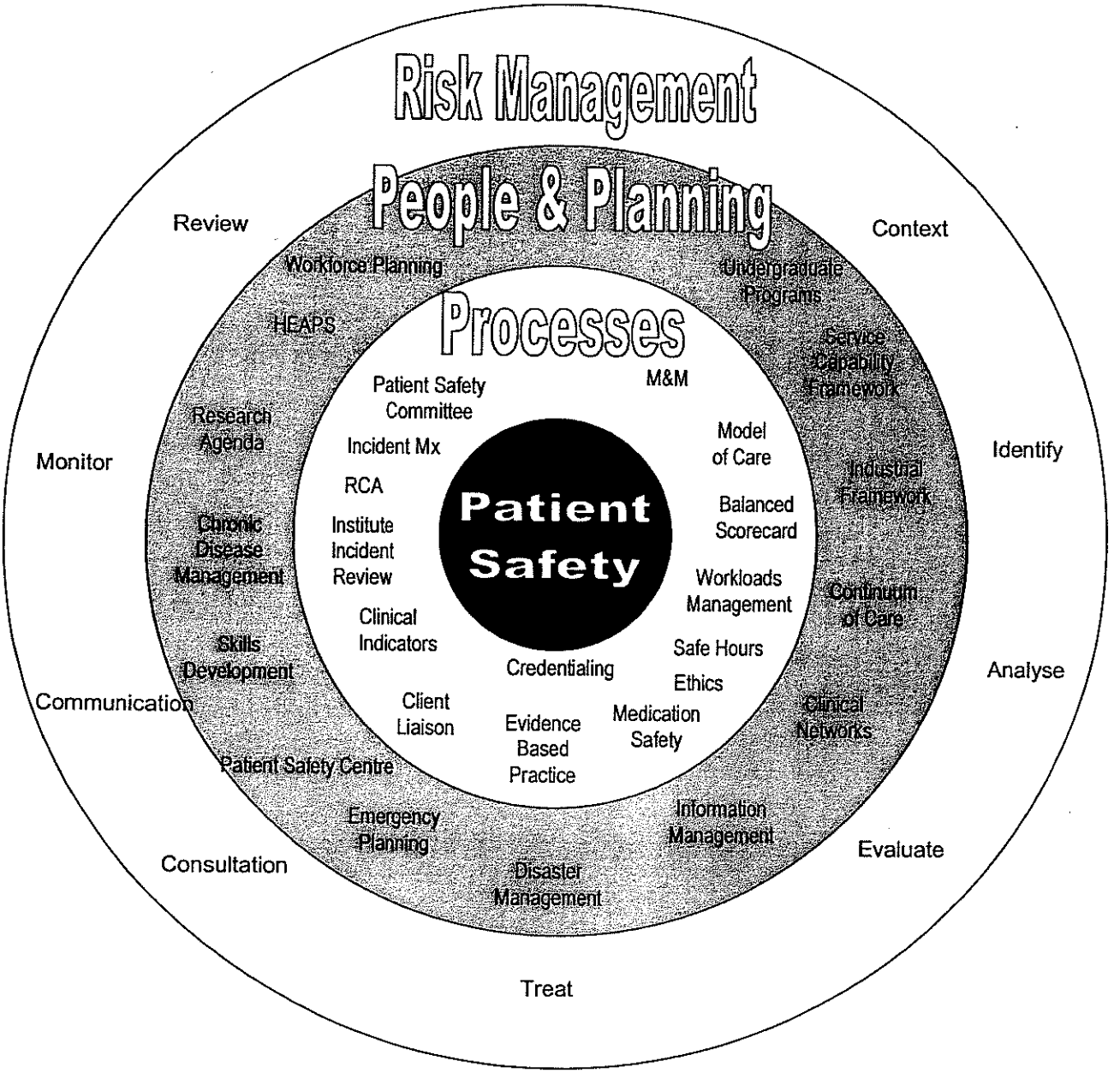
AJJ-12

Townsville Health Service District
PATIENT SAFETY FRAMEWORK



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Introduction and Background

The issue of clinical safety has been firmly on the health policy agenda for over a decade in Australia, since the Quality in Australian Health Care Study (QAHCS[1]), revealed levels of adverse events in our health care institutions that were, in most quarters, unexpected and disturbing. QAHCS identified that 16.6% of hospital admissions were associated with an adverse event. Of these 51% were deemed preventable, 13.7% resulting in permanent disability and 5% resulted in death.

Extrapolating from the figures provided by the QAHCS would suggest that Townsville Health Service District (THSD) could expect over 6000 adverse events per year, of which half might be preventable. More than 845 might be expected to result in a permanent disability and those adverse events may be a contributing factor in 300 deaths in the THSD annually.

The organisation needs to have business in place that identify adverse events when they occur, understand why they have occurred, and learn from these events such that the risk of them happening again is reduced.

The THSD Patient Safety Framework is based on sound risk management principles and demonstrates how risk management pervades all areas of the THSD activities including management and development of people, planning activities, and the way in which we conduct our day to day processes, to ensure the safety of patients using our services (see figure 1).

Applying Risk Management to the People, Planning and Processes of THSD

Risk is defined by AS/NZS 4360 as the "...chance of something happening that will have an impact upon objectives".
Risk management is something that we all do every day. Risk Management is defined as "..the systematic application of management policies, procedures and practices to the tasks of establishing the context, identifying, analysing, evaluating, treating, monitoring and communicating risk[2]."

Identify the Risks

Risks are all around us in health care. We work in imperfect environments, which are often held together by the professionalism and goodwill of the individuals involved. The people, the environment within which they work, and the systems and structures that create that environment harbour both the risks and the often complex management strategies that have developed consciously or unconsciously, in many cases, over a period of years.

There are many sources that can be exploited to assist with the identification of risk in clinical areas:

- Coroner's reports
- Clinical indicators
- Medical record audit
- Incident reporting
- Medico-legal reports
- Clinical audit
- GP feedback
- Complaints
- Peer review
- Death audit

[1] Quality in Australian Healthcare Study http://www.health.gov.au/pubs/hlthcare/recomm.htm
[2] AS/NZS 4360- Risk Management

Analyse the Risks
Risk analysis involves consideration of the sources of the risk, their consequences and the likelihood that those consequences may occur. Risk is analysed by combining estimates of consequences and likelihood in the context of existing control measures.
The reality is that many of the control measures used to address risk in the past have been relatively ineffective. Therefore when analysing risks, it is important to gain an understanding of the effectiveness of controls currently in place. The "Hierarchy of Controls" concept highlights the fact that education of staff, in isolation, is often ineffective, and certainly less effective than more structural and physical approaches.

Evaluate the Risks
This step is about deciding whether the risks are acceptable or unacceptable and hence require treatment or action. Defining a risk as acceptable does not imply that the risk is insignificant. The significance of the risk and importance of the policy, program or process, need to be considered in deciding if the risk is acceptable. The evaluation should take into account the degree of control over each risk and the cost impact, benefits and opportunities presented by the risks.

Treat the Risks
Treating the risks is about considering the options for managing risks that were identified as non acceptable at the previous step of the risk management process. A combination of options will probably be necessary
Options for treating risk may include:
- Avoid the risk
- Reduce the likelihood or consequence of the risk or both
- Transfer the risk
- Accept the risk

There are two major approaches for implementing the treatment options described above. They are treat the risk before the risk arises (Proactive) or treat the risk after the risk arises (Reactive)

Proactive approaches include
- Credentialing- eg. Mandating that all clinicians must have a credentialing process.
- Use of clinical guidelines.
- Application of Evidence-based practice through journal reviews and Clinical detailing is encouraged.
- Education in Error and Human Factors.

