

An Introduction to Root Cause Analysis in Healthcare

1 Introduction to Causation

The investigation of adverse events can be decomposed into a number of different activities. For example, data must be collected about the events that led to a mishap. Interviews and the analysis of data logs and charts provide the information that is necessary to understand what happened. Elicitation techniques may also extend more widely into the organisational and managerial context in which an incident occurred. Together these different sources of information can contribute to our understanding of why there was an accident or near-miss. Any causal analysis, in turn, helps to guide the identification of recommendations that are ultimately intended to minimise the likelihood of any future recurrence. It is important to stress that these different activities often overlap so that, for instance, it is often necessary to gather additional evidence to support particular causal hypotheses. Similarly, the identification of potential recommendations often forces analysts to reconsider their interpretation of why an adverse event occurred. The US Joint Commission on Accreditation of Healthcare Organizations (2004) identifies similar stages when it argues that a “meaningful improvement in patient safety” is dependent upon:

- “Identification of the errors that occur.
- Analysis of each error to determine the underlying factors -- the "root causes" -- that, if eliminated, could reduce the risk of similar errors in the future.
- Compilation of data about error frequency and type and the root causes of these errors.
- Dissemination of information about these errors and their root causes to permit health care organizations, where appropriate, to redesign their systems and processes to reduce the risk of future errors.
- Periodic assessment of the effectiveness of the efforts taken to reduce the risk of errors.”

Previous sections in this book have described problems that complicate the various activities involved in the analysis of healthcare incidents. In particular, the last chapter focussed on the problems of under-reporting and on the difficulty of eliciting adequate information in the aftermath of an accident or near-miss incident. In contrast, this chapter focuses more narrowly on the problems of determining *why* a mishap occurs. In particular, the following pages consider a number of different perspectives on the role of human ‘error’ as a causal factor. Several authors have identified the ‘perfective’ approach to incident analysis in healthcare systems (Johnson, 2003, Helmreich and Merritt, 1998). In the past, many medical adverse events have been ‘blamed’ on the clinicians who were most closely involved in the immediate events leading to an adverse event. This led to recommendations that focussed on improvements in operator performance, most often this involved exhortations to ‘be more careful’ or to attend additional training sessions. It is important to stress that healthcare was not alone in adopting this perfective approach. Wagenaar’s (1992) survey of industrial practice in energy production and the transportation industries observed that 80-100% of all incidents were attributed to human failure. More recently, however, attention has shifted

away from the individuals at the ‘sharp end’ of an adverse event. Reason (1997) argued that greater attention should be paid to the context in which an incident occurs. Analysts must understand the ‘error producing conditions’ that make mishaps more likely. This work has contributed to the popularity of “systemic” theories as an explanation of accident causation (Leveson, 2003). In this view, individual errors rarely create the causes of an adverse event. Instead, we must look at the complex conjunction of managerial, regulatory and even legislative constraints that jeopardised the safety of a more general ‘system’. There are problems with this approach. It arguably undervalues the importance of individual responsibility. It also creates a recursive problem when we must try to understand the circumstances that led, for example, to management error that, in turn, contributed to clinical ‘error’ (Johnson, 2003).

1.1 The Case Study Incident

The previous paragraph provided a deliberately broad overview of causal arguments about healthcare incidents. Chassin and Becher (2002) provide a more focussed example from the healthcare domain. They studied the causes of an adverse event in which a patient mistakenly underwent an invasive cardiac electrophysiology study. She had struck her head and was found to have two cerebral aneurysms. She was, therefore, admitted for cerebral angiography. The day after admission, this procedure successfully embolized one of the aneurysms. A subsequent admission was planned for surgery to treat the second aneurysm. The patient was, therefore, transferred to the oncology floor prior to discharge rather than her original bed on the telemetry unit. The next morning, however, the patient was taken for an invasive cardiac electrophysiology study. After approximately 60 minutes it became apparent that this procedure was being performed on the wrong patient. The intended patient had a similar name and had recently been transferred from an outside hospital for a cardiac electrophysiology procedure. She had also been admitted to the telemetry unit. This second patient’s procedure had been delayed for 2 days but was now scheduled as the first electrophysiology on the day of the first patient’s planned discharge. The electrophysiology nurse used the electrophysiology laboratory computer to check the schedule and saw the second patient correctly listed. She telephoned the telemetry floor, identified herself by name, and asked for the patient by their surname only. The person answering the telephone incorrectly stated that the patient had been moved to oncology when the second intended patient was still on the telemetry floor. The electrophysiology nurse was told that her patient would be transferred from oncology to the electrophysiology laboratory.

The original patient’s nurse was nearing the end of her shift but agreed to transport her to electrophysiology even though she had not been told about any change of plan over her expected discharge. When asked about the procedure, the patient told the nurse that she had not been informed of any electrophysiology and that she did not want to undergo the procedure. Her nurse told her that she could refuse the procedure after she had arrived in the electrophysiology laboratory. The patient repeated her reservations in the lab and so the attending physician was called. He was surprised to hear of this apparent change in opinion because he mistakenly believed that he was now talking with the same patient that he had beefed about the procedure on the previous evening. He reassured the first patient and prescribed medication to reduce the nausea that partly explained her

reluctance to undergo the procedure. The electrophysiology nurse reviewed the patient's chart and noted that no consent had been obtained even though other records indicated that consent had been obtained. She paged the electrophysiology fellow scheduled to do the procedure. He reviewed the chart and was surprised at its relative lack of pertinent information. However, he then discussed the procedure with the patient and had her sign the consent for "EP Study with possible ICD and possible PM placement" (EP refers to electrophysiology; ICD refers to an implantable cardiac defibrillator; PM refers to a pacemaker). The charge nurse arrived and was told by the electrophysiology nurse that their first patient had arrived, however, the patient's name was not referred to. A temporary nurse then placed the patient on the table, attached monitors, and spoke to them about the procedure. The patient stated that the original injury to her head had occurred when she had "fainted". The nurse thought that this was a reasonable indication for an electrophysiology procedure.

Meanwhile, a resident from the neurosurgery team was surprised to find that the original patient was absent from her room. He discovered that she had been moved to the electrophysiology laboratory and then demanded to know why the patient was there. Again, the patient's name was not used in the conversation. He was told that the patient had already missed this procedure on two previous occasions and was now being taken as the first case of the day. The resident left assuming that his attending had ordered the study without telling him. An additional electrophysiology nurse and the electrophysiology attending arrived. They stood outside the procedure room at the computer console but could not see the patient's face because her head was draped. The procedure was then started.

A nurse from the telemetry floor, telephoned the electrophysiology laboratory to find out why no one had called for the second patient who was correctly scheduled for the electrophysiology. The electrophysiology nurses advised the telemetry nurse to send the second patient down when they estimated that the procedure on the first patient would have been completed. The electrophysiology charge nurse, making patient stickers for the morning cases, noticed that the first patient's name did not match any of the five names listed in the morning log. She raised the problem with the fellow who reassured her that this was 'our' patient. The nurse did not want to enquire any further because she was concerned about interrupting such a demanding procedure. An interventional radiology attending went to the first patient's room and was also surprised to find it empty. He called the electrophysiology laboratory to ask why she was undergoing the procedure. At this point the radiology attending and the electrophysiology charge nurse identified that the first patient's name was similar to the intended patient who was still waiting to be transferred from the telemetry floor.

The importance of Chassin and Becher's (2002), study partly lies in their detailed exposition of the type of adverse event that is depressingly familiar within many healthcare systems. The significance of their work also lies in their subsequent analysis of the active, latent and environmental conditions that they argued were causes of this incident. The perfective approach, mentioned in previous paragraphs, might focus blame on the individuals involved in the events that led to the electrophysiology procedure. For

example, a causal analysis might argue that the nurse who mistakenly brought the first patient to the electrophysiology lab should have checked more carefully that their identity matched the names scheduled for the morning's procedures. Similarly, it can be argued that the attending physician should have introduced themselves more directly to the patient prior to the procedure taking place. Chassin and Becher's analysis identified seventeen such instances of individual 'failure'. However, their interpretation of Reason's work led them to emphasise the systemic causes. In other words, "the errors of many individuals (active errors) converge and interact with system weaknesses (latent conditions), increasing the likelihood that individual errors will do harm". In particular, they distinguish between environmental factors that are not readily changeable in the short run and latent conditions. These are system faults that can be remedied but if they are ignored will increase the probability that individual errors will have an adverse effect.

Subsequent analysis revealed a number of environmental factors that form the background to this incident. These included the increasing specialization of medical disciplines, pressures to reduce the number of hospital staff and the increasing range of procedures being conducted on a "short stay" basis. These environmental pressures act together to make it less likely that the patient will be familiar with the individuals and teams who are responsible for their care. Latent conditions in this incident were identified as including failures of communication, teamwork and procedures for the verification of the patient's identity. Nurses failed to communicate with their colleagues, physicians failed to communicate with nurses, attendings failed to communicate with residents and fellows and so on.

1.2 Previous Studies of Causation in Healthcare Incidents

Chassin and Becher's (2002) study of an individual incident has been supported by more sustained studies into the causes of adverse healthcare events. For example, Van Vuuren's (19XX) study of Intensive Care, Accident and Emergency and Anaesthesia related incidents in UK hospitals found that poor communication was a major factor amongst the many organisation issues that contributed to adverse events. A recent investigation into the causes of near miss incidents in an Edinburgh Intensive Care Unit also focussed on organisational factors, including poor communication between healthcare professionals (Busse and Johnson, 1999). This study was based on over ten years of incident data that was collected by a consultant, Dr David Wright. Over the lifetime of the reporting system, a study of the human factors literature together with operational experience were used to inform a classification scheme for adverse events. Each report was analyzed to identify 'causes', 'contributory factors', and 'detection factors'. 'Causes' included human error and equipment failure. Incidents involving human error were further associated with particular tasks, such as "vascular lines related", "drugs-administration-related" or "ventilator-related". Contributory factors included: inexperience with equipment; shortage of trained staff; night time; fatigue; poor equipment design; unit busy; agency nurse; lack of Suitable equipment; failure to check equipment; failure to perform hourly check; poor communication; thoughtlessness; presence of students/teaching; too many people present; poor visibility/position of equipment; grossly obese patient; turning the patient; patient inadequately sedated; lines not properly sutured into place; intracranial pressure monitor not properly secured;

endotracheal tube not properly secured; chest drain tube not properly secured and nasogastric tube not properly secured. Finally, incidents were analyzed to identify detection factors. This illustrates an important issue. It can often be difficult to entirely remove the potential for adverse events; especially when healthcare professionals rely on information and services from other groups and individuals. In such circumstances, it is particularly important to strengthen those detection factors that have successfully identified potential adverse events in the past. The subsequent study of the Edinburgh reports was centered on a comparison of two samples. One included reports that were received between January and February 1989. The second included reports received between May and November 1998. The study focused on a random selection of 25 reports from each period.

1989	Frequency of Cause		Contributing Factor		Frequency of Detection Factors	
	'Ventilator'	10	Poor Communication	14	Regular Checking	11
	'Vascular line'	6	Poor Equip. Design	11	Alarm	11
	'Miscellaneous'	5	Inexperience with Equipment	5	Experienced Staff	8
	'Disposable Equipment'	4	Lack of Suitable Equipment	4	Patient Noticed	1
	'Drug-administration'	3	Night Time	3		
	'Non-disposable Equipment'	2	Fatigue	3		
			Unit Busy	2		
			Failure to Perform Hourly Check	2		
			Thoughtlessness	2		

Table 1: Summary of Categories Used in Analysis of 1989 Sample (25 reports)

Tables 1 and 2 summarize the results from analyzing the 25 incidents in each sample. The totals in each column can exceed the sample size because each causal, contributing and detection factor can appear more than once in each incident. As can be seen poor communication remains a cause of adverse events across both samples (14 of 25 incidents in 1989 and 8 of 25 in 1998). However, thoughtlessness has increased

considerably as a cause identified in these samples (2 in 1989 and 11 in 1998). It is, however, very difficult to interpret any changes in the distribution of causal, contributory and detection factors over time. On the one hand, these may be due to differences in the underlying incidents that occurred in the unit being studied, For example, there was a determined training initiative between August 1995 and August 1998 to address the recurring problem of dislodged endotracheal tubes. Such can initiatives can have a dual effect to both reduce the frequency of such incidents but also to sensitise staff so that they are now more likely to report these incidents in the first place. Changes in the distribution of causes do not only stem from differences in the underlying incidents. They may also reflect changes in the way in which healthcare professionals performed the classification. In particular, it seems likely that the attitudes towards human ‘error’ within the Unit will have changed as they became increasingly familiar with some of the changes in human factors research, summarised at the start of this chapter.

1998	‘Cause’ Occurrence		‘Contributing Factors’ Occurrence		‘Detection’	
	‘Drug-administration’	10	Thoughtlessness	11	Regular Checking	9
	‘Ventilator’	8	Poor Communication	8	Experienced Staff	8
	‘Vascular line’	4	Inexperience with Equipment	4	Alarms	2
	‘Miscellaneous’	4	Night Time	3	Unfamiliar Noise	1
	‘Non-disp. Equipment’	1	Failure to Check Equipment	3	Patient Noticed	1
			Failure to Perform Hourly Check	2	Handover Check	1
			Endotrach. Not Properly Sutured	2		
			Poor Equipment Design	1		
			Patient Inadequately Sedated	1		
			Turning the Patient	1		

Table 2: Summary of Categories Used in Analysis of 1998 Sample (25 reports)

The Edinburgh classification scheme can be compared to the causal factors and other conditions identified by Chassin and Becher (2002). For example many of the contributory factors in the ICU study are similar to the latent factors from the Chassin and Becher incident, such as poor communication. However, the Edinburgh scheme does not explicitly focus on meta- level environmental factors, such as the increasing specialization of medical staff. This was a deliberate decision by the proponents of the scheme who chose to 'target the doable'. As Chassin and Becher observe, environmental factors are by definition difficult to change.

1.3 Bias and Causation

The causal analysis of adverse events helps to identify recommendations that are intended to avoid or mitigate any subsequent recurrence. The previous examples have shown, however, that it can be difficult to interpret whether changes in the distribution of causal factors reflect changes in the underlying pattern of incidents or in the interpretation of those adverse events. Further problems arise from the many different forms of bias that can affect the analysis of incidents and near misses (Johnson, 2003). For instance, author bias arises when individuals are reluctant to accept the findings of any causal analysis that they have not themselves been involved in. Confidence bias occurs when individuals unwittingly place the greatest store in causal analyses that are performed by individuals who express the greatest confidence in the results of their techniques. Previous work into eye-witness testimonies and expert judgments has shown that it may be better to place greatest trust in those who do not exhibit this form of over-confidence (Stebly, 1992). Hindsight bias arises when investigators criticize individuals and groups on the basis of information that may not have been available to those these participants at the time of an incident. More generally it can be seen as the tendency to search for human error rather than deeper, organizational causes in the aftermath of a failure. Judgment bias occurs when investigators perceive the need to reach a decision within a constrained time period. The quality of the causal analysis is less important than the need to make a decision and act upon it. Political bias arises when a judgment or hypothesis from a high status member commands influence because others respect that status rather than the value of the judgment itself. This can be paraphrased as 'pressure from above'. Sponsor bias arises when a causal analysis indirectly affects the prosperity or reputation of the organization that an investigator manages or is responsible for. This can be paraphrased as 'pressure from below'. Professional bias occurs when an investigator's colleagues favor particular outcomes from a causal analysis. The investigator may find them excluded from professional society if the causal analysis does not sustain particular professional practices. This can be paraphrased as 'pressure from beside'. Recognition bias arises when investigators have a limited vocabulary of causal factors. They actively attempt to make any incident 'fit' with one of those factors irrespective of the complexity of the circumstances that characterize the incident. Confirmation bias arises when investigators attempt to interpret any causal analysis as supporting particular hypotheses that exist before the analysis is completed. In other words, the analysis is simply conducted to confirm their initial ideas. Frequency bias occurs when investigators become familiar with certain causal factors because they are observed most often. Any subsequent incident is, therefore, likely to be classified

according to one of these common categories irrespective of whether an incident is actually caused by those factors. Recency bias occurs when the causal analysis of an incident is heavily influenced by the analysis of previous incidents. Weapon bias occurs when causal analyses focus on issues that have a particular 'sensational' appeal. For example, investigators may be biased to exclude factors that are considered to be everyday occurrences.

