perspectives on safety a fortiori require a solid, constructive safety culture. Evidently, health care leaders should keep in mind that risk-awareness is not a matter of course and that full attention is needed in order to build a constructive safety culture. The study described in this thesis showed that with relatively small effort the necessary attention can be given and that this actually leads to safety culture improvement.

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English summary

Patient safety is key in health care. Though, as a subject for policy and research it came into focus after the publication of the report 'To Err is Human'. Patient safety is defined as: "The (almost) absence of (the risk of) patient harm (physical/mental) that is caused by not acting according to the professional standard of care providers and/or failure of the health system". An important element of patient safety is patient safety culture – shared values, attitudes and perceptions regarding patient safety – or in short "the way we do things around here". Patient safety culture covers topics as: collaboration, (daring to) speak up to each other, reporting and learning from incidents and discussing patient safety in the practice. Research showed that a positive, open safety culture contributes to or even is a precondition for the success of safety interventions. Creating a constructive culture, therefore, is often the first step for patient safety improvement.

In 2008 a platform, 'ZorgvoorVeilig' (Care for Safety) was launched to engage all primary care professions in the development of policy on patient safety in the Netherlands. In this project, the need emerged for tools that could be used to visualise and improve patient safety in the whole primary care setting. At that moment, only a validated Dutch questionnaire was available to measure patient safety culture in general practice. The first part of this thesis describes the measurement and exploration of patient safety culture in Dutch primary care (chapter 2 &3). Next, we performed a literature search for interventions affecting safety culture conducted in primary care and developed our own intervention (chapter 4 & 5). Subsequently, we tested these interventions in a randomised trial in 30 general practices (chapter 6 & 7).

Chapter 2 describes the development and validation of a questionnaire to measure patient safety culture in primary care, the SCOPE-PC. SCOPE is a Dutch acronym for systematic culture inquiry on patient safety. Because the first (general practice) questionnaire was named SCOPE, PC (Primary Care) was added to the questionnaire for the other primary care professions. The culture questionnaire for general practice was used as a starting point. In a written feedback round professionals of eleven professions – dentists, dental hygienists, dietetic, exercise therapy, physiotherapy, occupational therapy, midwifery, anticoagulation therapy, general practice, skin therapy, speech therapy – were asked to give feedback on the adjusted questionnaire. Adjustments were made mainly in the terminology and wording. The questionnaire was subsequently conducted in March and April 2011. A confirmative factor analysis showed that the factor structure of the original SCOPE questionnaire did not match well with the factor structure of the SCOPE-PC questionnaire. A subsequent explorative factor analysis showed seven dimensions:

1. Open communication and learning from error;

2. Handover and teamwork;
3. Adequate procedures and working conditions;
4. Patient safety management;
5. Support and fellowship;
6. Intention to report events;
7. Organisational learning.

The reliability of the dimensions was satisfactory and the coherence was good.

Chapter 3 presents the state of affairs regarding patient safety culture in the different primary care professions. Nine hundred and six individual questionnaires (519 practices) were completed by professionals from nine different professions: dental care (dentists and dental hygienists together), dietetic, exercise therapy, physiotherapy, midwifery, anticoagulation care, skin therapy and speech therapy. Six hundred and twenty-five questionnaires were eligible for analysis. Overall, safety culture was perceived positively. The dimension '*intention to report events*' and '*patient safety management*' were scored lowest. '*Open communication and learning from error*' and '*support and fellowship*' scored highest. The dimension 'intention to report events' showed the largest variation within the professions itself, possibly indicating the early developmental stage of incident reporting. It could also be that the reporting of incidents in some professions is perceived as less relevant. Differences between professions were however small.

