Chapter 7
Risk Management

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A ship in harbor is safe, but that is not what ships are built for
From Salt from My Attic
—by JA Shedd

Abstract Doctors are highly skilled at managing patients' clinical risks and consider these as part of everyday care. Many have also participated in clinical quality improvement processes, again aimed at reducing clinical risk. Yet when it comes to system level risk management, involvement by medical practitioners is much lower, and valuable insights can be missed. This chapter provides a practical example of a significant clinical risk in contemporary medicine and shows how formal risk management approaches can assist in reducing the risk of undetected patient deterioration due to alarm fatigue. It guides the reader through the core elements of risk management as described in the Australiana and New Zealand Standard, highlighting the importance of considering the context, through to identifying, applying and monitoring appropriate solutions.

Keywords Alarm fatigue · Analysis · Assess · Communication · Context · Evaluation · Governance · Hazard · Human factors · Identification · Improvement · Monitoring · Patient · Risk · Safety · Solutions · System · Team · Treatment

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Key Points

- Medical clinicians already have many risk management skills embedded in their clinical practice, even if they don't recognise this
- Risk management frameworks assist in prioritising risks, and help to differentiate between hazards which may have no impact in a particular setting, and those which do (risks)
- Formal risk management approaches are applicable to frontline health care and provide a structured approach to dealing with risks to patient safety
- Health care delivery is about people working with other people to help patients. All risks and approaches to manage these must be considered in context and must therefore must also consider human factors
- The only way in which sustainable effective improvements to the safety and quality of care can be made is by clinical staff, management and support services all working together to identify and manage risk.

For most clinicians, mention of risk management usually conjures up images of graphs prepared by specialised staff dissociated from the clinical frontline, for the purposes of committee discussions, unfavourable comparison with imposed benchmarks or worse still, the threat of legal claims. It is not perceived to be part of daily clinical practice. Yet most clinicians consider risks whenever they prescribe treatment for their patients. They inherently quantify and stratify these before determining whether to accept that risk or attempt to mitigate it. For example, the decision to withhold or reverse the effects of anticoagulants if a patient with a known cardiac history requires surgery involves a risk management approach. Organisations which adopt procedural guidelines to ensure this component of care is considered for each patient are demonstrating the same risk management strategy on a broader scale. They are aiming to reduce the effects of uncertainty (unknown/uncontrolled coagulopathy) on the objective of patient safety and best possible clinical outcomes.

Quantifying the overall level of risk associated with health care is the subject of ongoing debate [1, 2]. Amalberti describes that while there has been a lot of work "on identifying and reducing preventable events[and] important changes have already been made to the accident and incident reporting system, and the associated techniques of analysis, the upper limit of harm prevention is unclear". The risk of dying during health care may be as high as 1:1,000, compared with 1:1,000,000 in commercial aviation [3]. Attempts have also been made to quantify the cost of risks to patient safety, but this is not easy. Etchells et al were only able to identify evidence of improvements for five conditions/protocols, three of which related to healthcare associated infections [4].

This chapter aims to describe the principles and processes of risk management as it occurs in the public health organisational context and the similarities to management of clinical risk at the patient bedside.

What is Meant by Risk?

The Australian and New Zealand Risk Management Standard AS NZS ISO 31000-2009 Risk Management—Principles and Guidelines defines risk as *the effect of uncertainty on objectives.* Risk Management is defined as the architecture (principles, framework and process) to control risks effectively. Managing risk refers to applying that architecture to a particular risk [5].

Risk Management

Most risk management models are designed to assist the user in considering all relevant sources of information and contributors to risk within their organisation, such as incident reporting systems, patient complaints, audits and comparison with expected standards. As Vincent tells us, simply counting the number of reported incidents by type does little to inform us about the underlying risks within our systems [6]. We need to identify underlying causes for incidents, so that risks can be addressed at the most basic level. We need to understand the narrative [6]. The same applies to risk management.

Amalberti and Hourlier advise that "the risk run by patients [receiving acute health care] remains hard to assess" [7], primarily because the risks don't occur in isolation. For example the patient may have inherent risk factors (comorbidities) as well as the presenting problem and the risks associated with its treatment. There is also a continual trade-off between throughput and safety [8] in order to meet demand; conditions under which Williams states that staff are more likely to make errors or take short cuts in order to get the job done [9].

