

NO. 8

Clinical Risk Management **Guidelines** for the Western Australian Health System

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1. INTRODUCTION

The Western Australian Department of Health is dedicated to ensuring the best achievable health status for all of the Western Australian (WA) community (Mission Statement 2001/2). This is being achieved by delivering a well-managed, high quality health care service that is recognised for its high standards and commitment to continually reviewing and updating practice in the light of tested and evaluated evidence-based best practice.

The Department of Health recognises that health care is increasingly complex in its delivery, personnel, technology and demand pressures. Inevitably, the WA public sector health system is exposed to many clinical and corporate risks on a daily basis. These risks may arise from:

- (i) provision of health care and its related activities;
- (ii) operational management activities and control;
- (iii) human behaviour;
- (iv) commercial and legal relationships;
- (v) strategic management;
- (vi) natural events;
- (vii) political circumstances; and
- (viii) technology and technical issues.

The Department of Health has a number of Statutory responsibilities to protect the government and the general community from unnecessary costs and losses, including the human cost of adverse incidents, and as such risk management is a key responsibility for all managers and staff.

In complying with these Statutory requirements and public sector governance requirements, the Department of Health requires all Health Service Chief Executives and corporate and clinical staff to focus on material risks at all levels of their organisation and to take necessary action to manage those risks.

2. PURPOSE OF THE CLINICAL RISK MANAGEMENT GUIDELINES

Risk management is a core requirement of the Department of Premier and Cabinet's *Guidelines for Managing Risk in the Western Australian Public Sector* (1999)¹, the *Corporate Governance Guidelines for Western Australian Public Sector CEOs* (1999)² and *Treasurer's Instruction (TI) 825: Risk Management and Security*^{3,4}. This requirement is part of the high order of diligence required in custodial care of the assets and other resources entrusted to CEOs as part of the powers provided to them under the Public Sector Management Act 1994.

Risk management is also a core element of the WA Clinical Governance Framework⁵ and is included in the Western Australian Strategic Plan for Safety and Quality in Health Care 2003 – 2008.⁶

The Office of Safety and Quality in Health Care has developed the Clinical Risk Management Guidelines for Western Australian Health Services to strengthen the Department of Health's risk management activities within the *WA Clinical Governance Framework*⁵ and to assist Health Service Executives, Clinicians, Risk Management and Quality Co-ordinators to meet their risk management responsibilities through the identification and management of clinical risk areas in a consistent and systematic way, in accordance with State and local priorities.

The Clinical Risk Management Guidelines for Western Australian Health Services is consistent with the following Policies and Standards:

- Department of Premier and Cabinet (1999). *Guidelines for Managing Risk in the Western Australian Public Sector*;
- Standards Australia (2004). Australian/New Zealand Standard *AS/NZS 4360:2004 Risk Management*; and
- Department of Health (2005). *Health Risk Management Framework and Health Risk Management General Procedures Manual*.⁷

The primary focus of the guideline is to provide context to assist health service staff to address risk management within a clinical setting. It is acknowledged that there is significant overlap between clinical and corporate risk within Health Services and a co-ordinated approach should be maintained.

A Clinical Risk Management Toolkit has also been developed to compliment these guidelines. The Clinical Risk Management Toolkit is designed to be a quick reference for staff to follow the five-step process, with these guidelines being available for further reference and context.

3. THE CLINICAL RISK MANAGEMENT PROCESS

The Clinical Risk Management Guidelines for Western Australian Health Services has been broken down into five easy to follow steps (see Figure 1). Each of the five-steps have been detailed with reference to the Australian/New Zealand Standard AS/NZS 4360:2004 Risk Management^{8,9}, and strategies and questions have been provided, where appropriate to guide their application to clinical risk management.

STEP 1: ESTABLISH THE CONTEXT.

Identify and understand your organisation's operating environment and strategic context in order for your Health Service's clinical risk management program to be effective.

STEP 2: IDENTIFY THE RISKS.

Identify internal and external clinical risks that may pose a threat to the health system, organisational, business unit and team and/or patient.

STEP 3: ANALYSE THE RISKS.

Undertake a systematic analysis of the health system, organisational, business unit and team environments to understand the nature of risk and to identify tasks for further action.

STEP 4: EVALUATE AND PRIORITISE THE RISKS.

Evaluate the risks and compare against acceptability criteria to develop a prioritised list of risks for further action.

STEP 5: TREAT THE RISKS.

Identify the range of options to treat risks, assess the options, prepare risk treatment plans and implement them using available resources.

Two additional processes flow across the five-steps of the clinical risk management process: 'Communication and Consultation' and 'Monitoring and Review'. Both are vital to effective clinical risk management and need to be implemented simultaneously at each level of the clinical risk management process.

COMMUNICATION AND CONSULTATION

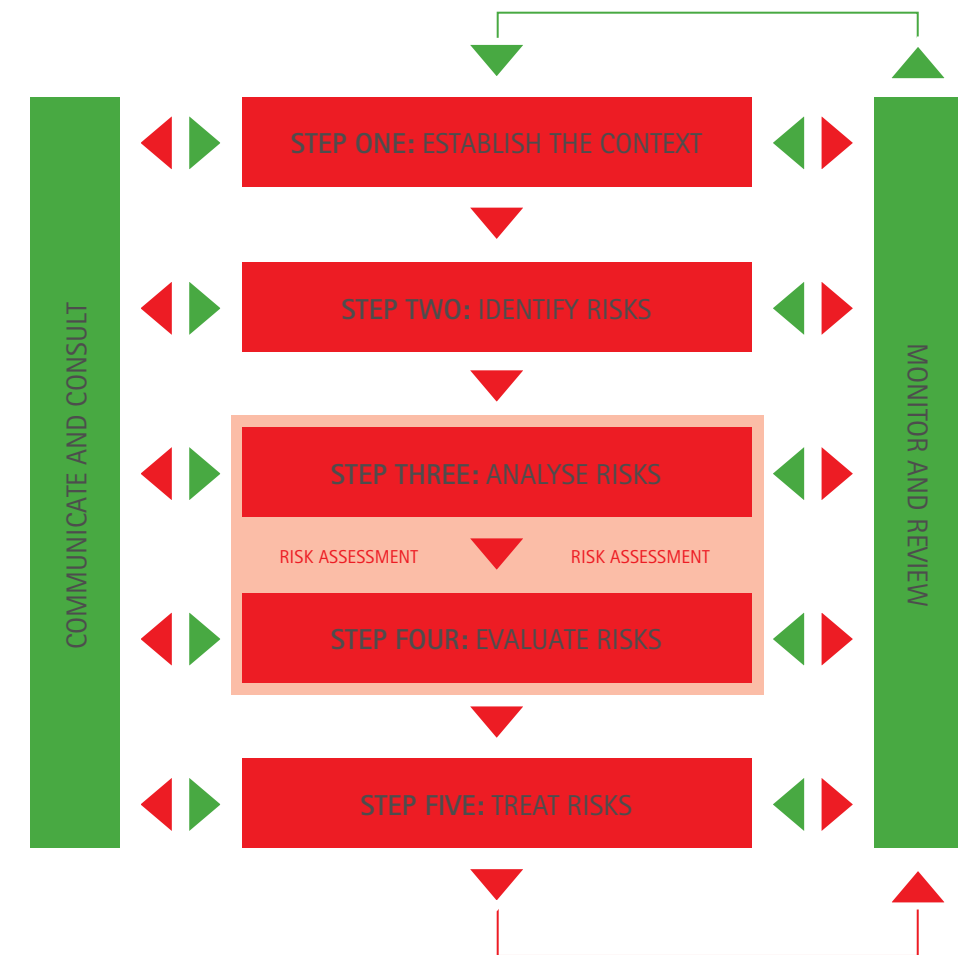
Health Services need to develop appropriate communication strategies to engage internal and external stakeholders at each stage of the clinical risk management process and concerning the process as a whole. The key elements of an organisational communication strategy include:

