Addressing Patient Safety Hazards Using Critical Incident Reporting in Hospitals: A Systematic Review

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Introduction: Critical incident reporting systems (CIRS) are in use worldwide. They are designed to improve patient care by detecting and analyzing critical and adverse patient events and by taking corrective actions to prevent recurrence. Critical incident reporting systems have recently been criticized for their lack of effectiveness in achieving actual patient safety improvements. However, no overview yet exists of the reported incidents’ characteristics, their communication within institutions, or actions taken either to correct them or to prevent their recurrence. Our main goals were to systematically describe the reported CIRS events and to assess the actions taken and their learning effects. In this systematic review of studies based on CIRS data, we analyzed the main types of critical incidents (CIs), the severity of their consequences, their contributing factors, and any reported corrective actions.

Methods: Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines, we queried MEDLINE, Embase, CINAHL, and Scopus for publications on hospital-based CIRS. We classified the consequences of the incidents according to the National Coordinating Council for Medication Error Reporting and Prevention index, the contributing factors according to the Yorkshire Contributory Factors Framework and the Human Factors Classification Framework, and all corrective actions taken according to an action hierarchy model on intervention strengths.

Results: We reviewed 41 studies, which covered 479,483 CI reports from 212 hospitals in 17 countries. The most frequent type of incident was medication related (28.8%); the most frequent contributing factor was labeled “active failure” within health care provision (26.1%). Of all professions, nurses submitted the largest percentage (83.7%) of CI reports. Actions taken to prevent future CIs were described in 15 studies (36.6%). Overall, the analyzed studies varied considerably regarding methodology and focus.

Conclusions: This review of studies from hospital-based CIRS provides an overview of reported CIs’ contributing factors, characteristics, and consequences, as well as of the actions taken to prevent their recurrence. Because only 1 in 3 studies reported on corrective actions within the healthcare facilities, more emphasis on such actions and learnings from CIRS is required. However, incomplete or fragmented reporting and communication cycles may additionally limit the potential value of CIRS. To make a CIRS a useful tool for improving patient safety, the focus must be put on its strength of providing new qualitative insights in unknown hazards and also on the development of tools to facilitate nomenclature and management CIRS events, including corrective actions in a more standardized manner.

Key Words: patient safety, incident reporting, critical incident reporting system, incident reporting system, hospital, risk management, systematic review

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Within a functional feedback loop, reported instances of patient safety hazards become data for causal analyses; the results of those analyses allow elimination or reduction of the identified causes. By increasing patient safety, this process is expected to improve future care. However, the latest World Health Organization report on CIRS notes that as many incident reports remain unaddressed, their current use often leads to few real improvements; that is, CIRS data are largely wasted.2

As CIRS are used in hospitals worldwide, numerous studies discuss aspects of learning from reported incidents. Unfortunately, comparable information on the characteristics of the reported CIs, as well as comparative reviews on corrective actions following reported CIs, is currently lacking. To address this shortfall, we set 2 main objectives for the current review: first, to systematically analyze hospital-based CIRS studies regarding each reported incident's type, severity, and contributing factors and, if possible, second, to evaluate the actions taken to prevent further such incidents.

METHODS

This systematic review was conducted and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.15

Search Strategy

We searched the MEDLINE, Embase, CINAHL, and Scopus databases. Our queries used 4 normal-text strings—“Critical Incident Reporting System,” “Incident Reporting System,” “Critical Incident Reporting” and “Patient Safety Learning System”—and the following MeSH terms and Boolean operators (including parentheses): (“Hospitals”[Mesh] OR “Patients”[Mesh] OR “Inpatients”[Mesh] OR hospital*[tiab] OR Patient*[tiab] OR inpatient*[tiab] OR hospital*[Mesh] AND (Medical Errors/methods)[Mesh] OR Medical Errors/statistics and numerical data[Mesh] OR “Risk Management/methods”[Mesh] OR “Risk Management/statistics and numerical data”[Mesh] AND (Critical Incident*[tiab] OR Incident Reporting*[tiab] OR Near Miss*[tiab] OR Safety Incident*[tiab]).

Inclusion and Exclusion Criteria

We included observational studies using data from established hospital-based CIRS that reported CIs’ characteristics and/or improvement actions. To be eligible for inclusion, studies had to be published between 2000 and 2019 in English or German, use compatible definitions of CI reporting (i.e., incidents that affected or could have affected 1 or more patients’ safety), and include data from a minimum of 100 reports. We excluded studies from national and statewide reporting systems,16–18 those in nonhospital settings19,20 (e.g., primary care, nursing homes), and those for reporting specific incident types21,22 (e.g., falls, equipment, transfusions).

