

Maternity - Clinical Risk Management Program

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Summary The Maternity Clinical Risk Management Program is the application of the NSW Patient Safety and Clinical Quality Program in the maternity setting.

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Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Affiliated Health Organisations - Declared, Public Hospitals

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Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

**NSW Patient Safety and Clinical Quality
Program**

**Maternity Clinical Risk Management
Program**

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1. INTRODUCTION

A successful Patient Safety Management System provides a systematic, explicit and comprehensive process for managing the risks that patients face in a health care setting. All successful Patient Safety Management Systems have the following elements:

- discovery and assessment of the hazards of particular operations;
- specifying how these hazards are to be managed; and
- what is to be done if things, despite their best endeavours, go wrong.¹

This Policy Directive requires Area Health Services to implement a standardised Maternity Clinical Risk Management Committee (MCRMC) for each maternity service. The MCRMC will report through the clinical stream quality committees to the Chief Executive, the Directors of Clinical Governance and the Department of Health.

2. RELEVANT NSW HEALTH POLICY DIRECTIVES AND GUIDELINES

This policy directive should be read in conjunction with the following policy directives and guidelines.

PD2005_608 NSW Patient Safety and Clinical Quality Program
http://www.health.nsw.gov.au/policies/pd/2005/PD2005_608.html

PD2005_609 Patient Safety and Clinical Quality Program Implementation Plan
http://www.health.nsw.gov.au/policies/pd/2005/pdf/PD2005_609.html

PD2006_102 Safety Alert Broadcast System
http://www.health.nsw.gov.au/policies/pd/2006/PD2006_102.html

PD2007_075 Lookback Policy
http://www.health.nsw.gov.au/policies/pd/2007/PD2007_075.html

PD2007_040 Open Disclosure
http://www.health.nsw.gov.au/policies/pd/2007/PD2007_040.html

GL2007_007 Open Disclosure Guidelines
http://www.health.nsw.gov.au/policies/gl/2007/pdf/GL2007_007.html

PD2007_061 Incident Management
http://www.health.nsw.gov.au/policies/pd/2007/PD2007_061.html

¹ Safety and Quality Council DRAFT Patient Management Systems Checklist 2004. <http://www.acsqhc.com.au>

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PD2005_219 [Deaths - Reporting of Maternal Deaths to the NSW Department of Health](http://www.health.nsw.gov.au/policies/PD/2005/PD2005_219.html)

http://www.health.nsw.gov.au/policies/PD/2005/PD2005_219.html

PD2008_070 [Death – Management of Sudden Unexpected Death In infancy](http://www.health.nsw.gov.au/policies/pd/2008/PD2008_070.html)

http://www.health.nsw.gov.au/policies/pd/2008/PD2008_070.html

PD2006_006 [Deaths - Perinatal - Hospital Procedures for Review and Reporting of Perinatal Deaths](http://www.health.nsw.gov.au/policies/pd/2006/PD2006_006.html)

http://www.health.nsw.gov.au/policies/pd/2006/PD2006_006.html

The Maternity Clinical Risk Management Committee will assume the responsibilities set out in PD2006_006 Deaths – Perinatal - Hospital Procedures for Review and Reporting of Perinatal Deaths.

3. MATERNITY CLINICAL RISK MANAGEMENT PROGRAM

3.1 Aim

The aim of the Maternity Clinical Risk Management Program is to provide Area Health Services with a framework for the articulation of the NSW Patient Safety and Clinical Quality Program into maternity services. This includes the integration of additional risk management activities undertaken in maternity services.

3.2 Objectives

The objectives of the Maternity Clinical Risk Management Program are to:

- establish a standard approach to risk management in maternity services
- assist health services with timely and effective management of incidents
- ensure a consistent and coordinated approach to the identification, notification, investigation, analysis of incidents and near misses with appropriate action on all
- allow the lessons learned to be shared.

The program incorporates the policy and standards of the NSW Patient Safety and Clinical Quality Program and includes the following underlying principles of risk management as defined in the Australian Standard AS/NZSA 4360:2004:

- Risk Identification
- Risk Assessment
- Risk analysis and evaluation
- Risk Control
- Lessons learned.

