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Supporting Error Management and Safety Climate in Ambulatory Care Practices: The CIRSforte Study

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Background: To improve patient safety, it is important that healthcare facilities learn from critical incidents. Tools such as reporting and learning systems and team meetings structure error management and promote learning from incidents. To enhance error management in ambulatory care practices, it is important to promote a climate of safety and ensure personnel share views on safety policies and procedures. In contrast to the hospital sector, little research has been dedicated to developing feasible approaches to supporting error management and safety climate in ambulatory care. In this study, we developed, implemented, and evaluated a multicomponent intervention to address how error management and safety climate can be improved in ambulatory care practices.

Methods: In a prospective 1-group pretest-posttest implementation study, we sought to encourage teams in German ambulatory practices to use proven methods such as guidelines, workshops, e-learning, (online) meetings, and e-mail newsletters. A pretest-posttest questionnaire was used to evaluate level and strength of safety climate and psychological behavioral determinants for systematic error management. Using 3 short surveys, we also assessed the state of error management in the participating practices. In semistructured interviews, we asked participants for their views on our intervention measures.

Results: Overall, 184 ambulatory care practices nationwide agreed to participate. Level of safety climate and safety climate strength (rwg) improved significantly. Of psychological behavioral determinants, significant improvements could be seen in "action/coping planning" and "action control." Seventy-six percent of practices implemented a new reporting and learning system or modified their existing system. The exchange of information between practices also increased over time. Interviews showed that the introductory workshop and provided materials such as report forms or instructions for team meetings were regarded as helpful.

Conclusions: A significant improvement in safety climate level and strength, as well as participants' knowledge of how to analyze critical incidents, derive preventive measures and develop concrete plans suggest that it is important to train practice teams, to provide practical tips and tools, and to facilitate the exchange of information between practices. Future randomized and controlled intervention trials should confirm the effectiveness of our multicomponent intervention.

Trial registration: Retrospectively registered on 18. November 2019 in German Clinical Trials Register No. DRKS00019053

Key Words: patient safety, error, safety management, organizational culture, ambulatory care, methods, incident, reporting

Abbreviations: CIRS: critical incident reporting system, CIRSforte: study aimed at refining critical incident reporting systems (CIRS) for use in German ambulatory care, FraSiK: Frankfurt Patient Safety Climate Questionnaire for General Practices, HAPA: Health Action Process Approach, HCA: healthcare assistant, P: physician, rwg: reliability within groups, SD: standard deviation

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Ethics approval and consent to participate: Practice teams participated voluntarily, and consent for participation could be withdrawn at any time without negative consequences. The study was approved by the ethics committee of the Medical Faculty of Goethe University Frankfurt in April 2017 (no. 185/17).

The data sets generated and analyzed during the current study are not publicly available, as they will form the basis for further papers in the future. However, they are available from the corresponding author upon reasonable request.

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BACKGROUND

It is important that healthcare facilities learn from critical incidents.[1,2] Sustainable learning from incidents can be promoted through the use of structured error management, which is the process of identification, reporting, and analysis of errors and the implementation and evaluation of preventive measures.[3] Error management tools such as reporting and learning systems and team meetings are well accepted by healthcare staff, if there is a positive safety climate in the institution.[4–6] Safety climate refers to the attitudes, values, and beliefs of all employees with regard to safety issues. If error management shall be enhanced, it is essential to also improve safety climate. In the hospital sector, many studies have developed best-practice examples of how safety climate and error management can be promoted.[7–12] Feasible approaches to supporting safety climate and the large-scale implementation of structured error management are scarce in the ambulatory sector.[13–15] When addressing behavioral change like improving

error reporting and deriving preventive measures, it is important that there is an underlying theoretical construct, for example, like the "Health Action Process Approach" (HAPA). The HAPA model specifies factors that influence a behavior, also referred to as key psychological determinants. The model describes the development and translation process of intention into actual action. It helps assess the various factors (determinants) that influence behavior and can show at which point in a process, an intention fails to be translated into the required action. It also reveals where interventions may provide support.

In Germany, error management is mandatory in ambulatory care practices.[16] German ambulatory care practices vary considerably in terms of their specialties and size.[17] In most cases, practice owners care for the patients themselves and are supported by a team of healthcare assistants, whereby the practice owner sometimes employs further physicians. According to the argument that the promotion of error management and safety climate is the responsibility of management,[18] the impulse to implement structured error management and to promote a positive safety climate should come from the physician(s) managing the practice. Although error management is mandatory, there are no negative consequences for practices that disregard it.[19] Therefore, much depends on the safety climate within the practice,[20] and particularly on both the personal commitment of the practice owner, and the understanding of the practice team that structured error management is crucial. Studies have shown that in everyday practice, priorities can vary and often depend on workload.[21–23]

To find out how to best support error management and safety climate in ambulatory care practices, we initiated the study "CIRSforte" (CIRSforte = "study aimed at refining CIRS = critical incident reporting systems for use in German ambulatory care") in which we implemented and evaluated a multicomponent intervention. We used proven methods from safety climate and error intervention research such as guidelines,[15,24] workshops,[25,26] e-learning,[27] (online) meetings to discuss critical incidents,[8,28] and e-mail newsletters as reminders.[29,30] We focused in particular on engaging healthcare assistants and physicians working in the practice team.[31]

METHODS

Study Design and Setting

The CIRSforte study has a prospective 1-group pretest-posttest design and was carried out in German ambulatory care over a period of 17 months. As first part of the multicomponent intervention, practice teams had to attend an introductory workshop on error management and safety climate, which was either conducted in person or as an e-learning course. The workshop comprised basic explanations on what safety climate is and why it is important. First steps toward structured error management were also explained, for example, how to discuss critical incidents in team meetings and how to derive preventive measures. At the beginning of the study, practices also received a study file containing various information materials, and a telephone hotline was available for any questions. Most importantly, the file included a brochure with recommendations on error management and safety climate in German ambulatory care.[32] During the course of the study, we regularly offered practices a monthly email newsletter with tips on error management and safety climate. Further optional training courses on error management were also provided and could be attended by members of the practice teams. These training courses consisted of advanced e-learning modules on team engagement and preventive measures as well as interactive workshops to discuss critical incidents with other practices (as a live web-conference or a face-to-face event) (see Fig. 1 and supplementary files for more details, http://links.lww.com/JPS/A600).

