Government of **Western Australia**
Department of **Health**

# Clinical Risk Management Guidelines

## A best practice guide

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# Key Definitions

The following key definitions are used in the Clinical Risk Management Guidelines:

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| **Consequence** | is an outcome of an event affecting objectives. It refers to the outcome or impacts of an event expressed qualitatively or quantitatively, being a loss, injury, disadvantage or gain. There may be a range of possible outcomes associated with an event. |
| **Control** | A measure that maintains and/or modifies risk. Controls include, but are not limited to, any process, policy, device, practice, or other conditions and/or actions which maintain and/or modify risk. Controls may not always exert the intended or assumed modifying effect.<br>Controls may be **preventative** whereby a control prevents the cause of a risk or **mitigative** whereby the consequences of a risk are reduced. |
| **Likelihood** | is a chance of something happening and refers to a qualitative description of probability or frequency. |
| **Risk Management System** | means the organisational structure, procedures, processes and resources needed to manage clinical and corporate risk and to monitor organisation's performance and outcomes. |
| **ERMS** | The enterprise risk management system used by the WA health system |
| **Risk** | Risk is the effect of uncertainty on objectives (either positive or negative).<br>**Clinical Risk** refers to risks associated with delivering clinical functions<br>**Corporate Risk** refers to risks associated with providing corporate functions<br>**Residual Risk** refers to the remaining level of risk after the risk treatment process has been completed. |
| **Risk Treatment** | refers to the selection and implementation of appropriate management options for dealing with identified risk. |
| **Stakeholders** | are those people and organisations who may affect, be affected by, or perceive themselves to be affected by, the decision or activity. |
| **Standard** | refers to the Australia/New Zealand Standard on Risk Management AS/NZS ISO 31000:2018. |
| **WA health** | refers to the whole of the WA public health system, particularly the Department of Health, Health Service Providers and their hospitals. |
| **Department of Health** | refers to the system management of WA health located at Royal St, East Perth. |
| **Organisation** | refers to a hospital or Health Service Provider or other designated public health provider. |

An expanded list of terms is available in the Appendix A – Glossary.

# Introduction

***Why is clinical risk management important for all clinicians?***

In clinical practice there are a lot of things that can contribute to effective patient outcomes. One of the most important things is avoiding unintentional harm to the patient. Patients trust clinicians and expect that hospitals will be safe, caring environments which will contribute positively to improving their health, and that is why risk identification and management is so important. Risk management often requires busy clinicians to take a step back and not just look at the patients under their care, but also at the processes, structures and environment within which they provide this care. This process enables staff to identify vulnerabilities and take corrective action when they see an unsafe situation or environment.

For example, taking steps to ensure a slippery floor is dry and preventing a patient, visitor or another staff member from falling over is as important as ensuring that the medication a patient is taking is the correct one.

Furthermore, who would think that there is a risk of drowning in a hospital?

But there is this risk when the physiotherapy department operates a hydrotherapy pool. Could a young child waiting with their parent wander into an unattended and unsecure pool facility? What plans are in place as control measures to stop this child from drowning? Are these adequate? What is the risk rating?

These are the type of questions that should be considered for all of our areas of clinical practice. These guidelines will assist all clinicians to understand the importance of identifying hazards and areas of clinical risk as we work to keep our patients safe and prevent unintended harm.

## What is clinical risk management?

Health care services are provided to patients in an environment with complex interactions among many factors, such as the disease process itself, clinicians, technology, policies, procedures, and resources. When these complex factors interact, harmful and unanticipated outcomes (e.g. errors) can occur resulting in unintentional harm to a patient.[1]

As illustrated in the examples above, clinical risk management is an ongoing process for judging risk and subsequently making appropriate clinical plans for the patient considering the risks identified.[2] It is a daily activity of all staff involved in clinical care. Clinical risk management is about minimising risks and harm to patients by:

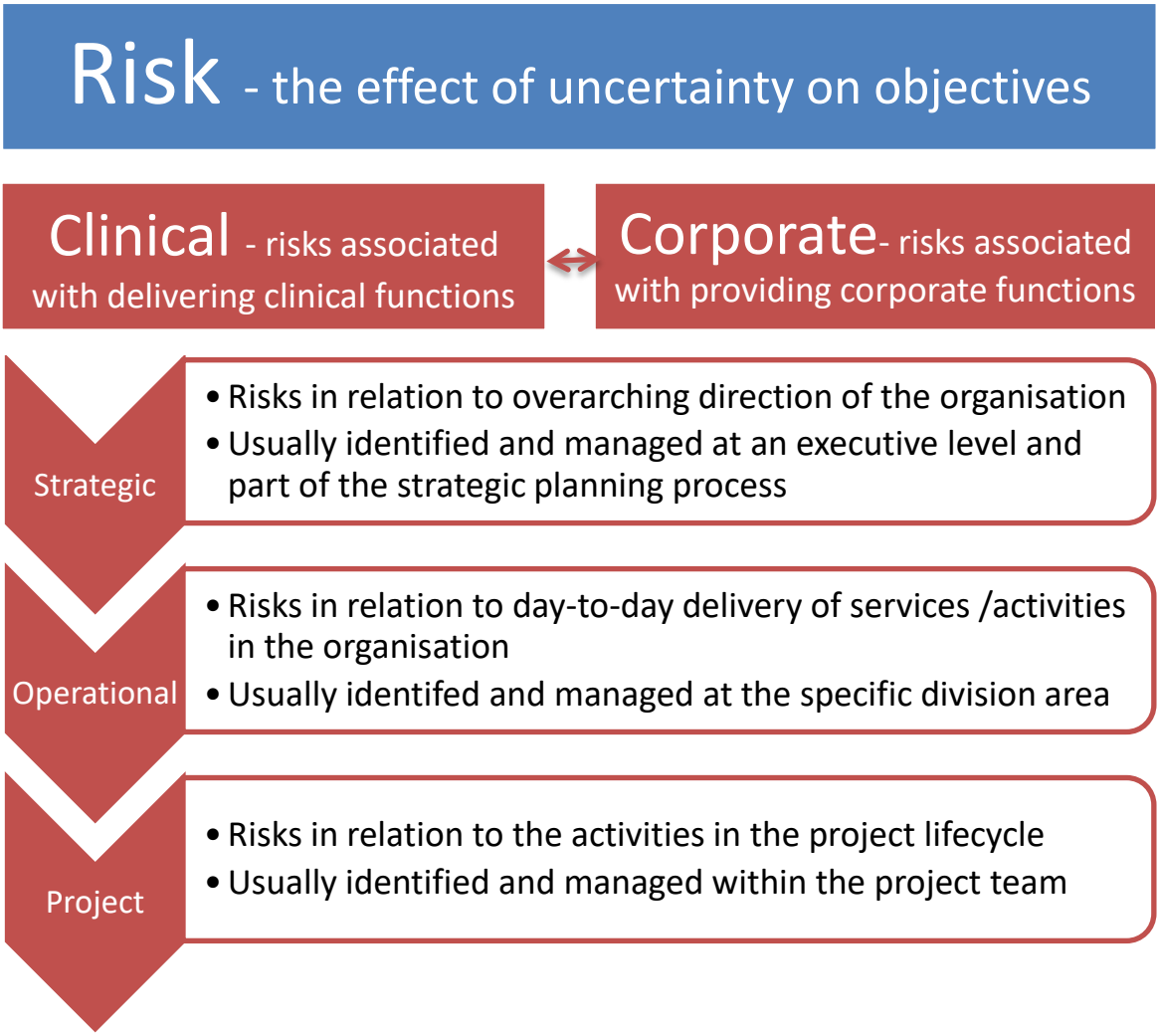
- identifying what can and does go wrong during care
- understanding the factors that influence this
- learning lessons from adverse events
- ensuring action is taken to prevent recurrence
- putting systems in place to reduce risk

Clinical risk management is part of a good clinical governance system through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care. As outlined in the Clinical Governance, Safety and Quality Policy Framework[3], this is achieved by creating an environment in which there is transparent responsibility and accountability for identifying and managing risks, issues and opportunities so that excellence in clinical care may flourish.

### What is risk?

The Australian/New Zealand Standard AS/NZS ISO 31000:2018 defines risk as the effect of uncertainty on objectives.[4] Risks are measured in terms of consequence and likelihood. Risks can be classified into the categories as outlined in Figure 1.

**Figure 1:** Risk categories




As indicated in Figure 1, clinical and corporate risks can cross over and impact on both clinical and corporate functions. The WA health system is exposed to many clinical and corporate risks on a daily basis as can be illustrated in Appendix B – Risk Categories and areas of risks. These risks may arise from:

- provision of health care and its related activities
- operational management activities and control
- human behaviour
- commercial and legal relationships
- strategic management
- natural events
- political circumstances
- technology and technical issues
- facilities and assets management
- demographic and demand factors

## Why manage risk?

Risk management proactively reduces identified risks to an acceptable level by creating a culture founded upon assessment and prevention of harm. Risk management is a key responsibility for all managers and staff and should be embedded into the structure, processes and culture of an organisation to support continuous quality improvement.