Principles of Risk Management

Risk management is about addressing uncertainty. It is a structured approach, intended to assist teams and organisations in achieving their goals, maintaining health and safety of all stakeholders, and the organisation's values and integrity. In the health context, it needs to be applied to patient and staff safety, as well as the structures and processes of the health care services provided by the organisation. To do this effectively, it must use the best available information, be embedded in organisational processes and used in decision-making processes at all levels of the organisation in a structured and timely way. Management decisions must be informed by frontline staff because they have intimate knowledge about risks and their impact. The processes by which decisions are made must be logical and transparent, so that the best solutions are implemented.

As with incident management, risk management must be tailored to the context of the organisation. It must consider the human and cultural factors associated with

each risk and how each may influence the strategies proposed to manage these. Risk management approaches should be proactive, to prevent harm or loss occurring, rather than just trying to prevent recurrence. Effective risk management needs to be dynamic, responsive to changes that occur in every health care setting over time. The general quality improvement cycle approach is just as applicable to risk management as it is to specific clinical projects.

Frameworks and Policies

Under the Australian and New Zealand Risk Management Standard ISO31000-2009 (10), organisations are expected to establish a framework for risk management, not just in relation to clinical or corporate incidents, but "enterprise-wide" [10]. Achieving this relies on engagement of those who have the authority, ability and will to set up and maintain the core elements of the framework. As Margaret Mead would tell us, this is best done by "a small group of … committed people" [11] with good leadership, and it involves:

- Defining and understanding the context (internal and external)
- Establishing governance, including allocation of resources and policy
- Communication, engagement and integration of the framework with existing systems
- Ongoing monitoring, review and improvement of the framework [10]

As discussed earlier, risk management should be embedded in all processes, policies and management practices. Communication and consultation must be ongoing, beginning with provision of mechanisms for input to identify and document risks (including incident and trigger reporting, patient feedback systems, audits, measurement against relevant standards). There should be no constraint or punishment associated with the reporting of risks. The core processes for identifying risks must include consideration of the internal and external contexts, and the risks associated with each, robust risk assessment processes (including identification, analysis, evaluation), treatment of the risk, followed by monitoring and review of the effect of risk treatment and any ongoing threat [10].

Considerations When Applying Risk Management Processes

"Most accidents are attributed to human error, but in almost all cases the human error was a direct result of poor design" [12]. James Reason, well known for his work on organisational accidents and human error, describes different types of risks requiring different responses. In his terms, latent risks are the conditions under which a worker operates [13, 14]. The more complex the task or organisation, the greater the likelihood that these will be imperfect or unstable, setting us up to make errors

[15]. We may fail to do something we intended to because we had to "work around" a barrier or make do with what was available. We may experience cognitive overload due to the amount of information presented to us, or be distracted by a noisy or busy environment, competing priorities or our own intruding thoughts.

The most effective risk management frameworks are those which recognise human factors, both strengths and weaknesses, "hazard and hero" [13]. The definition used by the Clinical Excellence Commission, NSW is derived from the Society for Human Factors and Ergonomics and the work of Canadian Professor Jan Davies. Human factors is about people's abilities, characteristics and limitations, their work environments, equipment interfaces, tasks, and their relationships with others [16].

In other high risk industries human factors have been recognised and managed in more structured ways. This does not always sit well with clinicians' perceptions of self-autonomy, intelligence and problem-solving abilities, the very qualities on which their careers are founded [3]. There are fundamental differences between the safety context in health care and most other industries, so even though the core components are the same, they need to be tailored to fit [17].

The findings of the public inquiry into the issues in the Mid Staffordshire NHS Foundation Trust, UK [18] show how the lack of leadership and management engagement with clinicians contributed to the breakdown of safe and effective care. This highlights the importance of ongoing efforts at all levels of the organisation in risk management.