It is difficult, if not impossible, to avoid the many different forms of bias that can affect the causal analysis of healthcare incidents. One reason for this is that many investigatory techniques provide guidance that is likely to influence the outcome of any causal analysis. On the one hand, this can be seen as beneficial if analysts are directed towards a broader consideration of potential causes. The influence of such direction can also be potentially dangerous if it places undue constraints on an investigation¹. The latter sections of this chapter will present a range of techniques that can be used to reduce some of the biases that affect the causal analysis of adverse healthcare events. In contrast, the following paragraphs present some of the underlying theoretical and practical problems that complicate incident investigation. The problems created by these various forms of bias are compounded by the complex nature of causation. For example, the FDA describe a case study in which a violent patient in a wheelchair was suffocated through the use of a vest restraint that was too small. The risk manager, JC, used an FDA coding sheet to categorise the causes of the adverse event: "She finds the list of event terms, which was detached from the rest of the coding manual... She muses: 'Mr. Dunbar had OBS which isn't listed in these codes; he had an amputation which is listed; he had diabetes which isn't listed; and he had hypertension which is listed'. JC promptly enters 1702 (amputation) and 1908 (hypertension) in the patient codes. She then finds the list for Device-Related Terms... She reviews the terms, decides there was nothing wrong with the wheelchair or the vest restraint, and leaves the device code area blank." (Weick-Brady, 1996). The resulting classification of 1702 (amputation) and 1908 (hypertension) provided few insights into the nature of the incident.

2. Theoretical Approaches to Causation

The previous example illustrates the practical difficulties that complicate the causal analysis of healthcare events. There are also a number of theoretical problems about defining what exactly is a cause of any observed effect. For instance, it can be difficult to determine whether or not an incident was *caused* by a particular staffing level on a ward rather than by the actions of individual clinicians. The distinctions between latent and active causes and between environmental and contributory causes can be used to guide such an analysis.

2.1 Epidemiological Approaches

Epidemiology has a number of well-considered requirements that must be satisfied in order to conclude that there is a causal connection between two events. These can be summarised in the following manner. Firstly, there is a temporality requirement. Most obviously the cause must precede the effect. However, it may well be that the

hypothesised cause and the effect are both the effect of some earlier root cause. Hence, any investigation must consider a range of temporal relations. It is also important to stress that there need not be any causal relationship simply because a hypothesised cause precedes an effect. We can also impose a requirement for reversibility. In epidemiological terms this implies that the removal of a presumed cause will result in a reduced risk of some adverse consequence, such as a fall in the prevalence of a particular disease. Equally, however, there may be some confounding factor that reduces the observed effect in a manner that is independent of the hypothesised cause. We might also expect that investigators demonstrate the strength of association between a cause and an effect. In particular, we would like to show that exposure to a potential cause has a significant impact on the relative risk of an adverse effect. This requirement is important because there is seldom a deterministic relationship between cause and effect in healthcare incidents. The fact that a unit is short-staffed, for example, does not guarantee that an incident will occur. However, there may be a strong association between these situations and particular types of adverse event. Epidemiologists also expect some relationship between exposure and response. This requirement is slightly different from the strength of association because it refers to the exposure and dose associated with a cause or risk. Exposure is usually quantified as a product of duration and intensity. For example, the period of time at which a unit is under-staffed at a particular level. Dose is a measure of the 'infecting agent' that is taken up by the human body. In terms of this chapter, it might be thought of as the number of incidents and near misses that occur in a particular time period. The establishment of a relationship between dose and exposure can provide powerful evidence of a causal relationship, providing it is not due to a confounding factor as described above. This requirement can also be used constructively to establish risk thresholds. For example, by establishing staffing minima that are intended to reduce the negative outcomes to an 'acceptable' level.

A number of problems arise when epidemiological approaches are applied to identify the causes of adverse events in healthcare. In particular, a requirement for reversibility is often difficult to satisfy in more complex incidents. This requires that the removal of a cause would also lead to a reduction in the risk of an adverse event without any confounding factors. This recognises that the identification of previous causal factors involves a study of future incidents. In the immediate aftermath of an adverse event, this creates a number of practical problems. In particular, it often forces investigators to construct counterfactual arguments of the form 'an incident X would not have occurred if causal factor Y had not also occurred'. This is counterfactual because we know that Y did happen and then the accident X also occurred. Practical problems arise because these arguments are non-truth functional. In other words, it can be difficult to provide evidence to support assertions that the removal of any single cause would have avoided an adverse event. A number of cognitive psychologists, for example Byrne and Tasso (1999), have studied the problems and paradoxes that stem from counterfactual reasoning. For example, in the incident described by Chassin and Becher (2002) it might be argued that the wrong patient would not have been selected by electrophysiology nurse if she had referred to the intended patient's name during the initial phone call. However, previous incidents have shown that such verbal procedures can be error prone

and that confusion can still occur where patients have similar names (Johnson, 2003). If we were to adopt the reversibility requirement described above then it would be sufficient to show that the risk of treating the wrong patient is diminished by ensuring the use of patient names while arranging for transfers between units. This would ignore many of the systemic factors identified as being critical to an understanding of adverse events across the human factors and systems engineering literature.

2.2 Primary (Catalytic) Failures

Further problems complicate the application of epidemiological approaches to understand the causes of accidents and incidents in healthcare. For instance, it can be difficult to talk about the exposure to a hazard when the risk depends not on an ‘infecting’ agent but on a complex conjunction of technical, social and managerial precursors. The problems that lead to accidents often form part of a more complex landscape of managerial and regulatory failure, of poor design and equipment malfunctions, of environmental conditions and of operational inadequacies Mackie (1993) uses the term ‘causal complex’ to describe this landscape of failure. Although he was looking purely at the philosophy of causation, it is possible to apply his ideas to clarify some of the issues that complicate the investigation of healthcare accidents and incidents. Each individual factor in a causal complex may be necessary for a mishap to occur but an adverse event will only occur if they happen in combination. Several different causal complexes can lead to the same accident even though only one may actually have caused a particular failure. For instance, initial confusion over the location of the patient from the electrophysiology treatment can be compounded by inadequate confirmation of the patient’s identity in the electrophysiology lab or by confusion over whether the patient had already provided consent to result in treatment of the wrong patient. It is for this reason that most accident investigations consider alternate scenarios in order to learn as much as possible about the potential for future failures.

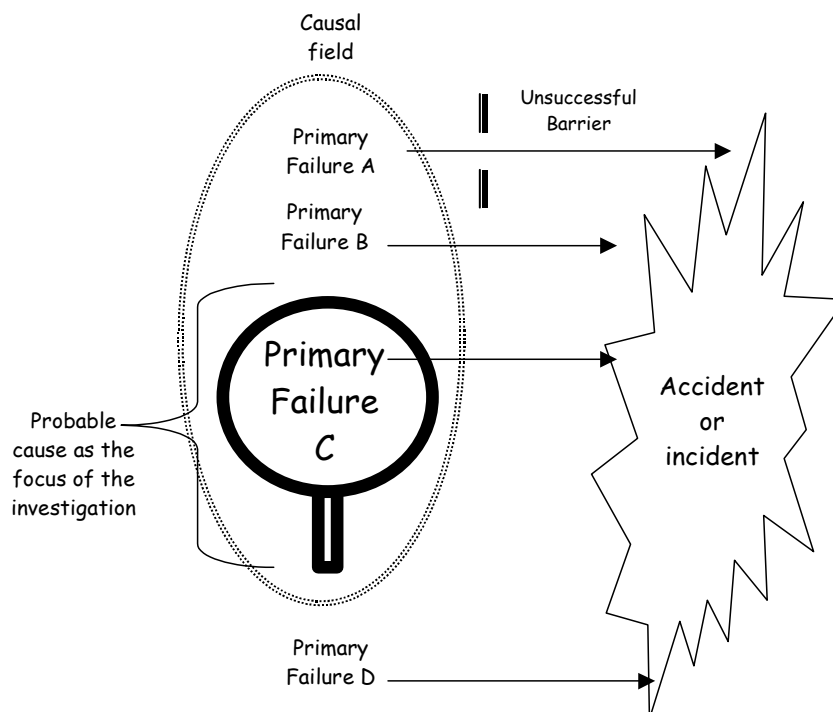


Figure 1: Causal Fields and Primary Interaction Failures

Mackie goes on to argue that we often make subjective decisions about those factors that we focus on within a causal complex. The term ‘causal field’ refers to those factors that an investigator considers relevant to a particular investigation. If a cause does not appear within this subjective frame of reference then it is unlikely that it will be identified. This philosophical work has empirical support from the findings of Lekberg (1997) who was able to show a strong correlation between the findings of accident investigators in the Swedish nuclear power industry and the subject of their first degree. Human factors graduates were more likely to identify usability issues, process engineers were more likely to find problems in plant design and so on. Figure 1 provides an overview of Mackie’s ideas and how they might relate to a Reason’s (1997) view of accident investigation, mentioned in the opening paragraphs of this chapter. The causal field in this case concentrates on primary causes A, B and C. Within that, we can focus on particular issues that we raise to the status of ‘probable causes’. This is illustrated by the magnifying glass. For example, an investigator might be predisposed, or biased, to look at the behavioural issues in a particular working group. This would be illustrated by the focus on primary failure C in Figure 1. However, the causal field may not encompass a sufficient set of conditions and in this case primary failure D is not within the range of issues being considered by the investigator. For instance, if the investigation focuses on team-based issues then correspondingly fewer resources will be available to consider other potential problems, including managerial or equipment concerns.

2.3 Secondary (Latent) Failures

We can trace back the events leading to an adverse event to form what are termed ‘causal chains’. For instance, secondary or latent problems create the preconditions for primary failures. These events might include particular decisions to reduce staffing levels within the various departments involved in the Chassin and Becher study. These events make it more likely that, for example, the original patient’s nurse from the telemetry unit would not double check at the end of their shift before agreeing to move the patient down to the electrophysiology laboratory. Hence secondary problems do not directly cause an adverse event but can help to create the conditions in which a mishap is more likely to occur. Figure 2 provides an overview of secondary failures. As can be seen, these problems contribute to primary failures.

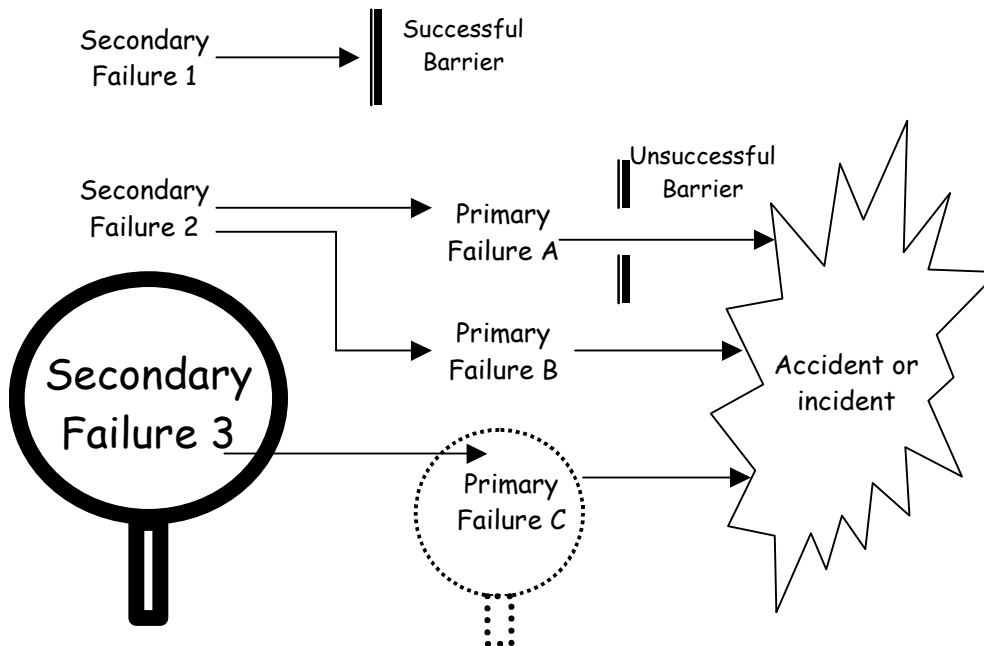


Figure 2: Causal Fields and Secondary Failures

For instance, the fact that the electrophysiology laboratory's computer system was isolated from the main hospital system, represented by secondary failure 2, can create a situation in which personnel are more likely to make an error over the name and identity of an electrophysiology patient. This is illustrated by primary failure B in Figure 2. Alternatively, effective crosschecking procedures, for example, by the electrophysiology fellow prior to commencing the procedure might have discovered the potential adverse event. The successful barrier to secondary failure 1 in Figure 2 would illustrate this. An important aim of this chapter is to extend the causal field of accident investigations to consider these secondary or latent causes of adverse events. This is illustrated in Figure 2 by moving the magnifying glass to the left. The dotted ellipse used to denote the causal field in Figure 1 could also be redrawn to show the extended scope of an investigation in this figure. Our emphasis on secondary problems is intended to guide the composition of a causal field, which Mackie argues can be a subjective and arbitrary process. These latent failures are an increasingly common factor in the assorted lists of 'contributory factors' that appear in accident reports. We would, therefore, argue that these secondary failures deserve greater and more sustained attention.

2.4 Tertiary (Analytic) Failures

First order failures lead directly to an incident or accident. They are cited as the probable cause of an adverse event when, for instance, a clinician performs a particular procedure on the wrong patient. Such primary failures are rare. In contrast, there is a host of secondary failures in most organisations that create the preconditions for an adverse event but for which there are, as yet, insufficient primary failures to trigger an adverse event. Figure 3 illustrates a final form of 'failure' that complicates the analysis of adverse events in healthcare. Tertiary problems stem from the difficulty that investigators face when they use particular analytical tools to identify the primary and

secondary causes of adverse events. Some techniques are poorly documented, especially if they were developed for domains other than healthcare. These techniques are, therefore, often used incorrectly when they are introduced to analyse adverse events in surgeries and hospitals. Other techniques require considerable training and expertise in order to understand and apply the underlying concepts. In particular, the application of the same techniques by different analysts can yield radically different insights into the same adverse event. This can create problems when healthcare organisations have to establish the priorities that will guide any subsequent recommendations. Figure 3 uses a darkened magnifying glass to illustrate the tertiary problems that complicate the use of causal analysis techniques. The remainder of this chapter describes a range of tools and techniques that are intended to support root cause analysis.

