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Research Article

Quality management and safety culture in medicine – Do standard quality reports provide insights into the human factor of patient safety?

Qualitätsmanagement und Sicherheitskultur in der Medizin – Findet der „Human Factor“ für Patientensicherheit Berücksichtigung in standardisierten Qualitätsberichten?

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Abstract

In 1999 the Institute of Medicine (IOM) published the landmark report “To err is human: building a safer healthcare system” highlighting critical deficiencies within the area of patient safety. As a consequence, safety culture evolved as a core component of quality management in medicine. Purpose of the investigation at hand was to find out to what extent this is reflected in standard quality reports issued by German hospitals providing maximum medical care. Reports issued for the year 2006 were analysed with respect to the appearance of indicators for the presence of a safety culture. Results suggest that despite the huge awareness for patient safety caused by the IOM report, the topic of safety culture does not get the anticipated attention within the quality reports. This may indicate that the current requirements for the quality reports do not facilitate transparency when it comes to the human factor of patient safety.

Keywords: safety culture, error culture, error elasticity, patient safety, quality management, quality report

Zusammenfassung

Mit der Publikation von „To err is human: building a safer health care system“ hat das Institute of Medicine (IOM) 1999 in den USA auf grundlegende Mängel in Zusammenhang mit Patientensicherheit aufmerksam gemacht. In der Konsequenz ist Sicherheitskultur zu einem essentiellen Teil des Qualitätsmanagements geworden. Die vorliegende Untersuchung beschreibt die Analyse von Qualitätsberichten deutscher Krankenhäuser der Maximalversorgung für das Jahr 2006 hinsichtlich des Auftretens von Indikatoren für das Vorhandensein einer Sicherheitskultur. Die Ergebnisse zeigen, dass relativ zur großen Aufmerksamkeit für den Bericht des IOM und damit verbunden für Sicherheitskultur, dieses Thema noch unterrepräsentiert ist in der Dokumentation von Qualität. Eine mögliche Ursache dafür könnte in der fehlenden Spezifikation von Anforderungen für einen Standard bezüglich des „Human factor“ und der Patientensicherheit liegen.

Schlüsselwörter: Sicherheitskultur, Fehlerkultur, Fehlerelastizität, Patientensicherheit, Qualitätsmanagement, Qualitätsberichte

Introduction

With the publication of “To err is human: building a safer health care system” and an estimate of up to 98.000 death per year due to treatment errors, the Institute of Medicine in 1999 not only highlighted substantial deficiencies in patient care but also raised public awareness for the meaning of patient safety for quality in medicine [1]. During the following years this report triggered various international projects at the World Health Organization (WHO – World Alliance on Patient Safety), the Organization for Economic Cooperation and Development (OECD –

Health care quality indicator project), and the European Union (European Commission on public health – SImPatIE: Safety improvement for patients in Europe), with the common objective to improve patient safety. In line with a core postulation of the IOM report, safety culture is included as an integral part into the scope of these initiatives. The most recent international project, the European Network for Patient Safety (EuNETPaS), a collaboration of all 27 EU-countries also mentions "promoting a culture of patient safety" as one of 5 focus areas and puts it first on its list of priorities. Taken together, it is well recognized that safety culture is pivotal for quality in medicine and that "patient safety encompasses...the attributes of organizations that help guard against harm and enable rapid recovery when risk escalates" [2].

Background

Generally spoken, the term "safety culture" refers to an "organizational culture focused on safety objectives". Even though "safety culture" is a widely and frequently used term, so far no common definition of it exists [3]. "Researchers tend to use safety culture, safety climate and perhaps safety management interchangeably, as the terms are not so clear cut" [4]. According to the "European Society for Quality in Health Care" safety culture is defined as follows: "Culture of safety: an integrated pattern of individual and organizational behavior, based upon shared beliefs and values, that continuously seeks to minimize patient harm which may result from the processes of care delivery" [5]. In German, it is common practice to also use the word "error culture" analogue to safety culture. Taking the definition provided by the "Physicians centre for quality in medicine" as a basis, "error culture" represents a revised management of error away from a superficial reactive culture of blame towards a system oriented proactive safety culture [6]. Along this line, the German "Advisory Council for the Concerted Action in Health Care" demands systematic and prospective error management to become an attribute for quality in medicine (new error culture) which can overcome the notion of physician's infallibility, and the tendency to search for a single guilty individual [7].

