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Critical Incident Reporting System (CIRS): a fundamental component of risk management in health care systems to enhance patient safety

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Abstract

Background: The complexity of health care systems, the development of clinical approaches, and both scientific and technological advancements give rise to new requirements in clinical risk management. An expedient risk management is expected to deal with as many risks as possible to ensure patient safety. A prerequisite for a clinical risk management is a well-functioning error-reporting culture in health care organizations. The present study analysed the relationship between the Critical Incident Reporting System (CIRS) and patient safety. In particular, the aim of this work is to evaluate whether data from available sources provide sufficient evidence for the utility of CIRS and to derive recommendations for both theorists and practitioners. On paper, CIRS is expected to be useful in clinical settings because it allows the identification of weak spots, hazards, and critical situations such as 'near misses'. However, neither a general CIRS database based on clinical reports exists nor a universal CIRS policy or CIRS direction has been established so far, which can be attributed to the inhomogeneity of the literature and the variability of approaches. Therefore, ordering and analysis of clinical reports are highly desirable.

Methods: First, inclusion criteria, exclusion criteria, and keywords were defined to collect studies, reviews, and other sources on CIRS from official databases. After the collection of appropriate articles, a description of the individual data is given. Then, data are classified into different sections based on their respective central statements, and a brief description is given. Finally, the reports are analysed in order to detect patterns and differences.

Results: There is a close correlation between the establishment of CIRS in a health care organization and patient safety, although a quantitative relationship between reporting systems and safety is still unproven. CIRS allows the identification and implementation of appropriate actions and strategies toward patient safety. Several prerequisites were identified: top management commitment, transparency, training, anonymity, incentives, and an open error-reporting culture. Personnel have an important impact on the reduction of risk and on the development of safety. The leadership should accept the implementation of a "no blame" error and feedback culture and the security of an absolutely anonymous reporting system. The position of a risk or safety manager is highly recommended.

Conclusion: As immediate recommendations, health care organizations are encouraged to adopt CIRS. On the other hand, several research topics were identified, such as the quantitative relationship between CIRS and safety or the development of reliable incident-reporting indices and the ways on how to deal with them. Intensified empirically based research may help in answering open questions concerning CIRS.

Keywords: Critical Incident Reporting System, Clinical risks, Literature review, Patient safety, Risk management

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Background

A pivotal task in health care systems is to provide the best possible diagnosis and treatment of specific diseases. However, an increase in complexity, both time and cost pressure, and workload in conjunction with novel medical technologies may turn health care institutions and organizations into high-risk areas, suggesting risks for patients, negative consequences for health care organizations, and an increase of cost. A study by the Institute of Medicine [1] in 1999 has shown that between 44,000 and 98,000 Americans per year are dying due to avoidable errors in medication. For the first time, medical attendance errors are placed within the list of the ten most frequent causes of death before breast cancer or traffic accidents. Therefore, it is obvious that processes and even staff in the health care sector can be regarded as a source of risk. On the other hand, based on existing ethical policies and legal regulations, health care institutions and organizations are to regain and maintain patient confidence [2]. Therefore, they have to align processes and courses of action for the benefit of patients. To avoid risky measures, the implementation of a well-developed clinical risk management in conjunction with a "no blame" mission is one of several options in this optimization process.

In Germany and Austria, a matured error-reporting culture is not fully developed [3]. The establishment of a well-functioning error-reporting culture in health care institutions and organizations is often hampered by staff, which can be attributed to the fear of financial and personal consequences. More transparency in risk reduction processes in health care institutions and organizations is highly desirable [4]. In this context, several issues must be addressed:

- The creation of a combined illustration of international results concerning voluntary incident-reporting systems such as the Critical Incident Reporting System (CIRS)
- Verbalization of international, European, and national risk management requirements in health care facilities
- Illustration of current quantitative and qualitative data concerning avoidable errors and frequency of errors, as well as damage to health with lethal consequence in relation to therapy and health care

The aim of this study is (i) to provide an overview on CIRS and its utility in clinical risk management; (ii) to gain insight in the institutional CIRS implementation processes, i.e. to provide a generic direction on how an efficient and sustainable adoption of CIRS in a clinical organization can be achieved; and (iii) to investigate the relationship between the CIRS application and patient safety.

Methods

Currently, neither national nor international reviews on CIRS exist. Therefore, a systematic literature review of available public sources was conducted in order to ascertain the impact of CIRS on clinical risk management and patient safety. A systematic review is expected to reduce the operator bias concerning the selection of relevant studies in comparison to a more conventional narrative literature review. The literature search was done in relevant literature databases including CINAHL, Cochrane Library, Google Scholar, MEDLINE, PubMed, and Thieme e-book library using a varying combination of German and English keywords (Table 1) between October 28, 2014, and May 25, 2015.