Applying Risk Management Processes

Alarms in medical devices are intended to be a patient safety feature. The number of medical devices with alarms and the frequency with which they sound—up to 1200 times a day in a single ward [19]—is now recognised as a hazard. Alarm fatigue is a type of human error that occurs when a practitioner is desensitized to alarms and alerts [20–25]. A contemporary clinical hazard, the widespread use of medical devices with inbuilt alarms, is used to demonstrate how a risk management approach at organisational level could reduce the risk of harm for the patient, family, the staff involved, and the organisation.

The traditional corporate approach of regular audit or review processes, such as SWOT (strengths, weaknesses, opportunities and threats) analyses to identify hazards and risks are very beneficial in handling such issues. It is more common, however, for clinical risk management activities to stem from triggers, such as incident reports, investigation findings, review of literature or staff concerns. In this case, issues with alarms not sounding, not being heard or the frustration of false alarms may have been notified in the hospital's incident or complaint reporting system. Staff may also have heard about the issue from external sources. The Emergency Care Research Institute (ECRI) in the United States has been raising awareness about this issue for several years [26, 27]. It rated medical device alarms as the number one hazard for 2013, up from second place in 2011. Another US agency involved with health care quality and safety, produced a similar alert in April 2013 [28] as did the

Institute for Healthcare Improvement [29]. Numerous articles warning of problems with medical device alarms including alarm fatigue among staff, and the associated risk to patient safety have been published in the past ten years. The flow-on effects of responding to false alarms also warrants consideration, because the interruption itself may result in components care being missed. An Australian study found that 18% of tasks interrupted in an emergency department were never completed [30], posing further risk to patient safety.

There are clearly both extrinsic and intrinsic reasons to investigate the level of risk posed by this identified hazard. While it is a hospital-wide risk, it would be best to assess it initially by looking in depth at a single unit in the hospital where monitors are used frequently, e.g., an intensive care unit.

Understanding the Context

External Context First the team should consider the external context for this unit, remembering that risks may stem from legislative, operational, financial or resource frameworks in which health care organisations operate. These influences are often beyond the control of the organisation, but may have direct consequences on health service, such as nurse-to-patient ratios and medical training resources.

There is no standardisation of medical alarm tones. Suppliers continue to develop products with features based on their experience and market research to make them competitive rather than compatible with other manufacturers' products. Public health services are therefore likely to have contracts in place which enable purchase of medical devices intended for the same purpose from different suppliers, each with their own specific alarms tones or devices with the same alarm tones and different functions. Edgworthy's [25] research in other industries, about the way in which different tones are perceived, indicates that some alarms are easily ignored.

Another contextual layer to consider is how advances in the management of clinical conditions, introduction of new devices, and promotions by media can influence clinician practice and preferences. There are few organisational constraints to the adoption of new ideas, unless there is a significant cost or dissention among clinicians. This is very different from other high risk industries where there is a more structured organisational assessment before adopting any new practice. The length of time between significant changes in "best practice" is also much faster in health than other industries—about 5.5 years, compared with 10-year cycles in aviation [31]. This presents a risk management challenge often not considered the same way budgets, overarching policies, legislation and other perceived constraints might be. For example, when the Between the Flags Program [32] and related policy [33] were introduced in NSW in 2010–2011, it prescribed the rate and type of monitoring required and focussed attention on monitoring devices. The risks associated with increasing the number of alarms in the ward environment received little attention in the face of compelling evidence for increasing and responding to physiological monitoring. More recently, the Australian Commission on Safety and Quality in Health Care introduced the National Safety and Quality Health Service

Standards. To comply with Standard 9, Recognising and Responding to Clinical Deterioration in Acute Health Care [34], health services must have systems in place to quickly recognise clinical deterioration—another strong incentive for physiological monitors to be a standard component of care.

Local Context This is best understood through consultation with frontline staff and managers. This will give information about the influences on "how we do things here", and the cultural components which drive health care delivery more than is generally recognised. Assessment includes observing staff working under "normal" conditions, undertaking all necessary tasks. This provides information about what actually happens, including workarounds and shortcuts, rather than what people believe or report that they do. It begins the communication process which must continue throughout the risk management process. For this example, the team can assess aspects such as: How many devices with alarms are in use? Are alarm sounds audible where they need to be (signal-to-noise ratio)? Are staff able to distinguish between the different device alarms? Do staff change alarms settings according to their own preferences, or because other staff do?