Donald Berwick indicated already in 1989 that a "Theory of bad apples" is improper to address issues in quality and to support continuous improvement in health care [8]. Instead, the phenomenon of "human error" in medicine does require a far more sophisticated view which, based on the work by J. Reason, needs to differentiate between active failures of individuals and latent conditions hidden within the organization. His concept of safety culture is based on attitudes, values, and beliefs of people supported by appropriate infrastructure to manage data and system information [9]. Findings from investigations into real world examples like the "Bristol Royal Infirmary Inquiry" provide further evidence that "the culture of the future must be a culture of safety and of quality; a culture of openness and of accountability; ... a culture in which collaborative teamwork is prized" [10].

All together, the acceptance for applying human factor theory and system thinking to quality management in medicine has dramatically increased over the last decade, a fact that is reflected in the following statement of the Insitute of Medicine: "More commonly, errors are caused by faulty systems, processes and conditions that lead people to make mistakes or fail to prevent them" [11] This is also in line with Schrappe, who demands the integration of safety culture into the self-image of hospitals [12].

An organization's safety culture can be evaluated by using specific questionnaires. In addition, the presence of incident reporting systems, specific measures like crew resource management or high reliability trainings adopted from high reliability theory and other activities in conjunction with risk or error management can be used as implicit (indirect) indicators for the existence of a culture of safety [13], [14], [15]. Mearns et al. are referring to indirect indicators as a source of information about safety culture and argue: "The extent to which these factors are found to be in tune with each other may determine whether or not an organization has a positive safety culture" [16].

From a regulatory point of view, the German Health Care Reform 2000 already included comprehensive measures for quality assurance in hospitals. The following "Fallpauschalengesetz (DRG law)" in 2002 obligates all accredited hospitals to publish biannual quality reports (initially in 2005 for the prior year 2004) based on common standards. Objectives and metrics used in these quality reports were determined by the federal joint committee in 2004 and documented in the "Declaration according to § 137 Abs. 1 Satz 3 Nr. 1 SGB V on the basic requirements for a quality management for hospitals accredited in compliance with § 108 SGB V". The aim of the quality reports is to provide patients, sick funds, and referring physicians with orientation regarding health services offered and their corresponding quality. Furthermore, quality reports are expected to promote comparability between individual hospitals in relation to major quality dimensions [17]. While not demanding pre specified activities for risk and error management, both are mentioned explicitly in the outline for the quality reports issued by the "Gemeinsamer Bundesausschuss".

Given that safety culture has been identified and widely accepted as a major contributor to quality in medicine, one would expect documentation on this matter within hospital quality reports. However, as of today there is no knowledge to what extent these reports provide insights into the status quo of safety culture in Germany. The aim of the research at hand therefore is to analyze the 2006 hospital quality reports with respect to their informative value about the extent to which safety culture did find its way into routine quality management efforts. Based on that, first and of course preliminary conclusions on the awareness for the importance of safety culture as a key component of quality management in German hospitals are drawn.

Methodology

An initial assessment of the quality reports was performed by using safety culture, error culture and error management as search items in order to gain an understanding for the prevalence of explicit mentioning of safety culture and related concepts within the quality reports. Mortality and morbidity conferences, while not named specificly in the context of safety culture, were also included in the initial assessment, acknowledging their long tradition in assessing outcomes and treatment related adverse events including potential error [18].
In a second step a literature research was conducted in order to identify indicators which either allow for directly measuring safety culture (direct indicators), or which qualify as implicit measures (indirect indicators) for safety culture [19], [20].
As a result of this, the following methods for the direct assessment of safety culture were identified (e.g. [20]):