After this, predetermined exclusion criteria were used in order to identify and select the most relevant sources, which resulted in a core set of articles, paper, books, 'grey literature', etc. for data synthesis and analysis. In addition, the remaining abstracts of articles and full texts which were not taken into the core set were read for substantive relevance. Exclusion criteria were:

- Outdated data (sources published up to 2005). There were four exceptions, i.e. sources which contained data of general importance.
- No relationship between keywords found within the title, abstract, and content.
- Inadequate virtual studies and literature reviews (minimum requirements: introduction, applied method, reasonable results, discussion, and conclusion).
- No authorship and no date of publication.
- No content relevant to 'near misses', i.e. exclusion of sources dealing solely with 'adverse events' or 'sentinel events'.

Table 1 Keywords for literature search (inclusion criteria)

Entry	Keyword in German	Keyword in English
I.	Incident Reporting System(e)	Incident Reporting System(s)
II.	CIRS	CIRS
III.	Patientensicherheit	patient safety
IV.	Beinahe-Fehler	near miss(es)
V.	Beinahe-Fehler-Meldungen	near miss reports
VI.	Freiwilliges Meldesystem	Voluntary Reporting System
VII.	Meldesysteme	reporting systems
VIII.	Melde- und Lernsysteme	reporting (and) learning systems
IX.	Patientensicherheitsstrategien	patient safety strategies
X.	Fehlerberichtssysteme	error reporting systems
XI.	'Beinahe-Fehler-Meldungen-Effektivität'	near miss reports effectiveness
XII.	Fehler-Meldungen	error reporting

- Books and technical reports where the author(s) did not publish regular articles which can be found in regular databases so far.

After data collection, the articles were assigned to three categories: (i) studies and paper, (ii) reviews, and (iii) books and technical reports. The articles were searched for the following questions and issues:

(1) What was reported?
(2) Who has reported?
(3) What were the consequences about, i.e. which measures and courses of action have been taken into account and were implemented in order to improve or to resolve the risky situation, respectively?
(4) Impeding factors with respect to the acceptance, maintenance, and success of CIRS.
(5) Promotional factors with respect to the acceptance, maintenance, and success of CIRS.
(6) Relationship between CIRS and its impact on patient safety.
(7) Useful supplements on CIRS.

Results

After application of the selection criteria, 36 studies (Table 2), 6 textbooks (Table 3), and 14 technical reports (Table 4) for data synthesis and analysis came under scrutiny.

What was reported?

Most articles deal with the implementation and utilization of incident-reporting systems. Therefore, organizational culture, clinical staff, and safety issues play a major role in explanation of merits and demerits of CIRS and related reporting systems.

Many authors [5, 6] stated that incident-reporting systems capture only a small fraction of occurring incidents in hospitals. Reasons for non-reporting of errors are a lack of feedback, a lack of knowledge, time pressure, and underestimation of the critical incident (CI) [7]. It was found that a high incident-reporting rate correlates with a sound error and safety culture [8]. Another problem is the quality and validity of the incidents reports: CIRS indices are often skewed and ambiguous [9] or the information is often too generic [10]. To collect incident reports without in-depth analysis does not lead to a higher level of patient safety [11].

Incidents are prevalent in hospitals and can be found in nearly all clinical areas and operations. A field study from Switzerland [4] revealed that nearly half of all documented incidents (number (N) = 1.470) are human errors (49.5%). Other incidents can be ascribed to organizational settings (24.9%), infrastructure and environment (10.8%), and technical problems (6.2%), amongst others (8.6%). Another field study conducted in Italy and Romania [12] yielded the following results: in a hospital in Bucharest (Romania), most incident reports related to diagnostics (28%), surgery (14%), and patient falls (12%). In Genoa (Italy), patient falls (32%), incidents by nursing (20%), and incidents in diagnostics (19%) were reported, whereas in Milan (Italy), incidents by nursing (25%) and medication regulation and administration (21%) and incidents in diagnostic procedures (17%) can be found. A Japanese study [13] showed that most reports were based on medication errors (2815 reports, 46.6% of a total of 6041 reports), followed by complications and errors with medical stock (1.147 errors, 19.0%), and errors with patient falls (826, 13.7%). Here, the high number of reports was ascribed to an underdeveloped communication policy. A German analysis of 151 incidents [14] yielded the following results: 71 errors (47%) based on organizational and communication errors, 54 reports (35.8%) as a result of human errors, and technical errors (17 reports, 11.3%), amongst others (9 reports, 5.9%). Most errors were found in medication (29%), followed by patient falls (14%) and medical operations (15%) [15]. The authors stated that 59% of all reported errors can be classified as preventable [14].