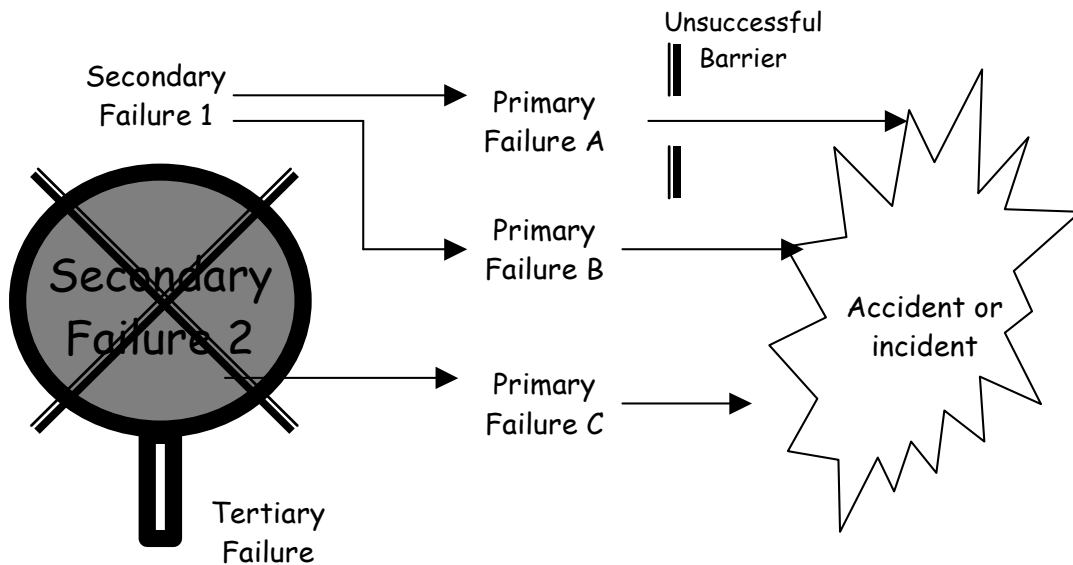


Figure 3: Causal Fields and Tertiary Interaction Failures

3. Causal Analysis Techniques

In the aftermath of adverse events, it is important to identify those hazards that threatened the safety of an application process. Each of these may stem from numerous causes. These can be catalytic or primary events that triggered the mishap. They can also stem from the secondary, background or latent conditions that emerge slowly over a longer period of time. The identification of these causal factors can, in turn, be jeopardised by a higher order or tertiary form of failure that occurs when biases or technical limitations affect the analysis of an adverse event. This section presents a number of techniques that are intended to reduce the likelihood of tertiary failures in the investigation of accidents and incidents. They are intended to help investigators identify the 'root causes' of adverse incidents. Unfortunately, few of these techniques have been specifically tailored to support the analysis of healthcare accidents. Most stem from work in the transportation and power production industries. The following exposition, therefore, uses the incident described by Chassin and Becher to illustrate how these different approaches might be applied to this domain.

Before introducing the various techniques it is important to reiterate a point made at the start of this chapter; the output from any causal analysis is not simply the ‘root causes’ and contributory factors. In particular, the tools and techniques must help investigators to identify recommendation and remedial actions. Table 3 illustrates a common format that is used to summarise these products of an incident investigation.

Hazard	Root Cause of the Hazard	Proposed remedial action	Responsible Authority
Hazard 1	Root Causes	Remedial Actions	Person or team to sign-off
Hazard 2	Root Causes	Remedial Actions	Person or team to sign-off

Table 3: The Results of an Incident Investigation

As we have seen from the previous section, Mackay’s work suggests that each incident may help to identify a number of different hazards. These can be thought of as different causal chains that are individually sufficient to result in an adverse consequence. For example, the Chassin and Becher incident illustrates the hazards that arise when staff fail to confirm the name of the patient being transferred between unit. Similarly, it also illustrates the problems that arise when the computer systems that hold information about patients in different units are not integrated so that cross-checks cannot easily be made on an individual patient as they move between those units. Each of these hazards may be sufficient to cause a mistake over the identity of a patient. Any particular incident can, therefore, involve several different hazards. Each hazard can be the result of several different combinations of secondary causes. For instance, there may be complex managerial and technical reasons for the lack of integration between the computerised records systems. These causes are likely to be very different from those that led to the lack of verbal confirmation for the patients identity during the transfer. Each of these causes may, in turn, require a range of remedial actions. The following pages introduce techniques that investigators might use to identify the root causes of hazards involving healthcare systems.

As mentioned, causal analysis forms part of a wider process of mishap investigation. Ideally, investigators and safety managers must ensure the immediate safety of a system and gather all necessary evidence before any attempts are made to identify causal factors. In practice, however, investigators may have preconceived notions about what led to a failure. This can bias the way in which they gather evidence so that they only look for information that supports preconceived theories. From this it follows that the use of a causal analysis technique does not guarantee that appropriate lessons will be learned from adverse events.

3.1 Elicitation and Analysis Techniques

A number of causal analysis techniques are tightly integrated into the elicitation of evidence and mishap reconstruction. Investigators who are still considering ‘what’

happened are encouraged to consider a number of possible causal factors so that they gather an appropriate range of evidence about the incident. This is important because, as mentioned previously, investigators' initial causal hypotheses may mean that evidence is only gathered if it supports their preconceptions. Barrier analysis provides an example of this form of causal analysis technique.

Barrier Analysis

Previous sections have described how barriers can be created to protect a safety critical system from particular hazards. These barriers include technical features, such as the safety inter-locks that physically prevent laboratory staff from placing their hands inside a moving centrifuge. They also include organisation and procedural requirements, such as the standard operating procedures that may require staff to confirm the name of a drug with a colleague before it is administered to a patient. Barrier analysis focuses on the ways in which these measures are undermined during an incident or accident. It traces the way in which an adverse effect stems from a potential hazard and ultimately affects the target. In this context, the target of the hazard is assumed to be the patient. In other incidents, the target might include other members of staff or even systems within a hospital. Figure 4 shows how the adverse effects of a hazard must pass through a series of potential barriers before they can reach the ultimate target. In this case, the final barrier prevents the incident from affecting the target. This typifies the way in which a final layer of defenses can make the difference between a near-miss and an accident. In such circumstances, incident reports provide important insights both about those barriers that failed and those that acted to protect the target from a hazard.

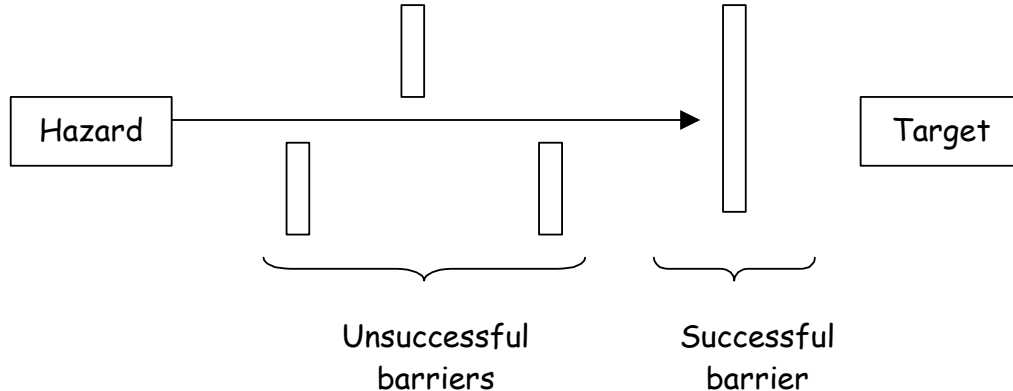


Figure 4: Targets, Hazards and Barriers.

What?	Rationale
Hazard	Cardiac electrophysiology study performed on the wrong patient.
Targets	The patient who incorrectly underwent the electrophysiology and the patient who missed their scheduled electrophysiology procedure.

Table 4: Hazard and Target Identification

Barrier analysis, therefore, begins by drawing up tables that identify the hazard and the targets involved in an incident or accident. Table 4 illustrates these entities for the Chassin and Becher case study. As can be seen, we have extended the targets to also include the second patient who was correctly intended to have the electrophysiology procedure. In this instance, missing the intervention had no apparent effects on their prognosis even though this incident delayed their study for a third time. They are, however, included in Table 4 to illustrate how an initial barrier analysis should deliberately consider as wide a range of targets as possible.

Analysis progresses by examining the barriers that might prevent a hazard from affecting the targets. Analysts must account for the reasons why each barrier might have failed to protect the target. Table 5 illustrates the output from this stage.

Barrier	Reason for failure?
Electrophysiology computer system provides patient details on the lab schedule.	No automatic way for telemetry nurse to crosscheck her patient's data with the electrophysiology schedule as the systems were incompatible.
	Manual crosscheck from the schedule fails because the electrophysiology nurse only uses the patient's surname.
Consent procedure requires patient's explicit permission for the procedure.	Telemetry nurse told patient she could refuse consent in the electrophysiology lab without crosschecking reason for patient's confusion over the procedure.
	Attending physician in electrophysiology did not pursue patient's apparent confusion over the procedure that had already been explained (to the other patient) on the previous evening.
	Nurses notice no consent on the patient's chart even though other records show it had been obtained, pass problem to Electrophysiology fellow.
	Electrophysiology fellow briefs patient to obtain consent without clarifying source of confusion.
Electrophysiology clinicians required to perform chart review before conducting procedure.	Staff surprised by lack of relevant information but assume procedure ordered as part of treatment from other department.
	Original 'fainting' mentioned by the patient considered reasonable indication for the electrophysiology procedure.

Table 5: More Detailed Barrier Analysis

Table 5 illustrates the way in which Barrier Analysis can be used to identify potential reasons for the failure of particular protection mechanisms. As can be seen, however, this initial analysis often focuses on the individual actions or primary causes of an adverse event. Further analysis may be required to identify the underlying, secondary causes, of an incident or accident. For instance, the previous analysis does not explain *why* the attending physician in electrophysiology did not pursue patient's apparent confusion over the procedure that had already been explained. For instance, "obtaining consent is frequently delegated to an overburdened or exhausted physician who has not met the patient previously and does not know the details of the medical history...cultural or social barriers to effective communication may be neither appreciated nor overcome" (Chassin and Becher, 2002).

The meta-level point here is that causal analysis techniques often identify additional questions about practices and procedures, which are intended to protect patients and staff. Asking questions about why barrier fail can help analysts to look beyond the immediate triggering events that led to the mishap. It can be difficult to predict all of the possible events that might individually contribute to an adverse incident. In contrast, analysts must focus on the protection mechanisms that were in place to prevent those individual events from threatening the safety of the system.

Change Analysis

Change analysis is similar to barrier analysis in that it provides a framework both for causal analysis and also for the elicitation of additional information about an adverse event. Change analysis looks at the differences between the events leading to an incident and 'normal' or 'ideal' operating practices. As with barrier analysis, this technique was not originally developed to support the investigation of healthcare incidents. It is, however, possible to use change analysis to analyse aspects of our case study. For example, the manner in which the patient's consent was obtained in this incident can be compared with the hospital's procedures or in the practices recommended by professional and regulatory organisations. The American Medical Association's Ethics Policy states that 'The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The patient should make his or her own determination on treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic social policy for which exceptions are permitted: (1) where the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent; or (2) when risk disclosure poses such a serious psychological threat of detriment to the patient as to be medically contraindicated. Social policy does not accept the paternalistic view that the physician may remain silent because divulgence might prompt the patient to forego needed therapy' (AMA, 2004). Similarly, the events leading to this mishap can be compared with the procedures and policies established for the identification of patients prior to treatment. For instance, Louisiana State University requires that "Prior to the administration of tests, treatments, medications, or procedures

the healthcare professional providing the care is responsible for verifying the patient's identity by utilizing two identifiers: patient name and patient medical record number. Whenever possible, staff shall also verbally assess the patient to assure proper identification, asking the patient's name and date of birth and matching the verbal confirmation to the written information on the identification...If the identification band is illegible, missing, or contains information that is incorrect the test, treatment, medication, or procedures will not be done until the patient is properly identified" (Louisiana, 2003)

Prior/Ideal Condition	Present Condition	Effect of Change
Patient identity should be confirmed prior to moving them from their current location within the hospital or performing procedure (Hospital guidelines).	Electrophysiology nurse only uses patients surname when requesting they be moved from telemetry. Electrophysiology attending fails to confirm this is the patient he discussed procedure with on previous evening. Charge nurse and resident do not refer to patient name when discussing the first case of the day. Charge nurse fails to pursue discrepancy noticed when making name stickers...	Patient with a similar surname receives procedure intended for electrophysiology patient. Electrophysiology patient does not receive their intended treatment.
Patient should provide informed consent prior to any procedure having been provided with adequate information about the risks and benefits. (American Medical Association Ethical Guidance E8.08)	Oncology patient told nurse she didn't know about the electrophysiology. Patient also told attending electrophysiology physician of her objections. He reassured her. Electrophysiology nurse notices no written consent even though records state it should be there.	Consent is obtained but it cannot be described as informed given that they agreed to an 'unnecessary' procedure. Staff had several prompts to enquire further into apparent anomalies over the missing consent forms.

Table 6: Change Analysis

Table 6 shows how the first column of a change analysis describes the ideal condition or the condition prior to the incident. This is an important distinction because the causes of an adverse event may have stemmed from inappropriate practices that continued for many months. In such circumstances, the change analysis would focus less on the conditions immediately before the incident and more on the reasons why practice changed from the ideal some time before the mishap. In this case, the analysis focuses

more on the prescribed procedures and practices identified by the American Medical Association and by local hospital guidelines. The middle column summarizes the way in which these ‘ideals’ may have been compromised during the incident under investigation. The final column discusses the effects of those changes from established guidelines and procedures. In this example, the result was that consent was obtained from the patient but this approval could not be described as ‘informed’. Similarly, Table 6 illustrates the way in which failures in the identification procedure led to a patient with a similar surname receiving the procedure that was intended for the electrophysiology patient. Conversely, the electrophysiology patient did not receive their intended treatment.

An important strength of change analysis is that it can help to identify potential recommendations in the aftermath of an adverse event. In the simple case, it may be sufficient to ensure that the prior or ideal situation should be restored. In many situations, however, it will be important to question the reasons why previous procedures were violated or why norms emerged that might otherwise threaten the safety of an application. For instance, stating that clinicians should follow the AMA guidelines does little to address the systems level issues identified by Chassin and Besson (2002) or by Reason (1997) and his colleagues. Further problems complicate the application of this technique. The previous example illustrates the manner in which change analysis often focuses on individual violations. The use of published policies and procedures in establishing ideal conditions can influence analysts to look for the individuals who were responsible for breaking those requirements. Finally, it can be difficult to connect this form of analysis to the mass of more immediate events that are, typically, documented in the evidence that is gathered following near miss events. Event-based causal analysis techniques arguably provide a more convenient bridge to these reconstructions.

3.2 Event-Based Reconstruction Techniques

Barrier analysis can help risk managers to distinguish successful protective devices and procedures from those that failed to safeguard the patient or any other associated targets. Change analysis can also be used to elicit information in the aftermath of an adverse event by prompting investigators to identify the particular circumstances that led to a mishap. The analysis focuses on those factors that distinguish a mishap from previously successful procedures or from the ‘ideal’ circumstances that are often embodied in relevant guidelines. Both of these approaches tend to analyse an incident at a relatively high-level of abstraction. They do not usually provide a detail reconstruction of the events that occurred during an incident or accident. In contrast, event-based techniques are intended to help analysts clarify *what* happened. They are often used in conjunction with a secondary form of analysis that uses these event reconstructions to determine *why* these events took place.

Timelines

Time-lines provide arguably the simplest form of event-based analysis technique. They provide a straightforward representation of the ways in which events unfold over time. For instance, many devices provide automatic means of generating a log of system level events. Table 7 recreates part of the alarm log that might have been derived from a monitoring system. These timelines raise a host of practical problems. For instance,

most devices have a very limited capacity to record alarm and status information. It, therefore, follows if the logs are not printed or saved in an aftermath of an adverse event then key records will be over-written. In consequence, many agencies in other domains such as Air Traffic Management have explicit requirements on supervisors to ensure that any relevant automated logs are protected (Johnson, 2003). There are further problems. Some device manufacturers view these logs as diagnostic tools that should be used during installation and calibration. They are not easily accessible to end-users and may even be disabled after deployment. It can also be difficult to interpret the meaning of these automatic logs without detailed technical support from device manufacturers.

