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REVIEW

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Tools for the investigation of adverse events: scoping review*

Ferramentas para investigação de eventos adversos: revisão de escopo

Herramientas para investigación de eventos adversos: revisión de alcance

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ABSTRACT

Objective: To map, in the literature, the risk management tools aimed at investigating health adverse events. **Method:** Scoping review according to the *Joanna Brigss Institute*, with acronym PCC (Population: hospitalized patients, Concept: tools for the investigation of adverse events, and Context: health institutions) carried out in MEDLINE (OVID), EMBASE, LILACS, Scopus, CINAHL, and gray literature. **Results:** The search totaled 825 scientific productions, 31 of which met the objective of the study, which consisted of 27 scientific articles and 4 expert consensus. It was possible to carry out a synthesis of the necessary steps for the investigation of adverse events and use of the tools according to the extent of damage. **Conclusion:** The practice of investigating adverse events should be guided by a thorough understanding of contributing factors, a fair culture, and the involvement of senior leadership.

DESCRITORES

Patient Safety; Risk Management; Patient Harm; Health Quality Management; Safety Management.

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INTRODUCTION

In 2013, from the publication of the Resolution of the Collegiate Board of Directors – RDC no. 36/2013, it was possible to understand that risk management is a form of proactive and reactive approach to the risks that the patient runs in the health services[1–2].

The construction of the concept and the practical applicability of risk management has its origins in the industry and aviation segments. Moreover, activities related to this topic represent a proactive approach to identified risks, insofar as they allow the identification, planning, and implementation of actions and activities that work as barriers to prevent a risk from resulting in an incident[3].

In Brazil, in 2013, the Ministry of Health (MS) launched the National Patient Safety Program (*PNSP*), through the publication of Ordinance No. 529, of April 1. PNSP aims to prevent, monitor, and reduce the incidence of adverse events (AE) in the care provided, promoting continuous improvement related to patient safety[2].

A study carried out in Brazil showed an incidence of 7.6% adverse events, of which 66.7% were preventable. Thus, the incidence of patients with adverse events in the three hospitals included in the study was similar to that of international studies; however, the proportion of preventable adverse events was considerably higher in Brazilian hospitals[4].

The investigation of adverse events in health services, considered a requirement of the *PNSP*, is a fundamental action to identify and map the failures occurring in assistance and explore the possible causes leading to the incident, and devise action plans to allow the reduction of the level of damage and the prevention of a possible recurrence[1–4].

Therefore, health institutions shall be aware of the challenges imposed by patient safety, such as that of developing a more careful investigation regarding the error and harm patients experience. Because immediately after an incident, people make quick judgments and very often blame the person most obviously connected with the disaster[2–3].

Currently, there are tools and/or instruments to help in the investigation, conducting a robust analysis and reaching consistent results. The most used tools for investigation of AE in health are: Root cause analysis with contributing factors adapted *from Three levels of RCA investigation*; *Human Factors Analysis and Classification System* (HFACS); *Canadian Incident Analysis Framework*; *Yorkshire Contributory Factors Framework* and the London Protocol. However, in the midst of this variety of instruments, many institutions make the mistake of selecting a complex tool, or perhaps one not suitable for the investigation process, where the manager him/herself has difficulty conducting the operationalization[3,5–6].

Therefore, it is necessary to explore tools aimed at investigating adverse health events. Furthermore, since the implementation of the reactive risk management methodology in healthcare organizations, there has been a reduced number of tools that fully serve the healthcare sector and which take all the steps required to complete the root cause analysis and the identification of all contributing factors to the elaboration of an efficient improvement plan.

This study aims to map, in the literature, the risk management tools focused on the investigation of health adverse events.

METHOD

Design of Study

This is a scoping review aimed at mapping the literature in a particular field of interest, identifying and exploring the nature of the productions and allowing the synthesis of existing scientific evidence related to the theme, in addition to identifying gaps in research knowledge, especially when reviews on the topic have not yet been published. The review was developed based on the recommendations of the *Joanna Briggs Institute* (JBI)[5]. The research question was based on the acronym PCC (Population, Concept and Context): what tools are used in patient safety to investigate health adverse events? The term Population refers to inpatients; Concept, to tools for the investigation of health adverse events, and Context, to health institutions.

Eligibility Criteria

From the PCC acronym, this review population were patients hospitalized due to any pathologies. Thus, studies involving hospitalized patients in any inpatient unit in a health institution were included. Regarding the concept, studies addressing the tools for investigating health adverse events were included. They are techniques or instruments that aim to identify and analyze the root cause of healthcare-associated unnecessary harm. Studies describing one or other tools to investigate adverse events based on root cause analysis were included. Finally, in the context, studies with patients hospitalized in a health institution were included.