It is recognised that health care is increasingly complex in its delivery, personnel, service demand and technology pressures. As such, risk management plays a vital role supporting and informing decision-making in providing a safe and secure environment for patients, carers and staff.

Note, having risks is inevitable in every organisation and there can be a positive relationship with risk. Managing risk appropriately would assist in identifying opportunities for action and improvements.[5] However from a clinical perspective, most risks, if they are realised, are detrimental to the patient.

The successful management of clinical risk would identify issues raised from incidents or other lessons learned, provide adequate resources to control for the causes of the risk and ensure the prevention of adverse events. Whilst not recognised as such, clinicians are an important component of employing risk management strategies. Their daily clinical practice is embedded with a range of risk controls (such as policies, processes, procedures and tools) that aim to ensure adequate practices. Managing risks lead to effectively and efficiently providing safe, high quality care to patients.

## Purpose of Clinical Risk Management Guidelines

The primary focus of the Clinical Risk Management Guidelines (CRM Guidelines) is to provide context and examples to illustrate how to apply risk management in a clinical setting. While the CRM Guidelines have been written for service managers, safety, quality and risk officers/coordinators/managers as well as staff involved in the risk management of day-to-day operations of clinical services, the CRM Guidelines are relevant to all health employees to understand and employ within comprehensive clinical governance system. It is acknowledged that there is significant overlap between clinical and corporate risk within health services/hospitals and a consistent and co-ordinated approach should be maintained.

The information and examples included in the CRM Guidelines are intended to highlight that risk management is being undertaken by all health employees every day and is fundamental to maintaining safe, high quality care. The examples that have been included were chosen from recognised high risk areas but have been (in certain cases) extrapolated to the worst-case-scenario for the purpose of demonstrating the application of risk principles. The risk management processes and suggested tools in the CRM Guidelines are designed to support structured clinical judgement so staff are better placed to make well informed decisions and plans for the safe delivery of care to patients. The information, examples and tools provided do not replace the requirement for clinical judgement and the examples do not encompass the subjective nature of clinical scenarios.

The CRM Guidelines expand upon and underpin the overarching mandatory requirements in the Clinical Governance, Safety and Quality Policy Framework[3], the Risk, Compliance and Audit Policy Framework[6] and the Information and Communications Technology (ICT) Policy Framework[7].

The CRM Guidelines are closely related to the Clinical Incident Management Policy, Guideline and Toolkit documents in that they may complement but not replace one another. The clinical risk management processes outlined correspond to the clinical incident management processes in ensuring the embedding of recommendations and prevention of further incidents.

The success of WA health's approach to clinical risk management depends on the support and commitment of the Health Service Boards, Chief Executives and the hospital/health service executive teams with the active involvement of all staff including medical, nursing and allied health professionals. Hospital/health service managers need to ensure that the contents of this Guideline are disseminated, understood, implemented and maintained at all levels of the organisation. Comprehensive but streamlined and coherent risk management systems, underpinned by clear accountability arrangements throughout the organisational structure, must also be established within each health service provider.

The specific details and processes for how to identify, register, escalate and manage risks will be outlined by each health service provider, contact your local Risk Coordinator for more information.

# Clinical Risk Management Process

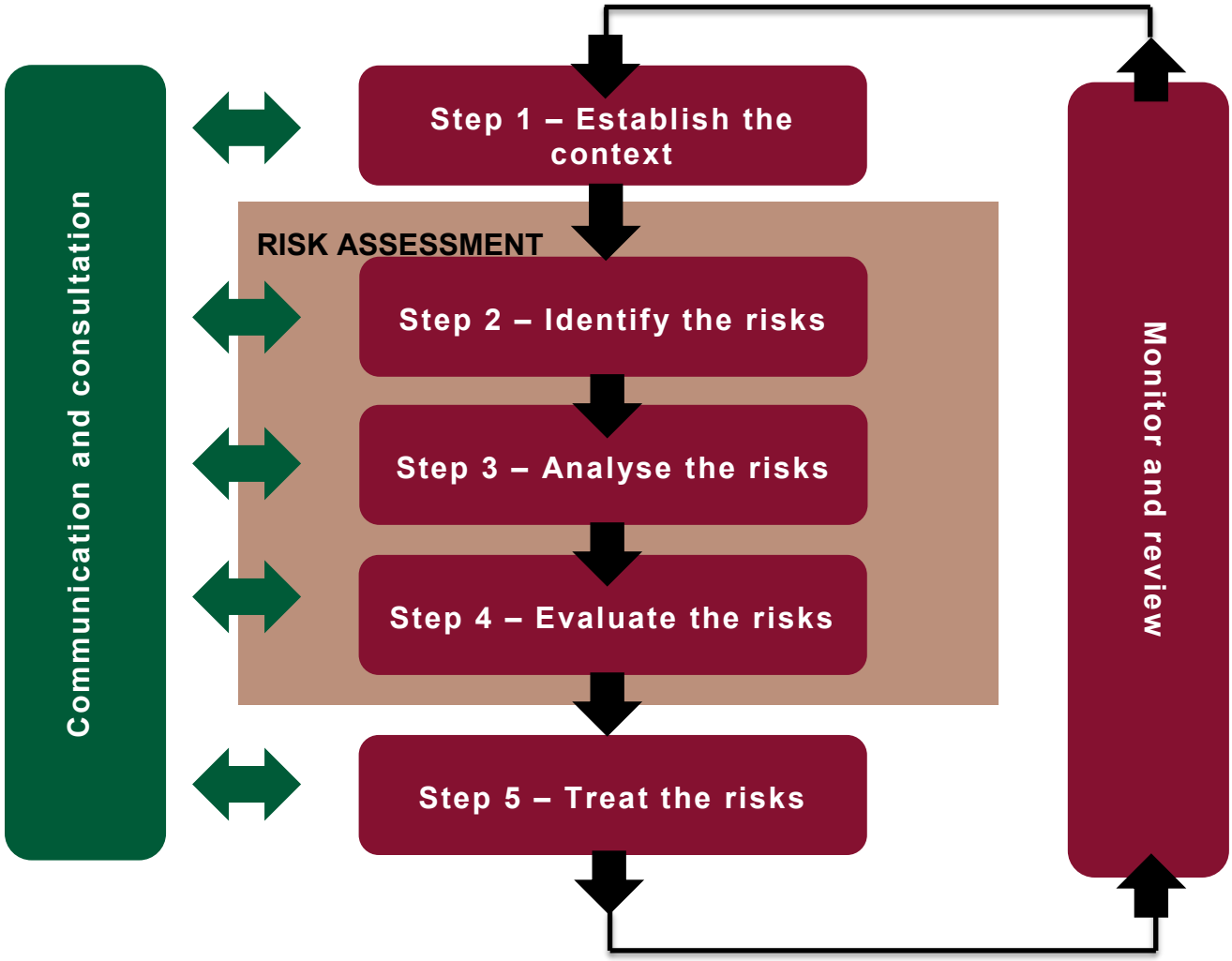
An overview of the structured and systematic risk management process as detailed by the Australian/New Zealand Standard AS/NZS ISO 31000:2018 Risk Management[4] is shown in Figure 2. The risk management process outlined is intended to be an integral part of any organisation's practices and be applicable to all contexts. As such, clinical risks can be managed using the 5 steps that are:

- Step 1: Establish the context
- Step 2: Identify risks
- Step 3: Analyse risks
- Step 4: Evaluate risks
- Step 5: Treat risks

Additionally, the overall processes of 'Communication and Consultation' and 'Monitor and Review' should be included during all stages of the risk management process.

All organisations should record their risks and management activities in a Risk Register.

**Figure 2:** Risk Management Process[4]




The following sections will detail each process/step and provide tips/examples and case studies of how to apply the process in a clinical setting.

## Communication and Consultation

For clinical risk management to be successful, continuous communication and consultation with the relevant staff, patients and families need to be in place at every step of the process.

Without an effective communication and consultation process, stakeholders will not be aware of why clinical risk management strategies and policies have been developed and implemented. Neither will they understand their individual roles and responsibilities for clinical risk management.

All WA health staff have the responsibility to identify risks, manage them and when required, report them to their manager for assessment and/or treatment. Many clinical risks may not be raised or escalated to the next level of management as they can be adequately managed using the controls that have been identified and implemented.

Health service providers need to develop appropriate communication and consultation strategies to engage internal and external stakeholders during all stages of the clinical risk management process. The key elements of an organisational communication strategy include:

- clearly defined objectives for communication
- identification of which internal/external stakeholders should be included
- identification of what beliefs and perspectives need to be taken into account during the clinical risk management process
- development of communication strategies to be used during the clinical risk management process
- processes to be used to measure and evaluate the effectiveness of the organisation's communication programs
- the truthful, relevant, accurate and understandable exchanges of information
- the mutual desire to achieve the best clinical outcome.[5]

Clinical risk management should not be a stand-alone process outside of the normal management activities of staff.[5] Each step of the clinical risk management process should be incorporated into the daily activities of all health employees.

