
ROOT
CAUSE

Root Cause Analysis: Enhancing Patient Safety and Quality Control

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LEARNING OBJECTIVES

1. Describe the steps of a root cause analysis
2. Use common investigative tools for root cause analysis
3. Develop a corrective action plan

Root cause analysis (RCA) is a problem-solving approach that aims to identify the fundamental cause or causes of an issue or problem. The easiest way to understand RCA is to think about a common problem, such as the need to find an alternative mode of transportation when one's car stops working. The person may take the bus, for example, and even though this solves the immediate transportation need, it does not address the underlying cause—the inoperable car. To solve the problem, the owner takes the car to the mechanic and has parts replaced until the vehicle runs. But will the repair endure? A mechanic who analyzes the problem for a root cause is more likely to provide a better solution and longer-lasting repair.

Objective 1: Describe the steps of a root cause analysis

When a product is not conforming to standards, or a procedure deviation is seen, leaders must be made aware so immediate action can begin. Completing a systematic investigation uncovers not only the immediate factors but also the root cause.

RCA helps leaders dig beneath the surface to find the issue's source, making it easier to solve the problem effectively and prevent a future reoccurrence. Finding the root cause may be quick and easy or difficult and time-consuming depending on the stability of the current process. If processes are unstable, with no standardization and various methods used that produce varying results, it is often difficult to pinpoint the root cause. It may be necessary to identify and eliminate process variations before finding the root cause. The following steps are essential:

Define the problem – A systematic approach begins with a clear and accurate problem definition. This could be issues related to infection control, equipment failures or process inefficiencies. To define the problem, it is important to be specific by asking when, how many, how often, which pieces of equipment, and by whom.

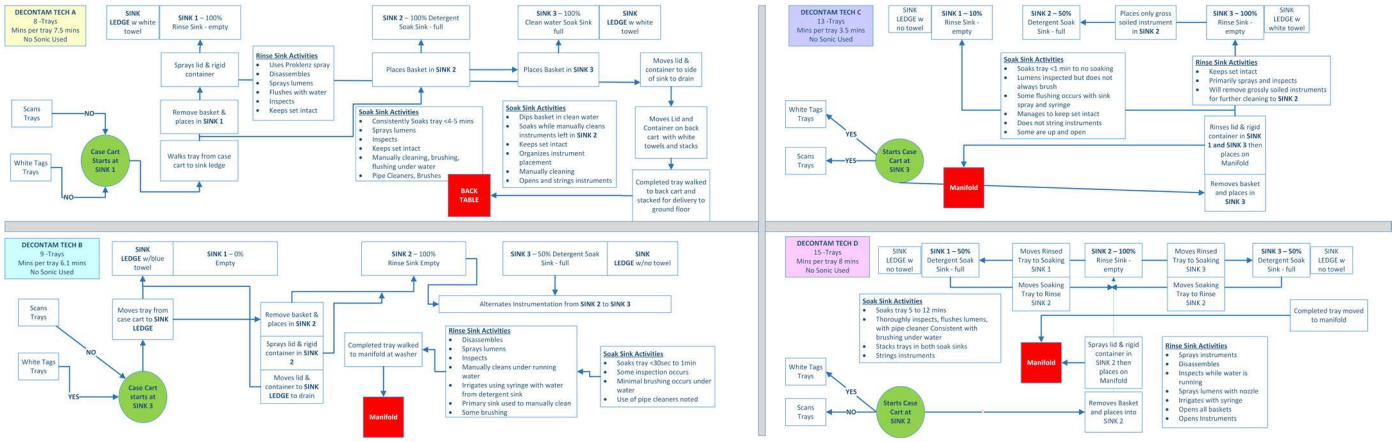

Figure 1: Sample process flow diagram from receipt to assembly

Find potential causes – Assemble a cross-functional team that includes staff from various roles and disciplines, including technicians, infection preventionists, Operating Room (OR) staff, Biomedical professionals and other relevant stakeholders. Work with the team to collect data and information related to the problem. This may include process flow diagrams, instrument tracking records, and quality reports. Ensure accuracy and completeness of all data. Next, analyze the data to find underlying causes or factors that could contribute to the problem. The goal is to identify as many causes as possible.

Narrow the scope – Drill down to the primary or root cause responsible for the problem. This step may include the use of fishbone diagrams, asking why (five times), and other RCA tools.