Chapter 4 describes a review of patient safety interventions conducted in primary care that affected safety culture. This showed a lack of published interventions in primary care. In total, 214 articles were retrieved, but only two articles met the inclusion criteria: 1) the research was conducted in primary care, 2) a patient safety intervention affecting culture had to be described, and 3) the effect on patient safety culture had to be reported. The first article described the implementation of an electronic medical record as part of on-going quality and safety improvement efforts. Safety culture measurement showed significant improvement. The second article described an intervention in which practices were given the opportunity to participate in two workshops, a risk management workshop and a workshop about incident analysis (Significant Event Audit). The authors reported an overall improvement on risk management after participating in one of the workshops. Both studies were conducted in general practice. The level of evidence of both studies was low, both did not include a control group and there were other methodological problems. The most important finding of the review was the lack of well-designed research of culture interventions in primary care.

Chapter 5 is a detailed description of the study protocol. The aim of the SCOPE Intervention Study was to test two culture interventions in general practice. To this end, we designed a three-armed cluster randomised trial with ten general practices in each research arm. In the control group no intervention was conducted. Practices in intervention I were asked to fill-out the SCOPE questionnaire with the whole team. Contact persons of each practice were able to download reports with their results and benchmark scores. The practices could then decide what to do with their results. In the intervention II group practices were also asked to complete the SCOPE questionnaire, however, these contact persons could not download their report. Instead, these practices participated in a practice-based workshop. The workshop consisted of two parts. The first concerned education about safety science, in which the concept of patient safety and the size of the problem, terminology and causes of human error (human factors engineering) were discussed. In the second part we facilitated discussion about patient safety culture using the SCOPE results of their own practice and parts of the Manchester Patient Safety Framework (MaPSaF). The MaPSaF is a matrix of nine safety dimensions described in ascending maturity stages of safety culture. This instrument was used to start-up a discussion about the practices' safety culture. The workshop ended with a brainstorm on possible improvements and the drawing of an action plan.
The primary outcome measure consisted of the number of reported incidents in the year before the trial and one year after the intervention. Because incident reporting was still at its infancy in general practice we expected an increase in reports. It was assumed that this would indicate improved openness and communication and thus an improvement in safety culture. Secondly, we assessed safety culture using the SCOPE questionnaire a year after the intervention at all participating practices, including the control practices. In addition, we collected data on quality- and safety indicators such as analysing incidents, having a complaint procedure, discussing patient safety during team meetings and having a formal safety policy.

Chapter 6 presents the results of the trial. After the baseline measurement of number of reported incidents, the two interventions were deployed, and a year after follow-up measurements were conducted. Statistical analysis of the number of incidents showed that the practices in the workshop group reported 42 times more incidents than the control group during follow-up when adjusted for the number of incidents known at baseline, accreditation status and size of the practice. The SCOPE group reported 5 times more incidents than the control group. Both results were statistically significant. Closer examination of the results showed that one practice in the SCOPE group was an outlier. This practice chose to participate in a workshop on incident reporting outside our study after reading their SCOPE results. This practice reported 57 of the 82 incidents in the follow-up measurements in this

group. Repeating the analysis without this practice resulted in a non-significant result for the SCOPE group compared to the control group. A few of the quality- and safety indicators showed meaningful changes. Having a formal reporting system remained unchanged in the control group, though, doubled in both intervention groups. In the workshop group incidents were also more often analysed, more often there were orientation procedures for new employees and patient safety was more often an agenda item of practice meetings.
Patient safety culture showed little improvement in the intervention practices, however, statistical analysis showed that the three groups did not differ significantly at follow-up. The assessment of patient safety (patient safety grade) showed a major improvement in the practices that participated in the workshop.

Chapter 7 describes the findings of the qualitative study of the trial. Next to the quantitative analysis we conducted interviews with the caregivers in the participating practices. Twenty four general practitioners and 24 assistants and practice nurses from the three groups were interviewed. The interviews from the control practices were in line with the quantitative results indicating little to no change had taken place. Thirty six interviews from the intervention practices were analysed to explain the found effect and differences in effect. We used the theoretical framework of 'Communities of Practice' (CoP) to interpret the results. A CoP is a group of people who share a purpose, problem or interest, and who deepen their knowledge and expertise by an ongoing interaction. Three elements: a domain, a community and a 'practice' (meaning 'actual daily practice ') have to be present. In this study, the domain was patient safety. The interviews showed that more risk-awareness was present in practices that participated in the workshop. In addition, there was more interaction on the topic, incidents were discussed and analysed, in other terms: a community was formed. In the SCOPE practices we found that a dialogue about the topic was established only scarcely. Eight of the ten contact persons within the SCOPE practices had not read nor shared the feedback report containing their results and the benchmark scores. During the interviews it was stated that they missed the 'getting together' and the attentional awareness given to the subject, in contrast with the workshop practices where the workshop was experienced as a shared experience, a shared starting point. The workshop also seemed to have contributed to the practice of patient safety in everyday practice – instruments, jargon, experiences – in these practices.
Combining the measurement of culture and the mutual approach had a positive effect on both behaviour and culture. With the qualitative analysis we showed that actual changes occurred and that patient safety as a subject of activity and discussion came to life in the teams.