## Step 1 – Establish the context

*Aim: To determine the objectives and goals against which risks will be identified and managed.*

This step involves identifying the goals, objectives, strategies, scope and parameters of the activity, or part of the organisation to which the clinical risk management process is being applied. The process should be undertaken with full consideration of the need to balance costs, benefits and opportunities. As outlined in Figure 1, there are risks at the strategic, operational and project levels. Each level should be considered in regard to the context when applying clinical risk management.

### Defining the scope

When defining the scope and depth of the clinical risk management program, hospital/health service staff should consider whether the clinical risk management process is to cover service-wide issues, or be limited to a specific clinical practice area, business unit, function, or project. Setting the scope and boundaries of an application of clinical risk management involves:

- defining the organisation, process, project or activity and establishing its goals and objectives
- specifying the nature of the decisions that have to be made
- defining the extent of the project activity or function in terms of time and location
- identifying any scoping or framing studies needed and their scope, objectives and the resources required
- defining the depth and breadth of the clinical risk management activities to be carried out, including specific inclusions and exclusions.

### Establish the context

Once the scope has been established, both the internal and external context should be identified. This includes understanding the external organisations that may contribute to any threats or opportunities which may impact on your hospital's/health service's risk management process. The establishment of the internal context needs to begin with the identification of the key internal stakeholders. In order to conduct a risk management process, it is necessary for an organisation to understand itself, in terms of its culture, structure, financial and human resource capabilities, as well as its goals, objectives and the strategies that are in place to achieve them.

The following should be considered when establishing the external context:

- External stakeholder groups including funding providers and patients.
- The business, regulatory, financial and political environment, such as:
  - minimising disruption to services
  - occupational health and safety requirements which influence your organisation
  - funding availability and/or restrictions placed on use of funding
  - employment requirements in terms of staffing

Some examples of matters to consider when establishing the internal context include:

- Whether the culture of your organisation has already embraced risk management concepts and strategies?
- What financial resources are available to conduct the risk management process?
- Is there support from all the key internal stakeholders? If not, why not?
- What awareness is there of risk management principles and what tools are available to facilitate the process?

One of the key stakeholders is the Health Service Provider Board. The Board will set overall goals, objectives, values, policies and strategies along with the organisational risk appetite.

This will assist management to define the criteria by which the organisation determines whether or not risk is acceptable and forms the basis of controls and management options.

**Key questions in establishing context**

- What is the policy, function, process or activity to be assessed for risk?
- What are the major threats and opportunities to the clinical risk management program?
- How is the organisation accountable to its stakeholders?
- What are the significant issues in the organisation's internal and external environment?
- What clinical risks have been identified in previous reviews?
- Is there a new strategic planning cycle that requires a risk management component?
- Is risk assessment included in business planning for clinical services?

**Reminder**

- Hospitals/health services must **communicate and consult** with internal and external stakeholders and **monitor and review** clinical risk processes and outcomes at each step of the clinical risk management process.

## Step 2 – Identify the risks

*Aim: To identify all the risks associated with achieving the objectives identified in Step 1.*

A systematic process is required to comprehensively identify all clinical risks within a hospital/health service. Over time, all clinical risks at the State, health system, organisational, business unit, team or patient level need to be identified, assessed, treated and monitored. To start the process of identifying clinical risks, it is necessary for the hospital/health service to identify and prioritise internal and external clinical risks that may pose a threat.

In the delivery of health care, WA health may be exposed to different types of risks, for example:

- operational risks such as clinical services and procedures, clinical management process failures, or lack of training and compliance with credentialing requirements
- legal risks such as complaints, medico-legal liability or statutory liability
- political or strategic risks such as organisational governance or State/Federal legislation or regulations
- financial risks such as resource allocations, budget and resource management
- technology risks related to the procurement, development, deployment and use of ICT systems/applications

Identification of clinical risk requires staff to have a thorough understanding of the following components:

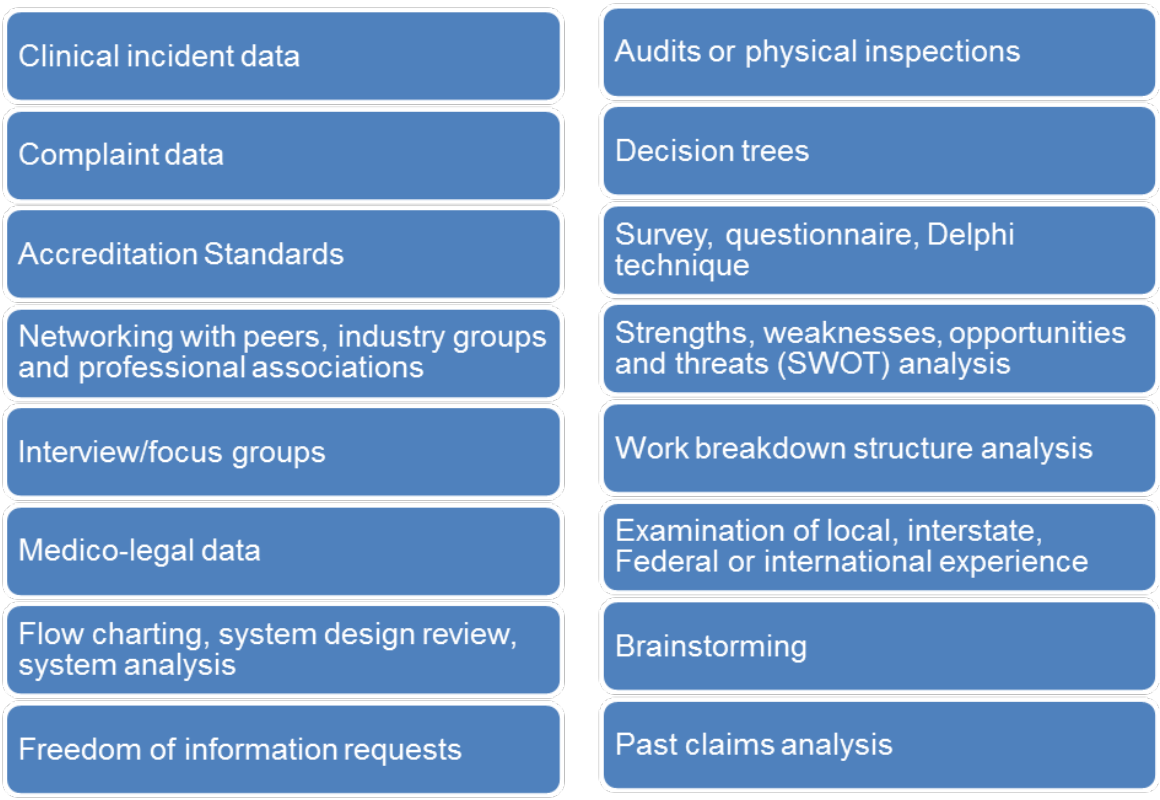
| | |
|---|---|
| The **main cause of the clinical risk** that has the potential to result in harm. | • e.g. main cause: similar/look-alike packaging on medications dispensed from a hospital's pharmacy |
| The **event or incident** that could occur if the risk is not managed and the impact on the organisation or its internal/external stakeholders. | • e.g. risk of inappropriate medication being administered to patient |
| The other **causes** (what and why) for the presence of the clinical risk or hazard of the event occurring. | • e.g. storage of the medications, training of the clinicians involved, lack of checking processes |
| Identification of the potential **result or outcome** of the clinical risk on the organisation or its stakeholders. | • e.g. clinical incident where the patient is harmed from being administered the wrong medication |
| **When and where** the clinical risk or hazard could occur. | • e.g. during the dispensing of medication in the pharmacy or administration of the medication to the patient in the ward |

In order to ensure that each organisation engages in an effective process of clinical risk identification, the following strategies should be followed:

- Examine all causes of clinical risk from the perspective of all stakeholders, both internal and external. By identifying each clinical risk cause, the organisation can consider the contribution that each cause and its control/s makes to the likelihood and the consequences of the risk (see Step Three). Possible methods of identifying clinical risks are outlined in Figure 3.
- Clinical risk identification should be integrated into all new project scoping, assessment and change management activities.
    - For example, clinical risks should initially be identified in new business cases for ICT projects or medical equipment to be procured. In addition, the Patient Safety Risk Assessment (PSRA) process and document is incorporated in the ICT Governance Policy and the ICT Project Management lifecycle. A PSRA must be completed during the project initiation phase for every ICT project that impacts, either directly or indirectly, on patient data.
- Access good quality information which will assist the service unit/team in understanding their risks. The information should be relevant, comprehensive, accurate and timely. The results of this assessment should be recorded. This can include data that has been generated by the service unit/team themselves or from others.
    - For example, the Patient Safety Dashboards produced by the Patient Safety Surveillance Unit, provide data on the number and trends of clinical incidents by themes/categories (National Safety and Quality Health Service Standards have been included). Priority areas for risk assessment could be drawn from reviewing the types of clinical incidents with high volume, such as falls, medication, obstetric and mental health areas. The quarterly CIMS Check Up reports highlight a key area that provides further data and insight into topics such as clinical handover and deterioration.
    - For example, the health service trends and important topic areas can be further investigated by reviewing audit data collected from the service unit/team to identify specific risks that are relevant.
    - For example, accreditation data, reports and recommendations (including National Safety and Quality Health Service Standards) are great sources of information as they provide health service providers with an organisation-wide framework to ensure the delivery of safe, high quality patient centred health care.
- Employ various methods of identifying risks and make sure to include all relevant stakeholders to comprehensively identify risks.[8] It may be necessary to draw from experience, knowledge and expertise from outside (including patients and their family and carers) as well as inside the immediate treating team/unit/division.[5]
    - For example, patients of concern that are identified as high risk during the clinical handover process draws on a range of information from various stakeholders.
    - For example, the evaluation of comorbidities plays a major role in considering the cumulative risk to the patient if they proceed with medical treatment (such as surgery).

