

Desktop Guide to Clinical Risk Management



SAFETY & QUALITY
WESTERN AUSTRALIA



Department of Health
Government of Western Australia

ACKNOWLEDGEMENTS

The Desktop Guide to Clinical Risk Management is designed to support Area Health Service Executives to develop appropriate policies, processes and systems to manage clinical risk within their organisation.

The Desktop Guide should be read in conjunction with the following documents:

- Department of Health (2005). Health Risk Management Framework and Health Risk Management General Procedures Manual;
- Department of Health (2005). Clinical Risk Management Guidelines for the Western Australian Health System;
- Standards Australia (2004). Australian/New Zealand Standard AS/NZS 4360:2004 Risk Management;
- Standards Australia (2004). Australian/New Zealand Handbook HB 436:2004 Risk Management Guidelines Companion to AS/NZS 4360: 2004

The Office of Safety and Quality in Health Care would like to acknowledge Aerosafe Risk Management, who developed the concept of this Guidebook – www.aerosafe.com.au

Additional information on Clinical Risk Management and copies of the Desktop Guide may be obtained by contacting:

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Managing Clinical Risk in Health Care

Clinical Risk Management in health care is based on the effective identification, analysis and management of potential and actual corporate, clinical and organisational risks and adverse events which are inherent in the provision of health care services to the community.

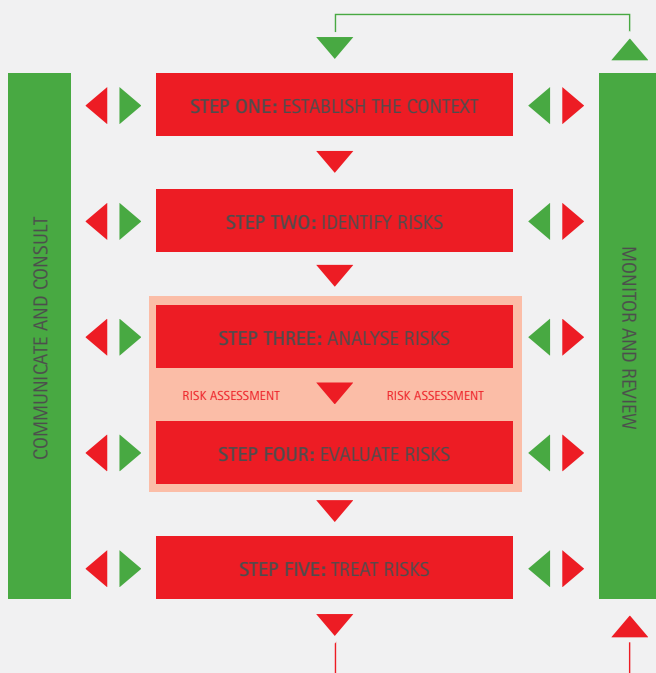
Implementation of Clinical Risk Management

Implementation of clinical risk management programs at all levels of the organisation is a challenge for 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 clinical risks;
- acknowledging, rewarding and empowering good clinical risk management practices;
- ongoing identification and management of systemic problems and their causative/contributory factors and treating them appropriately;
- encouraging organisational learning;
- developing appropriate clinical risk treatment strategies to reduce the likelihood or recurrence of the problem and/or consequences; and
- ongoing monitoring of implemented strategies to make sure they are effective in treating/reducing clinical risk.

The Five-Step Clinical Risk Management Process

This Desktop Guide has been structured to follow the risk management process outlined in the Australian and New Zealand Standard (AS/NZS) 4360:2004. The five-step Clinical Risk Management process is outlined below:



(Sourced from the Australia/New Zealand Standard on Risk Management AS/NZS 4360:2004)

Communicate and Consult

Aim

Communication and consultation are key elements of the clinical risk management process.

Area Health Services should develop appropriate communication strategies to engage internal and external stakeholders to ensure that they are aware of why clinical risk management strategies and policies have been developed and implemented and to ensure that they understand their individual roles and responsibilities for clinical risk management.

What to do

Establish an organisational communication strategy that includes:

- (a) Clearly defined objectives for communication;
- (b) Identification of which internal and external stakeholders should be consulted:
 - (i) Stakeholder groups and individuals
 - (ii) Specialists/experts
 - (iii) Communication teams
- (c) Identification of what beliefs and perspectives need to be taken into account during the risk management process;
- (d) Development of communication strategies to be used during the risk management process;
- (e) Processes to be used to measure and evaluate the effectiveness of the organisation's communication programs.