Develop and implement solutions – Create and adopt corrective actions that directly address the identified root cause(s). The cross-functional team will agree upon the root cause and brainstorm potential solutions or corrective actions to address it. Once the team has determined the best solution(s), an implementation plan will be developed and executed, with responsibilities assigned and timelines for completion.

Monitor and communicate – After implementation, it is vital to continuously monitor and validate the effectiveness to prevent the problem's reoccurrence. Document and report all findings, actions taken and outcomes to the relevant stakeholders. Periodically review the effectiveness of the implemented solutions and adjust as needed.

Objective 2: Use common investigative tools for root cause analysis

Determining which tools are right for a particular problem depends on the complexity of the issue. Starting with basic questions and tools may lead the team to the root cause. The team may find additional potential causes and require a more complex RCA tool. *Note: RCA tools can be used individually or in combination depending on the situation.*

Complex problems require a thorough understanding of the processes that could result in the problem that is under investigation. If the OR reported an increase in contaminated instruments found when opening trays, for example, the investigation team may assume that the technician missed the soil, or a washer-disinfector malfunctioned. Digging further into the entire process may reveal that the water quality was inadequate, or a new brand of cleaning chemistry was in use. A process flow diagram is an ideal RCA tool to document the process (see **Figure 1**). This diagram visually represents and documents the entire process under investigation. It provides detail on every activity or task within the process and exposes the true complexity of the workflow.

Creating a process flow diagram based on a manager's beliefs is usually different than one developed from employees' experience. This helps explain why a cross-functional team is necessary; it encompasses not only the technicians who perform the individual tasks, but also the Biomedical professionals who support the equipment, and support from leadership. It is essential to establish the boundaries of the process to be mapped. Where are the starting and end points? In assessing contaminated devices in the OR, the investigation data may show residual soil. The end point for the process may be the last stage where the devices are inspected for residual soil: assembly for sterilization. The starting point may be point-of-use treatment in the OR, the first process that could result in residual soil.

Next, it is vital to map the process. The easiest way is to use a large blank wall, a 3x10-foot roll of paper, sticky notes, and a black and red marker (if wall space is not available, consider using

multiple flip-chart papers). Each step or activity can be written on a sticky note and placed in sequence. Arrows can be drawn to connect the steps and represent the flow. Be sure to ask how each person performs the task and encourage honest feedback. Sticky notes can be added for each variation. From there, it will be necessary to drill down the probable causes. For each step, look for variations and discrepancies in the process and instructions for use (IFU), equipment performance, consumables used, environment, and utility changes.

Process flow diagrams have an added benefit: process improvement. Leaders can address and improve upon variances in practice, lack of standardization, workarounds or hidden processes created by staff members, and differences between practices and IFU. It can also help to improve workflow by finding bottlenecks and inefficiencies.

A simple and systematic approach to performing RCA is the 5 Whys method. Each ask of "why?" helps drill down to the cause of the issue. Despite the name of this method, it is necessary to continue asking "why" until the root cause is theoretically revealed (it may be necessary to ask far more than five times). Consider the following scenario, using the previous example of residual soil on surgical instruments:

Why didn't staff members discover the contaminated instrument during the assembly process?
Answer: Technicians were not properly trained, and standard work practices are not in place.

Why wasn't the instrument cleaned thoroughly before it arrived in the assembly area?
Answer: Staff in the decontamination area skipped steps in the cleaning process.

