

Root Cause Analysis

Compendium for use by Patient Safety Officers and
others responsible for conducting root cause analysis
of adverse events



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Introduction

The Danish Society for Patient Safety has taken the initiative and prepared a compendium intended to provide the reader with an overview of the topic, based on the international literature and experiences gained from completed Root Cause Analyses.

The compendium is intended as a supplement to the Handbook for root cause analysis published by the Danish Society for Patient Safety in November 2003 (1), which will continue to be used by teams conducting Root Cause Analysis.

The Danish Society for Patient Safety especially wishes to thank director James P. Bagian, the Department of Veteran Affairs National Center for Patient Safety (NPSF) for inspiration, guidance and support.

The compendium is presented as a practical guide for professionals who possess a good knowledge of adverse event reporting systems as well as a system-orientated approach to patient safety.

The target audience is specifically current or future patient safety officers who already work with or will work with root cause analysis related to adverse events that resulted in or could have resulted in serious patient outcomes.

The purpose of the compendium is to provide patient safety officers with new knowledge and awareness of how to work analytically with the method so that it becomes evident that the finished root cause analysis is based on a specific method.

In addition, the purpose of the compendium is to ensure that the analysis of adverse events is conducted in a sufficiently comprehensive and in-depth manner to support the identification of the actual root causes of the event. Only in this way can the basis be created for establishing action plans that produce measurable results in terms of increased patient safety.

The compendium offers an overview of the steps involved in performing a root cause analysis – from the initial decision to perform the analysis to the preparation of the final report and its approval by the professional members of the investigation team.

The compendium reviews the individual steps of the root cause analysis. The steps are further supported with examples from a sample case study inspired by actual adverse events analysed using the root cause analysis method. The examples are based on a hypothetical adverse event to give the reader an impression of how a completed root cause analysis can be disseminated.

We hope that the compendium may assist clinical risk managers in gathering, analysing and summarising large amounts of qualitative and quantitative data for the purpose of maintaining system approach and disseminating learning gained from the analysis of an adverse event.

The Danish Society for Patient Safety
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Background and introduction

Background

The root cause analysis method was introduced to Denmark only a few years ago. The introduction took place concurrently with a new focus on patient safety and the importance of reporting adverse events.

For example, the hospitals in the Copenhagen Hospital Corporation began using the root cause analysis method at the same time that the adverse events reporting system was implemented at the end of 2001 and beginning of 2002.

The method continues in use for the analysis of the most serious adverse events. At the end of June 2004 a total of 3,000 events had been reported, 66 of which provoked a root cause analysis.

With the legislation of the Danish Act on Patient Safety in the Danish Health Care System which came into effect on 1 January 2004, and the resulting obligation to report adverse events to the national reporting system, the root cause analysis method will probably be performed on an ever-increasing scale in future.

Some health care professionals wonder why it is necessary to expend resources on performing Root Cause Analyses instead of working proactively to prevent adverse events through clinical risk management. It is important to emphasise that although Root Cause Analyses are primarily used in a reactive way to investigate adverse events, the method is also useful in analysing existing issues before they lead to a situation that could result in serious patient harm.

The analysis of existing issues attains full scope in the aggregate root cause analysis, which is an analysis of several events of the same type gathered over a given period of time. These events are characterised by being less significant from a factual perspective, but can also be considered potentially significant or catastrophic. The aggregate analysis method is performed using the same steps as the individual root cause analysis.

Both individual and aggregate root cause analysis comprise a highly useful learning tool and therefore promote cultural change, so system perspective on adverse events achieves increasing impact, both in terms of professional thought and in the construction and maintenance of safety systems.

Introduction

A root cause analysis can be briefly defined as an investigative process in which both qualitative and quantitative data are systematically gathered and analysed with the purpose of identifying the underlying causes and contributory factors of a serious adverse event. The goal is to obtain knowledge and thereby prevent recurrence of the serious adverse event. A root cause analysis will always yield recommendations for specific initiatives expected to contribute to improvements in patient safety.

In a nutshell, the root cause analysis answers the questions:

- What happened?
- Why did it happen?
- How can it be prevented from happening again?

As a root cause analysis is a relatively extensive process, it is performed chiefly when an adverse event has occurred which resulted in serious patient harm or which had the potential to cause serious patient harm.

In this respect, performing a root cause analysis can prove to be a sensitive process, one in which it is important to emphasise that the investigation does not provide an answer to the question, "Who is responsible?" nor does it bring forth a scapegoat.

Root cause analysis focuses solely on aspects such as work planning, communications and equipment; or rather, identifying the defects or vulnerabilities in the organisation's safety system that led to the occurrence of the adverse event.

By these means system perspective is maintained and thereby the view that to err is human, but through consistent work and ongoing reassessment of the organisational defences against adverse events, it is possible to take action to prevent future occurrences of the same type of event.

Steps of root cause analysis

A root cause analysis involves conducting the following steps:

1. Begin investigation of the adverse event
2. Determine the sequence of events
3. Identify contributory factors
4. Identify tentative root causes
5. Gather additional data and perform literature review
6. Discuss, determine and confirm identified root causes
7. Prepare action plan
8. Generate report and obtain approval

Step 1 is the formal step in which administration takes the decision to investigate the adverse event through root cause analysis. Next, an investigation team of professionals is assembled to perform the analysis in question, and procedures are agreed upon before actual work begins.

Steps 2, 3 and 4 involve the preliminary work of the analysis itself; the defined issues are discussed at the investigation team's first meeting.

Step 5 constitutes an interim step for the team wherein the clinical risk manager begins work on the first comprehensive analysis of the gathered data; the first investigation team meeting may have indicated the necessity of gathering further data. Sufficient time must also be set aside for reviewing the subject literature.

Steps 6 and 7 are characterised by the issues discussed at the team's second meeting. In these steps the team concentrates on the in-depth investigation processes and works in a highly systematic way to determine with certainty that the actual root causes of the adverse event have been identified. Only in this way can a basis be established for generating recommendations for a specific action plan to prevent the occurrence of a similar adverse event.

Step 8 is the final analysis based on all of the gathered data. The clinical risk manager summarises the data and draws conclusions about the findings reached by the investigation team. A root cause analysis always results in a report generated by the patient safety officer. The report is approved by the investigation team, either by email or a final meeting, before it is submitted to those responsible for the overall investigation.