The occurrence of incidents with respect to organization and processes [16, 17], surgery and anaesthesia [18–20], and medication [6, 20–25] were described, too.

Who has reported?

Although CIRS reports stem from very different clinical areas, i.e. theatre, ICU, patient falls, nursing care, and medication vide supra, CIRS and related voluntary reporting systems are predominantly used by nursery staff whereas it is rarely used by other clinical staff members, in particular physicians [7, 18, 26, 27]. In one case, it was found that physicians reported adverse events mostly via the clinical risk management, while nursing staff used more often CIRS settings [26]. This observation may reflect the reluctance of clinical professionals to internalize the necessity of an error culture [28]. In order to remedy these shortcomings, the promotion of a voluntary involvement of physicians was highly recommended [15]. Anyway, many authors suggest that the success of incident-reporting systems depend on whether it is regarded as a holistic approach, i.e. CIRS must integrate into the organizational processes of the health care system [29–33] and even necessitates the commitment of top management [34].

Different studies illustrate that the handling of CIRS depends on the kind of occupants and the medical discipline. A study [13] stated that the majority of reports are generated by nurses using their own CIRS paper form. Conversely, the medical profession reports

Table 2 Studies for data synthesis and analysis

Entry	Authors	Method	Analysed incidents	Sample size	Results
1	Spigelman/Swan (2005) [10]	Interviews	–	*N* = 12	The Australian Incident Monitoring System (AIMS) signifies a consistent system of coding, trending, and monitoring of incident data. Added promotion of patient safety culture and awareness of system errors such as failures and risk sources. More teamwork and patient safety strategy implementation were observed. Limitations: Low rate of CI reporting by staff. Information was often too generic.
2	Anderson et al. (2013) [53]	Documentary analysis and interviews	–	*N* = 62 (physicians, nurses, managers)	CIRS was perceived as having a positive effect on safety due to changes in care processes, staff attitudes, and knowledge. It can be useful in the development of awareness of risks in health care practice. Limitations: In practice, utilization of incident reports to improve care is difficult.
3	Brinkrolf, Prien, and Van Aken (2013) [24]	Retrospective analysis of CI	*N* = 235		Distribution of CIRS reports: (i) theatre 29%, (ii) ICU 21%, (iii) other workplaces 22%. Distribution of mistakes: (i) preparation of drugs, (ii) administration of drugs 37%, (iii) delivery and storage of drugs 5%.
4	de Feijter et al. (2013) [5]	Retrospective analysis of CI	*N* = 736		CIRS captures only a small fraction of occurring incidents in hospitals. It should be combined with complementary data about diagnostic errors, patient complaints, and retrospective chart reviews.
5	Desikan et al. (2005) [6]	Retrospective analysis of CI	*N* = 1.126	–	In voluntary incident-reporting systems, there is only a low and highly variable reporting rate of adverse drug events. The reporting rate can be increased by utilization of reporting systems that focus on certain types of events (medication programs may be more suitable for adverse drug events, whereas CIRS captures error patterns and conditions).
6	Dinkel/Eiche (2005) [14]	Data analysis	*N* = 151	–	Distribution of CIRS reports: (i) communication problems and organization 47%, (ii) human errors 36%, (iii) technical errors 11%. CIRS is deemed as efficient and safety promoting.
7	Evans et al. (2006) [7]	Anonymous cross-sectional survey	–	*N* = 186 (physicians), *N* = 587 (nursing staff)	65% of the physicians and 89% of the clinical staff made an error report already. Reasons for non-reporting are a lack of