- For example, the consideration of risks in relation to providing clinical care to specific patient groups such as patients living with mental illness or cognitive impairment and patients from Aboriginal and Culturally and Linguistically Diverse (CaLD) backgrounds may require involvement from a range of parties.

Figure 3: Possible methods of identifying clinical risks




## Categorisation of risk

Risk categories are used to examine common types of risk across an organisation. The same categories should be used across WA health, for both clinical and corporate services. A range of risk categories that should be considered is available in Appendix B. The categories in the table can assist in prompting risk identification as some examples of at risk areas are also provided.[9] Risk categories also assist in the analysing and reporting of risk but note that they are different to the consequence categories that are used to analyse risks and will be explained in the following section, Step 3 – Analyse the risks.

**Case Study 1 – Identifying risks in orthogeriatric ward**

A service area within St Nowhere Hospital is undertaking an Annual Quality Plan review and is considering risks.

**Step 1 – Establish the context**

Operational level clinical risks: to be considered within St Nowhere Hospital, Nightingale Orthogeriatric ward/unit

Goals/objectives: to treat geriatric patients with hip fractures within best practice guidelines to ensure that safe and high quality care leads to timely recovery and as low impact on the quality of life for the patient as possible.

Activities: Admission and assessment, surgery/treatment, medication, rehabilitation, discharge

**Step 2 – Identify risks**

Ward manager/coordinator may undertake a quality walk around. This could include talking to patients and staff, mapping the clinical pathways and activities that are undertaken and/or gathering relevant stakeholders for a brainstorm.

Data or other information that could identify risks include:

- Clinical registry information (e.g. Hip Fracture data collection) and the gaps or benchmarks that are being met/not met
- Clinical incident and audit data from that ward
- Accreditation reports
- Patient feedback and experience data including complaints
- Reported environmental hazards and near misses
- Occupational Health & Safety incidents including manual handling injuries
- Surgical site infection (SSI) surveillance data
- Hand hygiene compliance data

Upon review of the data and potential sources of risk, some risks identified could include:

1. Failure to provide appropriate care to prevent geriatric patients falling before or after surgery.
   This could be caused by:
   A. Inadequate staffing levels
   B. Environmental hazards
   C. Lack of appropriate equipment
   D. Patients' frailty and/or confusion
   E. Patients' pre-or post-operative pain and discomfort
   F. Inadequate or inaccurate falls risk assessment

   And could result in a consequence of increased length of stay, serious harm or death.

2. Failure to provide safe patient care for the prevention of health care associated infections. This could be caused by:

A. Inadequate cleaning of environment/equipment/patient
B. Poor Hand Hygiene
C. Poor aseptic technique
D. Inadequate patient nutrition
E. Evidence-based strategies to prevent SSI not implemented

And could result in a consequence of a health care acquired infection with an increased length of stay, serious harm or death.

**Key questions in identifying clinical risks**

- What, when, where, why and how are risks likely to occur, and who might be involved?
- What are the sources/causes of each risk?
- What are the consequences of each risk?
- What are the organisation's internal and external obligations?
- Is there a need for further research into specific risks?
- What are the objectives/scope of this research, and what resources are required?
- How reliable is the information?
- Have the right people been involved in the risk identification process?
- Is there scope for benchmarking with peer organisations?

**Reminder**

Hospitals/health services must **communicate and consult** with internal and external stakeholders and **monitor and review** clinical risk processes and outcomes at each step of the clinical risk management process.

## Step 3 – Analyse the risks

*Aims: To determine the effectiveness of any controls and to undertake research about the risk to support evaluating its risk rating.*

A systematic analysis of the health system, organisational, business unit and team environments should be undertaken to understand the nature of risk and to identify tasks for further action. Specifically, the objectives of clinical risk analysis are to identify the nature of the risk and its characteristics including where appropriate the level of risk.

Clinical risk analysis involves consideration of the sources of clinical risk, their consequences and the likelihood that those consequences may occur. Factors which affect consequences and likelihood are also identified. To calculate the risk level of an activity, elements of clinical risk are considered individually and then combined to create a risk level, using the following formula:

| Risk Level | = | Consequences | x | Likelihood |
|---|---|---|---|---|

The depth of analysis should be determined by the complexity of the activity and the availability of information/data to aid the risk analysis process.

Measurement and ranking of clinical risks is undertaken using the Risk Assessment Tables for the WA Health System[10] . The tables include the:

1. Consequences Rating Table
2. Likelihood Rating Table
3. Risk Level Matrix Table
4. Aggregate Controls Assessment Table
5. Risk Acceptance/Tolerance Criteria Table
6. Specific Risk Criteria

### Types of analysis

There are three methodologies that could be used to calculate the 'consequence' and 'likelihood' of the risks: quantitative, qualitative and semi-qualitative.

**(a)** **Quantitative methodology**: can be the most accurate method of collecting information. For example, data may be available to define quantitative risk levels for a particular medical procedure or define the likelihood and consequences of a disease developing in particular circumstances.

Some examples of quantitative methods of analysing risk include:

- descriptive statistics such as frequencies, cross tabulations, percentages and rates
- probability analysis
- simulation/computer modelling
- life-cycle cost analysis
- fault tree and event tree analysis
- consequence analysis
- statistical/numerical analysis

- decision trees
- influence diagrams.

**(b)** **Qualitative methodology:** relies on a manager using his/her experience, judgement and intuition to calculate the level of risk based on their knowledge. Examples of qualitative methods, include:

- structured interviews/questionnaires
- specialist and expert judgement
- peer review and/or discussion
- networking with industry and professional associations
- brainstorming
- evaluation using multi-disciplinary groups
- bench-marking
- qualitative mapping
- structured interviews with experts in the area of interest.

Where a qualitative methodology is to be used to identify the level of clinical risk, managers should ensure that they have a sound understanding of their organisation's risk criteria and organisational context, and find the closest match in the descriptions in the Risk Assessment Tables for the WA Health System[10]

**(c)** **Semi-quantitative methodology:** allocates numbers to qualitative work rankings such as high, medium or low. The rankings should be shown against an appropriate numerical scale, which allows the information to be processed quantitatively.

If using a semi-quantitative approach, it is important that managers do not interpret the results to a finer level of precision than is actually contained in the initial word ranking. Also, assessors should not use the numbers to give an appearance of precision where it does not exist.

Where a qualitative methodology is to be used to identify the level of clinical risk, managers should ensure that they have a sound understanding of their organisation's risk criteria and organisational context, and find the closest match in the descriptions in the Risk Assessment Tables for the WA Health System[10]

## Determining the adequacy of existing controls

Controls are processes or practices that are in place or planned to maintain or modify the risk. Controls can be established to address more than one risk and therefore need to be categorised to enable ease of identification and use. In addition to providing structure to reviewing controls, a clear outline of categories encourages consideration of controls from a wider range of topic areas that may not be initially examined. Control categories include:

- Patient Access and Care
- Workforce/HR
- Equipment
- Records Management
- Financial
- Contract
- Legislation/Standards and Compliance
- Documentation
- Environmental
- Training/Education
- Managerial
- Human Factor
- Incident Reporting System
- Facility
- IT/Communications
- Security.

For each control category there should be an organisational list of existing controls that can comprise policies, guidelines and tools. For example, the development of a comprehensive care plan based on integrating screening, assessment and risk identification processes is a control for the risks associated with the care of the patient. Examples of WA Health clinical controls are outlined in Appendix D. When analysing a risk, each control in place for that risk may be assessed using the control effectiveness guidance in Table 1.

Table 1 – Individual Control assessment guidance

| Level | Design Effectiveness | Operating Effectiveness |
|---|---|---|
| Fully effective | Well designed | Operating effectively and reliably |
| Substantially effective | Well designed | Some minor work required |
| Partially effective | Some work required | Some work required |
| Largely ineffective | Well-designed/some work required | Operating poorly |
| Totally ineffective | Poorly designed | Not applicable* |

Note: *If a control is not designed effectively for a risk then regardless of the operating effectiveness the control will be totally ineffective

To determine the aggregate effectiveness of the controls that are in place refer to Table 4 in the Risk Assessment Tables for the WA health System. Controls are rated as:

- Excellent
- Satisfactory
- Marginal or
- Weak

Controls that are assessed as below a satisfactory rating should be improved.

Once the adequacy of the controls has been analysed, the calculation of the current risk rating can be completed by scoring the consequence and likelihood of that risk.

## Consequences of clinical risk

When undertaking risk analysis, it is important to consider the consequences of risk and the likelihood of those consequences occurring.