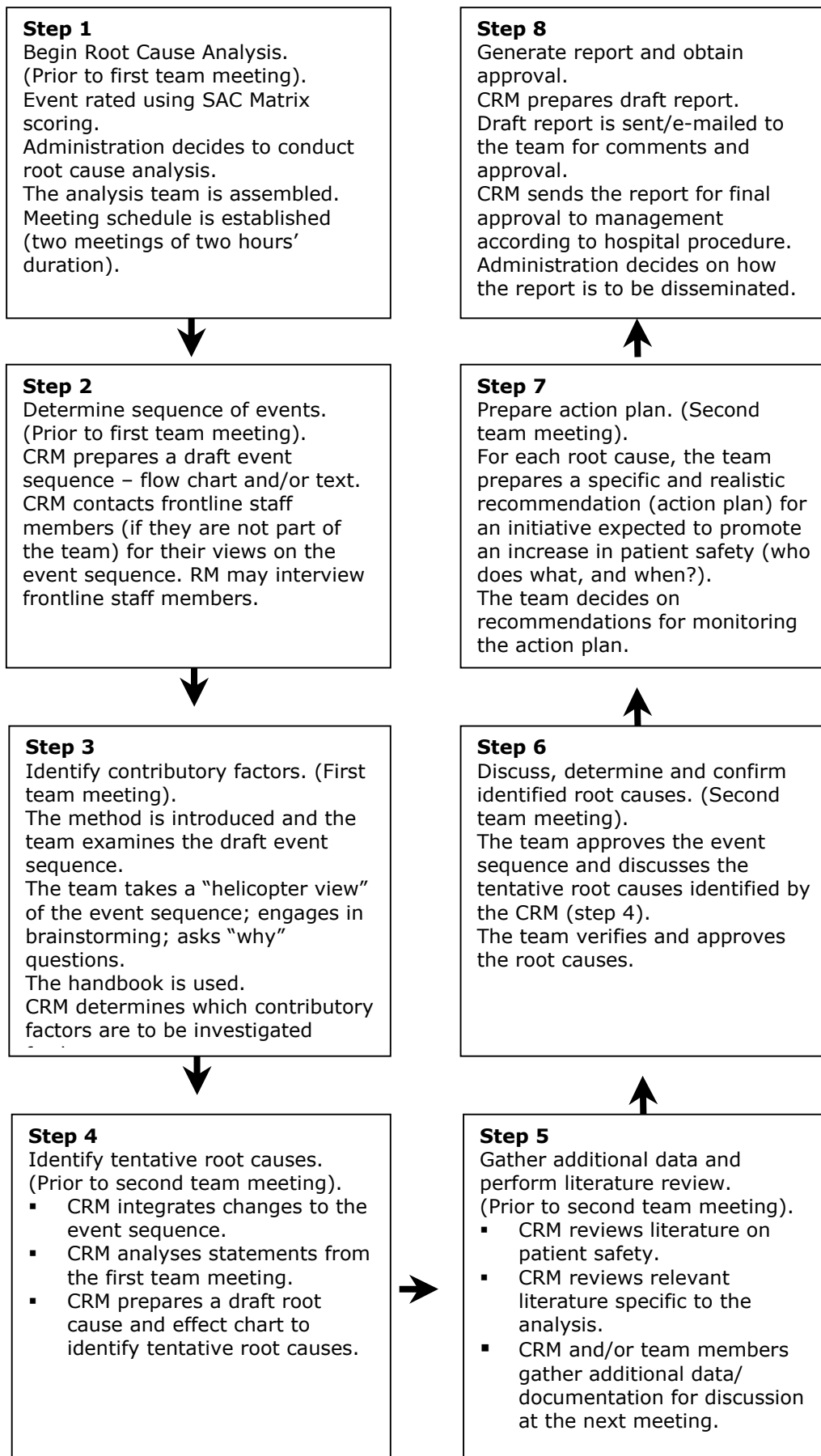
Flow chart illustrating the steps of a root cause analysis

The next page illustrates the eight steps of a root cause analysis as represented in a flow chart.

The flow chart aid provides an immediate overview of the analysis method as a whole, but cannot be used on its own.

In order to conduct a root cause analysis on a qualified basis, it is necessary to first review the entire compendium so that it may be used as a reference tool in conducting actual Root Cause Analyses.

Root Cause Analysis flow chart



Time management

Time spent on conducting a root cause analysis is typically 2-3 team meetings of approx. 2 hours in duration respectively. To this must be added time spent by the patient safety officer on performing case management, carrying out any interviews that may be necessary, visiting the location at which the adverse event occurred, performing the literature review and, last but not least, preparing the final report.

The following section will examine the individual steps of the root cause analysis in more detail.

Definition of terminology

This compendium does not provide definitions for the most commonly used patient safety terminology. It is assumed that the reader is conversant with terms such as error, complication, and adverse event, just as it is assumed that the reader is familiar with the concept underlying system perspective versus individual perspective. For more in-depth information on the above-named terms, please refer to the following publications:

- Sundhedsvæsenets kvalitetsbegreber og -definitioner, Dansk Selskab for Kvalitet i Sundhedssektoren, January 2003. Danish only. This publication can be downloaded from www.dskk.suite.dk
- James Reason: Human error: models and management. BMJ 2000; 320:768-770.

Step 1 – Beginning the root cause analysis

The decision to conduct the analysis

The decision to conduct a root cause analysis is based on the acknowledgement that a serious adverse event has either occurred or had the potential to occur. Most often it is the frontline staff members – healthcare professionals in direct contact with the patients – who are the first ones to realise that something has gone wrong.

Immediately following the occurrence of an adverse event, staff members should take necessary steps to ensure care for the patient or patients involved in the event. The event must also be reported immediately. This requires a climate of openness within the organisation as well as confidence on the part of staff members to speak up about what has occurred without fear of repercussions.

This kind of approach is based on the fundamental assumption that all healthcare professionals perform their work responsibly and with care; no one goes to work with the deliberate intent of doing harm to patients. When an adverse event does occur, it is the result of a chain of safety system defects or gaps combined with specific circumstances in the working environment such as equipment problems, breakdown in communications or ambiguities in procedure or guidelines. (2).

After notifying administration of the occurrence of the event, the next step is to assess the seriousness of the event and decide whether it warrants conducting a root cause analysis.

An event can be assessed using the Safety Assessment Code (SAC) Matrix, which was developed by the National Center for Patient Safety (NCPS), part of the US Department of Veterans Affairs.

In conducting an assessment, the categories apply equally to both close calls and actual adverse events. This means that the risk of a given injury is assessed as though it had actually occurred.

The severity category of the injury to the patient/patients paired with the probability category produces a ranked matrix score (SAC rank) that indicates whether a root cause analysis ought to be conducted. Actual adverse events with a score of 3 are typically followed up by a root cause analysis. In addition, hospital administration may decide to conduct an analysis for potential adverse events (close calls) with a SAC score of 3, or other serious adverse events which have been assigned a high probability category.

Assigning a SAC score is always based on a combination of professional judgement and experience in event assessment. It is therefore best if the hospital's medical head of department and the patient safety officer work together to score the event. In this context it is important to be aware of the fact that inexperience in assessing events can cause a tendency in investigators to focus on potential worst case scenarios and therefore assign all/most events a potential adverse event score of 3.

On the other hand, there will rarely be any doubt when an event can be definitively assessed as an actual adverse event with a score of 3, because in cases such as these the patient has died as a result of the event or has suffered permanent injury/disablement, and in these situations it is immaterial how rarely or frequently a similar event is assessed to be likely to recur.

In summary, it is recommended to conduct root cause analyses of the events which hold the greatest potential for learning. Furthermore, higher levels of motivation to undertake analysis are often found under these circumstances.

It is always the responsibility of hospital administration to decide to undertake a root cause analysis, just as it is the responsibility of administration to assemble the investigation team and establish the timeframe for the analysis. In addition, someone with administrative responsibility ought to be part of the team itself since only administration has the authority to implement the action plan that results from the analysis.

