

## Root Cause Analysis In Ensuring Patients Safety: A Narrative Review

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### Abstract

Patient safety, as defined by World Health Organisation is "the absence of preventable harm to a patient during the process of healthcare". It is imperative to understand common surgical errors in order to implement measures for improving safety and, consequently, the outcomes of surgery. The current narrative comprised a comprehensive literature search on PubMed, Cochrane, Scopus and Google Scholar databases, focussing on surgical safety protocols, root-cause analysis and complementary methodologies, pre-procedure verifications, structured checklists, failure modes and effects analyses, incident reporting systems and multidisciplinary team reviews of adverse outcomes, to highlight the role of root-cause analysis in enhancing patient safety in surgical specialties. Root-cause analysis, when combined with sound safety practices, forms the foundation of surgical error prevention and patient safety. A system-based approach, along with effective teamwork and communication, is essential for sustainable improvements in healthcare quality and patient care.

**Keywords:** Patient safety, Root cause analysis, Surgical errors.

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### Introduction

Patient safety is the protection of patients from injury or harm during the course of medical attention. The World Health Organisation (WHO) defines it as "the absence of preventable harm to a patient during the process of health care."<sup>1</sup> Surgical specialties are associated with high rates of patient complications, many of which are avoidable, reflecting the inherent risks of invasive procedures and the importance of improving safety measures.<sup>3</sup> Surgical errors can result in serious complications, long convalescence and even death. Estimates indicate that up to 25% of patients develop surgical complications related to inpatient surgery.<sup>2</sup> It is

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imperative to understand common surgical errors in order to implement measures for improving safety and, consequently, the outcomes of surgery. Wrong-site surgery, wrong patient, wrong procedure, and retained foreign bodies are among the common surgical errors that occur in the operating room (OR). It is worthy of noting that the two major and most frequent root causes of wrong-site and wrong-patient surgeries are misidentification of a patient, improper labelling of medical records, and ambiguities in documentation, such as incomplete or unclear consent about the surgical procedure. A wrong procedure on the right patient generally emanates for similar reasons, along with faulty surgical planning and insufficient surgical safety checklists. Retained surgical items, like sponges and instruments, come about because of breakdowns in surgical count policies or lack of adherence to proper standardised counting protocols and checks for safety. Enhanced safety, rigorous communication, and strict adherence to surgical safety checklists are critical in mitigating these errors.<sup>3,4</sup>

### Strategies to prevent adverse outcomes in surgical procedures

Patient safety consideration within healthcare involves several strategies. Of these, one of the most significant till now has been root-cause analysis (RCA), which investigates the reasons behind adverse events, and develops measures necessary for their prevention. However, there are a number of complementary approaches that may be considered relevant to healthcare organisations in achieving positive patient care and avoiding adverse outcomes.<sup>5</sup>

**Pre-procedure verifications:** Pre-procedure verification is the first step in ensuring patient safety, and involves the availability of both information and instruments before entering the OR. Healthcare providers should review patient records, diagnostic images and required surgical instruments to make sure everything is in order. Lack of certain information or materials may further result in critical errors during surgery.<sup>6</sup>

**Standardised protocols:** Introduction and implementation of standardised protocols in the OR, like standardised surgical safety checklists, enhance

communication and teamwork. Such checklists incorporate necessary steps, like sign-in, time-out and sign-out, that help confirm the proper identification of a patient, procedure and site before commencing surgical intervention. Indeed, studies have shown that adherence to such checklists leads to a significant decrease in surgical complications and mortality rates by introducing safety and accountability among surgical teams.<sup>7</sup>

**Preoperative assessment:** Thorough preoperative assessments are important for the safety of the patients. Assessment includes the review of medical history, current health status, and risk factors associated with the planned procedure. This enables clinicians to identify patients with higher risks for complications and adopt their approaches in such a way that additional monitoring or interventions can be instituted where need be.<sup>6</sup>