- ORMAG – Operating room management attitudes questionnaire
- SAQ – Safety attitudes questionnaire
- SLOAPS – Strategies for leadership: An organizational approach to patient safety
- PSCHO – Patient safety cultures in healthcare organizations
- VHA PSCQ – Veterans administration patient safety culture questionnaire
- HSOPS – Hospital survey on patient safety
- CSS – Culture of safety survey
- SCS – Safety climate survey
- MSSA – Medication safety self assessment
- HTSSCS – Hospital transfusion service safety culture survey
- HSPSC – Hospital survey on patient safety culture
- MaPSaf – Manchester patient safety framework

Indirect indicators for safety culture can be divided into tools for organizational development/teamwork and more technical tools for capturing or analyzing data related to incidents. For the first category the literature search yielded to the following findings (e.g. [21], [22]):

- CRM – Crew resource management
- ACRM – Anaesthesia crisis resource management
- TOMS – Team oriented medical simulator
- HRT – High reliability teams

Technical tools to collect safety relevant data are:

- CIRS – Critical incident reporting system [23]
- ICUSRS – ICU safety reporting system [24]
- CIRS medical – Reporting system AEZQ (http://www.cirsmedical.de/)
- PaSIS – Patient safety information system [25]
- PaSOS – Patient safety optimization system (https://www.pasos-ains.de/indexSSL.php)
- CIRS DGCH – http://www.dgch.de/de/cirs/index.html

Complementary to these data management applications used for incident reporting, a number of risk and error analysis tools exist which can also serve as indirect indicators for the existence of safety culture. In the literature, the following tools are mentioned:

- FMEA – Failure mode and efficiency analysis [26]
- FTA – Fault tree analysis [26]
- RCA – Root cause analysis [27]
- ERA – Error and risk analysis [28]
- HRA – Human reliability analysis [29]
- HAZOP – Hazard and operability study [30]
- SHERPA – Systematic human error reduction and prediction approach [30]
- PHA – Proactive hazard analysis [31]
- HFMEA – Healthcare failure mode and effect analysis [31]
- HACCP – Hazard analysis and critical control points [31]
- HVA – Hazard vulnerability analysis (Joint commission on accreditation of healthcare organizations 2002, http://www.jointcommission.org/)

The direct as well as the indirect indicators for safety culture served as a basis for the analysis-matrix that was compiled to evaluate the quality reports with respect to the appearance of indicators for safety culture.
In order to identify chapters relevant for “safety culture” the standard structure of the reports was reviewed. The reports themselves are divided into 4 subsections. Whilst chapter A and B are concentrated on structural and procedural data (e.g. number and type of wards, number of beds, number of specific interventions...), chapter C (measures and projects on quality assurance in the hospital) and D (internal quality management, e.g. systematic strategies and measures to support continuous improvement) are explicitly focused on the documentation of the implementation of quality management in hospitals. Consequently only chapters C and D of the quality reports were analyzed in terms of their reference to direct and indirect indicators of safety culture. Figure 1 summarizes the signal steps of the methodological procedure.
To minimize any potential for selection bias due to disease specialization only quality reports of hospitals providing maximum medical care (N=96, source: IMS 2007) were considered. Since the presented data are based on an analysis of published quality reports and not on information collected specificly on safety culture in the hospitals themselves, conclusions on the current distribution of safety culture within the present paper remain preliminary and have do be interpreted with precaution.

Results

Figure 2 shows the results of the initial search within the quality reports using the key words “safety culture”, “error culture”, “error management” and “morbidity/mortality conferences”.
As can be seen in Figure 2, only seven (7%) of all hospitals explicitly mentioned “safety culture” as an integral part