Table 2 Studies for data synthesis and analysis *(Continued)*

					feedback, a lack of knowledge, time pressure, and underestimation of CI.
8	Gupta et al. (2009) [19]	Retrospective analysis of CI	*N* = 112	–	Surveillance of CI is useful for detecting of new potential weak spots, problems, and risk factors. Identification of 'near misses' gives rise to learning potential and improvements.
9	Heidevel-Chevalking et al. (2014) [18]	Retrospective analysis of CI	*N* = 2.563	–	There is a relationship between non-compliance of perioperative SOPs and patient safety. Most of the reports are related to human errors (68%) and organizational shortcomings (23%).
10	Herzer et al. (2012) [38]	Analysis of a new concept	–	*N* = 57 (departments over 7 years)	Development of a "Good Catch" award that may serve as an incentive for clinical staff members. Awarded for valuable CIRS reports which give rise to more patient safety and risk minimization.
11	Hübler et al. (2006) [17]	Retrospective analysis of CI	*N* = 162	–	Systematic analysis of safety-related incidents based on CIRS is possible with the premise of an institutionalized error culture. Derived measures should include tailored staff training, technical modifications, improving standards, team work, and communication exercises.
12	Hutchinson et al. (2009) [8]	Analysis of trends over 18 months	–	*N* = 22 (nations)	A high CIRS rate correlates with a sound error and safety culture. The number of incident reports increases when CIRS is coupled with a national vigilance system. Positive association with patient safety culture.
13	Kaldijan et al. (2008) [46]	Survey	–	*N* = 338 (faculty and resident physicians)	Most physicians tend to report harm-causing hypothetical errors, but in reality, only a minority of the respondents have reported an error so far.
14	Khorsandi et al. (2012) [40]	Retrospective analysis of CI	*N* = 3142	–	In only 14.8% of the cases analysed, a vague description of the incident is given. There is an urgent need in improving the quality of CI reports, which can be achieved by appropriate staff training. Causal analysis tools such as root cause analysis (RCA) combined with reporting systems are highly recommended.
15	Chul-Hoon/Myoungsoo (2009) [21]	Retrospective analysis of CI	–	*N* = 75 (nursing staff)	A CIRS trial in a Korean hospital induces a more open-minded culture with respect to CIs. 77% of correspondents acted as an

Table 2 Studies for data synthesis and analysis *(Continued)*

					observer, while 23% of the correspondents were involved in the respective situation.
16	Levtzion-Korach et al. (2010) [26]	Retrospective analysis of CI	*N* = 8.616	–	5 distinct reporting systems were compared. Each of them captured specific although complementary patient safety issues. About half of the physicians reported adverse events via the clinical risk management, while the nursing staff used CIRS more often.
17	Moss, Embletion, and Fenton (2005) [55]	Retrospective analysis of CI	*N* = 562	–	Utilization of findings from CIRS in inter-hospital transfers of sick infants. Changes made as a result of CI review reduces the number of incidents caused by poor preparation and transport, clinical problems, and both ambulance delays and ambulance equipment failure.
18	Nakajima, Kurata, and Takeda (2005) [13]	Retrospective analysis of CI	*N* = 6.041	–	Web-based incident-reporting systems have been taken for developing patient safety programs. In conjunction with staff training and feedback, those voluntary and anonymous reporting programs can help promote an open-minded safety culture.
19	Nuckols et al. (2007) [15]	Retrospective analysis of CI	*N* = 1.000	–	9% of patients had suffered at least 1 reported incident but only 17 CI per 1.000 patient days have been report. Distribution of reports: (i) medication errors (29%), (ii) falls (14%), (iii) incidents during surgery (15%).
20	Orlicek (2010) [27]	Employee survey, expert interviews	–	*N* = 226 (employees)	37% of the respondents (UKH Graz) made at least 1 CIRS. The nursing staff used CIRS more often than other staff members, in particular physicians. Most respondents agree that CIRS is very important.
21	Panzica, Krettek, and Cartes (2011) [16]	Retrospective analysis of CI	*N* = 4.278	–	CIRS plays a major role in clinical risk management with respect to incident reduction in long terms. Based on CIRS data, a systematic and resource-efficient approach for minimization of risk has been recommended.
22	Ramanujam et al. (2008) [30]	Data analysis	*N* = 20.000	–	It is recommended that issues of patient safety must redeploy

Table 2 Studies for data synthesis and analysis *(Continued)*

					to the top level of governance (top management or strategic management in hospitals) in order to establish learning processes as a result of CIRS.
23	Reed et al. (2014) [31]	Interviews	–	6 persons in charge of CIRS from 6 European nations	With respect to anaesthesia, both national coordination by government and specialty-focused initiatives seemed to be necessary for an optimal functioning CIRS.
24	Rose/Germann (2005) [4]	Retrospective analysis of CI	*N* = 1.470	–	In 2004, there were 874 incident reports or 46% compared to the previous year (2003, 596). In response, the number of improvement measures increased from 83 (2003) to 120 (2004) (45%).
25	Schildmeijer et al. (2013) [20]	Retrospective analysis of patient documents	–	*N* = 350 (patient documents)	CIRS reports on 'near misses' are valuable to reveal weak spots in processes. Organizational learning relies heavily on anticipated risks and shortcomings.
26	Steyrer et al. (2013) [39]	Observations	–	*N* = 378 (patients), *N* = 57 (intensive care units (ICUs))	CIRS or any other kind of formally implemented safety procedure and policy did not work when the workload increase, i.e. a higher workload has a negative effect on safety.
27	Takeda et al. (2003) [52]	Retrospective analysis of CI	*N* = 1.550	–	After implementation of an electronic online incident-reporting system, the number of CIRS reports increases from 50 to 140–180 per month (+180–260%).
28	Tereanu et al. (2011) [12]	Retrospective analysis vs. CIRS reports	*N* = 185 (CI)	–	A test of a voluntary CIRS in Romanian and Italian hospitals showed that most adverse events occurred in diagnostics (17–28%), surgery (14%), patient falls (12–32%), nursing care (25%), and drug prescription and administration (21%). Results suggest that CIRS could be introduced on a larger scale (in Romania).
29	Valentin et al. (2009) [22]	24-h cross-sectional study	–	*N* = 1.328 (patients) (113 ICU)	Parenteral medication errors are identified as a serious safety problem in ICU. Error-reporting systems and routine checks can reduce the risk for such errors, especially in case of critically ill patients.
30	Wan et al. (2013) [50]	Retrospective analysis of CI	*N* = 2.519 CI from 75.331	–	CI reporting provides insight in the clinical system by being useful in identification of active and system errors in paediatric anaesthesia. It is also deemed as a foundation of prevention and strategy. A high and consistent reporting can be achieved by maintaining a culture that encourages reporting of CI.