Point	Time	State of the Alarm	Description	State - start of scan	Current status	State once scan complete
BLS_605	11:27:20	Normal	Gas detector	Acknowledged	Reset	Deleted
BLS_605	11:27:37	Beam Blocked	Gas detector	Nominal	Generated	Generated
BLS_605	11:27:40	Normal	Gas detector	Generated	Reset	Reset
BLS_605	11:28:30	Normal	Gas detector	Reset	Acknowledged	Deleted
PLT-23	11:28:34	Loop Fault	F/Disch	Nominal	Generated	Generated
...	...	...	...	...	...	...

Table 7: Example Summary from Automated Alarm Log

Table 7 illustrates the problem that exists in moving from device logs to the more ‘systemic’ forms of causal analysis, described earlier in this chapter. In particular, it can be difficult to incorporate operator interventions and management decision making processes, that will only be indirectly represented in the output of such systems. In consequence, most incident investigations construct higher-level, graphical timelines to record the events that contributed to an accident or near miss. Figure 5 illustrates this approach.

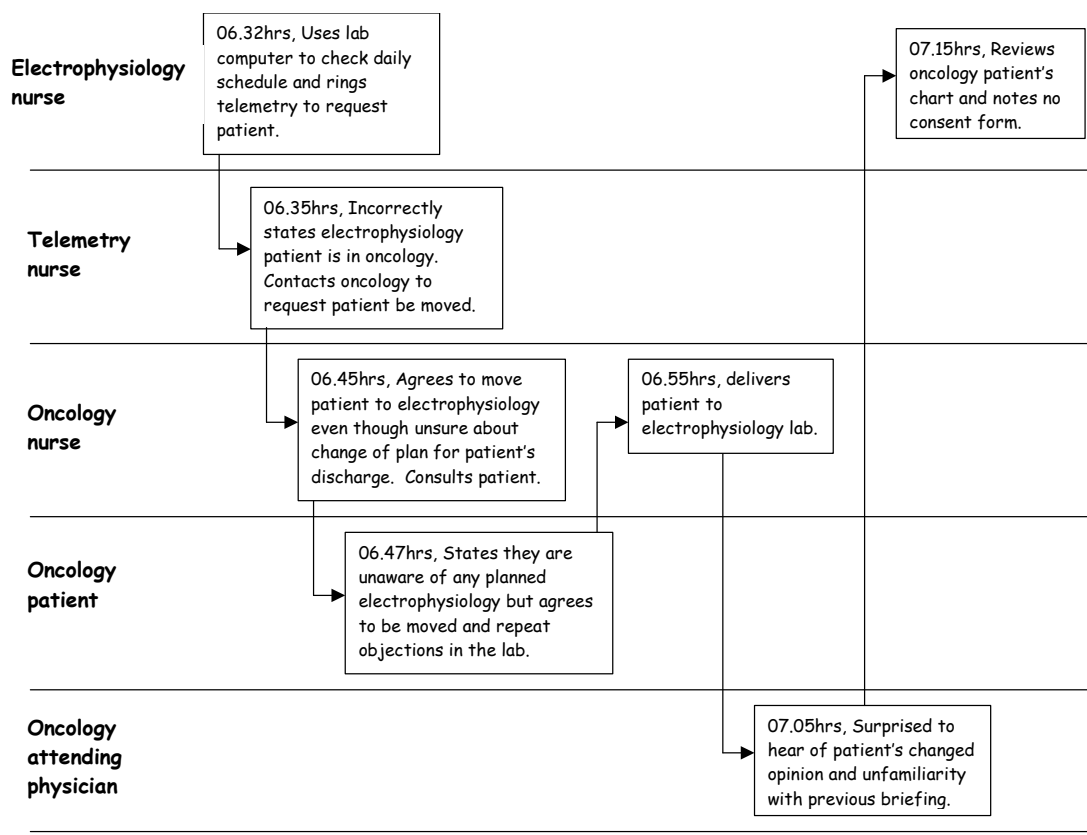


Figure 5: High-level Timeline of the Case Study Incident

Figure 5 illustrates a form of time-line that was developed by the US National Transportation Safety Board (Johnson, 2003). The 'actors' involved in an incident are named vertically on the left side. For instance, the events involving the oncology nurse can be distinguished from the telemetry nurse and the attending physician. The events that they are then involved in are enumerated on a horizontal time-line to their right. Once these events have been mapped out, it is then possible to draw arrows between those events to indicate 'informal' causal relationships. These are 'informal' because there are few rules to guide investigators at this stage. For instance, there is no way of determining whether the precursors are sufficient to cause an adverse event or whether there are other ways in which the mishap might have occurred. As we shall see, other techniques provide heuristics or rules of thumb that can be used to support these different forms of causal analysis.

Practical problems arise because in complex incidents it is relatively easy to run out of space on any single sheet of paper. Using continuation sheets can reduce this problem. However, investigators often adapt this approach by using sticky notes on a large section of wall. These can be placed and replaced as more information becomes available. Further problems complicate the use of time-lines in the causal analysis of adverse healthcare events. First, it can be difficult to obtain exact timings for many different events distributed across several departments. Hence there will often be inconsistencies and contradictory evidence for exact timings. This caveat has persuaded many analysts to represent and reason about adverse events at a more abstract level. The intention is not

to model every detailed event that occurred but to sketch critical causal relationships between lesser numbers of more important events.

Accident Fault Trees

Fault trees extend concepts from systems engineering to support the analysis of adverse events. The key idea is that the causes of a complex event can be analysed in terms of a conjunction of simpler precursors. In other words, an accident is the result of A happening and B happening and C happening, and so on. Disjunctions can also be used to represent alternative causes. For instance, an accident is the result of A or B or C etc. These distinctions help to clarify the causal relationships that were less apparent in timelines. Sufficient causes are represented by a conjunction of events that lead to an adverse event. There may be several of these conjunctions if disjunctions appear in the tree. Necessary causes are events that appear in every sufficient conjunction. In other words, if a necessary cause is omitted then the accident will be avoided. Figure 6 provides an overview of one form of accident fault tree.

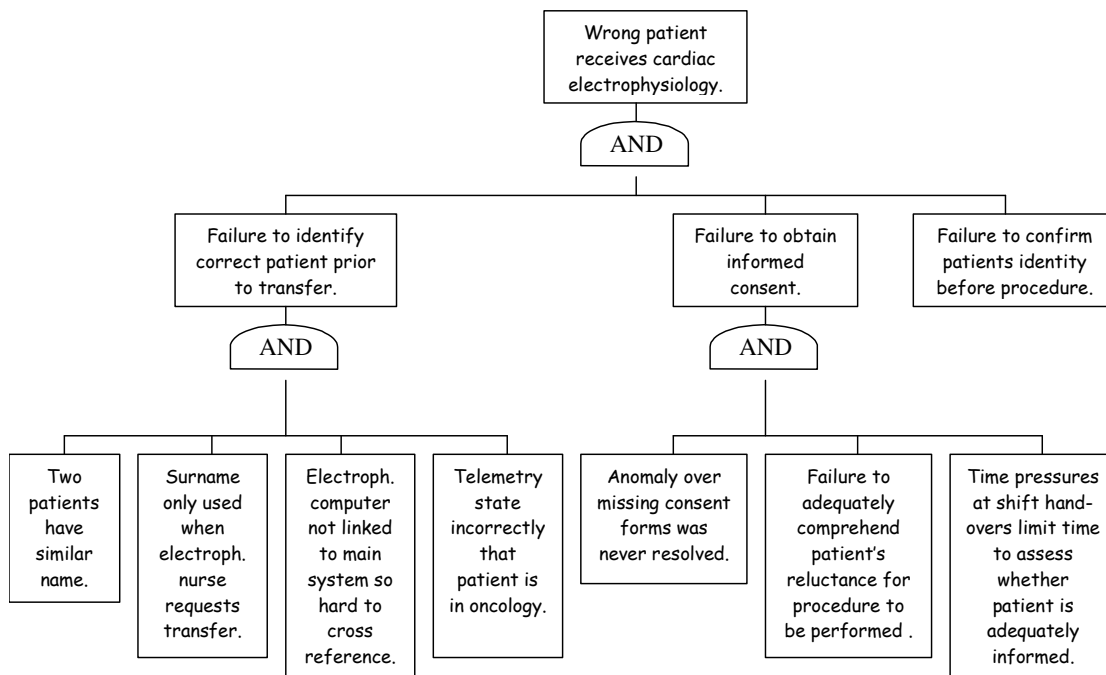


Figure 6: Overview of an Accident Fault Tree

The events that contribute to a mishap are represented as rectangles. In this case, the tree only includes conjunctions, these are denoted by the semicircles labelled 'AND'. For example, the bottom left sub-tree illustrates the observation that two patients shared similar names AND the surname was only used when the electrophysiology nurse requested the transfer AND the electrophysiology computer was not linked to the main hospital system AND the telemetry department stated incorrectly that the patient was in oncology. These four observations together are used to conclude that there was a 'failure to identify the correct patient prior to transfer'. If any one of the component events were omitted, for example if the patient's forename was used as well, then the

identification failure need not have occurred. Similarly, this diagram also includes some of the events that led to the failure to obtain informed consent. This event and the right-hand ‘failure to confirm patient’s identity before procedure’ illustrate how Accident Fault Trees can be used to incrementally build up the level of detail in an analysis. Subsequent investigation might focus on adding additional information so that these aspects of the diagram mirror the detail devoted to explain the ‘failure to identify the correct patient prior to transfer’.

Although accident fault trees avoid some of the problems that affect timelines, there are a number of additional problems (Johnson, 2003). In particular, it is unclear how to represent the way in which any response to an incident helps to determine the eventual outcome. In conventional fault-trees the analysis stops with a potential hazard. In our example, this is the top-level event ‘wrong patient receives cardiac electrophysiology’. Extending the diagrams to representing different outcomes, from the subsequent mitigation or exacerbation of a mishap, would create considerable differences with the analytical use of fault trees in design. It might also result in complex diagrams that hinder rather than support the analysis of what are often complex failures. Further problems stem from the lack of any explicit temporal information in accident fault trees. There is an implicit assumption that lower level events in the diagram occur before the top-level events and that events in the same level occur from left to right. However, these are informal conventions and there is no explicit relationship to real time which can be critical, for instance in drug misadministration mishaps. Figure 6 also blurs the distinction between events and conditions. For example, the use of the surname only during patient transfer is an immediate event that cannot easily be decomposed any further. In contrast, the lack of any link between the two computer systems and the time pressures between shift handovers are both conditions that could be decomposed to identify the detailed events that led to these problems. This distinction between events and conditions can create confusion about whether any analysis has explored the causes of an incident in sufficient depth.

Failure Event Tree, ECF Charts, MES and STEP

As mentioned, Fault Trees were originally developed to support the design and engineering of complex applications. The previous paragraphs have described how this approach can be extended to support the analysis of adverse events in healthcare. In contrast, a range of event-based techniques has been specifically developed to support the reconstruction and interpretation of accidents and incidents. There are strong similarities between many of these approaches, including Events and Causal Factors charting (ECF), Multilinear Events Sequencing (MES) and Sequential Timed Event Plotting (STEP). For more information on each of these techniques see Johnson (2003).

Figure 7 provides an illustration of these event-based approaches by applying a Failure Event Tree to our case study. In contrast to the previous timeline, this diagram focuses on what happened after the patient had reached the electrophysiology department. All timings are indicative and should not be read as an accurate representation of any particular accident. The sequence of events leading to a mishap is denoted by the rectangles at the top of the image. For example, the diagram includes the events

'07.35hrs, procedure started' and '07.19hrs, Electro(physiology) fellow reviews chart and had patient sign consent form'. Outcomes are denoted by bold rectangles with dotted borders. In this example there are two. One is associated with the performance of the procedure on the oncology patient. The second is associated with the failure to perform the procedure on the intended patient. This represents a slightly unusual application of the Failure Event Tree technique (Johnson, 2003). It could be argued that the decision to halt the procedure at 08.30hrs represents the outcome of this incident. However, the current version of the diagram focuses attention on the adverse outcome rather than this mitigating event. This decision could be revised during any subsequent investigation of the mishap.

Figure 7 also uses rectangles with a double line border to denote direct factors that influence an adverse event. These factors can be thought of as conditions that influence the course of a mishap but that cannot easily be captured by particular events. For example, it would be possible to extend the diagram back many months or years to consider the precise moments when the decisions were made that prevented any cross-referencing between the telemetry and electrophysiology computer systems. However, in the aftermath of many adverse events it can be extremely difficult to identify the particular moments that led to such decisions. It is often easier simply to represent these more detailed precursor events as direct influences on the course of events. Similarly, it is often easier to represent cognitive and human factors influences on decision making as direct factors rather than attempt to trace the individual events that might have affected their actions. As before, we could extend the diagram to represent these factors as events. For example, the observation that the 'Electrophysiology attending believes he spoke to patient on the previous evening' could be associated with a particular location in the timeline at the top of the diagram. However, it can be difficult to explicitly identify the moment at which such cognitive events occurred. It can also be hard to gather necessary evidence to support such inferences about individual cognition.