The team needs to ensure that issues identified from review of external and local context, and from literature search and incident reporting are also assessed. For example: Is there a culture of turning alarm tones down or off? They could observe the actual time staff spent in patient rooms, the time taken to respond to different alarms, and if there are any other sounds on the ward e.g., patient call bells, which may have similar tones. This needs to be done in a respectful and objective way, with open communication, so that a learning culture is conveyed, rather than a punitive one.

There is another vital source of information often overlooked in incident investigations and risk management—patients. They cast fresh eyes on our processes, as do their families and carers who may spend all day on the ward and can provide great insights. Again respect and sensitivity are required. If the task being assessed is not a common occurrence, then the risk management team may consider conducting a simulated exercise in a comparable clinical area, perhaps using a high fidelity mannequin. Both observation and simulation provide great opportunity to assess what actually happens, and whether suggested solutions will work.

Assessing the Risk

There are three core components to risk assessment, once the hazard and the context have been established. The risk must be identified, i.e., does the hazard present a risk in the situation where it exists, given the external and internal context. If it does, the next step is to analyse the risk, i.e., determine what could happen if nothing was done about the risk and how serious the consequences might be. The risk then needs to be evaluated, so that decisions can be made in regard to whether or not it needs to be managed, and if so, how this will be done.

Risk Identification

In this example, the team needs to decide from the information gathered, if alarms pose a risk to patient safety. Is there evidence of alarm fatigue, poor signal-to-noise ratio or practices which negate the benefits of necessary alarms? Could patients suffer harm as a result? When the answer is yes, there is a risk identified.

Risk Analysis

The team considers their findings against the relevant risk rating scale to determine the (1) likely consequences of the risk, i.e., the amount of harm to the patient, (2) likelihood of this harm occurring (based on the probability of it actually happening and the frequency with which this might occur—a two-component assessment of likelihood).

Most risk management policies in Australia have associated risk assessment matrices, which are generally "traffic light" coloured and prescribe the type and urgency of response required, for example, the Matrix associated with the NSW Health Policy [35]. In our example, the risk of harm to patients due to failure to detect or respond to an alarm would be classified as major or even catastrophic (i.e. one or more patients could die or suffer significant harm as a result). The final rating would depend on the likelihood determined.

Risk Evaluation

Without eliminating all monitors with alarms, the risk of alarm fatigue cannot be eliminated. The hospital will need to decide whether to accept this risk, i.e., do nothing, or to do something to reduce it—either by reducing the likelihood of occurrence or mitigating the consequences. Under a risk management framework, organisations may choose to accept a certain level of risk, especially if the assessment is that it has minimal consequence or is unlikely to recur. They can then direct resources and effort towards more serious or frequent risks. It is seldom possible for health care services to eliminate risks altogether. As Amalberti et al. report [3], public health providers cannot shut the door to patients.

The Risk Management Standard [10] recommends that organisations maintain a Risk Register and build review of this into their risk management framework. Most jurisdictions require that public health organisations have governance committees in place to regularly review recorded risks and oversee progress of remediation activities.