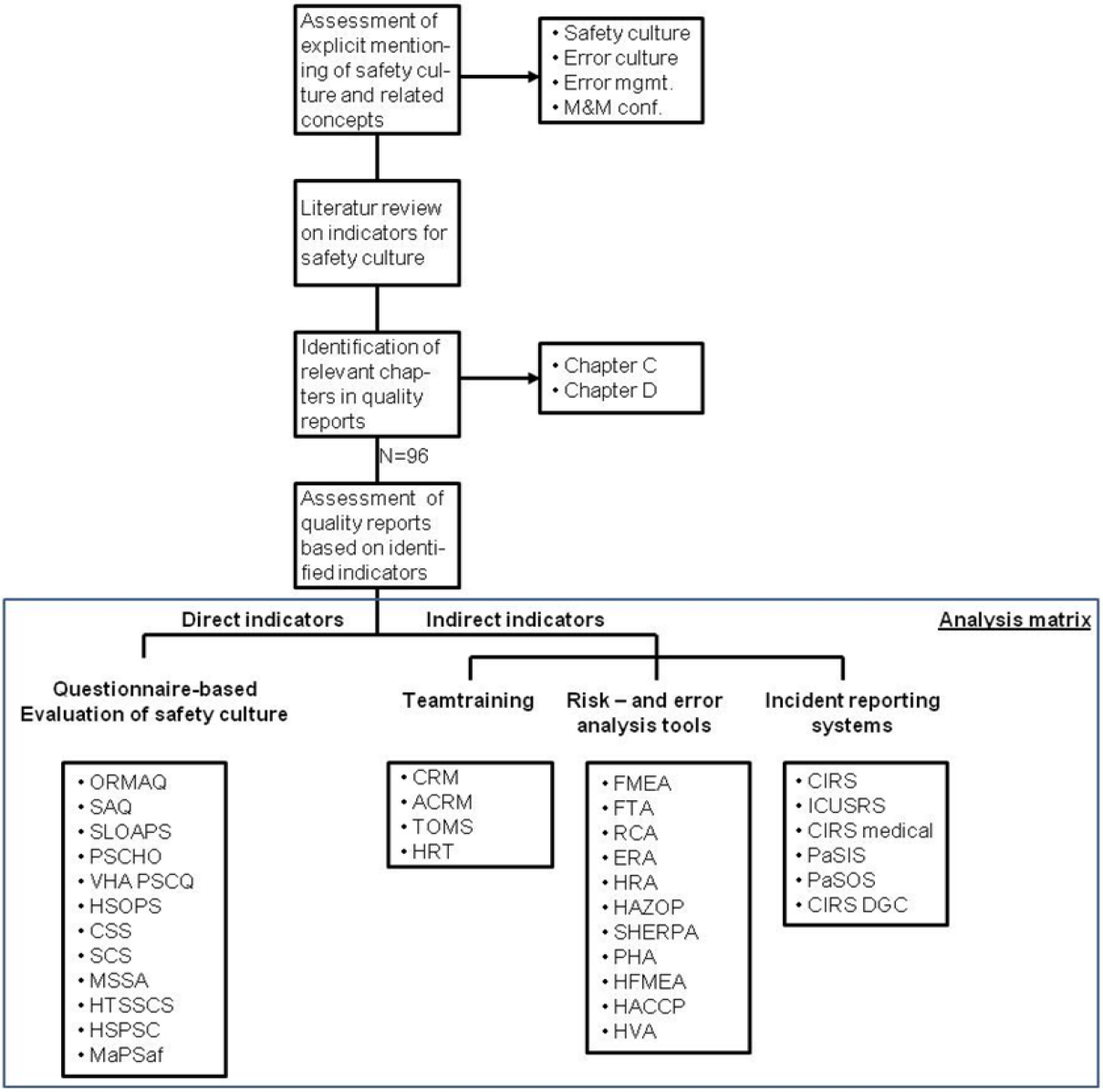

Figure 1: Sequence of steps performed to assess the quality reports with respect to the appearance of indicators for safety culture