Participants and Recruitment

All ambulatory care practices, regardless of specialty, were eligible for participation. Recruitment took place between January and September 2018. For recruitment purposes, the study team approached practice networks and ambulatory healthcare centers (formal associations of several practices). In addition, we invited practices to participate by placing advertisements in professional journals published by the German Association of General Practitioners, and the Association of Statutory Health Insurance Physicians in Westphalia-Lippe, and in 3 different newsletters (Frankfurt Institute of General Practice, German Coalition for Patient Safety, and German Agency for Quality in Medicine). Written informed consent had to be provided and signed by at least one physician in the practice. Each practice received 400 euros for taking part in the study. Nationwide, 184 practices with 2250 employees (601 physicians) agreed to participate.

Evaluation Instruments and Data Collection

Pretest-Posttest Questionnaire

At the beginning (T0) and end of the study (T1), a questionnaire addressing (1) level and strength of safety climate and (2) psychological behavioral determinants for systematic error management was distributed to every participating practice team member.

The level and strength of the safety climate was assessed using the Frankfurt Patient Safety Climate Questionnaire for General Practices (FraSiK).[33] To limit the length of the questionnaire, we only included those 2 FraSiK factors that were most closely related to error management. These were the factors "error management" consisting of 7 items and "perception of causes of errors" comprising 6 items.

The HAPA model was used to assess psychological behavioral determinants.[34] The operationalization of the model for our study was based on the "PSYGIENE" study on hand hygiene in hospitals.[35] We defined the "analysis of critical incidents and the derivation of preventive measures" as key behaviors of structured error management and assessed eight dimensions of behavioral determinants. These were "risk perception," "outcome expectancy," "self-efficacy expectancy,' "intention," "action/coping planning," "action control," "resources," and "organizational barriers."

The pretest-posttest questionnaire consisted of 56 items (13 on safety climate, 35 on behavioral determinants, 8 on demographics). Responses to quantitative items were given on a 5-point rating scale ranging from 1 ("strongly disagree," "never," etc.) to 5 ("strongly agree," "always," etc.).

Short Surveys

We used short surveys to ask practices about the state of their error management 3 times during the course of the study. Specifically, we asked about critical incident reporting and learning systems and any sharing of information on patient safety issues with other practices. We also asked each practice to send us an anonymous incident report from the CIRS they used. The short survey consisted of 13 questions. On each of the 3 occasions, practices were required to fill out a survey. Survey questions were based on recommendations on error management in German ambulatory care[32] and were designed by the project team. The survey was piloted using cognitive interviews[36] with 2 general practitioners, after which minor wording changes were made.

Interviews

Using semistructured interviews, we assessed barriers and facilitating factors for structured error management in ambulatory care. In particular, we wanted to explore what practices thought

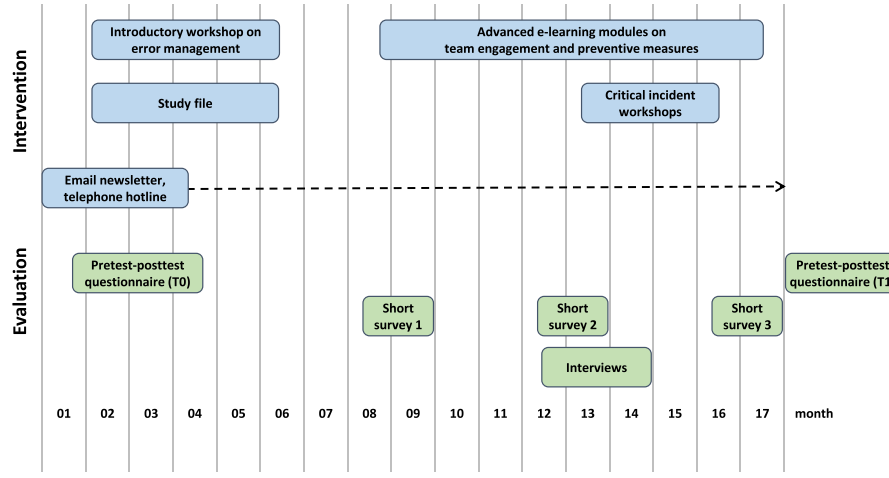

FIGURE 1. Study timeline.

of our intervention measures. The interview guide was based on our own previous work and relevant literature on the subject (see supplementary files for interview guide, http://links.lww.com/JPS/A599).[21,22,32,37] Between months 13 and 16 of the study, all practices were invited to take part in an interview. Overall, 61 persons showed interest. In the end, 2 researchers conducted telephone interviews with 40 persons from 40 different practices, whereby each interviewee was interviewed by one researcher.