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Locally, clinical risk management must be integrated with general management, business planning and Area Health Service strategies and initiatives.

Area Health Services must develop and implement an Area Health Service wide risk management strategy.

Each facility must:

- Establish a multidisciplinary Maternity Clinical Risk Management Committee. Appendix 1 provides a guide to the risk management process.
- Develop a written risk management strategy identifying a multidisciplinary Maternity Clinical Risk Management Committee (MCRMC) with a designated lead.
- Incorporate a typical membership such as a senior obstetrician, a Clinical Midwifery Consultant, a Maternity Unit Manager, a manager in charge of the birth suite and may include junior medical and midwifery staff, a paediatrician or neonatologist and an anaesthetist.
- Report to the Chief Executive through the clinical stream and the Clinical Governance Units through existing quality committee arrangements (Appendix 2).

3.3 Risk Identification

The MCRMC should have formal processes for identifying risks to ensure the provision of a safe, high quality service. Risks are identified from a number of information sources, both internally and externally to the maternity service (Table 1).

Table 1 Risk identification – possible sources of information

Internal	External
Risk assessment Incident reporting Trigger reporting Complaints and claims Staff consultation Clinical audit Clinical indicators	National and State death review reports Health Care Complaints Commission Coroners reports Ombudsman reports Professional Colleges NSW Department of Health

Principles that govern these activities are:

- Wherever possible a multidisciplinary approach be taken

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- The process is transparent and accountable not only to clinicians but to health service managers and the patient
- Information be de-identified to ensure confidentiality
- Evaluation should look at systems issues and not “blame”
- Involvement of junior staff should be facilitated and supported
- Feedback to clinical staff to facilitate continuous improvement.

Two levels of reporting are required using the Incident Information Management System (IIMS):

- Incident reporting of incidents
- Trigger reporting of near misses

Incident reporting and monitoring

The first line of incident reporting (reactive response) is governed by the Incident Management Policy². To ensure consistency, incidents are categorised with a Severity Assessment Code (SAC) used broadly across the health care system in NSW.

Not all reported incidents require investigation. However, investigation of incidents including Root Cause Analysis, as required by PD2007_061 Incident Management Policy applies.

Once a decision is taken to investigate, the following steps should be taken:

- Identify which member of the MCRMC will investigate (obstetrician, midwife etc) and provide a synopsis to the MCRMC
- Gather data and relevant documents
- Determine the chronology of events
- Identify care provision problems i.e. unsafe acts (e.g. failure to act)
- Identify contributory factors (e.g. lack of supervision)
- Devise and implement an action plan.

Trigger reporting

Trigger reporting focuses attention on the identification and examination of near misses. A set of maternity specific trigger events have been identified and set out

² PD2007_061 Incident Management Policy

in Appendix 3. IIMS notification is required for all outcomes. The MCRMC must examine all cases identified in the set of 'triggers' or symptoms of potential harm

3.4 Risk Assessment

Risk assessment is most commonly applied when there are proposed changes to a work process or service offered by a hospital or Area Health Service. The process has a number of simple steps (see Appendix 4):

- Describe how the proposed changes affect existing services in relation to who does what, where, when and how
- Assess the risks associated with those changes and
- Make recommendations for systems and procedures that need to be in place to support the changes to maximise safety.

Risk assessment should also be utilised in the review of existing services where there are continuing adverse events.

3.5 Risk Analysis and Evaluation

The assignment of a SAC code as described under incident reporting and monitoring provides a consistent and efficient approach. This helps identify the appropriate response of the MCRMC as to whether an in-depth investigation or immediate action is required.

3.6 Risk Control

Options for dealing with risks are weighed up against the risk ranking and will lead to an appropriate method of identification. This may include elimination, reduction or acceptance.

Inherent within health care services are many existing controls that serve to make it safe and not do harm e.g. clinical guidelines, professional registration, simulated practice, credentialling of clinicians etc.

