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**Patient Matters**

**CHAPTER 17 - OBSTETRICS**

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Last updated: 12/09/2019
MATERNITY – PUBLIC HOMEBIRTH SERVICES (PD2006_045)


This Policy Directive should be read in association with the following documents:

- NSW Health 2000 The NSW Framework for Maternity Services, NSW Health Department
- NSW Health 2003 Models of Maternity Service Provision Across NSW, NSW Health Department
- NSW Health 1999 Framework for Managing the Quality of Health Services in NSW, NSW Health Department
- NSW Health 2002 Draft Supporting Families Early, Families First Health Home Visiting Guidelines, NSW Health Department

1. Introduction

1.1 NSW Health recognises that the place of birth is a decision for women and their families and that a small number of women will choose to birth at home. It is recommended that AHSs make arrangements for the provision of a range of models of care, which may include public homebirth services. Public homebirth services, when provided, must comply with the standards set out in this document.
1.2 Until recently, the availability of homebirth services was restricted to the private sector, usually provided by an independent (private) midwife or medical practitioner.

1.3 Wherever the setting that birth takes place, safety is a priority and practitioners with the necessary knowledge, skills and attributes should attend women.

1.4 The *NSW Framework for Maternity Services* (the Framework) is the current policy that forms the platform for maternity services across NSW. It promotes continuity of care and consistent information as essential aspects in the provision of care that is culturally sensitive and appropriate. Within the stated five-year goals of the Framework, the provision of publicly funded homebirth is supported.

1.5 *Models of Maternity Service Provision Across NSW* further articulates the models of care and level of services outlined in the Framework. It recommends AHSs further develop primary maternity services that are effectively linked and networked across secondary and tertiary levels of care.

1.6 NSW Health’s first obligation is to provide women with models of care where the appropriate safety controls and processes for the local population needs are the first priority. This includes risk assessment, strict exclusion criteria, consultation and referral guidelines, networked arrangements providing appropriate obstetric support and transfer, credentialling of the midwives, clinical privileges for medical practitioners and rigorous evaluation of the models.

All women require timely access to appropriate levels of care. Service response is reliant on robust processes and systems. Collaborative networks within these systems rather than any one factor such as the geographical location of the service are critical.

1.7 Public homebirth services, when provided, must comply with the standards set out in this document. These standards are provided under the *Framework for Managing the Quality of Health Services in NSW* and further developed in *Models of Maternity Service Provision across NSW*. These standards are applicable to public homebirth services and are articulated under the following headings:

- Safety and risk minimisation
- Continuity of care
- Competence of the workforce
- Information management to support effective decision making
- Networked services
- Education and training
- Consumer participation
- Monitoring and evaluation

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1. As this document considers public homebirth options funded by the NSW Health Department, professionals providing home birth services are required to be NSW Health employees. Any GP or Obstetrician with obstetric clinical privileges in NSW Health will be entitled to provide services under a publicly funded model.

2. NSW Health 2000 The NSW Framework for Maternity Services, NSW Health Department

3. NSW Health 2003 Models of Maternity Service Provision Across NSW, NSW Health Department

4. NSW Health 1999 Framework for Managing the Quality of Health Services in NSW, NSW Health Department
2 Safety and Risk Minimisation

2.1 The focus of primary health care is to provide local services that are developed with the local community taking into consideration their unique context. When developing homebirth services, AHSs must include a risk assessment methodology that identifies the necessary processes, training and guidelines to minimise harm and maximise client safety.

2.2 Risk assessment should always include consideration of local issues such as travel to the nearest maternity unit (Role delineated Level 3 and above) and the size of the caseload.

2.3 Clinicians providing homebirth services are required to comply with all incident reporting requirements of NSW Health.

2.4 Two clinicians (both credentialled or privileged) are required to be present at each birth at home. Student midwives/medical students under supervision may also attend with the prior consent of the woman and her family.

2.5 Guidelines for occupational health and safety issues are provided elsewhere by NSW Health.

3 Continuity of Care

3.1 Continuity of care is defined as the provision of care throughout the antenatal, intrapartum and postnatal periods.

3.2 Existing continuity of care models could be extended to incorporate homebirth services.

3.3 Area Health Services are to provide the appropriate structures and processes that ensure there is a smooth transition between the levels of services as required.