The level of clinical risk is defined by the relationship between the consequence and likelihood applicable to each of the risks identified. The Consequence Rating Table 1 is used to identify the worst, realistic , primary consequence(s) should an incident occur given the existing level of controls.[4,10]

Using the 1-5 rating category from the Consequences Assessment Table, the best fit is then chosen. Note it is not necessary to address each consequence category within the table. However there may be multiple consequence categories applicable to this risk. Where this occurs, it is important to assess each consequence individually.

### Likelihood of the risk

Likelihood of a risk is measured on a five-point scale using the Likelihood Rating Table 2. For the clinical scale the likelihood is based on the risk occurring per separations/episodes with the rating of one referring to the likelihood of the risk occurring as "rare" (1 in 100,000 or more separations) through to a rating of five referring to the likelihood of the risk "very likely" (1 or more in 10 separations). Whilst this encourages quantitative assessments and determining a 'real frequency' of the incidents that occur as a result of the risk, when the data is unavailable, the best fit within clinical experience/knowledge can be used. Where multiple consequence categories have been identified, it is important to assess the likelihood of each for this risk.

### Determining the level of clinical risk

The level of clinical risk is then defined by the relationship between the consequence and likelihood applicable to the identified risk. A risk rating score is calculated with the corresponding scores in the consequence and likelihood tables multiplied together i.e. Risk rating score = consequence x likelihood. See Risk Level Matrix Table 3.

Where there are multiple consequence categories and their likelihood rating identified for a risk, the highest risk ranking should be chosen as the overall risk rating for the risk.

To determine the risk acceptability/tolerance, refer to the Risk Acceptance/Tolerance Criteria Table 5. Other factors may need to be considered in determining risk acceptability/tolerance. Ensure decisions and the reasoning in each case is documented. For a risk rated as "high" or "extreme" acceptance decisions must be made by at least a Tier 2 officer.

**Case Study 2 a) – Analysing risks to sole practitioners in home visits to a patient**

**Step 1 – Establish the context**

A Hospital in the Home (HiTH) nurse could not tend to a patient at home due to an aggressive, large dog in the front yard of the patient's house having no alternative way to contact the patient within the house. This experience was raised to the HiTH Manager with the nurse's concern for the patient who needed care after day 3 from a Total Hip Replacement. A number of staff have been in similar situations.

**Step 2 – Identify the risks**

The HiTH Manager conducted a brainstorm session with the HiTH team to identify the risks within the context of attending patients at home. The risk that was identified included:

- A failure to provide a safe environment for patient care for the patient at home
- A failure to provide a safe work environment for HiTH staff

The risks are caused by:

- Staff not aware of the environment and any issues/risks that may exist before their first visit to a patient's home such as aggressive pets, hazardous or unusual neighbourhood situations, potential altercations in the home
- Patient or family/carers were not adequately prepared for the visit from staff
- Staff were unable to contact patient or family/carers whilst outside the home

The controls currently in place include:

- Contact either via call or letter with patient before the visit to confirm the appointment for a home visit
- A diary entry in the HiTH office to note the home visit by each staff member

The consequence of this risk could be that a staff member may be harmed, or a patient may not receive the required care resulting in a deterioration of their condition.

**Step 3 – Analyse the risks**

The Controls Assessment was rated as **Marginal** because the limited controls did not address all of the causes of the risks and there was no periodic review of the controls.

Considering the controls, the Consequence Category was identified as: Health impact on patients (HP) and Health Impact on Staff or Others (HS).

The Health Impact on the Patients (HP) was assessed as **Level 3 (Moderate)** because an additional moderate level of care would be required for the patient (with an extension of their length of stay/care required between 72 hours to one week)

The Health Impact on Staff (HS) was assessed as **Level 3 (Moderate)** because staff who were injured would require time off work between 1 week and 1 month.

The likelihood of the risk was assessed as **Level 4 Likelihood (Likely)** because the HiTH Manager and team approximated that the frequency of failure to attend to a patient was 1 in 100 episodes of care.

The Risk Rating was then calculated as: **3x4=12 being HIGH**

This case study example will be continued in the following steps of evaluating and treating the risk outlined in the following sections.

**Key questions in analysing the risks**

- What are the current systems and controls to prevent the causes, detect or deter or reduce the consequences of potential or undesirable risk?
- What is the potential likelihood of the risks occurring?
- What are the potential consequences and impact of the risks if they do occur?
- What factors may increase or decrease risk?
- What additional factors might need to be considered and modelled?
- What are the limitations of the analysis and assumptions made?
- Are there limits of likelihood and consequence beyond which the analysis does not hold true?
- How confident is the organisation in its judgement of likelihood and consequences?

**Reminder**

Hospitals/health services must **communicate and consult** with internal and external stakeholders and **monitor and review** clinical risk processes and outcomes at each step of the clinical risk management process.

## Step 4 – Evaluate the risks

*Aims: to assess what action the level of risk determined in Step 3 requires, including the evaluation to determine if treatments should be developed and/or the risk should be escalated.*

Risk evaluation and prioritisation involves comparing the level of risk found during the analysis step with previously established risk criteria and developing a prioritised list of risks for further action. A decision should be made for the risk treatment options include:

a) Avoid the risk
b) Improve risk controls
c) Share or transfer the risk

### Clinical risk evaluation

When establishing evaluation thresholds for the clinical risk framework, health service providers should identify the levels of clinical risk the organisation is prepared to accept from various areas of its internal and external environment. The risk criteria will be used to measure and rank risks, to indicate which, if any, are acceptable and at which level of the organisation they should be managed. Refer to Risk Acceptance/Tolerance Criteria in Table 5.

### Roles and responsibilities

The Boards and/or Chief Executive for each organisation must endorse the delegated responsibility for management action of specified levels of clinical risk. The delegations should be clearly communicated to management and be regularly reviewed.

Risks whose risk rating exceeds a staff member's authority to manage should be escalated to the level of authority corresponding to the risk's rating. Escalation is to ensure that risk owners have the authority to make the decisions required to manage the risk. As outlined above risk rated as high or extreme must have acceptance decisions made by at least Tier 2 Officers. Using pre-determined organisational roles and responsibilities allows risks to be managed in a systematic way to help prevent incidents and improve care provided.

Decisions concerning risk acceptability and risk treatment may be based on clinical, operational, technical, financial, legal, social, humanitarian or other criteria. These often depend on an organisation's internal policy, goals, objectives and the interests of stakeholders.

### Determining acceptability of clinical risk

This risk evaluation should take into account the degree of control that the organisation has over each risk and the potential cost impact, benefits and opportunities. The potential consequences and risks borne by other stakeholders should also be considered.

Reasons why a clinical risk may be deemed as acceptable include:

- the likelihood and/or consequence of the risk being so low that specific treatment is inappropriate given the available resources.
- there is no treatment available for the risk.

- the opportunities presented outweigh the threats to such a degree that the risk is justified. For example surgical interventions will always be associated with high risks so it is important to ensure that all controls (e.g. surgical checklists) are in place and operating to prevent or mitigate causes and effects of all known risks.

If the clinical risks are not considered as being acceptable to the organisation, the activity/event should be avoided or additional treatments added. The clinical risks to be avoided or treated should then be prioritised for appropriate management action under the organisation's strategic clinical risk management and operating plans in the next step.

**Case study 2 b) – Evaluating risks to sole practitioners in home visits to a patient**

| **Step 3 – Analyse the risks** |
| --- |
| The Controls Assessment was rated as **Marginal** because the limited controls did not address all of the causes of the risks and there was no periodic review of the controls.<br><br>Considering the controls, the Consequence Category was identified as: Health impact on patients (HP) and Health Impact on Staff or Others (HS).<br><br>The Health Impact on the Patients (HP) and Staff (HS) was assessed as of **Level 3 (Moderate)** because an additional moderate level of care would be required for the patient (with an extension of their length of stay/care required between 72 hours to one week) and staff who were injured would require time off work between 1 week and 1 month.<br><br>The likelihood of the risk was assessed as **Level 4 Likelihood (Likely)** because the HiTH Manager and team approximated that the frequency of failure to attend to a patient was 1 in 100 episodes of care.<br><br>The Risk Rating was then calculated as: **3x4=12 being HIGH** |
| **Step 4 – Evaluate the risks** |
| Evaluating the risk score of 12 against the Risk Level Matrix- Table 3 the risk was High which is generally considered intolerable. Risk Tables 5 and 6 guide decisions on risk acceptance/ tolerance.<br><br>Controls should be at least Satisfactory (in step 3, the controls were rated as Marginal) and improved to an Excellent rating as soon as practicable and monitored.<br><br>The risk was listed on the hospital's risk register and escalated to the Chief Executive (the appropriate Tier 2 equivalent executive as outlined in the hospital's guidelines) to review, address the next steps and monitor the risk. |

This example will be continued onto Step 5 – Treat the risk in the following section.

**Key questions in analysing and ranking risks**

- What is the acceptable level of clinical risk?
- What level of clinical risk am I delegated and authorised to accept?
- If I cannot accept the clinical risk who can I refer it to for action?
- What are the potential positive and/or negative results of treating a clinical risk?
- What is the priority of the clinical risks (e.g. high, medium, low)?
- Is immediate action required?
- Who do I communicate the results to?