The MCRMC is required to ensure that the standards set out in Appendix 5 are implemented and maintained. Appendix 6 sets out the clinical care guidelines that every maternity service must have in place.

3.7 Lessons learned

To optimise the reporting of incidents, staff should be aware and motivated. Motivation is driven by feedback, not only at periodic summaries of reported incidents and most importantly, what changes have been implemented and what demonstrable benefits have resulted.

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Currently, most maternity services have a culture of peer review and morbidity and mortality (M&M) meetings. The application of this approach is dependent upon individual clinicians and is more likely to occur in the higher delineated hospitals. The MCRMC will be responsible for ensuring that the M&M meetings are formalised as a risk management activity and utilised as a feedback mechanism from the activities of the MCRMC.

Lessons learned from the identification and treatment of risk should be shared with other parts of the hospital and with the wider community, as may be appropriate, through channels such as multidisciplinary team meetings, ward meetings, newsletters, intranet and educational meetings.

4. REPORTING

Area Health Services are to provide the following reports:

1. Facility level – MCRMC monthly³ to the clinical stream

Analysis of trends from statistics and IIMS reports.
Actions taken to address local system improvements.
Actions taken to provide local feedback.
Outcomes of audit of standards and clinical policies.

2. Area Health Service level – Women’s and Children’s Stream Quarterly to the Chief Executive

Aggregated analysis from statistics and IIMS reports
Recommendations and actions about system improvements
Aggregated outcomes of audit of standards and clinical policies

3. State level – Chief Executive annually (August 1) to Director, Primary Health and Community Partnerships Branch

Aggregated information about clinical risk management activities and their outcomes.
Aggregated outcomes of audit of standards and clinical policies.

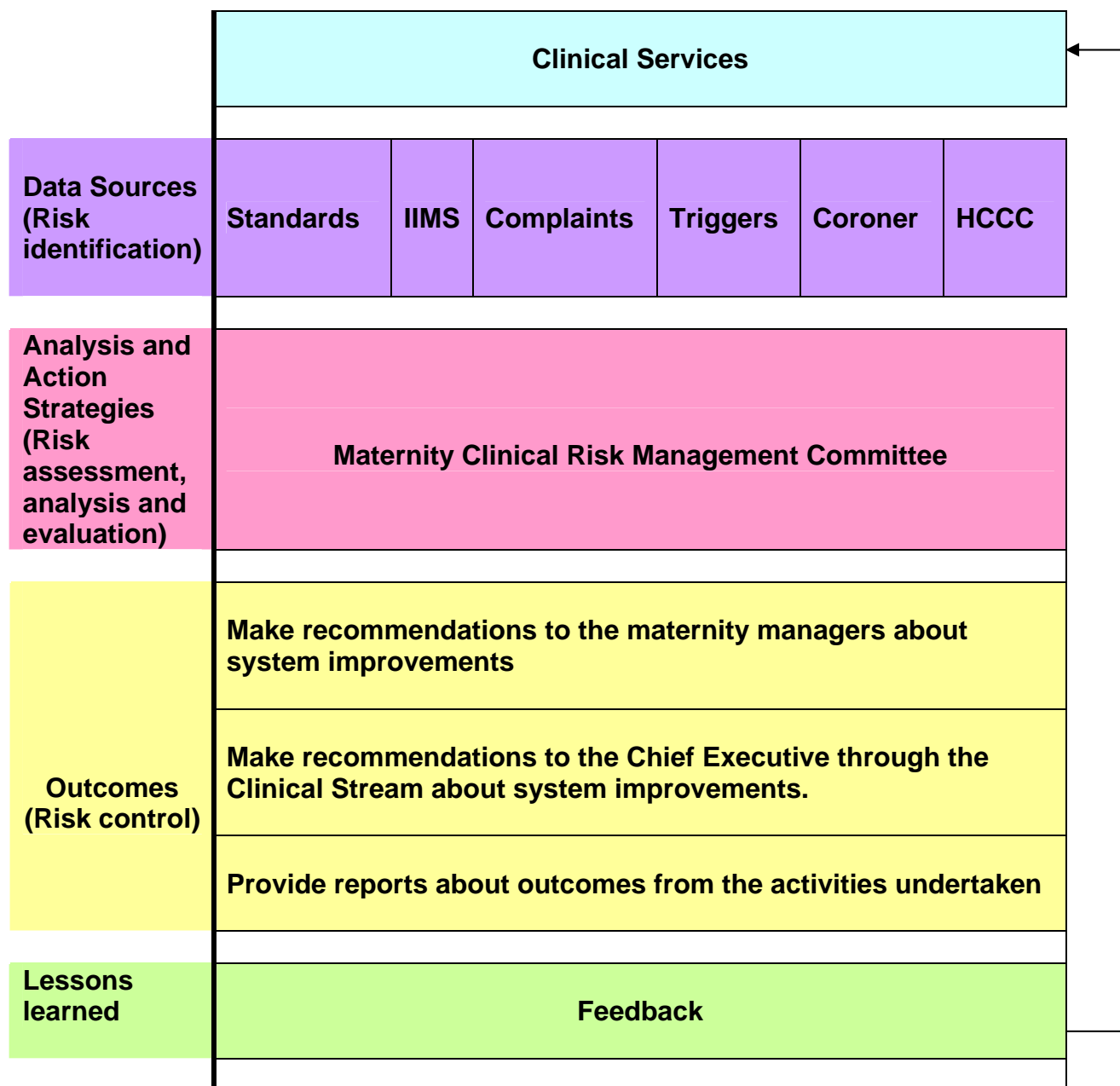
These reports will be considered by the Maternal and Perinatal Health Priority Taskforce.