- (a) clearly defined objectives for communication;
- (b) identification of which internal and external stakeholders should be included:
 - (i) stakeholder groups and individuals;
 - (ii) specialists/experts; and
 - (i) communication teams.

- (c) identification of what beliefs and perspectives need to be taken into account during the clinical risk management process;
- (d) development of communication strategies to be used during the clinical risk management process; and
- (e) processes to be used to measure and evaluate the effectiveness of the organisation's communication programs.

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.

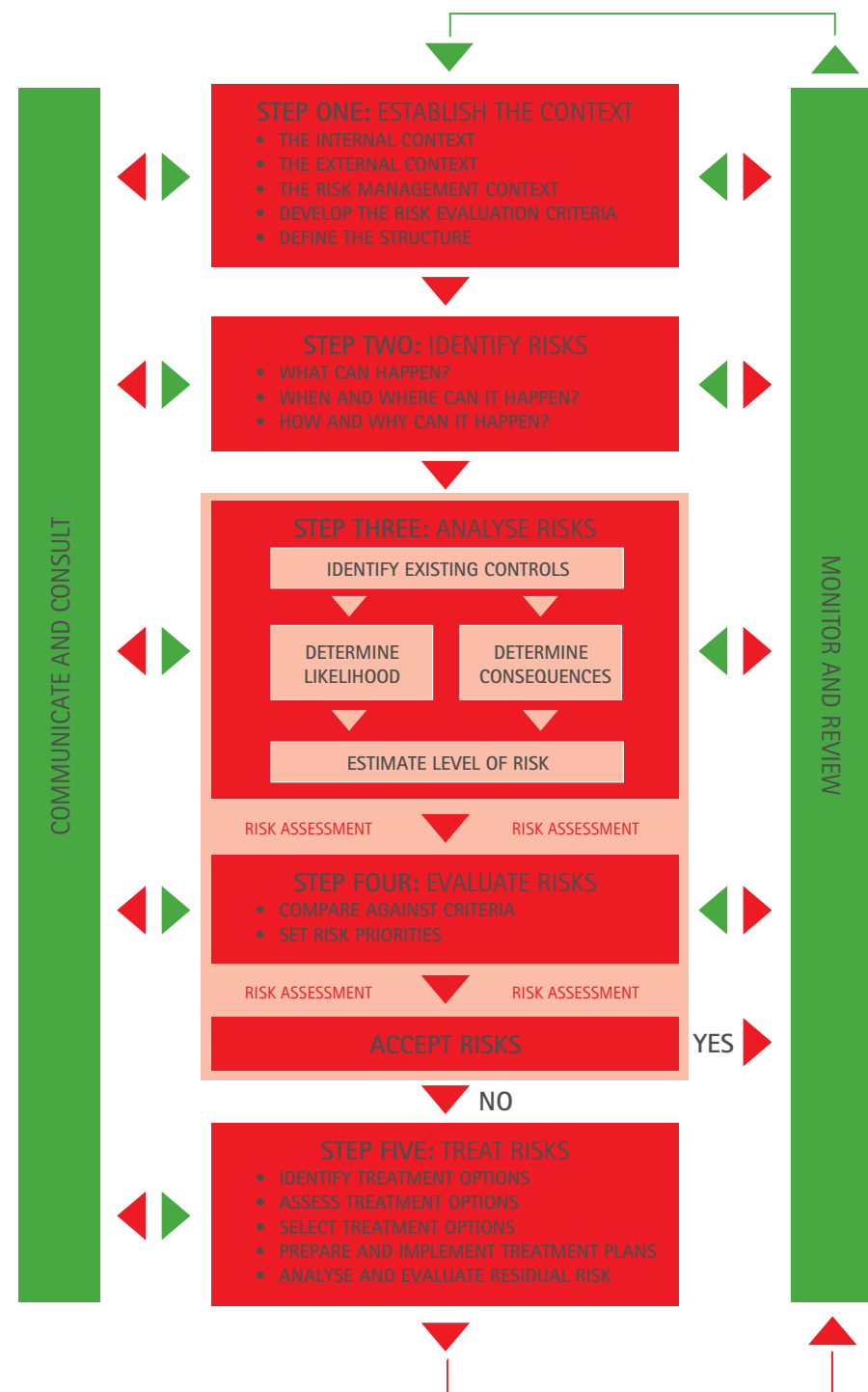
Figure 1: Overview of the Clinical Risk Management Process^{8,9}



MONITORING AND REVIEW

Ongoing monitoring and review of clinical risk is essential to ensure that the organisation's clinical risk management plan remains relevant. Given that the factors affecting the likelihood and consequences of a risk may continually change, it is necessary for organisations to continuously repeat the monitoring and review step throughout the clinical risk management process.

Figure 2: The Detailed Clinical Risk Management Process^{8,9}



Implementation of effective monitoring and review processes will ensure that clinical risk management strategies continue to be an integral component of the organisation's business processes. Possible methods of monitoring and reviewing the effectiveness of an organisation's clinical risk management systems and processes include:

- external audit by independent auditor (eg Auditor General);
- internal performance and review audits;
- reviews of organisational policies, strategies and processes; and
- evaluation of programs and risk treatments to ensure system learning.