Reactive approaches include
- Incident reporting
- Root Cause Analysis
- Aggregated review processes
- Complaints
- Coroner's reports
- medico-legal requests

Monitor and Review the Risks
It is essential to complete the loop so that the effectiveness of strategies, plans and management processes are monitored and reviewed on a regular basis.

Communication and Consultation
This is an important interaction that must occur at all steps of the risk management process. THSD ensures an effective communication and consultation process by providing access to relevant information at all levels of the organisation through the following mechanisms

- Individuals- email, memos, access to management etc
- Wards/ Units- Ward/ Unit meetings, communication books
- Department/ Institutes- Morbidity & Mortality meetings / Institute Safety group processes, Institute meetings with standing agenda item regarding CRM
- Executive- Patient Safety Committee, Balanced Scorecard, 3 on 3 meetings between District and Institute executive teams
- External- consumers and community groups, corporate policies / directives, unions/ professional bodies

1. Introduction

Patient Safety has been identified by the Australian Council for Safety and Quality in Health Care as the most important issue in healthcare reform today. To address this important issue requires a coordinated and systematic approach.

With the primary focus on improving patient care and safety, encouraging clinician participation and improving the work environment, the Townsville Health Service District's (THSD) clinical risk management framework will:

- Encourage and support the identification, recording, monitoring and reporting of incidents that occur in the THSD;
- Encourage self-learning from risk identification, analysis, evaluation and treatment;
- Lead to the investigation of serious adverse events and critical incidents in order to promote the redesign of systems as the main method for improving safety;
- Ensure the action upon recommendations from these investigations;
- Create an environment conducive to quality improvement;
- Provide feedback to the health service and individual clinicians;
- Supports a culture where every clinician takes responsibility for patient safety and where reporting of events and problems is rewarded, not punished; and
- Ultimately improve patient safety and the quality of healthcare in the THSD.

2. Background

The issue of clinical safety has been firmly on the health policy agenda for over a decade in Australia, since the Quality in Australian Health Care Study (QAHCS[3]), revealed levels of adverse events in our health care institutions that were, in most quarters, unexpected and disturbing. QAHCS identified that 16.6% of hospital admissions were associated with an adverse event. Of these 51% were deemed preventable, 13.7% resulting in permanent disability and 5% resulted in death.

Extrapolating from the figures provided by the QAHCS would suggest that Townsville Health Service District (THSD) could expect over 6000 adverse events per year, of which half might be preventable. More than 845 might be expected to result in a permanent disability and those adverse events may be a contributing factor in 300 deaths in the THSD annually.

For the last several years debate has ensued about what to do to improve clinical safety, and this has been the subject of much analysis by august groups and much controversy as the mainstream media has picked upon the themes of medical error and patient safety.

High profile reports such as those from inquiries into King Edward Memorial Hospital [4], the Royal Melbourne Hospital [5] and the Campbelltown and Camden Hospitals [6] have highlighted the difficulties faced by the service providers, staff, politicians and regulatory authorities in dealing with risk and safety issues.

The concept of error in health care has not been well understood over the years, with significant emphasis on individual knowledge and expertise as the determinants of health outcomes. This focus on the individual is giving way to recognition that the individual is important but is only one part of a complex milieu and a broader focus is developing on systems as determinants of performance of the health care system. This does not accord with the political and practical imperative to identify and deal with the "accountable" practitioner who happened to be in the wrong place at the wrong time, otherwise known as the P*ATSE (Poor **** at the Sharp End).

There is a growing recognition that people do not come to work to do a bad job or make a mistake, but certain circumstances and the work environment combine to result in unwanted outcomes. Health care workers do not work in isolation. The root cause of problems leading to incidents is usually found in the design of the system that permitted the event in the first place. Clinical Risk Management (CRM) allows us to view the healthcare continuum as a 'system' that emphasises prevention, not punishment.

To minimise error we must have a healthcare system where risks are managed in such a way that makes it easy to do the right thing and difficult to do the wrong!

3[1] Quality in Australian Healthcare Study http://www.health.gov.au/pubs/hlthcare/recomm.htm

4[2]King Edward Memorial Hospital Inquiry Reporthttp://ww2.slp.wa.gov.au/publications/publications.nsf/inquiries+and+Commissions accessed 23 July 2004

5[3]Royal Melbourne Hospital Inquiry Report, http://www.health.vic.gov.au/hsc/rmh_report0802.pdf accessed 23 July 2004

6[4] Camden and Campbelltown Hospitals Inquiry Report http://www.lawlink.nsw.gov.au/Lawlink/Corporate/ll_corporate.nsf/vwFiles/Interim_Report_31March2004.pdf/$file/Interim_Report_31March2004.pdf and http://www.health.nsw.gov.au/pubs/i/pdf/invstign_hccc_2.pdf accessed 23 July 2003

The THSD patient Safety Framework is based on sound risk management principles and demonstrates how risk management pervades all areas of the THSD activities including management and development of people, planning activities, and the way in which we conduct our day to day processes, to ensure the safety of patients accessing the THSD (see figure 1)