**Incident reporting systems:** Establishment of efficient incident reporting systems allows healthcare organisations to monitor adverse events and near-misses in a systematic manner. The data collected supports informed decision-making for RCA efforts, and significantly aids in identifying critical safety trends that require attention.<sup>6</sup>

**Failure modes and effects analysis:** The Failure modes and effects analysis (FMEA) is a proactive process in which potential failure points are taken into consideration in all processes before they create adverse events. Such an analysis scrutinises workflow and provides a risk assessment that enables healthcare teams to introduce the changes that really improve patient safety.<sup>6</sup>

**Site-marking:** The proper marking of the surgical site is another very significant and important strategy towards the prevention of wrong-site surgeries. It should be done by a qualified healthcare professional who may also be present during the surgery to ensure that the proper site is understood by all members of the surgical team.<sup>7</sup>

**Communication:** There is a need to encourage effective communication among members of the surgical team. Effective structured communication protocols allow for all those involved in a procedure to understand their roles and responsibilities. Teamwork can be enhanced through regular briefings before, and debriefings after surgery to learn where improvements are needed.<sup>6,8</sup> Moreover, a structured post-handover surgery is equally significant to ensure that critical patient details are properly conveyed between the teams to minimise risks.

### **RCA and steps to performing RCA in surgeries**

RCA represents a core methodology in healthcare, deployed for the reduction of errors in various clinical

settings to enhance patient safety. Systematic identification and correction of underlying causes of adverse events by RCA enable healthcare systems to move away from symptom-focused interventions towards comprehensive and evidence-based corrective actions. It incorporates multiple analytical frameworks, but the most prominent tool is the "5 Whys" technique, which allows the clinical team to iteratively interrogate the causal pathway of an event down to the primary aetiology.<sup>9</sup> RCA goes further and identifies isolated procedural lapses to include contributory factors, such as breakdowns in interdisciplinary communication, environmental ergonomics less than optimal, and deficient protocols and policies of an institution. This, in short, is a total-system approach to understand and deal with preventable iatrogenic outcomes.<sup>10,11</sup>

It is essential to have precise standards that define sentinel events and significant adverse events in the surgical environment before starting the RCA procedure. These criteria aid in identifying the situations that call for a formal RCA investigation. A sentinel event is often defined as an unanticipated incident that involves death, significant bodily or psychological harm, or the threat of such harm, and necessitates prompt attention. Any major injury sustained during or following surgery is considered a serious adverse event. To guarantee prompt, consistent and suitable reactions to such situations, healthcare institutions must have clear standards and procedures defining when an RCA should be carried out.

**Incident reporting:** The process of RCA is initiated once an incident is reported, which includes any untoward event in surgery or a near-miss. Each healthcare organisation must encourage open reporting culture where personnel feel secure enough to report errors, knowing that no retribution or threat would. As a matter of fact, it is one of the first important steps taken for the commencement of the RCA process in order to ensure that all relevant incidents will be investigated.<sup>12,13</sup>

**A multidisciplinary team:** The RCA team typically consists of 4-6 individuals with wide experience, including surgeons, nurses, specialists in quality improvement, and other personnel, specially experts in RCA methodology. The membership should not include those directly involved in the case under review for objectivity. The team leader or facilitator guides the analysis process and ensures that all voices are heard when discussion occurs.<sup>14,15</sup>

**Data-collection:** Information on the incident is gathered in detail by the team. This includes reviewing medical records, surgical logs and other documentation that