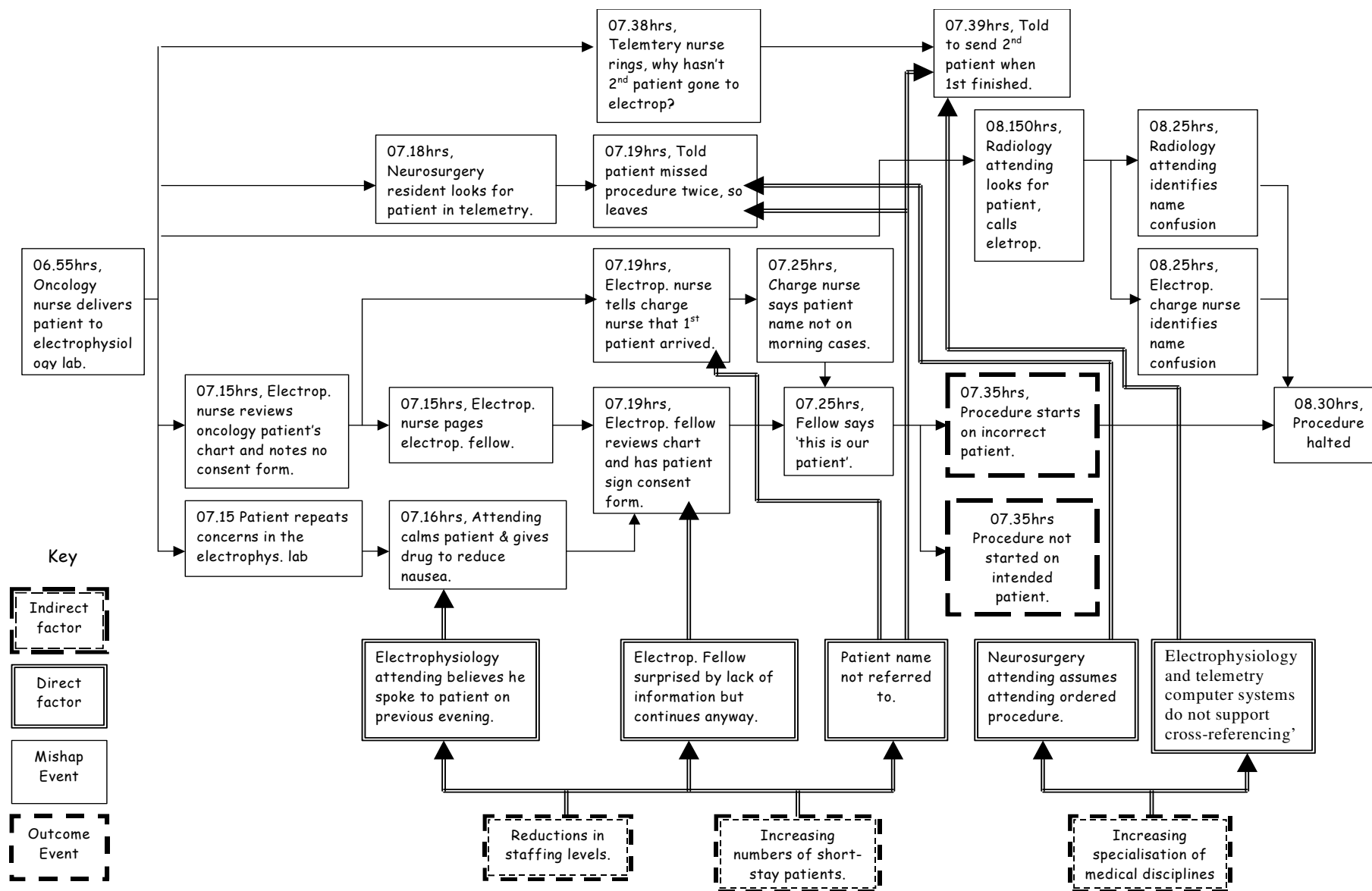


Figure 7: A Failure Event Tree

Failure Event Trees can also capture the less direct, or distal, factors that contribute to an incident. Dotted double borders around a rectangle denote these. For example, Chassin and Becher (2002) observe that the underlying causes of our case study include reductions in staffing levels; the increasing number of short-stay patients and the increased specialisation of medical disciplines. Unfortunately, they do not explain precisely how these distal factors affected the direct factors and events in this incident. As can be seen from Figure 7, Failure Event Trees provide a means of explicitly representing these relationships between proximal and distal factors. The underlying indirect factors help create the conditions for more direct factors, which in turn, contribute to the events leading to this particular mishap. For instance, reductions in staffing levels and increasing numbers of short-stay patients may have combined to increase the pressures on staff that were then less likely to carefully confirm the name of particular patients. Hence these pressures may indirectly have contributed to electrophysiology nurse's failure to state the forename of the first patient on their schedule. There are, however, no agreed rules for distinguishing events from direct or indirect factors. These distinctions often, therefore, result from a process of negotiation between the participants in an investigation.

Figure 7 shows how event-based techniques often 'map' out the course of an incident or accident in a manner that is very similar to a timeline representation. The key difference is that techniques such as Failure Event Trees and Events and Causal Factors charts also explicitly represent the distal factors that indirectly contribute to an adverse event. Most of these approaches rely upon a secondary stage of analysis to identify the root causes of a mishap. The central problem is to distinguish these critical aspects of an accident or near miss from the other less significant events in the diagram. Counterfactual reasoning is again used to identify these root causes. Analysts begin by looking at the event closest to the incident. In Figure 7, we ask would the procedure still have started on the wrong patient if the Electrophysiology fellow had not confirmed that 'this is our patient'. If the answer is yes and the mishap would still have happened then this event cannot be a candidate root cause of the incident. If the answer is no and the mishap would not have occurred without this event then we can argue that it was necessary for the incident to occur so it can be considered as a root cause. The process continues for each of the mishap events shown in the diagram. Once potential root causes have been identified, remedial measures can be introduced to address the direct and indirect factors that led to each of the particular mishap events that were identified as the root causes of this mishap. For instance, in our case study it is conceivable that the procedure would still have started even if the fellow had not made his pronouncement. However, it seems less likely that the problem would have arisen if they had not persuaded the patient to sign the consent form. Hence the indirect factors associated with this event, including the rising number of short stay patients and reduced staffing levels, can be considered root causes of the incident as a whole.

A number of caveats complicate the use of event-based analysis techniques. For example, we have already argued that the distinctions between 'first class' events, direct and indirect factors can be arbitrary. Further problems arise because there are few

heuristics for determining the scope of the analysis. For example, we could have pushed the initial event in Figure 7 back to consider the moment when the two patients were admitted or to precursor events such as the acquisition of the hospital computer system. In consequence, it is entirely likely that two investigators might produce different models from the same accident. The subjective nature of these approaches need not be a weakness. These techniques are relatively easy to learn and in consequence the members of a multidisciplinary team might conduct a semi-independent analysis of the incident. The different perspectives offered by these studies could then be combined into a unified model of an adverse event. However, the arrows between events introduce further confusion. They represent causal relationships. For example, the Charge Nurses statement that the patient's name is not on that morning's list causes the Electrophysiology Fellow to remark that 'this is our patient'. Elsewhere they represent the 'flow of events' without any causal information. For instance, there is no immediate causal relationship between the electrophysiology nurse telling the charge nurse that their first patient has arrived and the charge nurse's observations about the names on that morning's list. Such criticisms have resulted in alternative forms of causal analysis techniques such as Leveson's STAMP and Ladkin's WBA, which avoid some of these confusions between temporal sequences and causal relationships. These techniques are described in the later sections of this chapter.

3.3 Flow Charts and Taxonomies

One of the main criticisms levelled at elicitation techniques, such as Barrier Analysis, and event-based approaches, including Failure Event Trees, is that they provide little explicit encouragement for consistency between investigators. Different investigators will produce very different models of the same adverse events (Johnson, 2003). In contrast, flow charts, typically, guide the analysis towards a number of predefined causal factors. This supports the extraction and validation of statistical information from large-scale incident reporting systems. The flow charts help to ensure that analysts consider the same range of causal factors by constraining the scope of their analysis.

MORT

Management Oversight and Risk Trees (MORT) provide a flow-chart approach to the analysis of organisation 'failures' (W. Johnson, 1973). Figure 8 provides an abbreviated version of a MORT diagram that is at the heart of this technique. The diagram is built from components that are similar to those in the accident fault tree, introduced in previous sections. For instance, an adverse event is caused because the oversight of an application was less than adequate AND because there were risks involved in the operation of the system. These two components of an incident are related by the conjunction at the top level of Figure 8. The causal analysis of an adverse event begins at these top levels of the tree. Investigators must ask themselves whether the mishap was the result of an omission of some management function and whether the incident occurred from a risk that had already been recognized. In the tree, the term LTA refers to a 'less than adequate' performance of some necessary activity. If there was an oversight problem then analysis progresses to the next level of the tree. Investigators are encouraged to consider why a mishap occurred. The reasons why an oversight might occur include less than adequate management policy, implementation or risk assessment.

The analysis progresses in this manner under investigators reach a number of terminal nodes, not shown here, that describe the more detailed causes of the incident. In passing, it is important to note that the bottom left hand branches of Figure 8 show how MORT encompasses aspects of Barrier Analysis, introduced in previous sections of this chapter. This illustrates how the elements of the MORT tree capture high-level categories that can be applied to describe management problems in many different domains. This enables comparisons to be made between the management of adverse events across many different healthcare sectors. The tree structure also encourages consistency because investigators must use the tree to ask the same analytical questions determined by a left to right traversal of Figure 8.

As we have seen, our case study involved risks to the patient. It can also be argued that oversight was less than adequate. Analysis can, therefore, progress to the lower levels of the tree. We must determine whether the oversight during either development or operation was adequate. If it was not then we can begin to analyze what happened during the incident by going down the far left branch of the figure. This involves the identification of hazards, barriers and targets in an identical fashion to barrier analysis introduced previously. After having identified these components of what occurred, analysis might go on to consider the right branches including the reasons why management might have been less than adequate. Figure 8 encourages analysts to consider whether the policy, the implementation or the risk assessment in the design and operation of the system might have contributed to the mishap. This might lead an investigation to question whether the policies identified in our previous Change Analysis had been successfully implemented, for example in order to obtain informed consent.

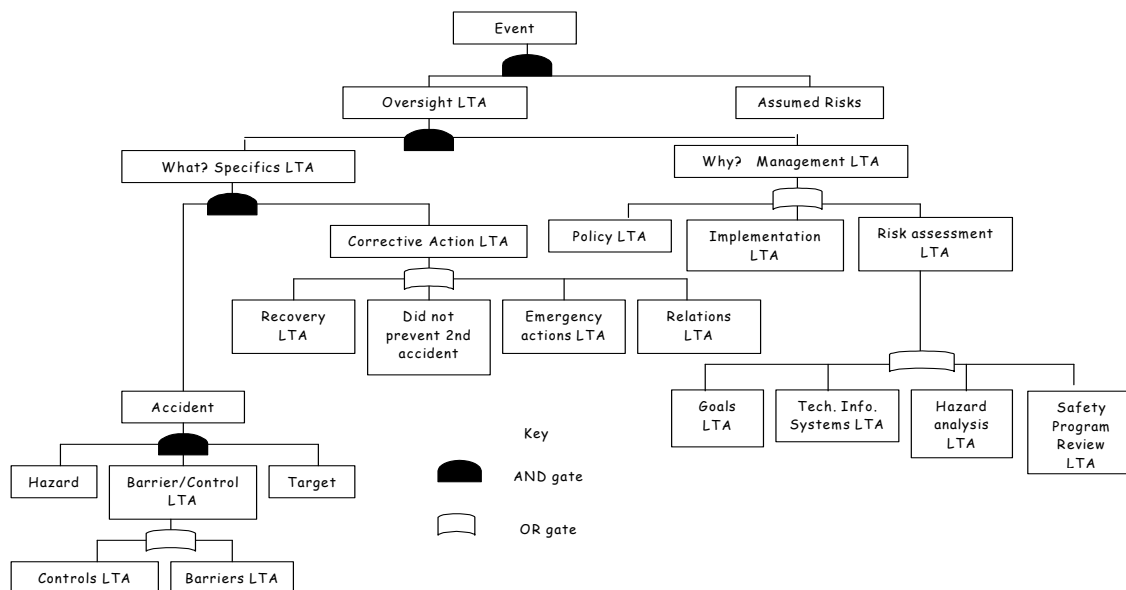


Figure 8: Abbreviated form of a MORT diagram

Investigators must document the results of such causal analysis. Table 8 illustrates one technique that can be used in conjunction with MORT diagrams. A brief argument states the reasons why a mishap was caused by one of the factors that are represented in the

nodes of the tree. In this case, the risk assessment was less than adequate because the danger of a loss of control functions after a system trip for the crew and the vessel was not considered in sufficient detail. Such documentation is important if others within an organisation are to understand the reasons why particular causes have been identified in the aftermath of an adverse event or near miss incident. They can act as a focus of subsequent discussion and can help to direct resources to improve areas where previous management activities have proven to be less than adequate.

Branch in Mort Tree	Node of MORT Tree	Incident description
Risk Assessment Less Than Adequate	Hazard	Electrophysiology procedure performed on wrong patient.
	Target	The patient who received the treatment and the patient who should have received it but did not.
Hazard Analysis Less Than Adequate	Control Operability Problems	Failure to identify potential confusion caused by lack of cross referencing between two patient record systems.

Table 8: Documenting the Products of a MORT Analysis

As mentioned, MORT is a generic technique intended to help identify management problems across many different industries. It lacks the technical details necessary for example to distinguish some of the more detailed problems that can arise in healthcare. In particular, it seems ill suited to consider the technical causes of adverse events and their interaction with, for example, failures in teamwork across departmental boundaries. There are several other flow-chart techniques that arguably avoid some of these problems because they have been tailored to particular domains.

PRISMA

The PRISMA technique is similar to some of the event-based approaches in that it consists of a reconstruction phase and an analysis phase. The initial reconstructions develop accident fault trees similar to that seen previously in this chapter (van der Schaaf, 1992). The leaf or terminal nodes on the tree are then classified to identify more generic root causes. This is important because a number of different incidents could yield very different trees. For instance, one might address the communications issues that led to confusion over a particular patient as in our case study. Another subsequent incident within the same hospital might, in contrast, yield an accident tree with nodes describing an drug misadministration. By classifying each of these different nodes it may be possible to identify common causes, for instance involving staff reduction, that led to both of these apparently different adverse events. A flow chart is, therefore, used to provide a higher-level classification of these more detailed causes. The use of this flow chart not only enables investigators to identify common causes between different incidents. It can also encourage a consistent analysis of individual mishaps. Investigators may disagree about the detailed causes of an adverse event but may exhibit greater agreement about the higher-level classification.

Unlike some of the other methods reviewed in this chapter, PRISMA has been trialled and tailored for use in the healthcare industries. For instance, Figure 9 presents a flow chart that was developed for use within the UK NHS and the Netherlands' healthcare systems. As can be seen, each terminal node is associated with a particular abbreviation such as OK for an organisational factor related to the transfer of knowledge, this might be applied in our case study to explain the problems in cross referencing patient names between telemetry, oncology and electrophysiology. It is also extremely important to stress that the ordering of terminal nodes can bias the insights obtained from any causal analysis. In Figure 9, organisational issues appear before technical factors and human behaviour. It is therefore more likely that analysis will identify organisational issues before considering these other potential classes of causal factors. When PRISMA was adapted for the process industries the ordering was altered so that technical issues were considered first to reflect the relative priorities of safety managers in these different industries. A further difference between figure 9 and other variants of the PRISMA flow chart is that it includes 'patient related factors' as a potential cause in healthcare incidents.