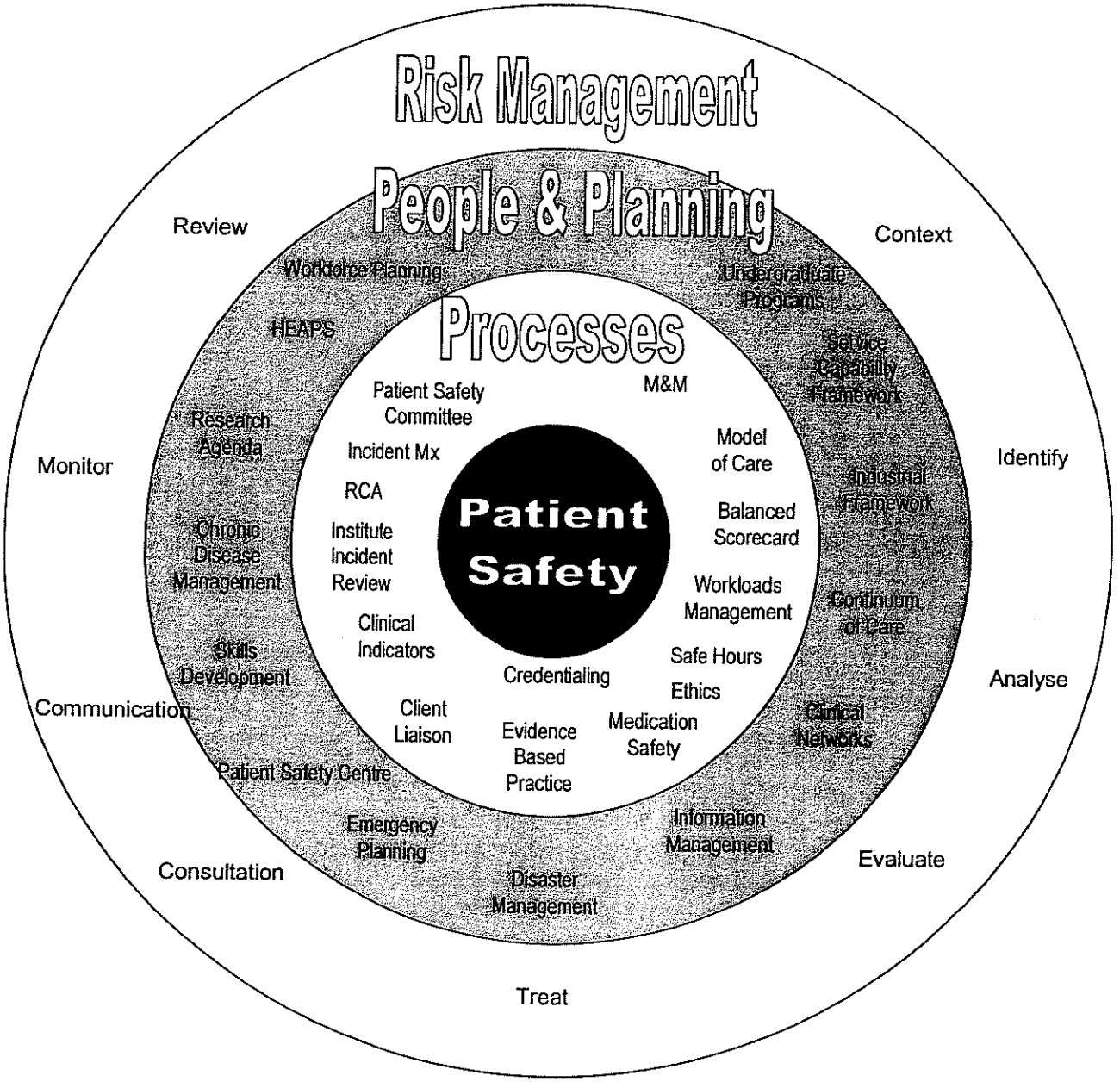

Figure 1- How risk management applies to people, planning and processes within the THSD to ensure patient safety

3. Applying Risk Management to the People, Planning and Processes of the THSD

Risk is defined by AS/NZS 4360 as the "...chance of something happening that will have an impact upon objectives".
Risk management is something that we all do every day. Risk Management is defined as "..the systematic application of management policies, procedures and practices to the tasks of establishing the context, identifying, analysing, evaluating, treating, monitoring and communicating risk[7]." (see figure 2)
A systematic approach to the management of risk is essential. The following sections describe how the risk management process is used within the THSD.

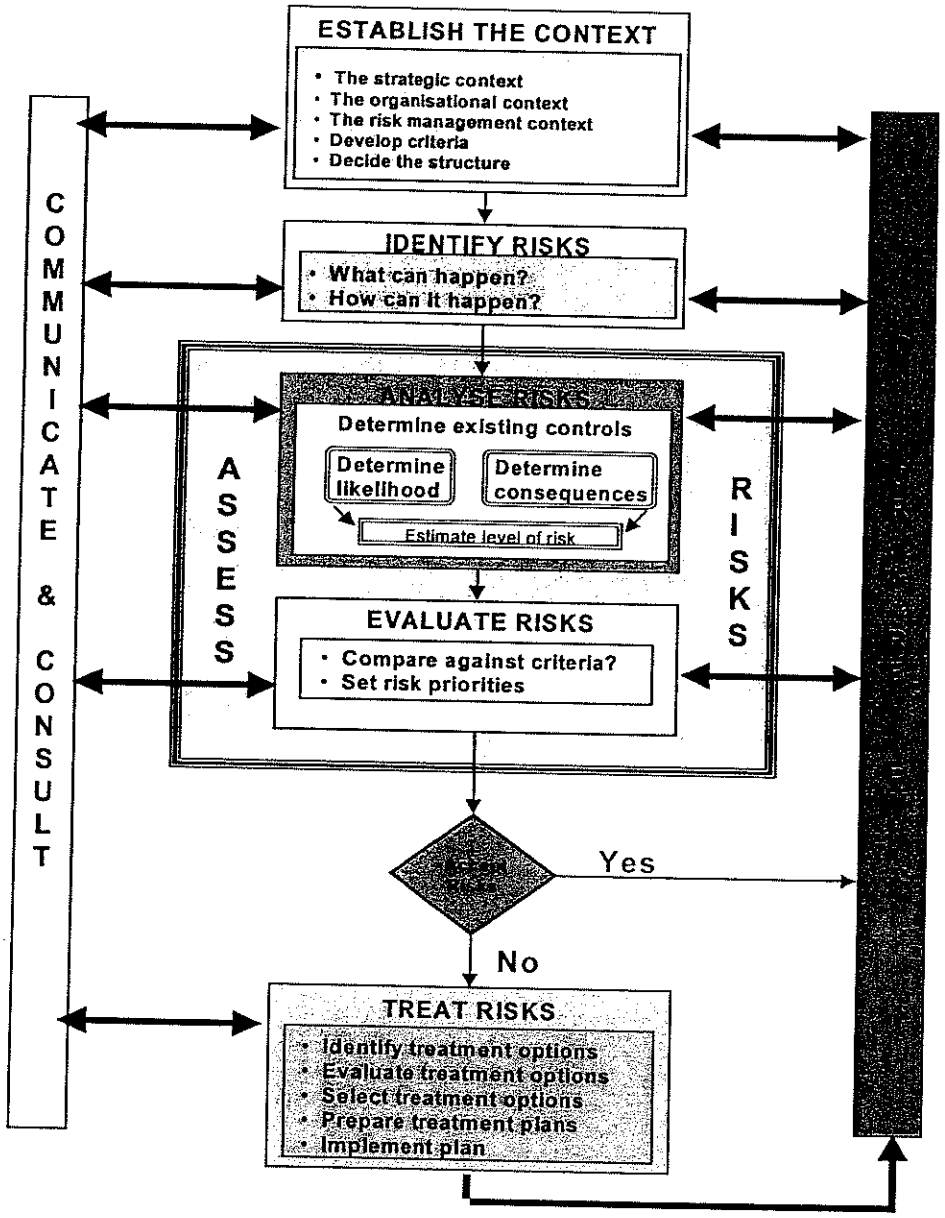

Figure 2- Australian and New Zealand Standard 4360, Risk Management

[7] AS/NZS 4360- Risk Management

3.1 Establish the Context

3.1.1 Organisational Context

The organisational context refers to what it is that the organisation does, its capabilities and what it is hoping to achieve i.e. Its goals or objectives. In the case of Queensland Health, and in particular THSD, the goal is to provide the highest quality healthcare service possible by investing our limited resources wisely to ensure the best possible results.

- Reviewing THSD demographic data to build services to meet the needs of the population
- Examining what services we provide in terms of effectiveness and efficiency
- Redesigning systems and processes to improve accessibility to services
- Increasing the investment in "wellness" models of care ie encouraging the development and maintenance of healthy lifestyles
- Increasing and improving the level of consumer consultation and participation

The organisational context helps to define the criteria by which it is decided whether a risk is acceptable or not. Managers need to consider their role in achieving the organisational goals when making decisions about risk.

