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Root Cause Analysis Using the Prevention and Recovery Information System for Monitoring and Analysis Method in Healthcare Facilities: A Systematic Literature Review

Babiche E.J.M. Driesen, MD, PhD,* Mees Baartmans, MSc,† Hanneke Merten, PhD,‡ René Otten, MD,§ Camilla Walker, MD,// Prabath W.B. Nanayakkara, MD, PhD,¶ and Cordula Wagner, PhD†‡

Objectives: Unintended events (UEs) are prevalent in healthcare facilities, and learning from them is key to improve patient safety. The Prevention and Recovery Information System for Monitoring and Analysis (PRISMA)method is a root cause analysis method used in healthcare facilities. The aims of this systematic review are to map the use of the PRISMA-method in healthcare facilities worldwide, to assess the insights that the PRISMA-method offers, and to propose recommendations to increase its usability in healthcare facilities. **Methods:** PubMed, EMBASE.com, CINAHL, and The Cochrane Library were systematically searched from inception to February 26, 2020. Studies were included if the PRISMA-method for analyzing UEs was applied in healthcare facilities. A quality appraisal was performed, and relevant data based on an appraisal checklist were extracted.

Results: The search provided 2773 references, of which 25 articles reporting 10,816 UEs met our inclusion criteria. The most frequently identified root causes were human-related, followed by organizational factors. Most studies took place in the Netherlands (n = 20), and the sample size ranged from 1 to 2028 UEs. The study setting and collected data used for PRISMA varied widely. The PRISMA-method performed by multiple persons resulted in more root causes per event.

From the *Department of Emergency Medicine, Amsterdam Public Health Research Institute, Amsterdam UMC, Vrije Universiteit Amsterdam, Amsterdam; †Netherlands Institute for Health Services Research (NIVEL), Utrecht; ‡Department of Public and Occupational Health, Amsterdam Public Health Research Institute, Amsterdam UMC, Vrije Universiteit Amsterdam; §Medical Library, Amsterdam UMC, Vrije Universiteit Amsterdam, the Netherlands; ||Faculty of Biology, Medicine and Health, University of Manchester, Manchester, United Kingdom; and ¶Section of General and Acute Internal Medicine, Department of Internal Medicine, Amsterdam, Amsterdam, the Netherlands. UMC, Vrije Universiteit Amsterdam, the Netherlands. Correspondence: Babiche E.J.M. Driesen, PhD, Amsterdam UMC, Vrije

Universiteit Amsterdam, De Boelelaan 1117, 1081 HV Amsterdam, the Netherlands (e-mail: b.driesen@amsterdamumc.nl).

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Conclusions: To better understand UEs in healthcare facilities and formulate optimal countermeasures, our recommendations to further improve the PRISMA-method mainly focus on combining information from patient files and reports with interviews, including multiple PRISMA-trained researchers in an analysis, and modify the Eindhoven Classification Model if needed.

Key Words: PRISMA, root cause analysis, root cause, unintended event, incident, error, Eindhoven Classification Model, patient safety

Abbreviations: ECM = Eindhoven Classification Model, ED = emergency department, GLD = gastroenterology and liver disorders, IC = intensive care department, MERS-TM = medical event reporting system for transfusion medicine, NICU = neonatal intensive care unit, NHLBI, NIH = National Heart, Lung, and Blood Institute Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies, PICU = pediatric intensive care unit, PRISMA = Prevention and Recovery Information System for Monitoring and Analysis, RCA = root cause analysis, UE = unintended event

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O ne of the key elements to improve patient safety is learning from adverse events.¹ Especially unintended events (UEs) can be a valuable source of information to improve patient safety. Unintended events are a broad group of events, including near misses, that might but do not necessarily result in patient harm.^{2,3} They can be both preventable and unexpected. In clinical practice, there is an increasing interest in the development of systems to systematically evaluate UEs, because several large studies showed that medical errors result in patient harm, leading to temporary or permanent disability or death.⁴⁻⁶ To gain insight into the quality of care, it is necessary to know more about the types of UEs and their root causes, which will simultaneously give insight into possibilities for prevention of UEs. However, there is no standard method to systematically collect, analyze, and compare data related to UEs and their causes among healthcare facilities.⁷

A frequently used approach to improve patient safety is to thoroughly study and analyze a UE to find contributing factors and root causes, and formulate corrective measures.⁸ A number of analysis tools are brought together under the term root cause analysis (RCA), for example, fishbone diagrams, cause-effect charts, and "five whys."⁸ A comprehensive RCA-method that is frequently used in Dutch healthcare facilities is the Prevention and Recovery System for Monitoring and Analysis (PRISMA)-method.^{9,10} This method examines the relative contributions of latent factors (technical and organizational root causes), active failures (human behavior– related root causes), and other factors (patient-related and other root causes). The main goal of the PRISMA-method is to build a quantitative database of UEs and process deviations, to facilitate the development and evaluation of system-based preventive strategies.