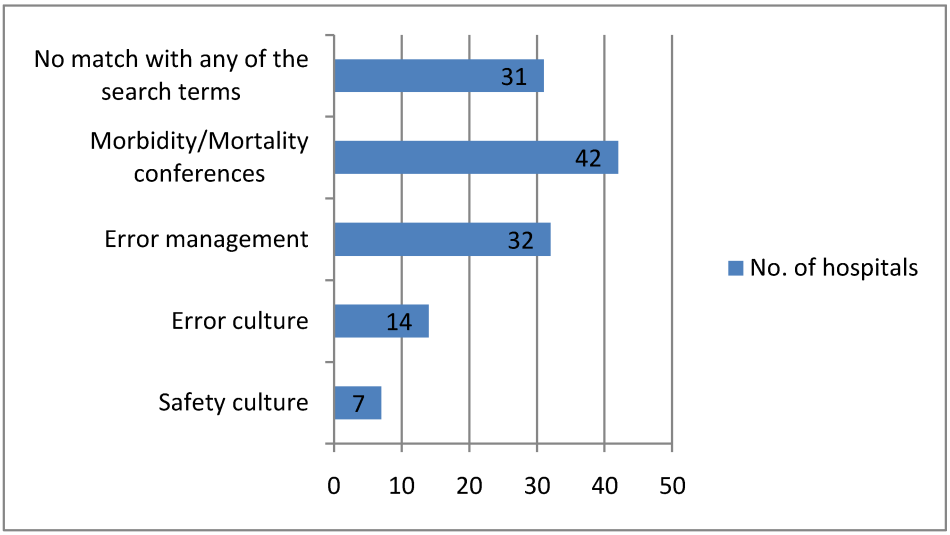

Figure 2: Frequency of occurence for any of the key words within the sample (multiple occurrence per institution possible)

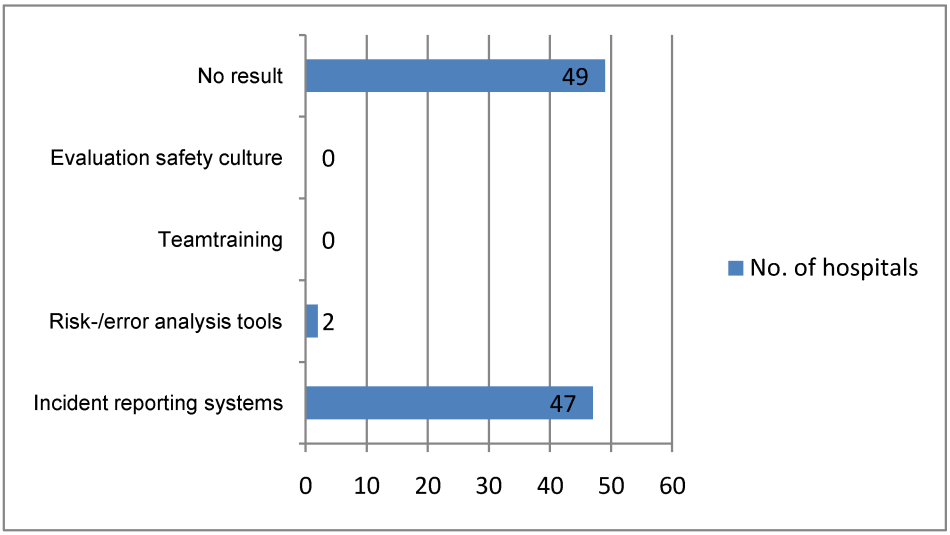

Figure 3: Number of hospitals naming individual indicators for safety culture (total exceeds 96 since risk management tools were documented in hospitals with incident reporting)

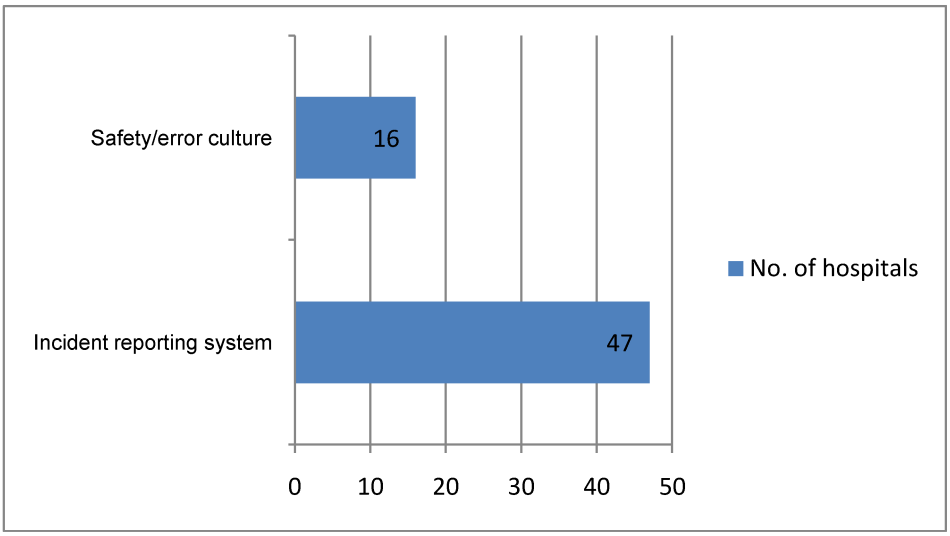

Figure 4: Frequency of safety/error culture mentioned in hospitals with incident reporting systems

