How to undertake a root cause analysis investigation to improve patient safety


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Rationale and key points
Root cause analysis is a tool that can be used when determining how and why a patient safety incident has occurred. Incidents that usually require a root cause analysis include the unexpected death of a patient, serious pressure ulcers, falls that result in injury, and some infections and medication errors. This article outlines the stages of the investigation process for undertaking a root cause analysis.

» Root causes are the fundamental issues that led to the occurrence of an incident and can be identified using a systematic approach to investigation. Contributory factors related to the incident may also be identified.

» Crucial questions in a root cause analysis are: what happened? How did it happen? And why did it happen?

» Undertaking a root cause analysis can assist in identifying areas for change and developing recommendations, with the aim of providing safe patient care.

Reflective activity
‘How to’ articles can help update your practice and ensure it remains evidence-based. Apply this article to your practice. Reflect on and write a short account of:

1. A patient safety incident that has occurred in your clinical practice, such as the unexpected death of a patient, a fall that resulted in injury, a serious pressure ulcer, an infection or a medication error. What happened next? Was a root cause analysis undertaken and what was the outcome of this?

2. How you can support your colleagues to undertake a root cause analysis after a patient safety incident occurs.

Keywords
clinical procedures, clinical skills, duty of candour, incident reporting, investigations, patient safety, root cause analysis, service improvement

ROOT CAUSE ANALYSIS is a tool that can be used to investigate how and why a patient safety incident has occurred. It can be used to identify areas for change and develop recommendations that aim to deliver safe patient care. The root causes are the fundamental issues that led to an incident occurring, and can be identified using a systematic approach to investigation. This article uses the stages of the National Patient Safety Agency* (n.d.) investigation process for undertaking a root cause analysis (Box 1). A root cause analysis is usually undertaken for incidents such as the unexpected death of a patient, serious pressure ulcers, falls that result in injury, and some infections and medication errors.

Preparation
Getting started
» Read your healthcare organisation’s policy on managing patient safety incidents for guidance on conducting an investigation for incidents of varying severity, who to involve, and the
timeframe for the investigation and completion of the investigation report.

» Establish whether you are the appropriate person to lead the investigation, with the skills required to undertake a root cause analysis, or if you will contribute as part of a team.

» Gather all relevant documentation, including paper and electronic patient records, incident reports, relevant policies or guidelines, photographs and imaging.

<table>
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<th>TABLE I. Levels of investigation</th>
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| **Concise or local investigation** | » Used for incidents, complaints, claims or concerns where there has been no harm, or low or moderate harm  
  » Commonly involves completion of a short or summary structured template  
  » Conducted by one or more people in the locality or directorate where the incident occurred, for example in the ward, clinic, department, team or GP practice |
| **Comprehensive or significant investigation** | » Used where there has been actual or potential death or severe outcomes as a result of the incident  
  » Conducted to a high level of detail  
  » Conducted by a multidisciplinary team, or involves expert opinion or independent advice  
  » Conducted by people not involved in the incident, locality or directorate in which it occurred  
  » May be overseen by a director-level chair or facilitator |
| **Independent investigation** | » Includes the criteria for a comprehensive or significant investigation  
  » Must be commissioned and conducted by people who are independent to the healthcare organisation involved  
  » Used for incidents of high public interest or those attracting media attention  
  » Conducted in accordance with national guidelines, for example for mental health homicides |

» Consider the involvement of the patient, their family and relevant staff members in the root cause analysis, and how best to support them.

**Procedure**

**Gathering and mapping the information**

1. Review the available information about the incident and determine the level of investigation that is required. This could be a concise (local), comprehensive (significant) or independent investigation (Table 1).

2. Establish whether the person or people have been informed of the incident and investigation if it has involved them. Determine if the ‘duty of candour’ requirements to be open and honest when things go wrong (Healthcare Improvement Scotland 2015, Nursing and Midwifery Council 2015, Care Quality Commission 2017) have been met where appropriate, and if not establish why not.

3. Scope the investigation to establish how far back to investigate in relation to the incident, and whether any other organisations are involved, such as the GP or ambulance service.