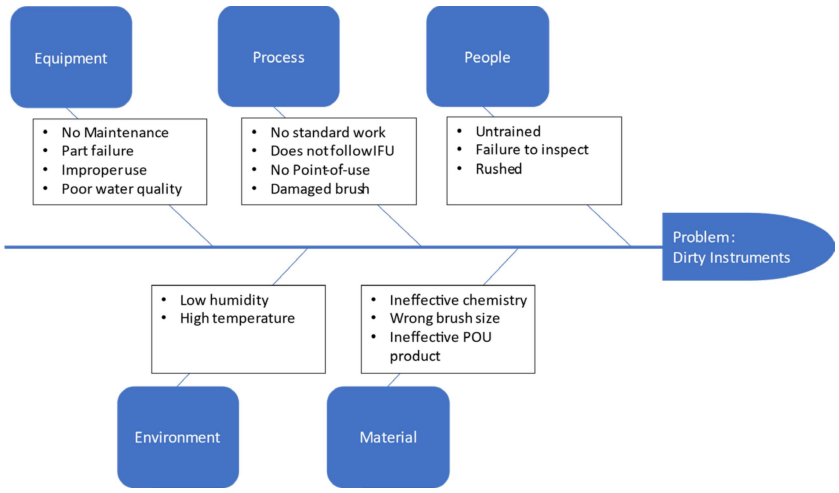

Figure 2: Example of a fishbone diagram

Why were cleaning steps skipped?
Answer: Staff felt pressured to turn the instruments around quickly, and the cleaning equipment was not dosing the chemistry properly.

Why was the equipment dosing incorrectly?
Answer: It hadn't been properly maintained and serviced.

Why wasn't it maintained properly?
Answer: There was no regular maintenance schedule established or followed.

Although the root cause of the residual soil was a combination of skipped steps and a failure to maintain the washer, several checks and balances along the way also contributed to the problem, including a lack of standard work, untrained staff performing inspection in assembly, and pressure to complete tasks quickly.

Another tool that assists in determining root causes, especially when multiple causes are possible, is a fishbone diagram, also known as an Ishikawa diagram. (See **Figure 2**) A cross-functional team that includes those who are affected by the problem, the technicians performing the work, SP leadership, Biomed and other necessary stakeholders will begin by brainstorming possible causes, which are then grouped into categories. Under each category, team members will list the potential causes and continue to brainstorm additional ones.

The categories and their list of causes are placed on the diagram to visually reflect the cause-and-effect relationship. The problem is the "head" of the fish, with each category and its list of causes becoming a "bone." Five standard categories often used in SP-related investigations include equipment, process, people, environment and material.

Once the brainstorm activity is complete, the resulting possibilities are then investigated to determine which may have contributed to the problem experienced by the facility. This type of analysis encourages a structured and collaborative approach to problem solving and keeps teams focused on their efforts to proactively address the reasons behind the issue instead of reacting to the symptoms.

Objective 3: Develop a corrective action plan

A corrective action plan is a comprehensive strategy designed to correct the root cause(s) and prevent recurrence. Although SP leadership is responsible for completion of the corrective action plan, it takes a team to develop the plan.

It is imperative to compile a team that is representative of each area found to be a root cause or contributing factor. Stakeholders can be added from all areas affected by the original problem, which helps ensure a well-rounded perspective, and more team members may be needed depending on the extent of the problem. The team will brainstorm potential ways to correct and prevent the cause from occurring or reoccurring. Several solutions may be proposed for each root cause, with each potential solution rated to decide the best solution. Items to consider include but are not limited to:

- How effective the solution is
- Ease of implementation
- Required capital or consumable products to implement
- Cost of implementation
- Cost of maintenance

Once selected, a plan is formulated to obtain necessary equipment and consumables; revise or create standard work; train and establish staff competence; and implement quality measurements to determine the effectiveness of the solution. The plan should clearly define who handles each action item in the plan and a timeline for completion.

The example from the 5 Whys analysis found a root cause and several contributing factors. A corrective action plan for this problem could include revising cleaning and assembly procedures to ensure thorough and effective cleaning and inspection during assembly (this would list staff training and competency needs and ensure those needs were completed). A regular maintenance schedule for all equipment, including routine servicing and inspections, would be added to the maintenance staff's responsibilities.

It is also critical to ensure that preventative measures, reporting and continuous improvement are part of the plan. The plan may not entirely eliminate the problem the first time it is implemented. More investigation and brainstorming may be needed to develop a new plan to fully resolve the issue or concern. From there, it will be necessary will review the plan periodically for effectiveness and make adjustments. At minimum, the plan should be evaluated when equipment is updated, new equipment or consumables are obtained, and procedures are changed.

Conclusion

RCA is a valuable tool that can enhance patient safety and quality control in SP. By identifying underlying causes, improving process efficiency and enhancing communication and training, SP leaders, their teams and interdisciplinary stakeholders can work proactively toward the goal of error prevention and quality control. Following the steps and making RCA a part of the SP workflow allows SP leaders to systematically identify and address inefficiencies and, ultimately, improve the quality of all sterilization processes. P

RESOURCES

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