STEP ONE: ESTABLISH THE CONTEXT

Establish the Context (Refer to Section 3.2 of AS/NZS 4360:2004)

Define the organisational and environmental parameters within which the clinical risk management process should take place, the purpose of the risk activity and the potential consequences which could arise from internal and external influences.

Health Service Managers must select clear parameters within which the clinical risk management process should take place and identify and adequately understand their organisation's operating environment and strategic context if the Health Service's clinical risk management process is to be effective.

Once the parameters are agreed upon, decisions about clinical risk need to be made within the context of the organisation's internal and external environment. It is imperative that the environment within which the organisation operates is clearly defined, so that subsequent steps in the clinical risk management process have a meaningful context.

(I) ESTABLISH THE CLINICAL RISK MANAGEMENT CONTEXT

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, should be established. The process should be undertaken with full consideration of the need to balance costs, benefits and opportunities. The resources required and the records to be kept should also be specified.

When defining the scope and depth of the clinical risk management program, Health Service Managers 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; and
- defining the depth and breadth of the clinical risk management activities to be carried out, including specific inclusions and exclusions.

Consideration should also be given to the adequacy of existing controls and whether these need adjustment to enable the Health Service to adequately manage clinical risks.

(II) ESTABLISH THE EXTERNAL CONTEXT

The first step in establishing the external context is identifying who the relevant stakeholders are and what their relationship is with your organisation. The objectives and interests of these organisations need to be identified as well as any threats or opportunities which they may pose on your organisation's risk management process.

The following should be considered:

- 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;
 - time frames and strategic directions stipulated by the Minister for Health; and
 - union requirements in terms of staffing.
- the organisation's strengths, weaknesses, opportunities and threats.
- external stakeholders and key business drivers, such as:
 - providers of funding; and
 - customer/patient requirements.

Appropriate clinical risk management criteria and communication strategies should be developed to enable the organisation to respond to external threats and opportunities as they occur. Refer to *Step 4: Evaluate and Prioritise the Risks* for details on determining the appropriateness of existing clinical risk management processes. Areas of responsibility for clinical risk management and clear lines of accountability should also be clearly defined.

(III) ESTABLISH THE INTERNAL CONTEXT

As with the establishment of the External Context, the establishment of the Internal Context needs to begin with the identification of the key internal stakeholders. In order to conduct a clinical 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 and objectives and the strategies that are in place to achieve them.

Some examples to consider 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 the all of the key internal stakeholders? If not, why not?
- do the goals and objectives of the organisation include clinical risk management as a priority?

One of the key internal stakeholders is the Department of Health. Health Service Managers should identify how their organisation will contribute to the Department of Health's overall goals, objectives, values, policies and strategies. This may assist management to define the criteria by which the organisation determines whether or not clinical risk is acceptable and forms the basis of controls and management options.

KEY QUESTIONS IN ESTABLISHING CONTEXT¹

- What is the policy, function, process or activity?
- What are the major threats and opportunities the clinical risk management program presents?
- 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?
- What risk criteria should be established?

REMINDER: Health Services must **communicate and consult** with internal and external stakeholders and **monitor and review** clinical risk processes and outcomes at each stage of the clinical risk management process.

STEP TWO: IDENTIFY THE CLINICAL RISKS

Risk Identification (Refer to Section 3.3 of AS/NZS 4360:2004)

Comprehensive identification of the risks to be managed using a well-structured systematic process is critical, as a potential risk not identified at this stage is excluded from further analysis and treatment. All material risks should be identified, whether or not they are under the control of the organisation.

Over time, all significant clinical risks at the State, health system, organisational, business unit or team level needs to be identified, assessed, treated and monitored. However, to start the process, it is necessary for the Health Service to identify and prioritise internal and external clinical risks that may pose a threat.

The WA public health system may have exposure to risk in many areas relating to the process of providing health care, which may result in specific clinical risks, for example:

- (i) physical environment of care;
- (ii) operational management activities and control;
- (iii) human behaviour;
- (iv) commercial and legal relationships;
- (v) strategic management;
- (vi) natural events;
- (vii) political circumstances; and
- (viii) technology and technical issues.

Identification of clinical risk requires the Health Service Executive to have a thorough understanding of the following components:

- (a) the **source of the clinical risk or hazard** that has the potential to cause harm;
- (b) the **event or incident** that occurs and the impact on the organisation or its internal/external stakeholders;

- (c) identification of the **consequence, outcome or impact** of the clinical risk or event/incident on the organisation or its stakeholders;
- (d) the **contributing factors** (what and why) for the presence of the clinical risk or hazard or the event occurring; and
- (e) **when and where** could the clinical risk or hazard occur.⁸

Table 1: Possible Methods of Identifying Clinical Risks^{8,9}

SENTINEL EVENT REPORTS	COMPLAINT DATA
AMS DATA	MEDICO-LEGAL DATA
WORK BREAKDOWN STRUCTURE ANALYSIS	OPERATIONAL MODELLING
INTERVIEW/FOCUS GROUP DISCUSSION	FLOW CHARTING, SYSTEM DESIGN REVIEW, SYSTEMS ANALYSIS, SYSTEMS ENGINEERING TECHNIQUES (E.G. HAZARD AND OPERABILITY (HAZOP) STUDIES)
AUDITS OR PHYSICAL INSPECTIONS	DECISION TREES
NETWORKING WITH PEERS, INDUSTRY GROUPS AND PROFESSIONAL ASSOCIATIONS	SURVEY, QUESTIONNAIRE, DELPHI TECHNIQUE
EXAMINATION OF LOCAL, INTERSTATE, FEDERAL OR OVERSEAS EXPERIENCE	STRENGTHS, WEAKNESSES, OPPORTUNITIES, THREATS (SWOT) ANALYSIS
BRAINSTORMING	PAST INCIDENT AND CLAIMS ANALYSIS (EXCLUDING EXGRATIA BENEFITS)
FOI REQUESTS	

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

1. Examine all sources of clinical risk from the perspective of all stakeholders, both external and internal. By identifying each source of clinical risk, the organisation can consider the contribution that each source makes to the likelihood and the consequences of the risk. This will be discussed further in Step Three-Analyse the Risks. Possible methods of identifying clinical risks are outlined in Table 1.

The results of this assessment should be recorded in the Clinical Risk Identification Worksheet (see Attachment A).