Chapter 8 is an overall reflection on the thesis and describes recommendations for future research and policy. We performed a first inventory of patient safety culture in Dutch primary care. In this first measurement we found indications that caregivers overestimate their own culture and underestimate risks. Therefore, it is important to search for dialogue with professionals their needs and their opinion on relevance of patient safety interventions in their setting.

The trial results with respect to the SCOPE questionnaire showed no significant changes in time nor between the three groups at follow-up. It could be that there were no changes, that the questionnaire was completed too optimistic in the first round, that the one-year period was too short to change culture or it could be that the questionnaire was not sensitive enough to measure the difference. Relevant characteristics of the questionnaire, such as responsivity and interpretation of the results are important to examine further in the future. Notable was that the interviews indicated that there was an improvement in patient safety culture in the workshop practices in contrast to the other two groups.

The interviews further showed that education is an important first step when improving patient safety and culture. Participants in the workshop practices had more risk-awareness and this was among others ascribed to the theoretical part of the workshop where issues such as incidents and how these develop were discussed. In addition to that, the workshop seemed important to translate the SCOPE results to daily routine. Contrary, in the SCOPE practices this important process of feedback and interpretation virtually was not established. In sum, the trial showed that approaching patient safety as a team was most effective.

Patient safety and its maintenance initially focused on mistakes and trying to prevent these. Instead, recently the focus shifted towards learning from the things that are going right. Mainly in an environment such as health care, which cannot easily be standardised and with a high degree of uncertainty, resiliency next to reliability is considered as an fruitful approach. Particularly in such a resilient environment the professionals themselves are the key players in sustaining patient safety where indeed, a generative culture, clear risk-awareness and having a good judgement about when to intervene are crucial.

The study in this thesis showed that with relatively little effort, the necessary attention can be given to patient safety culture and that this leads to positive changes.

Nederlandse samenvatting

Patiëntveiligheid is een kernwaarde van de gezondheidszorg. Toch is het als onderwerp voor beleid en onderzoek pas echt onder de aandacht gekomen na de publicatie van het rapport '*To Err is Human'*. Patiëntveiligheid wordt gedefinieerd als "*Het (nagenoeg) ontbreken van (de kans op) aan de patiënt toegebrachte schade (lichamelijk/psychisch) die is ontstaan door het niet volgens de professionele standaard handelen van hulpverleners en/of door tekortkoming van het zorgsysteem*". Een belangrijk onderdeel van patiëntveiligheid is patiëntveiligheidscultuur – de gedeelde waarden, attitudes en opvattingen over patiëntveiligheid – of in het kort "*de manier waarop we de dingen hier* doen". Patiëntveiligheidscultuur omvat onderwerpen als; samenwerken, elkaar (durven) aanspreken, het melden en leren van incidenten en het bespreken van patiëntveiligheid in de praktijk. Uit onderzoek is gebleken dat een positieve, open veiligheidscultuur bijdraagt of zelfs een voorwaarde is voor het succes van patiëntveiligheidsinterventies. Het creëren van een constructieve cultuur is daarom vaak de eerste stap bij het verbeteren van de patiëntveiligheid.