The PRISMA-method consists of 3 important pillars: incident description, root cause classification, and the translation to structural measures. First, the incident is described using a causal tree that provides a visual interpretation of the chronological chain of critical activities and decisions leading to an UE. At the top of the tree, the top event, a brief description of the event, is formulated, which is the start of the analysis. By continuously asking "why" the event occurred, all direct causes are identified. When no further objective causes can be identified, the last indirect cause is considered as the root cause. All root causes are logically related to each other and incorporated into the tree (Appendix 1, http://links.lww. com/JPS/A433, and Fig. 1). After compiling the causal tree, the root causes, which form the bottom layer of the causal tree, are classified using the Eindhoven Classification Model (ECM; Appendix 2, http:// links.lww.com/JPS/A434). The ECM distinguishes 4 main categories, namely, technical, organizational, human, and other factors, including patient-related factors and unclassifiable factors. These main categories can be subdivided into 20 subcategories. After root cause classification, information on the event and the identified root causes are placed in a database. Prevention strategies can then be directed at these most frequently occurring (combinations of) root causes.

Although this method is accepted in healthcare facilities and adopted by the World Health Organization,^{11,12} little is known about the application (type of event, study setting) and implementation (data collection, study size, execution of analysis) of the PRISMA-method for analyzing UEs in healthcare facilities. This knowledge gap hinders our ability to learn from insights the PRISMA-method has already provided, and makes it difficult to further improve the application of PRISMA to prevent UEs in healthcare facilities worldwide.

The aims of this study are therefore to give a systematic literature overview of the use of the PRISMA-method in healthcare facilities and to assess the overall insights the PRISMA-method offers to better understand the causes of the UEs. We are particularly interested in the application and implementation of the PRISMAmethod and the most common root causes contributing to UEs in healthcare facilities. Moreover, we intend to provide recommendations for further improvement of the method.

METHODS

To achieve this aim, we performed a systematic literature review. Two researchers (B.E.J.M.D., R.O.) used the structure and recommendations from the Preferred Reporting Items for Systematic Review and Meta-Analysis checklist (PRISMA statement, www. prismastatement.org) as a guideline to conduct the literature search.¹³ We performed systematic searches to find all relevant publications about the "Prevention and Recovery Information System for Monitoring and Analysis" (PRISMA) in the analysis of medical incidents and events searching the bibliographic databases PubMed, EMBASE.com, CINAHL (via EBSCO), and The Cochrane Library (via Wiley) from inception to February 26, 2020. Search terms included controlled terms (e.g., MeSH in PubMed and Emtree in Embase) as well as free-text terms. We used freetext terms only in The Cochrane Library. Search terms expressing "PRISMA" were used in combination with terms comprising "medical events." In the search, all languages were accepted. The references of the identified articles were searched for relevant publications. The full search strategies for all databases can be found in Appendix 3, http://links.lww.com/JPS/A435.

Subsequently, all search results were uploaded to Endnote, to facilitate organizational and removal of duplicates. Second, results (duplicates excluded) were imported in Rayyan, an Internet-based software program that facilitates collaboration among reviewers during the study selection process. Two reviewers (B.E.J.M.D., M.B.) independently screened titles and abstracts and assessed these for eligibility. Ineligible records were excluded (reasons were recorded), and full texts of the remaining studies were assessed independently for eligibility. Results of these assessments were compared, and in case of uncertainty about inclusion, the articles were discussed with a third researcher (H.M.). English- or Dutchwritten articles were included in the study if they (1) published original findings using PRISMA analysis in healthcare facilities, (2) classified the root causes using the ECM, and/or (3) used an observational study design, which included prospective and retrospective cohort studies, case-control studies, cross-sectional studies, case series, and case reports. Studies that applied PRISMA outside of healthcare facilities, articles only focusing on elaborating PRISMA, and articles using the ECM in combination with an unknown RCA or RCA other than PRISMA were excluded. When there was no full text available, articles were excluded. There were no restrictions by publication year, type of setting within healthcare facilities, or follow-up.



FIGURE 1. Example of root causal tree.

Quality Appraisal and Data Synthesis

Two authors (B.E.J.M.D., M.B.) independently assessed the quality of included studies using the National Heart, Lung, and Blood Institute Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies¹¹ to ensure an objective evaluation process. This tool includes 14 questions assessing the internal validity of the studies resulting in an overall quality rating of "good," "fair," or "poor." The tool considers information such as specification of study population, participation rate, measurement of exposure(s) of interest, time frame, and blinding of outcome assessors.

Data Extraction

The following data were extracted from each included study; title, first author, journal, publication year, language, aim, design, study period, study population, hospital setting, department setting, data collection, PRISMA analysis, intervention, type of ECM used, follow-up, outcomes, limitations, future research, and implications. In addition, specific data regarding characteristics and application of the PRISMA-method were extracted, such as number of researchers conducting the PRISMA, training/experience in PRISMA of researchers, ECM-classification profiles, and types of suggested measures for improvement. During the whole process, uncertainties were resolved through team discussions (B.E.J.M.D., M.B., and H.M.) and consensus.