Data Extraction, Quality Assessment, and Analysis

All titles and abstracts of the identified articles were independently screened for eligibility by 2 reviewers and arbitrated by a third to reach consensus in cases of disagreement. For data extraction, we used 2 forms: (1) study characteristics, that is, author(s), publication year, country of origin, setting/sample, study design, the used definition of CIs, and study duration in months and (2) incident-related details, that is, characteristics/types, consequences, contributing factors, and organizational actions taken/lessons learned. We classified the incidents’ consequences according to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index,23 the contributing factors according to the Yorkshire Contributory Factors Framework and the Human Factors Classification Framework,24,22 and any actions taken according to an action hierarchy model on strengths of interventions to improve patient safety as proposed in the literature.26,27

For quality assessment, as no specific critical appraisal tools are available for studies on “critical incident reporting systems.” Two authors (K.G., R.S.) assessed each study’s reporting methodology, that is, they decided whether its included information was adequately structured—first on the basic characteristics of each reported CI (type, consequences/severity, contributing factors) and then on the actions taken to prevent that CI’s recurrence. Disagreements between the 2 study reviewers were discussed until consensus was reached. Based on this process, they narrowed our literature search’s 3621 initial returns to 41 that were eligible for detailed review (Fig. 1).

RESULTS

Study Characteristics

The 41 included studies were conducted between 2004 and 2019 and referred to 479,483 analyzed reports from 212 hospitals. The majority were conducted in Europe (n = 21, 51.2%), followed by North and South America (n = 13, 31.7%), Asia (n = 6, 14.6%), and Middle Eastern (n = 1, 2.4%) regions. Thirty were single-center studies; 11 were multicenter. For the single-center group, incident report sample sizes ranged from 11428 to 8809.29 For the multicenter group, the numbers of included hospitals ranged from 2 to 29, with CI numbers ranging from 58430 to 266,224.31 Across all studies, durations ranged from 12 to 132 months. Settings included “university/academic/teaching hospitals” (n = 29), “acute care hospitals” (n = 23), “suburban hospitals” (n = 13), “urban hospitals” (n = 11), “tertiary hospitals” (n = 7), “quaternary hospitals” (n = 3), “rural hospitals” (n = 2), and “community hospitals” (n = 1); for the remaining 147, no hospital type was specified. Critical incident–reporting clinical departments included surgical disciplines, anesthesia, standard, pediatric and neonatal intensive care units, pediatrics, internal medicine, emergency, ophthalmology, and radiology (see supplementary file, http://links.lww.com/JPS/A508, summarized study characteristics).

Reporter Characteristics

In 22 of the 41 studies (53.6%), the incident reporters’ professions were specified. Of these 22 studies’ reporters, 83.7% were nurses (range, 0.8%32–84.7%33), 6.5% pharmacists (range, 1.3%34–51.9%35), 4.8% physicians (range, 1.1%31–50.3%36), and 5% other professions, including laboratory technicians, paraclinical staff, dieticians, etc (range, 0.1%33–10%37).33,34,37,41 In 2 studies,32,36 most reports were made by physicians. In 1 study,44 apart from “physician,” no professions were specified.

Incident Types

In 35 of the 41 included studies (85.4%, n = 467,616 CIs), the types of CI were specified (Fig. 2). The 3 most commonly reported CI categories were: medication related (28.8%; range, 3.4%45–63.3%48), administration related (12.9%; range, 2.3%45–18.9%47), and fall related (11.5%; range, 0.2%40–16.6%26). In 1 study,31 adverse clinical events were classified as events related to medical treatment. Across the 24 studies (58.5%) that provided CI incidences, these ranged from 1.648 to 266,224.31

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Consequences of Incidents
In 23 of the 41 studies (56.1%, n = 341,097 CIs), CIs’ consequences were reported. As recommended by the NCC MERP index, we divided these consequences into 5 groups, no error (circumstances or events that have the capacity to cause error), error, no harm (an error has occurred but has not caused any harm to the patient), error, harm (an error has occurred and harmed the patient), error, death (an error has occurred that could have contributed to or could have led to the death of the patient), and not coded (not classified; Fig. 3).23 As detailed in Figure 3, 21.7% (74,086/341,097) of incidents resulted in temporary or permanent patient harm, and 0.4% (1208/341,097) resulted in patient death.

