

How Much of Root Cause Analysis Translates into Improved Patient Safety: A Systematic Review

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Significance of the Study

- Root cause analysis is a widespread technique used in the last two decades to investigate latent causes of adverse events.
- Lack of expertise and time and a weak legal framework are some of the difficulties in fulfilling action plans from root cause analysis.
- It is not clear if root cause analysis is effective in preventing the recurrence of adverse events.

Keywords

Root cause analysis · Patient safety · Quality assurance · Translational medicine

Abstract

Objectives: The aim of this systematic review was to consolidate studies to determine whether root cause analysis (RCA) is an adequate method to decrease recurrence of avoidable adverse events (AAEs). **Methods:** A systematic search of databases from creation until December 2018 was performed using PubMed, Scopus and EMBASE. We included articles published in scientific journals describing the practical usefulness in and impact of RCA on the reduction of AAEs and whether professionals consider it feasible. The Mixed Methods Appraisal Tool was used to assess the quality of studies. **Results:** Twenty-one articles met the inclusion criteria.

Samples included in these studies ranged from 20 to 1,707 analyses of RCAs, AAEs, recommendations, audits or interviews with professionals. The most common setting was hospitals (86%; $n = 18$), and the type of incident most analysed was AAEs, in 71% ($n = 15$) of the cases; 47% ($n = 10$) of the studies stated that the main weakness of RCA is its recommendations. The most common causes involved in the occurrence of AEs were communication problems among professionals, human error and faults in the organisation of the health care process. Despite the widespread implementation of RCA in the past decades, only 2 studies could to some extent establish an improvement in patient safety due to RCAs. **Conclusions:** RCA is a useful tool for the identification of the remote and immediate causes of safety incidents, but not for implementing effective measures to prevent their recurrence.

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Introduction

Root cause analysis (RCA) emerged in the health care field almost 20 years ago. This technique is used worldwide to understand the remote and direct factors favouring the occurrence of an avoidable adverse event (AAE) [1], and improvement of patient safety [2].

Three studies have analysed the utility and limitations of this technique [3–5], all agreeing that barriers to implementing RCA correctly remain, and most of these were focused on active errors and not latent causes. The published results invite us to reflect on whether the impact of this technique in practice is proving to be all that is theoretically expected, first, because substantial resources and human talent are required [5], and, second, because many of the recommendations made in the framework of this technique are not applied failing to prevent the same incidents from recurring [6].

It is one thing to perform a multidisciplinary and multicausal analysis of why an incident occurred, and another, totally different thing to ensure that the proposals derived from this analysis to avoid the recurrence of safety incidents are implemented successfully. The usefulness of RCA may depend on the safety culture of health institutions, decision-making procedures and middle management leadership styles. The objective of this study was to assess the usefulness (i.e., its capacity to improve patient safety) of RCA in health care practice in order to avoid recurrence of AAEs.

Methods

We conducted a systematic review of studies published in scientific journals from database creation until December 2018 on the practical usefulness of RCA in the reduction of recurrent AAEs.

Eligibility Criteria

Only studies that analysed the efficacy of RCAs in the improvement of patient safety and studies that analysed the views of professionals on its feasibility were included. This study was designed to address whether the results of RCA improve patient safety, whether the RCA methodology has been fully carried out, and whether health professionals consider it feasible.

The MOOSE protocol was followed. Studies published in scientific journals were included to describe the AEs commonly analysed and the practical usefulness of RCA in the reduction of AAEs or its limitations in improving patient safety. No exclusions were made based on the year of publication, the design of the study, or language. Both quantitative and qualitative studies were included. Research taking a descriptive approach was also included.

Search Strategy

The review of published studies was carried out on MEDLINE, Scopus and EMBASE. The search strategies were defined based on the combination of keywords related to RCA (“root cause analysis”[MeSH Terms] OR (“root”[All Fields] AND “cause”[All Fields] AND “analysis”[All Fields]) OR “root cause analysis”[All Fields]) AND (“delivery of health care”[MeSH Terms] OR (“delivery”[All Fields] AND “health”[All Fields] AND “care”[All Fields]) OR “delivery of health care”[All Fields])) AND (“patient safety”[MeSH Terms] OR (“patient”[All Fields] AND “safety”[All Fields]) OR “patient safety”[All Fields]), and using the Boolean operators “AND” and “OR.”