RESULTS

Study Selection

A total of 3926 studies including duplicates were retrieved from all databases after the initial search. After removal of 1153 duplicates, 2773 unique studies remained for the title and abstract review. Next, 2150 studies were excluded after screening titles and abstracts. Main reasons for exclusion were "Descriptive," "Use of causal tree, no PRISMA," "Not in Healthcare facility," "No RCA," and "Other type of RCA." From the resulting 623 articles, there was no access to a full-text version of 72 of the studies, and 17 articles were poster or congress abstracts. Another 509 studies were excluded after full-text evaluation because the study applied a different type of analysis from the PRISMA-method. Eventually, 25 studies were included in the final review. Figure 2 outlines the article selection process.

Quality Assessment

Overall, 3 studies were rated as "poor," 8 studies as "fair," and 14 studies as "good" quality (Table 1). The articles with a "poor" quality rating lacked information concerning research question, study design, study population, and description of implication of the PRISMA-method. Because of the aim of the study was to give a comprehensive overview of the application of PRISMA, we also included these "poor"-rated studies in our sample. Overall agreement on methodological quality score between researchers was 88%.

Study Characteristics

The characteristics of the included articles are presented in Table 2. The publication year of the 25 articles ranged from 1998 to 2019, and most of the studies (n = 20) took place in the Netherlands. The sample size ranged from a single case study²¹ to a multicenter study analyzing 2028 UEs.²⁷ All studies were presented as observational cohort studies, with a retrospective (n = 23) and prospective (n = 1) design. Van Dulmen et al¹⁶ combined a retrospective patient record review with prospective event reporting. The design was not clearly mentioned in 5 studies but interpreted as observational by the researchers.

Study Population

Variations in definitions, type of event, and measurement of the study population were evident. In 6 studies, events without deviations were analyzed.^{14,15,17–20} The study objects in these articles were event reports in transfusion medicine,²⁰ readmissions,^{14,17,19} unplanned intensive care department admissions,¹⁸ and an emergency department (ED) length of stay >6 hours.¹⁵



FIGURE 2. PRISMA flow diagram of article selection.

 TABLE 1. NHLBI, NIH: National Heart, Lung, and Blood

 Institute Quality Assessment Tool for Observational Cohort and

 Cross-Sectional Studies¹¹

Reference	Author	Score	Missing Information in Description of:
12	Battles and Shea	Fair	Study population Exposure measures and assessment
14	Cooksley et al	Fair	Study population Exposure measures and assessment
15	Driesen et al	Good	
16	Van Dulmen et al	Fair	Sample size justification Exposure measures and assessment
17	Fluitman et al	Good	
18	Van Galen et al	Good	
19	Van Galen et al	Good	
20	Kaplan et al	Poor	Research question Study population Participation rate Time frame
21	Klemt-Kropp et al	Poor	Research question Exposure measures and assessment Outcome measures
22	Lubberding et al	Good	
23	Merten et al	Good	
24	Van Noord et al	Good	
25	Rodrigues et al	Poor	Research question Study population Exposure measures and assessment Outcome measures
26	Sasaki et al	Fair	Study population Blinding of outcome assessors
27	Smits et al	Good	
28	Smits et al	Good	
29	Smits et al	Fair	Study population Groups recruited from the same population
30	Snijders et al	Good	I I I I I I I I I I I I I I I I I I I
31	Sniiders et al	Fair	Study population
32	Thomas and Mackway-Jones	Good	The second se
33	De Vries et al	Fair	Sample size Blinding of outcome assessors
34	Wagner et al	Good	
35	Van Wagtendonk et al	Good	
36	Wubben et al	Fair	Sample size justification Time frame
37	Zegers et al	Good	

In 19 studies, events with deviations were analyzed, including incidents, $^{16,24,26,30-32,34,36}$ UEs, 22,27,28,33,35 errors, 12,21,25 and adverse events. 23,29,37 In almost all (n = 7) of the studies analyzing incidents, a clear definition of "an incident" was mentioned. For example: "A critical incident was defined as an event that had actual or potential harmful effects on the outcome of the management of a patient or group."³³ Unintended events were defined

as "a broader group of events—including near misses—that do not necessarily result in patient harm."^{22,27,28,32,35} The adverse events in the study by Zegers et al³⁷ and Merten et al²³ were defined as "unintended injuries among patients that results in disability, death or prolonged hospital stay, and is caused by health care management."

Study Setting

The majority of the studies (n = 23) were conducted in a hospital setting. In the 2 other studies, patients were included from 3 allied healthcare disciplines (physical therapy, occupational therapy, and Cesar-Mensendieck exercise therapy)¹⁶ and from a blood and transfusion center.²⁰ The majority of studies (n = 16) limited the study population to one department or specialty,^{14,15,17–19,21,22,24–26,28,29,32,33,35,36} whereas others included cases from various hospital departments.^{19,29,33,36–39}

Data Collection and Implementation of PRISMA

The collected data used for the PRISMA analysis were gathered using different sources. In 9 studies, the information for the PRISMA analysis was based on patient files, ^{14–18,23,24,29,37} and in 5 studies, the data were collected from a report form.^{20,26,30,31,33} In 3 studies, the report form was based on voluntary, nonpunitive reporting.^{26,30,31} In some studies, the data were collected from a combination of sources; 6 studies used a combination of a report form, an interview, and a patient record.^{32,36} In 3 studies, the sources underlying the data used for analysis are unknown.^{12,21,25}