3.1.2 Strategic Context

The strategic context refers to the relationship between the organisation and its environment eg the physical, socio-economic, cultural, legal and political factors that influence the way we do business. By identifying the organisation's strengths, weaknesses, opportunities and threats in relation to the factors described above the THSD can map out strategies to successfully manage risks that have been identified.
As can be seen from the organisational context above, an overall goal of the THSD is to provide a high quality health care service to improve the overall health and well being of people accessing services within the THSD.
Strategies identified to assist the THSD in achieving its goal include creating and building;

- Healthier staff,
- Healthier partnerships,
- Healthier people and communities,
- Healthier hospitals and ,
- Healthier resourcing

3.1.3 Clinical Risk Management Context

The clinical context refers to identifying and managing risks associated with clinicians practicing their respective specialties to deliver a high quality health service. As can be seen from the information supplied in point 1.0 (Background), adverse events are far more likely to occur than most of us would have expected.
The organisation needs to have processes in place that identify adverse events when they occur, understand why they have occurred, and learn from these events such that the risk of them happening again is reduced.
The THSD patient Safety framework aims to address this risk and facilitate the delivery of a high quality health service by;

- Educating employees about the concepts of risk management, understanding human error and the importance of effective communication and team work
- Encouraging a culture that supports the identification and reporting of risks
- Developing tools and implementing methodologies to learn from identified risks
- Demonstrating management commitment to clinical risk management through resource allocation and organisational relationships, and
- Ensuring adequate communication and consultation to all levels of the THSD.

3.2 Identify the Risks

Risks are all around us in health care. We work in imperfect environments, which are often held together by the professionalism and goodwill of the individuals involved. The people, the environment within which they work, and the systems and structures that create that environment harbour both the risks and the often complex management strategies that have developed consciously or unconsciously, in many cases, over a period of years.

There are many sources that can be exploited to assist with the identification of risk in clinical areas:

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The medico-legal process and individual performance issues are noted to be part of an overall clinical risk management process and represent useful opportunities to learn, however where these issues arise, they must be kept separate from the patient safety and quality improvement processes. This gives clinicians the confidence to report and investigate in an environment that encourages system review and improvement.

By keeping a "System Eye" looking for opportunities, even the most innocuous of indicators can help identify a weakness. For example, following up on a letter from a senior doctor complaining about clinical files being removed from his desk may reveal that in fact that files awaiting review for abnormal results regularly are removed without the knowledge of the doctors involved. Given that the files are recalled to assist in determining management of abnormal pathology reports, this could result in abnormal pathology not being acted upon.

In the same way, a Coroners report from a death in another facility, indeed another state, may offer some recommendations or "riders". These will often point to areas that the Coroner believes could be systemic weaknesses. Many serious Coroners Cases will get significant publicity, and transcripts are readily available. One example of such a case involved the intrathecal administration of Vincristine to a patient whom subsequently died. The coroner made recommendations regarding the preparation and packaging of Vincristine that would reduce the risk of the event occurring again

Risks may become apparent through numerous means and at this stage we do not have perfect systems to let everyone know about the risks evident within the system. Through our patient safety team we look for as many sources as possible to identify potential risks for the organisation. This includes close working relationships with the Queensland Health Patient Safety Centre, other hospitals and a network of safety groups throughout the District.

It is important that all staff realise that they may in fact be the first to identify a risk and they should not assume that "someone else" knows about it or is "dealing with it".

One of the most effective techniques currently being employed in risk identification is the process known as "Root Cause Analysis".

Root Cause Analysis

Root cause analysis (RCA) is a method that can help us learn as much as possible from both adverse events and close calls. It emphasises that it is the underlying system issues that lead to errors, not individuals. It is not enough to just learn the truth about why things happened the way they did. What really counts is applying what we have learned constructively, so we can do things better in the future and ultimately prevent adverse events and close calls from happening again.

The aim of root cause analysis is to understand how and why an event occurred. It uses a systematic process that uses information gathered during the investigation of an event to determine the underlying reason or the fundamental 'root cause' and considers both localised and systemic problems that may create deficiencies that cause such events occurring.

The method outlines two fundamental challenges:

- To understand how and why the event occurred and
- To prevent the same or similar event from occurring in the future

Characteristics of Root Cause Analysis:

- Focuses primarily on systems and processes, not individual performance,
- Repeatedly digs deeper by asking "why"
- Identifies changes that could be made in systems and processes –through either redesign or development of new systems or processes
- Non punitive
- Focus is on how to improve systems in order to prevent the occurrence of serious adverse events
- Digs deeper into existing systems to find new ways to do things

3.3 Analyse the Risks

It is easy to get swamped in the volume of risks that exist in every complex organisation. The process of analysing risks allows you to sort the wheat from the chaff and therefore apply your energies to the areas most likely to cause significant consequences, or where there is the greatest likelihood of events occurring. Risk analysis involves consideration of the sources of the risk, their consequences and the likelihood that those consequences may occur. Risk is analysed by combining estimates of consequences and likelihood in the context of existing control measures.

The reality is that many of the control measures used to address risk in the past have been relatively ineffective. Therefore when analysing risks, it is important to gain an understanding of the effectiveness of controls currently in place. Later in this framework we will discuss the

"Hierarchy of Controls". This concept highlights the fact that education of staff, in isolation, is often ineffective, and certainly less effective than more structural and physical approaches.

The use of a qualitative risk matrix (see attachment 4), allows for a more consistent categorisation of the event requiring analysis. While there is undoubtedly a level of subjectivity or judgement involved in the classification, use of the risk matrix provides an objective assessment against defined criteria by which to prioritise our actions. The use of the matrix at the start of the process ensures that our precious resources are applied where they have the greatest opportunity to improve the level of safety and quality in our processes.

Using our earlier example of the missing files, the risk (of missing a preventable condition) may be considered to be likely in its occurrence and potentially major in its consequence. This is so because the files are regularly being removed and this event is expected to recur. Without a mechanism for recall of the chart, the consequences could result in death, with a potentially curable cancer going untreated until it progresses beyond a salvageable point. However, the existing controls of pathology phoning through abnormal histopathology, and regular patient follow-up appointments as a routine after surgery, reduce the likelihood of the risk to possible. This gives us a rating of "Very High" risk

3.4 Evaluate the Risks

Treating the risks is about deciding whether the risks are acceptable or unacceptable and hence require treatment or action. Defining a risk as acceptable does not imply that the risk is insignificant. The significance of the risk, and the importance of the policy, program or process, needs to be considered in deciding if the risk is acceptable. The evaluation should take into account the degree of control over each risk and the cost impact, benefits and opportunities presented by the risks.

Where a risk is determined to be unacceptable, it must be treated in some way. Treatment of risks should be prioritised in order to best utilise resources.

In acknowledging that some risks have to be accepted, it is important that they are "As Low As Reasonably Practicable"(ALARP) or "As Low As Reasonably Achievable" (ALARA). The following diagram illustrates these principles.

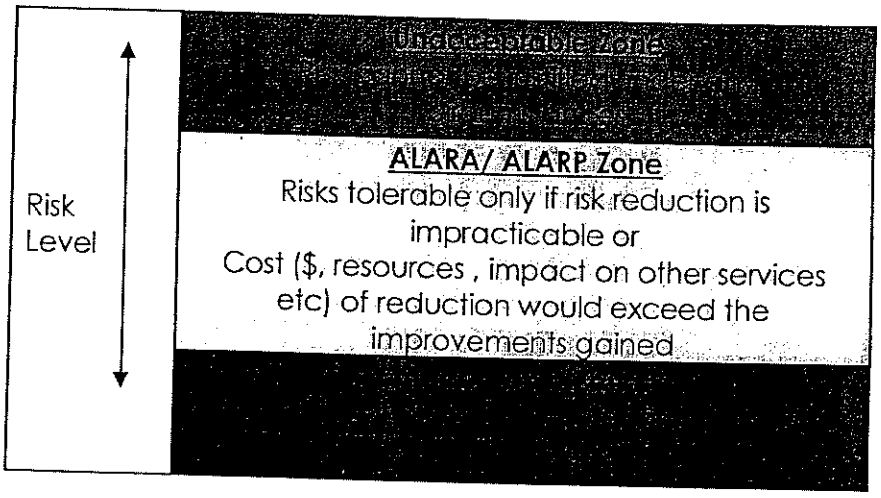


Figure 3- The ALARP/ ALARA Principle

Using our earlier examples, the very high risk presented by the files being removed may not place this at the top of the management agenda. However, the problem can be made to go away completely with a change in process at very little cost, therefore could be reasonably delegated by management to an appropriate department to come up with an organisation wide approach which either eliminates the risk or reduces the likelihood of occurrence. That is, the aim would be to introduce treatment to get to the "ALARA" zone.

