How can root cause analysis improve patient safety in operating units? Insights from a systematic literature review

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ABSTRACT

Purpose: The need to provide a current state of the art on patient safety in hospitals measured through the use of retrospective risk assessment tool: Root Cause Analysis.

Medical errors are still too numerous, suggesting that traditional quality improvement systems are unable to deal appropriately with hospital challenges. The purpose of this paper is to evaluate how RCA tool improves the clinical routine in healthcare system.

Methods: A systematic literature review was carried out. A search of academic Scopus database, including papers that focus on medical errors and risk reduction. The general characteristics of the selected papers were analyzed, and a content analysis was conducted.

Results: A variety of root causes actions, tools, and practices are being adopted in health care in order to reduce errors and ensure high quality and patient safety. These tools are useful not only for achieving efficiency objectives, but also for providing patient safety in the various operating units. Critical indications and guidelines for the implementation of retrospective risk assessment tools are described.

Conclusion: This research represents a current snapshot of the global healthcare system. It describes in a comprehensive manner as RCA tool is applied once a wrong procedure or operation has occurred in the different units.

Keywords: root cause analysis, medical error, patient safety, risk assessment.

1. Introduction

Patient safety is a worldwide issue which influences quality of care, clinical outcome effectiveness, patients' quality of life, patient satisfaction, and savings of financial resources (Najafpour et al., 2016).

The frequency of patient safety incidents, sometimes referred to as Adverse Events (AEs), incidents, or patient safety events, is unacceptably high, with up to one-third of hospitalized patients experiencing one (Pham et al., 2016). The burden of AEs on healthcare resources is important; Hooker et al., assess that it amounts to 1% of the Dutch national health budget (Hooker et al., 2019).

During the last 15 years, reducing Adverse Events (AEs), and, more broadly, the development of patient safety systems, has become an increasingly important focus for health care organizations (Corwin et al., 2017).

Medical errors murder between 210,000 and 440,000 people per year, more than from highway accidents, breast cancer or AIDS combined. Statistics show that preventable medical errors in hospitals are responsible for 11 per cent of all deaths globally, and are the eighth leading cause of death in the USA (Gilbert et al., 2018). Medical errors may contain a variety of systems derived missteps, involving treatment and medication mistakes, missed or delayed diagnoses, and miscommunications during transitions in care. These errors may result in a wide range of effects to the patients, from no harm to death, and some errors never reach the patient (Aboumrad et al., 2018). Typically, medical errors are the consequence of a combination of contributing factors such as poor communication, health care system weaknesses, staff 's lack of education, etc; rarely there is just one causal factor (Najafpour et al., 2016).

Despite the best efforts of individuals and organi zations to prevent harm in medicine, serious AEs still take place. When these occur, the first priority of health care providers is to ensure that the patient's condition is managed appropriately (Brook et al., 2015).

To raise the improvement in patient safety, risk identification is used as the main approach to support the process of finding, recognising, and describing risks within the risk assessment process (Simsekler et al., 2015).

Since the publication of the landmark Institute of Medicine (IOM) report "To Err is Human", there has been an enhanced focus on improving the safety of health care (Wittich et al., 2014) and there has been significant investment in developing

system-focused approaches to reducing health care-related adverse events. This has seen the widespread adoption of root cause analysis (RCA) in health-care systems. This was initiated in the USA in Veteran Affairs (VA) and Joint Commission hospitals and then implemented internationally, including in Denmark, UK and two Australian states – Queensland and New South Wales (Hamilton et al., 2018).

RCA is a structured and standardized method for investigating the causes of medical errors (Abmourad et al., 2018). RCA methodology is derived from engineering and other nonmedical disciplines (Balakrishnan et al., 2019). The focus of RCA is on the systemic and organizational factors that may have contributed to an AE. In general, RCA describes what happened, how it happened, and what should be done to avoid the same event happening again (Mills et al., 2014).