Researchers received a PRISMA-training in almost half (n = 12) of the included studies.^{15,17,18,20,22,24,27,30,31,34,35} This training ranged from a 3-hour workshop²⁰ to a 2-day course.^{30,31} In the majority of studies (n = 14), the PRISMA analysis was performed by 2 persons or a team (independent from each other). This team could consist of "analysts,"³³ "researchers,"^{15,17,18,22,34} a multidisciplinary safety commission consisting of at least 1 physician and 3 nurses,^{36,37} multiple doctors,^{12,23,26,33,37} or physical therapists.¹⁶ The mean root causes per event were 2.5 in the articles where the analysis was performed by multiple persons (range, 1.4–6.3). In 8 studies, the PRISMA analysis was conducted by a single person^{19,20,24,28,29,32,35,36}; here the mean root causes per event were 1.8 (range, 1.0–2.9). In 3 articles, it is unknown who performed the PRISMA.^{14,20,25} Furthermore, interobserver agreement on root causes and ECM classification was studied in 10 of the studies,^{16,24,27–33,37} with scores ranging from "moderate" to "good."

Root Causes and ECM

Human-healthcare worker–related root causes were the most frequently found ECM-classified root causes in the majority of the studies (n = 14).^{16,18,20,22–24,28,30,31,33–37} In other studies, the main category of root causes was organizational factors (n = 5),^{12,15,21,26,32} disease-related factors (DRF; n = 2),^{16,19} and patient-related factors (n = 2).^{14,30} The distribution of root causes was not mentioned in 2 studies.^{25,27} The most frequently reported human-healthcare worker–related root causes were as follows: knowledge-based behavior (n = 3),^{16,23,24} intervention (n = 2),^{22,36} verification (n = 1),³³ monitoring (n = 1),¹⁸ external (n = 1),⁶ and rule-based behavior (n = 1).³¹ In 5 studies, the further subdivision of the human/healthcare worker–related root causes was not reported.^{12,30,34–36}

In the 14 studies where human-healthcare–related root causes were most prominent, the majority of the studies analyzed incidents. 16,24,30,34,36 Furthermore, the analysis was limited to one department, $^{18,20,22,24,28,33,35-37}$ and the PRISMA was done by multiple persons $^{16,18,22,23,30-32,34,37}$ in most of the cases. Six

TABLE 2	. Descriptive Chara	icteristics of Included St	udies						
		Country, Yéar of		Setting	Data	No. Root	Root Cause	ECM	Most Reported ECM
Referenc	e Author	Publication	Type of Event	Department	Collection	Causes	Per Event	Modification	Classification
12	Battles and Shea	United States and the Netherlands, 2001	Error $(n = 3)$	ED and IC	NR	19	6.3	Original	Organizational, n = 11 (59%)
4	Cooksley et al	United Kingdom, 2015	Readmissions (event) (n = 50)	Oncology	Patient file	NR	NR	Original	Patient, n = 50 (100%) disease related
15	Driesen et al	The Netherlands, 2018	Increased ED-LOS (event; $n = 74$)	ED	Patient file	276	3.3	Modified Disease-related factor added 	Organizational, n = 216 (78%)
16	Van Dulmen et al	The Netherlands, 2011	Incidents (n = 18)	Physiotherapy, occupational therapy, and cesar-mensendieck therapy	Patient file	55	3.1	Original	Human, n = 40 (73%)
17	Fluitman et al	The Netherlands, 2016	Readmissions (event) $(n = 50)$	Internal medicine	Patient file	100	7	Modified Disease-related factor added 	Disease related, n = 46 (46%)
18	Van Galen et al	The Netherlands, 2016	Unplanned ad missions (event; $n = 49$)	IC	Patient file	155	3.2	Modified Disease-related factor added 	Human, $n = 71$ (46%)
19	Van Galen et al	The Netherlands, 2018	Readmissions (event, $n = 237$)	Surgery	Report form, interview	271	1.1	Modified Disease-related factor added 	Disease related, n = 218 (87%)
20	Kaplan et al	United States, 1998	Events/process $(n = 506)$	Blood center Transfusion center	Report form	1238	2.9	Modified • Content adopted for MERS-TM, no change in (sub)categories	Human, n = 569 (46%)
21	Klemt-Kropp et al	The Netherlands, 2011	Error $(n = 1)$	MDL	NR	8	8	Original	Organizational, n = 5 (63%)
22	Lubberding et al	The Netherlands, 2011	UEs (n = 625)	Internal medicine	Report form, interview	920	1.5	Original	Human, $n = 706$ (77%)
23	Merten et al	The Netherlands, 2013	Adverse events $(n = 663)$	All departments, excluding psychiatry, obstetrics, children<1 v	Patient file	1278	1.9	Modified • Human violation added • Human-other added	Human, n = 808 (63%)
24	Van Noord et al	The Netherlands, 2010	Malpractice claims (incident; n = 50)	ED	Patient file	114	2.3	Modified • Organizational x-ray results (OR) added • Organizational no contact with supervisor (OS) added	Human, n = 76 (67%)