Therefore, the types of sources this review considered were descriptive and analytical observational studies, individual case reports, expert consensus, guidelines, protocols, secondary studies, dissertations, and theses. Language filters and time periods were not applied. However, editorials, abstracts, correspondence, monographs, reviews, articles that were not available in full in the data sources were excluded. The searches were carried out in November 2020.

Search Strategy

According to JBI guidelines, the search strategy took place in three stages. In the first one, a limited search on the subject was carried out on the PubMed electronic database, on the Mesh and CINAHL platforms, to identify the descriptors most commonly used in the literature. In the second stage, the research was carried out in the following information bases: MEDLINE (OVID), EMBASE, LILACS, Scopus, and CINAHL, as shown in Chart 1.

In the third stage, the gray literature was consulted using the repository of the Brazilian Digital Library of Theses and Dissertations (*BDTD*), made available by the Ministry of Science, Technology and Innovation. In addition, searches were carried out in the agencies and foundations for Patient Safety to identify manuals and expert consensus on the investigation of adverse events.

Chart 1 – Databases and respective search strategies – Niterói, RJ, Brazil, 2020.

Data base	Search Strategy
MEDLINE (OVID)	1 epidemiologic studies/2 exp case control studies/3 exp cohort studies/ 4 cross-sectional studies/5 case control.ti,ab. 6 (cohort adj (study or studies or analysis*)).ti,ab. 7 ((follow up or observational or uncontrolled or non randomi#ed or nonrandomi#ed or epidemiologic*) adj (study or studies)).ti,ab. 8 ((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort*)).ti,ab. 9 or/1-8 10 (Incident or adverse event* or error* or accident*).ti,ab. 11 medical errors/ 12 or/10-11 13 ("risk management" or "Root Cause").ti,ab. 14 "risk Management"/15 or/13-14 16 safet*.ti,ab. 17 "patient safety"/18 or/16-17 19 (protocol or tool* or system* or guideline* or checklist* or framework*).ti,ab.20 9 and 12 and 15 and 18 and 19
EMBASE	('incident report'/exp OR 'incident report':ti,ab OR 'incident reports':ti,ab OR incident*:ti,ab OR 'adverse event'/exp OR 'adverse effect':ti,ab OR 'adverse effects':ti,ab OR 'adverse event':ti,ab OR 'adverse events':ti,ab OR 'adverse reaction':ti,ab OR 'medication error'/exp OR 'drug administration error':ti,ab OR 'drug administration errors':ti,ab OR 'medication error':ti,ab OR 'medication errors':ti,ab OR 'wrong drug administration':ti,ab OR 'error'/exp OR 'error':ti,ab OR 'error study':ti,ab OR 'human error':ti,ab OR 'mistake':ti,ab) AND ('risk management'/exp OR 'risk management':ti,ab OR 'risk sharing, financial':ti,ab OR 'root cause analysis'/exp OR 'root cause analysis':ti,ab) AND ('patient safety'/exp OR 'patient safety':ti,ab OR safet*:ti,ab) AND (protocol:ti,ab OR tool*:ti,ab OR system*:ti,ab OR guideline*:ti,ab OR checklist*:ti,ab OR framework*:ti,ab) AND [embase]/lim NOT ([embase]/lim AND [medline]/lim) AND ('article'/it OR 'article in press'/it OR 'review'/it) AND ('cross-sectional study'/de OR 'intervention study'/de OR 'observational study'/de OR 'prospective study'/de OR 'validation process'/de)
LILACS	((ti:advers* AND ti:event*) OR ti:incident* OR mh:"medical erros" OR ti:erro*) AND (tw:protocol* OR tw:tool* OR tw:ferramenta OR tw:system* OR tw:sistema* OR tw:guideline* OR tw:diretriz* OR tw:directr* OR tw:checklist* OR tw:framework*) AND (mh:"patient safety" OR tw:safet* OR tw:segurança OR tw:seguridad) AND (mh:"risk Management" OR tw:"risk management" OR tw:risk OR tw:riesgo OR tw:risco OR tw:"Root Cause" OR tw:"causa raiz")
Scopus	(TITLE ((advers* OR incident* OR erro*)) AND TITLE-ABS-KEY (((safet* AND (patient* OR hospital* OR health* OR clinic* OR nurs* OR medic*)) AND ("risk Management" OR "risk analysis" OR "Root Cause"))) AND TITLE-ABS-KEY ((epidemiologic OR "case control" OR cohort OR cross-sectional OR "follow up" OR observational OR randomiz* OR nonrandomiz* OR longitudinal OR retrospective OR prospective OR "cross sectional") AND (protocol* OR tool* OR system* OR "root cause" OR check*))) AND (LIMIT-TO (DOCTYPE , "ar") OR LIMIT-TO (DOCTYPE , "re") OR LIMIT-TO (DOCTYPE , "ip"))
CINAHL	TI ((Incident or adverse event* or error* or accident*)) AND TX ("risk Management" OR "risk analysis" OR "Root Cause") AND TX (protocol* OR tool* OR system* OR check* OR guideline) AND TX ("patient safety" OR safet*) AND TX (epidemiologic OR "case control" OR cohort OR cross-sectional OR "follow up" OR observational OR randomiz* OR nonrandomiz* OR longitudinal OR retrospective OR prospective OR "cross sectional")