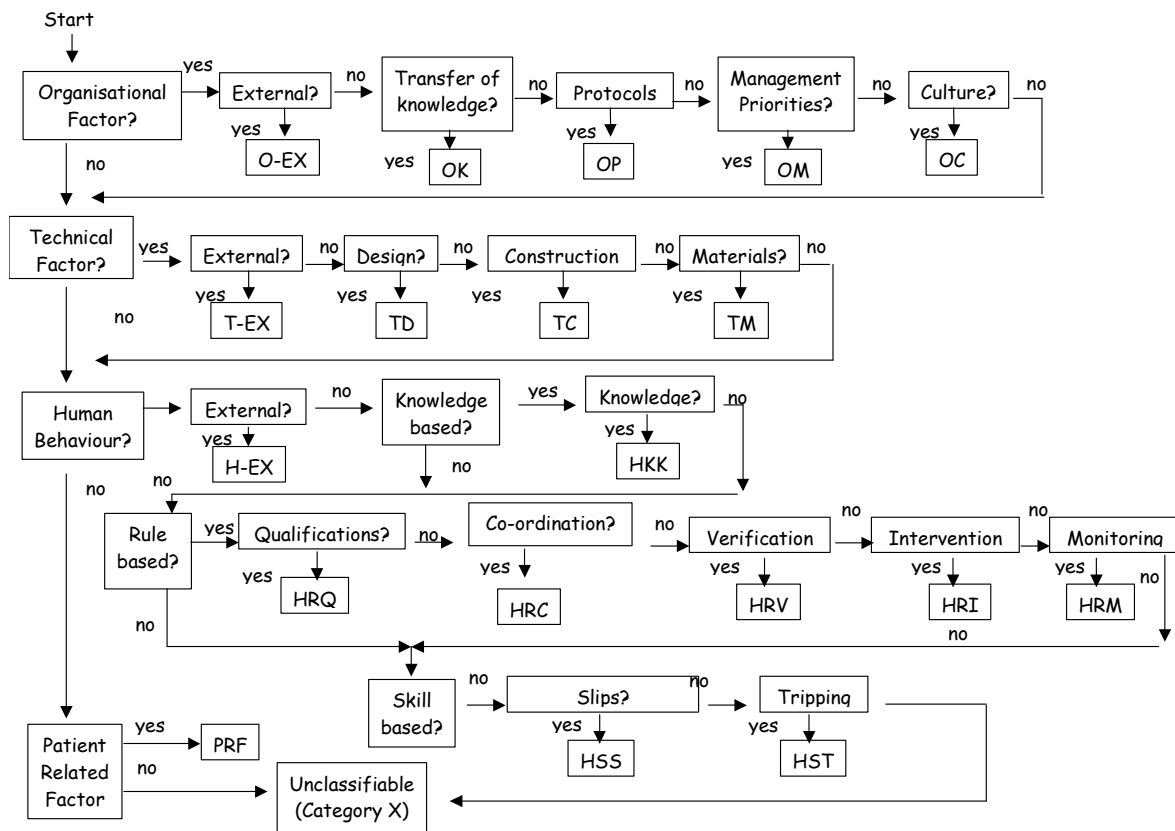


Figure 9: PRISMA Flow Chart (van der Schaaf, 1992, van Vuuren, 1998)

	External Factors (O-EX)	Knowledge Transfer (OK)	Operating procedures (OP)	Manag. priorities (OM)	Culture (OC)
Inter-departmental communication	X				
Training and coaching		X			
Procedures and protocols			X		
Bottom-up communication				X	
Maximise reflexivity					X

Table 9: Example PRISMA Classification/Action Matrix Van Vuuren (1998)

It is important that recommendations can be derived from the findings of an investigation. This can create problems. Even if a PRISMA flowchart can help to ensure that different investigators agree on the high-level causes of an adverse event there is no guarantee that they will agree on potential interventions to avoid future incidents. PRISMA, therefore, uses the output from the flowchart to direct the process of identifying recommendations. Table 9 illustrates a classification action matrix. This shows that if, for example, an incident were due to problems with management priorities then subsequent recommendations might focus more on ‘bottom-up communication’. This is intended to ensure that investigators offer a common response to incidents with similar causal factors. If incidents continue to recur with the same set of causal factors then safety managers might decide to revise the interventions advocated in Table 9. In practice, however, it is likely that the elements in Table 9 would have to be revised and carefully monitored. For instance, additional details must be provided in order to improve ‘bottom-up communication’. In terms of our case study, this might involve changes in the procedures by which staff confirm the patient’s identity during shift handovers or between clinical and nursing staff. Measures that are intended to improve ‘bottom-up communication’ must in turn be assessed to determine whether they are having the outcome intended by the rows in Table 9.

3.4 Accident Models

Many of the previous techniques assume that investigators can produce complex representations, such as accident fault trees or timeline event models, of the adverse events that are reported to them. This assumption may not be justified. For instance, it can be difficult to determine when an accident begins or ends. Our case study could begin when the patient was delivered to the electrophysiology lab, it could equally well begin when the transfer request was made to the telemetry unit, when the two patients were first admitted or even when the consent procedures were introduced into the hospital. Similarly, it could end when the procedure was started or if we are to consider mitigating actions it might also consider the chain of events that led to the error being detected. Similarly, it can be difficult to determine the level of detail to be included in any analysis. In some incident investigations, it is necessary to examine the exact verbal protocols used during shift transitions and the transfer of patients. In our case study, investigators might focus on the ambiguity in the request that was first made by the

nurses on the electrophysiology ward to the nurses in the telemetry unit. In other incidents, it may only be necessary to consider higher-level communications between individual working groups rather than the actual words and phrases that were used. Accident models can help to address some of these problems. In contrast to event-based approaches and flowchart techniques, ‘accident models’ provide strong guidance about what causes an adverse event. They enforce a particular viewpoint on the analytical process.

TRIPOD

The Tripod technique builds on a number of ‘general failure types’ that are assumed to cause the majority of adverse events. These generic causes include failures in: Hardware; Maintenance management; Design; Operating procedures; Error-enforcing conditions; Housekeeping; Incompatible goals; Communication; Organisation; Training; Defence planning. There are strong similarities between these general failure types and some of the concepts that are embedded in the techniques of previous sections. For instance, the failures in defence planning that are identified by Tripod are similar to the inadequate defences that are identified in Barrier Analysis. Similarly, operating procedures are considered within the PRISMA flowchart and are included in Tripod. However, some general failure types are not explicitly considered by the other techniques that we have introduced. These include maintenance management. Conversely, it can be argued that additional general failure types should be introduced into Tripod. In particular, it seems odd that hardware should be considered as a cause but not software.

Figure 10 illustrates the graphical model that Tripod provides to represent the way in which general failure types combine to create the conditions for an adverse event. As can be seen, Tripod uses many of the concepts that were introduced as part of Barrier Analysis. Defences fail to protect a target from a hazard. In our case study, there is a danger that cardiac electrophysiology procedures will be performed on the wrong patient. This hazard threatens both the patient on which the procedure is performed and the intended recipient who inadvertently missed their operation. In this case, the defences included hand-over procedures that are intended to establish patient identity prior to a transfer and the requirement for informed consent to be obtained prior to any procedure being performed. It is possible to identify a number of other barriers that failed in this incident, including the need to establish patient identity before the procedure is performed, however these are omitted for the sake of brevity and could be included in any subsequent analysis. Active failures are associated with each of the defences that did not protect the target. They are made more likely by a number of preconditions. For instance, the reliance on patient surnames was made more likely by a divergence from recommended practices and procedures. This precondition was, in turn, satisfied by a latent failure in terms of the time pressures that affected transfers between shifts. As with flow chart techniques the intention is to move away from the specific events that led to a mishap so that greater attention is paid to the generic or systemic failures that are likely to threaten future operation. It is unlikely that an identical failure will recur in the immediate future. Most safety-critical organisations can ensure that recommendations are put in place to prevent a pattern of identical failures. However, other similar

problems, for instance to do with limited time at shift handovers, may manifest themselves in future incidents unless these latent causes are addressed.

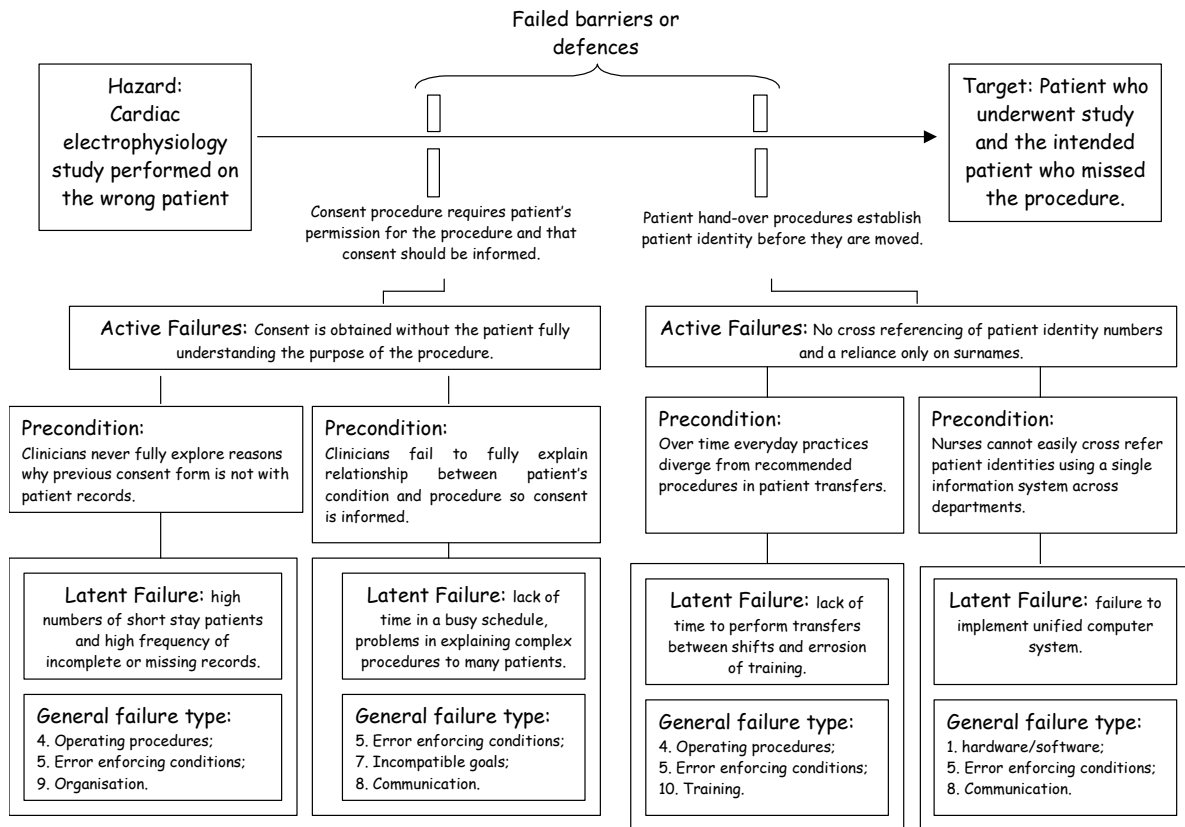


Figure 10: Example Application of a TRIPOD General Failure Types

TRIPOD builds on concepts from barrier analysis to develop a general model of how accidents occur. This model links general failure types, latent causes, preconditions and active failures to enable analysts to trace back from immediate events to the underlying causes of a mishap. A range of computer-based tools can also be recruited to support the application of this approach (Hudson, Reason, Wagenaar, Bentley, Primrose and Visser, 1994). Such support is critical because it can help to reduce the administrative costs associated with each analysis. It can be a non-trivial task to construct TRIPOD diagrams for relatively complex incidents. Tool support can be used to automatically perform certain consistency checks. It is also often possible to search for incidents that stem from similar patterns of active and latent failure (Johnson, 2003).

STAMP

The Systems Theory Accident Modelling and Process (STAMP) provides less supporting infrastructure than TRIPOD. It avoids any strong assumptions about the relationship

between latent and active failures or between barriers and hazards. Instead, STAMP exploits elements of control theory to help identify causal factors (Leveson, 2002). The motivations for using control theory resemble some of the arguments behind barrier analysis. Control theory is used because mishaps occur when external disturbances are inadequately controlled. Adverse events can also arise when failures go undetected or when the individuals that might respond to such a failure are unsuccessful in their attempts to control any adverse consequences. STAMP can be distinguished from more general techniques, such as accident fault trees, because it develops a particular view of adverse events in terms of ‘dysfunctional interactions’ between system components. These can arise if, for example, one subsystem embodies inappropriate assumptions about another process component. In our case study, the electrophysiology nurse might have assumed that the telemetry unit would double-check the identity of the patient being recalled from the oncology unit. Similarly, the neurosurgery resident assumed that another member of her care team had ordered the electrophysiology procedure for the cerebral angiography patient and that he had not been informed. This view of incidents as the product of suboptimal interactions is based on the argument that previous analysis techniques have been too narrowly focussed on event-based models. In contrast, STAMP focuses on relationships and the constraints that hold between system components. Safety is, therefore a dynamic property because the degree to which a system satisfies any constraints will evolve over time. For example, the interventional radiologist assumed that he would have been informed of any additional treatment for his patient. Unlike the neurosurgeon he was anxious to determine why this usual ‘constraint’ had been violated with the decision to conduct the electrophysiology procedure.

STAMP analysis begins by developing a control model of the relationships between entities in the system. Figure 11 shows how arrows can be used to represent communication and control flows. The rectangles are entities, including people, systems and organizations; they do not represent the events shown in the Failure Event Tree of Figure 7. As can be seen from Figure 11, the STAMP control analysis extends from individual staff members, such as the Electrophysiology Staff Nurse, and the systems under their immediate control, including the Electrophysiology Computer Systems, to also consider the relationships between units. These different relationships must be captured in any analysis because they have a profound influence on the operation of safety-critical systems. However, this is a partial diagram. Most previous examples of the STAMP technique would extend the diagram to consider higher levels of management. The scope of this analysis, typically, would also include the role played by governmental and regulatory agencies. This might cover, for instance, the manner in which procedures for informed consent were specified and monitored to ensure both conformance and quality control. These relationships are missing from the STAMP analysis because Chassin and Becher only consider these issues in passing. They provide few details that would be sufficient for any extended investigation of the higher-levels of control within hospital management. This information could, of course, be added as part of a more sustained analysis of the circumstances surrounding this and similar mishaps.

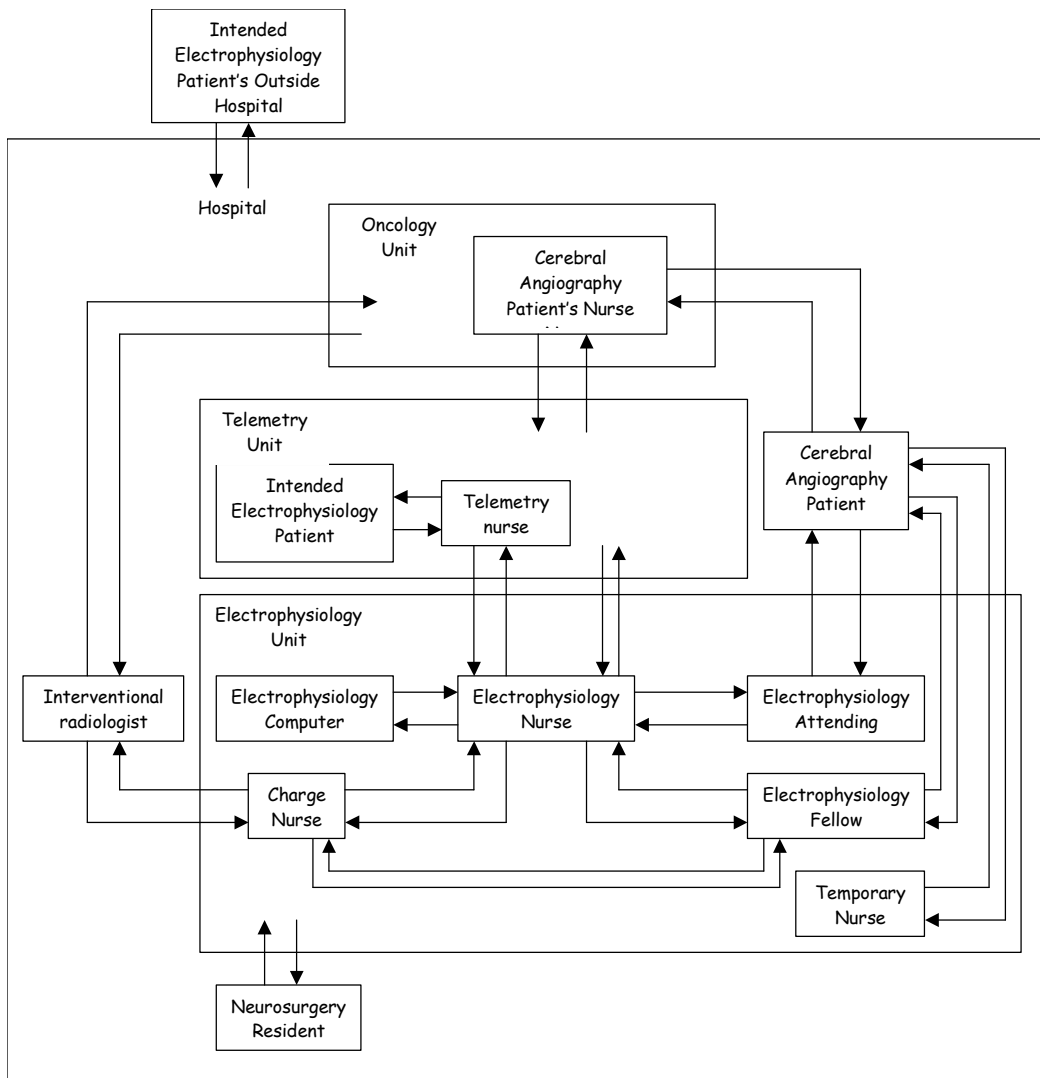


Figure 11: Control Model of the Example Case Study from a STAMP Analysis

Figure 11 traces the control and communication flows that led to the adverse event in our case study. As can be seen, information was widely distributed across several departments and between a number of key individuals. In particular, the diagram makes clear that the cerebral angiography patient was faced with a succession of clinical staff as they questioned the decision to undergo the electrophysiology procedure. This diagram also illustrates how the interventional radiologists decision to pursue the missing patient from one department to the next finally led to the discovery of the mishap. After having conducted the extended form of control analysis illustrated in this diagram, the STAMP technique considers each of the control loops that are identified in the ‘socio-technical system’. Potential mishaps stem from missing or inadequate constraints or from the inadequate enforcement of a constraint that contributed to its violation. Table 10 illustrates the general classification scheme that guides this form of analysis. It helps to identify potential causal factors in the control loops that exist at different levels of the

management and operation hierarchy characterized using diagrams similar to that shown in Figure 11.

