



Victorian Healthcare Association

Managing Clinical Risk in Primary Health Care

A Clinical Risk Management Resource

September 2009



HOW TO GET THE MOST OUT OF THIS DOCUMENT

This new and improved Version of the VHA Clinical Risk Manual is a useful resource for anyone working in risk, training or managing people in Primary Health Care.

We realise that not everyone has a fancy colour printer in their office, so we have designed this document for clear printing. It is a stripped-back version of the online Manual.

If you would like access to the online version, which is filled with quick and useful hot links to other documents, websites and important pages within the Manual, please contact Alison Brown: Alison.Brown@vha.org.au.

PREFACE

This document was prepared by the Clinical Risk Management Working Group of the Clinical Governance in Community Health Project. The project is under the auspices of the Victorian Healthcare Association's Clinical Governance Steering Committee. The Clinical Governance in Community Health Project is funded by the Victorian Department of Human Services.

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VMIA

VICTORIAN MANAGED INSURANCE
AUTHORITY

Taking care of risks

- **Victorian Managed Insurance Authority**
- **Wyndarra Consulting**
- **Guild Insurance**





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PURPOSE OF THE DOCUMENT

The *Managing Clinical Risk in Primary Health Care* document is designed as a resource for staff in primary health care services. The document has been developed after consultation with practitioners, managers, risk specialists and with reference to the conceptual framework provided by the Victorian Quality Council's *Better Quality Better Health Care* (2005 - <http://www.health.vic.gov.au/qualitycouncil/pub/improve/framework.htm>) and the draft risk management standard ISO 31000:2009.

The approach to the management of clinical risk is based on general risk management principles that can be applied in the governance of all areas of primary health care services, e.g. financial, project or strategic risk management.

The purpose of elaborating on the general risk management principles is to highlight some of the important concepts and methods specifically applicable to primary health care services when introducing risk management in clinical areas as part of governing the safety and quality of clinical services.

The layout of the document enables sections to be read by senior managers and team leaders responsible for implementing risk management with their clinical staff and tools and information to be given to staff when implementing clinical risk management activities.

Section one concentrates on general risk management principles that can be applied to any area of a primary health care service.

Sections two, three and four focus specifically on management of clinical risk. Section two presents the underlying principles and conditions to promote effective risk management in your primary health care service.

Section three provides a step-by-step guide to risk assessment with your clinical staff.

Section four provides a guide to managers who are responsible for risk management.

A number of tools and documents have been developed and included in section six to assist implementing risk management in the clinical areas of your service. This document can be accessed electronically via the VHA website at www.vha.org.au.

The intention of the document is to provide a general guide to risk management with an emphasis on risks in clinical areas. Individual services in the primary health care sector will need to modify or choose the approach most suitable for their service.

GLOSSARY

CLINICAL GOVERNANCE

The systems by which the governing body, managers and clinicians share responsibility and are held accountable for patient or client care, minimising risks to consumers and for continuously monitoring and improving the quality of clinical care.

CLINICAL RISK

Risks to the client during a course of care or treatment provided by a health service (see risk definition).

CLINICAL RISK MANAGEMENT

Clinical risk management focuses on improving the quality and safety of health care services by identifying the circumstances and opportunities that put patients at risk of harm and acting to prevent or control those risks.

CONSEQUENCE

The outcome of an event or change in circumstances affecting the achievement of objectives. An event or change in circumstance can have more than one consequence, which may have positive or negative effects on objectives.

CONTROL

Measure that is modifying risk.

CORPORATE GOVERNANCE

The systems by which business corporations are directed and controlled. Corporate structures specify the distribution of rights and responsibility among participants in the organisation.

CORPORATE RISK

Risks to an organisation considered across the business that apply to processes, structures and culture which include strategic, operational, compliance and financial risks.

INHERENT RISK

The intrinsic risk prior to considering any controls in place.

LIKELIHOOD

The chance of something happening. May be defined objectively or subjectively by general descriptors, frequencies or probabilities.

MONITOR

To check, supervise, observe critically or measure the progress of an activity, action or system on a regular basis in order to identify change from the performance level required or expected.

RESIDUAL RISK

Risk remaining after risk treatment.



RISK

The effect of uncertainty on objectives. May be an event or change in circumstances effecting the achievement of objectives. The risks may be clinical or non clinical.

RISK ANALYSIS

Risk analysis is the systematic process to comprehend the nature of risk and to deduce the level of risk.

RISK APPETITE

The amount and type of risk an organisation is prepared to pursue or take.

RISK ASSESSMENT

The overall process of risk identification, risk analysis and risk evaluation to determine risk management priorities by evaluating and comparing the level of risk against organisational standards, predetermined target risk levels or other criteria.

RISK CRITERIA

Terms of reference against which the significance of a risk is evaluated. Risk criteria are expressed in likelihood, consequence and risk rating scales.

RISK FACTORS

Factors that give rise to the risk (specific to the organisation).

RISK IDENTIFICATION

The process of finding, recognising and describing risks.

RISK MANAGEMENT

Coordinated activities to direct and control an organisation with regard to risk.

RISK MATRIX

Tool for ranking and displaying risks by defining risk categories (e.g. financial, OHS, clinical) and defining ranges for consequences and levels of likelihood for each category.

RISK PROFILE

A summary of key risks existing across an organisation.

RISK RATING

Categorisation of risk based on the level of risk.

RISK REGISTER

Document used for recording risk management processes for identified risks. Data recorded in the risk registers provides summary information for the Organisation Risk Profile.

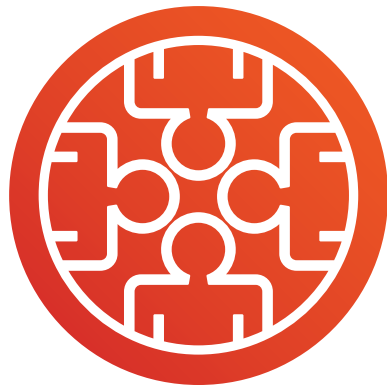
RISK TOLERANCE

Level of risk which an organisation will tolerate.

RISK TREATMENT

The development and implementation of measures to modify risk. Risk treatment measures can include, avoiding, changing likelihood and consequence, sharing or retaining risks.





SECTION ONE

RISK MANAGEMENT IN PRIMARY HEALTH CARE

1.1 Introduction

In this section an overview of the basics of risk management will be presented. These risk management principles can be applied to clinical and non-clinical areas of a primary health care service as potential risks exist at all levels of an organisation in many different spheres. Risk management is concerned with identifying risks that can affect the achievement of objectives. Some risks are related to issues of governance and strategy; others are concerned with the operational business of an organisation. This risk management document pertains mainly to clinical risk, that is, risks to a client throughout different stages of their care. The focus on clinical risk management is to assist organisations in ensuring clinical risks are identified and appropriately managed as an integral part of the organisation's overall risk management processes. The application of risk management principles to clinical risk in primary health care services is explained in more detail in sections two to four of the document.

Despite the focus on clinical risk in this document, the principles of risk management can be applied to all risks within the organisation. Primary health care services are encouraged to adopt a single organisation wide risk management framework in order to have a consistent approach to management of all risks.

1.2 What is Risk Management

Risk management can be defined as:

“...the systematic application of management policies, procedures and practices to the task of identifying, analysing, assessing, treating and monitoring risk”.

Auditor General Victoria (2004)

“The culture, process and structures that are directed towards effective management of risk”.

Australian Council for Safety and Quality in Health Care (2001)

“Coordinated activities to direct and control an organisation with regard to risk”

Draft ISO 3100:2009

1.3 The Purpose of Risk Management

The goals of risk management are to:

- Encourage proactive management
- Establish a reliable basis for decision making and planning
- Identify opportunities and threats

Risk management is a powerful tool in enabling organisations to meet their strategic and operational objectives. Risk management therefore is an integral part of the cycle of strategic planning activities and team or program planning. Risk management provides reasonable assurance that the organisation's objectives will be reached within an acceptable degree of residual risk (Standards Australia, 2005:15).



Primary health care services need to ensure risk management is an integral part of everyday operations. It is vital that risk management is incorporated into planning, budgeting, reporting processes and continuous improvement programs.

The ultimate purpose of conducting risk management is to identify all important risks that can then be prioritised and addressed systematically by a service. Risks may be identified prior to, (inherent risk) and after, the application of appropriate controls (residual risk).

It is important to manage risks that are inherently high as the residual risk rating is reliant upon effective working controls. The management of inherent risk requires ongoing auditing or monitoring of controls. It is important for primary health care services to ensure there are systems in place to determine whether the controls are functioning effectively and that responsibility is assigned for monitoring the controls. The effectiveness of risk management relies upon reviewing and evaluating the effectiveness of controls.

From the prioritisation of major risk, a risk profile for the primary health care service can be developed where risks across the agency are identified in the different contexts or areas of activity. The risk management process develops risk treatment plans with controls and strategies that relate directly to organisational objectives. Reporting on the effectiveness of risk management controls effectively becomes reporting on the achievement of organisational objectives. A key issue for primary health care is limited resources for risk management.

Risk management needs to be kept simple and seen as an added control to achieving organisational objectives. If risk management is seen as an integral part of setting and reviewing organisational objectives then risk management becomes one element in sound governance.

1.4 Principles of Risk Management

As outlined in the draft ISO 31000:2009 standard, risk management should:

- a) Create value and contribute to the demonstrable achievement of objectives
- b) Be an integral part of organisational processes and not a stand alone activity.
- c) Part of decision making.
- d) Explicitly addresses uncertainty.
- e) Be systematic, structured and timely.
- f) Be based on the best available information.
- g) Be tailored to the individual organisational context
- h) Take human and cultural factors into account.
- i) Be transparent and inclusive.
- j) Be dynamic, iterative and responsive to change.
- k) Facilitate continual improvement and enhancement of the organisation.



1.5 Benefits of Managing Risk and Consequences of Not Managing Risks

There are considerable benefits to implementing risk management, all of which contribute to the increased likelihood that the organisation will achieve its objectives.