**Table:** Root-cause analysis (RCA) in surgical errors.

#	Case	Type of Study	Incident	RCA Process	Outcome
1	Healthcare - Diagnosing Medical Errors <sup>25</sup>	Case Study	Rise in post-surgical infections due to contaminated surgical gloves with microscopic tears.	Investigated sterilisation procedures and discovered the source of contamination was defective gloves.	Gloves were recalled, additional quality checks were implemented, and infection rates dropped significantly.
2	Pediatric Emergency - Child's Death <sup>26</sup>	Retrospective RCA	Lack of accurate examination leading to a child's death.	Followed *NPSA protocol; identified issues through interviews and documentation, used fishbone diagram for root cause identification.	Proposed solutions included improved monitoring of assistants and adherence to proper examination protocols.
3	Emergency Department - Delayed Chest Tube Placement	Retrospective RCA	Arrest of an emergency patient in the waiting room due to delayed chest tube placement for pneumothorax.	Analysed care delivery problems and identified lack of timely intervention by the emergency medicine specialist.	Suggested establishing a legal solution for emergency procedures and improved training for emergency staff.
4	Surgical Error - Missing Pathology Samples	Retrospective RCA	Missing pathology samples leading to chemotherapy delays.	Investigated communication failures between the operating room and pathology unit.	Developed a standardised process for sending samples to pathology to prevent future occurrences.
5	Delivery Ward - Uterine Rupture	Retrospective RCA	Uterine rupture during delivery due to rapid intervention.	Identified management-related causes and lack of adherence to physiological delivery protocols.	Recommended regular retraining courses for midwifery staff and adherence to established delivery protocols.
6	Retained Guide-Wire <sup>27</sup>	Case Series	A piece of a guide-wire was retained during a mastectomy for breast cancer.	RCA identified two factors: lack of a post-insertion chest x-ray and failure to inspect the guidewire length during removal.	Implemented policies for fluoroscopy use during procedures, mandated chest x-rays post-insertion, and conducted staff education and random audits.
7	Retained Laparotomy Sponge	Case Series	A laparotomy sponge was suspected to be left behind after surgery.	RCA revealed issues with the counting process by the circulating nurse and scrub technician, including a drift in policy regarding sponge placement.	Introduced a Devon Bag-It sponge counter for better visibility during counts, reinforced leadership accountability, provided in-service education, and initiated random audits.
8	Wrong-Level Spinal Surgery	Case Series	A spinal decompression surgery was performed at the wrong level despite intra-operative imaging.	Identified that anatomical difficulties complicated pre-incision marking, leading to errors in level identification.	Established policies for intraoperative radiology consultation, required confirmatory intraoperative radiographs before closure, and provided education and proctoring for surgeons.
9	Missing Surgical Gauze <sup>11</sup>	Case Report	A missing gauze piece during an emergency caesarean section.	RCA identified inconsistent surgical counting practices; recommended standardisation of the counting process.	Implemented the *WHO Surgical Safety Checklist and required concurrent audible and visual counts by both scrub and circulating nurses.
10	LASIK Surgery Error	Case Report	The wrong eye was treated during *LASIK surgery due to a failure in iris recognition.	RCA emphasised verification procedures for each eye's refractive error before the procedure.	Instituted a verification process involving optometrists, technicians, and surgeons to confirm treatment plans before surgery.
11	YAG Laser Procedure Delay	Case Report	Delay in performing a *YAG laser iridotomy due to scheduling issues in a busy clinic.	RCA assessed workflow inefficiencies during busy periods; recommended improved scheduling practices.	Enhanced scheduling protocols to minimise delays and improve patient flow during laser procedures.
12	Heparin Administration Error <sup>28</sup>	Case Report	An anaesthesiologist accidentally administered 30,000 units of heparin instead of the intended 3,000 units during kidney transplant surgery.	An RCA was planned but faced challenges due to blame being placed on the anaesthesiologist rather than examining systemic issues; investigation was influenced by hospital leadership pressure.	The RCA concluded with no interventions or systemic changes implemented to prevent future errors; blame placed solely on the anaesthesiologist without addressing underlying issues.