**Reminder**

If you rely on other stakeholders to operate a control that you rely on to keep your risk ranking low, then you must communicate with those stakeholders on a regular basis.

Hospitals/health services must **communicate and consult** with internal and external stakeholders and **monitor and review** clinical risk processes and outcomes at each step of the clinical risk management process.

## Step 5 – Treat the risks

*Aim: to develop cost effective options for treating those risks that have been evaluated as being unacceptable in Step 4.*

Risk treatment involves identifying the range of options for treating risk, assessing those options and preparing and implementing risk treatment action plans. Where risks cannot be accepted a treatment option may involve avoiding the risk, improving the risk controls or sharing or transferring the risk. Each treatment option should be evaluated for effectiveness. A combination of options may be considered.

### Treatment options

Clinical risk treatment is concerned with options to treat the risks that were deemed as not acceptable to the organisation. Treatment options available may include:

#### (a) Avoiding the activity/event associated with the unacceptable risk

A health service provider may avoid the clinical risk by deciding either not to proceed with an activity that contains unacceptable risk, choosing an alternative activity that has less risk for the organisation, or choosing an alternative less risky methodology or process to complete the desired activity.

**Example for avoiding the risk**

- A ban was placed on elective surgery in a regional hospital for bariatric patients or heavy smokers.

It should be noted that clinical risk management is not an exercise in risk avoidance.[5] There are circumstances in which the health service provider may choose to retain and manage the risk, simply because it is the organisation best equipped (in terms of specialist staff and resources) to do so. In such circumstances, the health service provider should implement appropriate risk management processes and work practices to reduce the consequence and/or likelihood of harm to individuals or loss to the organisation.

#### (b) Reduce the risk by improving controls

Reducing the level of risk involves the reduction of the likelihood or consequences of risk, or both. Hospitals/health services may reduce the likelihood of clinical risk through enhancement of existing controls or additional controls. Examples of how health service providers may reduce risk include revision of documented policies and procedures, quality assurance, training, supervision and environmental monitoring.

**Example for improving a control**

- This is exemplified in the risk area of clinical deterioration of patients and the development and implementation of the WA Health Regognising and Responding to Acute Deteriotation Policy and the observation and response charts. These charts have incorporated a ‘track and trigger’ system for clinical staff to identify abnormal changes in patients over time and instigate the required actions to reduce the likelihood of patients deteriorating further and prevent an adverse event occurring.

**Example for introducing a preventative control**

- To reduce the risk of treating the wrong patient when two or more patients in a ward have the same surname a local “PATIENT WITH THE SAME NAME IN WARD" cautionary card must be applied to each patient's health care record. Alerts must also be applied to all ward bed lists and other patient documentation while both patients remain in the ward. The patient’s given name should also be printed on these cards.

**Example for a control that decreases the consquences of the risk**

- A hospital buidling is at risk of damage if placed in an extreme risk cyclone region. The hospital building itself can be constructed to the highest cyclone resistant building standards and surrounded by elevated earth embankments which can deflect debris blown by the winds from striking the hospital building.

It should be noted that there is often a compromise between the level of risk and the cost of reducing those risks to an acceptable level. Any number of decision points need to be considered, including:

- a satisfactory (but not optimum) solution
- the most cost-effective solution
- the accepted practice (industry norm, evidence-based best practice)
- the best achievable result (given current technology and resources)
- the absolute minimum result that can be accepted.[5]

### (c)Transferring the clinical risk

Transferring the clinical risk may involve sharing the risk with another party. As a general principle, risks can be transferred by contract, legislation or administrative processes to another party. For a clinical risk, this could take the form of transferring the activity completely to another hospital or provider.

In certain circumstances it may not be cost-effective to transfer clinical risks to an external partner or supplier who is less able to manage the risk. In such cases, health service providers should be aware of the hidden costs of transferring risk e.g. higher contract costs.

### (d) Retaining the clinical risk

Retention of the clinical activity with a high risk within the organisation may take place in circumstances where it is either impossible or too costly to avoid, reduce or transfer the risk to another organisation. Where clinical risks which would normally be considered unacceptable are retained, the decision and rationale should be carefully documented. Retained clinical risks should be listed on a centralised clinical risk register, monitored, and contingency plans developed.

## Evaluating treatment options

Each of the treatment options should be evaluated on the basis of the extent of clinical risk reduction, and the benefits or opportunities created. Following an evaluation process, health services may apply the alternative treatment options either individually or in combination.

Selection of the most appropriate treatment option will require health service providers to evaluate the cost of implementing each option against the benefits that may be derived from it.

## Preparing treatment action plans

When preparing treatment action plans, staff should document how the chosen treatment option(s) will be implemented. Each clinical risk analysis and clinical risk treatment action plan should ideally outline individual responsibilities, schedules, the expected outcome of the clinical risk treatment process, budgeting and performance measures and a mechanism for monitoring and reviewing the outcome of the treatment process.

## Implementing treatment action plans

Organisational responsibility for treatment of clinical risk should be held by those designated officers who are best able to manage and control the risk. Effective risk management treatment action plans specify the risk treatment method(s) chosen, individual responsibilities and accountabilities for action and monitor the outcome of risk treatment against specified outcomes.

**Case study 2 c) – Treating risks to sole practitioners in home visits to a patient**

| **Step 4 – Evaluate the risks** |
|---|
| Evaluating the risk score of 12 against the Indicative Risk Ranking and Criteria Table (Appendix C), the risk was High and intolerable/unacceptable.<br><br>Controls must be at least Satisfactory (in step 3, the controls were rated as Marginal) and need to be improved to an Excellent rating as soon as practicable.<br><br>The risk was listed on the hospital's risk register and escalated to the Director of Community Services (the appropriate Tier 3 equivalent manager as outlined in the hospital's guidelines) to review, address the next steps and monitor the risk. |
| **Step 5 – Treat the risks** |
| Upon consideration of the risk with the HiTH Manager and team, it was approved by the Director of Community Services to treat the risk by improving the controls rating to Excellent by introducing and closely monitoring the following controls:<br><br>• Develop a home visiting policy and guidelines to outline the agreed, standard procedures for staff to undertake before, during and after visiting a patient at home. The procedures include:<br>  ○ Staff to carry out a risk identification and assessment of the home visit (using the home visit risk assessment tool) prior to arranging the home visit with the patient.<br>  ▪ If patient was referred, the referring person should be queried about the client and others in the home. |

    - The visit should be classified as high risk if the patient is unknown to the HiTH staff or certain criteria are highlighted during the risk assessment.
    - For high risk home visits, an action plan should be developed with input and approval from the HiTH manager and two staff members are to attend the home visit.
    - Staff to arrange an appointment for a home visit with the patient and should routinely ask about pets or other safety issues at the home. Ask patient to secure the pet if staff feel uncomfortable or if patient indicates that pet may be disruptive.
    - Create system and processes for the HiTH manager to monitor the movements and safety of staff whilst visiting patients, including notification via mobile once the staff member has started and finished the home visit.
    - Provision of a mobile phone to staff during home visits. Ensure phone is charged, unlocked and has emergency contacts programmed in speed dial.
    - Staff to call before the home visit to reconfirm with patient about the home visit and prepare them with an estimated time of arrival.
    - Once home visit is completed, return to HiTH office and update the risk assessment and other patient records to reflect experience. If there are issues that were identified, notify the HiTH manager and any other staff members that may attend the home visit in the future.
- Education regarding the policy and guideline requirements is to be scheduled regularly for all HiTH staff upon induction and throughout each year.
- Regular (quarterly) review and audits of the compliance and knowledge of the procedures.

These controls are now considered Satisfactory and reduce both the likelihood and consequences of the risk. The subsequent risk rating is now calculated as **Level 2 (minor consequence) x Level 3 (possible likelihood) = Level 6 risk (Medium Risk)**.

This risk is now tolerable to the organisation if the controls are maintained and reviewed frequently and the risk is reviewed at least annually.

**Case Study 3 – Clinical risk management process for risk in Obstetrics Unit**

**Step 1 – Establish the context**

A busy Obstetrics Unit has had a number of clinical incidents related to neonatal harm evidenced by low Apgar scores and unexpected still births. Multiple Midwives have expressed their concerns to the Obstetrics Head of Department.

**Step 2 – Identify the risks**

A risk assessment is undertaken. The clinical risk was identified as:

- a failure to deliver effective, safe maternity care. resulting in This risk is caused by:
    1. Complex high risk obstetric cases presenting in labour to the Birth Suite including multiple pregnancy and Vaginal Birth After Caesarean (VBAC) without adequate antenatal preparation or planning.
    2. Operating Theatre not available for Emergency Caesarean Section.
    3. Midwifery staff not trained to fully utilise CTG including interpretation of CTG traces.
    4. Midwifery staff not available to assist in interpretation of CTG traces due to busy work load.
    5. Consultant Paediatrician not available due to rostering shortfalls.

The consequence of this risk could be neonatal harm including death.