2. Integrate risk identification into all new project scoping, assessment and change management activities. Identify and examine external and/or non-insurable risk. This would help identify clinical risks which are either new or have not been previously identified.
3. Access good quality information which will assist the organisation in the next step of understanding their likelihood and consequences. The information should be as relevant, comprehensive, accurate and timely as resources will permit. Existing information resources should be accessed and, where necessary, new information developed.
4. Ensure that the managers and staff involved in clinical risk management are knowledgeable about the policy, project, function or activity that is being reviewed. It may be necessary to draw from experience, knowledge and expertise from outside as well as inside the agency.¹

REMINDER: Health Services must **communicate and consult** with internal and external stakeholders and **monitor and review** clinical risk processes and outcomes at each stage of the Clinical Risk Management process.

KEY QUESTIONS IN IDENTIFYING CLINICAL RISKS¹

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

STEP THREE: ANALYSE THE CLINICAL RISKS

Clinical Risk Analysis (Refer to Section 3.4 of AS/NZS 4360:2004)

A systematic process to understand the nature of risk and to deduce the level of risk in order to separate the minor acceptable risks from the major risks, and to provide data to assist in their evaluation and treatment.

Risk analysis involves consideration of the existing controls over the clinical risk, the probable severity of the consequences should the risk give rise to an incident and the degree of likelihood that those consequences may occur. Measurement and ranking of clinical risks is undertaken using the Likelihood Categories Table (see Table 3), Consequence Categories Table (see Table 4) and Risk Assessment Matrix (see Table 5).

A preliminary analysis should be carried out so that low impact clinical risks can be excluded from detailed study. Excluded clinical risks shall, where possible, be listed and their exclusion justified and documented to demonstrate the completeness of the risk analysis.

(I) 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 methods 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 other examples of quantitative methods of analysing clinical risk include:⁹

- probability analysis;
- simulation/computer modelling;
- life-cycle cost analysis;
- fault tree and event tree analysis;
- consequence analysis;
- statistical/numerical analysis;
- decision trees; and
- influence diagrams.

(b) Qualitative methods: Although quantitative data provides the most accurate information, this is not always available and as such, often qualitative or semi-qualitative is more appropriate.

Qualitative methodologies rely 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:⁹

- qualitative mapping;
- 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; and
- 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 establish appropriate mapping tables for their own needs.

(c) Semi-Quantitative Methodology allocate numbers to qualitative word 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 that 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.

(II) DETERMINE THE ADEQUACY OF EXISTING CONTROLS

The first step in analysing clinical risk is to identify the adequacy of existing management, technical systems and procedures to control risk, and assess their effectiveness and adequacy. Rate the effectiveness of the organisation's controls using the controls adequacy assessment criteria, listed in Table 2.

The review process should seek to identify weaknesses in existing procedures and opportunities for error. This may enable the organisation to establish mechanisms to improve its treatment of risk by introducing appropriate monitoring procedures to reduce the likelihood of error occurring. Management should not assume that the controls which rely on people following correct procedures will always work.

The results of this assessment should be recorded in the Clinical Risk Identification Worksheet (see Attachment A).

Table 2: Controls Adequacy Assessment⁷

LEVEL	DESCRIPTOR	STATUS TEST
E	EXCELLENT	COMPREHENSIVE EFFECTIVE CONTROLS FULLY IN PLACE, COMMUNICATED, COMPLIED WITH, MAINTAINED, MONITORED, REVIEWED AND TESTED REGULARLY. ALL THAT IS PRACTICABLE TO BE DONE IS BEING DONE.
A	ADEQUATE	SUFFICIENT EFFECTIVE CONTROLS PROCEDURES ARE SUBSTANTIALLY IN PLACE FOR SPECIFIC CIRCUMSTANCES, COMMUNICATED, AND ARE COMPLIED WITH. PERIODIC REVIEWS ARE CONDUCTED.
I	INADEQUATE	CONTROLS ARE EITHER NOT PRACTICALLY IN PLACE, NOT EFFECTIVE, NOT COMMUNICATED AND/OR NOT COMPLIED WITH. NO REVIEWS UNDERTAKEN.
U	UNKNOWN	CONTROLS AND STATUS ARE UNKNOWN.

KEY QUESTIONS IN DETERMINING ADEQUACY OF CONTROLS¹

Using the clinical risk identified in Step Two as a reference, identify:

- What controls presently exist to mitigate each risk?
- What could cause the control not to have the desired effect on the risk?
- What alternative, appropriate controls are available?

(III) LIKELIHOOD

The 'likelihood' of each of the identified risks can be calculated using Table 3. First consider the expected or actual frequency of the risk occurring, as outlined in the right hand column. Secondly, determine the level of risk and likelihood. You will use the likelihood of risk to calculate the consequence and severity of the risk, using the Risk Assessment Matrix in Table 5.

The results of this assessment should be recorded in the Clinical Risk Identification Worksheet (see Attachment A).

Table 3: Likelihood Categories Table⁷

LEVEL	LIKELIHOOD	EXPECTED OR ACTUAL FREQUENCY EXPERIENCED
1	RARE	ONCE IN MORE THAN 10 YEARS
2	UNLIKELY	AT LEAST ONCE IN 5 TO 10 YEARS
3	POSSIBLE	AT LEAST ONCE IN 3 TO 5 YEARS
4	LIKELY	AT LEAST ONCE IN 1 TO 3 YEARS
5	ALMOST CERTAIN	MORE THAN ONCE PER YEAR

(III) CONSEQUENCES OF CLINICAL RISK

The level of clinical risk is defined by the relationship between the consequence and likelihood applicable to each of the identified risks located within the program/area under review. Using the Consequence Categories in Table 4, determine the potential 'consequence(s)' of each of the identified clinical risks, if the risk gives rise to an incident. Review the Consequence Categories and determine the realistic 'worst case' severity of risk that could be expected given the existing level of controls. Use the 1 to 5 scales.

This Descriptor will be used at a later stage to calculate the consequence and severity of the risk, using the Risk Assessment Matrix in Table 5.

