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Effects of patient safety culture interventions on incident reporting in general practice: a cluster randomised trial.

NJ Verbakel, patient safety researcher;

TJM Verheij, GP, professor of general practice;

DLM Zwart, GP, head of students education of general practice, associate professor, Department of General Practice, Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Utrecht, The Netherlands.

M Langelaan, patient safety researcher, Nivel, Netherlands Institute for Health Services Research, Utrecht, The Netherlands.

C Wagner, professor of patient safety, EMGO+ Institute, Department of Public and Occupational Health, VU University Medical Center, Amsterdam, The Netherlands.

ABSTRACT

Background: A constructive safety culture is essential for the successful implementation of patient safety improvements.

Aim To assess the effect of two patient safety culture interventions on incident reporting as a proxy of safety culture.

Design and setting A three-arm 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 30 general practices in the Netherlands.

Method: The primary outcome, the number of reported incidents, was measured with a questionnaire at baseline and a year after. Analysis was performed using a negative binomial model. Secondary outcomes were quality and safety indicators and safety culture. Mixed effects linear regression was used to analyse the culture questionnaires.

Results: The number of incidents increased in both intervention groups, to 82 and 224 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 42 (95% confidence interval [CI] = 9.81 to 177.50) times more incidents compared to the control group. Practices that only completed the questionnaire reported 5 (95% CI = 1.17 to 25.49) times more incidents. There were no statistically significant differences in staff perception of patient safety culture at follow-up between the three study groups.

Conclusion: 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.

INTRODUCTION

At the start of patient safety research, the Institute of Medicine states that ‘healthcare organizations must develop a culture of safety to focus on improving the reliability and safety of care for patients.’¹ Originating from organisational 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 organisation’s health and safety management.² Patient safety culture in general practice concerns matters such as (daring to) speak up and address each other and reporting and learning from incidents.

In the Netherlands, patient safety policy in general practice is being developed and among other reasons there was a clear need for effective intervention tools on safety culture. A patient safety culture questionnaire is available for general practice and is one of the optional modules in the accreditation process. There are no national incentives, contractual or financial, to engage practices in patient safety culture interventions. Two reviews examining culture improvement strategies in hospitals showed broad multi-part interventions and walk rounds with engaged leaders to be most successful.^{3,4} (A walk round is a way to engage senior leaders in safety [culture] issues. Senior leaders, clinicians and other staff perform regular rounds where they discuss patient safety items directly at the shop floor). Although a large part of health care 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} by increasing risk awareness and, to a lesser extent, contributing to awareness of issues surrounding patient safety. 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 a tool for change is determined by the process of digesting and reporting the data.¹³

In addition, educational activities, such as 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 settings¹⁷ and is increasingly being used.^{18–20}

How this fits in

Following hospitalised care, the focus on patient safety culture has reached general practice. A constructive patient safety culture is considered key in patient safety improvement efforts, however, to date, it is unknown which culture interventions are adequate for general practice. This study showed that administering a patient safety culture questionnaire raised awareness, but that the combination of such a questionnaire and a practice-based workshop was more successful in terms of increased incident reporting. This finding emphasises the importance of a team approach when implementing safety culture improvement interventions.

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

METHOD

Design and participants

A three-armed cluster randomised trial, in a mixed methods study was conducted. 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, and was performed by the data management department independent of the research team. The practices were enrolled and contacted by the first author. Due to the nature of the interventions blinding was not possible. Details of the study protocol have been described previously.²¹

[FIGURE 1.]

Interventions

Two interventions were studied: the administering of and feedback on a patient safety culture questionnaire (intervention I), the administering of the questionnaire complemented with a patient safety workshop (intervention II), and no intervention.

Patient safety culture questionnaire (intervention I)

The SCOPE questionnaire, translated and adapted originally from the Hospital Survey on Patient Safety Culture (HSOPS)²² specifically for Dutch general practices²³ was used as the intervention tool. SCOPE is the Dutch acronym for systematic culture inquiry on patient safety. 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

Practice based patient safety workshop (intervention II)

The workshop consisted of education on the concept of patient safety and culture, terminology, and human factor engineering. Appendix 1 shows the details of the

workshop. Discussion about the own culture was facilitated using their own SCOPE results and Dutch translations of the MaPSaF17 focusing on two SCOPE dimensions that scored lowest. A discussion of possible improvements resulted in an action plan. The workshop was led by an independent GP trainer who was well-informed on the subject. It was held at practice location, lasted 3.5 hours, and attendance of 75% staff was required. Each practice received one workshop about 1–2 months after completing the SCOPE questionnaire, one practice received the workshop after 4 months. To study the course of the workshop one author attended and kept observations. Participants were also 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. Contact persons were asked to report the number of incidents that were known from the year before the intervention and 1 year thereafter. If available they may have extracted this data from their intra-practice reporting system. Actual reporting is a prominent feature of a generative safety culture.²⁵ Because reporting is just in its infancy in general practice,^{26,27} it was hypothesised that an increase of reports would reflect a ‘pattern of behaviour’² congruent to improvement of patient safety culture. Hence, the number of incidents reported as a proxy of actual patient safety culture was considered.