3.4 It is recommended that the primary clinician provides postnatal care in the community for a minimum of fourteen days but not exceeding six weeks post partum. This clinician is responsible for:

- Arranging care according to the woman’s needs;
- Liaising with local community services where appropriate;
- Ensuring a smooth transition from maternity services to child and family health services;
- Early and effective engagement with child and family health nursing services in the care of families requiring additional support. This should commence in the antenatal period as per the Families First Initiative.

3.5 It is advisable to provide a minimum of two antenatal contacts in the home – i.e. booking and 36 weeks. Other contacts will be arranged between the woman and clinician according to individual circumstances.

3.6 It is acknowledged that the woman may decide to change her planned place to birth. In this event, AHSs are required to provide a smooth transition to accommodate this need.
17. OBSTETRICS

4 Competence of the Workforce

4.1 Medical practitioners providing homebirth services will have clinical privileges delineated according to NSW Health Policy Directive.\footnote{PD2005_497: Visiting practitioners and staff specialists Delineation of clinical privileges policy for implementation.}

4.2 All midwives providing home birth services will be credentialled according to the NSW Health Credentialling policy directive.

5 Information management to support effective decision making

5.1 Women and their families have a right to sufficient and appropriate information necessary for making an informed choice regarding the option of homebirth.

5.2 Access to the service will be determined utilising the \textit{Australian College of Midwives Inc. National Midwifery Guidelines for Consultation and Referral}.\footnote{To view the guidelines http://midwives.rentsoft.biz/lib/pdf/Consultation%20and%20Referral%20Guidelines%202010.pdf}

5.3 Clinical information will be managed and reported in accordance with existing requirements in the NSW public health system. Clinicians are required to comply with the reporting requirements of the Midwives Data Collection (MDC).\footnote{PD2015_025: NSW Perinatal Data Collection (PDC) Reporting and Submission Requirements from 1 January 2016}

5.4 The records that women hold should contain comprehensive, contemporaneous clinical information to maximise communication between health professionals.

6 Networked Services

6.1 All maternity, neonatal and community health services must maintain effective linkages and networks across primary, secondary and tertiary levels of care, focusing on prevention, early recognition of risk, timely referral, consultation and clinical effectiveness. Collaboration between all health workers at all levels is a critical factor in ensuring safe services.

6.2 The clinician must register women with their local maternity unit following their booking appointment.

6.3 AHSs may make arrangements for pathology and pharmaceutical services through local hospital services.

6.4 Examination of the newborn is to be negotiated locally and could involve local General Practitioners, paediatricians or appropriately trained midwives.

6.5 Access to the State-wide Infant Screening Hearing Program (SWISH) services is to be arranged with the local SWISH team.

6.6 AHSs must include discussions with local ambulance, paramedic services and the NSW Newborn and Paediatric Emergency Transport Service (NETS) when planning and implementing local public homebirth services.
17. OBSTETRICS

7 Education and Training

7.1 All midwives working in midwifery managed primary maternity services including public homebirth services must be credentialled.

7.2 Mandatory education about domestic violence and child protection must be available as per the NSW Health Policy Directive Identifying and Responding to Domestic Violence\(^{10}\) and Child Protection legislation.

8 Consumer Participation

8.1 Liaison with local consumers is essential at all stages of implementation and ongoing evaluation.

8.2 AHSs are encouraged to provide information and develop education strategies to inform and educate pregnant women, the community, clinicians, allied health staff and health services about the availability and safety of home birth for women with uncomplicated pregnancies.

9 Monitoring and Evaluation

The introduction of new models of maternity care must include comprehensive evaluation.

Components of data collection for ongoing monitoring and evaluation purposes should include:

- Clinical maternal and neonatal outcomes;
- Costs associated with the provision of the model;
- Women’s experience of care during pregnancy, birth and the postnatal period;
- Staff satisfaction including retention rates of clinicians working in this model of care;
- Transfer rates.