1. Inadequate Enforcements of Constraints (Control Actions)

1.1 Unidentified hazards

1.2 Inappropriate, ineffective or missing control actions for identified hazards

1.2.1 Design of control algorithm (process) does not enforce constraints

- Flaws in creation process
- Process changes without appropriate change in control algorithm (asynchronous evolution)
- Incorrect modification or adaptation.

1.2.2 Process models inconsistent, incomplete or incorrect (lack of linkup)

- Flaws in creation process
- Flaws in updating process (asynchronous evolution)
- Time lags and measurement inaccuracies not accounted for

1.2.3 Inadequate coordination among controllers and decision makers

2 Inadequate Execution of Control Action

2.1 Communication flaw

2.2 Inadequate actuator operation

2.3 Time lag

3. Inadequate or Missing Feedback

3.1 Not provided in system design

3.2 Communication flow

3.3 Time lag

3.4 Inadequate sensor operation (incorrect or no information provided)

Table 10: Control Flaws leading to Hazards (Leveson, 2002)

STAMP is similar to other techniques, such as Failure Event Tree Analysis and PRISMA, because it also uses a second stage of analysis to identify the potential causes of adverse events. In this case, each of the arrows in the control model is examined to determine whether any of the flaws in Table 10 can be identified in the relationships that they represent. It might be argued that there were unidentified hazards in the control loop between the Electrophysiology Computer and the Electrophysiology Nurse. Similarly, subsequent investigation might identify flaws in the creation process that led to the computer systems presentation of patient information. Subsequent analysis might also identify communication flaws in the passage of information between the electrophysiology nurse, unnamed individuals in the telemetry unit and the original nurse for the angiography patient. As mentioned, this second stage of analysis is similar to several other techniques. For example, both PRISMA and MORT rely upon taxonomies of general causal factors that have some similarities to the control flaws used to guide a STAMP analysis. The list of potential problems helps investigators to focus their analysis.

3.5 Argumentation Techniques

The previous sections in this chapter have reviewed a range of different causal analysis techniques. Barrier and Change Analysis can be used to determine why an incident occurred by looking at the differences between what happened actually did happen and what should have happened according to previous practices and procedures. Event based techniques provide general modelling tools that can be used with secondary forms of analysis, such as counterfactual arguments, to distinguish root causes from contributory factors. Flow charts and accident models provide additional guidance to analysts by restricting the way in which an incident is represented and the causes are identified. They often make strong assumptions about the ways in which safety constraints are violated during adverse events. All of these different approaches can be used to support arguments about the causes of an incident. For instance, Barrier Analysis can be used to show how safety measures failed to prevent a hazard from threatening a target. STAMP control models can be used to argue that there were problems in the relationships between systems, operators and management organisations. Few of these techniques provide explicit support for the development of causal arguments. This is an important issue because rhetorical techniques can be used to bias the findings that are derived from any causal analysis (Johnson, 2003). It is perfectly possible to develop a partial Failure Event Tree or PRISMA model to show that individual human error is the root cause of an adverse event even if managerial and organisational issues created the necessary preconditions for that failure. In contrast, a small number of alternate analysis techniques explicitly consider the structure of arguments that are made about the causes of incidents and accidents.

WBA

Why-Because Analysis begins like many other causal analysis techniques by developing a time-line (Ladkin and Loer, 1998). Angled arrows are used to denote the sequence of events leading to an incident. For example, Figure 12 uses one of these arrows to denote that the Cerebral Angiography patient arrives in the Electrophysiology unit before the nurse identified that there was no consent on the patient's records. It is important to stress, however, that this 'occurs before' relationship does not imply causation. We cannot in this early stage of the analysis say that the arrival of the patient actually triggered the nurse's observations about the consent form. In order to make this argument we must demonstrate that we have identified sufficient causes for an 'effect' to occur. For example, there may have been other factors including pre-existing procedures that motivated the nurse to check for the consent documents in the patient record. A more sustained causal analysis must consider these additional issues in order to fully explain the reasons why each event occurred.

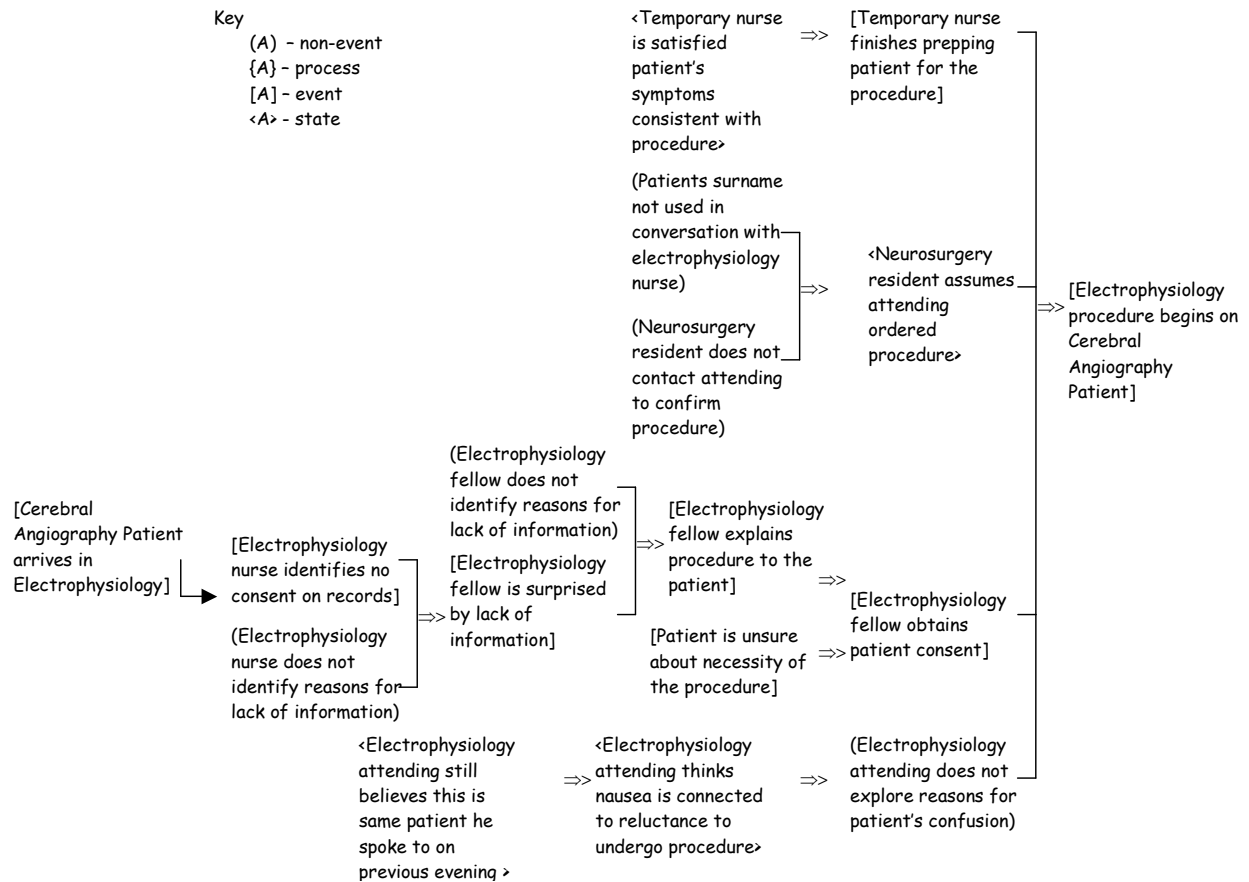


Figure 12: Example WBA Diagram

Figure 12 shows the results of applying a further stage of analysis to an initial WBA time-line. Each node in an initial diagram is considered in turn. Analysts must ask ‘why did this happen’. Each reason or cause is then added to the diagram and denoted using double headed arrows, =>. This transition from temporal sequences to more rigid causal relationships produces insights that are not apparent in purely event-based approaches, such as timelines. For example, Figure 12 arguably provides amore explicit representation of the non-events or omissions that led to the case study. These include the failure to use the patient’s surname, the resident’s failure to confirm the attending physician’s decision to order the electrophysiology procedure and so on. Figure 12 also illustrates that the Electrophysiology procedure begins because the neurosurgery resident assumed that the attending ordered the procedure and the temporary nurse prepared the patient for the procedure and the fellow obtained consent and the attending did not explore the reasons for the patient confusion over the procedure. If we explore one of these causal arguments back, we can find that the attending did not explore the patient’s confusion because they believe that this is part of a reluctance to undergo the procedure.

WBA provides a set of mathematically based procedures that analysts must follow in order to replace the angled arrows of a temporal sequence with the double headed arrows of the causal relationship. They are based on counterfactual arguments of the form ‘A

causes B' if we know that A and B occurred and that if A had not occurred then B would not have occurred. However, analysts must explicitly consider the level of formality that is appropriate to their needs. It would not be cost effective to conduct this form of mathematical modelling for many of the 'slips, trips and falls' that characterise the majority of adverse events in healthcare. Investigators must, typically, choose between restricting their analysis to the more accessible aspects of the informal graphical reasoning, based on Figure 12, and more complete forms of WBA involving the use of discrete mathematics. It remains an open question as to whether the additional assurance provided by the formal reasoning would ever justify the additional costs in analysing adverse healthcare events using this approach.

CAE Diagrams

It is important that the output from any causal analysis should inform the identification of appropriate recommendations. Analysts must help risk managers to reduce the likelihood of future failures or to mitigate their consequences. Table 11 presents a simple tabular form that can be used to associate root causes with potential recommendations. For instance, a recommendation introduce new verbal protocols governing patient transfers is supported by the argument that informal practices and procedures create the opportunity for confusion over patient identity. There is evidence to support this argument from the manner in which only surnames were used between the telemetry and electrophysiology departments during the initial transfer and by the neurosurgery resident when they checked on the location of the original patient.

Conclusion/Recommendation	Root Cause (Analysis)	Supporting Evidence
C1. Introduce verbal protocols governing patient transfers.	A1.1 informal practices and procedures can create the opportunity for confusion over patient identity.	E.1.1.1 Only patient surnames were used between telemetry and electrophysiology departments during initial transfer. E.1.1.2 Patient surnames were also used by neurosurgery resident in checking location of original patient.
C2. Introduce hospital wide computer system to support cross-referencing of patient transfers.	A2.1 Separate systems create considerable risk of confusion.	E2.1 Witness statements. E2.2 Previous incidents involving confusion between hospital and unit specific systems.

Table 11: General Format for a Recommendation Table

It can, however, be difficult to construct such tables for complex incidents. There may be many hundreds of items of evidence in complex failures. Similarly, can be competing arguments that undermine particular recommendations. For instance, any decision to introduce a hospital wide computer system for cross-referencing patient identities might force major changes in the existing infrastructure. These changes could introduce further problems and may undermine the autonomy of individual units who tailor their computational support for their particular requirements. Conclusion, Analysis and Evidence (CAE) diagrams can help designers to map out the competing arguments for and against particular conclusions or recommendations in the aftermath of a complex incident. These diagrams are simpler than many of the techniques we have described (Johnson, 2002). CAE provides a graphical representation with less strict rules on how to conduct the analysis. This arguably reduces the costs and increases the flexibility of the approach.

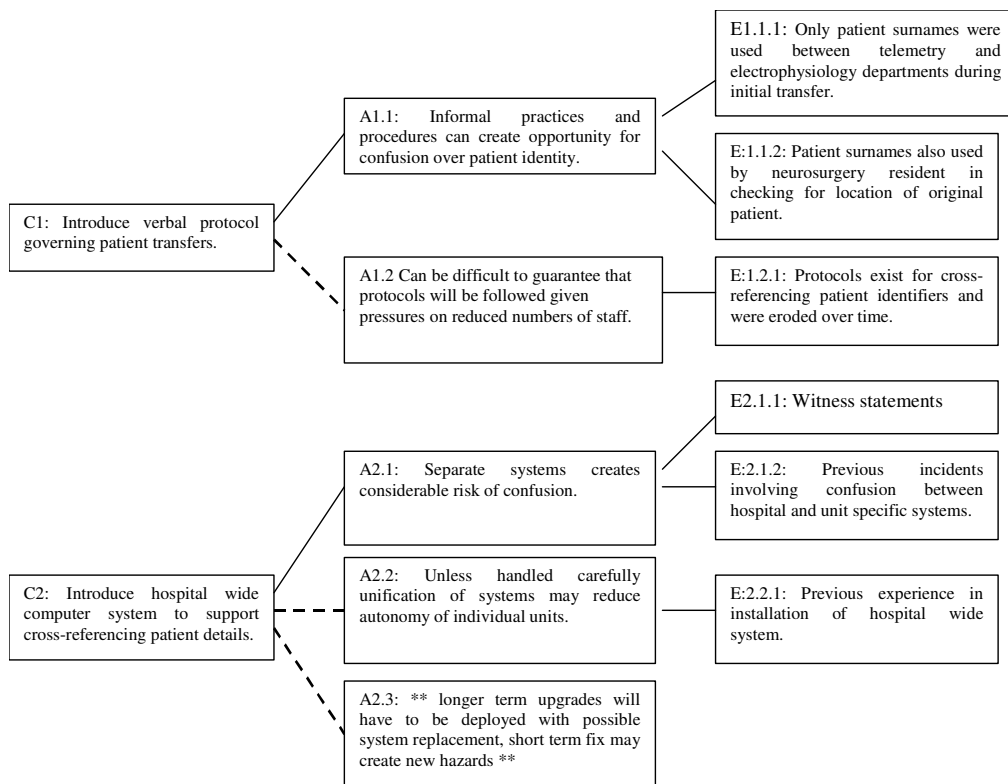


Figure 13: Example of a CAE Diagram

Figure 13 illustrates a Conclusion, Analysis and Evidence (CAE) network. As the name suggests, the rectangles labeled with a C are used to denote conclusions or recommendations, those labeled with an A are lines of analysis while the E rectangles denote evidence. Lines are drawn to show those lines of analysis that support particular conclusions.

For example, the recommendation to introduce verbal protocols governing patient transfers (C.1) is supported by the argument informal practices and procedures create the

opportunity for confusion over patient identity (A1.1). The evidence for this assertion is provided by the manner in which surnames only were used in the initial patient transfer (E.1.1.1) and by the neurosurgery resident's initial attempts to locate the original patient (E.1.1.2). Figure 13 also captures contradictory arguments. For instance, the dotted line in the first of the networks denotes that the introduction of protocols recommended in C.1 cannot guarantee staff will followed them under their everyday pressure of work (A.1.2). Evidence for this is provided by the manner in which the effectiveness of existing protocols had been eroded over time (E1.2.1).