Secondary outcome

Patient safety culture was additionally operationalised by quality and safety indicators (for example, the presence of complaints procedure, and patient safety being an agenda item of team meetings [Appendix 2]). Patient safety culture was measured at all practices at follow-up using the SCOPE questionnaire, consisting of 43 items distributed over eight dimensions completed by healthcare staff. SCOPE has sound psychometric properties: Cronbach’s α 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’ (patient safety grade [PSG]: 5-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 30 practices were needed for a power of 0.90 and an α of 0.05. Based on previous research¹¹ an increase from 50 to 70 (intervention I) and 100 (intervention II), respectively, with a standard deviation of 30, was assumed. The outcome was treated as a continuous measure for sample size calculation. 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 generalised linear model using a negative binomial model. Intervention, number of reports at baseline (as natural logarithm), accreditation status and practice size were included in the model. The model using a Poisson distribution showed large over dispersion and minor

violations of the assumptions of homoscedasticity and normally distributed residuals. Therefore, the negative binomial distribution was used, 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 for missing culture items.²⁸ The imputation model included culture items, sex, discipline and age as predictors. As formal management items could not be answered by everyone, 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, the cut-off value of >75% positive scores to indicate practices' strengths and by $\leq 50\%$ positive scores for weak dimensions were adhered to.²⁹ For two measurements in the same practice a 5% change was considered meaningful.³⁰ To analyse differences at follow-up mean dimension scores were calculated. To allow for correlation between staff members within one practice, mixed effects linear regression was performed. Intervention type, practice size, and accreditation status were included in the model. All analyses were conducted in SPSS (version 20.0).

RESULTS

Participants

After randomisation, two practices discontinued because of time issues. Therefore one random control practice was moved to intervention II. Table 1 gives an overview of practices and responder characteristics.

[TABLE 1.]

Number of incidents

Intervention I showed an increase of 67 incident reports (15 to 82), intervention II an increase of 154 (70 to 224) and the control group a decrease from 18 to 4 (Figure 2). Appendix 3 shows the distribution of incident reports, reporting procedure, and accreditation status at baseline and follow-up per practice. In intervention I most incidents were reported in three practices, one of these practices was an outlier with 57 reported incidents at follow-up. An employee of this practice participated in a workshop on incident reporting outside this study. An intention to treat analysis showed that intervention II resulted in 42 times (95% confidence interval [CI] = 9.81 to 177.50) more reports than the control group, and intervention I reported 5 times (95% CI = 1.17 to 25.49) as much when adjusted for baseline reports, accreditation status and practice size (Table 2). These results did not change relevantly, nor significantly, when analysed without the practice that had been moved from control to intervention II. Without the outlier mentioned above, 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 4).

[FIGURE 2.] [TABLE 2.]

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.

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. A total of 131 questionnaires (intervention I median 5, interquartile range [IQR] 3–10.5; intervention II median 8, IQR 5.5–11.5) and 168 (control median 5, IQR 3.5–7.5; intervention I median 5, IQR 4–9; intervention II median 7, IQR 4.5–9) questionnaires were included, respectively, as 3 baseline and 15 follow-up questionnaires had <50% of safety items completed. A missing analyses showed 2.6% missing items at baseline and 3% at follow-up.

Positive scores ranged between 63% and 86% at follow-up (Table 3). Several dimensions showed room for improvement (<75%), however, none were below 50%. In intervention I six dimensions improved $\geq 5\%$, 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 5).

[TABLE 3.]

Course of the workshop in intervention II

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

DISCUSSION

Summary

This study found that administering a safety culture questionnaire solely or integrated in a workshop both increased reporting incidents, however, the effect was much larger in practices receiving the workshop. These practices were also more active in analysing incidents and discussing the subject during team meetings. Increased numbers of reports were not perceived as a deterioration of patient safety but

contrary, as indicating improved readiness to report incidents that were already present. Therefore, changes in handling incidents may indicate patient safety culture improvement at the practices' 'shop floor' after a team-wise safety culture intervention. However, safety culture measurements did not show large improvements nor differences between the groups after 1 year of follow-up.