Data Analysis

Pretest-Posttest Questionnaire

Answers to safety climate items were aggregated at a person level, and the mean value per person per factor was calculated ("error management" and "views on causes of errors"). We then aggregated these values at a practice level and calculated the mean value per practice per factor. Finally, the mean value was calculated across all practices per factor and for all items as an indication of the overall level of safety climate. Changes in level of safety climate over time were tested using analysis of variance with repeated measures. We set the significance level at $\alpha = 0.01$ and calculated effect sizes (classification: $\eta^2 = 0.01$: small effect size; $\eta^2 = 0.06$: medium effect size, $\eta^2 = 0.14$: large effect size).[38] The analysis of safety climate level was conducted using IBM SPSS Statistics 22. SPSS (version 22; IBM Corp, Armonk, NY, USA). Safety climate strength (rwg, reliability within groups)[39] was assessed using the "Excel 2007 Tool Microsoft Excel (version 2016; Microsoft Corporation, Redmond, WA, USA) for Computing Interrater Agreement & Interrater Reliability Estimates for Consensus Composition Constructs."[40]

Following the "PSYGIENE" study,[35] answers to psychological behavioral determinants were presented at individual item level to gain a deeper understanding of the behavioral determinants. In the analysis, we excluded 1 free-text item and 2 items that only addressed practice management. Changes in psychological behavioral determinants over time were tested using an analysis of variance with repeated measures. We set the significance level at $\alpha = 0.01$ and also assessed effect sizes. The analysis of psychological behavioral determinants was conducted using IBM SPSS Statistics 22.

Short Surveys

Answers to the short surveys were analyzed descriptively. Incident reports were anonymized and then analyzed based on a method for the assessment of significant event analysis in general practice.[15,41] For the evaluation of preventive measures after critical incidents, we used the U.S. Department of Veteran Health Affairs criteria.[42,43] Details of the analysis of incident reports have been published elsewhere.[44] The short survey analysis was conducted using IBM SPSS Statistics 22 and Microsoft Excel 2016.

Interviews

The interviews were audiotaped and transcribed verbatim. Three researchers (D.Schü., K.R., M.Po.) with knowledge of qualitative research analyzed the transcripts using thematic analysis[45] and with the support of MAXQDA 18 (by Verbi Software).

RESULTS

Practice Characteristics

Of the 184 practices, 114 were group and 67 single-handed practices. Practices were located all over the country (Fig. 2). Most were general practices (95/184 = 52%), in which the physicians were specialists in general practice or internal medicine. Ambulatory care practices from other specialties also participated, e.g., gynecology (13 practices), surgery/orthopedics (12 practices), urology (7 practices), pediatrics (6 practices), ophthalmology (5 practices), dermatology (4 practices), and anesthesiology (2 practices). Practice teams consisted of nine persons on average, of whom an average of 3 were physicians.

Overall, 172 practices (93%) completed the study, and 5 practices withdrew their consent. Of these, 4 practices canceled within the first few weeks (2 practices thought the study demanded too much time, 1 practice had agreed to participate accidentally, and in 1 practice, the practice owner did not want any information on errors in the practice to be revealed to outsiders). The fifth practice ended participation shortly before the end of the study (lack of time due to a personal crisis). Seven practices agreed to participate but then did not take part in the introductory workshop or further intervention measures.

Pretest-Posttest Questionnaire

At T0, the questionnaire was filled out by 1325 persons from 153 practices (59% of 2250 participants, 83% of practices). At T1, the questionnaire was filled out by 1035 persons from 137 practices (46% of participants, 74% of practices). Overall, 129