4. Gather additional information to establish the facts and gather evidence. This may include visiting the site of the incident, interviewing or taking statements from staff members involved in the incident, and talking to the patient and their family.

5. Collect local data on similar incidents from the incident reporting system and, if available, national data. Assemble other material such as staff rotas, training records and medical device maintenance records. This list is not exhaustive and there may be other important records that should be included.

6. Keep all documentation and data relevant to the investigation secure and indexed.

**Identifying care and service delivery problems**

7. Map the information and produce a timeline or chronology of the incident, using the template provided by your healthcare organisation.
8. Identify problems related to:
   - Care delivery, such as actions or omissions by staff.
   - Service delivery, such as equipment breakdown or necessary equipment not being available.

9. Describe the problems using specific language and detailed description, for example ‘the nurse did not inform the doctor of the condition of the patient’s wound’ rather than ‘communication failure’. Identify what happened rather than why it happened, for example ‘the doctor did not wash or decontaminate their hands’ rather than ‘inadequate training on hand hygiene’.

**Analysing the information: identifying contributory factors and root causes**

10. Determine all the contributory factors related to the incident, including:
    - patient factors; staff factors; task factors; communication; team and social factors; education and training; equipment and resources; working conditions; and organisational and strategic factors. Using a tool such as the Fishbone diagram (Figure 1) may be helpful because it provides a logical approach to the identification of these factors.

11. Throughout the analysis, keep asking ‘why’ things happened, exploring the incident in increasing depth. The ‘5 whys’ technique can be used to identify the root cause of an incident. It originated from the Toyota Motor Corporation (Ohno 1988) and is now widely used in many circumstances. One example of the use of this technique is shown in Box 2, where it is determined that the system used to store medicines was a contributory factor in the patient safety incident.

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**Figure 1. Fishbone diagram to identify contributory factors**

![Fishbone diagram to identify contributory factors](image-url)

(Material developed by the National Patient Safety Agency 2010)
rather than the nurse who gave the medicine – the ‘why’ rather than the ‘who’.

12. Identify the lessons that have been learned from the investigation. In some cases, there might not be a clear root cause, but there will be relevant or contributory factors that should be addressed. Significant unrelated safety issues that require action to be taken may also be identified.

Generating recommendations and solutions

13. Develop an action plan, identifying SMART (specific, measurable, achievable, realistic and time-bound) actions that will be undertaken to address the root causes and contributory factors related to the incident and/or the lessons learned from it.

14. Determine what is to be done, by whom, and when (WWW can be used as a mnemonic to help remember these important components), and how the effect of the actions or changes will be measured.

Implementing solutions

15. Implement the changes outlined in the action plan.

Writing the investigation report

16. Include all the findings and the action plan in an investigation report, using a local or national template, such as the NHS Wales (2014) pressure ulcer reporting and investigation guidance, or ones to be used in specific cases such as meticillin-resistant Staphylococcus aureus infection (NHS England 2014).

Box 3 outlines the various aspects that should be included in the investigation report.

17. Use plain English, write in the third person and avoid jargon and acronyms in the investigation report. Be factual and accurate, avoiding negative or inflammatory descriptions. The report should be anonymised where possible; however, where this is not possible, people included in the report should be identified by their initials and full job title, with a record of their names kept separately. Share a draft of the report with these people before its final publication.

18. Submit the final version of the investigation report to those who need it, such as relevant committees and external organisations, and to the patient and their family. Arrange a meeting to discuss the content with them.

Continuing to implement solutions and monitoring progress

19. Monitor the progress of the actions taken and changes implemented, for example through an audit. Establish the staff and committees who it is appropriate to report progress to, and report to them as required.

Evidence base

The National Advisory Group on the Safety of Patients in England (NAGSPE) (2013) indicated that patient safety incidents occur in all healthcare systems, including the NHS. A report from NHS Improvement (2017) found that, in England alone, more than 1.8 million patient safety incidents were reported to the national reporting system between October 2015 and September 2016. Of these, 17% (around 308,000) were categorised as patient accidents, 13% (around 241,000) involved the implementation of care and ongoing
monitoring of patients, and 11% (around 192,000) were related to medicines. Most of these incidents did not result in harm to patients, but in nearly 3% of these incidents, moderate harm was caused and in 0.5% of these incidents, there was severe harm or death.