Strengths and limitations

This study is one of the first trials on culture improvement in general practice. Also, to the authors' 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 intervention I 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, practices that scored high at baseline showed improvement in intervention II. This study has some limitations. First, 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. Second, the absence of changes in culture measurements may be due to underpowering since the sample size calculation was based on the number of incidents, a practice feature. However, the culture questionnaires were conducted at a caregiver level, which resulted in clustered data requiring higher numbers of participants for measuring a potential significant effect. Also, it was not possible to match individual questionnaires before and after. Finally, asking practices to participate voluntarily may have led to selection bias. However, as in real life, such workshops would only be attended on a voluntary basis by interested parties.

Comparison with existing literature

The MaPSaF, when used in hospitalised settings, showed improvement in culture measurements over a 5-year follow-up.³¹ This study did not find such improvement. Interestingly, using the MaPSaF in general practice Hoffmann et al found effects on incident reporting and not on self-reported culture improvement similar to the current study.³² The lack of effect on culture measurements may be explained either by the short intervention time of 1 year or by the insufficient sensitivity of the used survey.³³ Responsiveness to change should be part of further research.

The 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, the SCOPE results were integrated in the workshop, both focusing the discussion and tailoring it to the participating practice. Hereby, the workshop became comprehensive and manageable. Furthermore, an educational part on safety science (such as the state of affairs, terminology, and examples) was added to the workshop. Education is perceived as important in quality improvement³⁸ and is 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, the workshops were built on the experiential learning principles of Kolb; for example, concrete experience, reflection, conceptualisation, 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 ideal for professionals since it explicitly connects daily practice with learning. Moreover, the workshop resulted in an action plan made up by all staff, thus matching their practice with team-based commitment, and increasing the feasibility of actual implementation.⁴¹ It was found that this format added to the workshop's impact in the current study.

Implications for research and 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. A step-by-step guide was compiled and, together with the workshop, is freely accessible for all practices. Practices are able to tailor the workshop to their own practice and the workshops can be conducted at relatively low cost and effort. For future research it is worthwhile to study the sustainability of the results found and the need for repeated interventions. An additional challenge 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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NOTES

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Ethical approval

The Medical Research Ethics Committee of the University Medical Center Utrecht concluded that the Medical Research Involving Human Subjects Acts did not apply to this study (protocol number: 12-049/C).

Competing interests

The authors have declared no competing interests.
Discuss this article

Appendix 1. 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 organisation according to the MaP-SaF vignettes on two dimensions (individually)

- Each responder 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 of same discipline
- Vignettes are discussed with all staff

Discussion on possible improvement actions

Drafting of practice improvement action plan

Evaluation and take home message

Appendix 2. 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

How many complaints were received the past year (both from employees and patients)?

Does your practice have an internal coordinator for complaints?

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 meetings? 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

Was the subject patient safety subject of training the past year?

Which training was this?

Was this training for the whole practice or individual?

Did you notice the learned being implemented in practice? If no, why not?

Safety management

1. Does your practice have an patients safety management plan or otherwise 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

Does your practice have a protocols book?

Do you participate regularly in pharmacotherapeutic consultations?

Do you have a procedure/method for controlling the content of the GP emergency bag? (inclusive medication)

Does your practice have an introduction procedure for new employees?

Does your practice have an emergency telephone?

Have you ever conducted a patient safety satisfaction survey?

Does your practice use 'ZorgDomein' (This is a referral aid for physicians)

Does your practice have a procedure to check repeat prescriptions?

When was the last time the equipment in the practice was calibrated?

Did you implement a quality improvement project last years?

Appendix 3. Distribution of number of known incidents, presence of formal reporting procedure and accreditation status at baseline and follow-up

Intervention	Incidents baseline, n	Incidents follow-up, n	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

Intervention	Incidents baseline, n	Incidents follow-up, n	Formal reporting procedure baseline	Formal reporting procedure follow-up	Accreditation status baseline	Accreditation status follow-up
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 4. Self-reported number of incident forms (outcome question included in the SCOPE questionnaire)

Intervention, n	Baseline		Follow-up	
	Frequency	%	Frequency	%
Control				
None			40	83.3
1–2			3	6.3
3–5			4	8.3
6–10			–	–
11–20			–	–
>20			1	2.1
SCOPE (intervention I)				
None	49	84.5	34	61.8
1–2	7	12.1	7	12.7
3–5	1	1.7	4	7.3
6–10	1	1.7	6	10.9
11–20	–	–	4	7.3