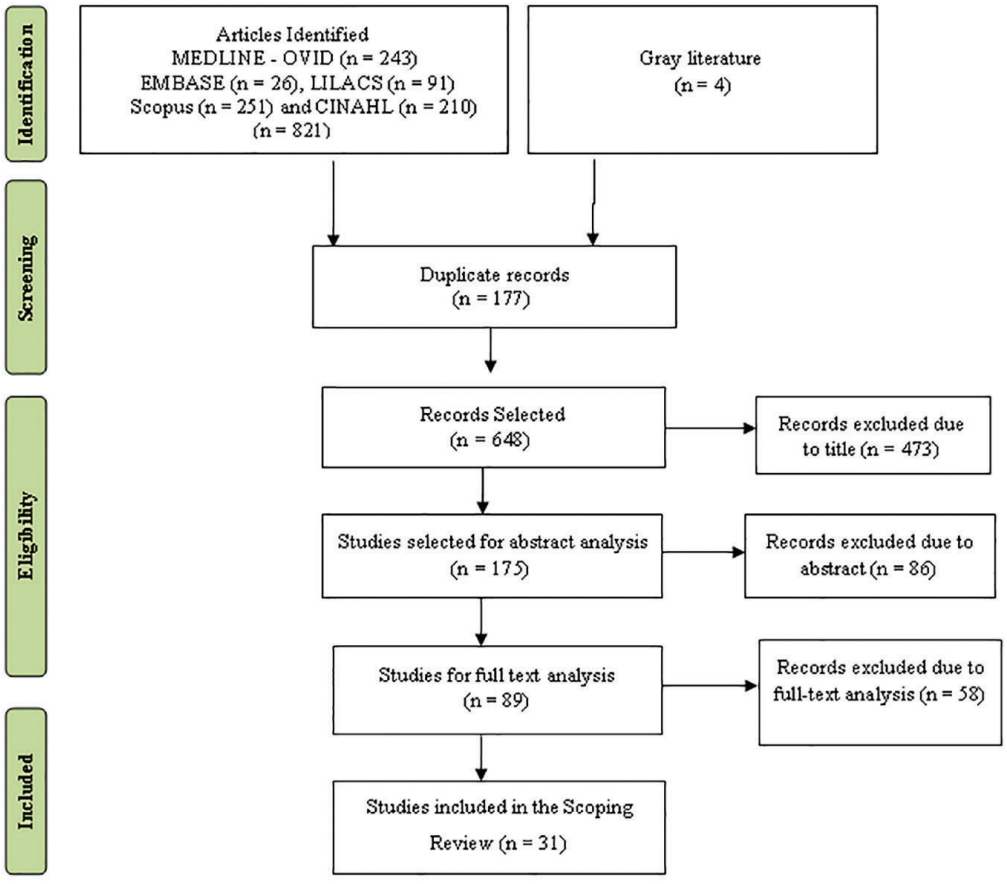

Figure 1 – Flowchart *Preferred Reporting Items for Systematic Reviews and Meta – Analyzes Extension for Scoping Reviews* (PRISMA-SCR) on the selection of studies, Niterói, RJ, Brazil, 2020.

Source Selection

The records were imported into a reference manager for information management (EndNote Web). Duplicate studies were considered only once. The study selection process was performed by two independent reviewers, and discrepancies were resolved by a third reviewer.

The selection was carried out in two stages. The first stage consisted of reading and evaluating the titles and abstracts of the records found through the search strategy, with potentially eligible studies having been pre-selected. In the second stage, the full text of the pre-selected studies was evaluated to confirm their eligibility (Figure 1). Subsequently, the two reviewers independently and blindly read the titles and abstracts to reduce the possibility of interpretative bias. Then, in the event of disagreement at this stage, a third reviewer was consulted to analyze the record and guarantee the resolution through a consensus meeting for inclusion or exclusion in the study.

Data Extraction and Items

For the process of extracting eligible articles, the instrument developed by the JBI was used as a basis, which contained the following topics: year of publication, authorship, journal/institution, title, study objective, methodology, country of study, and type of publication. In each publication, the tools used to investigate adverse events, the strengths in the application found by the authors, the problems and limitations described, and the recommendations for use were identified and extracted[5]. Study selection steps were carried out according to the scoping review flowchart (PRISMA – ScR).