The key output of RCAs is a set of recommendations for health services to implement in order to reduce the likelihood of a similar AE occurring again (Hibbert et al., 2018). Key resources required include an experienced facilitator; time to interview the staff, physicians, patients/family, and experts; time for at least one multidisciplinary team meeting; and time and personnel to prepare and distribute the findings, recommendations, and plan for execution (Pham et al., 2016).

In addition to providing a process for formally investigating an AE, the RCA principles can be applied to any real or perceived safety risk, near misses, and less severe or minor patient safety events (Brook et al., 2015). Its presumed effectiveness is such that the Joint Commission requires its application to all sentinel events (Balakrishnan et al., 2019).

This paper is focussed upon patient safety: it was conceived to select and review studies dealing with the RCA tool and how it applied to the different operating units, with the final aim of enriching the literature and deepening the knowledge in the field.

Finally, for greater understanding and appreciation of the study, it was structured to include section 2 and 3 regarding the main information on reasons and criteria for this review development.

The core section of the paper is the number 4, that was conceived to present the papers reviewed in terms of main objectives and findings.

The paper ends with section 5 to report upon findings regarding both RCA tool operation and its possible limits and conclusion remarks of the study.
Furthermore, set-up like this the study may be of support for economics, managers, and decision and policy makers to deepen their knowledge in the healthcare field, as the basis to operate and promote improvements for enhanced effectiveness of patient safety management and process management.

2. Rationale of study

World healthcare lags behind other industries in performing risk management techniques such as RCA and its application has been defined as a complex task for healthcare professionals. RCA, integrating elements from system engineering, psychology and the human factor approach, aims to prevent the repeat of errors by establishing the underlying causes of adverse events. RCA is based on the theory that errors are inevitable, and organizations must try to identify possible errors rather than blame individuals who make them (Abdi et al., 2016).
In 2006, the Canadian Patient Safety Institute (CPSI) defined RCA as "an analytic tool that can be used to perform a comprehensive, system-based review of critical incidents. The goals of RCA are to determine what happened, why it happened, and what can be done to reduce the likelihood of a recurrence. It includes the identification of the root and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plans." (West et al., 2014)
In this regard, several studies have been conducted over the course of last years to address small investigations characterising RCA solutions within a single department (Perotti et al., 2015). However, few qualitative reviews of the literature are available and those that have been done have examined the root causes identified by the teams, but without the cross-departmental comparison of the results obtained from the analysis conducted.
To the knowledge of the authors, such a review has not been developed in recent times or, at least, in the period considered. According to the authors, this is a novelty that deserves mention and can make the paper even more attractive to readers around the world.
However, a relevant study was conducted in 2015 by Paull et al., (Paull et al., 2015) to demonstrate how bad procedures affect surgical operations and

understand why some of these events are not captured by the passages of the Universal Protocol document. Differently from this work, where the focus is to evaluate the health performance through the use of the RCA, Paull et al. (Paull et al., 2015) made a qualitative, though relevant and useful, list on the root causes for the wrong surgery events investigated in the studies under review. For contrast, to be consistent with the objective and setting of the study discussed in this paper, aspects related to different medical specialities and risk assessment were addressed qualitatively, using values extrapolated from the papers reviewed, when reported.

Another study has been managed recently by Kellog et al. (Kellog et al., 2017) considering the types of solutions proposed in response to RCAs conducted at a large, tertiary care academic medical centre over an 8-year period. That paper was used anyway by this author team to learn more about, and draw general conclusions upon, biomass AD and related environmental assessment.

The research aimed to provide a revealing portrait of the different departments, to highlight the main organizational, technical, and cultural issues. Today these aspects are even more significant and existing in the global health care system because of the Covid19 pandemic.

In this way, the document could serve as a reference in the field and could contribute to further deepen and enrich both the literature and the knowledge on risk assessment practices and, through operational recommendations, try to prevent possible risks.

3. Methodology

In order to achieve the aims described in the previous section, a systematic review of the literature was conducted, answering the question: what are the practices, and key critical factors needed to successfully implement RCA tool, stressing safety performance? In addition, our intention is to provide directions for fruitful future research.