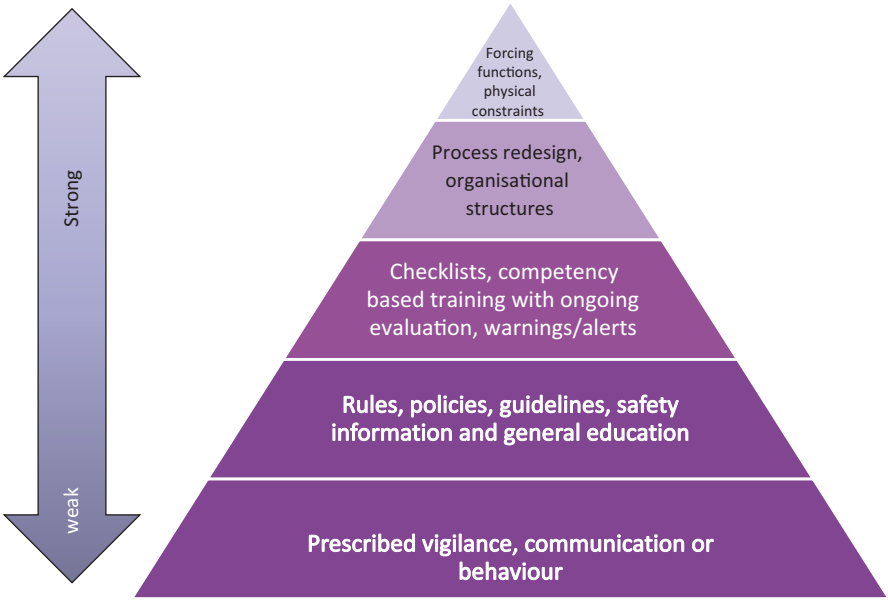

Fig. 7.1 Strength of risk management controls in health care. (Courtesy of the clinical excellence commission, NSW)

Risk Management

Once the risk has been described, the context in which it exists and must be managed is understood, and its severity has been ranked, the risk management team must decide how exactly it is to be managed ("treated"). This is a consultative and cyclical process which includes an understanding of what can and can't be changed.

Most efforts in health care improvement focus on process change, considering we rely on the actions of people to deliver care to patients. Knowing that we work with well-intentioned people, we expect that everything will be safer if we work together to maintain awareness of risks. We need to learn from other high risk industries, where human factors are considered a core element of the context and solution. Reviewing the hierarchy of controls in many safety systems is helpful, and in fact similar to the principles for managing risks. The aim is to consider options from the top of the pyramid first, as these have been shown to be more robust and reliable in preventing human error, as shown in Fig. 7.1.

Engineering solutions are not always applicable in health care, but are the most robust and should be considered more often than they actually are. For example, following an incident where a patient received a ten-fold dose due to a syringe driver programming error, the supplier worked with NSW Health staff to reprogram these devices across the state. This is a much stronger solution than adding a sticker to warn other staff (what happens when it wears off or is no longer novel?) or edu-

cating the current staff in the local area (what happens when they move on or are backfilled by agency staff? What about other areas with the same risk?).

Another common response in health care is policy or guideline development and general education. These are considered fairly weak, but are often the only option, and if done concurrently, consistently, with reinforcement and monitoring, can result in cultural and behavioural changes required.

We also need to consider the side effects. As Reason says, "don't cause the next adverse event while trying to prevent the last one [recurring]" [14]. Amalberti similarly advises us to identify potential side effects whenever we make changes to processes, and to measure these. He warns us not to fall for "the Tuesday paradigm", meaning don't design solutions which will only work in optimal conditions, when the full range of personnel and expertise is available. Sixty per cent of acute health care in Australia occurs after normal business hours or on weekends, so we need to build solutions to fit these conditions.

In the alarm fatigue example, how can the organisation manage this risk and maintain the benefits of patient monitoring? What solutions are realistic? We need to consider what is being done by National or jurisdictional bodies, by the Colleges, and check how other similar services are tackling the problem. The Joint Commission declared medical device alarm management as a patient safety goal for 2014 [36], and listed specific governance and risk management activities to reduce this risk to patients. Many of these can be applied locally and should be considered for this example. As Richard Know stated after visiting the Boston Medical Centre "it may be that less technology can actually be more effective" [19].

Monitoring the Effectiveness of the Solutions Applied

Once solutions are identified, the organisation needs to ensure their implementation and effectiveness is monitored at all appropriate levels across the hospital, and they are modified if indicated. This is likely to include structured audits, reviews and improvement cycles.

A worked example of all the stages utilised to manage this risk are shown in Table 7.1.

Applying Risk Management Principles to Clinical Care Decisions

The worked example describes an organisational approach to a hospital-wide risk. However, as mentioned earlier, many of the clinical practices and decision-making processes used daily by the clinicians are actually risk management. They may have been built from previous formal risk management processes, application of learning from other services or sources, or from discussions between clinicians or with