Presentation of Results

The extracted data were presented in the form of tables and figure, to align with the objective of this scoping review. The tables included data about the year of the study, authorship, title, design of study, and a description of the techniques, tools, and instruments used to investigate AE. A figure was created describing a synthesis of the findings of the review, allowing the creation of an important and necessary "guide" for the selection of tools and/or techniques to conduct the investigation process according to the extent of damage initially detected. This way, describing how the results were related to the objective and question of the review.

Ethical Aspects

As it is an investigation whose method consists of a scoping review, the present study was not submitted to the Research Ethics Committee of the Universidade Federal Fluminense. However, Resolution No. 466/12, of the National Health Council, was followed with regard to the analysis and sharing of study results.

RESULTS

The searches resulted in 825 scientific productions distributed in the databases. Figure 1 presents the stages of the study and the results obtained, consisting of 27 articles and four manuals and expert consensus, totaling 31 studies.

Chart 2 shows the authors, year of publication, design of study, study objectives, as well as the instrument used or described by the authors[6–36]. When analyzing the origin of the studies,

Chart 2 – Description of studies included in the review – Niterói, RJ, Brazil, 2020.

No.	Year	Authorship	Title	Study Objective	Design of study	Techniques, tools, and instruments used for AE investigation
1	2006	Ashcroft DM, Cooke J[6]	Retrospective analysis of medication incidents reported using an online reporting system	To review all drug-related incidents reported in an online hospital-based incident reporting scheme.	Cross-sectional, descriptive	Data collection; chronology; contributing factors and *feedback*.
2	2004	Woolf SH, Kuzel AJ, Dovey SM, Phillips Jr RL[7]	A string of mistakes: the importance of cascade analysis in describing, counting, and preventing medical errors	To determine whether waterfall analysis is important to clarify the epidemiology and causes of errors and whether medical reports are sensitive to the impact of errors on patients.	Cross-sectional multicentric, descriptive	Model of organizational accidents and contributing factors organized in cascade.
3	2004	Clark PA[8]	Medication errors in family practice, in hospitals and after discharge from the hospital: an ethical analysis	To examine medical errors and possible solutions proposed. To analyze, from an ethical perspective, the need to implement recommendations immediately.	Cross-sectional, descriptive	Documentary analysis without a "clearly defined" instrument, but based on an ethical analysis.
4	2004	Taylor-Adams S, Vincent C[9]	Systems analysis of clinical incidents the London protocol	To ensure reflective and comprehensive investigation through a structured process.	Expert Consensus	London Protocol
5	2008	Percarpio KB, Watts BV, Weeks WB[10]	The Effectiveness of Root Cause Analysis: What Does the Literature Tell Us?	To evaluate the effectiveness of Root Cause Analysis as a method for investigating AE ¶	Systematic review	RCA*
6	2009	Teixeira TCA, Cassiani SHB[11]	Análise De Causa Raiz: Avaliação De Erros De Medicação Em Um Hospital Universitário	To identify and analyze the types of medication errors observed in medication doses that were prepared and administered differently from those prescribed	Cross-sectional, descriptive	Two methods of root cause analysis: HPES† and SOURCE‡