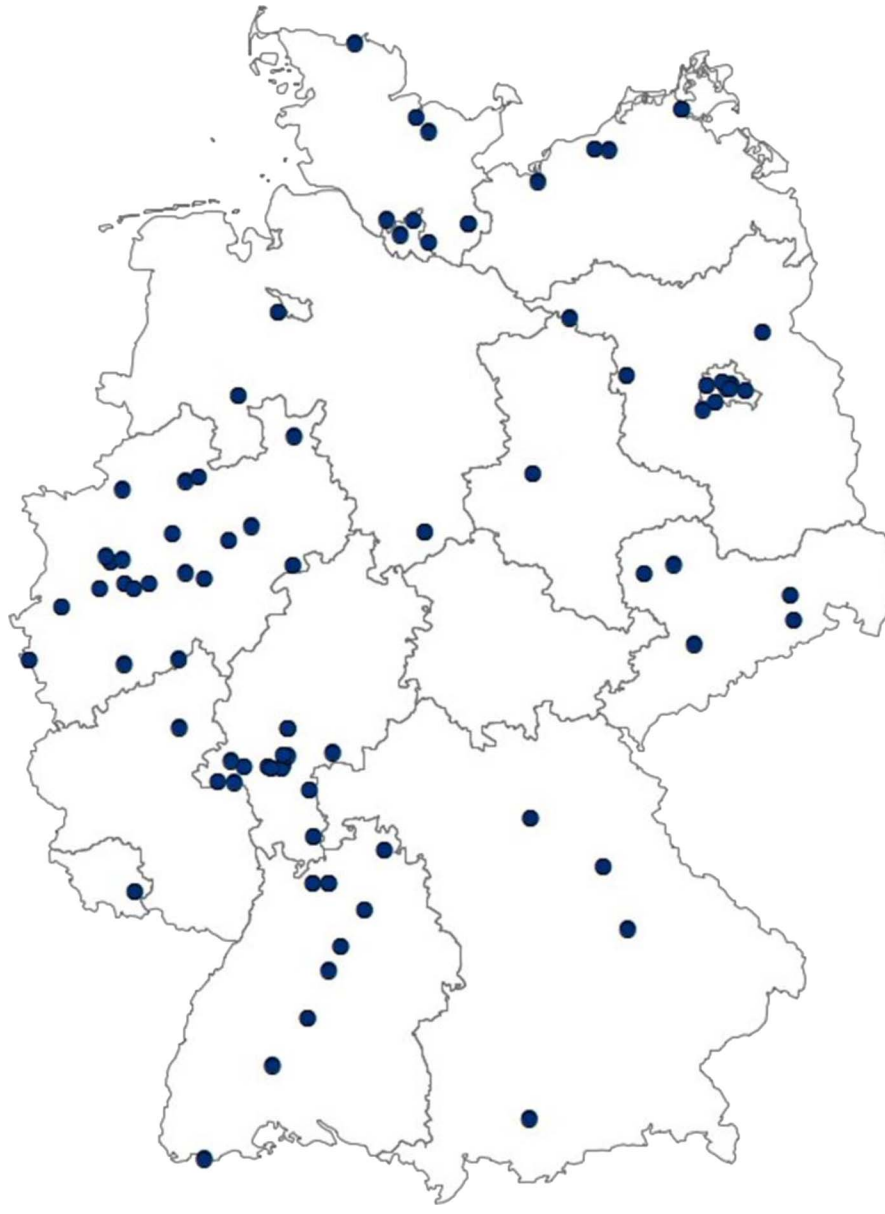

FIGURE 2. Nationwide distribution of participating practices in Germany.

practices (70%) participated in both surveys and were included in the pre-post comparison.

The overall safety climate level improved significantly and with a high effect size between T0 and T1. As shown in Table 1, safety climate strength (rwg) also increased. Changes in level and strength were mainly driven by changes in error management, while perception of causes of errors did not change significantly.

Between T0 and T1, there was significant improvement in the psychological behavioral determinants "action/coping planning" and "action control" (Table 2). This comprised, e.g., knowing how to analyze a critical incident and how to derive preventive measures, as well as having specific plans for dealing with obstacles regarding this behavior. Several behavioral determinants did not change over time, e.g., "risk perception" (perceived risk of critical incidents in the practice), "intention," "outcome expectancy" (expectation of positive or negative outcomes from analyzing critical incidents and deriving preventive measures), and "resources" (perceived appropriateness of the number of physicians or healthcare assistants in the practice).

Short Surveys

The first short survey was completed by 122 practices (66%), the second by 123 (67%), and the third by 116 practices (63%). Overall, 78 practices (42%) answered all 3 surveys (the results of these practices are shown in Table 3). The results showed that well over half the practices introduced new reporting and learning systems and that most were introduced at the beginning of the study. The exchange of information between practices, meanwhile, increased throughout the study. Sixty-six percent of practices (54% + 12%) did not use a CIRS before participating in the study, and 76% (63% + 13%) implemented a new CIRS or modified their existing system over the study period.

TABLE 1. Level and Strength of Safety Climate at T0 and T1 (129 Practices)

	T0 Mean (SD)	T1 Mean (SD)	*P*	Effect Size (Partial η^2)*	T0 rwg†	T1 rwg†
Perception of causes of errors	2.87 (0.49)	2.92 (0.58)	0.392	0.008	0.74	0.78
Error management	3.95 (0.51)	4.15 (0.58)	<0.001‡	0.146	0.84	0.89
Safety climate level, overall score	3.43 (0.26)	3.56 (0.30)	<0.001‡	0.193	0.88	0.92

*η^2 = 0.01: small effect size; η^2 = 0.06: medium effect size, η^2 = 0.14: large effect size.

‡Difference between T0 and T1 is statistically significant.

†All rwg values differ significantly from what would be expected by chance.

We received 280 incident reports from 110 practices. The reports also mentioned 243 preventive measures. For a detailed description of the reports' characteristics, please see the study by Müller et al.[44]

Interviews

We conducted 40 semistructured telephone interviews, of which 21 were with physicians and psychotherapists (P), and 19 with healthcare assistants (HCA). The interviews were conducted between March and May 2019. On average, the interviews lasted 26 minutes (min.: 7 min, max.: 52 min). In this article, we focus on feedback on the intervention measures provided by the practices.

All interviewees participated in the introductory workshop. The majority found it helpful, for example, in creating a common knowledge base for behavioral change concerning safety climate and error management.

I thought the workshop was well structured. For me personally, I learned to look for the guilty party less than I had done before, and just to analyze processes. […] To make sure you break out of the circle of thinking you have to find someone that did something wrong. That was really enlightening for me and helped me a lot. (P21)

I thought the Internet workshop was the most informative. […] that as part of the workshop you could get a grip on the basics and then, building on that step-by-step, put them into practice. (P16)

Practices used the materials provided in the study file, such as the report forms and instructions on how to arrange a team meeting. Some adopted the provided templates in their entirety, while others adapted them to suit their processes and procedures. Materials that did not provide concrete guidance for action, such as supplementary literature, were disregarded.

We used to do it rather chaotically, and then, if an error occurred, we'd make a brief note of it and talk about it afterwards - but without documenting it. And now we have the test patient, we can do it by entering things in the practice information system whenever it's necessary (P15)

Because it's written there, how you should write a report and how to deal with it. I think that probably helped us the most. (HCA07)

In the monthly info mails, the practical tips were considered to be very useful. The majority of the interviewees thought the mails ensured that the topic was not simply forgotten in the practices.

Yes, I think that's good. They're stories that make me think: "yes, it's true, it's about time I concerned myself with the CIRS," you see? That's why it makes sense. (P26)

And what we do differently, since we participated in the study—and it's one of the tips too—every practice meeting now includes an agenda item where we discuss any errors. (HCA11)

The hotline and the website were rarely taken note of or used by the practices.