These benefits include:

- Better identification of opportunities and threats,
- Prevention of potential risks from being realised,
- Reduction of the element of chance,
- Increased accountability and transparency for decisions,
- More effective allocation and use of resources,
- Improved incident management and reduction in loss and the cost of risk, including insurance premiums,
- Improved stakeholder confidence and trust,
- Improved compliance with relevant legislation and accreditation processes,
- Proactive rather than reactive management, and
- Enhanced governance.

In contrast, the consequences of not successfully managing risks are significant:

➤ Negative publicity	➤ Complaints
➤ Penalties and fines	➤ Litigation
➤ Loss of services	➤ Loss of management time
➤ Misuse of resources	➤ Injuries, and
	➤ Other adverse outcomes

1.6 Implementing Risk Management Components

The components of a risk management process are represented in Figure 1. The practical applications are further outlined in the subsequent sections and are based on the draft ISO 31000:2009 risk management standards and also incorporate VMIA guidelines and other relevant literature.

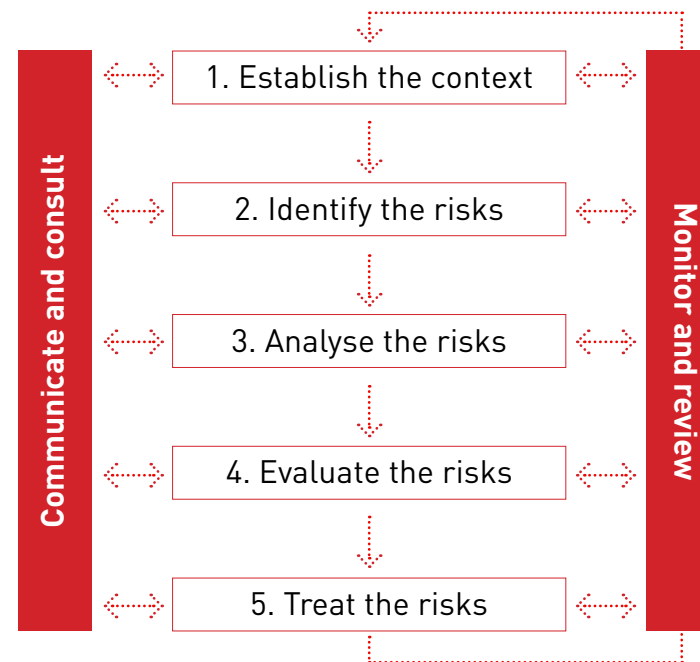


Figure 1: Components of a Risk Management Process - Consistent with draft ISO 31000:2009

As Figure 1. demonstrates, there are five steps in the risk management process, with two underpinning elements 'communicate and consult' and 'monitor and review'.

Step One: Establish the context

When setting up risk management processes organisations need to consider the context within which they operate. The context will vary from organisation to organisation according to several key aspects which include:

Organisational Context:

- **External Context** – An organisation must understand the external environment in which it operates and consider political, legal, regulatory, environmental, social and technological factors and the perceptions and values of key stakeholders.
- **Internal Context** – Any elements within the organisation that influence the way it manages risk. This includes consideration of the organisations objectives and strategies, culture, policies and processes, organisational structures (e.g. governance, roles) and capabilities (resources, knowledge, systems and technologies).

Risk Management Context:

The scope and parameters of risk management activities need to be clarified and include:

- **Scope of Risk Management** - the scope can cover risks to the organisation based on disciplines and/or programs or functions that span the whole organisation such as health promotion, human resources and finance.
The scope of risk management may encompass risks in a program area delivered via multiple agencies and may include

consideration of interagency risk. Risk Management occurs across the spectrum of primary health care services activities and generally fall into one of four main areas:

1. Business wide e.g. Strategic, financial, legislative
2. Specialist specific e.g. OHS, specialist committees
3. Business unit e.g. Clinical areas
4. Projects e.g. Short-term projects

- **Defining Responsibilities** - the primary health care service will need to delegate or appoint an individual or committee/team to initiate risk management across the organisation. This may be a consultant, an existing employee (or group of employees) or an appointed staff member. It is also essential that responsibility be given to the individual or team to monitor and review risks and treatment.
- **Policies and Procedures** – appropriate risk management policies and procedures for the organisation
- **Resources Required** – allocation of resources to manage organisational risk
- **Evaluation Mechanisms** – development of appropriate mechanisms to evaluate the organisation’s risk management framework
- **Risk Identification Tools** - decide what stages, areas, features and conceptual components will be used to identify risks. Tools for risk identification can be developed using elements of a work plan, the continuum of care or the flow of work. Refer to Section 6 Appendix 2 for relevant tools.



Risk Criteria:

Each organisation needs to develop risk criteria which enable evaluation of the significance of an identified risk. The following elements of risk criteria need to be considered

- How likelihood and consequence will be defined and any timeframes (e.g. consequence and likelihood tables)
- How the level of risk is to be determined (e.g. choice of risk matrix)
- The risk response - the level at which risk is acceptable or requires treatment. This includes consideration of who in the organisation needs to be informed about risks of different ratings.

Step Two: Identify the risks

The aim of risk identification is to develop a comprehensive list of risks and events that might have an impact on the achievement of objectives. There is no fool proof way to identify risks. Approaches used to identify risks include judgements based on experiences, brainstorming, incidents reports, complaints reports, insurance claim reports, records, performance indicators, literature review and scenario analysis.

Incidents are events in which harm occurred or could have occurred (referred to as a near miss). As incidents resulting from clinical care may not easily be identified in the primary health care setting, a proactive approach to risk identification is important. Unidentified risks can pose a major threat to the organisation or result in significant opportunities being lost.

A review of past risks from data from incident logs and complaints logs can be used to review and revise your assessment of risk.

Current and future risks identified through a proactive approach can be combined with information from past events to develop a comprehensive list of risks. This document provides tools for the proactive identification of risks which have been developed and trialled within community health services (see Section 6 Appendix 2). The Risk Management Standard (2004) and accompanying guidelines also provide detailed examples of identification tools.

Step Three: Analyse the risks

Once risks are identified, risk analysis needs to be undertaken. The main aim is to determine the level of risk and separate the minor acceptable risks from the unacceptable major risks. Risk analysis provides data to assist in the following stages of risk management: evaluation, prioritisation and treatment of risk. Risk is analysed by combining the consequence and the likelihood of the event or circumstance occurring. Typically the equation below is used:

$$\text{Risk Rating} = \text{Consequence} \times \text{Likelihood}$$

Where:

Consequence = the outcome of an event or change in circumstances expressed qualitatively or quantitatively, being a loss, injury, disadvantage or gain

Likelihood = the chance of something happening

Despite the mathematical formula, in most cases, risk analysis (except in areas like industry where detailed quantitative data is available) is a subjective, not an objective, process and the focus should be on prioritising risks rather than the detail of the risk rating.



There are many tools available for risk rating however in primary health care where the approach to risk analysis is mainly qualitative, a simple risk rating matrix to assist in the prioritisation of risk is all that is generally necessary.

When analysing risks, controls need to be considered. Controls are existing processes, policy or actions which modify risk. Both inherent risk (the level of risk which occurs naturally in an event without consideration of controls) and residual risk (the level of risk after controls have been considered) are useful to consider during the analysis stage. As the level of residual risk is reliant upon effective controls it is important to monitor closely risks that are inherently high.

The analysis of risks helps to facilitate a risk rating for each identified risk event. In turn, this assists in the prioritisation of risk treatments and informs planning processes and the strategic, operational and individual level.

Step Four: Evaluate the risks

The purpose of risk evaluation is to set priorities for risks requiring treatment. This entails making decisions, based on the outcomes of risk analysis, about which risks need treatment and the order of priority for risk treatment (Standard 2004:63).

The risk rating provides a guide to risk prioritisation but there are often other considerations such as ability to effect risk and comfort with consequences that will determine the priority for risk treatment.

Step Five: Treat the risks

The aim of risk treatment is to develop a treatment plan. This involves identifying a range of treatment options and selecting the most appropriate option(s). A treatment plan is then developed and the implementation monitored and reviewed. Selecting the appropriate treatment option(s) involves considering the effectiveness, benefit and cost of the treatment. Risk can be eliminated through discontinuing an activity however this usually is not the favourable option when providing clinical services. Where risks cannot be eliminated, a combination of treatment options should be considered and may include:

- 1. Avoiding the clinical risk.** Not proceeding with the activity where the risk is occurring
- 2. Reducing the level of clinical risk.** Reducing either the consequences and/or the likelihood of the risk through enhancement of existing controls or additional controls. It is essential that the organisation provide the resources for risk reduction as required
- 3. Sharing the clinical risk.** The risk may be shared with another party (transferred by contract, administrative processes etc), or
- 4. Retaining the clinical risk.** In instances where it is too costly, impossible or undesirable to avoid, reduce, transfer or eliminate the risk, the decision to retain the risk should be documented and listed on a centralised risk register. Periodic monitoring is essential to determine if controls are working effectively and contingency plans may be required to respond quickly to lessen the impact of an event.
- 5. Continue with an activity likely to create or enhance a risk.** To pursue an opportunity this option may at times be taken.



1.7 Underpinning Processes

The following processes are vital to ensuring successful risk management in your primary health care service.

a. Communication and consultation

The communication and consultation process is vital to effective risk management as risk management is not just a technical task but involves many discussions and decisions. The purpose of communication and consultation is to:

- Improve participants' understanding of risk and the risk management process and policies,
- Ensure participants are aware of their roles and responsibilities
- Ensure that all relevant stakeholders' views are considered in the process, and
- Ensure risks are adequately identified and analysed

Communication and consultation needs to be undertaken at each stage of the risk management process. A consultative team approach is useful to increase understanding of individual roles and responsibilities for risk management and allows staff to appreciate the benefits of particular controls and the need to support new treatment plans.