Professor Debora Picone AM
Director-General

³ This may vary according to the volume of clinical activity but no less than quarterly.

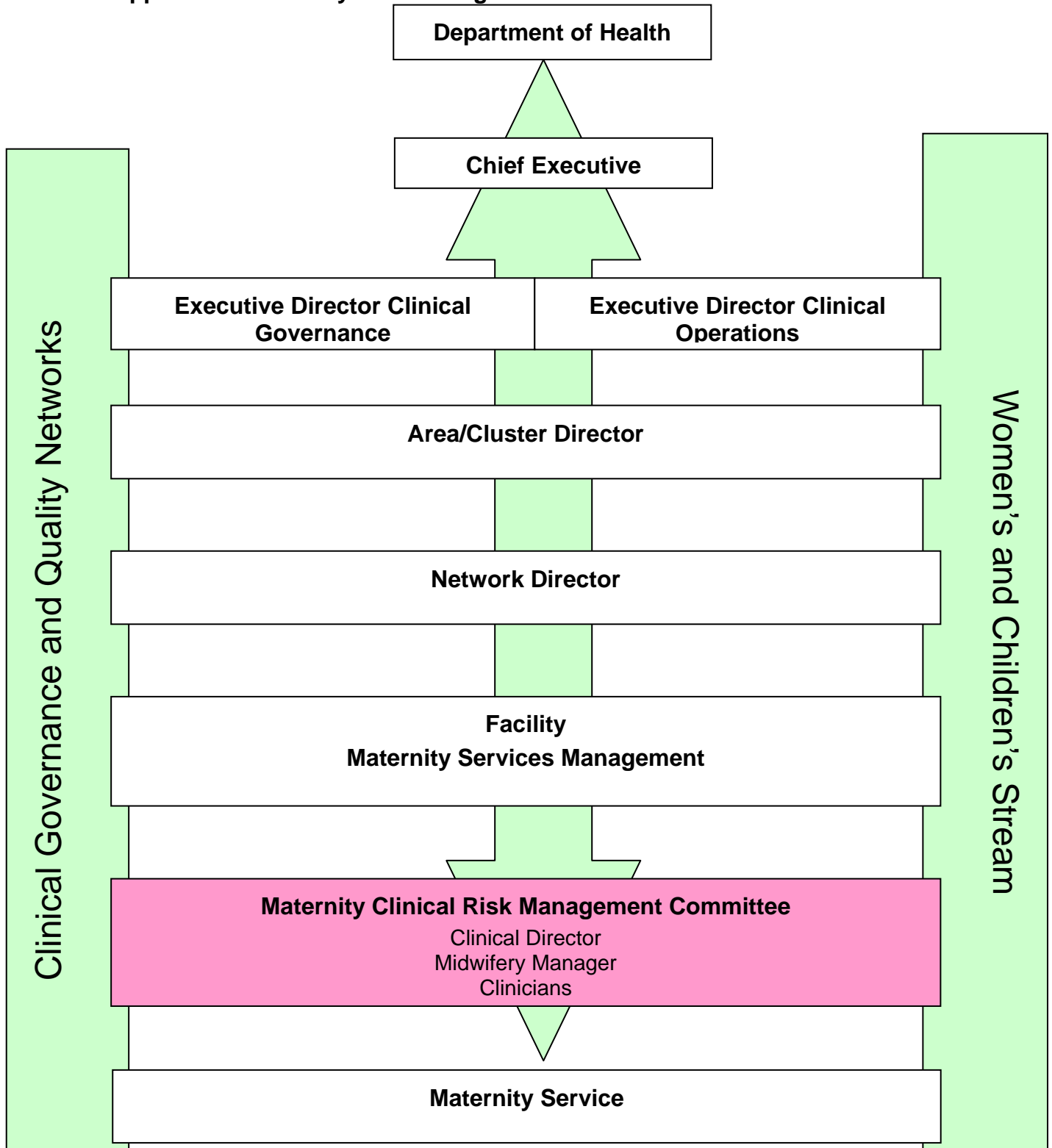
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Appendix 1 Maternity Clinical Risk Management process