Intervention, n	Baseline		Follow-up	
	Frequency	%	Frequency	%
>20	–	–	–	–
SCOPE + workshop (intervention II)				
none	56	77.8	21	35.0
1–2	9	12.5	11	18.3
3–5	7	9.7	17	28.3
6–10	–	–	9	15.0
11–20	–	–	2	3.3
>20	–	–	–	–

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

Appendix 5. Effect of interventions on SCOPE safety culture dimensions after 1 year of follow-up

	Regression coefficient (95% CI)a	P-value	Regression coefficient (95% CI)b	P-value
1. Handover and teamwork				
Intervention I	0.031 (−0.20 to 0.27)	0.796	0.072 (−0.15 to 0.30)	0.531
Intervention II	0.087 (−0.14 to 0.31)	0.449	0.123 (−0.09 to 0.34)	0.254
Accredited (y)			−0.039 (−0.25 to 0.17)	0.716
Practice size			−0.024 (−0.05 to 0.00)	0.069
2. Support and fellowship				
Intervention I	−0.216 (−0.52 to 0.09)	0.164	−0.224 (−0.54 to 0.09)	0.160
Intervention II	0.065 (−0.24 to 0.37)	0.674	0.076 (−0.23 to 0.38)	0.625
Accredited (y)			−0.201 (−0.50 to 0.10)	0.193
Practice size			−0.002 (−0.04 to 0.03)	0.089
3. Communication openness				
Intervention I	−0.170 (−0.46 to 0.35)	0.245	−0.144 (−0.43 to 0.14)	0.323
Intervention II	0.064 (−0.22 to 0.35)	0.660	0.102 (−0.18 to 0.38)	0.479
Accredited (y)			−0.113 (−0.39 to 0.16)	0.425
Practice size			−0.019 (−0.05 to 0.02)	0.279

	Regression coefficient (95% CI)a	P-value	Regression coefficient (95% CI)b	P-value
4. Feedback about and learning from error				
Intervention I	-0.024 (-0.41 to 0.36)	0.902	0.030 (-0.32 to 0.38)	0.866
Intervention II	0.102 (-0.28 to 0.48)	0.602	0.177 (-0.16 to 0.52)	0.308
Accredited (y)			-0.317 (-0.65 to 0.02)	0.064
Practice size			-0.028 (-0.07 to 0.01)	0.177
5. Intention to report events				
Intervention I	0.051 (-0.35 to 0.45)	0.800	0.064 (-0.34 to 0.45)	0.746
Intervention II	0.148 (-0.24 to 0.54)	0.455	0.168 (-0.20 to 0.54)	0.368
Accredited (y)			-0.327 (-0.66 to 0.00)	0.053
Practice size			-0.015 (-0.06 to 0.03)	0.712
6. Adequate procedures and adequate staffing				
Intervention I	0.075 (-0.26 to 0.41)	0.663	0.083 (-0.27 to 0.44)	0.459
Intervention II	0.123 (-0.21 to 0.46)	0.474	0.135 (-0.22 to 0.49)	0.459
Accredited (y)			-0.002 (-0.35 to 0.35)	0.992
Practice size			-0.001 (-0.05 to 0.04)	0.766
7. Overall perceptions of patient safety				

	Regression coefficient (95% CI)a	P-value	Regression coefficient (95% CI)b	P-value
management				
Intervention I	0.017 (-0.33 to 0.37)	0.922	0.024 (-0.34 to 0.39)	0.895
Intervention II	0.218 (-0.13 to 0.57)	0.211	0.237 (-0.12 to 0.60)	0.189
Accredited (y)			-0.122 (-0.48 to 0.23)	0.486
Practice size			-0.007 (-0.05 to 0.04)	0.736
8. Expectations and actions of managers				
Intervention I	0.001 (-0.37 to 0.37)	0.997	0.015 (-0.38-0.41)	0.936
Intervention II	0.133 (-0.24 to 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
Patient safety grade				
Intervention I	-0.035 (-0.48 to 0.42)	0.875	-0.008 (-0.44-0.42)	0.970
Intervention II	0.161 (-0.29 to 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

Intervention I = SCOPE questionnaire. Intervention II = SCOPE questionnaire + workshop. (y) = Yes.

a Crude (unadjusted) analyses.

b Adjusted for accreditation status and practice size.