DISCUSSION

Overall, 184 German ambulatory care practices with various medical specialties and an average of 3.3 physicians, as well as 5.6 other employees, participated in this study on error management and safety climate. The first part of our multicomponent intervention was an introductory workshop on error management and safety climate. Interviews with team members indicate that the workshop helped practices develop a shared understanding of safety climate and move away from a culture of blame. The evaluation results also support the assumption of a shared understanding, as safety climate strength improved significantly. It is a well-known phenomenon that the safety climate level in intervention studies increases over time, even in control groups.[15,25] We therefore used safety climate strength to assess how individuals within a practice team agreed on a perceived safety climate level.[39,46] High interrater agreement (strong safety climate) implies that it is clear what priority patient safety takes and what behavior is expected.[47,48] This is an important precondition of open discussions and shared decisions on measures to improve patient safety.

In the course of the study, we applied a nudging strategy[49] comprising regular email newsletters and further learning opportunities. In the interviews, participants rated those practical tips and concrete recommendations for action as positive, which they were able to implement swiftly in their daily work. Correspondingly, items of the behavioral determinants "action/coping planning" and "action control" improved significantly. Those determinants assess when/where/how plans related to a behavior and awareness of behavioral standards. Specifically, participants' subjective knowledge about how to analyze critical incidents and derive preventive measures improved. This was also the case in international studies that followed a similar intervention strategy.[50,51] There were also a number of behavioral determinants that did not change, for which there may be several reasons. Participants' "intentions" for analyzing critical incidents were high at the start of the study already; therefore, it was probably unrealistic to expect a further increase. Our intervention also did not aim at changing the perception of the appropriateness of "resources" like physicians and healthcare assistants. For the determinant "outcome expectancy," we can only guess why nothing changed during the study. One explanation could be that as for "intentions," values for "outcome expectancy" were high already and therefore hard to improve any further. It is also possible that these are items that take longer to change, as they are not only due to the attitude of the participants themselves, but external factors such as practice management also play a role. With regard to the behavioral determinant "risk perception," we found considerable differences between the specialties. This may have contributed to the fact that the values did not change over time. As the subgroups were too

TABLE 2. Psychological Determinants at T0 and T1, 129 Practices

Psychological Behavioral Determinants		T0 Mean (SD)	T1 Mean (SD)	*P*	Effect Size (Partial η^2)*
Risk perception					
How likely do you think it is that a critical incident will occur in your practice which causes no harm to a patient?	1 = very unlikely, 5 = very likely	3.00 (0.63)	3.10 (0.67)	0.196	0.014
How likely do you think it is that a critical incident will occur in your practice which causes harm to a patient?	1 = very unlikely, 5 = very likely	1.97 (0.48)	1.93 (0.53)	0.386	0.006
How severe is the patient harm caused by critical incidents in your practice?	1 = Not severe (negligible), 5 = very severe (life-threatening)	2.14 (0.74)	2.02 (0.75)	0.055	0.030
Outcome expectancy					
When I analyze critical incidents and derive preventive measures from my analysis …					
…then I am helping improve processes that are prone to errors in our practice.	1 = completely disagree, 5 = completely agree	4.64 (0.29)	4.59 (0.38)	0.227	0.012
…then I am helping improve patient safety in our practice.	1 = completely disagree, 5 = completely agree	4.71 (0.23)	4.65 (0.34)	0.050	0.031
…then it increases the time pressure I am under at work.	1 = completely disagree, 5 = completely agree	2.69 (0.58)	2.67 (0.73)	0.786	0.001
…then I receive recognition from my boss.	1 = completely disagree, 5 = completely agree	3.43 (0.70)	3.44 (0.80)	0.839	0.000
…then I am a role model for my colleagues.	1 = completely disagree, 5 = completely agree	3.65 (0.58)	3.71 (0.61)	0.308	0.009
When I mention critical incidents in our practice …					
…then I may have problems.	1 = completely disagree, 5 = completely agree	1.47 (0.40)	1.48 (0.51)	0.764	0.001
…then my colleagues think I'm incompetent.	1 = completely disagree, 5 = completely agree	1.40 (0.38)	1.39 (0.39)	0.769	0.001
…then my colleagues think I lack team spirit.	1 = completely disagree, 5 = completely agree	1.54 (0.47)	1.54 (0.49)	0.883	0.000
Self-efficacy expectancy					
I believe I am capable of analyzing a critical incident and of deriving preventive measures from the analysis, even if …					
…my boss does not.	1 = not true at all, 5 = absolutely true	3.82 (0.52)	3.91 (0.61)	0.157	0.016
…my colleagues do not.	1 = not true at all, 5 = absolutely true	4.21 (0.39)	4.29 (0.45)	0.103	0.022
…it takes time.	1 = not true at all, 5 = absolutely true	4.07 (0.47)	4.13 (0.51)	0.246	0.011
…my boss is not in favor of it.	1 = not true at all, 5 = absolutely true	3.28 (0.66)	3.51 (0.75)	0.005†	0.062
…it caused no harm to the patient.	1 = not true at all, 5 = absolutely true	4.17 (0.43)	4.23 (0.49)	0.260	0.010
Intention					
To what extent do you plan to analyze critical incidents?	1 = it is not my intention at all, 5 = it is my firm intention	4.43 (0.33)	4.42 (0.39)	0.880	0.000
To what extent do you plan to derive preventive measures from your analysis of critical incidents?	1 = it is not my intention at all, 5 = it is my firm intention	4.49 (0.34)	4.49 (0.36)	0.922	0.000
Action/coping planning					
Recently, I have made specific plans on …					
…how to analyze a critical incident and derive preventive measures from the analysis.	1 = not true at all, 5 = absolutely true	3.29 (0.60)	3.44 (0.53)	0.020	0.043
…how to deal with obstacles that make it difficult for me to analyze critical incidents.	1 = not true at all, 5 = absolutely true	3.25 (0.63)	3.44 (0.55)	0.004†	0.065
…how to behave if I notice that in our practice, we have forgotten to analyze a critical incident and to derive preventive measures from the analysis.	1 = not true at all, 5 = absolutely true	3.15 (0.64)	3.38 (0.54)	<0.001†	0.103
Action control					