TABLE 4: Consequence Categories Table⁷

LEVEL	DESCRIPTOR	HEALTH IMPACTS (PATIENTS, STAFF, PUBLIC, CONTRACTORS ETC)	CRITICAL SERVICES INTERRUPTION	PERFORMANCE TO BUDGET	FINANCIAL LOSS LIABILITY PER EVENT BEFORE INSURANCE	ORGANISATIONAL OBJECTIVES OR OUTCOMES	REPUTATION AND IMAGE PER ISSUE	KPI VARIATION	NON-COMPLIANCE
1	MINOR	ROUTINE MEDICAL ATTENTION REQUIRED. TEMPORARY DIMINUTION OF NORMAL BODY/ MENTAL HEALTH OR FUNCTION. MAX 2 WEEKS INCAPACITY/ TIME LOST.	SHORT-TERM TEMPORARY SUSPENSION OF WORK. BACKLOG CLEARED IN DAY. NO PUBLIC IMPACT.	MORE THAN 2% UP TO 5% TEMPORARILY OVER BUDGET.	\$5,000 TO LESS THAN \$100,000.	INCONVENIENT DELAYS.	NON-HEADLINE EXPOSURE. CLEAR FAULT. SETTLED QUICKLY BY DEPARTMENTAL RESPONSE. NEGLIGIBLE IMPACT.	2% - <5%	BREACH, OBJECTION/COMPLAINT LOGGED. MINOR HARM WITH INVESTIGATION. EVIDENCE OF GOOD FAITH ARGUABLE.
2	MODERATE	INCREASED LEVEL OF MEDICAL ATTENTION REQUIRED. PROLONGED DIMINUTION OR LOSS OF NORMAL BODY/MENTAL HEALTH OR FUNCTION. 2 WEEKS TO 3 MONTHS INCAPACITY/TIME LOST.	MEDIUM-TERM TEMPORARY SUSPENSION OF WORK. BACKLOG REQUIRES OVERTIME OR ADDITIONAL RESOURCES TO CLEAR. MANAGEABLE IMPACT.	MORE THAN 5% TO 10% TEMPORARILY OVER BUDGET.	\$100,000 TO LESS THAN \$3M.	MATERIAL DELAYS. MARGINAL UNDER ACHIEVEMENT OF TARGET PERFORMANCE.	REPEATED NON-HEADLINE EXPOSURE. SLOW RESOLUTION. MINISTERIAL ENQUIRY /BRIEFING.	5% - <15%	NEGLIGENT BREACH. LACK OF GOOD FAITH EVIDENT. PERFORMANCE REVIEW INITIATED. MATERIAL HARM CAUSED.
3	MAJOR	SEVERE HEALTH CRISIS AND/OR INJURIES, PROLONGED ABSENCE BEYOND 3 MONTHS.	PROLONGED SUSPENSION OF WORK. ADDITIONAL RESOURCES, BUDGET, MANAGEMENT ASSISTANCE REQUIRED. PERFORMANCE CRITERIA COMPROMISED.	MORE THAN 10% TEMPORARILY OVER BUDGET OR MATERIAL OVER-RUN NOT RECOVERABLE WITHIN THE FINANCIAL YEAR.	\$3M TO LESS THAN \$20M.	SIGNIFICANT DELAYS. PERFORMANCE SIGNIFICANTLY UNDER TARGET.	HEADLINE PROFILE. REPEATED EXPOSURE. AT FAULT OR UNRESOLVED COMPLEXITIES IMPACTING PUBLIC OR KEY GROUPS OR MINISTERIAL INVOLVEMENT.	15% - 30%	DELIBERATE BREACH, OR GROSS NEGLIGENCE. SIGNIFICANT HARM. FORMAL INVESTIGATION. DISCIPLINARY ACTION. MINISTERIAL INVOLVEMENT.
4	CRISIS/EUPHIC	SEVERE HEALTH CRISIS, INJURIES OR DEATH CAUSED BY RELATED TO THE RISK BEING EVALUATED. DEATH OF AN INDIVIDUAL.	PROLONGED SUSPENSION OF WORK. ADDITIONAL RESOURCES, BUDGET, MANAGEMENT ASSISTANCE REQUIRED. PERFORMANCE CRITERIA COMPROMISED.	MORE THAN 10% TEMPORARILY OVER BUDGET OR MATERIAL OVER-RUN NOT RECOVERABLE WITHIN THE FINANCIAL YEAR. FOR BEING LIABLE TO PAY COST OF FINANCIAL SERVICES.	\$20M +.	NON-Achievement of OBJECTIVE OUTCOME. TOTAL PERFORMANCE FAILURE.	WIDESPREAD MULTIPLE HEADLINE EXPOSURE. MINISTERIAL CRISIS. DIRECT INTERVENTION. LOSS OF CREDIBILITY AND PUBLIC TRUST. STATE-WIDE SUPPORT.	30% +	SEVERE AND WIDELY BREACH. FORMAL INVESTIGATION. DISCIPLINARY ACTION. MINISTERIAL INVOLVEMENT.

The results of this assessment should be recorded in the Clinical Risk Identification Worksheet (see Attachment A).

(V) DETERMINING THE LEVEL OF CLINICAL RISK

Once the 'likelihood' and 'consequence' of each of the identified clinical risks has been determined, the next step is to use this information to determine the level of risk, which will be recorded in the Clinical Risk Identification Worksheet (see Attachment A).

The clinical risk assessment matrix is a tool that can be used to determine the level of risk to the Health Service and to future patients/consumers. As a corollary, the highest risk issues present the biggest opportunity for improvement in the organisation and may prevent future risks if the organisation's processes were to be re-designed.

To determine the level of risk move down the selected Consequence column until you reach the selected Likelihood row.

A Whole of Health risk matrix has been provided to assist Health Services to develop and implement clinical risk management policies and procedures that comply with Government policy and are suitable for the local health care environment. This Whole of Health risk assessment matrix is based on the Standards Australia Risk Management Standard AS&NZS 4360:2004.

Where an organisation has identified several extreme risks, there may be a need for the organisation to prioritise which risks will be investigated and treated first, given the available resources. Organisations may prioritise their risks by applying a numerical rating along the consequence and likelihood axis. The numbers and colours of the cell where both the level of outcome and likelihood meet indicate the level of risk and action to be taken (Table 6).

TABLE 5. Risk Assessment Matrix⁷

LIKELIHOOD	CONSEQUENCE				
	INSIGNIFICANT (1)	MINOR (2)	MODERATE (3)	MAJOR (4)	CATASTROPHIC (5)
RARE (1)	LOW 1	LOW 2	LOW 3	MODERATE 4	MODERATE 5
UNLIKELY (2)	LOW 2	LOW 4	MODERATE 6	MODERATE 8	HIGH 10
POSSIBLE (3)	LOW 3	MODERATE 6	MODERATE 9	HIGH 12	HIGH 15
LIKELY (4)	LOW 4	MODERATE 8	HIGH 12	HIGH 16	EXTREME 20
ALMOST CERTAIN (5)	MODERATE 5	HIGH 10	HIGH 15	EXTREME 20	EXTREME 25

(VI) RESPONSIBILITY FOR ACTION

The 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.