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Appendix 2 Maternity Risk Management Governance Structure⁴



⁴ Adapted from Dr Charles Pain, Director of Clinical Governance Sydney West AHS

Appendix 3 Triggers and incidents that must be reported on IIMS.

Maternal
Severe postpartum haemorrhage >1500 mls Peripartum blood product transfusion Unplanned return to theatre Anaesthetic complications Admission to a critical care area outside of the maternity unit' Thromboembolic events Caesarean section at full dilatation (all presentations) 3 rd /4 th degree tears Uterine rupture Unplanned readmission Transfer to a higher level facility Maternal death
Fetal/neonatal
Shoulder dystocia where more than positioning and/or McRobertts manoeuvre are required to effect delivery Apgar score <7 at 5 minutes Cord ph <7.10 arterial or cord lactate >5.2 Term baby admitted to NICU Transfer to a higher level facility Stillbirth
Organisational
Unavailability of health record Delay in responding to call for assistance Faulty equipment Conflict over case management Potential patient complaint Failure to follow local protocol

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Appendix 4 Process steps in risk assessment

(Source: Treasury Managed Fund)

Step One: Process map the work flow (define the context)

Before the risks associated with the way the service is delivered to patients can be understood, it is imperative to understand how the service will actually change. Process map the existing service and the proposed service – the difference identifies the ‘gap’ that will be risk assessed.

Record the changes – these should be entered into the risk assessment template.

e.g.

Process step	Proposed change in service
Career Medical Officer (CMO) Coverage	All midwives and Doctors involved in labour and birthing will be required to have training in Advanced Life Support Obstetrics (ALSO)

Step Two: Identifying risks

Once the changes have been identified and documented, the potential threats (risks) associated with the change can be analysed.

e.g.

Process step	Proposed change in service	Threat/risk					
CMO Coverage	All midwives and Doctors involved in labour and birthing will be required to have training in ALSO	Maintaining competence in ALSO training requires time & budget allocation					

Step Three: Analyse the risks

Determine the maximum reasonable consequence (C) of the threat, followed by the likelihood (L) of that occurring. The SAC matrix (Table 3) is used to assign a risk rank (R) to each threat. The letters A to E are added to the Consequence axis and numbers 1 to 5 added to the Likelihood axis.

e.g.