In a complementary manner, we conducted manual searches in Google Scholar for the identification of grey literature using the same search equation. We also carried out a manual search based on the bibliographic references of the selected publications.

Data Extraction

J.M.-D. and A.M.-G. independently reviewed all potentially relevant studies. When no consensus was achieved between them, a third researcher (J.J.M.) reviewed the study to reach a consensus. All reviewers were capable of understanding Spanish, English and French, and studies were included in local languages if they included an English abstract, which allowed the authors to decide whether they had to be included for full text reading. No unpublished studies were found, nor was there a need to contact any of the authors of the studies included. Data extracted from each study included country, review committee, inclusion of managers, inclusion of personnel involved, design, database used, employee review method, sample (RCA number, recommendations, audits or interviews conducted), the type of event analysed and the main findings. In addition, where possible, information was extracted on the applicability of the RCAs and the interest of health professionals in the RCA.

Data Synthesis

For each of the above variables, categories of possible options were generated and the presence or absence of information in each variable was coded. Heterogeneity in the methods and measures applied was described when possible. Numbers of participants and AEs were also included. AAEs were classified as sentinel where applicable.

Quality Evaluation

For the assessment of quality of the included studies, J.M.-D. and A.M.-G. used the Mixed Methods Appraisal Tool (MMAT) [7]. The results led to an overall score for methodological quality, varying from 40–60% (moderate quality) and 80% (considerable quality) to 100% (high quality). None of the studies were excluded based on the quality assessment.

Results

A total of 169 studies were identified, of which 127 remained after exclusion of duplicates. Seventy-seven were excluded as these studies did not include results concerning the effectiveness of RCA in decreasing the number of

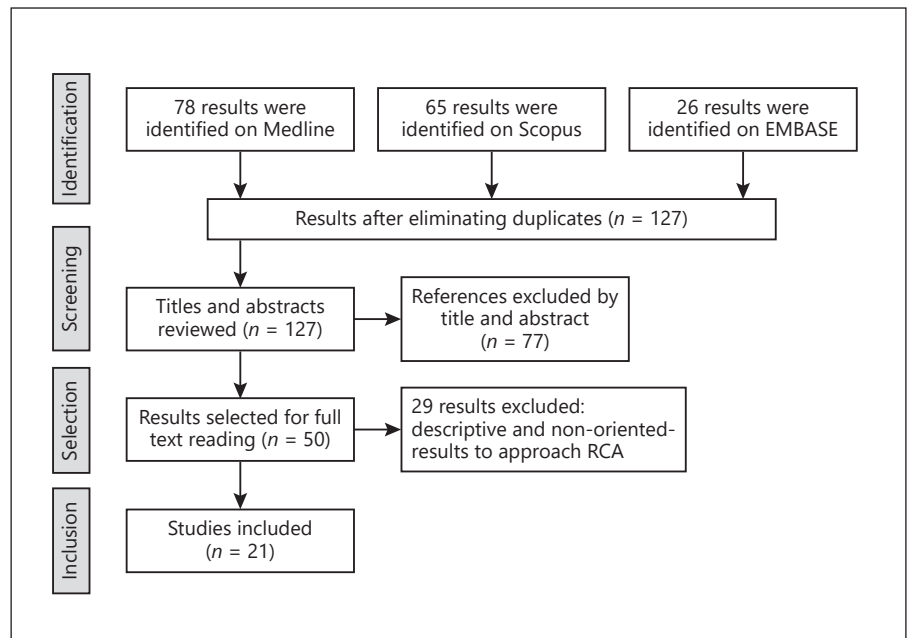


Fig. 1. Study selection flow diagram. RCA, root cause analysis.

AAEs. Finally, 21 papers meeting all inclusion criteria were included (Fig. 1).