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TABLES AND FIGURES

Figure 1: Flowchart enrolment and randomisation.

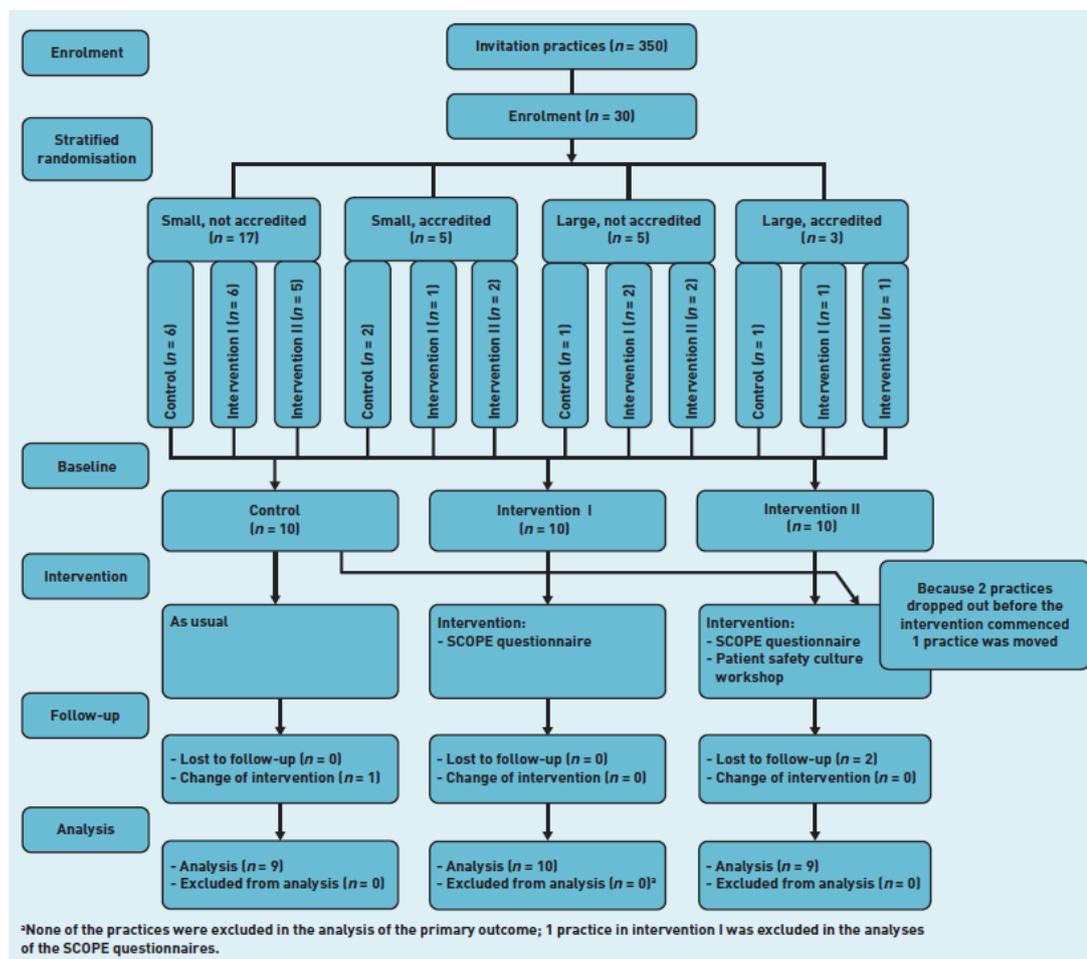


Table 1. Practices and responders characteristics

	Control	Intervention I	Intervention II
Composition of staff, %	<i>n</i> = 67	<i>n</i> = 87	<i>n</i> = 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
Mean age, ^a years (SD)	44.6 (9.9)	44.3 (12.4)	41.08 (10.7)
Female sex, ^a %	81.3	92.6	85.0
Mean years in current practice ^a (SD)	7.1 (6.3)	9.0 (8.6)	8.3 (6.2)
Practices, <i>n</i>	9	10	9
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

SD = standard deviation. (y) = Yes. ^aBased on data of the SCOPE questionnaires at follow-up.