The protocol for the systematic literature review included the following steps: 1) conceptual analysis of the problem, 2) definition of the literature review objective, 3) paper selection criteria, 4) single-paper analysis, 5) description of the main characteristics of the extracted papers, and 6) synthesis of interesting content. According to the mentioned methodology, the studies were identified in Scopus database.

We used the PRISMA flow diagram to obtain the final set of articles to work on. PRISMA considers four different phases: Identification, Screening, Eligibility Inclusion.

The following keywords were used: “Root Cause Analysis” AND “Medical Error”, “Root Cause Analysis” AND “Patient Safety”, “Root Cause Analysis” AND “Risk Assessment”.

Inclusion and exclusion criteria have been used in the following way. As inclusion criteria, only papers published from 2014 to 2019 have been selected. The subject areas: “Medicine”, “Nursing” and “business and management”.

Furthermore, the research only considers papers in English to obtain an international validity of studies. Instead, as exclusion, proceedings paper, conference proceedings, special issues and dissertations have not been taken into account to avoid study dispersion.

As shown in Fig. 1, 18 papers have been obtained. After a descriptive analysis of the obtained database of international relevance, a content analysis will be performed to examine root causes identified within the units.

4. Results

A systematic literature review (SLR) of RCA application tool was made and discussed in this paper, with the aim of finding key aspects related to various operating units. Amongst the papers accessed, a total of 18 papers were selected, based upon the criteria described in section 3, and reviewed subsequently.

However, if one looked at the publication year, an increasing publication trend could be observed in the period 2017-2018 (see Fig.2), mainly as the consequence of the interest and attention that all the involved stakeholders (clinicians, managers, policy makers) are showing towards such theme.

Table 1 shows the main characteristics of the papers included in the review; most of the papers had more than one author. With respect to the workplace of the first author, most of the papers were from the USA, followed by the Australia and Netherlands. As for the adopted methodology, most of the papers conducted case or action research (Fied research); there was just one simulation.

Literature reviews were included as they study previous experiences and/or because they give new suggestions for future research that could be useful, considering the scope of this research. Regarding the context of applicability, most

of papers focused both only on a single unit or department of a hospital (obstetrics, geriatrics, oncology) and many separate units, only one article analyzed a single care process.

In Table 2, all the articles were divided into three themes: "Medical Error", "Patien Safety", "Risk Assessment" and main purposes of the papers were reported.