The essential elements of a communication and consultation plan, whether a formal document or checklist, include:

- The objectives for communication e.g. raise understanding of risk management or obtain a better understanding of the risks,
- The participants to be consulted e.g. stakeholders, specialist/experts, teams,
- Differing participant beliefs and perspectives need to be taken into account during the risk management process,
- Consideration of communication strategies to be used during the risk management process, and
- Development of processes to be used to measure and evaluate the effectiveness of the organisation's communication program.

b. Monitoring and reviewing

Ongoing monitoring and review are essential components of the overall risk management process as factors that affect likelihood and consequence of risk may change, as may the suitability of a treatment option. Monitoring and reviewing is an ongoing cyclical process that ensures risk management plans remain relevant. The principles of continuous quality improvement and the "plan do check act" cycle are essential to effective risk monitoring and review.

What to monitor

- **Context** - to ensure new clinical risks are identified in periods of sudden or gradual change.
- **Stakeholders** - to ensure new stakeholders are included over time.
- **Consultation and communication** - to ensure all relevant stakeholders are consulted in an effective and timely manner.
- **Risk** - to ensure that new clinical risks are identified and analysed and old risks are appropriately treated and archived.
- **Verify** - analysis of risk against real data, if possible.
- **Analysis** - to ensure that there is a common understanding of clinical risk in the organisation.

How to monitor

Monitoring methods include:

- **Continuous** – routine checking of parameters that are embedded in everyday practice (e.g. steriliser checks).
- **Line Management** - routine checks of risks and their treatment in the risk plan/profile.
- **Internal and external audits** - focus on the effectiveness of controls and the compliance with internal and external policies and procedures.
- **Periodic formal review**

Performance indicators are practicable, measurable indicators of outcomes/ treatments/processes e.g. the extent to which recommendations for risk treatment are implemented, progress towards a specific organisational objective.

Each organisation will need to develop performance indicators for monitoring and review of risk management.

It is important to manage risks that are inherently high as the residual risk rating is reliant upon effective working controls. The management of inherent risk requires ongoing auditing or monitoring of controls.

It is important for primary health care services to ensure there are systems in place to determine whether the controls are functioning effectively and that responsibility is assigned for monitoring the controls. The effectiveness of risk management relies upon reviewing and evaluating the effectiveness of controls.

From the prioritisation of major risk, a risk profile for the primary health care service can be developed where risks across the agency are identified in the different contexts or areas of activity. The risk management process develops risk treatment plans with controls and strategies that relate directly to organisational objectives.

Reporting on the effectiveness of risk management controls effectively becomes reporting on the achievement of organisational objectives. A key issue for primary health care is limited resources for risk management.

Risk management needs to be kept simple and seen as an added control to achieving organisational objectives. If risk management is seen as an integral part of setting and reviewing organisational objectives then risk management becomes one element in sound governance.





SECTION TWO

CLINICAL RISK

2.1 What is Clinical Risk Management?

Clinical risk management is risk management in the clinical domain. Clinical risk management refers to the coordinated activities to direct and control an organisation with regard to risks to the client during a course of care or treatment provided by a health service. Clinical risk management focuses on improving the quality and safety of health care services by identifying the circumstances and opportunities that put patients at risk of harm and acting to prevent or control those risks (Safety and Quality Council, 2005). Clinical risk management occurs as part of normal risk management processes in which all risks to the organisation are assessed and managed.

The purpose of risk management in the clinical context is to:

- **Promote** a culture of risk awareness,
- **Proactively** identify the main risks to clients in receiving services at your primary health care service,
- **Prioritise** clinical risks and their treatment in a risk treatment plan, and
- **Monitor and review** risk management processes in clinical areas.

Clinical risks differ from occupational health and safety risks. Occupational health and safety risks are primarily concerned with risks to staff experienced at work either in a clinical or non-clinical setting.

2.2 Clinical Risks and Clinical Governance

Effective management of clinical risks is one of several important strategies that primary health care services can use to promote the safety and quality of clinical services. Managing clinical risks is an aspect of the broader work on clinical governance in the primary health care sector. Clinical governance has been defined as:

“The systems by which the governing body, managers and clinicians share responsibility and are held accountable for patient or client care, minimising risks to consumers, and for continuously monitoring and quality of clinical care.”

(Australian Council on Healthcare Standards)

The effective governance of clinical services involves the participation of Boards, managers and staff in a range of activities to ensure the quality and safety of clinical services. The Victorian Quality Council (VQC) describes, in detail, clinical governance activities in a framework for safety and quality in the document ‘Better Quality, Better Health Care’ (2005 - <http://www.health.vic.gov.au/qualitycouncil/pub/improve/framework.htm>).

Clinical governance requires that Boards and managers assume the same responsibility for the safety and quality of clinical services as they do with strategic, financial and statutory obligations. The ultimate responsibility for clinical governance rests with the Boards. The VQC’s publication ‘The Healthcare Board’s Role in Clinical Governance’ (2004 - <http://www.health.vic.gov.au/qualitycouncil/pub/improve/healthcareboard.htm>) is a useful reference.



2.3 Managing Clinical Risk in Primary Health Care Services

A robust risk management framework at your primary health care service will require attention to compliance with external regulatory and funding requirements as well as the development of effective internal structures and processes.

To effectively fulfil clinical governance obligations, the following principles have been identified in the literature and need to be considered in establishing risk management systems that effectively manage clinical risk internally within your service:

- **CEOs and Managers leading a culture where management of clinical risk is part of the core business.** CEOs and managers must lead a culture where it is easier for staff to make the change to incorporate the management of clinical risk.

The extent of staff participation in safety and quality activities has been shown to be related to the level of support from their direct manager, the belief that safety and quality activities will bring beneficial outcomes and having a good understanding of clinical governance through training in methods and tools of clinical governance.

- **A clear understanding of what managing clinical risk means in practice in the primary health care setting.** This includes the development of appropriate policies and procedures and linking with strategic objectives and planning processes.
- **Policies need to be developed in relation to governance and integrated risk management which includes the management of clinical risk.** This document provides a model risk management policy that can be adapted for your primary health care service (Refer to Section 6 Appendix 6).

- **Planning.** Planning for managing clinical risk needs to be incorporated at all levels (strategic, team and individual) of the agency.

- **Supportive organisational structure.** Sub committees of the Board and quality and safety committees within the primary health care service need to be given responsibility for managing clinical risks as an integral part of the organisations general risk management structures.

These structures provide formal pathways for communicating, reporting and responding to risks. Creating forums for discussion and establishing risk as standard agenda items on team meetings will support effective clinical risk management.

- **Training.** A thorough understanding of managing clinical risks is required at all levels of the primary health care service. Training is required to enable team leaders and managers to facilitate the risk management process. Training needs to be considered at staff orientation as well as targeted training to allow staff to participate fully in clinical risk assessment activities.

Boards need to understand their responsibilities and be able to interpret reports in relation to clinical governance and risk management in clinical and non clinical areas.



➤ **Governance, reporting structures and position description.**

A rigorous monitoring, reporting and response system is essential to the effective implementation of risk management strategies. Organisational commitment to quality and safety is formalised by assigning responsibility for clinical governance and management of risk in relevant terms of reference, positions descriptions and workplans. A formalised reporting structure is required to enable timely and accurate reporting on the quality of clinical services and the risk profile across the organisation including the clinical areas. This may include reports to team leaders, quality and safety committees, Boards and relevant subcommittees. At a board level, risk management reporting in the clinical areas may be part of reporting on broader clinical governance or integral to the organisational risk management profiles or reports presented to the Boards.

- **Monitoring and Review.** Mechanisms for monitoring and review of risk management plans in the clinical areas need to be established to ensure risk treatment plans are completed. Audits, conducted internally or externally, provide a useful way of checking compliance with policies and procedures and ensuring risk management controls are working effectively. Section 1.6 describes this process in more detail.

2.4 A Just Culture

Risk management in the clinical areas provides an opportunity for staff to be actively involved in developing the quality and safety of clinical services. The third section of this document provides a process and tool for proactively identifying clinical risks in teams or disciplines or program groups.

However the effectiveness of any tool is reliant upon the culture of a primary health care service. Building a culture where open discussion of risk is embedded in everyday practice is essential to any risk management process. The term 'silence kills' is pertinent to the health setting. If a culture of blame exists in an organisation then there is unlikely to be opportunities for staff to reflect and improve on clinical practice. While the term 'no blame' was originally used in relation to clinical incidents and risk management in the clinical areas it has now been replaced by the concept of 'just reporting'.

Staff need to be able to confidently discuss concerns, near misses and mistakes in a just, open and supportive environment. The culture of your primary health care service should therefore be just, not blame free.

Building a culture of openness requires all the elements described in Section 2.3 to be in place to enable the provision of regular time to reflect on clinical practices, near misses and clinical risks.

2.5 Open Disclosure

Open disclosure is a term used to describe the discussions between health care providers, clients and carers that take place as a result of a client being harmed during or after their health care. Regardless of the cause(s) of a harmful clinical event, a full explanation of what happened, the potential consequences and what will be done to fix the problem is essential.

Open disclosure contributes to quality and safe health care by taking care of the client after the event and taking steps to ensure that the problem does not happen again (Australian Council for Safety and Quality in Healthcare, 2005). National Open Disclosure Standards (Australian Council for Safety and Quality in Healthcare, 2003 - [http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/3D5F114646CEF93DCA2571D5000BFEB7/\\$File/OpenDisclosure_web.pdf](http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/3D5F114646CEF93DCA2571D5000BFEB7/$File/OpenDisclosure_web.pdf)) provide managers and health care workers with a step-by-step guide on how to improve the two-way communication process, including an offer of regret or apology.

Many health care workers are aware of negligence claims and fear that admitting an error or a bad outcome will result in legal action being taken against them. However the Australian Council on Quality and Safety in Healthcare (2005) describes some literature that indicates that being honest with patients immediately after an adverse event decreases the chance of receiving a negligence claim.

2.6 Risk Management In The Planning Cycle

To effectively manage clinical risk, risk management processes and reporting need to be built into every level of the existing planning cycles of the primary health care service. In this way, clinical risk is regularly reviewed, evaluated and reported on.

Risk management in the clinical areas can be a powerful planning and priority setting mechanism. The process by which this occurs is represented in Figure Two. This diagram highlights the general stages and activities involving risk management at each level of the organisation. It shows that risk management is an input that informs all levels of the primary health care service together with information obtained from other sources such as the Client/Staff Questionnaires and Hazard and Incident Reports. The diagram shows that a bottom-up input is necessary. Additionally, these plans and activities could not be achieved without the risk management principles being embedded into the culture of the organisation.