In very rare cases there may be circumstances under which a root cause analysis ought not to be conducted. There may be suspicion that one or more staff members directly involved in the event was under the influence of drugs or alcohol, or there may be a suspicion that a staff member deliberately intended to cause injury to a patient. In this case hospital regulations must be followed.

Adverse events that result in death must be reported to the police in accordance with the Inquests Act¹⁾. Despite the fact that the healthcare professionals involved in the event are distressed and in the midst of a situation to which they are particularly unaccustomed, a root cause analysis can prove helpful in removing some of the weight of responsibility from their shoulders. This is because the root cause analysis exposes flaws in work processes and failures in organisational safety systems rather than placing focus on the individual or assigning blame.

An adverse event

In order to provide the most realistic picture of a root cause analysis, a sample case study of an adverse event will be used throughout the remainder of this compendium. The example begins with the event being reported.

The following is an excerpt from the reporting form issued by the medical head of department to the hospital's patient safety officer:

¹⁾ Act no. 402 of 13 June 1990 on inquests, autopsies and transplantation etc. requires that a death must be reported to the police when said death may be a result of error, neglect or accident in connection with the treatment or prevention of illness.

Short description of the event (example)

A newborn baby delivered by emergency caesarean section is administered an intramuscular injection of Methergine immediately after the birth. The baby should have received an intramuscular injection of Vitamin K. The error is discovered when the ampoule is checked immediately after the administration of the medication.

The baby is admitted to the neonatal unit for observation and an intravenous drip is inserted to facilitate rapid intervention in case of symptoms of poisoning. The baby is also placed under constant observation.

At the present moment – 24 hours after the event – there is no sign that the baby has been harmed by the erroneous injection and the baby is therefore transferred to the postnatal unit.

Scoring the event

The event was assigned an actual adverse event score of 3 and thus provoked a root cause analysis.

The patient safety officer and medical head of department together assessed the event, and after finding both for and against an actual adverse event score of 2/potential adverse event score or actual adverse event score of 3, they reached a decision to assign an actual adverse event score of 3.

Of particular focus in the discussion was whether the extent of the hazard was moderate or major on the basis of increased care and intensity of treatment. The conclusion was that a newborn baby would, in most instances, not require treatment and particularly not in this case, where the pregnancy had been without problems and a normal birth expected; therefore the extent of the hazard must be considered to be major.

It was furthermore acknowledged that there were examples indicating that errors in both dispensing and administering medication to babies were frequently made at this hospital.

On this basis the decision was made to conduct a root cause analysis.

Assembling the investigation team

A root cause analysis is conducted by a team specially selected to investigate an individual, specific adverse event. The team is disbanded after the report has been completed and approved. The only staff member common to any given team is the patient safety officer.

In addition to team members with management expertise, staff members with direct patient contact must also be represented on the team. Depending on the specific event and with consideration for local working conditions, administration and the patient safety officer must together decide whether or not frontline staff members – those most closely involved in the event – will be included in the team.

On the one hand, the participation of frontline staff members on the team can be beneficial to the analysis because it is they who can offer the most insight into what actually occurred, and can contribute to understanding why the event occurred. At the same time, participating in the analysis allows frontline staff members to feel that the focus has shifted away from them and onto the underlying root causes as identified from a system perspective.

On the other hand, being part of the investigation team can sometimes prove too emotionally debilitating for frontline staff members. In this case the patient safety officer must undertake interviews of the staff members involved in order to include their information in the analysis, and healthcare professionals who perform functions

similar to the directly involved staff members must be selected to participate in the investigation team instead.

In summary, it is important to separate the needs of staff members to emotionally process an event from the root cause analysis itself, the primary purpose of which is to prevent future occurrences of a similar adverse event. For cases where the adverse event is experienced by staff members as very dramatic or stressful, gathering those who were involved for a debriefing session immediately after the event is the usual course of action. The hospital may also have agreements in place to provide psychological support to staff members as needed.

In this context it should also be mentioned that, when a serious adverse event has occurred, a follow-up discussion must be held with the patient(s) and relatives. This is important from a treatment perspective, but an apology should also be offered and assurances given that everything will be done to prevent a similar occurrence of the event in future. It is recommended that the hospital prepare an information guideline for patients and relatives; this can contain information on how to notify the Patient Insurance Association and the Patients' Complaints Board. It should also be mentioned that the patient medical records *do not* contain any mention of the fact that a root cause analysis is being conducted. (See step 8 for information on preparation and approval of reports).

Team size and composition

An investigation team should consist of a sufficient number of members, generally from four to ten participants. Too few participants can make for a narrowed focus, which may mean that some aspects of the investigation are overlooked. Too many participants can slow down the work of the team and hinder active involvement by individual team members. From a practical perspective, too many participants can make it difficult to find convenient times for everyone on the team to attend meetings.

An investigation team can also be supplemented with the addition of special experts during the course of the analysis; likewise it is possible to call in relevant clinical and other expertise on an ad-hoc basis.

It is the responsibility of hospital administration to assemble the team and establish a timeframe for conducting the root cause analysis. Management must also be represented on the team itself – partly to chair the meetings and partly to ensure learning from adverse events to increase patient safety.

In the case of the aforementioned sample case study of an adverse event, an investigation team was assembled that consisted of the following participants:

Investigation team for the analysis of a medication error

- Medical Head of Department
- Nursing Head of Department (chairperson)
- Chief pharmacist
- Clinical pharmacist (chairperson of hospital medication committee)
- Nurse (frontline staff member)
- Paediatrician (frontline staff member)
- Nurse (key person in medication issues)
- Patient safety officer (facilitates process, takes notes)

It was decided that the chief nurse for the unit would be responsible for chairing the meetings since dispensing and administration of medication is typically handled by nurses. The task of the chairperson is to facilitate the meeting so that everyone involved may participate in a fair and balanced discussion.

Hospital policy for managing adverse events indicates that the chairperson of the hospital medication committee must be included on the investigation team in cases of medication error.

The two frontline staff members were asked to participate on the team and both accepted the responsibility. In addition, a nurse with special knowledge of hospital medication guidelines was also asked to participate.

Finally, the patient safety officer joined the team as an unofficial member.

The root cause analysis was thereby ready to be conducted.

The framework for the analysis

When the investigation team has been assembled agreement must be reached on scheduling and the timeframe for the work of the team. This can be difficult in practice as several schedules must be coordinated. A typical agreement is for two meetings of two hours' duration. Management is responsible for ensuring that relevant staff members are allotted sufficient time to participate in the root cause analysis, as well as establishing the meeting schedule, the agenda, and reserving meeting facilities.

It is recommended to reserve a meeting facility located some distance from the unit under investigation, so that team members feel that they are on neutral ground and need not be disturbed by work demands. Ideally, the meetings should be held in a boardroom or classroom furnished with a whiteboard and flipchart.