Table 7.1 Health care risk management example

Risk Management Component	Activities required	Medical Device Alarm example	
Establish the Context			
Team gathers and reviews the relevant information. The risk components are defined, so that changes made can be evaluated against these.			
External context	Establish the broader influences on the hospital which influence what the hospital is required or expected to do.	Bring together information about National, jurisdictional, parent organisation & professional bodies' perspectives in relation use of medical monitoring devices which have inbuilt alarms.	
Internal context	Establish the local requirements and influences – how we do things here	Bring together information about the local context, including clinician preferences, in relation to need for and use of medical monitoring devices which have inbuilt alarms.	
Risk Assessment			
Risk identification	Identify risks or determine if known risk applies in this setting	Determine if the use of monitoring devices has or is likely to cause alarm fatigue (known risk) and poses a risk for patient safety at this hospital.	
Risk analysis	Determine the likely causes and impacts of the risk and rate it	Describe the risk componets. Use the relevant Risk Rating Scale to determine the level of risk in the hospital	
Risk evaluation	Determine whether the risk will be accepted or treated and decide how to tackle the problem	Follow the prescribed process so that the risk associated with alarm fatigue in the hospital can be considered by the peak risk management committee and/or team.	
Risk treatment			
Risk treatment	Develop a detailed plan and work with staff to address risk components	Decide what strategies will be used to reduce alarm fatigue and work with staff to trial and implement these. Adapt or reject until workable strategies are in place. This may include defining processes and authority for changing alarms settings, removing monitors.	
Risk monitoring			
Risk monitoring	Use the criteria agreed when establishing the context and articulating the risk to monitor and report on the effect of changes made	Decide which changes to monitor alarm usage will be measured and work out realistic ways to do this, e.g., audit tool. Defi will be assessed should it be required to introduce them. Track via the hospital's risk register or committee processes	Consult and communicate

patients. "Steal shamelessly, but implement wisely", as context and ownership can make or break safe practice.

Many embedded clinical risk management practices promote communication about risks at the point of care delivery. The considerations are the same as in the formal processes described above: Establish the context (what do we know about the patient's current condition(s) and what does the health care community know

about treating this?); Assess the risks (do they apply to this patient, if so, to what extent and what could happen next, as a consequence? The latter is also referred to as situational awareness [37]; Evaluate the risk **(**Should we accept the risk and proceed—or do we need to consider managing what might happen?); treat the risk (what are we going to do to reduce the risk or mitigate its harmful consequences?) Monitor the risk (Care planning would include recommendations about monitoring for any sequelae which the risk treatment did not address or may have caused). Discussing the outcome for patients in team or morbidity and mortality meetings or less formal contexts enables review and sharing of learning and continues the risk management cycle.

The aggregated learning from the application of these processes has resulted in many of the clinical structures and processes which clinicians are expected to follow. Decision support tools, protocols, guidelines and checklists have all evolved from management of identified clinical risks. For example, surgical safety checklists [38] and formal "rounding" [39] are intended to ensure staff consider the known risks for every patient and together determine how these will be managed. They also emphasise patient engagement as a vital risk management strategy. Similarly, clinical care bundles are built from information gathered about individual patient's risks and outcomes during death reviews, incident investigations and clinical audits. They build from the individual case to recommend how care should be delivered so that patient have the best possible outcome. Utilising bundles removes the need for clinicians to reconsider every risk each time they prescribe similar treatment, for example, applying the FASTHUG bundle [40] when managing ventilated patients. Considering the complexity of health care risks described by Amalberti [3], this is an important risk management strategy which allows clinicians to focus on other components of care.

In summary risk management is all about standardising the best possible care, by supporting and steering clinicians along the right pathways, for they are health care's greatest strength and our greatest hazard. Risk management is a core element of clinical practice and fits easily within the skill set of clinicians. Without their involvement, real change cannot occur. Safety, quality and risk management activities are pointless if they only occur in a domain removed from clinical care. This is not rocket science, but it does require a little time, optimistic problem solving and a commitment to a just, learning culture. This is another example of the importance of a team approach to health care. The bringing together of great minds, with a range of insights and practical knowledge is the best risk reduction strategy known to health care.

Whether the risk management cycle is part of proactive service review, or occurs in response to risks identified during incident investigations (such as root cause analysis), this tool can give us a free lesson and opportunity to prevent patient harm. Risk management utilises the most powerful element in health care—its frontline staff and managers, who are the only ones who can really improve the safety and quality of everyday care. Engaging in risk management activities and initiating them by speaking up for safety (ref) are essential elements of health care in the twenty-first century.

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