Figure 2: Clinical Risk Management in the Planning Cycle

2.7 Tools for Risk Management

There are many tools available for risk management including risk matrices, risk registers and risk management plans. A variety of software packages are available for risk management and generally include combinations of risk registers, incident systems and complaints systems. A number of different clinical risk management software systems are used currently in the acute sector throughout Australia. These systems have the potential to be used or adapted for use in primary health care. Section six of this document provides tool that have been developed by the Clinical Governance in Community Health project and trialled in community health.

The decision of whether to develop your own tool, use the tools provided in this document or purchase electronic software, is dependant upon many factors including the size, structure and complexity of your primary health care service. Irrespective of which tools you use, it is important to remember that the tool is simply the method of recording risks and plans and does not drive the risk management process. The most important features of risk management lie in the development of a supportive culture and the formalisation of risk management systems through policies, procedures and reporting and review structures in your primary health care service.



SECTION THREE

RISK ASSESSMENT WITH YOUR STAFF

3.1 Implementing Risk Assessment with Your Staff

The process for implementing risk management in your service can be seen as a two-stage process. The initial implementation phase consists of the development of an organisational risk management framework with appropriate policies and procedures, tools and resources, position descriptions and committee terms of reference and training requirements. The ongoing phase involves embedding risk management in the clinical and non clinical areas as part of normal practice (Australian Standards, 2005:31) as summarised in Figure 3.

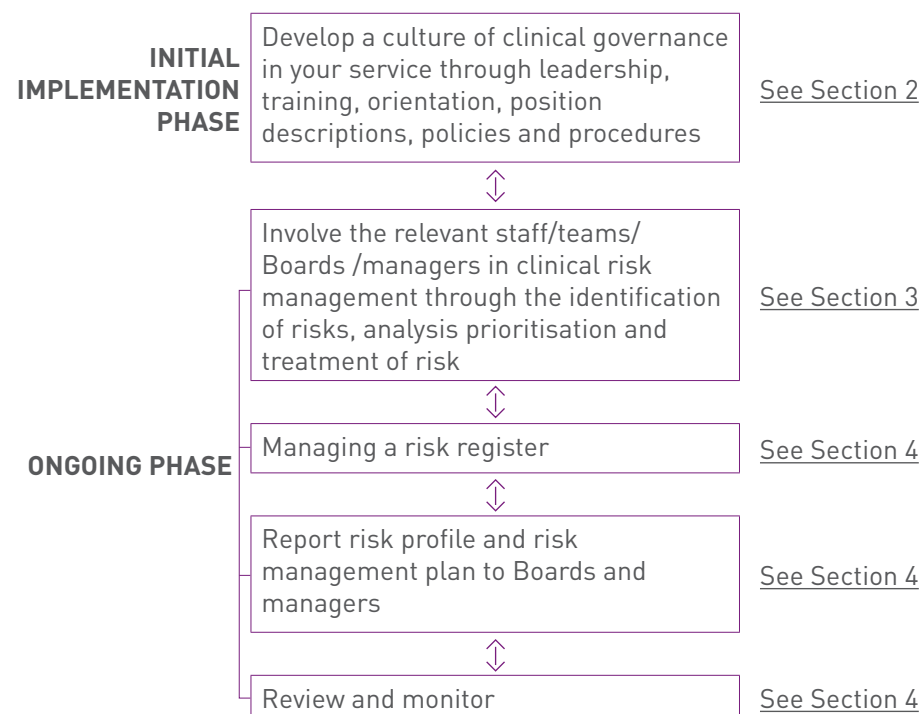


Figure 3: Implementing risk management at your primary health care service

Section Three provides a practical and systematic approach to clinical risk assessment with your staff. Clinical risk assessment will occur as part of a general risk assessment in a service or program area.

Risk assessment is the identification, analysis and evaluation of clinical risk (Steps 2-4 in risk management as shown in Figure 1, Section 1.5). Through this process of risk assessment staff may identify both clinical and non clinical risks (e.g. OHS).

In this section we are focussing on clinical risk assessment as the approach to identification of clinical risks in primary health care may require the involvement of a wide range of staff.

Clinical risk assessment in primary health care tends to rely more on proactive identification than retrospective identification through analysis of data.

A proactive approach to clinical risk assessment is described in this section to identify current and future risks. Existing systems such as incident reporting systems and complaints systems can provide information on past risks that can aid in the identification of risks.

A tool is provided in Section 6 Appendix 2 for primary health care services to use in analysing clinical risks. However, the focus needs to be on working with the team to identify, prioritise and manage risk rather than excessive focus on specific tools or risk rating values. The aim of involving staff in risk management process is not only to identify specific clinical risks and their controls but to promote a culture of risk awareness.

3.2 Getting ready

The manager or team leader facilitating the risk assessment process will need to consider a number of things before starting the process.

3.2.1 Establish the Context

The individual or team responsible for risk management will need to determine and communicate the context for risk assessment as the first step in the risk management process. As risk is the effect of uncertainty on objectives, the first step is to clarify objectives for the organisational activity that is being examined. For example, when considering risk assessment in occupational therapy services, the objectives and context may be as presented in the following example.

Example 1

Service Objective: To promote and maintain clients living independently in the community

Context components	Occupational Therapy example
Scope	Identify and analyse all risks to occupational therapy services (e.g. clinical, OHS, financial) and document appropriate controls and action required
Organisational Context	Identify external factors such as regulations, funding requirements etc related to occupational therapy and internal program factors such as occupational therapy related processes, procedures culture and capacity
Risk Management Context	Define responsibilities for managing risks in clinical and non clinical areas of occupational therapy and consider resources and tools to be used. May use continuum of care to identify risks (see Section 6 Appendix 2)

Table 1: Example of Context Setting In Occupational Therapy

It is important to be clear about these elements and articulate the context components in the initial stages of the risk management process.

3.2.2 How to Identify Risks

You cannot manage risks you didn't see or notice!

It is important to identify and analyse risks in a systematic fashion to ensure all major risks are discussed and addressed. Different tools can be used to identify risks in clinical and program areas within primary health care. The 'continuum of care' is thought to be a useful tool in brainstorming clinical risks and is provided in Section 6 Appendix 2. This tool provides general theme headings and prompts which require consideration when identifying risks and analysing risks.

It is important to note that the headings provided in the tool are prompts to assist in identifying risks systematically across disciplines. It is important to concentrate on identifying the risks under the headings provided in the tools rather than debating whether the themes are appropriate for your discipline. The purpose of this process is to promote discussion with your staff and increase risk awareness.

Risks should be recorded in a risk register. An example of a risk register pro forma that has been trialled in community health and that could be used is provided in Section 6 Appendix 1. The risk register will provide an up-to-date account of the risks within the team, unit or organisation.

It is strongly recommended that risk identification and analysis process is completed in teams as it allows for:

- Building of a risk aware culture,
- Pooling of experience,
- Building of commitment and ownership to the risk management process,
- Ensuring risks of different stakeholders are considered.

3.3 Risk Assessment with Your Staff

This section describes an approach to undertaking risk assessment in clinical areas with staff that has been trialled in community health. The steps outlined guide a facilitator, whether it be a manager or a team leader, through risk assessment. This could be done through the running of two staff/team meetings (as outlined below), as well as some extra work undertaken by team members between meetings.

The format, time and number of meetings may need to be changed to suit individual primary health care services.

This guide can be used in conjunction with the PowerPoint presentation - you will need Microsoft Powerpoint and an internet connection to download and use the presentation from:

http://www.vha.org.au/uploads/APPENDIX_5_VHA.ppt
and the staff handout for risk assessment.



FIRST MEETING WITH STAFF

The purpose of the first meeting with staff is to:

- Familiarise staff with risk identification and analyses,
- Identify risks, including clinical risks to client, and
- Analyse risks.

Use the following steps to act as a guide to facilitate the first meeting. One hour is sufficient time to introduce the concepts and to start to identify and analyse risks. Refer to the PowerPoint presentation to facilitate the first meeting .



STEP 1

Explain the concept of risk and clinical risk (**Slide 2 and 3**).

Tips - *Try to get staff to think of what these concepts are before you provide the definition.*

STEP 2

Explain the concept of risk management and what the organisation is trying to do in terms of risk management (**Slide 4**).

Tips - *Explain that although in health care, by nature, clinicians tends to aim for high quality services for their clients, errors do occur for every individual and are not always recognised. You can use the example of losing your keys or forgetting someone's name. The organisation needs to design systems to prevent errors and use a systematic, coordinated approach to proactively identifying risks before they become incidents.*

STEP 3

Explain that the process of risk assessment will give rise to different categories of risk e.g. clinical and non clinical (**Slide 5**). This process will enable the identification of clinical risks that clinicians and other relevant staff will need to manage.

Tips – *Explain that in this presentation clinical risks will be used to highlight the general risk assessment processes.*

STEP 4

Introduce the steps involved in risk management (**Slide 6**).

Tips – *highlight that you will be focussing on the steps involved in risk assessment (identifying, analysing and evaluating risks)*

STEP 5

Explain the various sources of information for risk identification (**Slide 7**).

Tips – *Ask staff to think about how to identify risks. Explain that incident data may be under reported in primary health requiring various sources of information to be used.*

STEP 6

Introduce the Clinical Risk Identification Tool (**Slide 8**).

Tips – Explain that there are numerous methods for identifying risks and that internal and external data can provide essential information to identify high risk areas. The Clinical Risk Identification tool has been especially developed for use in primary health care to assist proactive identification of risk. Explain that the use of the clinical risk identification tool may help systematically identify clinical risk through consideration of each stage of the client journey. Highlight that other tools can be used to identify risks in non clinical areas (see Section 6 Appendix 2)

STEP 7

Explain how risks can be analysed (**Slide 9 and 10**).

Tips – Explain that although there may be many possible consequences to the client arising from a risk it is important to choose the most likely consequence.