Table 6 below provides an example of how responsibilities and actions, such as the level at which there can be qualified acceptance of identified clinical risks may be documented.

REMINDER: Health Services must **communicate and consult** with internal and external stakeholders and **monitor and review** clinical risk processes and outcomes at each stage of the Clinical Risk Management process.

KEY QUESTIONS IN ANALYSING THE RISKS⁸

- What are the current systems and controls to prevent, detect or deter or lower 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?

TABLE 6: Responsibilities Table⁷

LEVEL OF RISK	QUALIFIED ACCEPTANCE WITH ACCEPTANCE CONTROLS	MANAGEMENT LEVEL INDICATED*
(1) LOW RISK	YES (WITH ADEQUATE OR EXCELLENT CONTROLS)	BUSINESS UNIT/CLINICAL DEPARTMENT MANAGER* (EXAMPLE ONLY)
(2) MODERATE RISK	YES (WITH ADEQUATE OR EXCELLENT CONTROLS)	BRANCH/DIRECTORATE/HOSPITAL/DISTRICT MANAGER* (EXAMPLE ONLY)
(3) HIGH RISK	NO	DIVISION/HEALTH SERVICE REGION MANAGER* (EXAMPLE ONLY)
(4) EXTREME RISK	NO	CHIEF EXECUTIVE/ EXECUTIVE DIRECTOR* AND/OR DIRECTOR GENERAL/ SHEF (EXAMPLE ONLY)

* NOTE: THE LEVEL OF RISK REPORTING IS TO BE DETERMINED BY EACH HEALTH SERVICE.

STEP FOUR: EVALUATE AND PRIORITISE THE CLINICAL RISKS

Risk Evaluation (Refer to Section 3.5 of AS/NZS 4360:2004)

Risk evaluation and prioritisation involves comparing the level of risk found during the analysis process with previously established risk criteria and developing a prioritised list of risks for further action.

As part of the clinical risk management process, Health Services should review their identified clinical risks against the risk criteria established in Step One: Establish the Context and determine whether a clinical risk is acceptable or unacceptable. If a clinical risk is deemed acceptable it will not be treated under Step Five: Treat the Risks. Defining a clinical risk as acceptable does not imply that the clinical risk is insignificant.⁷

(I) THE CLINICAL RISK EVALUATION CRITERIA

When establishing evaluation criteria for the clinical risk framework, Health Services 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.

Risk Evaluation Criteria may be affected by internal and external perceptions and legal requirements. It is important that appropriate criteria be determined at the outset.

A Whole of Health Consequence Categories Table is included in this Guideline (see Table 4). Please refer to Step Three: Analyse the Clinical Risks for further details on how to use the Risk Evaluation Criteria.

If it is necessary for Health Services to develop more specific criteria to serve their discrete clinical risk assessment needs, these criteria must be capable of nesting within the Whole of Health tables to provide a means of high-level broad reporting for Whole of Health purposes. Assistance should be obtained from your risk management co-ordinator who will liaise with the Office of Safety and Quality in Health Care.

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.

(II) DETERMINING ACCEPTABILITY OF CLINICAL RISK

The significance of the clinical risk and the importance of a policy, program, process or activity need to be considered when deciding if a clinical risk is acceptable. 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 to Health Services 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. For example, the risk that a project might be terminated following a change of government is not within the control of an organisation; and
- the opportunities presented outweigh the threats to such a degree that the risk is justified.⁷

If the clinical risks are not considered as being acceptable to the organisation, they should be treated. These clinical risks should then be prioritised for appropriate management action under the organisation's strategic clinical risk management and operating plans (Refer to Step Six: Treat the Clinical Risks).

REMINDER: Health Services must **communicate and consult** with internal and external stakeholders and **monitor and review** clinical risk processes and outcomes at each stage of the Clinical Risk Management process.

KEY QUESTIONS IN ANALYSING AND RANKING RISKS¹

- What is the acceptable level of clinical risk?
- What is potential positive and/or negative results of treating a clinical risk?
- What is the priority of the clinical risks (eg high, medium, low)?
- Does the Health Service have appropriately skilled staff and adequate resources to undertake the treatment process?