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

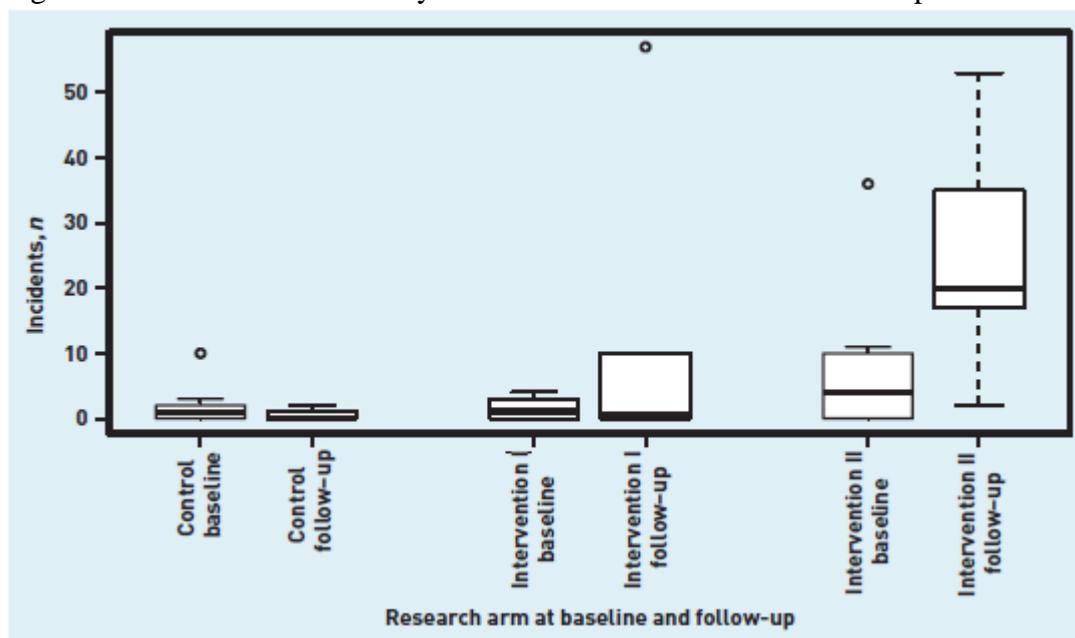


Table 2. Effect of interventions on number of incidents at follow-up

Parameter	Rate ratio ^a (95% CI)	P-value	Rate ratio ^b (95% CI)	P-value	Rate ratio ^c (95% CI)	P-value
Intention-to-treat analysis with all 28 practices						
Intervention I	18.45 (4.79 to 71.06)	<0.001	14.72 (3.72 to 58.20)	<0.001	5.45 (1.17 to 25.49)	0.03
Intervention II	56.00 (14.47 to 216.71)	<0.001	45.47 (11.56 to 178.93)	<0.001	41.72 (9.81 to 177.50)	<0.001
Number of incidents at baseline (ln)	-	-	1.66 (1.02 to 2.70)	0.04	1.78 (1.02 to 3.10)	0.04
Accredited at baseline (y)	-	-	-	-	0.28 (0.08 to 1.03)	0.06
Practice size in employees	-	-	-	-	1.22 (1.06 to 1.41)	<0.01
Analysis without outlier in intervention I						
Intervention I	6.25 (1.54 to 25.42)	0.01	6.11 (1.49 to 25.00)	0.01	4.12 (0.92 to 18.44)	0.06
Intervention II	56.00 (14.47 to 216.71)	<0.001	46.50 (11.86 to 182.22)	<0.001	40.15 (9.88 to 163.10)	<0.001
Number of incidents at baseline (ln)	-	-	1.37 (0.87 to 2.17)	0.180	1.46 (0.87 to 2.46)	0.15
Accredited at baseline (y)	-	-	-	-	0.52 (0.14 to 1.92)	0.33
Practice size in employees	-	-	-	-	1.15 (0.99 to 1.33)	0.07

Intervention I = SCOPE questionnaire. Intervention II = SCOPE questionnaire + workshop. (y) = Yes. ^aCrude (unadjusted) analysis. ^bAdjusted for baseline number of incidents (ln = natural logarithm). ^cAdjusted for baseline number of incidents (ln = natural logarithm), accreditation status and practice size. Values in bold are significant.

Table 3. SCOPE dimension scores for the control and both intervention groups

Dimensions (scale 1-5)	Control (follow-up), mean (SD) % positive (n= 50)	Intervention I (baseline), mean (SD) % positive (n= 59)	Intervention I (follow up), mean (SD) % positive (n= 57)	Intervention II (baseline), mean (SD) % positive (n= 72)	Intervention II (follow-up), mean (SD) % positive (n= 61)
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 $\geq 5\%$. Intervention I = SCOPE questionnaire. Intervention II = SCOPE questionnaire + workshop.