of their quality assurance. Both other search terms, "error culture" (14 hospitals/15%) and "error management" (32 hospitals/33%), were represented more frequently. Most commonly mentioned terms were "morbidity/mortality conferences" with a frequency of 44% (42 hospitals). 31 hospitals or 32% of the sample did not refer to any of these search items. The distribution of direct and indirect indicators according to the analysis matrix is shown in Figure 3.

According to the results presented in Figure 3, evaluation of safety culture as a direct measure based on specific questionnaires was not mentioned in any of the quality reports. Among the indirect indicators incident reporting systems turned out as the most prominent tool and were listed in 47 hospitals or 49% of the quality management reports as part of the quality assurance efforts. Only two hospitals (2%) are naming specific risk management tools in their reports. None of the investigated quality reports did refer to teamtraining activities identified as indirect indicators for safety culture. More than half of the reviewed reports (49 or 51%) did not make reference to any of the listed indicators for safety culture.

Matching the mentioning of CIRS against the explicit reference to safety culture within the quality reports lead to the following result: Amongst hospitals which use reporting systems a significant proportion (66%) did not explicitly adress "safety culture" or "error culture" in their quality report (Figure 4).

Discussion

Along with the DRG legislation 2002 went the decision to introduce standardized quality reports for German Hospitals. With respect to structural data and simple quantifiable parameters, such as an outline of the overall organization, number of beds, number of patients, frequency of specific interventions, the documentation instructions issued by the "Federal joint committee" in 2004 are characterized by a high degree of clarity and

specifity. Contrary to this, the requirements for the quality management relevant chapters C (quality assurance) and in particular D (quality management) are less explicit in terms of information mandatory to be included. As a consequence, the content of these chapters, in particular chapter D, comprises much more of individual initiatives by hospitals than of documentation standards which would allow for benchmarking implemented measures with prespecified reference values.

Our analysis revealed an incidence of 7% for the term "safety culture", or a total incidence of 20% when considering the synonym "error culture" within the quality reports of the investigated sample. Compared to the combined frequency of occurrence of 20% for the search terms safety/error culture, the appearance of the more general term "error management" was higher with 33% indicating an overall awareness for the need to adress error in at least one third of the hospitals. Most frequently the latter term was mentioned in association with incident reporting systems and/or the use of mortality and morbidity conferences. None of the other indirect indicators for safety culture turned out to play a significant role in this sample. From the authors' point of view, this finding may imply that the information value of the reports with respect to the issue of safety culture is not sufficient. At the same time, it seems plausible to conclude that the basic requirements from the IOM report did not evoque an unsolicited or sustainable response in the sense of documented activities related to safety culture for the majority of investigated hospitals.

One could argue that the frequent mentioning of incident reporting proofs the latter hypothesis wrong, in particular since available evidence on the use of critical incident reporting systems (CIRS) suggests that "high reporting rates may be indicators of a positive safety culture" [32]. However, even in the category of hospitals mentioning CIRS or any other reporting system 31 out of 47 (66%) neither refer to safety culture nor to error culture in their quality reports. As a consequence, it remains unclear whether or not the introduction of CIRS was accompanied by an awareness for the meaning of safety culture or not. This is of special importance since available evidence indicates that incident reporting systems tend to remain ineffective when implemented as an isolated measure [33], [7], [34]. Along the same line Barach et al. state that "management attitudes and institutional climate can greatly influence the success or failure of reporting efforts" [35]. Aside from the predominantely missing reference to safety culture, any referral to compliance with the incident reporting systems or information on the frequency of incidents being documented was lacking. Without that information, there is no reliable foundation for using the acceptance of documenting incidents as a sign for safety culture or for benchmarking the implementation across different hospitals based on the quality reports.