In the Mental Health example, the risk is clearly in the "unacceptable" zone and would require urgent attention at the highest level to resolve.

3.5 Treat the Risks

This step is about considering the options for managing risks that were identified as non acceptable at the previous step of the risk management process. A combination of options, as described below, will probably be necessary.

Wherever possible, the aim should be to eliminate risks completely. In a complex and dynamic environment such as healthcare, where so many processes are interlinked, it is often not possible to completely eliminate a risk in one area without creating unacceptable risks in another, so treatment may involve a combination of approaches outlined below.

Options for treating risk may include:

1. Avoid the risk- It may be possible to avoid the risk in its current form, by adopting an alternative practice, or ceasing an activity. In considering this option, it is important to look for potential "knock-on" effects, which may contain new risks.

2. Reduce the likelihood or consequence of the risk or both. Redesign of systems and processes to reduce the likelihood and/or consequence of risks can have a significant impact on the potential of the risk.

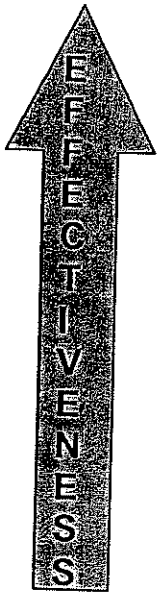
3. Transfer the risk- Give the risk to somebody else to worry about. In business terms this usually rests in insurance and outsourcing. These options are not always available in healthcare
   The success of this strategy is dependant on the receiving agency's ability to manage the risk in terms of specialisation and resources and also the costs incurred (people, time, money) by the organisation or department transferring the risk.
4. Acceptance of the risk- Sometimes this may be necessary, examples include:

- Where the risk is such that there are no further treatment options available
- The benefits of the existing process outweighs the threats to an extent where the risk is justified
- The level of risk is so low that specific treatment is not appropriate within the available resources

The ultimate aim should be to eliminate the risk completely. This however, is not usually possible and invariably there will be a residual risk that the organisation must accept

Hierarchy of Controls

When attempting to treat a risk there are always a number of options or approaches that can be employed, but choosing which one to implement can sometimes mean the difference between successfully treating the risk and having the risk realized.
It is important to recognise that certain actions are more likely to result in long term improvement than others.
The hierarchy of controls is a guide as to how to approach the management of risk using the options and strategies outlined in this section.



- **Eliminate the hazard**
- **Substitute with a safer process**
- **Incorporate engineering controls/ forcing functions (alarms, equipment modification, access restriction etc)**
- **Establish administrative controls (policies & procedures, training/ education etc)**
- **Use personal protective equipment**

Figure 4- The Hierarchy of controls

Of particular note in the hierarchy of controls are the position of administrative controls (policies, procedures, training etc) and the use of personal protective equipment in relation to approaches such as substitution and engineering controls.
Historically, the use of administrative controls has been one of the first approaches to be recommended to control identified risks, when as can be seen from the hierarchy, these types of controls are actually not that effective. For example remedial training may not be

effective because it requires the understanding and acceptance by staff and there is nothing physically to stop them from reverting to previous methods which may be quicker.

Personal Protective Equipment (PPE) is at the bottom of the list because the use of this approach on its own does nothing to reduce the risk of the event occurring, all it does is to try and prevent any harm to the employee. The effectiveness of the PPE is also dependant on the person using the equipment properly.

Additional Risk Treatment Approaches[8]

Reduce Complexity of Tasks- reducing complexity can be achieved by reducing number of steps in the task, decreasing the number of choices faced by the individual, decreasing the distractions and the information processing required, so that the outcome is less reliant on individual judgement and performance.

Optimise Information Processing- Much of what we do occurs at a subconscious level. Our brains cannot process in a deliberative manner all the stimuli we face. So we learn to recognise patterns and go into "autopilot" mode. This is a basic survival mechanism but it can get us into trouble where cues are misinterpreted.

We can take advantage of this by building on the coding systems (eg colour coding, size and shape) already well recognised in healthcare, increasing the likelihood that information can be absorbed in a streamlined manner. The aim here is to reduce reliance on short term memory, so that is can employed in essential processing tasks.

Automate Wisely- With the increasing use and intrusion of Information technology into our workplace, we have seen some tremendous (intended) improvements in efficiency and safety, and some difficult (and unintended) secondary effects, where new types of risks and errors are introduced.

Principles for the wise application of automation include:

- Automate for system improvement, not just because you can.
- Make sure that any automation interfaces well with the human operator, rather than increasing training demands and complexity at periods where the worker most needs to be concentrating.
- Use technology to support, not replace the human operator.

Use Constraints- a constraint restricts certain actions. When used to restrict actions that result in error, constraints can be a reliable form of error proofing.

- Physical constraint- Physical restraints take advantage of the properties of the physical world (engineering solutions) for example when connecting anaesthetic equipment it is impossible to connect an Oxygen regulator to an Air cylinder
- Procedural constraints- increase the difficulty of performing the action that results in error eg ensuring that concentrated potassium ampoules are not available for use on the ward or standardising the design of infusion pumps available across the hospital

Mitigate the Unwanted Effects of Change Advances aimed at improving the care, such as new medical procedures, new monitoring equipment or procedural changes often introduce unwanted side effects related to the alteration to routines or additional learning.

[8]adapted from Nolan T W, BMJ 320:18march 2000

Precautions can be taken to mitigate the unwanted effects of change:

- Use a formal process such as risk assessments to predict opportunities for error and harm before making the changes.
- Tests changes on a small scale with minimum risk, and devote resources to redesign the procedure as problems are identified
- Monitor the clinical outcomes, errors, and adverse events over time during testing and implementation

This process requires that changes in clinical care are introduced in a structured and careful way. Without careful monitoring and application, the unintended aspects of changes in practice may only be detected when an adverse event occurs.

To go back to our previous examples, the file management issue is amenable to an engineering fix, by implementation of an electronic record system. If that is not feasible, then working the way down the hierarchy of controls may offer another solution. We want to go for a fairly robust solution, so it may be worth considering things like:

- *assessing the reasons that files are removed, and whether a policy that files should not be retrieved from doctor's desks would be detrimental to care in any other part of the process; or*
- *developing a checklist for clinical file tracking and mandating that only certain staff may retrieve files from doctors offices.*

In the mental health issue, it may be that urgent treatments need to be considered to render the situation safe while more considered approaches are worked through. For example; dictating that no mental health patient may be discharged from the emergency department after hours may mean that the risk of patients being inappropriately discharged is reduced, but may have a "knock-on" impact in the overcrowding of the emergency department. At least in the initial phases, this may be considered to represent a lesser risk, and therefore be acceptable interim action.