LIKELIHOOD	CONSEQUENCE				
	Insignificant	Minor	Moderate	Major	Extreme
Almost certain	High	High	High	Extreme	Extreme
Likely	Medium	Medium	High	High	Extreme
Possible	Medium	Medium	High	High	High
Unlikely	Low	Low	Medium	Medium	High
Rare	Low	Low	Low	Medium	Medium

Table 2: Risk Matrix

STEP 8

Introduce the concept of risk assessment as per Figure 4 below (**Slide 11**).

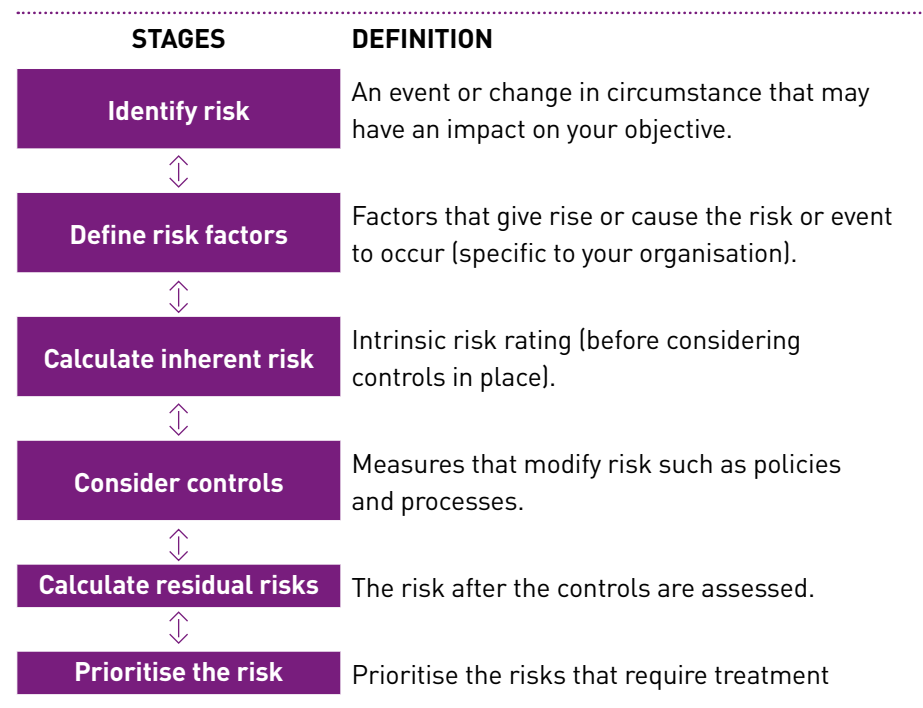


Figure 4: Stages of Risk Assessment - Identification, Analysis and Evaluation

Tips - This at first may seem complex and overwhelming to staff. Don't concentrate too much on making sure everybody completely understands the terms - just make sure they have some understanding of the overall concepts. Reassure staff that you will provide some examples to make it clearer. Note that these headings appear in the risk register.

STEP 9

Work through the 'Holiday in Thailand' example (**Slide 12**).

Tips - *Staff generally enjoy this example and it is easy for them to relate to. Prompt staff with the key headings and encourage them to think of examples.*

Flick to the Risk Matrix slide - or provide handouts (Section 6 Appendix 3) to discuss consequence and likelihood. Ask staff to physically plot consequence and likelihood on the Matrix for both inherent and residual risk so they understand how it works.

STEP 10

Discuss how to make the descriptions of risk meaningful so that another person would understand (**Slide 13**).

Tips - *Make sure that the risk description outlines the event or change in circumstance that leads to an impact. There is a tendency for people to include the specific reasons for the risks so it is worth emphasizing the difference between risks and risk factors.*

STEP 11

Work through a clinical risk example from the program area you are focusing on (**Slide 14**). The headings on this slide correspond to the headings on the risk register.

Tips - *Explain that you are now going to look at a health-specific example. Ask the participants to identify a risk in the area they work in (using the risk identification tool if appropriate) and work through the different stages of risk assessment.*

STEP 12

Now is it time to begin working on the team's own risk register.

Make sure you have the blank risk register found in Section 6 Appendix 1 to facilitate this.

STEP 13

Complete the identification and analysis of at least one complete risk with your staff before you finish the meeting so staff are comfortable to complete the register by themselves.

Tips - *Finish the meeting by explaining that there will be a second meeting to complete the risk register.*

- Save the risk register on a central location.
- You could designate a section of the Clinical Risk Identification Tool to members of the team to fill in with clinical risks from their area (e.g. 'clinical risks in the initial contact and screening area')
- Ask them to fill in the register in their own time before the next team meeting.
- Encourage staff to talk to other teams who may have completed the risk assessment process or are currently doing it.
- Explain the next team meeting will involve discussing the completed risk register and beginning the prioritisation process in the risk register.
- Remind staff NOT to fill in the prioritisation column on the risk register before the next staff meeting.



SECOND MEETING WITH STAFF

The purpose of the second meeting with staff is to:

- Prioritise risks
- Develop treatment plans for priority risks both clinical and non clinical

Another hour-long session will be required to facilitate the second meeting. There is no PowerPoint presentation for this meeting as the focus should be on presenting and discussing the completed risk register.

STEP 1

Start the second team meeting by presenting the completed risk register. The team needs to be comfortable with the risk ratings as high risks will become priority areas and conversely, risks with lower ratings will receive little priority. If the team does not feel the ratings reflect reality, further review will be required.

Tips - Allow staff to explain the sections of the risk register that they were responsible for completing. Encourage discussion between team members. It is important to get consensus among the group. This will take at least half the meeting.

STEP 2

Once the final risk register has been agreed upon, it is time to start prioritising the risks and complete the risk priority column of the risk register. This is the team's chance to decide where to focus the attention of team plans and individual plans.

There may be several risks in the high category and the organisation needs to decide which will have the highest priority.

As a guide, it is suggested that risks that have a higher inherent risk are given a higher priority. Also, risks that have the same risk rating for inherent risks and residual risk should be given a priority as it indicates the controls are not effective enough and need addressing.

You will need to assign each risk with a numerical priority and add it to the risk register e.g.

1 = high priority

2 = medium priority

3 = low priority

After the team has prioritised the risk, treatment plans need to be discussed. There may not be sufficient time to discuss plans during this meeting but steps need to be taken to ensure the treatment plans are embedded into the planning cycle and team members are familiar with their role in the plans.

3.4 Worked Examples

Example 1:

Occupational Therapy

Objective	To ensure all eligible people are appropriately prioritised and receive appropriate care in a timely manner
Heading from continuum of care tool	Initial contact/screening
Risk	Potential for client with urgent needs not identified resulting in a deteriorating condition leading to an adverse event
Risk factors	<ul style="list-style-type: none"> ➤ Service coordination not adequately trained in use of screening tool ➤ Screening tool has not been evaluated recently
Inherent risk (no controls)	Inherent risk is HIGH → Refer to risk matrix (Consequence 'major' x likelihood 'likely')
Controls	<ul style="list-style-type: none"> ➤ Bi-monthly meetings with Service Coordination ➤ Use of an evidence based screening tool ➤ Tool re-assessed during discipline Service Review (conducted every 3 years)
Residual risks	Residual risk is MEDIUM → Refer to risk matrix (Consequence 'major' x likelihood 'unlikely')
Prioritise the risk	To be completed after all risks have been identified and analysed

Example 2:

Dental Program

Objective	To ensure all eligible people are appropriately prioritised and receive appropriate care in a timely manner
Heading from continuum of care tool	Intervention
Risk	Potential loss of dental instrument (bur) resulting in client swallowing or inhaling the bur
Risk factors	<ul style="list-style-type: none"> ➤ Time not taken to ensure the bur is adequately secured ➤ Equipment replacement program not in place ➤ Primary health care services with an undergraduate teaching clinic have a high number of students on rotation during their clinical placement; human error and environment more difficult to control ➤ Dental students less experienced in adequately securing burs
Inherent risk (no controls)	Inherent risk is HIGH → Refer to risk matrix (Consequence 'major' x likelihood 'likely')
Controls	<ul style="list-style-type: none"> ➤ Clinicians check that bur is engaged in drill prior to use ➤ Equipment requiring replacement systematically identified ➤ Rubber dam used where possible for operative procedures ➤ Student training regarding use of burs
Residual risks	Residual risk is MEDIUM → Refer to risk matrix (Consequence 'major' x likelihood 'unlikely')
Prioritise the risk	To be completed after all risks have been identified and analysed.

3.5 Risk Treatment Plans

When it is clear how severe the risks are, you should think through the actions that might be taken to deal with them. Depending on the severity of the risk, you could:

- Eliminate the risk (usually not practical),
- Avoid the activity,
- Reduce its risk,
- Refer it to another organisation/site/provider, or
- Retain the risk.

To assist you with options for risk treatment, you could consider:

- Actions you can take in advance to stop the risk happening,
- Actions you can take in advance to reduce consequences or likelihood of the risk if it still occurs, and
- Preparations you might make if the unwanted outcome occurs to minimise the impact.

These actions may involve elimination or substitution of the process or service, or engineering of additional controls. It is important to assign responsibility for risk treatments to the appropriate person or team.

In Example 1 (risk in Occupational Therapy), a decision could be made to retain the risk as controls in place are deemed adequate, but there is a need to build in a regular review process to ensure those controls are working effectively.

In Example 2 (risk in Dental Program), you would not be able to reduce the consequences of a lost bur, however you could reduce the likelihood. For example, you might implement a written orientation program for undergraduate students which ensures students are routinely checking the engagement of burs and using rubber dams for restorative procedures.

As a guide for determining the type of treatment plan that might be carried out for high priority risks, it is important to consider the impact the treatment will have on the actual risk, clients, other individuals, other teams, stakeholders and the organisation as a whole.

It will be important to have some 'quick wins' with treatments. When developing the plans, refer to Figure 5. First focus on treatment plans which are easy to do resulting in a high impact. Then you can start to focus on plans that are harder to do which have a high impact. Avoid plans that have little impact, even if they are easy to implement and consider communication plans where appropriate.