Contributing Factors
In 20 of our 41 chosen studies (48.8%), the authors indicated factors (n = 51,650) that contributed to the reported CIs (shown in Fig. 4). Overall, the most frequent contributing factor was “active failure” (13,464/51,650, 26.1%), that is, failure regarding healthcare providers’ performance or behavior (e.g., carelessness, treatment errors, failure to meet standards). Additional main contributing factors were “communication” (6548/51,650, 12.7%), “patient factors” (4203/51,650, 8.1%) pointing to patient features (e.g., severity of diseases) that make care more difficult, and “individual factors” (4006/51,650, 7.8%), pointing to healthcare workers’ features that may contribute to active failure, such as inexperience. A secondary contributor was team-related factors (2734/51,650, 5.7%), which consisted of “team factors” (1214/51,650, 2.4%), “staff workload” (879/51,650, 1.7%), and “management of staff and staffing levels” (641/51,650, 1.2%).

Actions Taken
In 15 of our 41 studies (36.6%), organizational actions taken to prevent future incidents were reported. Of those 15, 13 provided 118 detailed examples of measures taken to improve patient safety (see supplementary file, http://links.lww.com/JPS/A508, summarized study characteristics). Following the Institute for Healthcare Improvement’s action hierarchy (2015),26,27,49 we divided those into three classes. Based on each action’s potential impacts on
systems change and improvement, we labeled it as “strong” (n = 32, 27.1%), “intermediate” (n = 49, 41.5%), or “weak” (n = 37, 31.4%; Table 1). Examples include improving the functionality of syringe pumps33 (a “strong action”), the introduction of medication cards for emergency situations and frequently used medications54 (an “intermediate action”), and a nurse-to-nurse check for intravenous pump settings (a “weak action”).

**DISCUSSION**

In reviewing studies about using CIRS in a variety of acute care hospital types, focusing on corrective measures and learning from incidents to improve patient safety, this study provides an overview of the types of CIs reported, their contributing factors, the extent of patient harm that resulted, and the actions taken.

The first important result is that there is a lack of standards in reporting the results of studies on CIRS: rarely were analytical frameworks mentioned, the characteristics of a “critical incident” were defined inconsistently, and the CI categorizations varied broadly. For example, regarding the reported events’ consequences, the studies analyzed in our systematic review used highly heterogeneous terminology: only one51 explicitly applied the NCC MERP index.23 As this lack of standardization and classification of CIs across healthcare systems impedes interstudy comparisons, it slows progress.

The second important result from the review is the lack of evidence of effective organizational learning and improvement of patient safety so far, which is supported by prior claims to change or improve CIRS processes.25,49 Remarkably, only approximately one third of the analyzed studies provided information on improvement actions that followed the analyses. Their main focus was on the processes of information feeding into the CIRSs (reports, reporters, and consequences) rather than the actions taken. The vital tasks of translating the findings into strong actions that would increase patient safety were much less discussed. Therefore, as a standard feature, any future report on CIRS research should include details of how the CI reports were used to improve patient care using a framework for describing the corrective actions.

The 41 hospital-based CIRS studies covered by this systematic review identified 479,483 CI reports from 212 hospitals. Investigating which kinds of events were reported and by which professional group allows to shed light on the capability of CIRS as an instrument for identifying patient safety hazards. For example, nurses were responsible to varying degrees for more than 80% of the reported incidents, which also reflects that nursing staff provide a vast majority of frontline hospital care.39 However, hazards within the physicians’ work processes may be underrepresented in the reports.

In line with prior research,25 the most frequently reported CIs were categorized as “medication related” (28.8%). This ranking reflects the high potential for harm from errors in drug administration.60–62 The second most reported class of CI (20.6%) was “unspecified clinical event.” As a catch-it-all term, it is similar to “administrative error,” a classification also used in CIRS-related studies to indicate arrays of unspecified CIs. The vagueness of classification points to relevant, unsolved issues in learning from incidents: the causes of an event are subject to analyses and are influenced by the knowledge, perspective, and interests that the analysts bring with them.63 The same event may be attributed different causes by different analyzing teams and at different points in time. For example, the classification of a report before it is analyzed may result in it being assigned to completely different categories than would be the case after analysis. A forgotten insulin administration, for example, may be considered an active failure due to inattention, while—after analysis—one may realize that it is also the result of a complex interplay between organizational factors, such as the usability of the medication

**FIGURE 2.** Types of reported critical incidents.

**FIGURE 3.** Consequences of critical incidents according the NCC MERP index.
chart, and the staffing around the time of administration. The topic “communication” also exemplifies the challenges of classifying CIs and their causes into meaningful categories: communication problems were attributed as causes for 12.7% of all CIs, apparently confirming communication’s “error proneness.” In addition, several of our reviewed studies included communication both in “incident type” and “contributing factors” or even in other factor classes (e.g., “human factors,”65 “individual (staff) factors”48).