The 'Communication and Consultation' process is vital to effective clinical risk management and needs to be undertaken at each level of the clinical risk management process.

Step One – Establishing the Context

Aim

In order for a Health Service's clinical risk management program to be effective, the organisation's operating environment and strategic context must be adequately defined and understood.

Decisions about managing clinical risk need to be made within the context of the organisation's internal and external environment – **the strategic context**. This includes definition of the criteria by which the organisation will determine whether or not a risk is acceptable. The type and level of clinical risk management planning, controls and management options are also selected.

What to do

ESTABLISH THE STRATEGIC CONTEXT

- Identify and examine the operating environment, including the legal, political, clinical and socio-economic influences
- Identify internal and external users of the system, including clinicians, consumers and stakeholders. Who needs to be involved in the process?

ESTABLISH THE ORGANISATIONAL CONTEXT

- Determine the objectives of each clinical risk management task
- What is the significance of the activity to the organisation's risk management program and its wider goals, objectives, values, policies and strategies?

ESTABLISH THE CLINICAL RISK MANAGEMENT CONTEXT

- Determine 'why' clinical risk management is required
- Establish objectives for the 'clinical risk management' task to be conducted
- Decide the timeframe, resources and output required
- Define the depth of analysis required
- Decide the structure or approach to be used
- Identify the tools and documentation required

Step One – Establishing the Context

DEVELOP THE CLINICAL RISK EVALUATION CRITERIA

- Develop the criteria against which clinical risk is to be evaluated
- Decide what is an acceptable level of risk for each task
- Determine what level of clinical risk is unacceptable

DEFINE THE STRUCTURE FOR THE REST OF THE PROCESS

- Divide the activity, process, project or change into small manageable and measurable parts
- Develop a structure that is suitable for the risk, scope of project, process or activity

KEY QUESTIONS

- Does the organisation understand the importance of the task and its relevance to the organisational objectives & policies?
- Have the strategic and organisational context been clearly defined with measurable objectives?
- Has the risk evaluation criteria been established and agreed by all relevant stakeholders?
- Has the clinical risk management framework been established and resources assigned?
- What additional assistance is required from internal & external stakeholders?
- What documentation is required?

Step Two – Clinical Risk Identification

Aim

The risk identification step seeks to identify the clinical risks that need to be managed. A comprehensive identification system using a well-structured systematic process is critical, because a potential risk not identified at this stage will be excluded from further analysis and treatment.

Requirements for effective clinical risk identification

- Identification and examination of all sources of internal and external clinical risk
- Access to quality information to enable staff to identify clinical risks and to understand the likelihood and consequences
- Staff and management who are knowledgeable about clinical risk management and the activity being reviewed

Key questions for identifying clinical risks

- What can happen?
- How can it happen?
- Why could it happen?
- How often could it happen?

Remember

Continually ask

What if... What if... So what!



Step Two – Clinical Risk Identification

What to do

- Decide on a structure and method for clinical risk identification (see page 8)
- Determine who needs to be involved in this step
- Identify the dimensions of clinical risk that will be examined (see page 10)
- Decide what types of information (data) is required to assist in clinical risk identification (mechanisms)
- Document the identified clinical risks in an appropriate risk register (see template page 22)

Key questions

- What, when, where, why and how clinical risks are likely to occur, and who might be involved?
- What is the source of each clinical risk?
- What are the consequences of each clinical risk?
- What controls presently exist to mitigate each clinical risk?
- What alternative, appropriate controls are available?
- Have each of the key stakeholders been consulted?

Remember

Continually ask

What if... What if... So what!