NR d,	Organizational– home facility, al $n = 74 (34\%)$	NR	Human, $n = 507$ (60%)	Patient related, n = (47, 4%)	Human, n = 1480 (64%)	Human, $n = 293$ (55%)	Organizational, L n = 295 (35%) L xd	Human, estimated 65%	Human, n = 2117 (70%) ae	Human, n = 904 (73%)	Human, $n = 16$ (40%)	Human, $n = 426$ (65%)
Modified • Content adopted for medical imaging fiel no change in (sub) categories	Modified • Home/facility category instead of organization	Original	Original	Modified • Violation added • Human skills added • Other added	Original	Original	Modified • Technical-other instea of Technical-materia • Human execution instead of human intervention • Multiple patients adde	Original	Modified • Patient related and other combined in or category	Original	Original	Original
NR	2.3	1.4	1.6	1.0	2.4	2.3	2.4	NR	1.5	1.4	2.7	1.8
NR	220	3015	845	588	2313	1233	852	NR	3015	1250	40	653
NR	Report form	Report form interview	Report form interview	Patient file	Report form	Report form	Report form, patient file, interview	Report form.	Report form interview	Report form interview	Report form, patient file, interview	Patient file
Radiology	Allergology	ED, internal medicine, surgery	ED	All departments, excluding psychiatry, obstetrics, children<1 y	NICU and PICU	NICU and PICU	ED	Urology	ED, Internal medicine, Surgery	Surgery	Operation room	Surgery
Error $(n = 79)$	Incidents $(n = 95)$	UEs (n = 2028)	UEs (n = 522)	Adverse events $(n = 571)$	Incidents $(n = 981)$	Incidents $(n = 533)$	Incidents (n = 349)	UE (n = 41)	Incidents $(n = 2028)$	UEs (n = 881)	Incidents $(n = 15)$	Adverse events ($n = 367$)
Portugal, 2011	Japan, 2018	The Netherlands, 2009	The Netherlands, 2009	The Netherlands, 2019	The Netherlands, 2008	The Netherlands, 2010	United Kingdom, 2007	The Netherlands, 2015	The Netherlands, 2016	The Netherlands, 2010	The Netherlands, 2010	The Netherlands, 2011
Rodriques et al	Sasaki et al	Smits et al	Smits et al	Smits et al	Snijders et al	Snijders et al	Thomas and Mackway-Jones	De Vries et al	Wagner et al	Van Wagtendonk et al	Wubben et al	Zegers et al
25	26	27	28	29	30	31	32	33	34	35	36	37

studies^{22,28,30,34–36} used a combination of data sources for the PRISMA-method. Patient interviews were used in 5 studies.^{28,30,34–36} The number of root causes per event ranged from 1.4^{35} to $3.2.^{18}$

In 13 studies, the original ECM was used, and in 12 studies, the ECM was modified because the current ECM did not sufficiently cover the observed types of failures (Table 2). In 4 studies, a new DRF category was added.^{17–19,29} The disease-related root cause was first described by Fluitman et al¹⁷ in 2016 and defined as "failures related to the natural progress of disease which are beyond control of patients, their carers and staff." In these 4 studies, the DRF refers to readmissions and unplanned admissions of patients. The authors assumed that progression of disease would be identified as root cause in many readmissions without other factors contributing. Other modifications included adaptation of the content of categories to the study population^{20,25} and addition of new subcategories, for example, human violation^{23,29} and organizational x-ray results.²⁴

DISCUSSION

This systematic review identified 25 original studies using the PRISMA-method for RCA. The results show that the PRISMAmethod is applicable in a wide variety of healthcare settings. Most studies analyzed UEs, predominantly incidents. Furthermore, most studies were limited to one department or specialty and used patient files or report forms for data collection, and the analysis was done by multiple persons. Overall, human-healthcare workerrelated root causes were the most common root causes, followed by organizational factor-related root causes.

Based on descriptions of various RCA methods in the literature^{10,38-42} and their limitations,⁴³⁻⁴⁶ and the results of this review, we believe that PRISMA has some important features that make it one of the most valuable RCA methods. First, PRISMA is suitable for events varying in seriousness and complexity, whereas other methods are designed to investigate more serious adverse events. Another advantage of PRISMA medical is that it intends to build a database of multiple events to find reoccurring patterns of root causes.9,10 Based on these patterns, it might be possible to formulate more effective corrective measures. Because both active failures (human failures) and latent failures (technical and organizational failures) are discovered through PRISMA, the total profile of root causes provides a more realistic view of how the system is actually working. The standardized root cause classification improves the comparability of investigated events between healthcare facilities as well as in the identification of common problems and concerns that exist throughout the medical field.