(Continued next page)

TABLE 2. *(Continued)*

Psychological Behavioral Determinants		T0 Mean (SD)	T1 Mean (SD)	*P*	Effect Size (Partial η^2)*
I know how to analyze a critical incident and how to derive preventive measures from my analysis.	1 = not true at all, 5 = absolutely true	3.83 (0.48)	4.17 (0.42)	<0.001†	0.292
I will make sure that every critical incident that I think is important is analyzed.	1 = not true at all, 5 = absolutely true	4.07 (0.46)	4.22 (0.49)	0.002†	0.074
I have to overcome internal resistance within myself to ensure that every critical incident that I think is important is analyzed.	1 = not true at all, 5 = absolutely true	2.41 (0.62)	2.39 (0.60)	0.844	0.000
Resources					
The number of doctors in our practice is appropriate.	1 = not true at all, 5 = absolutely true	4.29 (0.64)	4.15 (0.77)	0.011	0.052
The number of nonphysician employees in our practice is appropriate.	1 = not true at all, 5 = absolutely true	3.76 (0.81)	3.71 (0.96)	0.520	0.003
Frequent problems in our practice are caused by absence (vacation, sickness, part-time work).	1 = not true at all, 5 = absolutely true	2.89 (0.86)	2.94 (0.97)	0.530	0.003
Organizational barriers					
Joint team meetings (physicians and other practice team employees) regularly take place in our practice.	1 = not true at all, 5 = absolutely true	4.34 (0.82)	4.41 (0.85)	0.212	0.013
At our team meetings, we dedicate sufficient time to talking about critical incidents and preventive measures.	1 = not true at all, 5 = absolutely true	4.01 (0.71)	4.17 (0.70)	0.008†	0.057
The nonphysician employees in our practice work very well together.	1 = not true at all, 5 = absolutely true	4.17 (0.57)	4.18 (0.60)	0.810	0.000
Physicians and nonphysician employees in our practice work very well together.	1 = not true at all, 5 = absolutely true	4.23 (0.50)	4.19 (0.53)	0.435	0.005

*$\eta^2 = 0.01$: small effect size; $\eta^2 = 0.06$: medium effect size, $\eta^2 = 0.14$: large effect size.

† Difference between T0 and T1 is statistically significant ($P < 0.01$).

small for an adequate analysis, future studies with a larger sample should examine these items in more detail.

Over the course of the study, 76% of practices implemented a new CIRS or modified their existing system. We received 280 incident reports with 243 preventive measures from 110 practices. These numbers reflect the teams' ongoing commitment, as it was neither mandatory to send in incident reports nor to implement a CIRS at all. Nevertheless, it is hard to compare our study with other studies in this regard, as settings often differ significantly. In a study with seven primary care practices in the United States, for example, all practices (100%) introduced a CIRS. However, the reimbursement the practices received for implementing such a reporting system was more than 10 times as high as in our study.[29]

Strengths and Limitations

Certain factors should be taken into account when interpreting our findings. We used existing and validated evaluation instruments as far as possible. However, since few exist, we also developed our own instruments (items on behavioral determinants and the short survey). To avoid cluttering up the pretest-posttest questionnaire with too many questions, we also decided to only use parts of the FraSiK and to apply the commonly used evaluation methodology.[33,52] This may have affected the validity and reliability of the instrument. When interpreting the results, it should also be noted that participation in the intervention measures and in the evaluation was mainly voluntary. Only participation in the introductory workshop was compulsory, with everything else being optional for the practices. Against this background, the response rates are remarkable. It is also likely that a certain commitment to error management and safety climate already existed in the practices before our study. The fact that these presumably more committed practices were able to significantly improve their safety climate and error management processes indicates major deficits in the average practice. To narrow these deficits in future

TABLE 3. Use of CIRS and the Exchange of Information Between Practices (78 Practices That Responded to All Short Surveys)

	Short Survey 1	Short Survey 2	Short Survey 3
Has the reporting and learning system in your practice changed since taking part in the study?			
Yes, we have introduced a new reporting and learning system	42 (54%)	47 (60%)	49 (63%)
Yes, we have modified our existing system	6 (8%)	9 (12%)	10 (13%)
No, we have kept our old system	21 (27%)	16 (21%)	13 (17%)
No, we don't have a reporting and learning system	9 (12%)	6 (8%)	6 (8%)
Since taking part in the study, has anyone from your practice exchanged information on error management with someone from outside the practice?			
Yes, such an exchange has taken place	18 (23%)	35 (45%)	46 (59%)
No, no such exchange has taken place	60 (77%)	43 (55%)	32 (41%)

ambulatory care practice teams, the Institute of General Practice at Goethe University Frankfurt has begun to train medical students on safety climate and error management.[53] Even though the implementation seems to have been successful at first sight, our study lacks long-term follow-up. Future randomized and controlled intervention trials should confirm the effectiveness of our multicomponent intervention.