The samples of the studies show a high variability, from 20 to 1,707 subjects with analysed data (RCA number, recommendations, audits or interviews conducted). The studies were mainly conducted in North America (52%; $n = 11$), Australia (19%; $n = 4$) and Europe (14%; $n = 3$); 57% were quantitative studies (6 longitudinal and 6 cross-sectional), 1 study was a randomised controlled trial, and the rest were qualitative analyses. The most common setting was hospitals (86%; $n = 18$). The type of incident most analysed was AAEs, in 71% ($n = 15$) of the studies, where sentinel events represented 13% ($n = 2$) of the AEs, and serious AEs classified as Severity Assessment Code 1 (for Queensland Health) or 3 (for the Department of Veterans Affairs) accounted for 20% ($n = 3$), while for the remaining 10 studies, information about severity was not disclosed. Incidents related to safety made up 5% ($n = 1$), and in the rest of the included studies, interviews or mock-ups were implemented.

In only 5 studies (24%) were managers or coordinators included, and in only 1 study were personnel from the service taken into consideration. Independent hospital databases and national or regional databases were mostly used, each accounting for 29% of the studies. Although the Veterans Affairs National Center for Patient Safety database was used in 5 of the studies (24%), they also examined individuals. For the rest of the cases, databases were not used.

Quality Evaluation

Of the 21 articles, 9 were rated as having a moderate quality (MMAT 40–60%), 5 were rated as having a considerable quality (MMAT 80%), and 7 were rated as high quality (MMAT 100%). The key features of each study are presented in Table 1 [3–6, 8–24].

Utility of RCA

Only in 2 studies (9%) could it be established that RCAs contributed to the improvement of patient care to some extent. In these studies, only 54 RCAs were reviewed. In 3 other studies (15%), the authors did not conclude that their implementation contributed to the improvement of patient safety, and in 10 (50%) of them, the recommendations made were weak, which did not lead to a reduction of AEs.

Some studies warned that sometimes poorly designed action plans and measures may generate new risks and may be insufficient to prevent the occurrence of new events [5, 6, 10, 16]. In the study carried out by Hibbert et al. [4], in which the effectiveness and sustainability of the proposals arising from 227 RCAs were analysed, it was found that 72% of the recommendations categorised as relevant were not formulated and that the most common recommendations did not refer to latent causes in clinical practices but to active errors. Likewise, other studies [3, 6] stated that most of the proposed recommendations focused on active errors and neglected latent causes, which provides short-term solutions but only par-