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No.	Year	Authorship	Title	Study Objective	Design of study	Techniques, tools, and instruments used for AE investigation
7	2009	Wierenga PC, Lie-A-Huen L, Rooij SE, Klazinga NS, Guchelaar HJ, Smorenburg SM[12]	Application of the Bow-Tie Model in Medication Safety Risk Analysis	To study the usefulness of the model *bow tie* in the hospital environment for prospective risk analysis.	Cross-sectional, descriptive	*BOW-TIE*
8	2010	Kelly J, Eggleton A, Wright D[13]	An analysis of two incidents of medicine administration to a patient with dysphagia	To compare the administration of medication by two nurses to a patient with swallowing difficulties and To assess the safety of administering medication to a patient with dysphagia.	Cross-sectional, descriptive	Data collection; chronology and RCA *
9	2010	Devaney J, Lazenbatt A, Bunting L[14]	Inquiring into Non-Accidental Child Deaths: Reviewing the Review Process	To report the results of a UK review of the child death review process.	Cross-sectional, descriptive	Brainstorming, data collection; chronology; RCA*, expert opinion and action plan.
10	2011	Nicolini D, Waring J, Mengis J[15]	Policy and practice in the use of root cause analysis to investigate clinical adverse events: Mind the gap	To examine the challenges of investigating clinical incidents through the use of RCA*	Cross-sectional, descriptive	Data collection; meeting for multidisciplinary clinical discussion; conducting the meeting to define RCA* chronology; action plan and monitoring of actions.
11	2011	Government of Western Australia Department of Health[16]	Clinical Incident Management Toolkit	To create a clinical incident investigation toolkit.	Expert Consensus	Australian Protocol
12	2012	Canadian Patient Safety Institute [17]	Canadian Incident Analysis Framework	To create an investigation model for incidents that cause or near-cause harm to patients.	Expert Consensus	Canadian Protocol
13	2012	Health Service Executive – HSE[18]	Yorkshire Contributory Factors Framework	To create an instrument to define the contributing factors for the analysis and investigation of incidents.	Expert Consensus	New Zealand instrument
14	2014	Teixeira TCA, Cassiani SHB[19]	Análise de causa raiz de acidentes por quedas e erros de medicação em hospital	To identify fall incidents and medication errors reported in a general and private hospital and present the categories of causal factors for these incidents.	Cross-sectional, descriptive	Root cause analysis and Action Plan
15	2014	van der Starre C, van Dijk M, van den Bos A, Tibboel D[20]	Paediatric critical incident analysis: lessons learnt on analysis, recommendations and implementation	To identify causal and contributing factors to severe incidents regarding patient safety in a university pediatric hospital.	Cross-sectional, descriptive	Root cause analysis and Action Plan
16	2014	Lee A, Mills PD, Neily J, Hemphill RR[21]	Root Cause Analysis of Serious Adverse Events Among Older Patients in the Veterans Health Administration	To determine the root causes for the occurrence of events, report action plans that have been implemented in hospitals and analyze their effectiveness.	Cross-sectional, descriptive	Root cause analysis and Action Plan
17	2014	Diller T, Helmrich G, Dunning S, Cox S, Buchanan A, Shappell S[22]	The Human Factors Analysis Classification System (HFACS) Applied to Health Care	To describe the change in the human factors analysis classification system.	Cross-sectional, descriptive	HFACS Human Factors Analysis Classification System§ for root cause analysis.
18	2014	Miller KE, Mims M, Paull DE, Williams L, Neily J, Mills PD, et al[23]	Wrong-Side Thoracentesis Lessons Learned From Root Cause Analysis	To examine a root cause analysis database for incorrectly reported information on thoracentesis and determine contributing factors.	Cross-sectional, descriptive	Root cause analysis with contributing factors based on the Swiss cheese model of human error causality
19	2016	Hettinger AZ, Fairbanks RJ, Hegde S, Rackoff AS, Wreathall J, Lewis VL, et al[24]	An Evidenced-Based Toolkit for the Development of Effective and Sustainable Root Cause Analysis System Safety Solutions	To learn from AE* and near misses and implement proactive changes to reduce future events.	Cross-sectional, descriptive	Customized instrument with the following techniques and tools: data collection, interviews, RCA, and action plan.
20	2016	Fan M, Petrosoniak A, Pinkney S, Hicks C, White K, Almeida APS, et al[25]	Study protocol for a framework analysis using video review to identify latent safety threats: trauma resuscitation using in situ simulation team training (TRUST)	To identify latent safety threats defined as system-based threats to patient safety.	Cross-sectional, descriptive	Approach with data collection, scenario definition, and practical simulation.