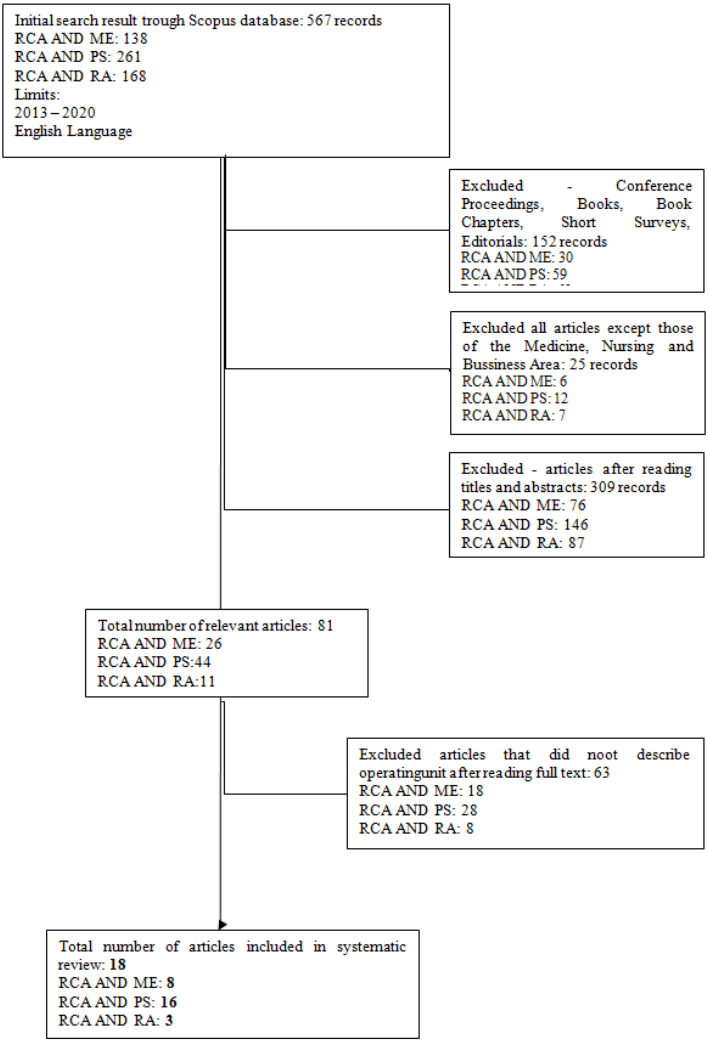

Fig.1: Flowchart / **Abbreviation:** ME: Medical Error; PS: Patient Safety; RA: Risk Assessment

Most objectives of the analyzed papers aimed to describe the implementation of RCA techniques and actions applied in health care, with the main purpose of achieving high quality and patient safety by improving workflows and efficiency and reducing errors. Table 2

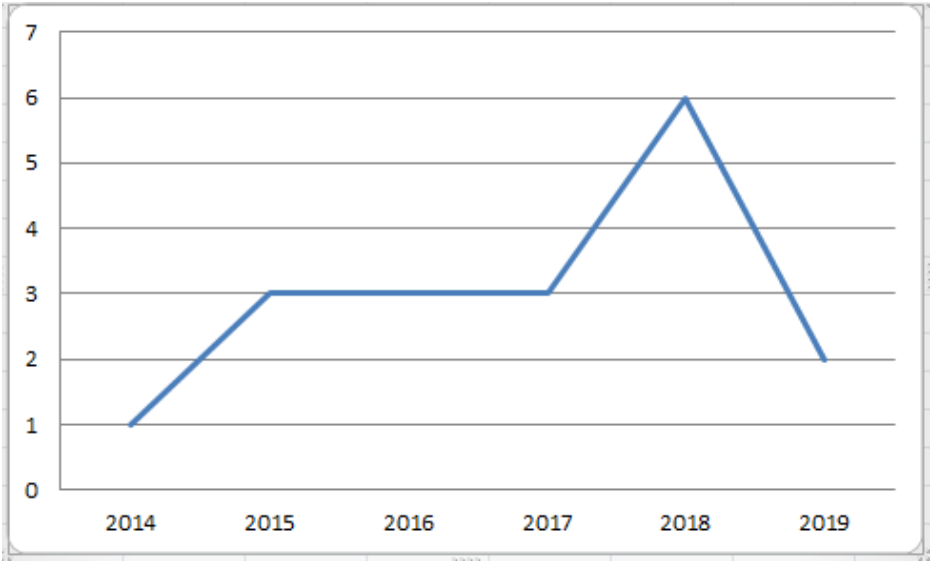

Fig.2: Number of papers reviewed, per publication year

Table 2 underscores that techniques relating to risk process management are always adopted, especially for understanding adverse events and sentinel event prediction.

Within the various units, team building, employee education, and culture are also emphasized, while ICT is often adopted as a support instrument. The benefits obtained relate to higher efficiency, a reduced amount of time spent in executing activities, reduced costs, improved accuracy, and fewer errors.

5 Discussion and Conclusion

All the studies analyzed in this review, as well as many others in the literature (Kellog et al., 2017; Paull et all., 2015), demonstrate that the use of the RCA tool brings benefits at different levels of the health system. Hooker et al. (2018) using the Eindhoven Classification Model (ECM) to classify AEs. In this model, latent failures are classified first to increase the likelihood of discovering all causes underlying the event. The main categories of the ECM system

are latent factors (technical and organisational), active failures (human), patient-related factors and unclassifiable factors. Considering this model, we have an initial identification of the cause that determined the adverse event.