Table 1. Main findings and features of the studies reviewed

Study [Ref], year; country	Design	Main findings	Review committee; method used	RCA sample ² , n	MMAT score, %
Mahmood et al. [8], 2018; Australia	Qualitative analysis	RCA provided a comprehensive understanding of how organisational factors, providers, patients and the community affect the quality of care	Hospital director, service coordinator, obstetrician and a public health specialist; interviews and folder audit	30	100
Singh [3], 2018; Australia	Qualitative analysis	RCA detected active errors that influenced patient safety, but it was not able to identify latent errors in medical care; weaknesses in the method were detected, such as the completion of the RCA or the role of individual errors; no conclusive results were obtained regarding the usefulness of RCA in improving patient safety	Team supervisor, director of patient safety and an associate professor; Queensland Clinical Management Toolkit	48	80
Hibbert et al. [4], 2018; Australia	Longitudinal observation	Difficulties were found in the implementation of the proposed improvement actions, and most of these focused on active errors and not latent causes	Team of experts; Recommendation Scale from Veterans Affairs	227	80
François et al. [5], 2018; France	Cross-sectional observation	There are still barriers that make the implementation of RCAs difficult, including time and resources on the part of health professionals; physicians expressed a positive opinion about the RCA, pointing out that it is a tool that allows improvements to patient safety and induces changes in the culture	Team from each service; Experience Feedback Committee Framework	1,707	100
Hooker et al. [9], 2019; The Netherlands	Cross-sectional observation	53% of the causes that the RCA identified were related to the human factor and another 40% to the organisational factor; some actions were taken in order to improve patient safety	Multidisciplinary; Systematic Incident Reconstruction and Evaluation method	23	100
Murphy et al. [10], 2017; USA	Qualitative analysis	The use of a mock RCA involved previous training before possible future adverse events; this provided the subjects with knowledge of the importance of patient safety and the quality of care; it was found that all of them saw their anxiety reduced due to the possibility of carrying out RCA, and their interest in participating in the process was greater after an adverse event had occurred	Oncology/haematology fellows; Veterans Affairs NCPS RCA framework	15	60
Abdi and Ravaghi [11], 2017; Iran	Qualitative analysis	RCA was perceived by professionals as a beneficial analytical instrument that facilitates increasing patient safety, safety culture, and communication among the team of professionals; however, the results of this study reflected the difficulties in actually carrying out RCA, the authors concluded that in order to maximise the benefits of this tool, it is necessary that medical professionals assign priority to it	Interviews with professionals experienced in RCA	32	100
Kellogg et al. [6], 2017; USA	Qualitative analysis	The study concluded that the corrective actions proposed were mostly weak and focused on active errors, which made the prevention of a future adverse event unlikely	Multidisciplinary (a quality person and at least one of the services involved); RCA	302	80
Ouslander et al. [12], 2016; USA	Randomised controlled trial	The RCA carried out showed that it is a tool that allowed identification of the factors that caused the transfers, and also offered information about the problematic areas in which it seems necessary to improve the quality of the service/care	Implementation teams; INTERACT QI	71	40
Najafpour et al. [13], 2016; Iran	Retrospective qualitative study	The RCAs performed identified 20 contributory factors for each event and 8 factors for each service or care delivery problem; the most important contributory factors were task factors, education and training factors, communication, and team and social factors; the study seems to have been effective in identifying the root causes of initial errors	Chief executive, patient safety coordinator and consultant, supervisor and head nurse; interviews with staff, examination of medical records, along with probing policies	16	100
Lee et al. [14], 2014; USA	Cross-sectional observation	RCA made it possible to identify that falls and communication were important factors related to adverse events; actions towards improvement were implemented; however, less than half of these actions were effective	Two researchers (κ = 0.825); NCPS and Donabedian's Framework	325	40
Alux Teixeira and de Bortoli Cassiani [15], 2013; Brazil	Cross-sectional observation	The application of RCA allowed the identification of causes that led to adverse events; the incidents mostly focused on systematic errors, derived from an unstable system and not individual errors	Quality and medication committee; tool developed by quality experts	62	80
Miller et al. [16], 2014; USA	Longitudinal observation	The RCAs made it possible to identify the factors contributing to the occurrence of adverse events in thoracostomy surgery	Patient safety specialist, human factors engineer and analyst; human factors engineering design	14	60
Perotti and Sheridan [17], 2015; UK	Longitudinal observation	The study concluded that RCA can improve patient safety but nevertheless presents difficulties in its implementation; it noted that professional committees do not have enough decision-making power to ensure that the recommendations made via RCA are carried out, as well as pointing out the lack of a formalised system that allows carrying out the improvement actions in a given time	RCA committee; NCPS Patient Safety Improvement Handbook	32	60
Bowie et al. [18], 2013; UK	Cross-sectional observation	Training of professionals in implementing RCA brought benefits such as greater confidence and understanding of the method, which increased the professionals' possibilities for using it should adverse events occur, despite this, difficulties in its implementation were detected, such as lack of time and interpersonal problems	Professionals with and without experience in RCA	228	60
Giardina et al. [19], 2013; USA	Longitudinal observation	Factors contributing to the occurrence of adverse events were identified and action plans provided to reduce their occurrence; although these improvements must be carried out, substantial changes are needed	1 physician and 2 researchers; NCPS Patient Safety Improvement Handbook	111	60
Hettinger et al. [20], 2013; USA	Qualitative analysis	This study concluded that RCA had the potential to produce an effective and sustainable improvement in patient safety	Interviews with front-line professionals; RCA solution toolkit	44	100
Percarpio and Watts [21], 2013; USA	Cross-sectional observation	It is concluded that larger centres carry out more RCAs than smaller ones; those that carry out more develop more corrective actions; those centres that carry out <4 RCAs per year have a higher prevalence of postoperative complications; this study concluded that it is not clear whether RCA directly improves patient safety or not	RCA framework	139	80

Table 1 (continued)