CONCLUSIONS

In this study, we succeeded in encouraging a large number of healthcare staff to take an active interest in the generally rather unpopular topics of safety climate and error management. Our results suggest that to best support safety climate and error management in ambulatory care practices, it is important to train practice teams, to repeatedly provide them with practical tips and tools, and to facilitate the exchange of information between practices.

Our findings and the instruments we developed can serve as a blueprint for further error management and safety climate interventions, ideally in a controlled setting, with a larger sample and over a longer period to measure their long-term impact.

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REFERENCES

1. Kohn LT, Corrigan J, Donaldson MS. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000: (Quality chasm series).
2. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med*. 1991;324:370–376.
3. Leape LL, Abookire S. *World Alliance for Patient Safety: WHO Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action*. Geneva, Switzerland: World Health Organization; 2004.
4. McFadden KL, Stock GN, Gowen CR. Leadership, safety climate, and continuous quality improvement: impact on process quality and patient safety. *J Nurs Adm*. 2014;44(10 suppl):S27–S37.
5. Appelbaum NP, Dow A, Mazmanian PE, et al. The effects of power, leadership and psychological safety on resident event reporting. *Med Educ*. 2016;50:343–350.
6. Kalteh HO, Mortazavi SB, Mohammadi E, et al. The relationship between safety culture and safety climate and safety performance: a systematic review. *Int J Occup Saf Ergon*. 2021;27:206–216.
7. Parmelli E, Flodgren G, Fraser Scott G, Williams N, Rubin G, Eccles Martin P. Interventions to increase clinical incident reporting in health care: John Wiley & Sons, Ltd; 2012. doi: 10.1002/14651858.CD005609.pub2.
8. Arabi YM, Al Owais SM, Al-Attas K, et al. Learning from defects using a comprehensive management system for incident reports in critical care. *Anaesth Intensive Care*. 2016;44:210–220.
9. Fox MD, Bump GM, Butler GA, et al. Making residents part of the safety culture: improving error reporting and reducing harms. *J Patient Saf*. 2021;17:e373–e378.
10. Dowell L. Implementing a patient safety team to reduce serious incidents. *BMJ Qual Improv Rep*. 2013;2:u201086.w697.
11. Kusano AS, Nyflot MJ, Zeng J, et al. Measurable improvement in patient safety culture: a departmental experience with incident learning. *Pract Radiat Oncol*. 2015;5:e229–e237.
12. Lamming L, Montague J, Crosswaite K, et al. Fidelity and the impact of patient safety huddles on teamwork and safety culture: an evaluation of the Huddle Up for Safer Healthcare (HUSH) project. *BMC Health Serv Res*. 2021;21:1038.
13. Spencer R, Campbell SM. Tools for primary care patient safety: a narrative review. *BMC Fam Pract*. 2014;15:166.
14. Litchfield I, Marsden K, Doos L, et al. A comparative assessment of two tools designed to support patient safety culture in UK general practice. *BMC Fam Pract*. 2021;22:98.
15. Hoffmann B, Müller V, Rochon J, et al. Effects of a team-based assessment and intervention on patient safety culture in general practice: an open randomised controlled trial. *BMJ Qual Saf*. 2014;23:35–46.
16. Richtlinie des Gemeinsamen Bundesausschusses über grundsätzliche Anforderungen an ein einrichtungsinternes Qualitätsmanagement für Vertragsärztinnen und Vertragsärzte. *Vertragspsychotherapeutinnen und Vertragspsychotherapeuten, medizinische Versorgungszentren*. Vertragszahnärztinnen und Vertragszahnärzte sowie zugelassene Krankenhäuser: Qualitätsmanagement-Richtlinie/QM-RL; 2015.
17. Kassenärztliche Bundesvereinigung. Statistische Kerndaten aus dem Bundesarztregister zum Stichtag 31.12.2020; 2021. Available at: https://www.kbv.de/html/bundesarztregister.php#content6889. Accessed May 31, 2022.
18. Morello RT, Lowthian JA, Barker AL, et al. Strategies for improving patient safety culture in hospitals: a systematic review. *BMJ Qual Saf*. 2013;22:11–18.
19. Kassenärztliche Bundesvereinigung. *Qualitätsbericht 2020*. Berlin: KBV; 2021. Available at: https://www.kbv.de/html/1748.php. Accessed May 31, 2022.
20. Falcone ML, van Stee SK, Tokac U, et al. Adverse event reporting priorities: an integrative review. *J Patient Saf*. 2022;18:e727–e740.
21. Gruber D, Blazejewski T, Beyer M, et al. Fehlermanagement in der ambulanten Praxis. Fokusgruppen mit Ärztinnen, Ärzten und Medizinischen Fachangestellten: Error Management in Outpatient Settings. Focus Groups Involving Physicians and Medical Assistants. *Z Allg Med*. 2018;94:110–115.
22. Müller BS, Beyer M, Blazejewski T, et al. Improving critical incident reporting in primary care through education and involvement. *BMJ Open Qual*. 2019;8:e000556.
23. Rea D, Griffiths S. Patient safety in primary care: incident reporting and significant event reviews in British general practice. *Health Soc Care Community*. 2016;24:411–419.
24. Mandavia R, Yassin G, Dhar V, et al. Completing the audit cycle: the impact of an electronic reporting system on the feedback loop in surgical specialties. *J Healthc Qual*. 2013;35:16–23.
25. Verbakel NJ, Langelaan M, Verheij TJ, et al. Effects of patient safety culture interventions on incident reporting in general practice: a cluster randomised trial. *Br J Gen Pract*. 2015;65:e319–e329.
26. Ameryoun A, Pakpour AH, Nikoobakht M, et al. Effectiveness of an in-service education program to improve patient safety directed at surgical residents: a randomized controlled trial. *J Surg Educ*. 2019;76:1309–1318.
27. Jeffs L, Hayes C, Smith O, et al. The effect of an organizational network for patient safety on safety event reporting. *Eval Health Prof*. 2014;37:366–378.
28. Sendlhofer G, Leitgeb K, Kober B, et al. The evolution of the critical incident reporting system in an Austrian university hospital [in German]. *Z Evid Fortbild Qual Gesundhwes*. 2016;114:48–57.
29. Crane S, Sloane PD, Elder N, et al. Reporting and using near-miss events to improve patient safety in diverse primary care practices: a collaborative approach to learning from our mistakes. *J Am Board Fam Med*. 2015;28:452–460.