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No.	Year	Authorship	Title	Study Objective	Design of study	Techniques, tools, and instruments used for AE investigation
21	2016	Wagner C, Merten H, Zwaan L, Lubberding S, Timmermans D, Smits M[26]	Unit-based incident reporting and root cause analysis: variation at three hospital unit types	To obtain information on types and causes of patient safety incidents in hospital facilities and explore differences among facility types.	Cross-sectional, descriptive	PRISMA-Medical and Eindhoven Classification Model (ECM)[||].
22	2017	Marfán L, Pedemonte JC, Sandoval D, Ferdinand C, Camus L, Lacassie HJ[27]	Analysis of incident reports in an anesthesiology unit of a university hospital	To classify and analyze incidents reported by an Anesthesiology department at a university hospital in Chile.	Cross-sectional, descriptive	Data collection, root cause analysis, and action plan.
23	2017	Figueiredo ML, Silva CSO, Brito MFSF, D'Innocenzo M[28]	Análise da ocorrência de incidentes notificados em hospital-geral	To evaluate spontaneously reported incidents in a general hospital in Minas Gerais.	Cross-sectional, descriptive	Data collection, root cause analysis, and action plan.
24	2017	Hibbert PD, Thomas MJW, Deakin A, Runciman WB, Braithwaite J, Lomax S, et al[29]	Are root cause analyses recommendations effective and sustainable? An observational study	To analyze the proportion of sustainability of RCA* recommendations originated from sentinel events reported in the health system in Australia.	Cross-sectional, descriptive	Australian Protocol
25	2017	Guerra-García MM, Campos-Rivas B, Sanmarful-Schwarz A, Vírseda-Sacristán A, Dorrego-López MA, Charle-Crespo Á[30]	Descripción de factores contribuyentes en sucesos adversos relacionados con la seguridad del paciente y su evitabilidad	To assess the AEs health care-related factors affecting the patient and their severity.	Cross-sectional, descriptive	Root cause analysis with adapted contributing factors and action plan.
26	2017	Judy GD, Mosaly PR, Mazur LM, Tracton G, Marks LB, Chera BS[31]	Identifying Factors and Root Causes Associated With Near-Miss or Safety Incidents in Patients Treated With Radiotherapy: A Case-Control Analysis	To identify factors associated with incidents in patients undergoing radiotherapy.	Cross-sectional, descriptive	Data collection, root cause analysis, and action plan.
27	2018	Hagley GW, Mills PD, Shiner B, Hemphill RR[32]	An Analysis of Adverse Events in the Rehabilitation Department: Using the Veterans Affairs Root Cause Analysis System	To determine the types of AEs, causes and action plans for risk mitigation existing in the disciplines of rehabilitation medicine.	Cross-sectional, descriptive	Customized instrument with the following techniques and tools: Data collection, interview, root cause analysis, and action plan.
28	2019	Vahidi S, Mirhashemi S, Noorbakhsh M, Taleghani Y[33]	Clinical errors: Implementing root cause analysis in an area health service	To radically analyze seven sentinel events reported to the University of Medical Sciences of Iran.	Cross-sectional, descriptive	Data collection, interviews, incident site visit, chronology, root cause analysis, and improvement plan.
29	2019	François P, Lecoanet A, Caporossi A, Dols AM, Seigneurin A, Boussat B[34]	Experience feedback committees: A way of implementing a root cause analysis practice in hospital medical departments	To investigate the functioning of the Experience Committees in the departments of a large hospital affiliated with a university in France.	Cross-sectional, descriptive	Orion method, based on the Reason model, *Association of Litigation And Risk Management* (ALARM††) and including the same steps.
30	2019	Borgnia D, Dip M, Cervio G, Martinitto R, Halac E, Aredes D, et al[35]	Sistema de análise de eventos adversos aplicado a pacientes transplantados hepáticos	To present the conceptual framework and the protocol implemented by the liver transplant morbidity and mortality committee.	Experience Report	Data collection, interview, brainstorming, chronology, root cause analysis, and action plan.
31	2019	Bolcato M, Fassina G, Rodriguez D, Russo M, Aprile A[36]	The contribution of legal medicine in clinical risk management	To analyze the contribution of medico-legal litigation in clinical risk management and to propose an organizational model to coordinate the intervention of clinical risk management and medico-legal services.	Cross-sectional, descriptive	It was not possible to identify the tool or technique used, but it described the importance of the need to analyze the medico-legal litigation.

*RCA = Root Cause Analysis; †HPES = *Human Performance Enhancement System*; ‡SOURCE = *Seeking Out the Underlying Root Causes of Events*; §HFACS = *Human Factors Analysis and Classification System*; ||ECM = *Eindhoven Classification Model*; ¶AE = Adverse Events; **WHO = World Health Organization; ††ALARM = *Association of Litigation and Risk Management*.

*RCA = Root Cause Analysis; †CEO = Chief Executive Officer

Figure 2 – Synthesis of techniques and tools used in the investigation according to the extent of damage, Niterói, RJ, Brazil, 2020.

it was evident that they were carried out in different continents, being predominant in Europe, with 11 [6,9,12–15,20,26,30,34,36] studies (35.48%) and North America, with 12 [7,8,10,17,21–25,31–32,35] studies (38.70%), South America totaling four [11,19,27–28] studies (12.90%), and finally the Asian continent with four [16,18,29,33] studies (12.90%).

In addition, it was possible to highlight the interest and growth of research on the subject, with emphasis on the years 2014–2019. It is important to point out that in 2004, in Europe, the tool entitled London Protocol was published[9] and then only in 2019, also in Europe, was the first study released[34] using the *Association of Litigation And Risk Management* based on *Reason model*. As for the method used, twenty were qualitative, four were quantitative studies, four were expert consensus, one was a systematic review, one was an experience report, and one was a study with mixed methods.

In Figure 2, it was possible to establish a synthesis of the review findings, allowing the creation of an important and necessary "guide" for the selection of tools and/or techniques to conduct the investigation process according to the degree of damage initially detected. In addition, the "guider" demonstrates the need for effective communication among the different levels of the organization, transparency in monitoring the investigation, and finally resulting in the practice of *disclosure*.

DISCUSSION

This review gathered information about the tools for investigating health adverse events, especially what instruments and techniques were applied and the results obtained. From this review, it was possible to identify the tools used to investigate AEs, such as *Bow tie*, ACR with contributing factors, 5 reasons, accountability matrix, and action plan; in addition, the techniques and instruments such as interviews, data collection, chronology and the methodology *tracer* itself.