The Controls in place included:

1. A Policy to identify the complexity of the pregnancy via a low, medium or high categorisation.
2. Midwifery staff to attend an Introduction to Fetal Monitoring Course.

**Step 3 – Analyse the risks**

The Aggregate Controls Assessment was rated as Marginal because not all causes have corresponding controls in place.

The Consequence Category was identified as: Health impact on Patients (HP).

The Health Impact on the Patients (HP) was assessed as of **Level 5 Consequence** (Catastrophic) and **Level 4 Likelihood** (Likely).

This can be assessed by using data from the Clinical Incident Management System (CIMS) on the severity of neonatal harm (especially reviewing SAC1 incidence).

The Risk Rating was then calculated as: **5x4=20 being EXTREME**.

**Step 4 – Evaluate the risks**

This level of risk was deemed not acceptable to the organisation and further resources would be made available to treat the risk.

**Step 5 – Treat the risks**

A decision was made that women with high risk pregnancies should be transferred to deliver their babies at a nearby, specialist facility. This would immediately reduce the risk from being

rated Extreme down to the next level of High. Consequence still assessed as Level 5 (Catastrophic) but Likelihood being reduced to Level 3 (Possible) so the risk rating would be **5x3 = 15 being HIGH.**

Additional Treatment Action Plan (TAP) items that were implemented so that the controls would be assessed as Satisfactory and included:

1. The introduction of a Maternity Observation Chart to prompt early recognition of clinical deterioration.
2. All obstetric staff to attend an Advanced Fetal Monitoring Training.
3. Midwifery rosters to recognise the need for two midwives to check CTG traces.

Implementation of these TAPs need to be reviewed (at a specific time period) in order to reassess the risk score and the successful treatment of the risk.

**Key questions in treating clinical risks**

- What and how will other areas of the organisation and/or WA Health be affected by the risk treatment action plan?
- What is the feasibility and cost effectiveness of each treatment option?
- What processes and controls exist, or are needed, to minimise the level of risk?
- What performance indicators exist, or are needed, to monitor the levels of risk, the performance of the control measures and the risk treatments?
- Who has responsibility for implementing the plan for managing risks?
- What resources are needed (money, people, and technical)?
- Has a cost benefit analysis been conducted with respect to the risk treatment action plans?
- Who is best placed to treat each risk, either through better knowledge, technical expertise or financial capability?
- What job design and work organisation options are appropriate for staff treating the risks?

**Reminder**

Hospitals/health services must **communicate and consult** with internal and external stakeholders and **monitor and review** clinical risk processes and outcomes at each step of the clinical risk management process.

## Monitor and review

It is the responsibility of the health service provider's executive team to monitor and evaluate all aspects of the organisation's clinical risk management framework including, accountability arrangements, development, implementation and utilisation of clinical risk management policies and processes, training and professional development for staff, clinical and organisational outcomes and internal audit findings.[4,5]

Health service providers should develop and apply mechanisms to evaluate the outcomes and impact of risk management systems at all levels of the organisation. The organisation should develop and implement performance indicators to demonstrate the effectiveness of the organisation's risk management performance.[11,12] Appendix E provides example measures that can be utilised for the implementation of a risk management strategy. Additionally, reviews by independent bodies may assist health services to monitor, review and report on performance and achievement of expected outcomes to stakeholders and to identify areas of concern that need to be addressed.

Line managers in the clinical organisational structures should periodically review their risks in the Enterprise Risk Management System and include their status with commentary on any significant risk issues in the reporting frameworks as outlined by the health service provider. Reporting of significant risk should escalate through existing structures in accordance with management responsibilities as outlined by each health service provider.

Monitoring and evaluation documentation may include:

- details of the mechanism and frequency of review of the clinical risks and the clinical risk management process as a whole
- the outcome of audits and other monitoring procedures
- details of how review recommendations are followed up and implemented.

In order to review risks, controls need to be reviewed. Assurance that controls are operating as described is important to maintain confidence about the level of risk that is being accepted.

**Case study 4 – Learning from experience and monitoring in a United Kingdom Primary Care Trust[13]**

The Lincolnshire South West Teaching Primary Care Trust established a 'learning from experience' group (LEG). This group was established in the context of large reform program where the accountability of safe, efficient and effective health services was shifted to the local chief executives' responsibility and clinical governance was a large focus. This parallels with the current WA health environment.

The LEG was established after an executive identified that despite a wealth of data being collected on clinical governance, each was being dealt with in silos. The group incorporated a multidisciplinary and varied cross section of members who met monthly to review all complaints, incidents, feedback/calls to patient advice and liaison services and any other relevant information, including patient surveys and national reports. The LEG aimed to and succeeded in bringing key stakeholders from various committees and areas together to discuss and share problems, opportunities, potential problems and develop solutions in a proactive and holistic way.

# Implementation of Clinical Risk Management

Implementation of clinical risk management programs at all levels of the organisation is a challenge for all clinicians and managers alike. The challenge for management is to support and encourage prudent clinical risk management by:

- communicating and demonstrating support for clinical risk management
- trusting and empowering all staff to identify, analyse, report and manage risks
- acknowledging, rewarding and empowering good clinical risk management practices
- identifying and managing systemic problems as they occur
- encouraging organisational learning
- developing positive strategies to reduce the likelihood of recurrence of the problem and/or consequences rather than responding by introducing restrictive controls.[5]

Health service providers are required to develop and implement arrangements to ensure that clinical risk management becomes an integral part of the planning and management processes and general culture of the organisation. Enabling strategies may include:

- communicating the hospital's/health service's clinical risk management arrangements throughout the organisation
- assigning responsibility for managing clinical risk at all levels of the hospital/health service e.g. outline a checklist of responsibilities by management level for self-assessment and planning as can be viewed in the Victorian Clinical Governance Policy Framework[14]
- ensuring that all staff have the necessary knowledge and skills needed to manage clinical risks, e.g. incorporating clinical risk management into internal orientation, staff development and training programs
- providing appropriate support and expertise to those responsible for managing clinical risks
- ensuring that an accurate and complete record of risks and risk management activities are maintained in the Enterprise Risk Management System (ERMS) which is supported by a regular review process
- ensuring that the expected outcomes of the clinical risk management framework are monitored and reported to the hospital's/health service's senior management for review
- ensuring that systems for staff rewards, recognition and sanctions include clinical risk management
- ensuring that internal reviews and evaluation, such as internal audit, clinical audit and incident monitoring and reporting take account of the organisation's philosophy towards clinical risk management.

As outlined throughout the CRM Guidelines, the involvement and commitment of all clinicians through to managers, executives and Health Service Boards is key to ensuring clinical risk management is embedded within the organisation's culture, structure and processes.

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[1] The Standard was updated in 2018. This document underwent minor updates in 2019 but a full review of the revised 2018 Standard was not undertaken at this time.

# Appendix A – Glossary

**Adverse event** is a clinical incident where an injury/harm is caused by medical management or complication thereof, instead of the underlying disease. It results in an increase in the level of care and/or prolonged hospitalisation and/or disability at the time of discharge. Medical management refers to management under health care services.

**Clinical incident** an event or circumstance resulting from health care provision (or lack thereof) which could have or did lead to unintended or unnecessary physical or psychological harm to a patient. Clinical incidents include:

- **Near miss:** an incident that may have, but did not cause harm, either by chance or through timely intervention.
- **Sentinel events:** a subset of serious clinical incidents that has caused or could have caused serious harm or death of a patient. It refers to preventable occurrences involving physical or psychological injury, or risk thereof.

**Claim** means any approach for compensation made via legal means to a hospital or health service.

**Consequence** is an outcome of an event affecting objectives. It refers to the outcome or impacts of an event expressed qualitatively or quantitatively, being a loss, injury, disadvantage or gain. There may be a range of possible outcomes associated with an event.

**Cost** refers to a measure of activities both direct and indirect, involving any negative impact, including time, money, labour, disruption, goodwill, political and intangible losses.

**Control** A measure that maintains and/or modifies risk. Controls include, but are not limited to, any process, policy, device, practice, or other conditions and/or actions which maintain and/or modify risk. Controls may not always exert the intended or assumed modifying effect.

Controls may be **preventative** whereby a control prevents the cause of a risk or **mitigative** whereby the consequences of a risk are reduced.

**Department of Health** refers to the management of WA Health located at Royal St, East Perth.

**ERMS** is the enterprise risk management system used by the WA health system.

**Hazard** is a source of potential harm or a situation with a potential to cause loss.

**Likelihood** is a chance of something happening and refers to a qualitative description of probability or frequency.

**Loss** means any negative consequence, financial or otherwise.

**Organisation** refers to a hospital or Health Service Provider or other designated public health provider.

**Risk Management System** means the organisational structure, procedures, processes and resources needed to manage clinical and corporate risk and to monitor organisation's performance and outcomes.

**Risk** is the effect of uncertainty on objectives (either positive or negative).

**Clinical Risk** refers to risks associated with delivering clinical functions

**Corporate Risk** refers to risks associated with providing corporate functions

**Residual Risk** refers to the remaining level of risk after the risk treatment process has been completed.

**Risk Acceptance** is an informed decision to accept the likelihood and consequences of a particular risk.

**Risk Analysis** means a systematic use of available information to determine how often specified events may occur and their likely consequences. The purpose of risk analysis is to identify the causes, effects and magnitude of risk and provide a basis for **risk assessment** and **risk treatment**.