Implementing Risk Treatments

There are two major approaches for implementing the treatment options described above. They are treat the risk before the risk arises (Proactive) or treat the risk after the risk arises (Reactive)

Proactive approaches include

- Credentialing- e.g. mandating that all clinicians must have a credentialing process.
- Use of clinical guidelines.
- Application of Evidence-based practice through journal reviews and Clinical detailing is encouraged.
- Education in Error and Human Factors.
- Mandating that interventions, which are new to an individual unit, must be appropriately assessed through a risk management process.
- Local management must maintain a record of current procedures and have a process in place to ensure no new procedures are implemented before approval.
- Encouraging clinicians to participate in communication skills training programmes.

Reactive approaches include

- Incident reporting
- Root Cause Analysis

- Aggregated review processes
- Complaints
- Coroner's reports
- medico-legal requests
- equipment failure
- audit and peer review programmes
- infection control
- clinical indicators
- death audits
- facilitated medical record screening

3.6 Monitor and Review the Risks

Risk treatment is far from the end of the story. To complete the loop, it is essential that the effectiveness of strategies, plans and management processes are monitored and reviewed on a regular basis.

The reality is that the environment within which the risk was originally identified and managed, will itself be dynamic, and the coincidence of factors which created the risk in the first place may have changed dramatically in the interim. Therefore, the process of monitoring and review needs to examine not only the effectiveness of the treatments, but also the validity of the risk over time.

Key Questions that need to be asked when reviewing and monitoring the treatment of risk:

- Are the treatments effective in minimising the risks?
- Are the risk treatments efficient and cost effective in minimising risks?
- Do the performance indicators address the key success elements for risk treatments?
- Do the risk treatments comply with legal requirements, government and organisational policies, including those concerning access, equity, ethics and accountability?
- How can improvements be made?

One effective tool implemented in the THSD for monitoring and reviewing risks is the utilisation of a risk register. This is a dynamic document, held in constituent parts at different levels of the organisation, coming together at a governance level as an organisation risk register. This allows for the documenting of risks, their likelihood and consequence, treatment plans, responsible officer and outcomes. To be effective, such documentation needs to be dynamic, and a routine part of business practices in the organisation.

3.7 Communication and Consultation

Risk communication and consultation can be defined as any two-way dialogue between stakeholders about the existence, nature, form, severity or acceptability of risks. This is an important interaction that must occur at all steps of the risk management process.

THSD ensures an effective communication and consultation process by providing access to relevant information at all levels of the organisation through the following mechanisms

- Individuals- email, memos, access to management etc
- Wards/ Units- Ward/ Unit meetings, communication books

- Department/ Institutes- Morbidity & Mortality meetings / Institute Safety group processes, Institute meetings with standing agenda item regarding CRM
- Executive- Patient Safety Committee, Balanced Scorecard, 3 on 3 meetings between District and Institute executive teams
- External- consumers and community groups, corporate policies / directives, unions/ professional bodies

4. Conclusion

With the primary focus on improving patient care, encouraging clinician participation and improving the work environment, the THSD patient safety framework will;

- Encourage and support the identification, recording, monitoring and reporting of incidents that occur in the THSD
- Encourage self-learning from risk identification, analysis, evaluation and treatment
- Lead to the investigation of serious adverse events and critical incidents in order to promote the redesign of systems as the main method for improving safety
- Ensure the action upon recommendations from these investigations
- Create an environment conducive to quality improvement
- Provide feedback to the health service and individual clinicians
- Supports a culture where every clinician takes responsibility for patient safety and where reporting of events and problems is rewarded, not punished
- Ultimately improve patient safety and the quality of healthcare in the THSD.

Glossary

Actual (see Adverse Event)

Adverse event
An incident in which unintended harm resulted to a person receiving health care
An incident in which harm is caused to the organisation
In the context of this policy, adverse event means where minimal harm has been caused
(see Serious Adverse Event)

Clinical Risk Management (CRM)
The identification, analysis and economic control of risk in a clinical setting and includes the systematic application of management policies, procedures and practices.

Close call (see Near Miss)

Contributing Factor
Contributing factors are additional reasons, not necessarily the most basic reason that an event has occurred.

Corrective Action
Corrective or remedial changes required to improve the system and address the root cause/s of the event. Actions can be strong, intermediate or weak. Examples of strong actions include architectural/ physical plant changes; standardisation of equipment and processes. Intermediate actions include checklists and eliminating look and sound alikes. Weak actions include warnings and labels, new policies, procedures or directives and staff training.

Error
The failure to complete an action as intended, the wrong use of or the wrong plan to achieve an aim. Errors may occur by doing the wrong thing (commission) or by failing to do the right thing (omission)

Event
An incident or situation, which occurs in a particular place during a particular interval or time

Expression of regret
An expression of regret made by an individual in relation to an incident alleged to give rise to an action for damages for personal injury, is any oral or written statement, expressing regret for the incident, to the extent that it does not contain an admission of liability (i.e. an admission of fault or negligence) on the part of the individual or someone else. (s69 & 71 Civil Liability Act 2003).
An expression of regret made by an individual, in relation to an incident alleged to give rise to an action for damages for personal injury, at any time before a civil proceeding is started in a court in relation to the incident, is not admissible in the court proceeding (s72 Civil Liability Act 2003)

Governance
The manner in which Queensland Health is directed, controlled and accountable for the achievement of its strategic goals and operational objectives. This includes a framework, structures and processes.

Harm
Death, disease, injury and or disability experienced by a person
Destruction, damage or threat to the organisation, loss of or damage to property, or pollution of the environment

Incident
An event including adverse incident or circumstances which could have, or did lead to unintended and/or unnecessary harm to a person or the organisation, and/ or a complaint, loss or damage

Incident monitoring
A system for identifying, processing, analysing and reporting incidents with a view to preventing their recurrence

Intentionally unsafe acts
A criminal act; a purposefully unsafe act; an act related to alcohol or substance abuse by an impaired provider/ and or staff; or events involving alleged or suspected patient abuse of any kind

Liability
Responsible for an action in a legal sense

Near hit (see Near Miss)

Near miss
An incident or close call that did not lead to harm, but could have

Open Disclosure[9]
The process of open discussion of adverse incidents that resulted in unintended harm to a patient while receiving health care and the associated investigation and recommendations for improvement

Potential (see Near Miss)

Qualified privilege
Section 31 Health Services Act 1991 affords protection to members appointed to a committee which has been declared as an approved quality assurance committee under the Act. This means that the information which may be relevant to litigation, and in which there would normally be an obligation to provide, can be withheld from discovery in legal proceedings and is inadmissible as evidence in court proceedings.

Risk Management
The systematic application of management policies, procedures and practices to the tasks of establishing the context, identifying, analysing, evaluating, treating, monitoring and communicating risk- AS/NZS 4360: Risk Management

Root cause
The most fundamental reason an event has occurred. If the root cause is prevented it will break the causal chain or sequence of events leading to the adverse event

Root cause analysis
A systematic process to identify and manage underlying factors and system vulnerabilities that contributed towards an incident or close call

Serious Adverse Event
1. An incident in which serious harm resulted to a person and where the combined likelihood and consequence score (according to the THSD Risk Matrix) is high or extreme
2. An incident in which serious harm resulted to the organisation and where the combined likelihood and consequence score is high or extreme

[9] *Open Disclosure Standard* Australian Council for Safety and Quality in Health Care July 2003

3. Include any incidents that satisfy one or more of the following criteria:
- Affects public health or safety
- Suggests a system or process problem affecting patient care that may require attention by the Health Service
- Has the potential to be of concern to the community or media

Sentinel Event
An adverse event is considered to be a 'sentinel' event when they have significant effect on the patient, resulting in permanent disability or death and result from the management of the patient's condition.
Sentinel events signal system vulnerabilities and the need for detailed investigation and response. They are events that are considered not to be a natural consequence of healthcare (see THSD Risk Matrix for Sentinel Event list)

Systems improvement
The changes made to dysfunctional operational methods, processes and infrastructure to ensure improved quality and safety

System failure
A fault, breakdown or dysfunction within an organisation's operational methods, processes or infrastructure.