While CIRS can be used to identify hazards, previous research has concluded that the distribution of incident types cannot be used to assess the severity of reported problems or to compare them with one another66: different incident types’ reporting rates may reflect different motivational factors; errors in medication administration may be more readily reported than complex diagnostic errors that become evident only over time. In addition, the culture may be inducive to reporting or not, so that higher reporting rates do not reflect greater problems, but a better reporting culture.67

Classifying contributing factors according to the Yorkshire contributory factors framework25 allowed us to compare them across studies. The most frequently mentioned contributing factor was “active failure,” which encompasses a broad spectrum of factors in healthcare workers’ performance or behavior (e.g., carelessness, any failure regarding treatment processes or standards of medical care).33,43,68,69 This is an important finding, because

![Contributing factors according the Yorkshire Contributory Factors Framework.](image)

**FIGURE 4.** Contributing factors according the Yorkshire Contributory Factors Framework.

| TABLE 1. Example Actions Sorted Along the Hierarchy of Impact for Change (N = 118) |
|-------------------------------------------------|-------------------------------|-------------------------------------------------|
| **Magnitude of Actions** | **No. Reported Actions** | **Examples** |
| Stronger actions (these tasks require less reliance on humans’ ability to remember to perform the task correctly) | 32 | -Expansion of spaces and personnel in emergencies.50 
-Barcode-assisted medication administration.51 
-Improvement in the operation of syringe pumps.33 
-Transit room for the care and follow-up of the patients in the transfer between hospitals within the complex.50 
-Equipment of the emergency cases on the normal wards.50 |
| Intermediate actions | 49 | -Monthly laboratory report of defective specimens sent to patient care units.53 
-Introduction of medication cards for emergency situations and frequently used medications.53 
-Introduction of standard dosages and dilutions.54 
-Communication skills were highlighted during regular meetings.50 
-Increases in nurse staffing.55 |
| Weaker actions (these tasks require more reliance on humans to remember to perform the task correctly) | 37 | -Medication orders in the presence of a nurse responsible for the patient’s care.56 
-Protocol for the use of high-risk medication in the hospital.50 
-Correct coding of level of impact for skin compromise.53 
-Extra training was provided for the personnel or new equipment was purchased.57 
-Use of syringe pumps in the operating room only prescribed with main operations.52 |

*As proposed in the action hierarchy model on strengths of interventions to improve patient safety.26,27,49

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it illustrates a common limitation of learning from incidents: If the reports are mainly attributed to factors that are “visible” in the situation, rather than trying to find more latent systemic causes, the potential for organizational learning is basically restricted to local improvements. From research about root cause analysis, this tendency to blame the actors involved at the sharp end of an event is well known.70  We therefore recommend based on this review finding that managers responsible for the analysis of incidents should closely track this tendency to assign the responsibility to frontline actors at the sharp end but also keep an eye on “the larger picture” with a more systematic approach. To this end, major changes in the use of CIRS may be necessary. Analyzing critical events, identifying systemic causes, and deriving strong actions demand considerable time and resources. Considering the current limited resources invested in healthcare CIRS, it would not allow to do this for every reported event.2  Thus, groups of incidents reporting similar events can be pulled together and used to do a major analysis, for example. In addition, series of events were proposed to be used to shed light on a patient’s journey.71  In this way, the strength of CIRS lies in providing new qualitative insights into unknown safety issues facing the healthcare organization rather than an unreliable count on an already known issues.72

Furthermore, the details of CI circumstances are essential for their causal analysis; however, these cannot be fully considered in an anonymous written report.73,74  Therefore, recent proposals have suggested to investigate broader time horizons, as well as the patients’ participation in the incident analyses. This would allow exam of the incident within the context of a patient’s journey.71

While none of the reviewed studies applied the Yorkshire framework,73 2 studies48,51 referred to Reason’s9,25 and Vincent’s31 models of accident causation. None of the other studies applied a theoretical framework. As noted in a previous study, this omission suggests a lack of overall consistency.13

Regarding the gravity harm involved, incidents not harming patients but clearly involving an error seem to be the most likely to be reported. This may be explained by the principle that as such errors result in actual occurrences, they are easier to detect than near misses. In addition, if no patients are harmed, many questions of personal responsibility are not raised in the analysis or are associated with less guilt, which might increase the motivation to report. However, poor staffing as system contributor to the occurrence of adverse events relates to excessive nurse workload and lower nurse-to-patient ratios as they are correlated with hospital mortality and morbidity as well as high levels of burnout, work absenteeism, and high job turnover among nurses.76

The error types were reported only in few instances, however, without specifying them for example as error of omission. We did therefore not systematically assess them. However, the fact that the category “error of omission” is not mentioned may also indicate a bias in hazard identification using CIRS, as reporting forgotten or missed actions is less probable than reporting actual behavior.