\*NPSA: National Patient Safety Agency, \*WHO: World Health Organization, \*LASIK: Laser-Assisted In Situ Keratomileusis, \*YAG: Yttrium-Aluminum-Garnet

could explain the series of events related to the commission of the error. More so, certain staff involved in

the incident are interviewed to bring out their perceptions and experiences of the event.<sup>12,15</sup>

**Event reconstruction:** Using the information gathered, the RCA team reconstructs what happened leading to and around the reported incident. This helps in highlighting both active errors, meaning active mistakes during care, and latent errors, meaning systemic flaws that led to the event. For example, active error could be miscommunication of a patient's surgical site; and the latent error may include poor verification processes.<sup>13,16</sup> The ideal process describes the standard procedure according to clinical protocols that should have been followed to ensure patient care and safety. The actual process is based on medical records, interviews and observations which entails what actually happened during the event or any deviations from the ideal process. By comparing the ideal process with the actual process, the team can actively identify any shortcomings, and this can be used to move beyond blaming individuals and improving surgical safety.

**Analysis of the contributing factors:** The RCA team uses several analytical tools to identify various contributing factors. Techniques, such as the "5 Whys" method, are used to drill down on each identified error by asking repeatedly "why" until the root cause is identified. Besides, cause-and-effect and fishbone diagrams might be used in an attempt to picture what could be the cause for every identified failure, using categories for, among other causes, people, processes, equipment and environment.<sup>13,16</sup>

**Root cause identification:** From the team, through systematic analysis, root causes leading to this adverse event is identified. This would also be an important step because it shifts the paradigm from individual blame towards an understanding of systemic issues needing resolution. For example, if a wrong-site surgery occurred due to poor communication among members, this would be documented as a root cause requiring intervention.<sup>12,13</sup>

**Formulation of corrective actions:** Based on the determined root causes, the team designs corrective actions to prevent the occurrence of similar incidents in the future. Such options may include the establishment of standardised site marking and verification criteria, training in improved communication by surgical teams, or the usage of new technologies in patient identification.<sup>12,16</sup> Clearly defining the timelines for implementing these steps, like the accountable group, maintaining sustainability, and how to verify that these actions have been carried out, are also crucial.

**Implementation of recommendations:** The recommended corrective actions must be appropriately

implemented in the surgical setting. This involves collaboration with the management and staff of the hospital in order to ensure that the changes in behaviour and practice are effected and integrated into everyday life.<sup>14,15</sup>

**Monitoring and follow-up:** The implementation of the corrective actions and their effectiveness should be observed over a continuous period of time following its implementation. This would mean tracking associated outcomes with incidents that are similar, and the ever-consistent use of new protocols. Periodic follow-up meetings can help reinforce accountability and subsequent commitment to patient safety.<sup>13,16</sup>

**Reporting findings:** Finally, the findings from the RCA process need to be recorded and then communicated to other appropriate stakeholders of the healthcare organisation. This transparency in sharing results enhances a safety culture promoting continuous learning among staff.<sup>12,14</sup>

#### **Advantages of RCA**

RCA offers critical advantages in clinical practice, particularly in enhancing patient safety and the quality of care. It allows healthcare professionals to identify the underlying pathophysiological, procedural or systemic factors driving adverse outcomes, rather than addressing superficial symptoms.<sup>17</sup> This targeted approach leads to sustainable interventions that reduce morbidity, prevent recurrence, and improve clinical outcomes.

RCA also fosters a culture of continuous quality improvement through data-driven analysis and evidence-based measures in managing workflow to reduce delays in resource utilisation. Economically, it points out operational inefficiencies and procedural redundancies, hence assisting in the reduction of unnecessary expenditures without compromising on the quality of care.<sup>18</sup>

RCA further helps in mitigating risks by systematically finding out the root cause of these adverse events for proactive prevention strategies. It reinforces evidence-based decision-making by decreasing cognitive biases, hence assuring that the effective implementation of validated interventions is done.<sup>19</sup> Root causes addressed by RCA improve not only individual patient outcomes, but also overall healthcare system resilience, which is reflective of a commitment to safer, more efficient and patient-centred care delivery.