Step Two – Clinical Risk Identification

Tools to aid clinical risk identification include:

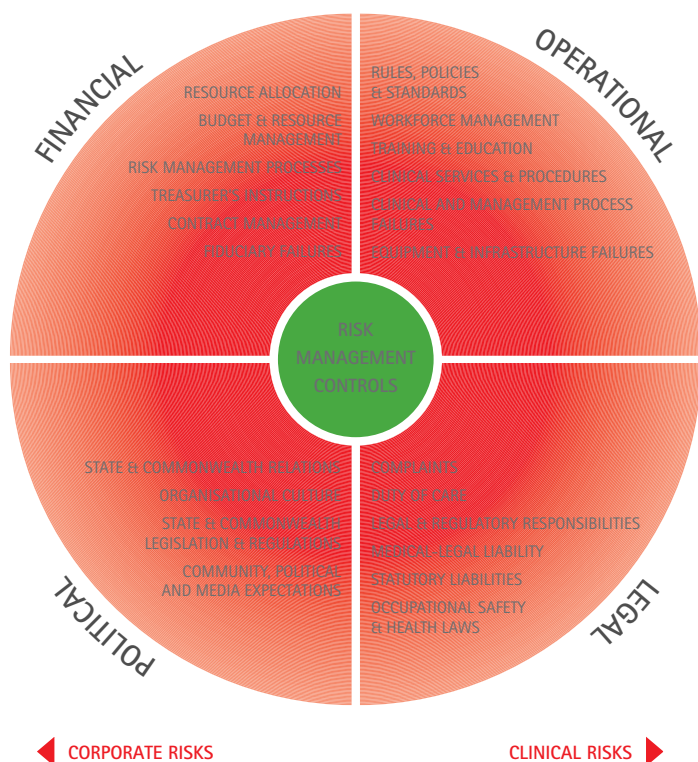
- Brainstorming
- Check lists and think prompts
- Process mapping
- Flow charts
- Equipment based structures
- Scenario analysis
- Task analysis
- Procedural change analysis
- Review of past data
- Use of expert judgement
- Audits and physical inspections
- Failure mode and effect analysis (FMEA)
- Hazard based risk identification
- SWOT Analysis
- Clinical incident management and reporting
- Sentinel Event Monitoring and Reporting
- Limited Adverse Occurrence Screening (LAOS)
- Examination of OSH Reports
- Medico-legal data
- Recommendations and findings from Coronial Inquiries
- Clinical audits
- Key Performance Indicators
- Patient Safety Indicators
- Morbidity and Mortality Reviews
- Complaints Data
- Performance satisfaction surveys and questionnaires

(Sourced from Aerosafe Risk Management (2003). Managing Risk in Aviation: Quick Reference Guide)

Step Two – Clinical Risk Identification

Aides to Clinical Risk Identification

DIMENSIONS OF CLINICAL RISK IN HEALTH CARE



(Sourced from the Australia/New Zealand Standard on Risk Management AS/NZS 4360:1999)

Step Three – Clinical Risk Analysis

Aim

The objectives of clinical risk analysis are to separate the minor acceptable clinical risks from the unacceptable major clinical risks, and to provide data to assist in the evaluation and treatment of clinical risks. 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 may also be identified.

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.


In order to calculate the clinical risk level of an activity, the individual elements of clinical risk can be considered individually and then combined to create a risk level, using the following formula:

$$\text{RISK LEVEL} = \text{CONSEQUENCE} \times \text{LIKELIHOOD}$$

Clinical risk is analysed by combining estimates of consequences and likelihood in the context of existing control measures

REMEMBER THE PRINCIPLE OF WORST CASE REASONABLE

(Sourced from the Australia/New Zealand Standard on Risk Management AS/NZS 4360:2004)



Step Three – Clinical Risk Analysis

Types of Analysis

- **Qualitative** – subjective description of clinical risk ie. a word picture
- **Semi-quantitative** – applies subjective numerical values to qualitative assessments
- **Quantitative** – statistical description of risk based on real or past data

What to do

- Identify the existing controls
- Has the worst-case reasonable scenario been considered?
- Determine the potential likelihood of the worst case risks happening?
(Worst Case Reasonable)
- Determine the potential consequences and impact of the worst case clinical risks if they do occur?
- Identify the factors which may increase or decrease clinical risk?
- Select the most suitable risk analysis tool and calculate the level of clinical risk
- Document the results

Key questions

- How good are the existing clinical risk management procedures?
- Is the analysis based on full facts?
- Have each of the key stakeholders been consulted?

Step Four – Clinical Risk Evaluation

Clinical risk evaluation involves comparing the level of risk found during the analysis process with previously established risk criteria. The output of a clinical risk evaluation is a prioritised list of risks for further action.