**Risk Appetite** The nature and extent of the risks the governing body is prepared to accept to meet objectives.

**Risk Assessment** refers to the processes used to determine risk management priorities by evaluating and comparing the level of risk against organisational standards, predetermined target risk levels or other criteria.

**Risk Avoidance** is an informed decision not to become involved in a risk situation.

**Risk Identification** refers to the process of determining what can happen, why and how.

**Risk Level** The risk level is determined by multiplying the consequence rating by the likelihood rating to achieve a risk level from 1 (Low) to 25 (Extreme).

**Risk Management** refers to the systematic application of management policies, procedures and practices to the task of **identifying**, **analysing**, **assessing**, **treating**, **monitoring** and **communicating** risk.

**Risk Reduction** means the selective application of appropriate techniques and management principles to reduce either the likelihood of an occurrence or its consequences, or both.

**Risk Retention** means the intentional or unintentional retention of responsibility for the loss, or financial burden, associated with a risk, within the organisation.

**Risk Treatment** refers to the selection and implementation of appropriate management options for dealing with identified risk.

**Risk Transfer** means shifting responsibility or burden for loss to another party through legislation, contract, insurance or other means. Risk transfer also refers to shifting a physical risk or part thereof elsewhere.

**Sentinel event** refers to unexpected occurrences involving death or serious physical or psychological injury/harm or risk thereof. There are ten nationally endorsed sentinel event categories. Preventable deaths identified via mortality review processes are to be notified as a SAC 1 event. See the Clinical Incident Management Policy 2019 for further information.

**Stakeholders** are those people and organisations who may affect, be affected by, or perceive themselves to be affected by, the decision or activity.

**Standard** refers to the Australia/New Zealand Standard on Risk Management AS/NZS ISO 31000:2018.

**Treasurer's Instruction** refers to Treasurer's Instruction 825: Risk Management and Security (formerly Treasurer's Instruction 109: Risk Management).

**Treatment Action Plan (TAP)** refers to the plan that is developed and reviewed during the risk treatment process of selecting and implementing the appropriate actions for dealing with identified risk. TAPs should include detail on the risk owner, proposed actions, resource requirements, timeframes and effect of the treatment on the risk.

**WA Health** refers to the whole of the WA public health system, particularly the Department of Health, Health Service Providers and their hospitals.

# Appendix B – Risk categories and areas of risk

Best practice in risk identification requires the categorisation of risks to both instigate identifying risks and also reporting of risks. If a risk has aspects that relate to more than one category, the predominant category is recorded on the risk register.

This list has been extracted in its entirety from the NSW Enterprise-Wide Risk Management Framework[9].

| Risk category | Examples of sources of risks | |
|---|---|---|
| Clinical care and patient safety | • Clinical KPIs in organisation Service Agreement<br>• Access appropriate to needs and prioritised according to clinical need<br>• Care evaluation, clinical handover, clinical ethics, clinical pathways and variance analysis<br>• Clinical quality improvement and clinical practice improvement<br>• Decision making at end of life and mortality management<br>• Discharge and transfer of care and recognition and management of deteriorating patients | • Ongoing care and management of chronic disease<br>• Patient safety, including infection control, medication safety and response to complaints and concerns about clinicians and near miss or incident trends<br>• Protection of children and others who are unable to care for themselves while accessing health services<br>• Monitor the continuum of care and clinical performance across the State |
| Health of the population | • Community health<br>• Disease prevention and control<br>• Human behaviour and demographics<br>• Health protection and surveillance | • Clinical strategic direction, planning, monitoring and performance of population health services across the State |
| Workforce | • Continuing education, learning and professional development<br>• Human resources performance management<br>• Claims (including general insurance)<br>• Visiting medical officers, contracts and volunteers | • Recruitment selection, credentialing, retention and appointment, including internationally trained medical officers<br>• Succession planning<br>• Workplace relations, including grievances<br>• Organisational culture |
| Communication and Information | • Hardware infrastructure (switchboards, pager systems, etc.)<br>• Information and data management system<br>• Informed consent<br>• Privacy and confidentiality<br>• Knowledge management<br>• Records management | • Risk communication<br>• Alerts<br>• Software<br>• Staff communication<br>• Technology and technical issues<br>• Release of information<br>• Digital Information Security e.g. electronic medical record<br>• Social Media |
| Facilities and Assets | • Assets management, including buildings, equipment, land, plant, vehicles, supplies and utilities<br>• Catering and food hygiene | • Preventative, repairs and maintenance<br>• Minor & Capital works<br>• Procurement |
| Security | • Access and controls<br>• Identification<br>• Surveillance/CCTV | • Personal threat<br>• Security management and monitoring |

| Risk category | Examples of sources of risks | |
|---|---|---|
| Emergency Management | • Business continuity planning, management and resilience<br>• Infectious disease outbreaks, including emerging infectious diseases, and other biological threats<br>• Drinking water, pharmaceutical, food or other contamination | • Natural disasters, (e.g. Extreme weather event)<br>• Man-made disasters (e.g. widespread power failure, explosion)<br>• Chemical, radiation or hazardous material incident |
| Legal | • Litigation<br>• Commercial and legal management | • Contract management<br>• Intellectual property<br>• Regulatory Compliance |
| Finance | • Fraud<br>• Medical indemnity insurance and Treasury managed fund<br>• Operational budgets and financial performance requirements under Service Agreements | • Public liability<br>• Administration, including accommodation, payroll and transport and travel<br>• Commercial income<br>• Procurement of goods and services, maintenance and contracts management |
| Work Health & Safety | • Workplace health and safety<br>• Contractor non compliance | • Workers compensation and injury management |
| Environmental | • Air quality, heating, noise, lighting and radiation<br>• Hazardous substances and dangerous good | • Waste management<br>• Cleaning services<br>• Infection control |
| Leadership & Management | • Complaints and compliments management<br>• Credentialing and delineation of clinical privileges<br>• Economic circumstances<br>• Effective Leadership<br>• Enquiries and ministerials<br>• External and internal auditing<br>• Governance structures, delegations and financial management<br>• Legislative compliance | • Monitoring performance<br>• Performance Management<br>• Political circumstances<br>• Professional development and Mentoring<br>• Reputation and image<br>• Resource accountability<br>• Service Agreement requirements<br>• Strategic and operational planning<br>• Succession planning |
| Community Expectations | • Access to services<br>• Consumer feedback, cultural and special needs, planned and delivered in partnership with patient rights and responsibilities | • Consumer engagement and empowerment, and stakeholders expectations<br>• The right care and services – including the protection of children – provided in the right setting within appropriate timeframes |

# Appendix C – Example Risk Management Measures

This example provides some suggestions for a risk management strategy plan and relevant measures to monitor compliance.

| Element | Description | When | Completed by | Approved by |
|---|---|---|---|---|
| Establish scope and organisation objectives/activities | Risk management will be incorporated into all normal business activities including planning, operational processes and reviews. | Biennially | All staff | Board |
| Risk Management Strategy/Framework | A review of the framework every two years allows the organisation to continually improve its processes without deviating too far from the policy and procedures | Biennially | Safety, Quality, Risk Committee | Board |
| Risk Management Policy and guidelines | A review of the policy every year allows for any changes to be incorporated and keep the information as updated as possible. | Annually | Safety, Quality, Risk Committee | Board |
| Risk Assessments | Formal risk assessment workshops will be undertaken as part of the annual business plan cycle, new initiatives, budget bids etc. | Annually | All units/divisions | Safety, Quality, Risk Committee |
| Roles and responsibilities | Review assignment of roles and responsibilities quarterly during the reporting cycle. If responsibilities for risks, controls or treatments have changed, they will be reflected in the reports. | Quarterly | All units/divisions | |
| Risk Management Reporting | Risk register review and related reporting to internal hierarchies (e.g. Managers-Executive Directors/Heads of Department-Chief Executive-Committees-Board). | Quarterly | All units/divisions | Board |
| Treatment Action Plans | TAPs should be reviewed regularly by the risk, control and treatment owners but are only reported on a quarterly basis. | Quarterly | All units/divisions | Safety, Quality, Risk Committee |
| Compliance and testing | Declarations are submitted quarterly and undergo a testing process to determine the quality of the report and level of compliance | Quarterly | Risk manager/team | Safety, Quality, Risk Committee |

| | | | | |
|---|---|---|---|---|
| Monitor and review | Lessons learned to be identified via audits and other processes to continuously improve on risk management processes | Quarterly | Risk manager/team | Safety, Quality, Risk Committee |
| Training and education | Risk workshops/training packages provided and presented to all staff | Bi-annually | Risk manager/team | Safety, Quality, Risk Committee |

## Document Control

| Version | Date | Amendment details |
|---|---|---|
| 2.5 | 16/8/2016 | Final |
| 3.1 | 26/11/2019 | Minor update to align with Risk Assessment Table changes October 2019 |

**This document can be made available in alternative formats on request for a person with a disability.**