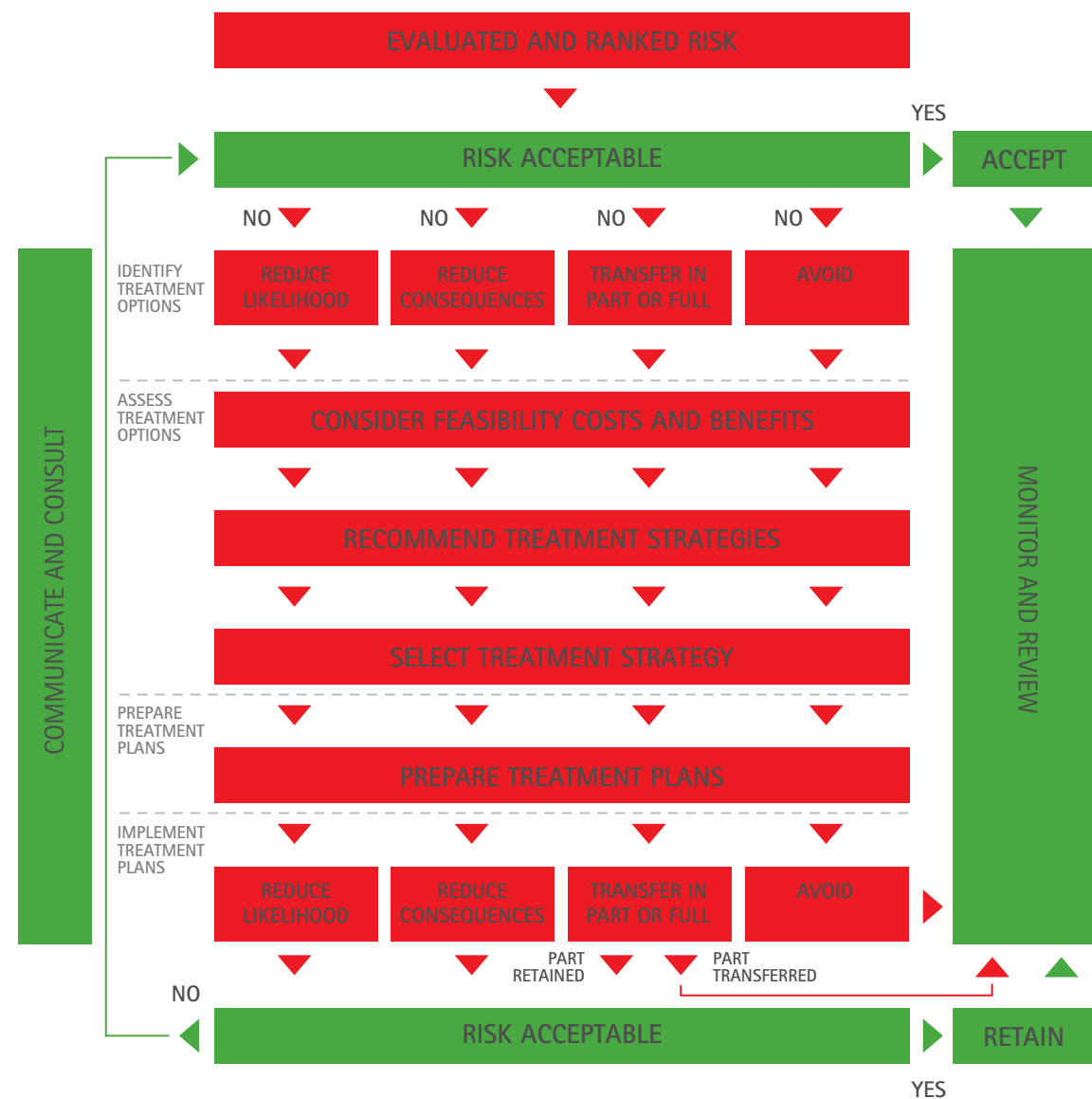
STEP FIVE: TREAT THE CLINICAL RISKS

Risk Treatment (Refer to Section 3.6 of AS/NZS 4360:2004)

Risk treatment involves identifying the range of options for treating risk, assessing those options, preparing risk treatment plans and implementing them.

Clinical *Risk Treatment* describes the activities involved in dealing with the identified risks. The term *Clinical Risk Management* describes whole of the clinical risk management process.

Figure 3: Clinical Risk Treatment Process¹⁰



(I) ALTERNATIVE TREATMENT OPTIONS

Step Four–Clinical Risk Treatment is concerned with options to treat the risks that were deemed as not acceptable to the organisation in Step Three–Evaluate and Prioritise the Risks. Alternative treatment options available to Health Services may include:

(a) Avoiding the Risk

A Health Service 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.

It should be noted that clinical risk management is not an exercise in risk avoidance. There are circumstances in which the Health Service 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 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) Reducing the Level of Risk

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

It should be noted that there is often a trade off between the level of risk and the cost of reducing those risks to an acceptable level. Any one of a number of decision points need to be considered in the decision making process, 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); and
- the absolute minimum result that can be accepted.^{8,9}

Which criterion is considered to be the most acceptable to the organisation, will depend on the circumstances and the established risk context within the organisation. Where risk reduction is deemed to be feasible and cost effective, the organisation must provide adequate funding and resources to the process, and ensure that appropriate accountability processes are in place to measure and evaluate the outcomes of the risk reduction program.

(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, administrative processes or insurance to another party that can exercise the most effective control over these risks.

It must be noted that transferring clinical risk to another party does not automatically reduce probability or consequence of the risk should it materialise. Neither does it absolve a Health Service of accountability for the provision of services to the community, or responsibility should service failure occur.

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 Services should be aware of the hidden costs of transferring risk eg. higher contract costs. Other issues that need to be considered prior to transferring risk include:

- ensuring that the Health Service only accepts the imposition of others' risks, or the limitation of rights it may have against others, as a last resort to achieve an outcome that benefits the public, the state, and the organisation's purposes in accordance with RiskCover guidelines;
- ensuring risks are not transferred unfairly to clients, particularly the public, who are in a poor position to accept them. Principles of equity and fairness should be maintained in accordance with the Western Australian Public Sector Code of Conduct; and
- ensuring that the external service provider is held responsible for its own negligence, malfeasance, misfeasance etc.^{8,9}

(d) Insuring the Clinical Risk

Medical Indemnity Insurance is co-ordinated through the Department of Health's Legal and Legislative Services, to whom all enquiries should be directed.

(e) Retaining the Clinical Risk

Retention of the clinical 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 under Step Three – are retained, the decision and rationale should be carefully documented. Retained clinical risks should be listed on a centralised clinical risk register (See Attachment D), monitored, and contingency plans developed.

(II) EVALUATING TREATMENT OPTIONS

Each of the alternative 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 Services to evaluate the cost of implementing each option against the benefits that may be derived from it.

(III) PREPARING TREATMENT PLANS

When preparing treatment plans, Health Services should document how the chosen treatment option(s) will be implemented. Each clinical risk analysis worksheet form (see Attachment B) and clinical risk treatment action plan (see Attachment C) 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.

(IV) IMPLEMENTING TREATMENT 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. Health Services should establish effective clinical risk management treatment action plans (see Attachment C), which specify the clinical risk treatment method(s) chosen, individual responsibilities and accountabilities for action and monitoring the outcome of clinical risk treatment against specified outcomes.

REMINDER: Health Services must **communicate and consult** with internal and external stakeholders and **monitor and review** clinical risk processes and outcomes at each stage of the clinical risk management process.

KEY QUESTIONS IN TREATING CLINICAL RISKS¹

- What and how will other areas of the organisation and/or WA health system be affected by the risk treatment 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, technical)?
- Has a cost benefit analysis been conducted with respect to the risk treatment 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?

4. 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:^{11,12,13}

- 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; and
- developing positive strategies to reduce the likelihood of recurrence of the problem and/or consequences rather than responding by introducing restrictive controls.

Health Services 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 agency. Enabling strategies may include:

- communicating the Health Service's clinical risk management arrangements throughout the organisation;
- assigning responsibility for managing clinical risk at all levels of the Health Service;
- ensuring that all staff have the necessary knowledge and skills needed to manage clinical risks, eg. 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 the expected outcomes of the clinical risk management framework is monitored and reported to the Health Service's senior management for review;
- ensuring that systems for staff rewards, recognition and sanctions include clinical risk management; and
- ensuring that internal reviews and evaluation, such as internal audit, clinical audit and incident monitoring and reporting take account of the agency's philosophy towards clinical risk management.

The success of the Department of Health's approach to clinical risk management depends on the support and commitment of the Chief Executive and the Health Service Executive Team with the active involvement of all staff including medical, nursing and allied health professionals.