What to do

- Compare the level of clinical risk against the risk criteria set in Step 1
- Decide if a clinical risk is acceptable or whether it requires treatment to reduce the level of risk to the organisation
- Develop a prioritised list of clinical risks for treatment

Guidance

The following table provides guidance on clinical risk acceptance and risk referral. It consists of key questions to facilitate the risk acceptance process and suggested actions:

- Accept the clinical risk
- Refer the clinical risk to a higher authority for acceptance
- Amend activity or task to reduce the level of clinical risk
- Cancel activity or task

Step Four – Clinical Risk Evaluation

Suggested Questions

QUESTION	ACCEPT	REFER	AMEND	CANCEL
I have the resources and authority to implement recommended treatments	✓			
I do not have the resources or authority to implement recommended treatments		✓	✓	✓
The level of risk is above my level of delegated authority		✓	✓	✓
The level of risk is within my delegated authority	✓			
The level of risk is within my level of delegated authority, however the task or activity is significant, new, unusual or infrequent	✓	✓		

Key Questions

- What is the acceptable level of risk for this clinical activity?
- 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 is the priority of the risks (eg high, medium, low or 1,2,3)?
- Is any one clinical risk or combination of clinical risks a certain threat to the organisation?
- Is immediate action required?
- Who do I communicate the results to?

Step Five – Clinical Risk Treatment

Aim

Risk Treatment is used to describe the activities involved in dealing with risks identified in Step 4. Risk treatment involves identifying the range of options for treating clinical risk, assessing those options, preparing risk treatment plans and implementing them. Where risks cannot be eliminated, a combination of treatment options should be applied to control or treat the risks to the maximum extent possible. Each treatment option should be evaluated for effectiveness.

What to do

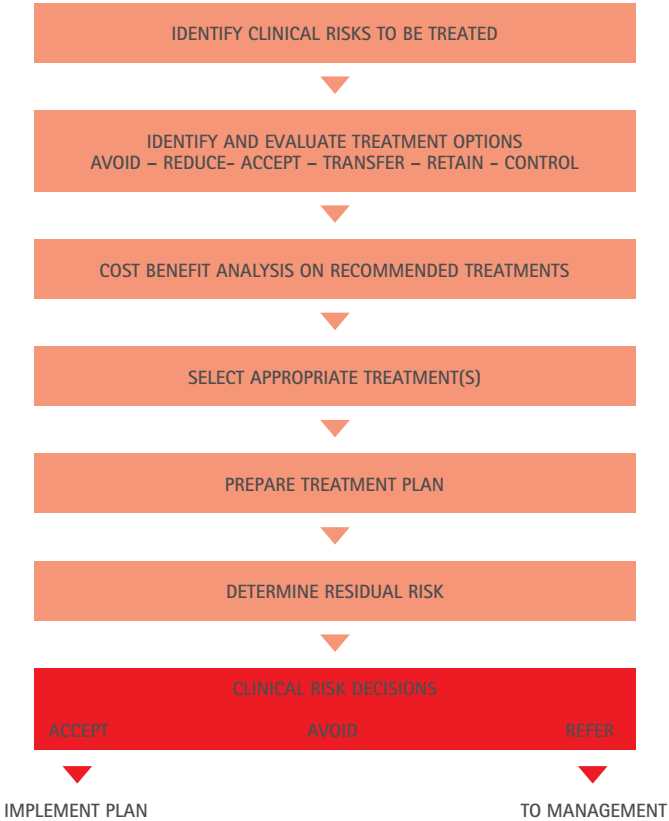
1. Identify appropriate treatment options:
 - Risk avoidance
 - Risk acceptance
 - Risk transfer
 - Risk retention
 - Reduction of consequence
 - Reduction of likelihood
 - Risk control
2. Assess feasibility of treatment options – cost-benefit analysis
3. Select the most appropriate treatment option(s)
4. Prepare treatment plan – see template on page 23
5. Determine residual risk level and its acceptability
6. Implement treatment plan

Step Five – Clinical Risk Treatment

Key Questions

- What are the advantages and disadvantages of each option for treating a clinical risk(s)?
- Do the benefits of treatment outweigh the costs of treatment?
- Who is authorised to accept residual risk?
- Who has responsibility for implementing the risk treatment plan?
- What resources are needed (money, people, technical)?
- How will the effectiveness and cost-benefit of the treatment be evaluated?
- Is an emergency plan or recovery plan required?