The costs of patient safety incidents are measured in human and financial terms. Estimates of the financial costs vary, but a report commissioned by the Department of Health suggested at least a £1 billion cost per year to the NHS (Frontier Economics 2014). Another review indicated that 15% of hospital expenditure and activity in Organisation for Economic Co-operation and Development (OECD) countries can be attributed to safety failures in treatment (Slawomirski et al 2017). Therefore, it is essential to identify ways to reduce the number of patient safety incidents that occur in healthcare settings, and to improve the quality of care.

The NAGSPE (2013) asserted that quality in the NHS entails:
- Safety – avoiding harm from the care that is intended to help.
- Effectiveness – aligning care with science and ensuring efficiency.
- Patient experience – including person-centred care, timeliness and equity.

The NAGSPE (2013) also suggested that the priority should be quality and safety of patient care. To achieve this, staff require support in their development, including their ability to improve practice in their healthcare organisation. When incidents occur in healthcare, detailed investigations can improve systems of care, where necessary, and enable staff, patients and families to understand what went wrong, what actions will be taken and if these actions are effective.

Root cause analysis is a systematic approach through which staff can learn from patient safety incidents and use this knowledge to improve patient care (NHS England n.d.). The purpose of undertaking a root cause analysis following a patient safety incident is to: find out what happened, the how and why; identify the lessons that can be learned; determine improvements and appropriate actions to reduce the risk of future incidents; and to meet the duty of candour requirement to be open and honest with patients and their families when things go wrong. The crucial root cause analysis questions of: what happened? How did it happen? And why did it happen? can be answered by collecting relevant information and using a logical approach to consider all contributory factors relating to an incident.

Improving patient safety following a root cause analysis relies on staff taking corrective action, implementing changes and measuring the effect of these. While such changes may be implemented in the local healthcare organisation, it may be necessary to disseminate the information more widely so that lessons can be learned throughout the healthcare system. Serious incidents require a root cause analysis,

**Box 3. Elements that should be included in the investigation report**

- Incident details – description, date, type (category), effect on patient, severity
- Background and context – information about the organisation, the service or area in which the incident occurred such as the number of beds, patients and staff, and information about previous similar incidents
- Terms of reference – why the investigation and report is being undertaken, members of the investigation team
- Involvement of the patient and their family in accordance with the duty of candour – whether and how they have been kept informed of the incident and the investigation
- Involvement and support of staff involved – whether and how staff involved have been debriefed and offered support
- Information and evidence gathered, including the methodology used for this – how relevant information was collected in the investigation
- How the root cause analysis was undertaken and the tools that were employed
- Identification of the incident – when and how the incident was first identified
- Narrative chronology of events – a straightforward account of what happened in date and time order, written clearly using complete sentences, similar to an essay
- Timeline – the ‘what’ information, giving precise dates and times of the significant events written in the form of a table
- Notable practice – the good aspects of the care and service delivery
- Care and service delivery problems identified
- Relevant issues – the relevant contributory factors identified in the investigation
- Lessons learned – areas for change to prevent similar incidents recurring
- Recommendations – corrective actions and changes to practice to make care safer
- Action plan – the SMART (specific, measurable, achievable, realistic and time-bound) actions that will be undertaken, and what is to be done, by whom and when, as well as the measures that will be employed to mitigate risk
- Monitoring – identifying who has responsibility for overseeing implementation of the action plan, as well as the audit and data monitoring to measure the effectiveness of the actions taken
- Reporting and sharing – identifying who should receive the report and who will ensure it is distributed to them and by when

(Adapted from materials developed by the National Patient Safety Agency n.d.)
and it is necessary to decide when it is appropriate to conduct one. In nursing, certain incidents – such as the unexpected death of a patient, serious pressure ulcers, falls that result in injury, and some infections and medication errors – usually require a root cause analysis to be completed. This is so that changes can be implemented to prevent the occurrence of these incidents in the future and reduce the incidence of harm to patients. However, it is important for healthcare staff to be alert to the potential need for a root cause analysis in any situation in which there has been actual or potential harm, including ‘near misses’.

References