Table 2 Studies for data synthesis and analysis *(Continued)*

31	Westbrook et al. (2015) [25]	Analysis of documents	*N* = 3.291	–	Reported incidents do not reflect the real number of medication errors or underlying rates. Of 12.567 prescribing errors which were identified at audit, only 1.2/1.000 errors were reported. Of 539 clinically important prescribing errors, only 218.9/1000 errors were detected by staff, but only 13.0/1000 errors were reported. New approaches such as data mining of electronic information systems were highly recommended.

Table 3 Reviews for data synthesis and analysis

Entry	Authors	Method	Analysed incidents	Sample size	Results
32	Benn et al. (2009) [43]	Triangulation: analysis of reporting systems and interviews	–	*N* = 23 (reporting systems)	15 requirements for the design of effective systems in health care were identified, although further work is necessary to establish best practices for feedback systems in health care with respect to safety. The relative strength of different feedback mechanisms for incident reporting is not well understood.
33	Cousins, Gerrett, and Warner (2012) [23]	Retrospective analysis of medications CI	*N* = 526.186	–	A total of 526.186 medication incident reports were found which means 9.68% of all patient safety incidents. The establishment of an effective infrastructure in all sectors of health care organizations is highly recommended in order to promote and oversee safe medication practice.
34	Doupi (2009) [54]	Analysis of CIRS literature and data	–	*N* = 13 (countries)	In Europe, 3 different types of national patient safety incident-reporting systems were identified, of which only one health care system-wide, comprehensive reporting systems include 'near misses'. There is no one right way of establishing national patient safety incident-reporting system yet.
35	Barach/Small (2000) [45]	Analysis of non-medical reporting systems	–	*N* = 12 (reporting systems)	Complex non-medical industries such as aviation have established consistent incident-reporting systems that may serve as a framework for health care organizations. These reporting systems focus on near misses, foster voluntary reporting, ensure confidentiality, and emphasize both data collection and analysis and improvements.
36	Wong/Beglaryan (2004) [33]	Analysis of CIRS literature	–	*N* = 58	Based on a review on patient safety strategies for hospitals, several recommendations ('Providing Leadership for Patent Safety Initiatives', 'Creating a Culture of Safety', 'Providing Training and Continuous Education', 'Improving Reporting Systems', 'Establishment a National Patient Safety Strategy') were given and next steps in research were proposed.