Health Service Managers will ensure that this Guideline is 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.

5. DOCUMENTING THE RISK MANAGEMENT PROCESS

The clinical risk management process is an integral part of managing risks and meeting Government accountability requirements. Treasurer's Instruction 825 Risk Management and Security (formerly Treasurer's Instruction 109) stipulates:

"The Accountable Officer or Authority shall ensure that there are procedures in place for the periodic identification, assessment and treatment of risks inherent in the operations of the department or statutory authority, together with suitable risk management policies and practices, and that these are documented in the accounting manual or other relevant policy materials".^{3,4}

It is recommended that Health Services maintain an appropriate level and standard of documentation as part of the clinical risk management process, in order to enable them to:

- communicate policy expectations;
- provide all staff with appropriate information of the organisation's clinical risk management process and relevant input for training;
- ensure that the clinical risk management process is managed correctly;
- enable decisions, processes and action plans to be reviewed by relevant internal and external auditors;
- demonstrate accountability and provide an audit trail; and
- meet the requirements of Treasurer's Instruction 825 Risk Management and Security.

The level of clinical risk management documentation required by Health Services will vary between organisations according to their operational requirements and specific risk contexts. In order to comply with Treasurer's Instruction 825, Health Services should refer to relevant Department of Health Guidelines and

the Department of Premier and Cabinet's Guidelines for Managing Risk in the Western Australian Public Sector, which outlines the suggested minimum documentation for risk management.

(A) DEPARTMENT OF HEALTH CLINICAL RISK MANAGEMENT DOCUMENTATION REQUIREMENTS

The Department of Health's Clinical Risk Management Guideline outlines the requirements for documenting a Health Service's clinical risk management program. This includes documentation of:

- the objectives of the program, rationale for managing clinical risk and the extent or range of issues to which the program applies are clearly identified;
- demonstrated links between the clinical risk management program and the organisation's strategic/corporate plan;
- clear guidance on what may be regarded as acceptable clinical risk to the organisation;
- the identification of responsible officers for managing clinical risk;
- the support/experience available to assist those responsible for managing risk;
- the definition of the level of documentation required; and
- the plan for reviewing organisational performance in regard to the clinical risk management framework.

(B) ORGANISATIONAL CLINICAL RISK REGISTER

Health Services should establish formal risk registers to assist them to identify and record each clinical risk. The Clinical Risk Register is a living document and will include risks identified from all types of sources, including strategic reviews, clinical audit assessments, compliance with standards and trend monitoring from systems such as AIMS and Sentinel events etc. A Clinical Risk Register is provided as Attachment D.

Ideally, for each identified clinical risk, the risk register should record:

- the source of the risk;
- the nature of the risk;
- existing risk controls;
- the likelihood and consequences of the risk;
- initial risk ratings; and
- vulnerability to external/internal risk factors.

Clinical risk registers can form part of an integrated risk register that incorporates clinical and other organisational risks.

(C) RISK TREATMENT SCHEDULE AND ACTION PLAN

Health Services should develop risk treatment schedules and action plans that document the risk management controls adopted by the organisation. A copy of the Risk Analysis Worksheet is provided in Attachment B and Risk Treatment Action Plan is provided at Attachment C.

The Risk Treatment Action Plan should outline:

- who has responsibility for implementation of the treatment plan;
- who is to be involved – stakeholders; personnel, participants, contracts etc;
- what resources will be allocated to the treatment program;
- timetable for implementation; and
- details of the mechanism and frequency of review of compliance with the treatment plan.

A sample Risk Treatment Action Plan is provided in Attachment C.

6. MONITORING AND EVALUATION RESPONSIBILITIES

It is the responsibility of the Health Service'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.⁷

Health Services must 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.

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. Performance reviews will give the organisation and Department of Health assurance that risk management policies and processes are working satisfactorily and that local and State targets are being met.

The Department of Health and Health Services are required to establish a single point or committee with responsibility for reviewing and reporting their respective risk management.

The Office of Chief Clinical Advisors (Chief Medical Officer), supported by the Office of Safety and Quality in Health Care has responsibility for reviewing and reporting clinical risk management across all of Health.

Line managers in the clinical organisational structures are to periodically review their risk management and include its status with commentary on any significant risk issues in their existing reporting frameworks. Reporting of significant risk will escalate upwards through existing structures in accordance with management responsibilities.

The State Health Executive Forum will consider Health's overall exposure to risk as well as unresolved significant risks common across Health, and provide direction where appropriate.

The Audit Committee will review compliance and governance in respect to risk including Health's exposure and the effectiveness of its risk management processes.

(B) MONITORING AND EVALUATION DOCUMENTATION

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; and
- details of how review recommendations are followed up and implemented.

7. FURTHER INFORMATION

Health Services should refer to the Australian/New Zealand Standard on Risk Management AS/NZS 4360:2004 (www.standards.com.au) and Treasurer's Instruction 825 (<http://www.treasury.wa.gov.au/registration/wafabentry.asp>) for further information and guidance in the development of risk management strategies.

The Department of Health has developed the Health Risk Management Framework and Health Risk Management General Procedures Manual⁷, which sets out the mandated policy and procedures for the management of corporate risks in the WA Health system.

Information, support and co-ordination is also available from experienced staff located throughout the Department of Health. These officers should be contacted first for assistance with design and delivery of appropriate risk management strategies, programs and workshops. Contact details are available from the Office of Safety and Quality or the HOLII "Insurance and Risk Management" intranet site at: <http://intranet.health.wa.gov.au/RiskManagement/home/>.

External providers should only be used where Health resources with particular skills and experience are not available.

8. REFERENCES

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7. Department of Health (2005). *Health Risk Management General Procedures Manual* (<http://intranet.health.wa.gov.au/RiskManagement/manual/index.cfm>).
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DIVISION REF	SUBJECT/ELEMENT AT RISK	CSFS/DEPENDENCIES	REF	THE RISK	CAUSE	COMMENTS

SIGNED _____						RISK REF	DIVISION
						THE RISK	
POSITION _____						SUMMARY OF CONTROLS	DIRECTORATE
						INDIVIDUAL CONTROL RATING	
DATE ____/____/____						OVERALL CONTROL RATING	BRANCH
						CONSEQUENCE CATEGORY	
						CONS. RATING 1 - 5	
						LIKE RATING 1 - 5	
						LEVEL OF RISK 1 - 25	
						RISK RANK	
						ACCEPTANCE DECISION (YES / NO)	
						DATE FOR COMPLETION OF TREATMENT	

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