Table 1. Characteristics of the selected papers.

N	Authors	Research methodology	Field	Journal classification	N of authors	Paper country*
1	Aboumrad et al. (2018)	Field Research	Oncology	Man and Mad	6	USA
2	Balakrishnan et al. (2019)	Field Research	Otolaryngology	Med	4	USA
3	Brook et al. (2015)	Literature Review	Radiology	Med	4	USA
4	Charles et al. (2016)	Literature Review	Orthopaedic Surgery	Med	8	USA
5	Corwin et al. (2017)	Field Research	Intensive Care Unit	Man and Med	4	USA
6	Gilbert (2016)	Case Study	Oncology	Med	1	Canada
7	Gilbert et al. (2018)	Case Study	Geriatrics	Man and Med	2	Australia
8	Hamilton et al. (2018)	Field Research	Pediatrics	Med	4	Australia
9	Hibbert et al. (2018)	Field Research	Many units, separately	Man and Med	11	Australia
10	Hooker et al. (2018)	Literature Review	Many units, separately	Man	4	Netherlands
11	Klein (2019)	Literature review	Obstetrics	Med	1	USA
12	Lee et al. (2014)	Literature Review	Geriatrics	Man and Med	4	USA
13	Neily et al. (2018)	Field Research	Operating Theater	Med	9	USA
14	Perotti et al. (2015)	Field Research	Neurosurgery	Med	2	Australia
15	Pettker (2017)	Literature Review	Obstetrics	Med	1	USA
16	Smith (2017)	Literature Review	Obstetrics	Med	1	UK
17	Wagner et al. (2016)	Field Research	Many units, separately	Med	6	Netherlands
18	Zastrow (2015)	Simulation	Process of care	Med	1	USA

Authors repeated themselves as they deal with more research areas.

In this way, more stringent recommendations are adopted based on the context under consideration. Hibbert et al., (2018), through a table, summarizes the types of recommendations by strength, number of type of recommendation and number of RCAs containing the type of recommendation for any unit. In fact, it is a list of guidelines to follow and contextualize for each adverse event.On the other hand, in the literature there are opinions in contrast with the effectiveness of the RCA tool.

Vrklevski et al. (2015) argues that "the RCA model is better suited to medical incidents that occur with moderate to high frequency, such as medication errors, operative and postoperative complications, slips, falls, and wrong-site surgery." Indeed, is not the best model for examining rare errors or those errors that involve complex interactions of human variables that are difficult to control such as suicides and homicides.
Peerally et al. (2016), on the other hand, argue that RCA has potential value in the healthcare setting, but has been widely applied without sufficient attention and without adequate personalization for healthcare specifics. This led to an underestimation of the potential of the RCA tool.

When asked for the title, the revision achieved the proposed objective: to provide an answer in contextualized operational terms to the various operating units. The focus of the review was on patient safety and how it improved with the use of risk tools. However, opinion differences were found amongst the studies reviewed, so generating variability in the results and difficulties of making evaluations and drawing conclusions.
Although the current retrospective study provides an important contribution to the field, predictive systems have become more prominent than in the past. Root Cause Analysis considers the analysis of an adverse and happended events, and therefore the risk profile has turned into harm for the patient.

To date, risk managers are interested in conducting studies on predictive and, therefore, improving data that can prevent the random event from becoming objective and transforming from a risk event to a real event.

The RCA tool, as this study demonstrates, has improved the efficiency of health systems by reorganizing entire operational units and developing a culture of no blame among health workers; but all this is not enough now.

In a society where the patient is at the center of the health system, it is necessary to develop and implement techniques and actions to prevent possible adverse events. For this reason, the theme of the prospective risk analysis method is emerging with greater insistence.
Working with predictive risk models, in addition to being able to guarantee greater safety to the patient, would arise to a decrease in health costs caused by the increasing claims against health professionals and an optimization of time and human resources within the departments.