Acknowledgment of References

List of Hospitals/ Organisations utilised

- AS/NZS 4360:1999, Risk Management

Contact library or Workplace Health & Safety for access to copy of Standard

- HB:228, 2001, Guidelines for Managing Risk in Healthcare

As above

- Queensland Health Integrated Risk Management Policy (#13355)

http://165.86.4.72/hssb/risk/Adobe/13355.pdf

- Queensland Health- Incident Management Policy (Draft , Mar 2004)

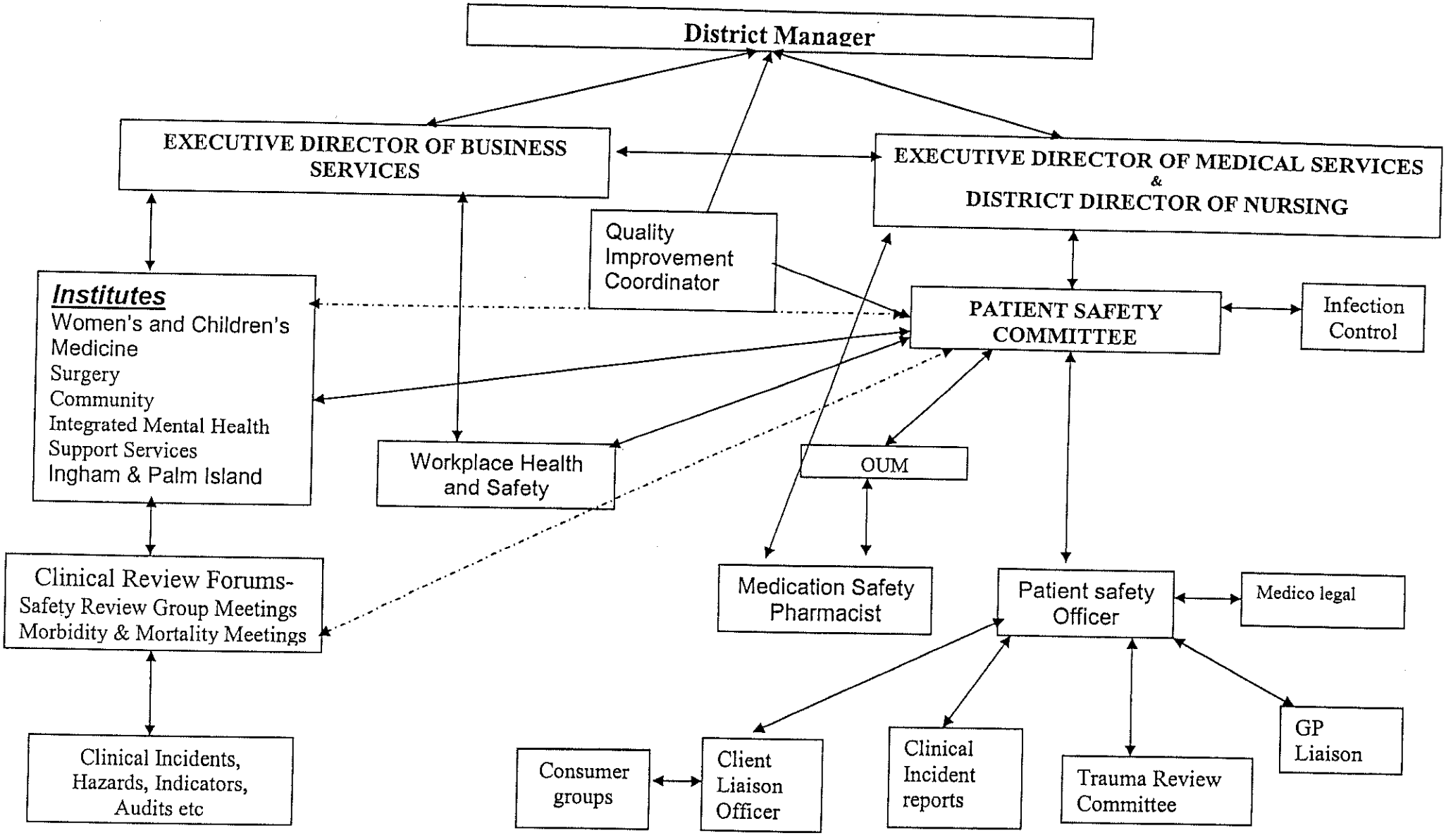
http://165.86.4.72/hssb/risk/Adobe/21935.pdf

- QLD, West Moreton District Health Service, Patient Safety Framework
- NSW, Hunter Area Health Service; Clinical Risk management Framework & Patient Safety Process, Clinical Governance Unit 2003

http://www.hunter.health.nsw.gov.au/docs/CGU_CRMFrameworkBooklet.pdf

- NSW, Mid North Coast Area Health Service, Risk Management Framework
- VIC, Bayside Health Service, Risk Management Guidelines
- SA, The Queen Elizabeth Hospital & Health Service, Safety Quality and Risk Management System (Sep 2003)

Attachment 1-Clinical Risk Management Structure



Attachment 2-THSD Accountabilities for Clinical Risk Management

District Manager and Executive Management Team.	These positions are responsible for: • The implementation and support of the Clinical Risk Management Framework within the THSD • Ensuring the development and maintenance of risk registers that contain identified risks and risk action plans • Formulate policy and strategic direction • Provide adequate, equitable resourcing for the safety and effectiveness of clinical programs • Ensuring reports are provided to Queensland Health corporate on risks that: 1. Have the potential to be or are strategic in nature 2. Require coordination between responsibilities areas within Queensland Health or between departments and/or 3. Have a serious consequential impact to the THSD and/or QHealth
Institute Executive and Department Directors	These positions are responsible for: • Coordination and support of clinical risk management processes • Ensuring high priority actions recommended from investigations are implemented • Ensuring that audit processes are in place and functioning in each clinical unit • Ensuring evidence based processes are incorporated in clinical procedures • Progress clinical indicator development and monitoring
Pt Safety Committee, Patient Safety Manager / Quality Manager	• Responsible to work with individual clinical units to ensure quality improvement processes are put in place in response to identified problems • To prioritise the investigation of clinical events and provide regular reports to Executive and other relevant bodies as required • Monitor the actioning of recommendations and report to the Executive and other relevant bodies as required • Coordinate quality improvement processes by active involvement and facilitation of clinical improvement projects, and report to Executive and the Directors of Institutes on progress. • To provide feedback and act as a resource for matters relating to clinical risk management in the THSD
Managers / Supervisors	• Ensure that all staff are aware of the THSD clinical risk management process • Support clinical risk management strategies through encouragement of staff in the reporting and investigation of incidents. • Ensure recommendations are implemented and supported
Clinical and Non-Clinical Staff	• All staff have the responsibility to participate in clinical risk management activities such as reporting of identified risks, audit processes, Root Cause Analysis and clinical reviews where required.