AN EASE IMPACT ANALYSIS	
Easy to do Has little impact	Easy to do Has high impact
Hard to do Has little impact	Hard to do Has high impact

Figure 5: An Ease Impact Analysis (Source: Royal Australian College of General Practitioners, 2005)

Additionally, budget constraints may be an issue for the treatment of some risks. It is important to consider the full cost of not taking the action against the budgetary savings.

The treatment plans should include:

- Expected benefit,
- Proposed Actions,
- Resource requirements,
- Roles and responsibilities,
- Timing,
- Performance measures, and
- Reporting and monitoring requirements.

3.6 Ongoing Identification of Risks

New risks may be identified through incident or hazard reporting, complaints, client or staff satisfaction surveys or through service reviews. Newly identified risks need to be added to the risk register and analysed according to the Risk Management Framework.

The same principle applies to new work, projects and events being undertaken by the team or the organisation. A separate risk register may need to be created or the risks added to existing risk registers.

Overall review and assessment of risks need to be conducted regularly. Unit and staff meetings are a good way to discuss and review the concept of risk. From time to time it might be useful to review the risk register. An annual review of the risk register is required. This should be coordinated with the development of the operational, team and individual plans.

3.7 Conclusion

Primary health care services are not without risks as clients have increasingly more complex health needs. Risk is inherent in the core business and clinical activities but these should not necessarily be avoided. A systematic approach to risk management, consistent with the standards provides significant opportunities for improving quality and safety within primary health care services.

This document provides a straightforward user-friendly approach to risk management. The primary focus is aimed at embedding clinical risk management principles into the culture of the organisation and providing staff with a different view of their clinical and administrative work. The same process for risk identification, analysis and prioritisation can be used for non-clinical areas and some suggested tools are provided in Section 6 Appendix 2.

Over time, the processes can be refined and a more sophisticated approach can be evolved. In the mean time, introducing the principles in this document and incorporating the practical recommendations will move your organisation well on the way to improved quality and safety.





SECTION FOUR

CLINICAL RISK FOR MANAGERS

4.1 Introduction

This section will focus on the key tasks for managers with designated responsibility for risk management. The areas of training, maintenance of a risk register, development of risk treatment plans and preparation and presentation of risk reports will be discussed.

4.2 Training

As described in Section 3.1 the process for implementing risk management in your service can be seen as a two-stage process with an initial implementation phase and an ongoing phase. Training of staff, team leaders, managers and Board will need to fit in with this two stage process.

During initial implementation, managers, team leaders and Board will need education in risk management, clinical risk and clinical governance.

During the ongoing phase, new staff, managers and Board members will need to be made aware of your primary health care services policies and mechanisms for ensuring the quality and safety of clinical services through orientation.

Prior to staff involvement in risk assessment and risk management activities, all participants will need more specific information to prepare them for their specific roles.

4.3 Risk Register

Responsibility for maintaining and updating a risk register should be clearly assigned in your primary health care service. While staff will contribute to the information in the register, the final entering of data and risk prioritisation in an organisational risk register should be delegated to a specific person or manager.

As discussed in Section 2.7 there is software for electronic risk registers available or you can develop your own. A risk register, based on the standards, has been developed and trialled in community health (see Appendix 1).

The risk register is designed with some flexibility so that either categories or numerical values can be added for the consequence, likelihood and risk ratings columns. The use of categories rather than numerical ratings simplifies the process and avoids the excessive focus on numbers determining relative priorities for action. Numerical ratings can give the appearance of an objective measure based on quantitative data for what is usually a subjective rating.

An organisation will normally have one risk register with multiple components detailing risk for the various areas in the organisation including discipline-specific or program-specific clinical areas.

The discipline or program risk component will contain all the risks identified related to that program or discipline and the associated risk assessment. The discipline or program risks can be updated annually with archiving of previous years risks. The organisational risk profile will contain only those risks the primary health care service have decided need to be reported to the executive level. The organisation's risk profile can be updated as part of the regular planning cycle.



4.4 Prioritising and Treatment Plans

Each organisation has to decide on which risks it will report and to what level of management. Only those risks that are deemed unacceptable may need to be reported and treated. Some agencies may choose to report all risks with a high or extreme consequence irrespective of the likelihood whereas other agencies may decide that the CEO and Board should receive reports on all high and extreme risks.

The level of inherent risk should be considered along with the level of residual risk, as it is important to monitor the effectiveness of controls on risks that are inherently high. Inherently high risks may need routine monitoring and reporting. Your primary health care service may choose to report according to the Table Four below.

Level of risk (Inherent or residual)	Action	Management Reporting Level
Low	Retain and monitor	Program manager
Medium	Retain/reduce/transfer (Minor action)	Program manager
High	Retain/reduce/transfer (Major action)	CEO and Board
Extreme	Reduce/Transfer/Avoid (Critical)	CEO and Board

Table 3: Example of Risk Reporting Schedule

4.5 Board Reporting

A structured process for regular reporting on clinical quality is essential in enabling senior managers and the Board to fulfil their clinical governance responsibilities. Reporting on clinical governance will include information such as

- Clinical activities
- Adverse events/incidents
- Complaints
- Risks identified
- Clinical indicators
- Credentialing/registration/performance appraisals
- Audits/surveys
- Legislative and regulatory compliance

The format for reporting on clinical risk can be in the form of an organisational risk profile so that the senior management and Board receive information on all risks across the entire agency or alternatively can be part of an overall clinical governance report for a program.

In the case of the management of interagency risk the governance arrangements and reporting of risk needs to be clearly articulated among the partner agencies providing the service to clients.

An example of an organisational risk profile for a service that has decided it will report all high and extreme risks to the Board is presented on the following page in Table Four.

KEY: **Extreme risk** **High risk**

Organisational Risks - Strategic, Financial	Clinical Risk	Specialist areas OHS	Project risks
Budget deficit with new building	Infection rates in dental	Staff injury on home visits	Client throughput not achieved
New health promotion report not completed	Failure to document consent	Staff safety after hours	

Table 4: Organisational Risk Profile

The risk profile could include more detailed information on:

- **Issue** – description of risk and inherent and assessed risk level,
- **Potential effect** – description of consequences,
- **Potential risk factors** for the organisation – description of contributing factors in this organisation,
- **Current controls**, or
- **Future strategies** – treatment plan.

For example:

Issue		Potential Effect	Potential risk factors for the organisation	Current Controls	Future Strategies
Inherent	Residual				
Cross infection in dental care provision		Client illness Organisational reputation	Locum / agency dental assistants	Infection control procedure Staff orientation	Review strategies for retention of dental nurses

Table 5: Example of Risk Profile Detail

4.6 Monitoring and Reviewing

Effective monitoring and review of risk management requires appropriate structure and processes to be in place in your primary health care service. A committee should be assigned responsibility for receiving and reviewing reports. That committee could be a subcommittee of the Board or an organisational committee comprised of staff and management. The committee can use a number of monitoring methods (see Section 2) including:

- **Continuous** – routine checking of parameters that are embedded in everyday practice (e.g. steriliser checks),
- **Line management** - routine checks of risks and their treatment in the risk plan/profile,
- **Internal and external audits** - focus on the effectiveness of controls and the compliance with internal and external policies and procedures. Internal audits provide information about the effectiveness of controls and provide a proactive system for anticipating change (Standards Australia, 205:49). External audits provide independent assurance of the control of risks and achievement of organisational objectives, and
- **Periodic formal review.**

The focus on this section is on the line management review of risks and risk treatment plans. The manager or staff member with responsibility for clinical risk needs to develop a planning timeframe for risk management activities.

All risks should be recorded on a risk register and reviewed at least annually at each level of the primary health care service. Reporting on risk treatment plans should occur annually with quarterly updates at governance level. Review of the implementation of risk treatment plans could occur annually with monthly reviews (agenda items) at service provider level.

Table Six below provides an example of a risk management timetable.

Activity	Frequency	Mechanism
Discipline/program risk register review	Annually	Annual team planning
Reporting on risk registers	Annually	Operational Planning
Development of risk treatment plans	Annually	Annual team/ operational planning
Review of risk treatment plan	Monthly	Team meeting
Reporting on risk treatment plans	Quarterly	Board or management

Table 6: Risk Planning Timetable

4.7 Audits

To assist your primary health care service ensure controls are working effectively, organisation or program area audit calendars can be developed. An audit calendar enables a regular cyclical review of your organisation's controls for ensuring the quality and safety of clinical services. An example of an organisation-wide audit calendar is presented below and might include some of the following activities in relation to clinical risk management.

Audit Activity	Frequency
Client satisfaction survey	3 yearly
Policy review	3 yearly
Equipment maintenance checks	Annual
Client feedback/complaints audit	Annual
Incident audits	Annual
Performance appraisal audit	Annual
Professional development/training audit	Annual
OHS audit	6 monthly /Annual
Client file audits	Annual
HR/personnel file audit	Annual

Table 7: Example of Audit Calendar for Organisational Clinical Risk

Similar audit calendars could be developed for each discipline. Examples of suggested discipline-specific audit calendars are presented below in Table Eight and Nine for dental and physiotherapy.

Dental Clinical Audit Activity	Frequency
Re-processing requirements for sterilisation	Daily
General cleaning cycle and radiographic developer	Fortnightly / Monthly
Dental indicators & dental care profiles	3 monthly
Practitioner registration	Annual
CPR training	Annual
Dental client records compliance audit	Annual
Registration of x-ray machine	Annual
Storage of unused radiation materials and used solutions	Annual
Calibration and validation of autoclave	Annual
Infection control audit	Annual with periodic repeats depending on result or audit
Radiation safety check	Annual
Irradiating apparatus operating license	2 Years

Table 8: Example of Audit Calendar for Dental Clinical Risk

Physiotherapy Clinical Audit Activity	Frequency
Practitioner registration	Annual
CPR training for hydrotherapy	Annual
Pool rescue/safety audit	Annual
Equipment checks	Annual
Client record audit	Annual

Table 9: Example of Audit Calendar for Physiotherapy Clinical Risk

4.8 Conclusion

This section has provided a broad overview of some of the management tasks that need to be in place in your primary health care service to enable effective management of clinical risk. These risk management activities in clinical areas should be in line with existing risk management activities at your service and implementation should only require review of existing systems rather than introducing separate systems.