On the other hand, if potential health failures can be prevented, it will be thanks to established retrospective analysis techniques (such as the RCA tool) that have paved the way.

Table 2. Purposes of the papers

Area	Authors	Title	Main Aim
Medical Error	Aboumrad et al. (2018)	Root Cause Analysis of Oncology Adverse Events in the Veterans Health Administration	To describe the most frequent oncologic errors and adverse events based on closed claims malpractice data. In those data, the primary reasons for litigation include failure to diagnose and treat, patient injuries, and failure to adhere to safety protocol. In this study reports oncologic errors and adverse events in specific areas of oncology, including errors in chemotherapy and radiation.
	Balakrishnan et al. (2019)	Patient Safety/Quality Improvement Primer, Part II: Prevention of Harm Through Root Cause Analysis and Action (RCA2)	To establish to system errors, recording adverse events, and determining which events warrant RCA.
	Brook et al. (2015)	Root Cause Analysis: Learning from Adverse Safety Events	A description through the Ishikawa diagram of adverse events with subsequent RCAs for the radiology unit.
	Charles et al. (2016)	How to perform a root cause analysis for workup and future prevention of medical errors: a review	Introduction of a comprehensive model to provides guidance on the development and implementation of quality improvement initiatives to reduce surgical orthopaedic errors.
	Lee et al. (2014)	Root Cause Analysis of Serious Adverse Events Among Older Patients in the Veterans Health Administration	List of the most common reported adverse events among older patients: falls , delays in diagnosis and/or treatment, unexpected death, and medication errors.
	Neily et al. (2018)	Assessment of Incorrect Surgical Procedures Within and Outside the Operating Room A Follow-up Study From US Veterans Health Administration Medical Centers	To provide a follow-up description of incorrect surgical procedures, wrong patient, side, site, procedure, or implant. In this study, events include those in or out of the operating room, adverse events or close calls, surgical specialty, and harm.
	Perotti et al. (2015)	Root cause analysis of critical events in neurosurgery, New South Wales	To declare adverse events in neurosurgey: delays in transfer of patients or wrong-site surgery, which always involved poor adherence to correct patient and site identification procedures. Breaches inpolicy account for the majority of root causes identified.
	Wagner et al. (2016)	Unit-based incident reporting and root cause analysis: variation at three hospital unit types	Description of two different types of accidents for the two different units: the emergency unit reported more adverse events related to poor communication between health workers, while the surgery and internal medicine units reported more accidents related to the use of drugs .

Aboumrad et al. (2018)	Root Cause Analysis of Oncology Adverse Events in the Veterans Health Administration	To identify major areas of safety concern in oncology and to offer suggestions and actions for improvement to prevent similar events from reoccurring. Standardization of processes and improved communication are the first steps to safeguard patient safety in oncology unit.
Balakrishnan et al. (2019)	Patient Safety/Quality Improvement Primer, Part II: Prevention of Harm Through Root Cause Analysis and Action (RCA2)	To present a proposed on automated searches of the electronic health record, natural language processing of electronic record data, or statistical methods of testing and validation.
Brook et al. (2015)	Root Cause Analysis: Learning from Adverse Safety Events	To present recommendations of strategies should be implemented to mitigate the future occurrence of adverse events. This should be done within the environment of a culture of safety taking into account the emotional effects on the involved staff.
Corwin et al. (2017)	Root Cause Analysis of ICU Adverse Events in the Veterans Health Administration	To reporte ICU adverse events typically with protocol and process-of-care issues (lack of standardized approaches) consistently identified as problems. Actions often include standardization of processes and the development and implementation of appropriate training and education.
Gilbert (2016)	The Human Factor: Designing Safety Into Oncology Practice	To demonstrate that the complete elimination of human error from human-driven processes in oncology care and elsewhere is never possible, much can be done to prevent tragic incidents from happening and to improve the quality of care for all patients. Oncology professionals can access a variety of resources to learn to apply the human factors mind-set to their work to the benefit of both patients and staff.
Gilbert et al. (2018)	To err is human: medication patient safety in aged care, a case study	The case study presented highlights the risk factors and events that contributed to the medication errors for elderly individuals. Human error based in fatigue, high stress and workloads are common and can start the progression of a medication errors.
Hamilton et al. (2018)	Implementation and strength of root cause analysis recommendations following serious adverse events involving paediatric patients in the Queensland public health system between 2012 and 2014	To evaluate the implementation rate and strength of the recommendations developed in all root cause analyses (RCAs) performed following serious clinical incidents involving children that have resulted in permanent harm or death in public hospitals. This study describes the execution of recommendations and classifies them in terms of potential to prevent patient harm and save lives.
Hibbert et al. (2018)	Are root cause analyses recommendations effective and sustainable? An observational study	To present actions that can be taken include more human factors expertise and independence in investigations, more extensive application of existing tools that assist teams to prioritize recommendations that are likely to be effective, and greater use of observational and simulation techniques to understand the underlying systems factors.