Table 4 Specialist books and technical reports for data synthesis and analysis

Entry	Authors	Title	Type	Content (gist)
37	Aktionsbündnis Patientensicherheit (2007) [56]	Empfehlungen zur Einführung von Critical Incident Reporting Systemen (CIRS)	Recommendations for action	In fact, a well-implemented CIRS is seen as an effective way to minimize risk. CIRS data in clinical risk management may prevent high consequential costs and promote safety and culture.
38	Gluyas/Morrison (2013) [11]	Patient Safety – An Essential Guide	Specialist book	The sole collection of CI reports did not improve patient safety automatically. To do so, the underlying factors of a certain incident must be identified and analysed. In addition, both reports and data must be evaluated with respect to probable trends or developments.
39	Gunkel et al. (2013) [9]	CIRS – Gemeinsames Lernen durch Berichts- und Lernsysteme	Technical contribution	CIRS indices are often skewed and ambiguous. More reliable parameters are the number of CI reports (per month or organizational unit), number of reports including analyses, number of implemented improvement measures.
40	Hofinger et al. (2008) [57]	Das Lernen aus Zwischenfällen lernen: Incident Reporting im Krankenhaus	Specialist book	Implementation and establishment of reporting systems in hospitals requires stamina and top management commitment. Privileges are detrimental to an effective establishment. Confidence-building measures are mandatory.
41	Kaloud (2009) [37]	Das Fehlermelde- und Präventionssystem "CIRPS"	Technical contribution	The practical implementation of CIRPS ('Critical Incident Reporting and Prevention System') of the "Allgemeine Unfallversicherungsanstalt" (AUVA) (Austria) started in 2006. Between October 2006 and October 2008, 294 changes were made as a result of 113 CIRPS reports.
42	Schreiner-Hecheltjen (2015) [51]	Qualitätsmanagement und Qualitätssicherung in der Medizin	Specialist book	CIRS is adapted for identification of CI in daily routine work and under conditions of certification. In addition, CIRS serves as an effective communication tool. Efforts are undertaken to connect CIRS networks of different hospitals.
43	Klauber et al. (Eds.) (2014) [41]	Krankenhausreport 2014: Schwerpunkt Patientensicherheit	Specialist book	Voluntary reporting systems are regarded as tools for identifying weak spots in hospitals. A survey from 2010 cited therein revealed that 35% of 484 acute care hospitals with more than 50 hospital beds employed locale report and learning systems over 2 years on average.
44	Koebberling (2005) [58]	Das Critical Incident Reporting System (CIRS) als Mittel zur Qualitätsverbesserung in der Medizin	Technical contribution	The concept of CIRS is founded on the observation that there is a correlation between the occurrence of incidents or near misses without consequences and severe incidents with consequences. Transparency and veracity is deemed

Table 4 Specialist books and technical reports for data synthesis and analysis *(Continued)*

				as prerequisite for a well-functioning error management.
45	Koebberling (2008) [47]	Lernen aus CIRS – eine Kasuistik	Technical contribution	A good collaborative work between CIRS teams and QM teams is decisive for a well-functioning CIRS. The implementation of CIRS denotes a contribution to clinical risk management.
46	Levinson (2012) [59]	Hospital Incident Reporting Systems Do Not Capture Most Patient Harm	Technical contribution	As a matter of fact, 86% of occurred incidents are not reported. This is attributed to misjudgement and lack of perception. As a consequence, clear reporting policies and staff training are recommended.
47	Mahajan (2010) [44]	Critical Incident Reporting and Learning	Technical contribution	CI reporting is deemed as a key in improving safety but underutilized in health care. A non-punitive handling of reports as well as regular and detailed feedback is crucial in engaging clinical staff in the safety loop. Immediate incidents such as falls or equipment errors are better reported than subtle incidents with gradual development.
48	Merkle (2014) [29]	Risikomanagement und Fehlervermeidung im Krankenhaus	Specialist book	Incident-reporting systems are successful when they are a component part of clinical risk management and a process management focusing on patients is implemented.
49	PHAM, GIRARD, Pronovost (2013) [49]	What do with healthcare incident reporting systems?	Technical contribution	Despite its influence on improving patient safety, several limitations of CIRS have been addressed. Significant values of CIRS and strategies to maximize value were also taken into account.
50	Rohe et al. (2014) [60]	Erfahrungen mit Critical Incident Reporting-Systemen	Technical contribution	The Ärztliche Zentrum für Qualität in der Medizin (ÄZQ) recommends that only near misses without consequences are worth to be reported. Reports on consequences should be included when the liability and insurance are clarified beforehand.
51	Rohe/Thomeczek (2008) [61]	Aus Fehlern lernen: Risikomanagement mit Fehlerberichtssystemen	Technical contribution	Safety culture and patient safety might be strengthened by relevant analyses, reasonable improvement strategies, and consistent reporting systems with relevant key figures. However, the causal relationship between introducing a reporting system and changes of the number of incident occurrences can never be clarified.

Table 4 Specialist books and technical reports for data synthesis and analysis *(Continued)*