Most studies reported events where the reporting system and analysis was limited to a single department or service within the hospital. Local, department-based reporting systems can help to get faster and more detailed insight into unit-specific safety issues. The assumption is that incidents differ between departments and that incidents reported and analyzed by the department where the incident happened will create a greater sense of urgency and willingness to change practice. Wagner et al³⁴ found significant differences in incident types and especially in root causes between emergency, surgery, and internal medicine departments, therefore recommending department-based reporting. A limitation of department-based analysis is that causes occurred in other departments are classified as external. It is possible that an external factor in fact had more underlying root causes, and they remain hidden because of the choice to examine just one department. In 4 studies, events from the ED were collected and analyzed.^{15,24,28,32} Many of the root causes in the studies restricted to the ED were classified external. Driesen et al¹⁵ found 76% of the ED length of stay of more than 6 hours was due to organizational causes, of which 94% was outside

the influence of the ED.¹⁵ This indicates that a large number of events occurred in collaboration with departments outside of the ED, and the healthcare for patients depend on good collaboration between departments.

The patient file method for data collections was the most used, but this may not be the most accurate method. Technical and organizational causal factors are less often reported in patient files and may therefore be underestimated. An organizational factor could, for example, be a shortage of hospital staff. However, such causes are not typically written down in patient files and therefore remain invisible to the researchers. This is in line with our results; in the studies where the patient file was the only data source, the majority of the articles had a human factor as most common root cause^{16,18,23,24,37} in contrast to other data sources. Multiple studies^{14,17,18,23,29,37} suggested that besides the patient file or a report, an interview with those involved at a local level can lead to a deeper understanding. The interview depends on the recall of the reporters, and UEs should be discussed within a few days. This is in line with our results showing that when the data were based on interviews only, organizational root causes were most prominent.

On average, there were more root causes per event in the studies where the PRISMA analysis was done by multiple persons (2.5 versus 1.8). An explanation could be that multiple persons have different perspectives, especially when there is a multidisciplinary team including different healthcare workers, for example, doctors and nurses, or people without direct patient healthcare experience or contact, for example, experts in the field of human factors/ ergonomics, clinical technologists, or PhD researchers. This could also contribute to finding more technical and organizational root causes. Furthermore, based on our practical experience, we believe it is important for the reliability of the PRISMA-method that the researchers are trained in PRISMA and that they have knowledge of the department and its processes. In this study, almost half of the articles mentioned that the researchers received training. Only in a small part of the studies the content and the duration of the training were mentioned, and therefore, it was difficult to substantiate this hypothesis. Overall, human-healthcare workerrelated root causes were most prominent in the included studies. These root causes can be defined as "errors and violations committed by those in direct contact with the human-system interface."47 Our finding that the root causes were mainly human-related is in line with other studies investigating (adverse) events that also found that causes related to the people involved, such as human behavior, cognitive biases, and poor communication, were frequently or dominantly reported.^{38,48-51} However, as mentioned before, the type of root cause can be dependent on the source of the data collection used and PRISMA team composition. To get an overall view, a report form should be combined with patient file and an interview, and various disciplines should be represented in the team.

Strengths

This is the first systematic literature review giving an overview of the use of the PRISMA-method in healthcare facilities. An experienced librarian (R.O.) assisted in the literature search, and the screening of the articles, the data collection, and the quality assessment were independently done by 2 researchers (B.E.J.M.D. and M.B.).

Limitations

First, 3 studies were rated "poor quality" because information on several study characteristics was not reported. However, we included these studies because the aim of our study is to provide an overview, and therefore, the lacking information does not bias our results or discussion. Second, 20 of the 25 included studies were concerned with Dutch healthcare facilities. This may be the result of the popularity of the PRISMA analysis in the Netherlands, which in turn could be explained by the Dutch origin of the method and its founders.

Recommendations

To get a complete view of all contributing root causes of UEs, we recommend combining patient files and reports with interviews when conducting a PRISMA analysis, thereby striving for a small time lag between the occurrence and the assessment of the UE to decrease the likelihood of memory failure.³⁵ In that case, involved healthcare providers can be interviewed to provide more information on organizational and technical factors that might have contributed to the UE. Preferably, the PRISMA should be performed by multiple researchers representing various disciplines, who should get training in making causal trees and classifying root causes, as training of researchers increases reliability.⁵² When using department-based analyzing, it is advisable to modify the ECM to gain more insight into the causes outside of the department, for example, the addition of the DRF.

CONCLUSIONS

This study outlines the current variety of the use of the PRISMAmethod in healthcare facilities worldwide. Human-healthcare worker-related root causes were found to be the most commonly reported root causes, followed by organizational factor-related root causes. The selected studies showed that the PRISMA-method is a useful tool with added value for analyzing UEs in healthcare facilities. To improve the usability of PRISMA, we suggest combining information from patient files and reports with interviews, including multiple PRISMA-trained researchers representing various disciplines in an analysis, and modify the ECM if needed, to make care safer and more efficient by learning from UEs in healthcare processes.