In most cases, only a few or perhaps no team members will have prior experience in conducting root cause analyses. The patient safety officer should therefore prepare a short introduction to the method prior to the meeting. (Appendix 2)

It is important to point out the following during the introduction:

- Meetings take place at fixed times and begin and end on schedule. Attendance is mandatory and absence is permitted only under special circumstances. Pagers and mobile phones must be turned off during meetings
- Wearing street clothing during meetings can be beneficial in creating a relaxed environment that encourages fair and balanced discussion
- Information shared and derived from the meeting process must be considered confidential. Information can only be disseminated outside meetings on prior agreement.
- Working documents used during the root cause analysis are reserved solely for the use of team members
- The final report will – after it has been approved by the team – constitute the document to be disseminated for learning purposes within the unit/at the hospital

The final report will be anonymised to ensure that neither the patient nor the healthcare professionals involved in the event can be identified

Maintaining system perspective is the core of a successful root cause analysis. From this viewpoint it is the event itself and its underlying causes that are of vital importance – never *who* is to blame for the event

- The root cause analysis process should be conducted so effectively that it can be fully completed within approx. 10 days of the occurrence of the event. Working in a timely manner is the best way to facilitate the gathering of information for use in the root cause analysis. However, it can be difficult in practice to achieve completion of a root cause analysis in such a relatively narrow timeframe.

Step 2 – Determining the sequence of events

Prior to the first team meeting, the patient safety officer prepares a draft event sequence for the adverse event based on information obtained from the reporting form, the anonymised medical records, the visit to the location where the event occurred or from interviews, etc. Frontline staff members not participating on the team are presented with the draft event sequence prior to the team meeting so that their contributions can help clarify and add detail to the final event sequence. This information may also be gathered through interviews with the patient safety officer.

The event sequence is a precise chronological ordering of the chain of events that preceded the occurrence of an adverse event.

The event sequence is the basis for the work conducted during the remaining steps of the root cause analysis process, so it is highly necessary to invest sufficient time and effort in the work it entails. The event sequence can be described in a narrative, but a pictorial summary in the form of a flow chart is even more useful over the course of the analysis process.

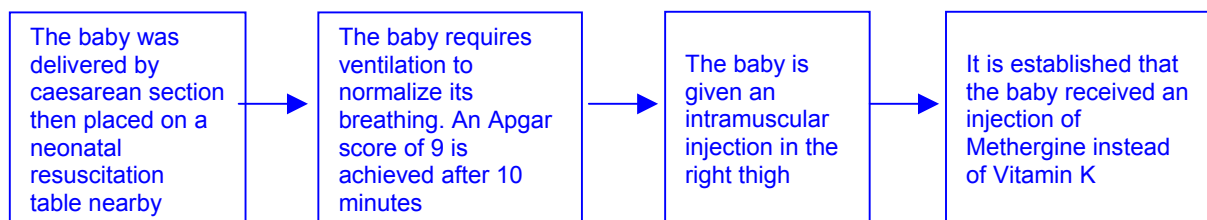
The preparation of a flow chart is more time-intensive than a written description and it requires experience in working with text boxes on a PC. However, the benefits can be substantial in that a flow chart provides an overview of the event sequence as well as better conditions for teamwork, allowing team members to add and subtract information and facts, which facilitates the rapid establishment of an event sequence that all team members can agree upon.

The patient safety officer may also decide to ask the team to generate the event sequence from the ground up. In this situation it can be beneficial to use the “sticky note method” where the team writes out the various aspects of the event on sticky notes to order the event sequence as a whole. The disadvantage of using this method is that much of the first meeting can end up being spent performing this exercise. Another disadvantage is that some team members may find it pointless that so many people spend so much time on a preliminary exercise; most will prefer to proceed directly to the actual analysis work itself.

An adverse event

The following illustrates the draft event sequence prepared by the patient safety officer based on the reporting form and anonymised copy of the case notes from the birth itself:

Event sequence (sample case study)



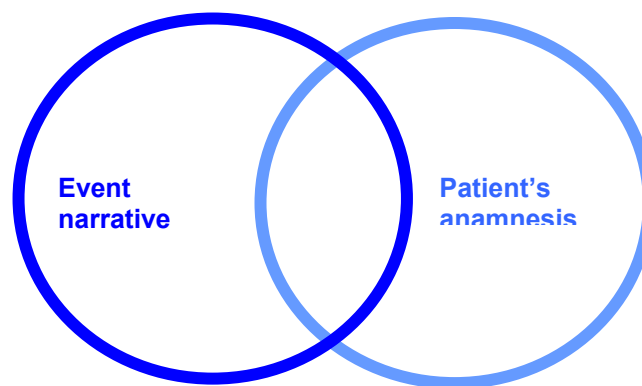
The patient safety officer decided to describe the event sequence in a succinct way that provided relatively little information. The reason for this decision is made clear in the summary below.

Summary

As noted previously, the event sequence is a precise chronological ordering of the chain of events that preceded the occurrence of an adverse event. The event sequence is not a summary of the patient’s case history!

It can prove difficult in practise to separate the narrative of the event from the patient's case history. Therefore it is important that the patient safety officer begins the analysis process by emphasising the importance of including in the analysis only major events, those which are of decisive importance to achieving an understanding of *what* happened, and which led to the occurrence of the adverse event itself. This can/will of course include fundamental aspects of the patient's case history to support the establishment of the event sequence.

As represented in the diagram shown below, the event sequence is based on the narrative of the event, but may include elements of the patient's case history:



As shown in the sample case study event sequence, actual people are never mentioned – neither by name nor description of their position. Nor are dates and times noted in the event sequence. This is done in order to maintain system perspective towards the adverse event.

The first draft of the event sequence should be simple and concise so that both directly and indirectly involved healthcare professionals are provided sufficient opportunity to add information about what actually occurred.

Dates and times can be incorporated into the event sequence for overview purposes if needed, but they should be omitted from the final report to ensure that anonymity is maintained. The present tense is generally preferred for event sequences as it is considered the easiest to read, but in other cases the past tense may be useful.

At the first meeting, the members of the team should review and discuss the event sequence until everyone has obtained an overview and has the same knowledge of what actually occurred. It is important to make sure that *only* the actual facts are discussed because teams often demonstrate a tendency at this point to begin the analysis and to offer recommendations. The team facilitator – usually the chief consultant or chief nurse – must obtain consensus and approval of the event sequence. He/she can conduct a round of the team to obtain individual agreement if necessary. If agreement cannot be reached, this must be noted. However, this occurs very seldom.

In summary, the event sequence constitutes the basis of the actual root cause analysis; therefore it must contain the necessary details without being too comprehensive. By these means it is possible to establish conditions by which the team can rapidly approve the event sequence, allowing them to begin work on the analysis itself.

In short, the event sequence is finalised in the following way:

1. The patient safety officer prepares the draft event sequence – concise and without details

2. The patient safety officer asks the frontline staff members – those not included on the team – to consider the draft event sequence
3. At the first meeting, the team discusses the draft and adds details. The facilitator leads the discussion and ensures that only factual events are brought in for consideration; teams often demonstrate a tendency at this point to begin the analysis of the event.
4. The draft (including additions) is approved by the team
5. The patient safety officer edits the draft event sequence and this is approved at the next team meeting.

Generally, a period of approx. 15 minutes is set aside for discussing the event sequence. The team can then proceed to the next step in the root cause analysis.

Step 3 – Identifying contributory factors

Based on the event sequence, the team identifies the major contributory factors that led to the occurrence of the event. This is the true first step towards uncovering the actual root causes of the adverse event.