52	Rose/Hess (2008) [36]	Melden von Near Misses im Krankenhaus	Technical contribution	It is estimated that about 50% of incidents with potential harm to patients could be avoided. In a specific hospital reposting system that resembles to CIRS, it was possible to promote active handling of safety issues, resulting in a positive effect on the management of failures and damages. The reporting system is deemed as a first step in the development of clinical risk management.
53	St. Pierre (2013) [32]	Safe patient care- safety culture and risk management in otorhinolaryngology	Technical contribution	CIRS is useless in the absence of clinical risk management and QM systems. Furthermore, both technical and non-technical skills of health care professionals are deemed as decisive with respect to a safe and efficient delivery of patient care.
54	Waterson (2014) [62]	Patient safety culture: theory, methods and application	Specialist book	The number of CI reports can be explained by two ways. First, it can mean a high-risk potential and a high probability of a patient harm. Second, it can be seen as an indicator of an organizational culture of openness and willingness to learn.
55	Weimann/Weimann (2013) [28]	Das Swiss Cheese Model als "critical incident reporting system" zur Risikoreduzierung und Erhöhung der Patientensicherheit in Klinik und Praxis	Technical contribution	CIRS serves as an example of a "Swiss Cheese Model". All staff members have to know how to deal with CIRS, pointing to the necessity of transparency because in hospitals, error analysis is often associated with recrimination.
56	Zapp (Eds.) (2011) [63]	Risikomanagement in Stationären Gesundheitsunternehmungen. Grundlagen, Relevanz und Anwendungsbeispiele aus der Praxis	Specialist book	In comparison to a control group, the implementation of CIRS give rise to changes in communication and collaboration, in the attitude toward error management, accountability, and assessment of safety measures.

preferentially clear errors. In a European study [27], about 30% of the CIRS reports (N = 226) stemmed from nursing personnel, about 15% from medical professionals, and about 24% from medical-technical service staff. These results are consistent with those from [35]. An analysis of different medical disciplines illustrates that mainly anaesthesia and surgical care staff use CIRS (37%) [15]. Another source [18] revealed that mainly anaesthesia and surgical care staff report errors (37%), followed by ward nurses (31%), medical professionals (17%), and administrative staff document errors (5%). Similar results were described in a comparative study of the hospital from New York, Utah, and Colorado [15]. Here, 3407 (88%) errors of all registered notifications were reported by the nursing staff, 73 reports (1.9%) by physicians, and 346 reports (8.9%) by other staff. About 50% (1859) of all CIRS reports were submitted by the patient ward, 797 (21%) from the intensive care units, 544 (14%) from surgery, and less than 5% from other areas. Other authors [15] confirmed that the minority of CIRS will be generated by medical professionals. As a consequence, they called for a more active collaboration to increase the effectiveness of reporting systems in hospitals [15].

Documented improvement action

The study of Rose and Hess [36] showed that 585 suggestions for improvement were implemented from a total of 5000 CIRS reports, although it was found that processes and measures might generate new errors. Therefore, an effective error management has to be implemented in addition to the CIRS system. In two studies, acquisition of new equipment, improvements in medication and administration, adoption of novel standards, and training programs amongst other measures were implemented as a result of incident reports [10, 37]. The training of staff was recommended by most authors. The utilization of incentives (establishment of a 'Good Catch Award') was proposed by Herzer et al. [38]. Hübler et al. [17] gave recommendations in terms of surgery and anaesthesia.

Obstructive and assisting aspects

Several factors detrimental to a well-functioning CIRS can be identified: work overload (a higher workload has a negative effect on safety [39] and/or time pressure [7]), untrained staff (ignorance or lack of knowledge amongst staff members) [5, 13, 17, 40], lack of feedback, lack of communication and/or team work [17], a poor quality of incident reports (inconclusive statements or too generic data) [9, 10], and the collection of incident reports without an in-depth analysis [11]. During the implementation phase of a reporting system, resentments amongst staff members which affect the acceptance of CIRS might arise [41]. With respect to the validity of the report error data and information, this can primarily be attributed to the profession [42]. Other issues were discussed in greater detail: anonymity and consequences [4], provisions and time [8, 18, 32], and feedback [7, 43].

Many authors wrote about factors that can positively affect the acceptance and effectiveness of CIRS. First of all, professional leadership is indispensable for the implementation and application of an efficient CIRS. This can be attributed to a company-specific authority and the role model function. Leadership must accept an open error-reporting culture for the safety and benefit of patients. One element is to ensure and promote effective work at all levels to increase patient safety. These can be mediated by education and training to increase the knowledge and skills of the staff [25, 27, 30]. Another aspect is the implementation of a "no blame" error and feedback culture and the security of an absolutely anonymous reporting system [4, 37, 41, 44]. Similarly, transparency, trust, and knowledge on CIRS are mandatory and are closely related to the training and skills of clinical staff [4, 14, 45–47]. In addition, feedback was identified as an essential part of CIRS [4, 13, 43, 44, 46].

Some features and criteria of an effective CIRS process [11, 36] and generic positive factors of CIRS [13, 16] were described in detail, too.