For CIRS to be effective in improving patient safety, the corrective actions derived need to be defined, implemented, and followed up upon. In addition, deriving strong improvement actions not only also demands considerable resources but often requires actions outside the action repertoires of the participating individuals.77 This means that if systemic causes such as staffing levels or issues in the design of work areas or instruments were identified as important contributors, strategic decisions on the hospital, or sometimes even on the regulatory, national level would need to be taken to generate and sustain strong systemic corrective actions. A good example is the design of healthcare information technology that is often involved in adverse events and that is hard to change from a local level but needs cooperation with industry and sometimes even regulatory demands to be improved.78 Because of these limitations in power to invest resources and bring about systemic change within analysis teams, the causal analyses often derive corrective actions that are the direct cure of an identified issue.79

Attributing incidents to active failures makes the process of identifying a corrective action that can also be implemented fairly simple. Readily available cures include warning signs, updated protocols, or training courses. Although all of these are quite easy to implement, because they target provider behavior, they are also known to offer rather low effectiveness in terms of reducing patient safety hazards.49,80  As Kellogg et al80  sobering illustrated, weak actions derived from event analyses failed to prevent events from recurring during their 8-year study period.

To sum up, the scattered and unsystematically reported evidence in learning from CIRS to improve patient safety paints a rather dire picture of the current situation. Thus, new ways of using CIRS need to be developed. As outlined previously, using reports as qualitative information for uncovering potentially unknown hazards could be a fruitful approach. New tools supporting causal analyses therefore are needed, and best practices in prioritizing action within CIRS management should to be urged30 including schemes to decide which reports to analyze, which to observe, and how to analyze groups of similar incidents. Concerning insights from other instruments to detect patient safety hazards, such as morbidity/mortality conferences and patient complaints, need to be incorporated into the creation of a detailed and comprehensive picture of emerging hazards. Furthermore, we consider it useful to differentiate the target level of potential improvements to not only generate “quick fixes” on the local level, but also develop corrective actions that target systemic levels. Our study proposed framework for classifying incidents, contributory factors, and consequences, systematizing research and practice is an important baseline for improving the current CIRS to not generate waste,14 but actual learning on departmental, hospital, and healthcare system level.

As a final note, we want to highlight that none of the studies systematically reported on the sustainability of the corrective actions or how and when a follow-up happened. This lack of long-term perspective is particularly outstanding, as CIRS aim at systemwide improvements for safety.

**Limitations**

While all of our reviewed studies focused on hospital CIRS, their broad heterogeneity, particularly regarding their methodologies and terminology, impeded the comparability of their data regarding, for example, types of incidents, contributing factors, or actions taken after a CI. Furthermore, as no specific tool was available to assess the quality of our selected CIRS-based studies, we based their eligibility entirely on our study aims. Using a pragmatic approach, our assessment depended heavily on each candidate study’s methodology and primary end points. Nevertheless, to support the comparability of our review findings, we addressed issues of study heterogeneity by applying the NCC MERP index and the Yorkshire contributory factors framework. Finally, for reporting and learning systems such as CIRS, no uniform nationwide legislations does exist across countries and their hospitals, although recommended by the World Health Organization.

**CONCLUSIONS**

This systematic review of studies of hospital-based CIRS data provides an overview of the characteristics of reported incidents, their contributing factors, their consequences, and their actions taken to prevent future incidents. Two main conclusions are drawn from the review: first, research on CIRS-related studies needs to
systematize and align the reporting using frameworks to improve understandability and comparability of their results. Second, the reviews illustrate that there is only scarce evidence showing that systemic change in a hospital is initiated using a CIRS: there was a focus on situational, sharp-end factors in the analyses of the incidents; remarkably, only a third of the reviewed studies described the corrective actions taken; and the sustainability of the derived corrective actions was not addressed systematically. To make a CIRS a useful tool for improving patient safety, there is a need to focus on its strength in providing new qualitative insights into unknown hazards and also on developing tools to facilitate the nomenclature and management of CIRS events, including corrective actions, in a more standardized manner.

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