Study [Ref], year, country	Design	Main findings	Review committee; method used	RCA sample ² , n	MMAT score, %
Sauer and Hepler [22], 2013; USA	Qualitative analysis	RCA identified a specific number of pharmacological therapies related to common system errors; in addition, it seems that RCA is a useful method for identifying potential errors in the medication use system and allows interventions to be developed to prevent them	Financial director, medical director, pharmacist, nurse and laboratory technician; RCA framework	4	100
Lee et al. [23], 2012; USA	Longitudinal observation	The RCAs that were carried out identified the factors that led to the occurrence of falls and provided some recommendations on how to implement a plan of action successfully; some limitations were identified, such as the difficulty of determining which improvement actions were responsible for reducing the occurrence of falls (adverse events), since several actions were implemented simultaneously	2 researchers (κ = 0.98); NCPS Patient Safety Improvement Handbook	75	60
Morse and Pollack [24], 2012; USA	Longitudinal observation	This study demonstrated that RCAs can be used effectively to generate moderate- and high-impact action plans to address a wide range of adverse events within a children's hospital, with almost complete implementation of the action plans being achieved	Team supervised by the director of the quality department; Joint Commission framework	20	40

RCA, root cause analysis; MMAT, Mixed Methods Appraisal Tool; NCPS, National Center for Patient Safety. ¹ Interventions to Reduce Acute Care Transfers Quality Improvement tools. ² Number of incidents. RCA, professionals, surveys, centres, indicators and recommendations.

tially helps to avoid future incidents. However, 1 study (5%) *did* demonstrate the usefulness of RCA and its recommendations [20].

Three studies (15%) showed that the RCA method was not applied properly [3, 5, 25]. François et al. [5] stated that only 23% of the 98 events selected for in-depth analysis covered all the domains defined by the method. Singh [3] pointed out that 65% of the RCAs carried out were not properly completed. In 5 studies (25%), the involvement of the professionals in the realisation of the RCA was analysed. While these appear to suggest a consensus that the relevance of RCA to establishing improved procedures caused it to be perceived as a beneficial analytical instrument, the researchers concluded that professionals encounter difficulties in conducting RCAs [8, 14].

Discussion

The literature collected analysed the usefulness of RCA as a process that allows the determination of factors that contribute to the occurrence of AAEs. Most of these were caused by communication problems among professionals [3, 13, 14, 19], human error [9] and, finally, faults in the organisation of the health care process [3, 22].

Weaknesses in Using RCA

Despite the fact that for professionals, RCA is a tool that allows improvements to the safety culture through the prevention of future AAEs [3, 5], studies have identified the main weaknesses diminishing the usefulness of RCA in the framework of patient safety [5]. RCA is an extensive process that requires proper qualifications and attitudes. Studies have shown that the RCA method is often not properly applied, which directly affects the rigor and depth of the analysis of this tool [3, 5, 25]. The most common difficulties are a lack of time and resources of the work teams. Although none of the studies reviewed refers to how much time is needed to perform an RCA, in the study conducted by McGraw and Drennan [26], the results of an RCA investigation of pressure ulcers showed that a nurse can take up to 20 h to complete it. These factors directly affect the RCA process, hindering its complete execution [5].

Lack of time does not seem to be the only element that hinders the performance of RCAs; describing the events from a perspective different from individual error is challenging to professionals, who are sometimes reluctant to participate because of the distrust generated by possible future consequences. The belief that there is a culture fo-

cused on searching “those responsible” – in addition to creating tension in the work environment that may cause interprofessional problems [5, 18] – is one of the main reasons for professionals refusing to participate in incident reporting systems [27].

Impact on Reducing AAEs

None of the studies reviewed assessed the ability of this process to reduce future AAEs. Moreover, in the study by Lee et al. [23], difficulties were found in determining whether the improvement actions implemented after the RCA were able to reduce the occurrence of AAEs, as the action plans did not follow a pattern of controlled implantation. On the other hand, Morse and Pollack [24] and Sauer and Hepler [22] were the only ones that found sufficient follow-up time, which allowed the determination of whether the recommendations agreed on in the RCA reduced the occurrence of AAEs to some degree. In order to increase the commitment and interest of health professionals in carrying out RCA, some studies have evaluated the usefulness of a mock RCA as prior training to provide medical staff with basic knowledge about patient safety and the methodology of this tool. The results showed that its use raised their confidence in being able to perform RCA and decreased their anxiety in the face of a possible AE [10, 18]. This is supported by Boussat et al. [28], who found that professionals who were involved in Experience Feedback Committees had better scores on the Hospital Survey on Patient Safety Culture, especially in non-punitive response to error, communication and organisational learning dimensions.