This is achieved by the team adopting a “helicopter view” towards the event sequence: transcending the facts of the analysis in a frank and open discussion to brainstorm and asking a series of questions beginning with “why ...?”, “how could this happen ...” or “what ...?”. During this step the team should avoid asking “who?” questions.

In advance of the meeting, the meeting facilitator appoints a team member in advance to note all statements on a whiteboard or flip chart during the exercise. The team does not provide answers to the “why?” questions.

When the “why?” questions can no longer be meaningfully asked, the process is halted to sort out the statements that have been noted. The aim is to achieve an overview of the situation and a sense of the core issues involved in the matter.

After having classified the various statements into issues, the team refers to page 19 of the Handbook for Root Cause Analysis (Danish Society for Patient Safety, November 2003) and determines whether contributory factors exist in the following categories:

- C communication
- T training
- S scheduling
- E environment and equipment
- R rules/policies/procedures
- B barriers

The individual areas in which there were contributory factors are then prioritised to enable review using the supplementary questions in the Handbook.

An adverse event

Below are listed the “why?” questions that the team spontaneously generated based on the event sequence. The statements are listed in the order in which they were made and then categorised by contributory factor type in accordance with the yellow pages in the Handbook.

Please note that some of the statements will express frontline staff members’ experiences and perceptions from the time the adverse event occurred.

Team “why?” questions (from sample case study of an adverse event)

- How was it possible to mistake Methergine for Vitamin K?
- Why did Vitamin K have to be administered at that exact time?
- How was the medication checked?
- Why wasn’t it discovered before the injection was administered?
- Where was the medication stored?
- Why was the medication removed from its packaging?
- Why do ampoules of Methergine and Vitamin K look alike?
- Why was there such a rush in the delivery room?
- Why was Methergine right next to the warming table upon which the newborn baby was placed?
- Why is Vitamin K not available in a pre-filled, ready to use syringe with a very thin needle?
- Why has interrupting work become such a habit in the unit?

From the listed questions, the patient safety officer extracted three contributory factors which the team agreed to prioritise as follows:

1. Risk of confusion as a result of similarities between ampoules (B)
 - How was it possible to mistake Methergine for Vitamin K?
 - Why do ampoules of Methergine and Vitamin K look alike?
 - Why is Vitamin K not available in a pre-filled, ready to use syringe with a very thin needle?
 - Why wasn't it discovered before the injection was administered?
2. Unit guidelines for storage, dispensing and administering medication (R, T)
 - Why did Vitamin K have to be administered at that exact time?
 - How was the medication checked?
 - Where was the medication stored?
 - Why was the medication removed from its packaging?
 - Why was the Methergine ampoule right next to the warming table upon which the newborn baby was placed?
3. Unit working conditions and culture (C, S)
 - Why was there such a rush in the delivery room?
 - Why has interrupting work become such a habit in the unit?

The contributory factors were prioritised thusly because several staff members in the unit had been involved in near miss events in the past in which confusion involving look-alike ampoules was discovered at the last minute. The team thus felt that it was vitally important to examine whether this type of mistake could be avoided in future, and that there had to be a way to prevent similar occurrences.

Furthermore, the team found that it was necessary to go over the unit's medication guidelines. Change was definitely needed in this area and, in addition, a number of new staff members had begun work in the unit who were still unfamiliar with the guidelines themselves.

Finally, it was acknowledged that time pressures, combined with the unit's work culture in which staff members did not always communicate properly and in which interruptions were acceptable, created a general problem which merited examination.

The team then reviewed the supplementary questions in the Handbook on pages 21 – 40 relating to the areas in which contributory factors were defined. The team indicated that contributory factors could be found in the following areas:

1. Risk of confusion as a result of similar ampoule packaging/labelling (B)

- B3 Patient safety was not considered in the design of medication ampoules and packaging so that it would function as a barrier against error
- B9 Properly functioning control measures could have contributed to preventing the adverse event

2. Unit guidelines for storage, dispensing and administration of medication (T, R)

- T3 Similar events had occurred previously in the unit for which root cause analyses were not conducted
- T8 The unit's written procedures for medication had not been updated
- T10 Medication procedures were not clear, understandable and easily accessible for all unit staff members
- R4 The staff training programme was not designed to help prevent medication errors
- R7 Staff members were not trained in the relevant control measures to prevent medication errors, including read back

3. Unit working conditions and culture (C, S)

C10 A need was demonstrated for further development of the working environment in the unit

S16 Communication between staff members was inappropriate

S21 Medication procedures and guidelines had not been satisfactorily communicated to staff members.

Reviewing the supplementary questions in the Handbook is a lengthy process but it is also a process of recognition that helps to put the adverse event in perspective.

The review is lengthy because the team can usually point out problems within most or all of the main questions on the yellow pages, which can potentially make relevant all of the questions listed on the coloured pages to follow.

However, this is far from the case, which is why the patient safety officer – who has an advance in-depth knowledge of the Handbook – must guide the team through the questions.

It is however worthwhile to spend sufficient time on the review as it helps the team focus on and maintain system perspective on the adverse event. Reviewing the Handbook contributes to reducing any self-reproach on the part of frontline staff members and also in reducing other healthcare professionals' voiced or unvoiced perceptions of individual blame related to the occurrence of the event.

After all of the relevant questions have been answered, the patient safety officer is responsible for summarising what was discussed at the team meeting.

The first meeting is usually scheduled to last two hours, and at this step of the root cause analysis process the team will often run out of time. The meeting facilitator concludes the meeting and the next meeting is scheduled and confirmed.

During the course of the meeting the patient safety officer notes important statements and strong arguments that arose during the team's discussion of the event.

At this point, the patient safety officer has gathered a large amount of qualitative data and possibly quantitative data. This data must be organised in preparation for more in-depth analysis so that at the next meeting the team can be presented with the tentative root causes that can be deduced at this step.

The patient safety officer must then return to his or her desk and devote sufficient time to working purposefully and systematically to discover patterns and tendencies in the gathered data. The need to gather additional data may also arise during this step of the process.

Finally, sufficient time must be set aside for the literature review to ensure that relevant literature is included in the root cause analysis.

Step 4 – Identifying tentative root causes

A root cause can be defined as the underlying cause to which an adverse event can be ultimately attributed.

Using the event sequence and contributory factors as a foundation, root causes are identified by drilling down through all the layers of a sequence of events to find its innermost core, that is, the actual root cause or causes of an adverse event that caused harm to one or more patients.

This step of the root cause analysis is of particular importance; it is also a difficult step that requires the patient safety officer to analyse and summarise large amounts of qualitative and quantitative data while ensuring that system perspective is maintained:

Adverse events in a hospital occur as a result of people working together in a complex organisation with complex roles and often complicated clinical pathways. Whether or not barriers have been established against error, the very dynamic generated by a fast-changing daily working environment can result in safety system gaps, and a combination of unfavourable circumstances can create conditions that lead to the occurrence of adverse events (2,3).

This is the type of perspective required for examining the root cause analysis as a whole; and it is especially important for identifying the root causes themselves.

Identification of root causes is therefore concerned with rendering visible the not obviously visible gaps and vulnerabilities in barriers and safety systems.

This is done together with the team conducting the root cause analysis, but it is recommended that the patient safety officer attempt to identify the tentative root causes of the adverse event prior to the second team meeting.