REFERENCES

- Institute of Medicine (US) Committee on Quality of Health Care in America. *To Err Is Human: Building a Safer Health System*. Kohn LT, Corrigan JM, Donaldson MS, eds. Washington, DC: National Academies Press (US); 2000. PMID: 25077248.
- Rodziewicz TL, Houseman B, Hipskind JE. Medical Error Prevention. Treasure Island, FL: StatPearls Publishing; 2020. StatPearls [Internet]. October 17, 2020. PMID: 29763131.
- Leape LL. Reporting of adverse events. N Engl J Med. 2002;347: 1633–1638.
- de Vries EN, Ramrattan MA, Smorenburg SM, et al. The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care.* 2008;17:216–223.
- Hogan H, Healey F, Neale G, et al. Preventable deaths due to problems in care in English acute hospitals: a retrospective case record review study. *BMJ Qual Saf.* 2012;21:737–745. Erratum in: BMJ Qual Saf. 2013 Feb;22(2):182.
- Zegers M, de Bruijne MC, Wagner C, et al. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. *Qual Saf Health Care*. 2009;18:297–302.
- Morello RT, Lowthian JA, Barker AL, et al. Strategies for improving patient safety culture in hospitals: a systematic review. *BMJ Qual Saf.* 2013;22: 11–18.
- Kellogg KM, Hettinger Z, Shah M, et al. Our current approach to root cause analysis: is it contributing to our failure to improve patient safety? *BMJ Qual Saf.* 2017;26:381–387.

- Van Vuuren WSC, Schaaf TW. The development of an incident analysis tool for the medical field. 1997. Available at: https://pure.tue.nl/ws/files/ 1370080/493452.pdf. Accessed March 10, 2020.
- Van der Schaaf TWHM. PRISMA-Medical. A Brief Description. Eindhoven, the Netherlands: Eindhoven University of Technology, Faculty of Technology Management, Patient Safety Systems; 2005. Available at: https://www.who.int/patientsafety/taxonomy/PRISMA_Medical.pdf. Accessed March 10, 2020.
- National Institutes of Health. Quality assessment tool for observational cohort and cross-sectional studies. 2014. Available at: www.nhlbi.nih.gov/ health-pro/guidelines/in-develop/cardiovascular-risk-reduction/tools-cohort. Accessed March 10, 2020.
- Battles JB, Shea CE. A system of analyzing medical errors to improve GME curricula and programs. *Acad Med.* 2001;76:125–133.
- Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. *BMJ*. 2009; 339:b2700.
- Cooksley T, Merten H, Kellett J, et al. PRISMA analysis of 30 day readmissions to a tertiary cancer hospital. *Acute Med.* 2015;14:53–56.
- Driesen BEJM, van Riet BHG, Verkerk L, et al. Long length of stay at the emergency department is mostly caused by organisational factors outside the influence of the emergency department: a root cause analysis. *PLoS One.* 2018;13:e0202751.
- van Dulmen SA, Tacken MA, Staal JB, et al. Patient safety in primary allied health care: what can we learn from incidents in a Dutch exploratory cohort study? *Med Care*. 2011;49:1089–1096.
- Fluitman KS, van Galen LS, Merten H, et al, safer@home consortium. Exploring the preventable causes of unplanned readmissions using root cause analysis: coordination of care is the weakest link. *Eur J Intern Med*. 2016;30:18–24.
- van Galen LS, Struik PW, Driesen BE, et al. Delayed recognition of deterioration of patients in general wards is mostly caused by human related monitoring failures: a root cause analysis of unplanned ICU admissions. *PLoS One.* 2016;11:e0161393.
- van Galen LS, Vedder D, Boeije T, et al. Different perspectives on predictability and preventability of surgical readmissions. *J Surg Res*. 2019; 237:95–105.
- Kaplan HS, Battles JB, Van der Schaaf TW, et al. Identification and classification of the causes of events in transfusion medicine. *Transfusion*. 1998;38:1071–1081.
- Klemt-Kropp M, van der Lans SM. Patiëntenverwisseling bij een endoscopische ingreep. Aanleiding voor verbetering van procedures [Switch of patients undergoing an endoscopic procedure]. *Ned Tijdschr Geneeskd*. 2011;155:A3659. Dutch.
- Lubberding S, Zwaan L, Timmermans DR, et al. The nature and causes of unintended events reported at 10 internal medicine departments. *J Patient* Saf. 2011;7:224–231.
- Merten H, Zegers M, de Bruijne MC, et al. Scale, nature, preventability and causes of adverse events in hospitalised older patients. *Age Ageing*. 2013;42:87–93.
- van Noord I, Eikens MP, Hamersma AM, et al. Application of root cause analysis on malpractice claim files related to diagnostic failures. *Qual Saf Health Care*. 2010;19:e21.
- Rodrigues S, Brandão P, Nelas L, et al. A logic programming approach to medical errors in imaging. *Int J Med Inform.* 2011;80:669–679.
- Sasaki K, Nakagawa T, Sugiura S, et al. Identifying the factors and root causes associated with the unintentional usage of an adrenaline autoinjector in Japanese children and their caregivers. *Allergol Int.* 2018;67: 475–480.
- Smits M, Janssen J, de Vet R, et al. Analysis of unintended events in hospitals: inter-rater reliability of constructing causal trees and classifying root causes. *Int J Qual Health Care*. 2009;21:292–300.