Hooker et al. (2018)	Aggregate analysis of sentinel events as a strategic tool in safety management cancontribute to the improvement of healthcare safety	To detail as clustering variables of SEs and contributory factors of failure through RCA helps to delineate a hospital-specific profile by providing a detailed insight into risk factors, patterns and trends in an organisation and to determine the best strategies for improvement by drawing lessons across events.
Klein (2019)	Risk Management in Obstetrics and Gynecology	A description piece describing how improve patient safety in obstetrics trough initiation of safety processes, team training, improved staffing, courses, simulation trainings.
Lee et al. (2014)	Root Cause Analysis of Serious Adverse Events Among Older Patients in the Veterans Health Administration	The RCA process identified falls and communication as important themes in serious adverse events. Corrective actions, such as process standardization and changes to communication, improve patient safety among older.
Neily et al. (2018)	Assessment of Incorrect Surgical Procedures Within and Outside the Operating Room A Follow-up Study From US Veterans Health Administration Medical Centers	To reduce the possibility of incorrect surgical procedures must promote a safety culture and behavior that minimize events and are transparent in reporting events.
	Perotti et al. (2015)	Root cause analysis of critical events in neurosurgery, New South Wales	Through the aggregation of RCA data and dissemination strategies, healthcare professionals can learn from adverse events and prevent the occurrence of future events, improving the patient safety profile.
	Pettker (2017)	Systematic approaches to adverse events in obstetrics, Part II : Event analysis and response	Description of the design of a strong action plan depends on how the actions address or control the human factors that interact with the environment, tools, computers, protocols/guide- lines, and other systems.
	Wagner et al. (2016)	Unit-based incident reporting and root cause analysis: variation at three hospital unit types	From the analysis of three different departments, it emerges that through employ of a unit-based incident reporting gives specific information and therefore makes improvements easierand feedback system than by a hospital national reporting system providing aggregated general information back to all units.
	Zastrow (2015)	Root Cause Analysis in Infusion Nursing Applying Quality Improvement Tools for Adverse Events	Description of a set of typical actions and techniques by RCA (organizational recommendations, conducting the investigation, assembling a team, determining root causes, developing and executing the action plan) to guide investigation, analysis and action, aimed prevent future mistakes.
Risk Assessment	Hooker et al. (2018)	Aggregate analysis of sentinel events as a strategic tool in safety management can contribute to the improvement of healthcare safety	To examine if clustering of root causes of sentinel events can contribute to organisational improvement of healthcare and patient safety by providing insight into organisational risk factors, patterns and trends.
	Klein (2019)	Risk Management in Obstetrics and Gynecology	To apply risk assessment tool is significant to illustrate positive patient safety measures that reduced risk to an organization in obstetrics. In this study, is describe as risk management tool: the incident reporting system (IRS).
	Smith (2017)	Clinical risk management in obstetric practice	To highlight the importance and absence of complications of IRS: whenever staff recognize a situation where harm has occurred to a patient they report it via the IRS, and the report is then reviewed and dealt with by the risk management team.

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