Summary of Clinical Risk Treatment Process



(Sourced from Aerosafe Risk Management (2003), Managing Risk in Aviation: Quick Reference Guide)

Step Five – Clinical Risk Treatment

Treatment options include:

RISK AVOIDANCE

An informed decision not to become involved in a risk situation

RISK REDUCTION

The selective application of appropriate techniques and management principles to reduce either the likelihood of an occurrence or its consequences, or both

RISK TRANSFER

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

RISK RETENTION

The intentional or unintentional retention of responsibility for the loss, or financial burden, associated with a risk, within the organisation

RISK CONTROL

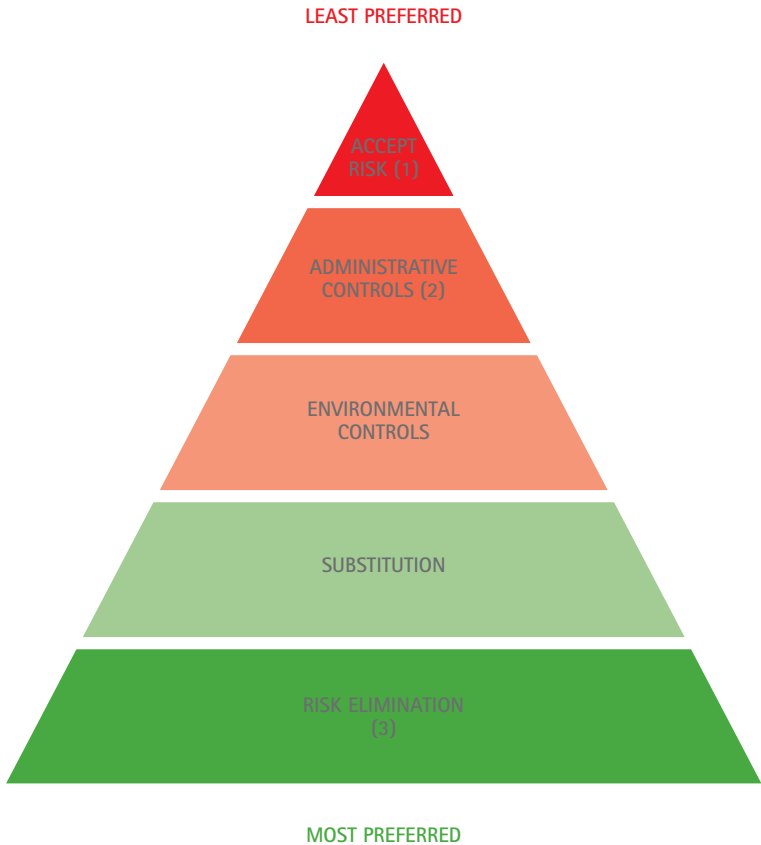
The development and implementation of policies, standards, procedures and physical changes to eliminate or minimise adverse events and risks. For management purposes, the processes used to eliminate known hazards and risks should follow a structured process known as the 'Hierarchy of Controls'

(Sourced from the Australia/New Zealand Standard on Risk Management AS/NZS 4360:2004)

Step Five – Clinical Risk Treatment

Aides to Clinical Risk Treatment

'HIERARCHY OF CONTROLS' PYRAMID



(Sourced from Aerosafe Risk Management (2003). Managing Risk in Aviation: Quick Reference Guide)

Monitoring and Review

Aim

Monitoring and review is an essential component of the risk management process. It is essential that clinical risks and risk treatment plans, strategies and management systems are continually monitored to ensure that the organisation is able to control the implementation of risk treatments.

The 'Monitoring and Review' process is vital to effective clinical risk management and needs to be undertaken at each level of the clinical risk management process.

What should be monitored?

- **Context** – to ensure new clinical risks are identified
- **Stakeholders** – to ensure new stakeholders are included over time
- **Consultation** – to ensure all relevant stakeholders are consulted
- **Communication** – to ensure the quality and timeliness of communication with stakeholders
- **Risk** – to ensure that new clinical risks are identified and old risks are treated or removed from register
- **Verify** – analysis of risk against real data, if possible
- **Analysis** – to ensure that there is a common understanding of clinical risk in the organisation
- Quality of decision making
- Changes in legislation and regulations
- Whether treatment is implemented effectively
- The effectiveness of the treatment

Few risks remain static.