- Smits M, Groenewegen PP, Timmermans DR, et al. The nature and causes of unintended events reported at ten emergency departments. *BMC Emerg Med.* 2009;9:16.
- Smits M, Langelaan M, de Groot J, et al. Examining causes and prevention strategies of adverse events in deceased hospital patients: a retrospective patient record review study in the Netherlands. *J Patient Saf.* 2021;17: 282–289.
- Snijders C, van der Schaaf TW, Klip H, et al, NEOSAFE Study Group. Feasibility and reliability of PRISMA-medical for specialty-based incident analysis. *Qual Saf Health Care*. 2009;18:486–491. Erratum in: Qual Saf Health Care. 2011;20(5):396. van Lingen WPF Fetter, RA [corrected to van Lingen, RA]; Fetter, WPF [added]. PMID: 19955462.
- 31. Snijders C, van Lingen RA, van der Schaaf TW, et al, NEOSAFE Study Group. Incidents associated with mechanical ventilation and intravascular catheters in neonatal intensive care: exploration of the causes, severity and methods for prevention. *Arch Dis Child Fetal Neonatal Ed.* 2011;96: F121–F126.
- Thomas M, Mackway-Jones K. Incidence and causes of critical incidents in emergency departments: a comparison and root cause analysis. *Emerg Med J.* 2008;25:346–350.
- de Vries AH, Boute MC, Kuppen MC, et al. Patient safety risks of basic urological procedures performed by junior and senior residents. *J Surg Educ.* 2015;72:918–926.
- Wagner C, Merten H, Zwaan L, et al. Unit-based incident reporting and root cause analysis: variation at three hospital unit types. *BMJ Open.* 2016; 6:e011277.
- van Wagtendonk I, Smits M, Merten H, et al. Nature, causes and consequences of unintended events in surgical units. *Br J Surg.* 2010;97: 1730–1740.
- 36. Wubben I, van Manen JG, van den Akker BJ, et al. Equipment-related incidents in the operating room: an analysis of occurrence, underlying causes and consequences for the clinical process. *Qual Saf Health Care*. 2010;19:e64.
- Zegers M, de Bruijne MC, de Keizer B, et al. The incidence, root-causes, and outcomes of adverse events in surgical units: implication for potential prevention strategies. *Patient Saf Surg.* 2011;5:13.
- Charles R, Hood B, Derosier JM, et al. How to perform a root cause analysis for workup and future prevention of medical errors: a review. *Patient Saf Surg*, 2016;10:20.
- Leistikow IP, den Ridder K, De Vries B. Patiëntveiligheid: Systematische Incident Reconstructie en Evaluatie. 2nd revised ed. Maarssen, the Netherlands: Elsevier gezondheidszorg; 2009.

- Joint Commission Resources I. Root Cause Analysis in Health Care: Tools and Techniques. 6th ed. Oak Brook, IL: Joint Commission Resources; 2017.
- Woloshynowych M, Rogers S, Taylor-Adams S, et al. The investigation and analysis of critical incidents and adverse events in healthcare. *Health Technol Assess*. 2005;9:1–143, iii.
- 42. Tan H. Elk incident heeft een context. Het analyseren van een incident heeft het meeste effect als dit de organisatie áchter het voorval blootlegt. Want menselijk falen heeft altijd een context. *Medisch Contact*. 2010;65:2290.
- Peerally MF, Carr S, Waring J, et al. The problem with root cause analysis. BMJ Qual Saf. 2017;26:417–422.
- Wu AW, Lipshutz AK, Pronovost PJ. Effectiveness and efficiency of root cause analysis in medicine. JAMA. 2008;299:685–687.
- Nicolini D, Waring J, Mengis J. The challenges of undertaking root cause analysis in health care: a qualitative study. *J Health Serv Res Policy*. 2011; 16(Suppl 1):34–41.
- 46. Card AJ. The problem with '5 whys'. BMJ Qual Saf. 2017;26:671-677.
- Reason J. Understanding adverse events: human factors. *Qual Health Care*. 1995;4:80–89.
- Lee A, Mills PD, Neily J, et al. Root cause analysis of serious adverse events among older patients in the Veterans Health Administration. *Jt Comm J Qual Patient Saf.* 2014;40:253–262.
- Hooker AB, Etman A, Westra M, et al. Aggregate analysis of sentinel events as a strategic tool in safety management can contribute to the improvement of healthcare safety. *Int J Qual Health Care.* 2019;31: 110–116.
- Soncrant C, Mills PD, Neily J, et al. Root cause analyses of reported adverse events occurring during gastrointestinal scope and tube placement procedures in the Veterans Health Association. *J Patient Saf.* 2020;16: 41–46.
- Spraker MB, Fain R 3rd, Gopan O, et al. Evaluation of near-miss and adverse events in radiation oncology using a comprehensive causal factor taxonomy. *Pract Radiat Oncol.* 2017;7:346–353.
- Brown C, Hofer T, Johal A, et al. An epistemology of patient safety research: a framework for study design and interpretation. Part 3. End points and measurement. *Qual Saf Health Care*. 2008;17:170–177.
- 53. Zegers M, de Bruijne MC, Wagner C, et al. Design of a retrospective patient record study on the occurrence of adverse events among patients in Dutch hospitals. *BMC Health Serv Res.* 2007;7:27.
- Graves CM, Haymart B, Kline-Rogers E, et al. Root cause analysis of adverse events in an outpatient anticoagulation management consortium. *Jt Comm J Qual Patient Saf*. 2017;43:299–307.