It is important to highlight the definitions of each of the tools identified in this review. *Bow Tie* was originally created for risk identification; however, it allows the investigation of the possible causes that led to the AE and still establish contingency actions[1–7]. On the other hand, RCA with contributing factors allows the reconstruction of the logical sequence of factors that

favored the occurrence of the incident in a systematic way. The 5 reasons tool allows the identification and investigation of the possible causes that led to the incident, based on the problem, using the five questions[8–12].

In the literature, it is observed that all studies used a tool to identify and categorize the contributing factors aiming at root cause analysis, since this step allows the investigator to identify all the factors that contributed to the occurrence of AE[8,10,13–22].

In several studies, the authors referred to the effectiveness of RCA, using quantitative and qualitative measures, as well as knowledge based on clinical experience. However, it reinforces the need to exhaustively apply this method, besides creating a database of contributing factors[23–30].

In some authors' opinion, the performance of an RCA varies from institution to institution, due to the lack of standardization and minimal attention to reliability among evaluators and intra-evaluators, thus leading to findings driven by personal behaviors and the inconsistent identification of systematic errors[10,21,29,31–40].

Furthermore, an RCA that only focuses on "what happened?" and "who was responsible?", rather than identifying the real root causes that define the "why?" the event occurred, allows a culture of guilt in which the health professional is formally or informally punished, instead of identifying the impact on the patient, the employee, and the institution. Even the Canadian investigation model begins with the "Preparation for Analysis" stage, thus consisting of a preliminary investigation aimed at determining the appropriate follow-up of an incident, including the need for analysis; an initial investigation or fact-finding is required. The main outcome of this step will be the construction of a high-level chronology and documentation of known facts related to the incident[17].

Another point that draws attention in the studies is the interview stage. The use of interviews is a limited method, but it is the most used tool compared to observation or *tracer*[30]. This practice cannot be the only one used, as it weakens the RCA strength, as employees can present biased speeches and report what "should have happened" and not what actually happened. However, observation techniques, auditing of the therapeutic itinerary, *in loco*, collaborate with the investigation stage and the exclusion of professionals' individual attitudes[25,41].

Therefore, the *tracer* is the method most used as an evaluation mechanism in the accreditation processes in health institutions, thus allowing the identification of conformities and non-conformities and even incidents, in line with established standards and requirements, resulting in the evaluation of the quality of care practices and aspects related to patient safety[25,41].

Another point, strongly recommended, is the use of the accountability matrix, with the objective of guiding actions based on the detection related to the professional's factor as a contributor to the occurrence of the incident or influence on the extent of damage[25,39,42].

According to the *Agency for Healthcare Research & quality* (AHRQ), from a just culture, frontline professionals are comfortable reporting incidents related to patient safety, including their own, while maintaining their professional responsibility. Thus, in the constant search for excellence and patient safety, health institutions implemented the matrix proposed by the *National Patient Safety Agency* (NPSA)[25,39,43].

According to several studies on this topic, an error, based on the professionals' factors, specifically on their professional ability, occurs when they are involved in a task that is very familiar to them or commonly practiced in their work routine. In the hospital setting, professionals often perform repetitive tasks that require attention; however, these seemingly automatic practices and behaviors are particularly susceptible to attention or memory failures, especially if someone is interrupted or distracted during the process[21,23,34,38,39].

However, sometimes, errors can also occur when professionals consciously do not perform or do not follow the previously defined flow, as they do not consider it as a risk prevention barrier that could result in damage, thus resulting in a violation. This phenomenon is the result of intentional deviations from accepted practices. The failure mode in this case is intentional, that is, the individual knew the accepted practice and still chose to ignore it[18,31,38,42].

In addition, routine violations in many segments tend to be habitual in nature and are generally permitted by institutions that tolerate *rule bending*. This way, they become ingrained in the professionals' culture and habits. In the hospital setting, this is often manifested by routine failure to follow policy or by the development of an alternative solution to a process or task; in fact, many professionals do not identify this as an intentional act[12,24,28,31,43–45].

In this context, it is important to highlight that the London protocol applies the Organizational Accident model proposed by James Reason, in which he emphasizes that the analysis shall have a much broader understanding of the cause of the incident, with less focus on the professional and/or individual who made a mistake, and more on systemic organizational factors existing in the institution[9].

Several studies point out that institutions with a positive culture are characterized by communications based on mutual trust, a shared perception of the importance of safety and trust in the effectiveness of prevention measures; above all, they recognize the differences between human error, negligence, violation, and reckless conduct[10,30,39–40].

However, the operationalization of the method cannot be based only on the steps of data collection, interviews and chronology, because as mentioned above, these steps may still undergo human interference. Therefore, the recommendation is to use the observation technique, more specifically a *tracer*, plus practical simulation of the processes, techniques and/or routines being examined[25,30,41].

Other studies have emphasized the need for validation of the *Chief Executive Officer* (CEO), as the highest authority of the organization, with the objective of stimulating communication and the certainty that this topic will be seen with the same degree of importance as, for example, financial results, but also ensuring that these actions were carried out[10,39,43].