In 2008 is het platform ZorgvoorVeilig gelanceerd, om alle eerstelijns beroepsgroepen te betrekken bij het ontwikkelen van beleid rond patiëntveiligheid in Nederland. Binnen dit project ontstond de vraag naar middelen waarmee veiligheidscultuur in de brede eerstelijns setting zichtbaar gemaakt kon worden en kon worden verbeterd. Er was op dat moment alleen een gevalideerde Nederlandse vragenlijst beschikbaar voor het meten van patiëntveiligheidscultuur in huisartsenpraktijken. Het eerste deel van deze thesis beschrijft dan ook het meten en exploreren van patiëntveiligheidscultuur in de Nederlandse eerste lijn (hoofdstuk 2 & 3). Daarnaast hebben we in de literatuur gezocht naar interventies in de eerste lijn die effect hadden op de cultuur en hebben we in dit onderzoek een interventie ontwikkeld (hoofdstuk 4 & 5). Vervolgens hebben we deze interventies in een gerandomiseerde trial getoetst binnen 30 huisartspraktijken (hoofdstuk 6 & 7).

Hoofdstuk 2 beschrijft de ontwikkeling en validatie van een vragenlijst om patiëntveiligheidscultuur te meten in de eerste lijn, de SCOPE-PC. SCOPE is een afkorting voor Systematisch Cultuur Onderzoek Patiëntveiligheid Eerstelijn. Omdat de eerste (huisartsen) vragenlijst SCOPE genoemd is, is PC (Primary Care) toegevoegd voor de vragenlijst voor de andere eerstelijns beroepsgroepen. De cultuurvragenlijst voor huisartsen is als uitgangspunt genomen. In een schriftelijke feedbackronde zijn professionals van elf disciplines – tandartsen, mondhygiënisten, diëtetiek, oefentherapie, fysiotherapie, ergotherapie, verloskunde, anticoagulantia, huisartsgeneeskunde, huidtherapie, logopedie – gevraagd om feedback te geven op de aangepaste vragenlijst. Aanpassingen werden met name gedaan in de gebruikte terminologie en formulering. De vragenlijst is vervolgens van maart en april 2011 in deze professies uitgezet. Een confirmatieve factoranalyse liet zien dat de factorstructuur van de

SCOPE-PC niet overeenkwam met de structuur zoals vastgesteld voor de SCOPE vragenlijst voor huisartsen. Een exploratieve factoranalyse resulteerde vervolgens in zeven dimensies:
1. Communicatie over en leren van incidenten;
2. Overdracht en samenwerking;
3. Adequate procedures en werkomstandigheden;
4. Patiëntveiligheidsmanagement;
5. Steun en collegialiteit;
6. Meldingsbereidheid;
7. Lerende organisatie.

De betrouwbaarheid van de dimensies bleek bevredigend en ook de onderlinge samenhang was goed.

Hoofdstuk 3 presenteert de stand van zaken van de veiligheidscultuur in de verschillende eerstelijns beroepsgroepen. Negenhonderd zes individuele vragenlijsten (519 praktijken) werden ingevuld door professionals vanuit negen verschillende professies: mondzorg (tandartsen en mondhygiënisten samen), diëtetiek, oefentherapie, fysiotherapie, verloskunde, anticoagulantia, huidtherapie en logopedie. Zeshonderdvijfentwintig vragenlijsten waren geschikt voor analyse. Over het algemeen werd cultuur positief gepercipieerd. De dimensies '*meldingsbereidheid*' en '*patiëntveiligheidsmanagement*' werden het laagst gescoord. '*Communicatie over en leren van incidenten'* en '*steun en collegialiteit'* scoorden het hoogst. De dimensie 'meldingsbereidheid' liet de meeste variatie binnen de professies zelf zien, wat een indicatie zou kunnen zijn van het vroege ontwikkelingsstadium waarin het melden zich bevond. Mogelijk wordt het melden van incidenten in sommige professies gepercipieerd als minder relevant voor de dagelijkse praktijk. De verschillen onderling tussen de professies waren niet groot.