Improvements in Introducing Changes

The studies reviewed show that managers and the personnel involved in AAEs had a low participation in the committees in charge of carrying out RCA. Peerally et al. [25] pointed out the need to professionalise the investigation of incidents by involving experts, as well as patients and family members, who can provide a unique perspective on the care received. Including those professionals who have been directly involved in the event also seems to have positive consequences, as it can contribute to the recovery of second victims by making them part of the solution [29]. Despite the progress and improvement in quality of care, the involvement of report systems such as RCA, especially the implementation of measures adopted, does not seem to be successful. Most of the included countries have so-called apology laws (39 states of the USA have Medical Professional Apologies Statutes; e.g., the Maryland Courts and Judicial Proceedings Code Ann.

§10-92041), which aim to improve the relationship with the patient and their families, allowing them to provide information that improves the quality of care [27]. However, the presence of the professionals involved in an AE in RCA committees was mentioned in only 1 study [6], and in none of the cases were relatives present.

Although AEs are sometimes inevitable and part of the uncertainty of medical practice, the ultimate goal of the RCA is to help to produce solutions and apply necessary measures to ensure they do not happen again, that there is a lower probability of their occurrence, or that if they occur the possible consequences are mitigated. Although some studies have demonstrated the usefulness of RCA and its recommendations [24], most published studies found that just over half of the recommendations that resulted from RCA were not useful enough to prevent the same incidents from recurring in the future [6, 14, 25]. For this reason, researchers have proposed RCA-based tools that seek greater involvement of frontline professionals in the implementation of proposals to prevent the recurrence of serious AEs [30]. The non-existence of a formalised system that allows these recommendations to be addressed in a specific period of time, as well as the limited power of RCA committees to ensure compliance with these improvement actions [17], hinders implementing the proposed actions. It must be borne in mind that, normally, the people who will have to assume the responsibility of approving the measures suggested by the RCAs and the professionals who must implement these measures are usually not those who participated directly in the RCA. This makes it difficult for the proposals to be carried out.

It seems, therefore, that RCA is a process with considerable validity through which much may be learned about incidents [12, 15]. However, it does not seem to produce enough benefits to address and resolve the problem [23, 25] and, thus, to avoid possible AAEs. As explained by Najafpour et al. [13], RCA is a reactive method for investigating an event and finding its underlying factors. This method could provide answers to questions related to what happened, and how and why it happened, and should be used to design preventive interventions. It should be performed using an outlined framework process of investigation and analysis of clinical incidents performed by professionals with experience in patient safety and should include at least one manager and one of the personnel involved in it.

Limitations

Some of the limitations encountered are that most of the published data related to RCAs pertain to analysing

the method of determining whether RCA is being implemented. Only reported results and quotations were assessed. Finally, little of the scarce evidence available regarding the impact – which was our objective – of carrying out RCAs can actually contribute to reducing the recurrence of the same incident, which may be due to the limited decision-making power of committees or to the proposed plan of action not being followed up in time.

Conclusions

Although early studies suggested that RCAs are effective in promoting ideas for preventing recurrence, more recent studies do not confirm these findings. A common gap that limits the effectiveness of this tool lies in the fact that RCAs are not usually accompanied by subsequent control of whether the devised improvement plan is carried out. Further research should focus on how to translate the results of ACR recommendations into practice to prevent recurrence of AAEs.

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Statement of Ethics

For this systematic review, the MOOSE protocol was followed.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

The conception and design were made by J.J.M.; the data were collected by A.M.-G. and J.M.-D.; the article was supervised by J.J.M.; all the authors contributed to writing, revising and approving the final draft.

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