The effective monitoring, reviewing and reporting of clinical risk becomes an integral part of reviewing the progress of your primary health care service in achieving stated objectives in the quality and safety of clinical services.



SECTION FIVE

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SECTION SIX

APPENDICES

Appendix One	Risk Register Proforma Risk Treatment Plan Proforma
Appendix Two	Risk Identification Tools
Appendix Three	Risk Matrix and Consequence and Likelihood Tables
Appendix Four	Staff Handout for Risk Assessment
Appendix Five	PowerPoint Presentation - you will need Microsoft Powerpoint and an internet connection to download and use the presentation from: http://www.vha.org.au/uploads/APPENDIX_5_VHA.ppt
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APPENDIX ONE: PROFORMA

You can download a copy of the Risk Register Proforma online:

http://www.vha.org.au/uploads/Appendix_1a_Blank_Risk_Register.xls

[You will need Microsoft Excell and an internet connection for this link to work]



You can download a copy of the Risk Treatment Plan Proforma online:

http://www.vha.org.au/uploads/APPENDIX_1b_Risk_Treatment_Schedule.xls

[You will need Microsoft Excell and an internet connection for this link to work]



The Victorian Managed Insurance Authority (VMIA) offers a free, downloadable risk register software that has been developed for VMIA clients to support their risk management process. The software can be customised and has a range of commonly requested reports including heat maps, visual reports and summaries.

For further information go to:

<http://www.vmia.vic.gov.au/display.asp?entityid=5719>

or to request access, email your contact information and organisation name to:

riskregister@vmia.vic.gov.au

Risk Register Software


- Reduce time in risk management recording
- Improve quality of reports
- Easy to use and secure
- Free downloadable software for VMIA clients



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APPENDIX TWO: RISK IDENTIFICATION TOOLS

The following risk identification tool can be used to assist in the systematic identification of clinical risks in primary health care services.

Continuum of Care Clinical Risk Identification Tool	
Initial contact/screening/waiting lists	
Assessment/care planning	
Intervention/treatment	
Off site service provision	
Groups	
Discharge/review/referral/recall	
Documentation	

In a similar way the following risk identification tools can be used to assess risks in other areas of a primary health care service.

Human Resources Components	Health Promotion Components	Finance Components
Recruitment selection	Vision and principle setting	Fixed assets control
Appointment	Priority setting	Insurance coverage
Day to day management	Problem definition	Funding
Student placements	Devising the intervention	Budgeting systems
Training and development	Capacity building, support and resourcing	Compliance
Performance management	Planning for evaluation and dissemination	External reporting
Employee Relations & Industrial Relations	Quality implementation	Audit practices
Compliance		Resourcing
WorkCover		Treasury
Organisational change management		Payroll
Workforce planning		
Information management		
Discrimination & harassment		

APPENDIX THREE: RISK MATRIX, CONSEQUENCE & LIKELIHOOD TABLES

Risk Matrix

The following risk matrix is used in this document, however there are several variations on this matrix that can be found in the literature. It does not matter which matrix you use as long as you consistently use the same matrix.

LIKELIHOOD	CONSEQUENCE				
	Insignificant	Minor	Moderate	Major	Extreme
Almost certain	High	High	High	Extreme	Extreme
Likely	Medium	Medium	High	High	Extreme
Possible	Medium	Medium	High	High	High
Unlikely	Low	Low	Medium	Medium	High
Rare	Low	Low	Low	Medium	Medium

Likelihood Table

The following can be used as a guide for determining likelihood. However this tool has limitations as likelihood and frequency of events tend to vary between disciplines and functional areas.

Level	Likelihood	Expected or actual frequency experienced
1	Rare	May only occur in exceptional circumstances; simple process; no previous incidence of non-compliance
2	Unlikely	Could occur at some time; less than 25% chance of occurring; non-complex process &/or existence of checks and balances
3	Possible	Might occur at some time; 25 – 50% chance of occurring; previous audits/reports indicate non-compliance; complex process with extensive checks & balances; impacting factors outside control of organisation
4	Likely	Will probably occur in most circumstances; 50-75% chance of occurring; complex process with some checks & balances; impacting factors outside control of organisation
5	Almost certain	Can be expected to occur in most circumstances; more than 75% chance of occurring; complex process with minimal checks & balances; impacting factors outside control of organisation

Consequence Table

The following is a guide to determining consequence. The applicability of the operational definitions of each category of consequence will vary in different Primary health care services and program areas and thus is recommended as a guide only.

Level & descriptor	Health Impacts	Critical services interruption	Organizational outcomes/objectives	Reputation and image per issue	Non-compliance
Insignificant (1)	First aid or equivalent only	No material disruption	Little impact	Non-headline exposure, not at fault; no impact	Innocent procedural breach; evidence of good faith; little impact
Minor (2)	Routine medical attention required (up to 2 wks incapacity)	Short term temporary suspension – backlog cleared ← 1 day	Inconvenient delays	Non-headline exposure, clear fault settled quickly; negligible impact	Breach; objection/ complaint lodged; minor harm with investigation
Moderate (3)	Increased level medical attention (2 wks to 3 mths incapacity)	Medium term temporary suspension – backlog cleared by additional resources	Material delays; marginal under-achievement of target performance	Repeated non-headline exposure; slow resolution; Ministerial enquiry/ briefing	Negligent breach; lack of good faith evident; performance review initiated
Major (4)	Severe health crisis (incapacity beyond 3 mths)	Prolonged suspension of work – additional resources required; performance affected	Significant delays; performance significantly under target	Headline profile; repeated exposure; at fault or unresolved complexities; ministerial involvement	Deliberate breach or gross negligence; formal investigation; disciplinary action; ministerial involvement
Catastrophic (5)	Multiple severe health crises/injury or death	Indeterminate prolonged suspension of work; non performance	Non achievement of objective/ outcome; performance failure	Maximum high level headline exposure; Ministerial censure; loss of credibility	Serious, wilful breach; criminal negligence or act; prosecution; dismissal; ministerial censure

APPENDIX FOUR: STAFF HANDOUT FOR RISK ASSESSMENT

You can download a copy of the
Staff handout for risk assessment online:



[http://www.vha.org.au/uploads/APPENDIX_4_
CLINICAL_%20RISK_%20ASSESSMENT_HANDOUT.doc](http://www.vha.org.au/uploads/APPENDIX_4_CLINICAL_%20RISK_%20ASSESSMENT_HANDOUT.doc)

(You will need Microsoft Word and
an internet connection for this link to work]

This document is a handout that can be used with staff
when providing information on risk assessment.
The document can be modified to suit your own organisation.

APPENDIX FIVE: POWERPOINT PRESENTATION

You will need Microsoft Powerpoint and an internet connection to download and use the presentation from:

http://www.vha.org.au/uploads/APPENDIX_5_VHA.ppt



This document is a PowerPoint presentation that can be used with staff when providing information on risk and risk assessment. The document can be modified to suit your own organisation.

APPENDIX SIX: RISK MANAGEMENT POLICY

Name and logo of community health service	Risk	Approval date:
	Management	Review Date:
	Policy	Page 1 of 4
	Authorised by:	DRAFT Jan-09

1. Policy

The Community Health Service is committed to establishing organisational culture, processes, resources and structures that ensure risk management (RM) is an integral part of corporate and operational objectives, management systems, processes, policies and procedures. Risk has dimensions that include strategic, operational, property, financial, and clinical.

RM can be defined as the coordinated activities to direct and control an organisation to provide a reasonable assurance that the organisation's objectives will be reached within an acceptable degree of risk.

Adoption of a formal approach to RM, in conjunction with other quality improvement activities will improve decision-making, performance, accountability and enhance outcomes at x community health.

2. Purpose And Scope

The purpose of this policy is to outline the structured approach to risk management across the organisation. Systems have been developed that will ensure that potential risks, strategic, operational and clinical, are identified, analysed, evaluated and subsequently managed. Both managers and clinical staff are involved in this process.

3. References

- ISO 31000 Draft Risk Management Standard
- VHA Managing Clinical Risk in Primary Health Care, 2009
- VMIA Risk Management in the Victorian Public Sector, July 2008
- VMIA Risk Management Guide for Community Services Organisation, January 2009

4. Definitions

Risk

The effect of uncertainty on objectives. The concept of risk has two elements: the likelihood of something happening and the consequences if it.

Risk Analysis

Risk analysis is the systematic process to comprehend the nature of risk and to deduce the level of risk

Risk Assessment

The overall process of risk identification, risk analysis and risk evaluation to determine risk management priorities by evaluating and comparing the level of risk against organisational standards, predetermined target risk levels or other criteria.

Risk Identification

The process of finding, recognising and describing risks.

Risk Management

Coordinated activities to direct and control an organisation with regard to risk.

Risk Profile

A summary of key risks existing across the organisation which provides a reporting framework.

Risk Treatment

The development and implementation of measures to modify risk.

5. Guiding Principles

The implementation of this policy is supported by the following principles:

- All employee and volunteers are responsible and accountable for managing risks in their workplace on an ongoing daily basis
- Action taken to manage risks should be integrated with existing planning and operational processes

- Employee consultation and other stakeholder participation is an integral part of risk management processes
- Risk management processes need to be grounded in a no blame culture and in an environment of continuous improvement and empowerment.

6. Risk Governance

X Community Health will apply RM to each organisational level: strategic, operational, team, and individual. Both bottom-up and top-down approaches will be employed to facilitate a comprehensive RM program. The governance structure for integrated risk management at x community health is as represented below:



7. Roles And Responsibilities

The roles and responsibilities for risk management throughout the organisation are outlined below:

Board

The board provides direction and oversight of risk management across the

organisation. The board's key risk management responsibilities may include:

- approving the organisation's risk management documentation including the strategic risk profile, risk appetite and tolerance, risk management policy and risk management procedure
- setting the standards and expectations of the organisation with respect to conduct and behaviour, and ensuring that effective risk management is enforced through an effective performance management system
- monitoring the management of high and significant risks, and the effectiveness of associated controls through the review and discussion of regular risk management reports
- satisfying itself that risks are effectively managed, with appropriate controls in place and effective reporting structures
- approving major decisions affecting the organisation's risk profile or exposure.