Process step	Proposed change in service	Threat/risk	C	L	R		
CMO Coverage	All midwives and Doctors involved in labour and birthing will be required to have training in ALSO	Maintaining competence in ALSO training requires time & budget allocation	A	3	1		

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Table 3 SAC matrix

Consequence Likelihood	Serious A	Major B	Moderate C	Minor D	Minimum E
1 Frequent	1	1	2	3	3
2 Likely	1	1	2	3	4
3 Possible	1	2	2	3	4
4 Unlikely	1	2	3	4	4
5 Rare	2	3	3	4	4

Step Four: Identify current controls and possible additional controls

This needs to be considered in light of the severity of the risk and the adequacy of current controls.

e.g.

Process step	Proposed change in service	Threat	C	L	R	Current controls	Possible additional controls
CMO Coverage	All midwives and Doctors involved in labour and birthing will be required to have training in ALSO	Maintaining competence in ALSO training requires time & budget allocation	A	3	1	<ul style="list-style-type: none"> * ALSO training completed for all currently employed midwives * Informal regular skill drills * One VMO has received ALSO training * Current CMO booked in for ALSO training 	<ul style="list-style-type: none"> * Budget allocation needed to support ongoing training for new recruits and refresher training for all staff every 5 years * Formalise skill drills

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Step Five: Identify priority risks and priority controls

The threats can then be sorted into priority order based on the risk rank. Then list all the possible additional controls that have been assigned to high risks. Use this summary of critical controls in the executive summary of the report.
e.g.

Risk priority	Process step	Possible additional controls	Responsible	Due date	Status
1 Extreme risk	CMO Coverage	Budget allocation needed to support ongoing training for new recruits and refresher training for all staff every 5 years	General Manager		
		Formalise skill drills	Manager Maternity Services		

Step Six: Implementation and evaluation

- The approval process on whether or not the proposed change will proceed
- The implementation project plan and budget
- The audit or quality processes which monitor performance and outcomes

Appendix 5 Maternity Service Standards⁵

Standard 1: Organisation	
<i>Local arrangements and accountability for implementing Risk Management and risk management are clearly defined.</i>	
1.1	There is a written maternity services Risk Management strategy that has been approved by the Area Health Service Quality Committee.
1.2	A nominated professional lead(s) has the responsibility for overseeing Risk Management throughout the maternity service.
1.3	There is a lead obstetrician and clinical midwife manager for labour and birthing matters.
1.4	Each maternity service or facility has a formal group, the MCRMC, in which Risk Management and risk related issues are discussed.
Standard 2: Learning from experience	
<i>The maternity service proactively uses internal and external information to improve clinical care.</i>	
2.1	Incidents, near misses and trigger events are reported in all areas of the maternity service by all staff groups.
2.2	Summarised incident reports are provided regularly to the Area Health Service Quality Committee.
2.3	The maternity service applies policy directives issued by the Department of Health.
2.4	The maternity services consider and apply recommendations from Area Health Service, State and national reports.
2.5	There is evidence of lessons learned and action arising from Risk Management activities.
Standard 3: Communication	
<i>Women are informed by competent professionals of all aspects and options concerning their treatment and care, and there are clearly documented systems for management and communication between professional staff.</i>	
3.1	There is information available to women and their partners, which is dated and describes the risks, benefits and alternatives of their proposed treatment through out maternity care.
3.2	The arrangements are clear concerning which named professional is responsible for planning and managing the woman's care at all times.
3.3	There is an agreed mechanism for direct referral and consultation to an obstetrician by a midwife at all stages of care.
3.4	There is a personal handover of care on labour ward when midwifery and medical shifts change.