Attach. ent 3-Incident Management Flo Chart

Notify Supervisor
Initiate Immediate Actions to prevent further Injury/ harm or damage

Clinical incident, Close call, Work Related Injury or Illness, Property damage, Safety or Procedure Concern

Identify

Note- Staff are encouraged to report identified vulnerabilities through whatever mechanism they feel comfortable with. The important point being that vulnerabilities are acted upon

Report incident using either PRIME- Clinical Incidents or WH&S carbon copy book.
A risk assessment is a mandatory component of PRIME- Clinical Incidents

Assess & Analyse

Clinical Incident

WH&S

Low & Medium Risk

Manager (eg NUM, Consultant etc) of area to e responsible for oordinating mplementation of orrective actions and versee any further nvestigation required.
Management actions to ntered into PRIME- linical Incidents
Report to be completed/ osed within 3-5 days.
ctions should be ompleted or initiated if ng term implementation

High Risk

* Unit or Dept manager to be notified immediately or by commencement of next working day
* Unit or Dept manager must oversee and be accountable for Investigation process.
* Management actions to entered into PRIME- Clinical Incidents
* Report to be completed within 3 weeks. Actions should be completed or initiated if long term implementation
* Results of investigation and recommendations to be communicated to Institute/ Department Managers
* Consideration should be given to documentation on local risk register

Very High Risk

* Most appropriate senior personnel advised immediately
* Institute Management Team informed by commencement of next working day and are accountable for investigation process
* Root Cause Analysis (RCA) to be strongly considered
* Institute Executive Management Team to be notified of incident outcomes.
* Discussion of incident outcomes to District executive and relevant hospital forums.
* Consideration should be given to documentation on Institute risk register
* Communication at Corporate level should be considered where appropriate.

Extreme Risk

* Most appropriate senior personnel available advised immediately.
* Executive Management Team informed as soon as possible and are accountable for investigation.
* If incident is a Sentinel Event, executive management team to ensure completion and faxing of Sentinel Events Memo to corporate office (refer to Sentinel Events Policy)
* Root Cause Analysis (RCA) to be conducted
* District Manager and relevant statutory bodies to be notified of incident initially and of outcomes.
* Communication at Corporate level should be considered.
Documentation of risk on District Risk Register

WH&S determine appropriate investigation

Evaluate

Treat

WH&S Investigation and reporting

Monitor & Review

Completed report returned to WH&S in a timely manner eg 1 month

Communicate & Consult

Attachment 4- THSD Risk Matrix

Risk Matrix

Likelihood	Consequences				
	Negligible	*Minor*	*Moderate*	*Major*	*Extreme*
Rare	Low	Low	Low	Medium	High
Unlikely	Low	Medium	Medium	High	Very High
Possible	Low	Medium	High	Very High	Very High
Likely	Medium	High	Very High	Very High	Extreme
Almost certain	Medium	Very High	Very High	Extreme	Extreme

Likelihood Table (Likelihood of the Risk)

Rare	May occur in exceptional circumstances
Unlikely	Might occur at some time (not to be expected)
Possible	Could occur at least once (capable of happening / foreseeable)
Likely	Is expected to occur occasionally (to be expected)
Almost certain	Is expected to occur frequently (in most circumstances)

Actions:

- All high, very high and extreme risks are considered notifiable and must be reported to your line manager immediately
- The risk assessment process is applicable to all processes and levels within the organisation
- All incidents including near misses must be recorded and reported

SENTINEL EVENTS:

1. Surgery/procedure on the wrong patient/wrong body part
2. Deaths including[5]:
(a) suicide of a patient
(b) death of a patient as a direct and immediate result of medication error
(c) death of a patient during inter-hospital transfer
(d) direct maternal death
(e) sudden and unexpected death of an infant associated with labour or delivery
(f) unexpected death of a patient during surgery
(g) unexpected death of a patient
3. Haemolytic blood transfusion reaction resulting from ABO incompatibility
4. Instrument or other materials inadvertently left in body cavity or operation wound following a procedure
5. Intravascular gas embolism resulting in death or neurological damage
6. Infant discharged to wrong family
7. Death of an employee during the course of their duties

Mental health specific:

8. Suicide or unexpected death in respect of:
8a. any patient (inpatient or community) of a mental health service.
8b. any person who has been in contact with a mental health service or emergency department within the 7 days preceding the incident.
9. Death of any person through shooting by the Queensland Police Service where the deceased had, or is reasonably suspected to have had, a serious mental illness.
10. Death of any other person due to the actions of a person who has, or is reasonably suspected to have, a serious mental illness.

Consequence Table

Degree of Severity						
Type of Consequences		**NEGLIGIBLE**	**MINOR**	**MODERATE**	**MAJOR**	**EXTREME**
Adverse Clinical Incident	**C**	No injury or harm caused, minor adjustment to operational routine	Minimal harm caused, minor interruption to routine	Loss of function, major harm caused	Loss of life	Multiple deaths
Outrage/Damage to Reputation	**O**	Minimal adverse local publicity	Significant adverse local publicity	Significant adverse statewide publicity	Significant and sustained statewide adverse publicity	*Sustain national adverse publicity, Qld Health's reputation significantly damaged*
Litigation	**L**	Minimum exposure to Qld Health	Significant exposure to Qld Health	Exposure will result in single claim	Claims greater than $500,000 or multiple claims resulting from single exposure	Claims greater than $1M or multiple claims resulting from multiple similar exposures
Disruption to established routines/ operational delivery (may include industrial action, power failure, natural or man-made disaster, etc)	**D**	No interruption to service	Some disruption manageable by altered operational routine	Disruption to a number of areas within a location or district & possible flow on to other locations	All operational areas of a location or district compromised, other locations or districts are affected	*Total system dysfunction and / or total shutdown of operations*
Staff Morale (may include absenteeism, establishment)	**SM**	Staff dissatisfaction within local unit. No effect on services or programs	*Alteration to routine practice required at local are or district*	Disruption spreads across services or programs	Disruption spreads to routine practice statewide	Statewide cessation of service or programs
Workplace Health & Safety	**H**	Incident or injury – no time lost	Injury / illness lost time of less than 4 days	Serious injury / illness event notifiable eg more than 4 days lost time	Fatality	Multiple fatalities
Security (may include major fraud/theft, IT failure, security breach at secure facility)	**S**	Event noted by local staff, no changes to routine required	Monitored by local staff, some effect on routine operations	Reportable event some threat to program / service that requires investigation & review	Significant event threatens program / service across the wider organisation	Extreme event affecting organisations ability to continue program / service
Environmental Impact	**E**	No lasting detrimental effect on the environment	Local detrimental effect on the environment	Short term local detrimental effect	Long term detrimental environmental effect (eg significant discharge of pollutant)	Extensive detrimental long term effect on the environment (eg extensive discharge of persistent hazardous pollutant)
Workforce Issues (may include recruitment and retention, capability)	**W**	No effect on services or programs	Some effect on specific service or program – alterations to routine practice required	Restrictions to service or program availability within a location or district, possible flow on to other locations	Cessation of service or program of a location or district, other locations of districts are affected	State wide cessation of a program or multiple programs
Operational Management	**O M**	No impact on local operations	Minor impact local operations	Moderate to long-term impact on wider operations	*Major impact across other areas of organisation*	Cessation of some operations
Corporate Management	**M**	Local management review	Management review on broader basis	Local Executive management review	Zonal / Branch / whole services review	Statewide Management review
Financial (anything that has the potential to cost the organisation as a whole or any unit thereof, money)	**F**	*~ 1% of monthly / project budget*	~ 2% of monthly / project budget	~ 5% of monthly / project budget	~ 10% of monthly / project budget	~ 15% of monthly / project budget