9.3 Reporting will include an analysis of incidents reported through the Safety Improvement Program.

MATERNITY – TOCOLYTIC AGENTS FOR THREATENED PRETERM LABOUR BEFORE 34 WEEKS GESTATION (PD2011_025)


PURPOSE

This policy provides direction to NSW maternity services, clinicians and emergency patient transport services regarding the use of tocolytic agents for threatened preterm labour before 34 weeks gestation. Preterm birth remains a major cause of perinatal morbidity and mortality and this policy will help inform maternity care providers in the development and implementation of local clinical practice guidelines and protocols.

MANDATORY REQUIREMENTS

All NSW Public Health Organisations providing maternity services and all emergency patient transport services involved in obstetric transfers must have clinical practice guidelines and protocols for the use of tocolytic agents in threatened preterm labour before 34 weeks.

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\(^{10}\) PD2006_084 Domestic Violence - Identifying and Responding
This policy should only be used in consultation with specialists who are familiar with the management of threatened and established preterm labour and the care of preterm infants.

**IMPLEMENTATION**

- Chief Executives of Local Health Networks are ultimately responsible for the implementation of this policy directive within the Network’s facilities.
- The Chief Executive of the Ambulance Service of NSW is responsible for the implementation of this policy directive in the NSW Ambulance Service.
- The NSW Aeromedical and Medical Retrieval Service (AMRS), a unit of the NSW Ambulance Service, provides statewide coordination of adult medical retrieval services for critically ill patients in collaboration with the Regional Retrieval Services. Similarly, the Regional Retrieval Services liaise with AMRS regarding all retrieval activity.

**1. BACKGROUND**

**1.1 About this document**

Preterm birth remains a major cause of perinatal morbidity and mortality.\(^1\) Although preterm birth is defined as being birth before 37 weeks gestation, most mortality and morbidity is experienced by babies born before 34 weeks.\(^2\) For many women in preterm labour it may not be appropriate to consider tocolysis, but where it is appropriate and safe to do so, tocolysis aims to delay preterm birth to allow time for in-utero transfer to a tertiary perinatal centre for multidisciplinary management, and/or maternal administration of corticosteroids to enhance fetal lung maturity.

It is outside of the scope of this document to discuss screening for risk factors associated with and/or prevention of preterm birth. It is also outside of the scope of this document to discuss the use of predictive tests for preterm labour. The resources available at individual sites will vary and if such screening or predictive tests are available at a particular site then these should be incorporated into local evidence-based clinical algorithms for the management of threatened preterm labour.

**1.2 Related Documents**

This Policy Directive should be read in conjunction with the following policy directives:

- GL2015_004 Maternity – Fetal Heart Rate Monitoring
- PD2010_069 Critical Care Tertiary Referral Networks (Perinatal)

**1.3 Key definitions**

**Preterm birth** means birth after 20 weeks and before 37 weeks gestation.

**Preterm labour** means labour that occurs after 20 weeks and before 37 weeks.

**Threatened preterm labour** means the presence of uterine activity (contractions) after 20 weeks and before 37 weeks gestation. Only a minority of women who present with preterm contractions will progress to actual labour and birth.

For the purposes of this document, the administration of tocolytic agents should be restricted to those pregnancies that are at a gestation where benefit may be gained by delaying preterm delivery to allow time for in-utero transfer to a tertiary perinatal centre for multidisciplinary management, and/or maternal administration of corticosteroids to enhance fetal lung maturity. Generally this is between 24 and 34 weeks gestation.
2. **KEY POINTS**

2.1 **Tocolysis**

The aim of tocolysis is to delay preterm birth to allow time for maternal administration of corticosteroids and in-utero transfer to a tertiary perinatal centre, thereby reducing neonatal morbidity and mortality. There is no clear evidence that tocolytic drugs in themselves improve outcomes following preterm labour. The women most likely to benefit from tocolysis are those needing in-utero transfer to a tertiary perinatal centre and/or those who have not yet completed a full course of corticosteroids to promote fetal lung maturation. Discussions with women and their families should include these points.