30. Mansfield JG, Caplan RA, Campos JS, et al. Using a quantitative risk register to promote learning from a patient safety reporting system. *Jt Comm J Qual Patient Saf*. 2015;41:76–86.
31. Colquhoun HL, Squires JE, Kolehmainen N, et al. Methods for designing interventions to change healthcare professionals' behaviour: a systematic review. *Implement Sci*. 2017;12:30.
32. APS e.V. Handeln bevor etwas passiert. Berichts- und Lernsysteme erfolgreich nutzen. *Handlungsempfehlung für ambulante Einrichtungen im Gesundheitswesen*. Berlin; 2018. Available at: https://www.aps-ev.de/wp-content/uploads/2018/04/APS_HE_CIRSambulant_web.pdf. Accessed May 31, 2022.
33. Hoffmann B, Domanska OM, Albay Z, et al. The Frankfurt Patient Safety Climate Questionnaire for General Practices (FraSiK): analysis of psychometric properties. *BMJ Qual Saf*. 2011;20:797–805.
34. Schwarzer R. Modeling health behavior change: how to predict and modify the adoption and maintenance of health behaviors. *Appl Psychol*. 2008; 57:1–29.
35. von Lengerke T, Lutze B, Krauth C, et al. Promoting hand hygiene compliance. *Dtsch Arztebl Int*. 2017;114:29–36.
36. van Someren MW, Barnard YF, Sandberg JA. *The Think Aloud Method: A Practical Guide to Modelling Cognitive Processes*. London: Acad Press; 1994.
37. Curran C, Lydon S, Kelly ME, et al. An analysis of general practitioners' perspectives on patient safety incidents using critical incident technique interviews. *Fam Pract*. 2019;36:736–742.
38. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. 2nd ed. Hillsdale, NJ: Erlbaum; 1988.
39. Ginsburg L, Gilin Oore D. Patient safety climate strength: a concept that requires more attention. *BMJ Qual Saf*. 2016;25:680–687.
40. Biemann T, Cole MS, Voelpel S. Within-group agreement: on the use (and misuse) of rWG and rWG(J) in leadership research and some best practice guidelines. *Leadersh Q*. 2012;23:66–80.
41. McKay J, Murphy DJ, Bowie P, et al. Development and testing of an assessment instrument for the formative peer review of significant event analyses. *Qual Saf Health Care*. 2007;16:150–153.
42. Hibbert PD, Thomas MJW, Deakin A, et al. Are root cause analyses recommendations effective and sustainable? An observational study. *Int J Qual Health Care*. 2018;30:124–131.
43. VHA National Center for Patient Safety. Guide to performing a root cause analysis: REV 02.05.2021; 2021 . Available at: https://www.patientsafety.va.gov/docs/RCA-Guidebook_02052021.pdf. Accessed May 31, 2022.
44. Müller BS, Lüttel D, Schütze D, et al. Strength of safety measures introduced by medical practices to prevent a recurrence of patient safety incidents: an observational study. *J Patient Saf*. 2022;18:444–448.
45. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006;3:77–101.
46. Mascherek AC, Schwappach DLB. Patient safety climate profiles across time: strength and level of safety climate associated with a quality improvement program in Switzerland—a cross-sectional survey study. *PloS One*. 2017;12:e0181410.
47. Bliese PD, Halverson RR. Group consensus and psychological well-being: a large field study 1. *J Appl Soc Pyschol*. 1998;28:563–580.
48. Tawfik DS, Thomas EJ, Vogus TJ, et al. Safety climate, safety climate strength, and length of stay in the NICU. *BMC Health Serv Res*. 2019; 19:738.
49. Thaler RH, Sunstein CR. *Nudge: Improving Decisions About Health, Wealth, and Happiness. Rev. and Expanded ed., with a New Afterword and a New Chapter*. New York, NY: Penguin; 2009.
50. Louis MY, Hussain LR, Dhanraj DN, et al. Improving patient safety event reporting among residents and teaching faculty. *Ochsner J*. 2016;16:73–80.
51. Krouss M, Alshaikh J, Croft L, et al. Improving incident reporting among physician trainees. *J Patient Saf*. 2016;15:308–310 Available at: URL: https://sp0002.dst.tk-inline.net/teamraeume/10179/CIRSforte_AP1_ArtikelBeschaffung/27617963.pdf.
52. Hoffmann B, Miessner C, Albay Z, et al. Impact of individual and team features of patient safety climate: a survey in family practices. *Ann Fam Med*. 2013;11:355–362.
53. Sawicki OA, Müller A, Pommée M, et al. Design and evaluation of a preclinical medical elective titled "Safety culture in healthcare: every error counts!". *Z Evid Fortbild Qual Gesundhwes*. 2021;161:57–62.