Hoofdstuk 4 beschrijft de review van patiëntveiligheidsinterventies in de eerste lijn die een effect hebben op de cultuur. De review liet een gebrek aan gepubliceerde interventies in de eerste lijn zien. In totaal leverde de zoekstrategie 214 referenties op, echter, slechts twee studies voldeden aan de inclusiecriteria: 1) het onderzoek moest uitgevoerd zijn in de eerste lijn, 2) een patiëntveiligheidscultuur interventie met effect op cultuur moest beschreven zijn, 3) het effect op patiëntveiligheidscultuur moest beschreven zijn. Het ene artikel beschreef de implementatie van een elektronisch medisch systeem als onderdeel van lopende kwaliteits- en veiligheidsinitiatieven. Patiëntveiligheidscultuur liet een significante verbetering zien. Het andere artikel beschreef een interventie waarbij praktijken de mogelijkheid geboden werd deel te nemen aan twee workshops, een risico management workshop en een workshop over incidenten analyse (Significant Event Audit). De auteurs rapporteerden

een algemene verbetering in risico management na deelname aan één van de interventies. Beide onderzoeken zijn uitgevoerd in huisartspraktijken. De kwaliteit van beide studies was laag, beide hadden geen controle groep en er waren andere methodologische problemen. De belangrijkste bevinding van het review was een gebrek aan goed opgezet onderzoek naar cultuurinterventies in de eerste lijn.

Hoofdstuk 5 is een gedetailleerde beschrijving van het studieprotocol. Het doel van de SCOPE Interventie Studie was het testen van twee cultuurinterventies in de huisartsgeneeskunde. Hiertoe hebben we een driearmige cluster gerandomiseerde trial opgezet met tien huisartspraktijken in elke onderzoeksarm. In de controlegroep werd geen interventie uitgevoerd. Praktijken in interventie I werden gevraagd om met alle medewerkers van de praktijk de SCOPE patiëntveiligheidscultuurvragenlijst in te vullen. De contactpersoon van de praktijk kon de feedbackrapportage met resultaten en benchmark scores downloaden. Vervolgens was het aan de praktijk om te besluiten wat te doen met de resultaten. In interventie II werden praktijken ook gevraagd de SCOPE in te vullen, echter, voor deze contactpersonen was het niet mogelijk de feedbackrapportage te downloaden. In plaats daarvan namen zij met zoveel mogelijk medewerkers deel aan een praktijkgerichte workshop. De workshop bestond uit twee onderdelen. Ten eerste, educatie over veiligheidskunde waarin het concept van patiëntveiligheid en de grootte van het probleem, de terminologie en oorzaken van menselijk falen (human factor engineering) behandeld werden. Ten tweede, een gefaciliteerde discussie over de eigen veiligheidscultuur met behulp van de SCOPE resultaten uit de eigen praktijk en onderdelen van het Manchester Patient Safety Framework (MaPSaF). De MaPSaF is een matrix van negen veiligheidsdimensies uitgewerkt in vijf oplopend volwassenheidsstadia van veiligheidscultuur. Dit instrument werd gebruikt om de discussie over de eigen veiligheidscultuur op gang te brengen. De workshop eindigde met een brainstorm over mogelijke verbeteringen en het opstellen van een actieplan.
Als primaire uitkomstmaat is gekozen voor het aantal gerapporteerde incidenten in het jaar voor de start van de trial en een jaar later. Omdat incidentmelden nog in de beginfase staat binnen de huisartsenzorg verwachtten we een stijging van het aantal gemelde incidenten. Dit werd gezien als een toename van openheid en communicatie en dus een verbetering van de patiëntveiligheidscultuur. Secundair hebben we veiligheidscultuur gemeten met de SCOPE vragenlijst een jaar na de interventie bij alle deelnemende praktijken, inclusief de controle praktijken. Daarnaast hebben we data verzameld over een aantal kwaliteits- en veiligheidsindicatoren zoals het analyseren van incidenten, het hebben van een klachtenprocedure, het bespreken van patiëntveiligheid tijdens teambijeenkomsten en het hebben van een formeel veiligheidsbeleid.