CIRS and positive trends

In a survey [27], 100% of medical professionals and 100% of nurses specified sustainable corrections for their organization based on CIRS reports, whereas 50% of the medical-technical staff indicated no improvements due to CIRS. It was found that CIRS is important in creating a positive error-safety culture, in detecting weak points, and in analysing necessary system changes [27]. CIRS can provide sufficient qualitative data for detecting critical system errors in health care institutions and organizations. The CIRS-based data allows the analysis of the current situation and development of possible counter-strategies to positively influence the increase in patient safety [6]. In an Australian study, it was found that system changes based on CIRS reduce the numbers of future adverse events [48]. Other positive trends were described elsewhere [49–51]. Certain measures were given by Leape and Berwick [2] and Merkle [29].

Further cognition

Several issues of further importance were found: (i) technical measures derived from incident reports may lead to new error resources [50]; (ii) the probable importance of national incident-reporting systems relevant to anaesthesia [31]; (iii) an inflationary push of CI-reporting systems without a sound comprehension or planning (see Ramanujam et al. [30] for an example in medication);

(iv) ineffectiveness in dealing with CI reports [4]; (v) the relationship between CIRS and related reporting systems with organizational quality management [52]; (vi) complementary approaches of CIRS [5, 6, 8, 16, 26]; and (vii) the dispute on the relationship between incident report frequency and patient safety [8, 12, 15, 17, 18, 20, 21, 25, 53].

Discussion

In recent years, CIRS and related reporting systems (there are three distinct reporting systems in European hospitals, at least: Doupi [54]) have become an essential prerequisite for many health care organizations [54]. The implementation of CIRS is an important undertaking for hospitals as it is expected to contribute significantly to the reduction of clinical risk. With respect to Austria, the integration of risk management in quality management systems (ISO 9001:2015) and in the national law of Austria (*Ministerialentwurf* 143/ME XXV, §4 (15)) necessitates the development of consistent risk management practices in clinical settings.

The purpose of this work was a literature search to provide an overview on CIRS and its utility in clinical risk management and the relationship between CIRS adoption and patient safety. Application of predetermined exclusion criteria and inclusion criteria led to a core set of articles consisting of 36 studies, 6 reviews, and 14 specialist books or technical contributions. Available data confirm a positive relationship between the utilization of CIRS and an increase in patient safety. A 'probable' positive effect of incident reporting on patient safety was established, but CIRS must be planned and implemented in a systematic way.

Core elements of a well-functioning CIRS are feedback, involvement of the whole staff including top management commitment, and the integration of CIRS in both risk and quality management. It is important to illustrate the advantages of a CIRS system for a transparent risk reduction process for the benefit of the patients (and, of course, for the clinical staff at all hierarchical levels).

Anonymity and incentives play a pivotal role in maintaining incident reporting, too. Training of staff and transparency are very often mentioned throughout the sources which came under scrutiny. A well-planned and implemented CIRS may improve organizational error-reporting culture, learning processes, and overall safety. In practical terms, the establishment of a skilled risk manager position is highly recommended to point out the importance of CIRS and to encourage recognition and acceptance for a successful CIRS implementation. The risk manager has to find ways to convince members of the top management and clinical staff members to contribute to risk minimization and patient safety through CI reporting. Conversely, the risk manager needs the support of top management.

A CIRS not supported by managers of the higher organizational levels will be implemented with trouble and will not produce any quantifiable improvement. It should be also noted that key figures or indicators, which can be often found in literature on CIRS, are probably helpful in terms of process steering in health care organizations, but do not improve patient safety.

In addition, several limitations have been found:

- Because of the chosen method, there may be restrictions in validity imposed by the selection criteria and by the restricted number of pages.
- There are no pooled results due to the non-availability of intervention studies as a result of the predetermined selection criteria.
- Due to the heterogeneity of incident-reporting systems and the inclusion of similar designations such as near misses and CI, interpretations in literature reports often diverge.
- Because no fee-based databases were used in the literature search, there might be further restrictions in validity.
- There is an unmet need for a confirmation of the effectiveness of CIRS in clinical practice. This would provide another starting point for a Ph.D. thesis.

Conclusion

The literature search conducted in this study revealed unambiguously that incident reporting in hospitals is highly variable. This can be attributed to the non-availability of a global standard, norm, or certification guidance specific for CI. In practical terms, it seems that CIRS (or similar reporting systems as seen in Doupi [54] and in Levtzion-Korach et al. [26]) is often implemented in a more intuitive manner instead of in a systematic way. Nevertheless, CIRS was found to have a positive impact on safety culture in most cases, although description or analysis of the factual relationship between the reporting system and patient safety remains vague. When applied in an optimized manner, CIRS induces positive changes such as the adaption of processes [20, 53], awareness of risk [10, 16, 19, 53], and 'near misses' [19, 20].

Abbreviations

CI: Critical incident(s); CIRS: Critical Incident Reporting System; ICU: Intensive care unit; *N*: Number (statistics); SOP: Standard operating procedure

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