It is therefore important to repeat the risk management process regularly.

Monitoring and Review

Possible Methods of Review

- Internal or external audit by an appropriately qualified assessor
- Internal performance and review audits
- Reviews of incident and investigation reports (current and past data)
- Reviews of organisational policies, strategies and processes
- Program evaluation

Key Questions

- Do the performance indicators reflect effectiveness of Risk Treatment strategies?
- Are the assumptions, including those made in relation to the environment, technology and resources, still valid?
- Are the risk treatments efficient/cost-effective in minimising the risks?
- Are the management and accounting controls adequate?
- Do the risk treatments comply with legal requirements, government and organisational policies, including access, equity, ethics and accountability?
- What do we do if the treatment does not work or makes things worse?
- Is the risk management process regularly reviewed? If so, how frequently?
- How can improvements be made?

(Source: Department of Premier and Cabinet (1999). Guidelines for Managing Risk in the Western Australian Public Sector. Department of Premier and Cabinet, Government of Western Australia)

Aides to Clinical Risk Documentation



Templates

Please see templates and plans overleaf.



Risk Register Template

DIVISION REF	SUBJECT/ELEMENT AT RISK	CSFS/DEPENDENCIES	DIRECTORATE/BRANCH		COMMENTS
			REF	THE RISK CAUSE	

(Sourced from Department of Health (2005). Clinical Risk Management Guidelines for the Western Australian Health System)

Aides to Clinical Risk Documentation

Sample Risk Treatment Plan

DIVISION			
DIRECTORATE		BRANCH	SECTION
ACTIVITY AT RISK			
RISK REF		RISK	

CURRENT RISK ASSESSMENT			
LEVEL OF RISK		ACCEPTANCE DECISION	
		CONTROLS RATING	

PREDICTED ASSESSMENT POST TREATMENT			
LEVEL OF RISK		ACCEPTANCE DECISION	
		CONTROLS RATING	

ACTION PLAN TO ACHIEVE PREDICTED ASSESSMENT	
1. PROPOSED ACTIONS	
2. RESOURCE REQUIREMENTS	
3. RESPONSIBILITIES	
4. TIMING	
5. REPORTING AND MONITORING REQUIRED	

AUTHORISED BY	DATE	REVIEWER	DATE

(Sourced from Department of Health (2005). Clinical Risk Management Guidelines for the Western Australian Health System)

Key Clinical Risk Management Definitions

CONSEQUENCE

The outcome 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

Process, policy, processes or actions that act to minimise negative risk or enhance positive opportunities

COST

A measure of activities both direct and indirect, involving any negative impact, including time, money, labour, disruption, goodwill, political and intangible losses

HAZARD

A source of potential harm or a situation with a potential to cause loss

LIKELIHOOD

A qualitative description of probability or frequency

RESIDUAL RISK

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

RISK

The exposure to the possibility of such things as economic or financial loss or gain, physical damage, injury or delay, as a consequence of pursuing a particular course of action. The concept of risk has two elements: the likelihood of something happening and the consequences if it happens

RISK ACCEPTANCE

An informed decision to accept the likelihood and consequences of a particular risk

RISK ANALYSIS

The 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.

Key Clinical Risk Management Definitions

RISK ASSESSMENT

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

A decision not to become involved in, or to withdraw from a risk situation

RISK IDENTIFICATION

The process of determining what can happen, why and how

RISK MANAGEMENT

The systematic application of management policies, procedures and practices to the task of identifying, analysing, assessing, treating, monitoring and communicating risk

RISK REDUCTION

Action taken to lessen the likelihood, negative consequences, or both, associated with risk

RISK RETENTION

Acceptance of the burden of loss, or benefit of gain, from a particular risk

RISK SHARING

Sharing the burden of loss, or benefit of gain for a particular risk with another party

RISK TREATMENT

The selection and implementation of appropriate management options for dealing with identified risk

STAKEHOLDERS

Those people and organisations who may affect, be affected by, or perceive themselves to be affected by, the decision or activity

(Sourced from the Australia/New Zealand Standard on Risk Management AS/NZS 4360:2004)

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