The reason for this is that the team presumably contributed so much information during the first meeting that it probably is possible to extract the tentative root causes of the event by systematically analysing the qualitative statements obtained from the meeting.

Root causes are produced by asking "why ...", "why ...", "why ..." and answering "because ...", "because ...", "because ...", until it no longer makes sense. This exercise – based on the event itself or the factor that provoked the event – allows the team to construct a causal chain that concludes with the actual cause of the adverse event.

This causal chain can either be described in words or through a cause-and-effect diagram. It is preferable that the diagram be utilised as it affords the team the overview necessary to grasp the complex picture that always emerges from a root cause analysis process.

Regardless of whether the patient safety officer chooses to describe the tentative root causes in words or through the use of a cause-and-effect diagram, the five rules of causation must be observed (see Handbook, pages 41-43):

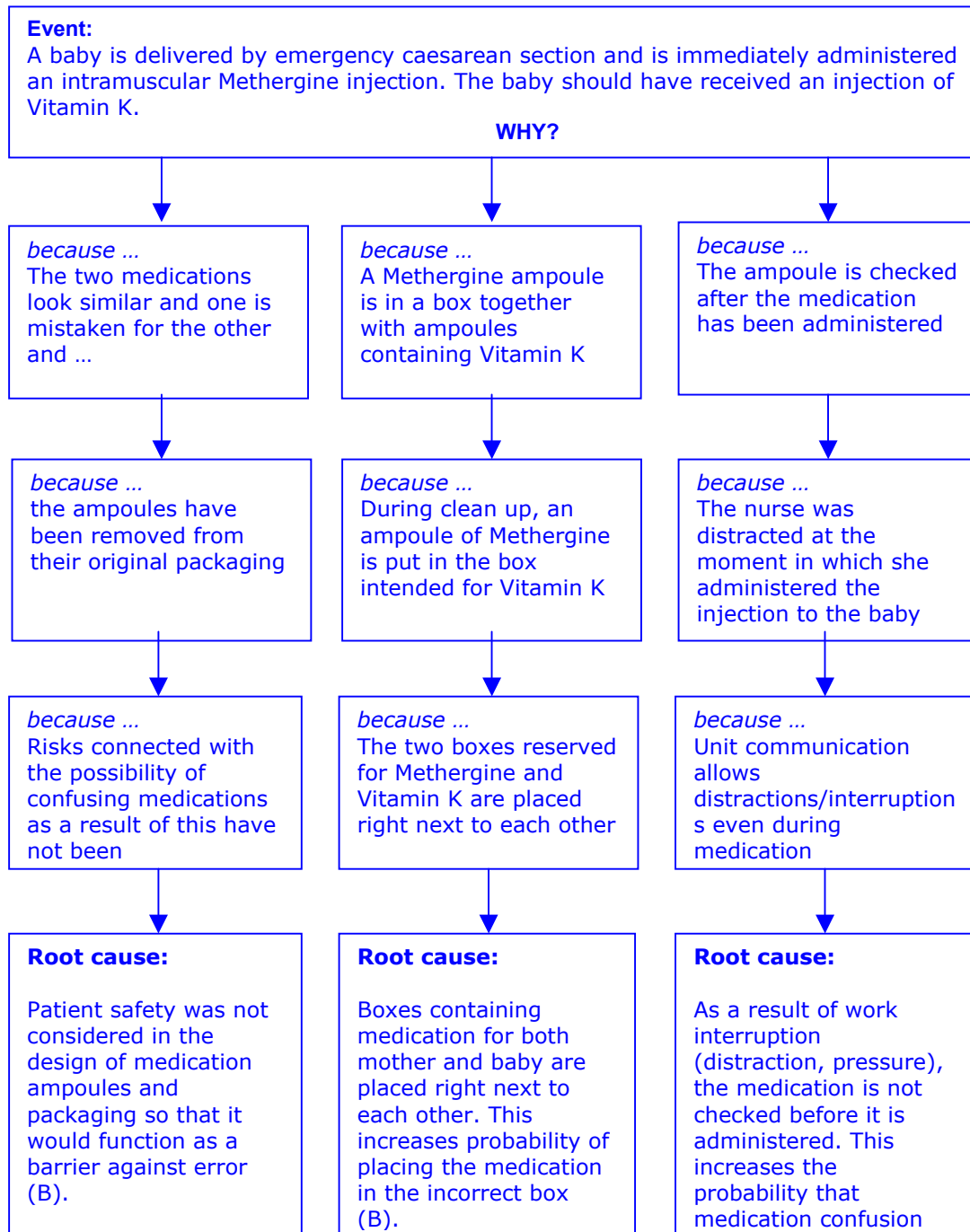
1. Causal statements must clearly show the 'cause and effect' relationship
2. Negative descriptors should not be used in root cause analyses
3. For every human error in the causal chain, there must be a corresponding condition cause that combined to contribute to the undesired effect
4. Each procedural deviation must have a preceding cause. Identify the cause of a procedural violation, not the violation

- Failure to act is only causal when there was a pre-existing duty to act. The duty to perform might arise from standards and guidelines for practice or other duties to provide patient care

An adverse event

Shown below is the draft cause-and-effect diagram prepared by the patient safety officer for discussion purposes in the second team meeting:

Cause-and-effect diagram (example)



The example reveals that data culled from the preceding steps of the root cause analysis has been integrated into the cause-and-effect diagram; however, the previously exposed problems related to procedures and guidelines, and to training, have not been included in the diagram.

The patient safety officer opted not to do so because, based on the available data, there was no apparent reason to find that unit guidelines for the storage, dispensing and administration of medication, or lack of training in relevant control measures for medicine administration, were part of the causal chain that resulted in the baby receiving the wrong medication.

Step 5 – Gathering additional data and literature review

It is a good idea to be meticulous when gathering additional data and performing the literature review. Thus the issues under consideration in the root cause analysis are further put into perspective to ensure a qualified report containing recommended initiatives that will make a real difference and will contribute to increased patient safety.

Additional data may include technical manuals, user instructions, safety precautions, procedures and policies, or legislation relevant to the analysis.

Additional data can also include photographs of equipment or surroundings important to the analysis. The patient safety officer may choose to bring these photographs to the team meetings to help aid discussions; photographs can also be included in the final root cause analysis report to provide enhanced illustration of conditions at risk for adverse event occurrences.

Relevant literature will naturally derive from the subject of the root cause analysis; the references list on the final page of this compendium will serve as a starting point for the literature search.

In addition, and regardless of the nature of the analysis, it is recommended that each root cause analysis always includes a minimum of two types of basic material, namely:

- Evidence Report/Technology Assessment
Number 43
Making Health Care Safer: A Critical Analysis of Patient Safety Practices
AHRQ Publication 01-E058
July 20, 2001

This report represents evidence-based knowledge on patient safety. It contains 662 pages and can be downloaded from www.ahrq.gov

- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
Sentinel Event Alerts

Since 1998 the JCAHO has issued recommendations that can contribute to increased patient safety. These recommendations can be downloaded from www.jcaho.gov.

The patient safety officer can assume responsibility for this task, but generally the team members offer to gather information as they have direct access to e.g. procedures and policies.

In addition, the patient safety officer and team members – as decided during the first meeting – can choose to contact other healthcare professionals capable of supplying further information.