The frequent mentioning of morbidity and mortality conferences as a more traditional approach for assessing performance and outcomes can also not reduce the impression of a limited awareness for the concept of safety culture. While these conferences can be seen as an ambition to investigate causes of error, it needs to be taken into consideration that they do suffer from some potential limitations. In particular, a narrow focus on individual performance rather than system thinking as well as hindsight bias and search for error instead of focusing on error promoting conditions are to be mentioned as weaknesses of that tool [36]. Further constraints are caused by the high variance in the understanding of how to adequately perform morbidity and mortality conferences. This fact is stressed by Aboumatar et al. according to whom "there is wide variation in how morbidity and mortality conferences are conducted across departments and little conformity to known models for analyzing medical incidents" [37].

A possible explanation for the poor consideration of safety culture and its direct and indirect indicators within quality reports may be that the prevailing understanding of quality is still based on a perception of error as an event happening at the sharp end, while latent or system-based issues remain in the background. This interpretation is supported by the fact that none of the investigated hospitals reported specific measures on teamtraining within the context of safety and risk management. Similarly, any mentioning of questionnaires for a systematic evaluation of safety culture is missing. Another potential explanation for this observation might be a preference to focus on quantifiable measures. Opportunities for improvement above and beyond the focus on numerical metrics was already expressed in a study bei Geraedts et al. who were looking at patient and physician opinion of the reported quality indicators [38]. In line with that, Reason highlights that "the corollary in healthcare institutions is a singular focus on critical numerical indices. Hospital managers live by numbers but they do not always appreciate their limitations" [34]. Culture as a soft factor for performance is less tangible and carries an element of uncertainty which people may want to escape through hiding themselves behind numerical metrics.

All in all, the findings from the analysis at hand are comparable to the results of the "Krankenhausbarometer 2008" . According to that survey, about 31% of all hospitals in Germany do use at least to some extent some sort of risk management systems. That number fits well with the identified 33% of hospitals referring to error management in their quality reports in the present study. However, the "Krankenhausbarometer" does not mention "safety culture" at all. Apart from that, according to the "Krankenhausbarometer 2008", the most frequently reported tool mentioned within the context of risk management was complaints management (90.9% of all hospitals with risk management) [39]. This high reliance on complaints management is thought-provoking, since previous research suggests that the reliability of patient information on medical error is rather limited, an issue which is raised by Tanne with reference to study findings: "More than half the incidents reported by patients were problems with the service rather than medical error" [40]. In

light of this, complaints management rather qualifies as an indicator for efforts regarding patient satisfaction than efforts for patient safety.

The preceding analysis leads us to the notion that despite all efforts, the matter of safety culture has not reached a level of awareness which automatically would translate into explicit reference and/or corresponding strategies/tactics in standard quality reports in Germany. In view of the high relevance of the human factor for safety in health care, it seems to be critically important to substantially improve the content of the quality reports through specifying requirements on risk and error management and in particular to offer a framework for establishing safety culture. A concrete example for that is provided by "The Joint Commission for Accreditation of Healthcare Organizations (JCAHO)" in the US, who integrated an annual assessment of safety culture in 2007 in their objectives on patient safety. Further guidance could also be taken from the NHS in the UK based on the work of the National Patient Safety Agency (NPSA). Building a safety culture is the first step in their program "Seven steps to patient safety" and corresponding tools for implementation are available online (http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/?entryid45=59787).

In line with the final report from the SymPaTIE project the authors of the present paper conclude that it can be considerd indisputable that "Patient safety management is a clear distinguishable, but inseperable part of our quality management system, that should be part of our normal management and leadership system, both professional and managerial" [41]. This in mind only the combination of technical skills with an appropriate safety culture acknowledging human failability and favouring patient safety will translate into error elasticity [42] as a concept for preventing harm to patients.

In light of this, a revision of the current requirements for the quality reports issued by German hospitals might be worth to be considered. As stated by the Institute of Medicine: "Setting and enforcing explicit standards for safety through regulatory and related mechanisms, such as licensing, certification, and accreditation, can define minimum performance levels for health care organizations and professionals" [10].

Notes

Conflicts of interest

None declared.

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