Hoofdstuk 6 presenteert de resultaten van de trial. Na de baselinemeting van het aantal incidentmeldingen per praktijk werden de twee interventies uitgevoerd waarna een jaar later de follow-up metingen zijn gedaan. Statistische analyse van het aantal incidenten liet zien dat praktijken in de workshop groep 42x meer incidenten meldden dan de controle groep tijdens de follow-up, wanneer er gecorrigeerd werd voor het aantal incidenten bekend bij de voormeting, accreditatie status en grootte van de praktijk. De SCOPE groep rapporteerde 5x meer incidenten dan de controle groep. Beide resultaten waren statistisch significant. Uit nadere bestudering van de resultaten bleek dat één van de praktijken in de SCOPE groep een outlier was. Deze praktijk besloot n.a.v. de SCOPE rapportage zelf een cursus over veilig incidenten melden te volgen buiten onze studie. Deze praktijk rapporteerde 57 van de 82 incidenten in de nameting van de SCOPE groep. Het herhalen van de analyse zonder deze praktijk resulteerde in een niet-significant resultaat voor de SCOPE groep ten opzichte van de controle groep.
Van de kwaliteits- en veiligheidsmanagement indicatoren lieten enkele betekenisvolle veranderingen zien. Het aantal praktijken met een formeel meldingssysteem bleef onveranderd voor de controle groep, echter verdubbelde in beide interventiegroepen. Daarbij werden In de workshop groep de meldingen vaker systematisch geanalyseerd , waren er vaker inwerkprogramma's aanwezig en stond patiëntveiligheid vaker op de agenda van werkbesprekingen.
Patiëntveiligheidscultuur liet een kleine verbetering zien in beide interventiegroepen, echter, statistische analyse liet geen significante verschillen zien tussen de drie groepen bij de nameting. De beoordeling van de patiëntveiligheid liet een grote verbetering zien in de praktijken die hadden deelgenomen aan de workshops.

Hoofdstuk 7 beschrijft de bevindingen van de kwalitatieve studie van de trial. Naast de kwantitatieve analyse in het voorgaande hoofdstuk hebben we interviews gehouden met zorgverleners in de deelnemende praktijken. Vierentwintig huisartsen en 24 assistenten en praktijkondersteuners uit alle drie de groepen zijn geïnterviewd. De interviews uit de controle praktijken waren in lijn met de kwantitatieve data die indiceerden dat er binnen deze praktijken weinig tot geen veranderingen hadden plaatsgevonden. Zesendertig interviews uit de interventiepraktijken zijn geanalyseerd om het gevonden effect en verschil in effect te begrijpen. We hebben het theoretisch raamwerk van 'Communities of Practice' (CoP) gekozen om de resultaten te interpreteren. Met de term CoP wordt een groep mensen aangeduid die een belang, een probleem of interesse delen en vervolgens hun kennis en expertise verdiepen door een continue interactie met elkaar. Drie elementen: een domein, een 'community' en een 'praktijk' (met praktijk wordt hier bedoeld de wijze van praktijkvoering) moeten aanwezig zijn. In deze studie was het domein patiëntveiligheid. De interviews lieten

zien dat er meer risico-bewustzijn aanwezig was in de praktijken die de workshop hadden gevolgd. Daarnaast was er meer interactie rondom het onderwerp, incidenten werden besproken en geanalyseerd, met andere woorden: er ontstond een community. In de SCOPE praktijken vonden we dat slechts in beperkte mate dialoog was ontstaan over het onderwerp. Acht van de tien contactpersonen binnen de SCOPE praktijken hadden het feedbackrapport met de SCOPE resultaten van de eigenlijk praktijk en een benchmark niet gelezen noch gedeeld met de andere zorgverleners. Tijdens het interview werd aangegeven dat ze het 'samenkomen' en de bewuste aandacht voor het onderwerp hadden gemist, in tegenstelling tot de workshop praktijken waar de workshop werd gezien als een gedeelde ervaring, een gedeeld startpunt. De workshop bleek ook bij te hebben gedragen aan de concrete uitvoering rond patiëntveiligheid in de dagelijkse gang– instrumenten, jargon, ervaringen – binnen deze praktijken.
Het combineren van het meten van cultuur en de gemeenschappelijke aanpak heeft een positief effect op zowel gedrag als cultuur. Met de kwalitatieve analyse hebben we laten zien dat er daadwerkelijk verandering optreedt en dat patiëntveiligheid als onderwerp van actie en gesprek meer gaat leven binnen de teams.