Finally, the patient safety officer may visit the location where the event occurred. Photographs of the location can help to facilitate the analysis as they allow team members to visualise the surroundings in which the event occurred.

An adverse event

For the analysis investigating the baby who received an injection of Methergine instead of Vitamin K, the following materials and literature were utilised:

- Photographs of the medication boxes placed next to each other and a photograph of the similar looking ampoules
- Unit procedures/guidelines for medication storage, dispensing and administration
- Unit introduction programme for new staff members

The following literature was reviewed:

- Sentinel Event Alert Issue 16 – February 27, 2001.
Mix-up Lead to a Medication Error, www.jcaho.org – can be viewed here:
<http://www.jcaho.org/accruited+organizations/ambulatory+care/sentinel+event/sentinel+event+alert/index.htm>
- Evidence Report/Technology Assessment
Number 43
Making Health Care Safer: A Critical Analysis of Patient Safety Practices
Adverse Drug Events
Part III Section A: 57-111
AHRQ Publication 01-E058 July 20, 2001
www.ahrq.gov
- Forveksling mellem kaliumklorid og natriumklorid ('Confusion between potassium chloride and sodium chloride', in Danish only) –
http://www.trygpatient.dk/Default.asp?ID=3&m=Cust_Case&CaseID=160
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www.annals.org

Step 6 – Discussion, prioritisation and acceptance of root causes

Identification of root causes must be done in tandem with the team responsible for conducting the root cause analysis. This process is carried out at the second team meeting and may proceed in one of the following ways:

- a) The patient safety officer gathers suggestions for the tentative root causes prior to the meeting
- b) The team itself identifies root causes based on an analysis of the collected data.

Regardless of the method used, the team is responsible for accomplishing the following tasks at the second meeting:

- Approval of the event sequence
- Approval of suggestions for identified root causes
- Preparation of recommendations for action plan.

The event sequence is usually quickly approved as it has already been thoroughly discussed as mentioned in the section on step 1.

However, the process of identifying root causes can prove difficult. In this case the necessary overview can be achieved by the patient safety officer having prepared a cause-and-effect diagram prior to the meeting, as described in the section on step 4.

On the other hand, if the team has been charged with identifying the root causes, these are elicited – based on the event itself or the factor that provoked the event –

by asking "why ...", "why ...", "why ..." and answering "because ...", "because ...", "because ...", until it no longer makes sense. The answer to the last "why" will then constitute a root cause. The root cause is then described according to the five rules of causation (Handbook, pages 41-43).

It is important at this point that the meeting facilitator ensures that everyone present is given the opportunity to speak. Both the meeting facilitator and the patient safety officer should be aware of the extent to which issues that could be discussed at length are downplayed, and how issues that could receive less attention are discussed in too much detail. The meeting facilitator should note whether the group dynamic is serving to slow down the process or further it, as moving forward too quickly is always a mistake. To ensure that everyone gets the opportunity to contribute and to feel a sense of ownership of the analysis, it is recommended that the team take part in one or more rounds of discussion.

Regardless of whether the patient safety officer chooses a) or b), the identified root causes must be verified. This is accomplished by asking: "If we eliminated this/these cause(s), could we have prevented this event?" (Handbook, page 41). If the answer is "yes", it can be concluded that the actual root cause(s) of the event has/have been identified.

In summary, the relationship between steps 4 and 6 of the root cause analysis is quite clear.

An adverse event

In the sample analysis, the patient safety officer decided to present the team with a draft cause-and-effect diagram in which three root causes were identified.

The team accepted the draft diagram without further comment on the grounds that it included all of the issues that had been discussed at the first meeting. The root cause was then verified as follows:

If interruptions had been avoided, the ampoule would (presumably) have been checked prior to administering the injection. If the ampoule had been stored in its original packaging until it was ready to be used, it would have constituted an additional control measure – particularly if the packaging had been specially marked to indicate Vitamin K. If the two ampoules had not looked similar, it would have been possible to see that the wrong ampoule was in the wrong box. If the boxes containing medication for mother and baby had not been next to each other, the chance of putting the wrong medication in the wrong box would (presumably) have been eliminated.

In summary, the team found that the stated root causes constituted the actual causes that led up to the adverse event. On the basis of this decision the team could proceed with preparing recommendations for the action plan.

Step 7 – Preparing the action plan

The last step of the root cause analysis for which the team is responsible is the preparation of corrective action recommendations for the action plan, which is expected to prevent the future occurrence of similar adverse events.

In other words, for each identified root cause, the team must prepare a recommendation for a specific initiative (corrective action) that can contribute to correcting the safety system defects that led to the adverse event.

Therefore an action plan must be specific, realistic, feasible to implement within a reasonable timeframe, and should address who is accountable for implementation, timelines and follow-up reporting of each corrective action.

It is of vital importance that unit leadership is represented during this step of the process, as only unit leadership has the authority required to decide the framework for the implementation of the action plan.

The Handbook (pages 45-46) outlines some measures that must be taken into consideration during this step.

It is also recommended that the categories/types of actions listed in the table below are considered at this point in the process; these specifically address root causes and can thus prevent the future occurrence of adverse events. The table was developed by the National Center for Patient Safety (NCPS), part of the US Department of Veterans Affairs:

Stronger actions	Intermediate actions	Weaker actions
<ul style="list-style-type: none"> ▪ Architectural/physical plant changes ▪ New device with usability testing before purchasing ▪ Engineering control or interlock (forcing functions) ▪ Simplify the process and remove unnecessary steps ▪ Standardise on equipment or process or caremaps ▪ Tangible involvement and action by leadership in support of patient safety 	<ul style="list-style-type: none"> ▪ Increase in staffing/decrease in workload ▪ Software enhancements/modifications ▪ Eliminate/reduce distractions (sterile medical environment) ▪ Checklist/cognitive aid ▪ Eliminate look and sound alike ▪ Read back ▪ Enhanced documentation/communication ▪ Redundancy 	<ul style="list-style-type: none"> ▪ Double checks ▪ Warnings and labels ▪ New procedure/memorandum/policy ▪ Training ▪ Additional study/analysis

Source: VA NCPS, 2002

The action plan must also contain considerations on monitoring the effects of the implemented changes and how this will be performed. It has been noted that it can be difficult to monitor implementation in the face of a busy, pressure-filled working day.

Therefore it is recommended that training and dissemination are included in recommendations for follow-up initiatives and that monitoring is integrated in the unit's ongoing quality development. It is also of particular importance that staff members receive sufficient feedback so that it is apparent that patient safety/increased quality have been achieved, or that there continues to be a need for improvements.