#### **Limitations of RCA**

In medical practice, RCA, while a valuable tool, has notable limitations. One significant drawback is its

resource-intensive nature, as performing an RCA requires substantial clinician time, interdepartmental collaboration and advanced diagnostic tools, which are resources that may be unavailable in many healthcare facilities.<sup>20</sup> Moreover, in complex medical systems, adverse events often result from multifactorial pathophysiology, making it challenging to isolate and identify all the contributing aetiological factors.<sup>20,21</sup> The results of RCAs often are event-specific, which limits generalisability to other clinical scenarios. For example, different analyses are required for each individual adverse event, which may not be feasible in clinically busy environments. In addition, there is often resistance to implementing recommendations identified through RCA, especially when such recommendations involve major revisions in established clinical guidelines, workflows or institutional policies. This resistance may come from the healthcare teams or administrative bodies, and could reduce the effectiveness of RCA in implementing necessary improvements in patient care and safety protocols.<sup>22</sup>

Its other significant weakness is the strength and efficacy of the identified correction measures in the RCA process. Joint Commission International (JCI) standards<sup>23</sup> classify action items on three levels of strength:

**Weak measures:** These typically include training, changes to policies, reminding, or the reliance on human vigilance. The measures are simpler to take, but less effective for permanent enhancements to safety.

**Intermediate actions:** These include implementing automation, simplifying processes, or adding checks that partially reduce risk.

**Strong measures:** These highlight the system-level removal or control of hazards by the design of processes, by forcing functions, or by the inclusion of fail-safes so that the error may not recur.

This constraint pushes the healthcare organisations not only to determine the root causes, but also to prioritise and take effective, sustainable measures for making meaningful reduction of risks.

### Literature review

Literature review outlines that the most common strategy for improving patient safety in healthcare organisations is RCA. Literature highlights (Table) that RCA has been effective in unravelling the contributing factors to the incidences, but its implementation often encounters specific barriers. Successful RCA is an active and cumbersome process by leadership and specialised teams with training in safety science, and this, therefore,

requires organisational commitment to the process. Additionally, effective error analysis ought to be oriented to systemic solutions rather than putting blame on an individual in order to achieve a culture of safety in healthcare organisations.<sup>23</sup> This approach of focussing on the systemic issue means that RCA can address immediate causes, but it also contributes to long-term improvements in patient care and safety.<sup>9,24</sup>

### Future directions

Future projects to enhance the value of RCA in surgical patient safety would need to emphasis on the following areas:

**Standardisation and rigorous methodology:** To ensure complete depth of investigation across institutions, development and adoption of standardised, evidence-based RCA protocols must be implemented along with experts in quality improvement and human factors engineering in RCA teams. This can improve analysis accuracy and interpretation.

**Prioritisation of strong corrective actions:** Healthcare organisations should emphasise the identification and implementation of strong, system-based corrective measures that eliminate hazards, redesign processes and build fail-safe mechanisms.

**Creating a safety culture:** The success of RCA heavily relies on a collaborative, non-punitive culture to promote reporting of incidents and open communication of findings. Developing these kinds of cultures within surgical teams and health organisations will promote the success of RCA.

**System-level and cross-organisational learning:** Future applications must take the findings of RCA from single events to the system level of the healthcare system to respond to cross-system issues. Common networks, which share lessons learned and best practices, can amplify the impact of the results of RCA.

**Technology Tools:** In order to facilitate proactive, continuous improvements in patient safety, data-collection, trend identification, and RCA recommendation follow-up can be further improved by utilising digital incident reporting, data analysis and monitoring systems.

### Conclusion

Systematically uncovering and treating the roots of errors, RCA enables evidence-based corrective actions and proactive safety measures. Strategies such as surgical safety checklists, pre-procedure verification and robust communication frameworks reduce risk and improve surgical outcomes. Finally, an overall approach to RCA

supports a safety culture and continuous improvement, placing the care of patients at the forefront of healthcare concerns.

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