CEO

- reviewing key risk information, identifying key risk trends and assessing the impact for the organisation as a whole
- monitoring the management of high and significant risks and the effectiveness of associated controls through the review and discussion of regular risk management reports
- ensuring that adequate processes are being followed in relation to lower level risks
- promoting a strong risk management culture

Risk Committee

- Oversight of the risk management framework, including the consideration and review of risk management policies and procedures on an annual basis.
- Establishing policies and reviewing the effectiveness of the organisation's approach to risk management including the status of major business risks.
- Reports to the Board advising of its activities, findings and recommendations, including risk management policies.
- Assist the board in discharging its responsibilities to exercise due care, diligence and skill in relation to business operations and to advice on any matters of financial or regulatory significance which may be referred to it from time to time.

Manager Risk Management

- develop, enhance and implement appropriate risk management policies, procedures and systems
- co-ordinate and monitor the implementation of risk management initiatives within an organisation
- work with risk owners to ensure that the risk management processes are implemented in accordance with agreed risk management policy and strategy
- collate and review all risk registers for consistency and completeness
- provide advice and tools to staff, management, the Executive and Board on risk management issues within the organisation, including facilitating workshops in risk identification
- promote understanding of and support for risk management

Managers and Team leaders

- manage the risk they have accountability for
- ensure the identification and analysis of risk in risk registers at each program /team level
- review the risk on a regular basis
- identify where current control deficiencies may exist
- update risk information pertaining to the risk
- escalate the risk where the risk is increasing in likelihood or consequence
- provide information about the risk when it is requested.

Staff and Contractors

- identifying risks and reporting these to the relevant person
- involvement in the management of risks where appropriate

8. Policy Review And Monitoring

This policy and underlying strategies will be reviewed annually by the Board and Executive Management team to ensure its continued application and relevance. An independent review of the adoption and effectiveness of this policy will be undertaken by internal audit (or some other independent party) prior to Board and Executive Management team review on a biannual basis.

9. Related Organisational Documents

Risk Management Procedure

Community Health Service Policies

- Governance Policy
- OHS Policy
- Other relevant policies

10. History

DATE:

Initial Issue:



APPENDIX SEVEN: RISK PROFILE EXAMPLES

Appendix Seven outlines general risks encountered in the primary health care setting and three discipline specific risk profiles

GENERAL RISKS FOR CLINICAL AREAS

The information presented below represents some of the more common risks that may be encountered in any clinical situation in primary health. While each primary health care service will have a different individual risk profile specific to the type of programs and services offered, this information is worth referring to when identifying clinical risks in your organisation to check you have considered the main or most likely sources of risk.

While this information is compiled from data from sources such as insurance companies and registration bodies, there are limitations in applying the data to a community health setting as the data is often collected from sources other than community health. The data should be used as a guide for providing information about potential risks in your organisation. Other data such as internal incident data and complaints data should also be referred to in identifying risks.

Risks For Clinical Areas In Primary Health

The common risk factors identified below have been identified through insurance documentation, registration bodies and feedback from the sector.

Informed consent

Obtain and document informed consent to each specific course of treatment (not a general consent form) and every time treatment changes. Informed consent means discussing the:

- Nature and likely prognosis of the condition
- The care options, benefit and approach
- Options for additional diagnosis and confirmation
- Warnings as to possible adverse outcomes estimation as to the degree of uncertainty or outcome
- Time and cost involved

Breach of privacy

Release of documents without consent – e.g. to an employer

Use of abbreviations in records

Abbreviations must be used consistently and be able to be reinterpreted later. Establishing a consistent abbreviation system in your community health service and among providers is important.



Inadequate documentation

More than 80% of claims against healthcare professional are difficult to defend because records are inadequate, missing or ambiguous (Guildwatch). Inadequate records imply inadequate care.

Internal environmental risks

Floor surfaces, fixtures and fittings need to be maintained as slips and falls represent a significant number of incidents in community health based on insurance data.

Data source	Complaint
Health Service Commission data 05/06 (n=80)	No service/inadequate service (8) Poor attitude or discourteous (8) Negligent treatment (6) Inadequate consent for disclosure (4)
Summary VMIA community health claim data 01-06 (5 most common claims)	Patient injury - Damaged teeth Patient injury - Physiotherapy Patient injury - Treatment Misdiagnosis Slip and Fall
Clinical Risk Management Tool Trial – commonly identified problems	Incorrect allocation of priority for client access to service Communication with CALD clients

PHYSIOTHERAPY SPECIFIC RISKS

The information below represents the major risks identified in the provision of physiotherapy services. This information is compiled from data from sources such as insurance companies and registration bodies. There are limitations in applying the data to a community health setting as the data is often collected from sources other than community health. The data should be used as a guide for providing information about potential risks in your Primary Health Care Service. Other data such as internal incident data and complaints data should also be referred to in identifying risks.

Identified risk for physiotherapy

Exacerbation of condition

Clients must be warned of any short-term exacerbation of their condition as a result of treatment as part of gaining informed consent for treatment and this warning should be documented.

Failure to conduct appropriate pre care tests and examination

All relevant pre care testing, questioning and examination must be asked or performed prior to treatment. E.g. In the Cervical and Lumbar area particular care must be taken to note and modify treatment if neurological symptoms are present.

Failure to document

Failure to record examinations, test results and treatment can be interpreted that these processes were not completed. All results whether positive or negative must be documented.

Supervision of equipment use

Clients must be adequately trained and supervised in the use of equipment and have easy access to a means of communicating with the practitioner (bell or buzzer).

Data source	Risk Area	%
Physiotherapy Registration Board of Victoria Annual Report 2005	Complaint	
	3 yr average (2005-3)	
	Over servicing	18
	Clinical Practice	45
	Sexual Misconduct	13
Clinical Risk Management Tool Trial – commonly identified problems in physiotherapy	Business Practice	10
	Advertising	13
	Client injured during participation in exercise program	
	Client injured while receiving electrotherapy	
	Client condition exacerbated while receiving manual treatment	

PODIATRY SPECIFIC RISKS

The information below represents the major risks identified in the provision of podiatry services. This information is compiled from data from sources such as insurance companies and registration bodies. There are limitations in applying the data to a community health setting as the data is often collected from sources other than community health. The data should be used as a guide for providing information about potential risks in your Primary Health Care Service. Other data such as internal incident data and complaints data should also be referred to in identifying risks.

Identified Risk For Podiatry

Failure to conduct appropriate pre care tests and examination

All relevant pre care testing, questioning and examination must be asked or performed prior to treatment. e.g. sensation tested and documented.

Orthoses

Orthotic prescription can be problematic when orthotics are issued and follow up appointments are not attended. Follow up of non-attendees and advice regarding possible adverse outcomes of follow up should be explained. Minimum standards exist for the prescription of orthoses as presented in the Australasian Podiatry Council's The Clinical Guidelines For Orthotic Therapy Provided By Podiatrists.

Diabetes Care

Careful education and development of care plans of clients with diabetes is essential to ensure any adverse event in their treatment and self care. Australasian Podiatry Council's Podiatric Guidelines For Diabetes outlines the principles in the podiatric care of diabetic clients.

Infection Control

All podiatrists should have documented procedure for infection control, that are reviewed regularly, in line with Commonwealth Government Department of Health and Ageing's Infection Control Guidelines (<http://www.health.gov.au/internet/main/publishing.nsf/Content/icg-guidelines-index.htm>) for the prevention of transmission of infectious diseases in the healthcare setting and Standards Australia AS/NZS 4815:2006 Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment.

Data source	Risk Area
Clinical Risk Management Tool Trial – commonly identified problems in podiatry (in addition to those mentioned above)	Client injury getting on/off podiatry chair Client failure to attend due to lack of recall, DNA follow up

DENTAL SPECIFIC RISKS

The information below represents the major risks identified in the provision of dental services. This information is compiled from data from sources such as insurance companies and registration bodies. There are limitations in applying the data in the primary health setting as the data is often collected from sources other than primary health. The data should be used as a guide for providing information about potential risks in your Primary Health Care Service. Other data such as internal incident data and complaints data should also be referred to in identifying risks.

Identified Risk For Dentistry

Restorative care

It is essential that care be taken in the provision of dental services. Guildwatch suggests that claims have involved:

- Where solutions are splashed or misapplied;
- Where compounds fail to adhere or are allegedly of a poor quality;
- Broken and retained instruments in root canals;
- Dissatisfaction with restorative care especially where clinicians have worked beyond conventional practice;
- Cuts/abrasions to the floor of mouth, lip and tongue.

Complications subsequent to treatment

Good communication and documented consent are essential for ensuring there is good understanding of the possibility of post-operative infections; ongoing pain or loss of sensation; and clearly understood expectations regarding dentures.

Procedural and diagnosis

Clinicians should take care to work within their scope and ensure that radiographs and other tests are used and documented appropriately as part of care provision. Claims have arisen regarding treatment provided to the wrong tooth; failure to test or follow up on pathology findings and alleged misdiagnosis.

Infection Control

All dental clinics are required to follow Infection Control (IC) Standards and be in possession of the following 3 documents:

- Procedural manual for implementation of IC practices specific to the clinic,
- Commonwealth Government Department of Health and Ageing's Infection Control Guidelines (<http://www.health.gov.au/internet/main/publishing.nsf/Content/icg-guidelines-index.htm>) for the prevention of transmission of infectious diseases in the healthcare setting, and
- AS/NZS 4815:2006 Office-based health care facilities - Reprocessing of reusable medical and surgical instruments and equipment, and maintenance of the associated environment

Data source	Risk Area
Clinical Risk Management Tool Trial – commonly identified problems in dentistry (in addition to those mentioned above)	Medical history not updated resulting in medical complications during/as a result of treatment Unqualified/not registered dental providers resulting in illegal practice





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