An adverse event

On the basis of the identified root causes of the sample adverse event, the team decided on the following recommendations for an action plan:

Action plan	Individual responsible	Timeframe
Medication boxes <ol style="list-style-type: none">1. Abolish the system using boxes to hold loose ampoules removed from their original packaging.2. In future, medication intended for the mother is stored with anaesthesia apparatus and medication intended for the baby is stored on a shelf near the warming table.3. Staff is informed of changes by a poster/staff "alert"	Unit leadership	To be implemented immediately Progress monitoring <ul style="list-style-type: none">▪ Nurse responsible for medication keeps a daily logbook of medication stored in the operating room – date, amount and where it is kept.
Look alike ampoules and packaging <p>Contact the Danish Pharmaceutical Association to find out whether it is possible to get ampoules and packaging that do not look similar so that risk of confusion is reduced. Particular emphasis must be placed on dissimilar packing for medication for mother and child; consideration should also be taken as to how medication errors resulting from look alike packaging can be prevented</p>	Chairperson of hospital medication committee	<ul style="list-style-type: none">▪ Within a week, request a meeting with the Danish Pharmaceutical Association.▪ An evaluation of potential ways in which regular inventory might be changed is expected to last a minimum of 6 months as financial considerations must be taken into account Progress monitoring <ul style="list-style-type: none">▪ The hospital patient safety officer is asked to monitor patterns and tendencies in reported medication errors.▪ The monitoring takes place on an ongoing basis over the next three months.▪ A status report is prepared on a quarterly basis.
Culture and communication <ol style="list-style-type: none">1. Change unit culture and communication that makes it acceptable to interrupt the work of others. Here the root cause analysis team can lead the way in setting a good example by not interrupting the work of others.	Root cause analysis team	Progress monitoring <ul style="list-style-type: none">▪ A "culture analysis" is conducted after three months; staff members are asked to complete a simple questionnaire on the extent of the culture changes within the unit. A poster is printed to announce the results.

Dissemination

The unit is made aware of the issue through the widespread dissemination of the results of the root cause analysis.

Unit leadership

- A question on work interruptions is part of the “culture analysis” mentioned above.

Step 8 – Generating the report and obtaining approval

Immediately after the conclusion of the second team meeting, the patient safety officer summarises the gathered material in a draft report that is submitted to the members of the team for approval.

Approval of the report is usually obtained after team members have forwarded their comments via email or after the team leader collects all of the comments, assembles them and forwards them to the patient safety officer.

In rare cases – if there are substantial changes or disagreement on the conclusions – it may prove necessary to schedule a third team meeting.

After integrating the final comments, the patient safety officer submits the report to unit leadership and hospital administration for final approval, according to hospital procedure. All Root Cause Analyses must be formally approved at the highest level of hospital administration.

It is recommended that the patient safety officer use a template to create the report. This ensures that all root cause analyses have a uniform appearance and structure and are easy to read. Each report must, at minimum, observe the following two rules:

- The report must not include personal registration numbers or other information that could identify the patient.
- The report must not include names or other information that could identify the healthcare professionals involved in the event.

The reason for this is that the report is not part of the patient's medical records; it is concerned with unit work processes and not the patient's treatment.

The report should be considered the property of the hospital administration/the unit involved, which is why it should not be widely disseminated within the hospital or externally unless it has been decided otherwise.

A root cause analysis is usually discussed by the hospital quality council. With regard to analyses that provide learning applicable elsewhere in the hospital, the decision is generally taken to disseminate awareness of the root cause analysis. Notification must also be made to the Danish Patient Safety Database in accordance with the Danish Act on Patient Safety (www.dpsd.dk).

The final duty of the patient safety officer may be to assess the time investment for the root cause analysis process; an assessment must also be made regarding the hospital's timeframes for completion of root cause analyses.

Finally, unit leadership – in addition to having responsibility for implementing the action plan – must provide feedback to those who originally reported the event. This is vitally important to ensuring that staff members continue to be motivated to report adverse events.

Guidelines for assessing an adverse event

An adverse event can be assessed using a *matrix score*. Pairing a severity category with a probability category for either an actual adverse event or close call results in a ranked matrix score that determines the methods to be used in the subsequent management of the event.

High risk/harm = 3 Moderate risk/harm = 2 Low risk/harm = 1

Events with a score of 2 and 1 are dealt with in accordance with the unit’s local guidelines, while events with a score of 3 indicate a serious adverse event and should be followed up with a root cause analysis.

Assessment of an event is always based on professional judgement and is therefore subjective. In conducting an assessment, the categories apply equally to both close calls and actual adverse events. This means that the risk of a given injury is assessed as though it actually occurred. Pairing a severity category with a probability category results in a ranked matrix score.

Safety Assessment Code (SAC) Matrix

	Catastrophic	Major	Moderate	Minor
Frequent	3	3	2	1
Occasional	3	2	1	1
Uncommon	3	2	1	1
Remote	3	2	1	1

Safety Assessment Code (SAC) Matrix. <http://www.va.gov/ncps/sac.html>

Severity of event

Catastrophic event: One of the following:

- Death
- Major permanent loss of function/disablement (sensory, motor, physiologic, or intellectual) unrelated to patient’s underlying illness/condition. Level of disability is assessed according to the potential injury that may result from the event.

Major event: One or more of the following:

- Major permanent loss of function/disablement (sensory, motor, physiologic, or intellectual) unrelated to patient’s underlying illness/condition. Level of disability is assessed according to the potential injury that may result from the event.
- Significant increase in evaluation/treatment; can include transfer to intensive care/dialysis/coronary care unit for one patient.
- Outcome for more than one patient exposed to same event: Slight increase in evaluation/treatment or increased level of care for at least three patients.

Moderate event: One or more of the following:

- Slight increase in evaluation/treatment, can be managed on same ward for one patient.
- Outcome for one to two patients exposed to same event: Increased length of stay.

Minor event:

- Neither injury nor increased length of stay nor increased level of care.

Probability rating scale

Frequent:

Likely to occur up to several times in one year at the hospital in question.

Occasional:

Probably will occur in one to two years at the hospital in question.

Uncommon:

Possible to occur in two to five years at the hospital in question.

Remote:

Unlikely to occur, may happen sometime in 5 to 30 years at the hospital in question.

Short introduction to the root cause analysis method

Background

In cases of serious adverse events that result in patient mortality (e.g. as a result of medication error) or that are expected to leave the patient with major permanent loss of function or disablement (e.g. as a result of equipment failure), a root cause analysis must be conducted.

An adverse event is defined as a harmful medical occurrence that takes place as a result of examination, treatment or care rather than the patient's underlying condition or illness.

A root cause analysis is a process in which both qualitative and quantitative data is gathered in preparation for identifying the root causes for the occurrence of an adverse event.

The result of the root cause analysis should provide the reasons why a given event took place. The goal is to obtain knowledge to help prevent a similar recurrence.

The fundamental questions of a root cause analysis are:

- What happened?
- Why did it happen?
- How can it be prevented from happening again?

A root cause analysis *never* asks who was to blame for the occurrence!

Framework for the analysis

The following conditions must be ensured:

- Meetings to be held on "neutral ground"
- No interruptions
- Fixed times that must be observed
- Mandatory attendance at meetings
- (Street clothing to be worn)
- Confidentiality:
All information is deemed confidential and cannot be disseminated beyond the team
The root cause analysis results in an anonymised report

The analysis itself

The team leader facilitates the team meetings so that everyone has the chance to take part in a fair and balanced discussion.

Team members contribute their professional knowledge and statements. The Handbook for Root Cause Analysis (Danish Society for Patient Safety, November 2003) is used as the basis for a systematic approach to the root cause analysis.

The gathered data is processed by the patient safety officer.
The conclusions are submitted to the team.
The final report is approved by the team prior to publication.

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