Finally, the need for the institution's legal department to actively participate in this process. According to one of the studies, the analysis of medico-legal disputes proves to be an excellent tool with high precision and reliability for the detection of

situations previously not recognized and/or not recorded in the investigation process by the responsible team.[31].

In none of the analyzed studies, it was evidenced that the analysis and investigation of events come from a single model. The operationalization of this practice is guided by numerous tools and instruments built for this purpose. For instance, the root cause analysis and action plan were adapted to the reality of the health segment and/or for institutional applicability [8–9,12,15,20,26,29,35–36,45–49].

STUDY LIMITATIONS

As limitations, despite efforts to develop a comprehensive search strategy, some aspects related to methodological procedures stand out, such as the number of selected databases, non-availability of the study full text. In addition, despite advances in health research on the tools used to investigate AEs, there are still limitations arising from the lack of studies with a high level of evidence, such as randomized clinical trials, systematic reviews with meta-analysis to assess the effectiveness of the tools for the investigation of AEs in health, and concentration of the most used tools in clinical practice, classified as gray literature. However, in spite of the existing scientific gap, arising from the fact that quality tools come from other segments other than health, this study is justified.

Contributions to Health-Related Research

Due to the need of in-depth analysis of this object of study, which is fundamental for the continuous improvement of health organizations, aiming to help filling the gap in the literature on this subject, this study is a great contribution. It is based on the provision of an analysis of studies on the tools used to investigate AEs, contributing to the improvement of work processes, especially in patient safety centers in the practice of investigating adverse events, resulting in an increase in the quality of care provided to the population.

CONCLUSION

The study identified scientific publications on tools and techniques for investigating adverse health events, highlighting the importance of a model based on a thorough understanding of the contributing factors to the occurrence of AE. The main measure is the use of a robust RCA method that allows identification and categorization of these factors.

It was evident that the interview, an extremely used technique, shall be complemented with other methods, such as the method *tracer*, to ensure the understanding of latent and active failures in clinical practice operated by the workers, allowing a systemic view of the work process.

The need to apply the accountability matrix should be noted, as it allows the increase of the AE management process, based on a fair culture, feeding the system back to a model based on the sharing of responsibilities at all levels of the organization .

The importance of involvement and active participation of senior leadership, especially the CEO of the organization, shall be highlighted, with the objective of equating the Patient Safety issue at the same level as the institution's financial results, considering that the organization's sustainability is directly related to quality of care, patient experience, value-based health.

RESUMO

Objetivo: Mapear na literatura as ferramentas da gestão de risco voltadas para investigação de eventos adversos na saúde. **Método:** Revisão de escopo segundo o *Joanna Brigss Institute*, com acrônimo PCC (População: pacientes internados, Conceito: ferramentas para a investigação de eventos adversos e Contexto: instituições de saúde), realizada nas bases MEDLINE (OVID), EMBASE, LILACS, Scopus, CINAHL e literatura cinzenta. **Resultados:** A busca totalizou 825 produções científicas, sendo que 31 atenderam o objetivo do estudo, sendo composta por 27 artigos científicos e 4 consensos de especialistas. Foi possível realizar uma síntese das etapas necessárias para a investigação de eventos adversos e utilização das ferramentas de acordo com o grau do dano. **Conclusão:** A prática de investigação de eventos adversos deverá ser pautada na compreensão exaustiva dos fatores contribuintes, cultura justa e envolvimento da alta liderança.

DESCRITORES

Segurança do Paciente; Gestão de Riscos; Dano ao Paciente; Gestão da Qualidade em Saúde; Gestão da Segurança.

RESUMEN

Objetivo: Mapeo en la literatura de las herramientas de la gestión de riesgo con énfasis en la investigación de eventos adversos en salud. **Método:** Revisión de alcance según *Joanna Brigss Institute* con el acrónimo PCC (Población: pacientes ingresados, Concepto: herramientas para la investigación de eventos adversos y Contexto: instituciones de salud) realizada en las bases de datos MEDLINE (OVID), EMBASE, LILACS, Scopus, CINAHL y literatura gris. **Resultados:** La búsqueda llegó a un total de 825 producciones científicas, siendo que 31 lograron el objetivo del estudio, el cual fue compuesto por 27 artículos científicos y 4 consensos de expertos. Fue posible realizar una síntesis de las etapas necesarias para la investigación de eventos adversos y utilización de las herramientas de acuerdo con el grado del daño. **Conclusión:** La práctica de investigación de eventos adversos deberá pautarse en la comprensión exhaustiva de los factores contribuyentes, cultura justa e involucramiento de alto liderazgo.

DESCRIPTORES

Seguridad del Paciente; Gestión de Riesgos; Daño del Paciente; Gestión de la Calidad en Salud; Administración de la Seguridad.

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