⁵ Adapted from Clinical Negligence Scheme for Trusts Maternity Clinical Risk Management Standards April 2006 NHS Litigation Authority

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Standard 4: Clinical care	
<i>There are clear guidelines for the management of general clinical care.</i>	
4.1	There are referenced, evidence-based multidisciplinary guidelines/pathways of care, for the management of all key conditions or situations on the labour ward.
4.2	There is a guideline on the use of antenatal and intrapartum fetal monitoring which includes guidelines on performing fetal blood sampling.
4.3	There are clear guidelines for when high dependency care for the mother is necessary.
4.4	There is a guideline for the management and investigation of perinatal death.
4.5	There are clear multidisciplinary guidelines that ensure that whenever mothers and babies move between care settings or professionals, there is effective transfer of information.
4.6	Each facility must have clear guidelines about the level of complexity that is appropriate for the role delineation of the maternity service.
4.7	Each facility must have an established mechanism to monitor clinical activity against the role delineation of the maternity service.
4.8	Networking arrangements for referral, consultation and management for the escalation and potential transfer of care due to clinical complexity must be clearly identified.
Standard 5: Induction, training and competence	
<i>There are management systems in place to ensure the competence and appropriate training of all professional staff.</i>	
5.1	All clinical staff attend a specific induction appropriate to the department in which they are working.
5.2	The maternity service complies with Department of Health requirements that all professional staff are to be competent and receive training in maternal and neonatal resuscitation.
5.3	As a minimum, all relevant obstetric and midwifery staff should have education/training sessions on CTG interpretation every three years.
5.4	There is a system in place to ensure that all relevant staff participate in skills drills and education for maternity emergencies every three years.
Standard 6: Health records	
<i>A comprehensive system for the completion of health records is in place. Documentation standards are completed as part of clinical audit activities.</i>	
6.1	Cardiotocographs and other machine based records are securely stored.
6.2	There is an annual multiprofessional audit of documentation (record keeping) standards, including high-risk areas.
6.3	Midwifery and medical records are written in chronological order and all professional records are filed together.

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Standard 7: Staffing levels	
<i>Maternity services provide safe care for mothers and babies at all times.</i>	
7.1	The labour ward has sufficient medical leadership and experience for the delineation of the hospital to provide a reasonable standard of care at all times.
7.2	Clinical areas are staffed appropriately by midwives at all times.
7.3	Staffing levels and the use of contingency plans are monitored. The number of incidents where staffing levels fall below the established levels are monitored to ensure women receive a reasonable standard of care at all times.
Standard 8: Monitoring and Reporting	
<i>A system to monitor and evaluate the risk management program is in place.</i>	
8.1	Compliance with policies and clinical guidelines are regularly audited.
8.2	The Maternity Service Standards are monitored annually and reported to the Network Quality Committee.

Appendix 6 Clinical care procedures

Each maternity service must have clinical guidelines that are consistent across the Area Health Service and appropriate for the role delineation of each service for the following key maternity events. The evidence base should be referenced and reviewed every three years.

- Accidental dural puncture (in epidural analgesia policy)
- Antenatal and intrapartum electronic fetal heart rate monitoring
- Antepartum haemorrhage including placental abruption
- Assisted vaginal birth
- Breech presentation including external cephalic version and selection for vaginal birth
- Care of newborn immediately after birth (including hypoglycaemia/hypothermia)
- Definition and repair of perineal tear
- Diabetes
- Eclampsia
- Epidural analgesia
- Failed adult intubation
- Fetal blood sampling
- Group B haemolytic streptococcus
- Induction of labour – including timing, augmentation and use of Syntocinon and prostaglandins
- Management of baby with meconium present at birth
- Management of ectopic pregnancy
- Management of reduced fetal movements
- Maternal death
- Management of women who decline blood products
- Multiple pregnancy
- Prolapsed cord
- Prophylactic antibiotics for caesarean section
- Severe hypertension
- Severe postpartum haemorrhage
- Shoulder dystocia

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- Thromboprophylaxis for caesarean section
- Timing of elective or pre-labour caesarean section
- Unexplained intrapartum/postpartum collapse – including amniotic fluid embolism
- Vaginal birth after caesarean

The maternity service must have a system for procedure approval and review and policy directives from the Department of Health that is consistent across the whole Area Health Service