Hoofdstuk 8 is een algemene reflectie op het proefschrift en beschrijft aanbevelingen voor toekomstig beleid en onderzoek. We hebben een eerste inventarisatie gemaakt van patiëntveiligheidscultuur in de Nederlandse eerste lijn. In deze eerste meting vonden we aanwijzingen dat zorgverleners de eigen cultuur mogelijk overschatten en risico's onderschatten. Het is daarom van belang om de dialoog te zoeken met de zorgverleners: waar is nu behoefte aan en welke aspecten van patiëntveiligheid zijn belangrijk voor iedere beroepsgroep afzonderlijk?
De trial resultaten met betrekking tot de SCOPE vragenlijst lieten geen significante veranderingen zien over de tijd of tussen de drie groepen in de nameting. Dit zou kunnen komen omdat er geen verschil is, omdat de vragenlijst in de eerste ronde te positief is ingevuld, omdat een tijdsperiode van 1 jaar te kort is om cultuur te veranderen of omdat de vragenlijst niet sensitief genoeg is om het verschil te meten. Relevante karakteristieken van de vragenlijst zoals responsiviteit en interpretatie van de resultaten zijn belangrijk om in de toekomst verder te onderzoeken. Opvallend was dat de interviews suggereerden dat er wel een verbetering in de veiligheidscultuur was binnen de workshop praktijken in tegenstelling tot de andere twee groepen.
De interviews lieten verder zien dat educatie een belangrijke eerste stap is bij het werken aan patiëntveiligheid en cultuur. Participanten die de workshop hadden gevolgd hadden daarna meer risico-bewustzijn, dit werd onder andere toegeschreven aan het informatieve deel van de workshop waar zaken besproken werden als het aantal incidenten en hoe deze

ontstaan. Daarnaast bleek dat de workshop een belangrijke rol heeft gespeeld in het vertalen van de SCOPE resultaten naar de praktijkvloer. In tegenstelling, in de SCOPE praktijken kwam dit belangrijke proces van feedback en interpretatie vrijwel niet tot stand. Samenvattend heeft de trial laten zien dat het benaderen van patiëntveiligheid als een team het meest effectief was.

Patiëntveiligheid en de waarborging ervan was voornamelijk gericht op fouten en het voorkomen daarvan. Echter, recentelijk is de focus verschoven naar het kunnen leren van dingen die goed gaan. Vooral in een omgeving zoals de gezondheidszorg, die niet te standaardiseren is en waar een hoge mate van onzekerheid bestaat, wordt veerkracht (resilience) naast betrouwbaarheid (reliability) gezien als een vruchtbare aanpak. Juist in zo'n 'veerkrachtige omgeving' zijn de professionals zelf sleutel figuren in het behouden van patiëntveiligheid, waar een generatieve cultuur, een duidelijk risico-bewustzijn en het hebben van een goed inschattingsvermogen cruciaal zijn.

De studie in deze thesis heeft laten zien dat met een relatief kleine inspanning, de nodige aandacht gegeven wordt aan patiëntveiligheid en dat dit positieve verandering leidt.

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Curriculum Vitae

Natasha Verbakel was born in Exeter, Great Brittain, on the 18th of April 1984 and was raised in the Netherlands.

In 2005 she obtained her Bachelor Degree in Nursing after which she studied Sociology (Policy & Consultancy) from 2005 to 2007 at the University of Groningen. After graduation she worked three years as a policy worker at the Foundation for Harmonisation of Quality in Care (Stichting HKZ). Here, she worked on the development and maintanance of certification schemes for quality management and later safety management systems in several professions.

Late 2010 she started working at the Julius Center, University Medical Center Utrecht on the research described in this thesis. In May 2014 she obtained her Masters of Science degree in Clinical Epidemiology at the University of Utrecht.