The lower of the two networks in Figure 13 illustrates the argument that a hospital-wide computer system should be introduced to help cross-reference patient details (C2). This recommendation is based on the observation that separate systems create considerable risk of confusion between different units (A2.1). This argument is based on evidence of witness statements (E.2.1.1) and on evidence from previous incidents involving the transfer of information between hospital and local systems (E.2.1.2). The recommendation to introduce a unified computer system is weakened by an argument that it may compromise the independence of individual units (A.2.2) given previous experience from centralised hospital systems (E.2.2.1). It is also weakened by the introduction of further hazards from the short-term expedients that must support the longer-term development of a more unified system (A.2.3). As can be seen from Figure 13, CAE diagrams capture general arguments about incidents and accidents. For example, a conclusion might refer to a recommended action rather than a causal relationship. It is also important to mention that this technique was specifically developed to enable investigators to sketch out the arguments that might appear in an incident report. This helps to ensure that any document avoids contradictory arguments prior to the publication of a report.

4. Recommendations and Monitoring

The previous section argued that the output from causal analysis techniques must help to identify the recommendations that will reduce the likelihood or consequences of any recurrence. Unfortunately, there has been relatively little research or even applied methods that can be used to generate recommendations from the products of a causal analysis (Johnson, 2003). Most of the available techniques, such as the tabular forms and diagrams shown in the previous section, can be criticised for being very simplistic. However, it is critical that there be some documented justification that links proposed interventions to the identified causal factors. If this link cannot be established then there is a danger that managers will fund changes that do not address the underlying problems or that even exacerbate any previous safety threats. The need to justify and document proposed recommendations is particularly important given that there is a traditional separation between the teams who derive recommendations from a causal analysis and those who must choose to implement them. For instance, the NTSB can propose regulatory changes that must then be implemented by the FAA. Similarly, the UK Health and Safety Executive might propose changes to the particular government departments dealing with energy production. There are good reasons why different people make and accept recommendations. For example, if the same individual is responsible for making recommendations and funding them then they may choose not to propose interventions

that cannot be funded in the short term. It is often better for safety managers to make recommendations independent of whether or not they can be funded from immediate resources. From this it follows that particular attention must be paid to documenting the reasons why a causal analysis has identified particular recommendations. Without such a motivation then it will be difficult for managers outside of an investigation to understand why funds should be spent on necessary improvements,

A number of more prosaic problems can affect the implementation of recommendations in the aftermath of healthcare incidents. It can be difficult for managers to obtain independent or expert advice about particular recommendations, for example involving human factors issues. Similarly, it can be difficult to obtain the funds that are necessary to implement longer-term changes. This creates a cycle in which the limited scope of potential recommendations can influence the course of any causal analysis. There can be a tendency to blame incidents on inadequate attention or on poor staff performance because relatively cheap remedies can be found. For example, a local reporting system identified a class of incidents in which the staff had failed to realign the taps that are used to control the flow of medication to a patient when bags are being changed. It was, therefore, recommended that acronyms be used to remind staff to perform particular actions. TAP stood for Tap Aligned Properly (Johnson, 2003). Such advice provides short-term protection against certain classes of adverse events. However, their effectiveness declines rapidly over time. It can also be difficult to ensure that new staff are taught to use these reminders. A subsequent study of many of the incidents that helped to generate these acronyms revealed that they were often 'work arounds' that were intended to support the use of poorly designed or faulty equipment.

Such examples illustrate the importance of linking incident reporting into the wider risk assessment practices that are being introduced into healthcare. The decision whether or not to fund a recommendation will partly be made on the perception of risk associated with any recurrence of an adverse event. It is also important to monitor the success or failure of a recommendation. If it is ineffective and an adverse event continues to recur then additional measures will be necessary. The human factors issues here relate to the reliance on short-term fixes and coping strategies in health care. As the previous example shows, many organisations respond to incidents by reminding staff to do better. This 'perfective' approach often fails to secure the longer-term safety of a system because training cannot easily sustain long-term changes in behaviour unless it is repeated and invested in over similar periods of time.

The Agency for Healthcare Research and Quality's Review of patient safety practices includes a chapter on root cause analysis (Wald and Shojania, 2001). Unlike the analysis in this document, the AHRQ report focuses less on explaining root cause analysis techniques and more on a critical assessment of the costs and benefits of incident analysis in general. It is argued that "there is little published literature that systematically evaluates the impact of formal RCA on error rates". They do, however, present the results of a study in a tertiary referral hospital in Texas that applied root cause analysis to all adverse drug events over a 19-month trial. This study reported a 45% decrease in the rate of voluntarily reported serious incidents between the 12 month study interval and a

19 month follow-up period (7.2 per 100,000 to 4.0 per 100,000 patient-days, $p < 0.001$). The authors of the study argued that a 'blame-free' environment helped senior management to focus on the underlying causes of these incidents. Procedures were revised and changes were made in organisational policies including staffing levels. As we have seen in previous chapters, the decline in reporting does not, however, guarantee any related decline in adverse events. It may reflect a decline in reporting behaviour as staff become disillusioned with the system. There is also a common phenomena known as the 'confessional period' in which reporting systems will initially elicit very high levels of participation as staff use these schemes to contribute information about long-standing concerns (Johnson, 2003). Hence, it is to be expected that contribution rates would decline after this initial uptake. The AHRQ analysis argued that the results of the Texas study are 'unclear'. In particular, it was suggested that 'as the study followed a highly publicized, fatal adverse drug event at the hospital, other cultural or systems changes may have contributed to the measured effect'. Further caveats related to the absence of any control group and to the lack of any longer term data on adverse drug events from the hospital. Finally, there was no attempt to determine the precise benefits that a formal root cause analysis might provide over less formal analysis.

A similar study reported in the British Medical Journal looked at the reasons why clinicians change their practice (Allery et al, 1997). A random sample of 50 consultants and 50 general practitioners were interviewed about key events that had caused them to revise their practice. The sample yielded 361 changes in clinical practice. These included major organisational changes, such as setting up an asthma clinic. They also included more specific changes in clinical practice, such as the decision to change from cefotaxime to cefuroxime for chest infections. The interviews probed for the reasons behind these changes. This yielded an average of 3 justifications per change. Of these, the most frequently mentioned reasons were organisational factors, education, and contact with professionals. These justifications accounted for 47.9% of the total number of reasons for change. Education accounted for 16.9% and was involved in 37.1% of the changes. This was defined to include 'reading medical journals, attending an organised educational event, participation in research and audit, and the provision of clinical guidelines'. Neither root cause analysis nor incident reporting were included amongst the list of twelve factors that were used to classify the results. The findings from such studies only had an indirect influence on clinical change through, for example, the education activities mentioned above. This provides another reminder that root cause analysis is a limited tool. It guides the recommendations that help to prevent any future recurrence. However, the lessons learned within particular clinical organisations will be of little benefit unless they are disseminated and acted upon. Studies such as that conducted by Allery et al, help to identify the most effective mechanisms for change in healthcare.

5. Conclusions

This chapter has introduced root cause analysis within the context of healthcare related incidents. The opening sections presented information about the distribution of causal factors that have been identified in a number of previous studies. In particular, we distinguished between primary or catalytic causes and secondary or latent failures.

Primary causes describe immediate failures that trigger an adverse event, such as individual human error. Secondary failures include the conditions that make these primary incidents more likely, these often stem from managerial and organisation factors such as changes in staffing levels.

Many previous reporting systems used informal and qualitative causal analysis techniques. This can create problems of individual and organisational bias. We have termed such problems tertiary failures. Rather than affecting the immediate operation of a healthcare system or the factors that contribute to an incident, these problems can impair effective learning from an adverse event. It can also be important to document the process that was used to identify particular causes and contributory factors. Subsequent sections, therefore, introduced a range of techniques for root cause analysis. These included elicitation approaches such as Barrier and Change Analysis. Such methods can be used to compare what happened in an adverse event with what should have happened according to previous practice and procedures. These techniques can also assist in the elicitation of information after an incident because they encourage investigators to determine both what did happen and what should have happened.

A second class of analysis techniques support incident reconstruction. For instance, timelines can be used to map out the sequence of events leading to an incident. This approach has important limitations. It can be difficult to represent the many subtle constraints that make particular events more likely. Organisational factors can affect many different individual actions and it is unclear how to represent this influence on a timeline. A number of other techniques, such as accident fault trees, suffer from similar limitations. Fortunately, there is a range of causal analysis techniques that provide means of representing these factors within a reconstruction. In particular, we have shown how Failure Event Trees can be applied to represent and reason about an example health care incident. Many of these techniques use a second stage of analysis based on counterfactual reasoning to distinguish root causes from contributory factors. Analysts must ask for each event whether an incident would still have occurred if the event had not occurred. If the incident would have happened anyway then that cause was not necessary for the accident to occur and so cannot be a root cause.

Most reconstruction techniques can be applied to analyse a wide range of different adverse events. This flexibility can create problems. In particular, there are few guarantees that different analysts will reach the same conclusions about the same incident. Flow chart techniques help to encourage consistency by guiding analysts to reach a limited number of conclusions about the causes of an adverse event. In particular, we presented the MORT and PRISMA techniques. MORT provides a general scheme for the analysis of management related incidents, focussing on risk assessment. PRISMA has been specifically tailored to support the analysis of healthcare related incidents. These techniques provide pragmatic tools for causal analysis but can still suffer from particular forms of bias. For example, analysts often tend to focus around the initial stages in any flowchart. Additional effort and concentration is required to pursue the causes of an incident through the details of embedded branches in the tree of options that these techniques present.

Flow charts and reconstruction techniques make minimal assumptions about the nature of adverse events. In contrast, accident-modelling techniques embody particular ideas about the manner in which accidents are caused. For instance, the TRIPOD method insists that analysts trace the way in which barriers fail to protect a target from a hazard. In addition, the preconditions for the failure of any barrier must be tied back to a limited number of General Failure Types. Similarly, STAMP models adverse events using control theory. Failures stem from the violation of constraints that are intended to hold between different agents in a control model. These agents can be human operators, electromechanical systems and even management structures.

One problem with all of these techniques is that it can be difficult to ensure that the output of a causal analysis informs the recommendations that are made in the aftermath of an adverse event. The final sections of this chapter, therefore, introduced argumentation techniques for causal analysis. Why-Because Analysis and Conclusion, Analysis and Evidence diagrams look at the reasons why particular causal findings are made. These approaches also, therefore, help to document the reasons that support particular recommendations.

This chapter closed by arguing that causal analysis is not an end in itself. It is important to monitor whether the findings from any investigation are having any impact on the patient care. This is a notoriously difficult problem; participation levels in a reporting system provide extremely ambiguous signals about the underlying incident rate. Root cause analysis will never yield 'zero incidents' and so questions must be asked about the cost effectiveness both of the recommendations that are produced and of the analysis that is performed to identify those recommendations. More generally, the identification of a root cause and the development of a subsequent recommendation do not guarantee that appropriate changes will be made in clinical practice.

6. References

L. A. Allery, P.A. Owen and M.R. Robling, Why general practitioners and consultants change their clinical practice: a critical incident study, *British Medical Journal*, 1997;314:870.

American Medical Association, Ethical Guidance Statement E8.08, 2004. Available from <http://www.ama-assn.org/ama/noindex/category/11760.html>

D.K. Busse and C.W. Johnson. Human error in an intensive care unit: A cognitive analysis of critical incidents. In J. Dixon, editor, *Proceedings of the 17th International Systems Safety Conference*, pages 138 -147, Unionville, Virginia, United States of America, 1999. The Systems Safety Society.

R.M.J. Byrne and A. Tasso. Deductive reasoning with factual, possible and counterfactual conditionals. *Memory and Cognition*, pages 726-740, 1999.

M.R. Chassin and E.C. Becher, The Wrong patient. *Annals of Internal Medicine* 2002. 136:826-833. Available at: <http://www.annals.org/issues/v136n11/full/200206040-00012.html>

R.L. Helmreich and A.C. Merritt, *Culture at Work in Aviation and Medicine*, Ashgate Press, Brookfield, USA, 1998.

P. Hudson, J. Reason, W. Wagenaar, P. Bentley, M. Primrose, and J. Visser. Tripod-Delta: Pro-active approach to enhanced safety. *Journal of Petroleum Technology*, pages 58{62, 1994.

C.W. Johnson, *A Handbook of Incident and Accident Reporting*, Glasgow University Press, Glasgow, 2003. Available on <http://www.dcs.gla.ac.uk/~johnson/book>

W.G. Johnson. MORT the management oversight and risk tree analysis. Technical Report Technical Report SAN 8212, Atomic Energy Commission, Washington DC, USA, 1973.

P. Ladkin and K. Loer (1998), Why-Because Analysis: Formal Reasoning About Incidents, Bielefeld, Germany, Document RVS-Bk-98-01, Technischen Fakultät der Universität Bielefeld, Germany.

A.K. Lekberg. (1997), Different approaches to incident investigation: How the analyst makes a difference. In S. Smith and B. Lewis, editors, *Proceedings of the 15th International Systems Safety Conference*, pages 178-193, Unionville, VA, United States of America, 1997. Systems Safety Society.

N. Leveson, (2002), A Systems Model of Accidents. In J.H. Wiggins and S. Thomason (eds) *Proceedings of the 20th International System Safety Conference*, 476-486, International Systems Safety Society, Unionville, USA.

N. Leveson, A New Approach to Hazard Analysis. In G. Einarsson and R. Fletcher (eds.), *21st International Systems Safety Conference*, 498-507, 2003.

Louisiana State University Health Sciences, Patient Identification, Policy number: 5.10.1. 2003. Available from http://www.sh.lsuhs.edu/policies/policy_manuals_via_ms_word/hospital_policy/Patid.pdf

J.L Mackie, (1993), Causation and conditions. In E. Sosa and M. Tooley (eds.), *Causation and Conditions*, pages 33-56. Oxford University Press, Oxford, 1993.

J. Reason, *Managing the Risks of Organisational Accidents*, Ashgate Press, Brookfield, USA, 1997.

N.M. Steblay. A meta-analytic review of the weapon foccus effect. *Law and Human Behaviour*, pages 413-424, 1992.

US Joint Commission on Accreditation of Healthcare Organizations, Reporting of Medical/Health Care Errors: A Position Statement of the Joint Commission on Accreditation of Healthcare Organizations, 2004. Available on:
<http://www.jcaho.org/accredited+organizations/patient+safety/medical+errors+disclosure>

T.W. van der Schaaf. Near Miss Reporting in the Chemical Process Industry. PhD thesis, Technical University of Eindhoven, Eindhoven, The Netherlands, 1992

W. van Vuuren. Organisational Failure: An Exploratory Study in the Steel Industry and the Medical Domain. PhD thesis, Institute for Business Engineering and Technology Application, Technical University of Eindhoven, Eindhoven, The Netherlands, 2000.

M. Weick-Brady. Those codes! Food and Drug Administration: User Facility Reporting Bulletins, 1996. <http://www.fda.gov/cdrh/issue18.pdf>.

W.A. Wagenaar, Risk taking and accident causation. In J.F. Yates (Ed.) *Risk taking behavior*. Wiley, Chicester, 1992.

H. Wald and K.G. Shojania, Root Cause Analysis, Chapter 5. In K.G. Shojania, B. Duncan, K.McDonald, R. Wachter, (eds.) *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*. Evidence Report/Technology Assessment Number 43, Agency for Healthcare Research and Quality. 2001. Available from:
<http://www.ahrpr.gov/clinic/ptsafety/chap5.htm>