2.1.1 **Choice of tocolytic agent**

Before pharmacotherapy with tocolytic agents was introduced, maternal bed rest, sedation or analgesia, and maternal hydration were used to reduce uterine activity. Maternal hydration promotes a diuresis by causing a reduction in vasopressin (antidiuretic hormone) secretion with less stimulation of V1a and oxytocin receptors for which there is crossover affinity. Alcohol, which inhibits both the secretion of oxytocin and vasopressin, was used until the 1980’s but had unacceptable maternal side-effects. ß-sympathomimetic agents (ß-agonists) were introduced in the 1980’s and became established as first line tocolytics. During the 1990’s there were increasing concerns about the potentially serious side-effects of ß-agonists and other agents with tocolytic effect were explored. Currently there are a number of tocolytic agents in use each with differing strengths of evidence base for their safety and efficacy. There is insufficient evidence to recommend exclusive use of one tocolytic agent. Oxytocin receptor antagonists are not available for use in Australia. The tocolytic agents available in Australia are not utero-specific and as such have potential fetomaternal side-effects. Therefore the choice of tocolytic agent should be based on the available evidence base for efficacy and fetomaternal safety (table 1).

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<thead>
<tr>
<th>Drug class</th>
<th>Efficacy</th>
<th>Fetomaternal safety</th>
</tr>
</thead>
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<tr>
<td>Calcium channel blockers (e.g. nifedipine)</td>
<td>No placebo-controlled trials. Randomised trials comparing nifedipine with ritodrine, magnesium sulphate and terbutaline. Meta-analyses show similar efficacy to ritodrine with decreased incidence of maternal side-effects.</td>
<td>Maternal flushing, headache, dizziness, nausea, transient hypotension, transient tachycardia, palpitations. Fetal hypoxia associated with maternal hypotension</td>
</tr>
<tr>
<td>ß-agonists (e.g. salbutamol)</td>
<td>Randomised placebo-controlled trials. Efficacy demonstrated in a number of systematic reviews.</td>
<td>Maternal tachycardia, headache, palpitations, sweating, tremor, dyspnoea, cardiac arrhythmias, myocardial ischaemia, pulmonary oedema, hyperglycaemia, hypokalaemia. Tachycardia, hypoglycaemia in neonate</td>
</tr>
<tr>
<td>Nitric oxide donors (e.g. GTN patches)</td>
<td>Randomised placebo-controlled trial demonstrated that transdermal nitroglycerin may reduce neonatal morbidity and mortality as a result of decreased risk of birth before 28 weeks. However randomised trial comparing transdermal nitroglycerin and ß2 sympathomimetics demonstrated GTN is a less efficacious tocolytic compared with ß2 sympathomimetics.</td>
<td>Maternal headache, hypotension. Neonatal hypotension</td>
</tr>
<tr>
<td>Prostaglandin synthetase inhibitors (e.g. indomethacin)</td>
<td>Randomised placebo-controlled trials. Meta-analysis showing demonstrated efficacy and reduced maternal side-effects.</td>
<td>Maternal gastro-intestinal side-effects, renal impairment, headache, dizziness, depression. Fetus/neonate – constriction of ductus arteriosis, pulmonary hypertension, reversible decrease in renal function (oligohydramnios).</td>
</tr>
<tr>
<td>Magnesium sulphate</td>
<td>Two systematic reviews demonstrate magnesium sulphate to be ineffective as a tocolytic</td>
<td>Maternal flushing, sweating, nausea, loss of deep tendon reflexes, respiratory depression, bradycardia, myocardial depression, neuromuscular blockade.</td>
</tr>
</tbody>
</table>
Broadly speaking, there are 5 classes of tocolytic agents available in Australia currently: calcium channel blockers, β-agonists, nitric oxide donors, prostaglandin synthetase inhibitors, and magnesium sulphate. The evidence to support the use of magnesium sulphate as a first line tocolytic is poor so it is not recommended for this purpose.

The use of β-agonists (like salbutamol) or multiple tocolytics is associated with a high incidence of serious adverse drug reactions. Both nitric oxide donors (like GTN patches) and prostaglandin synthetase inhibitors (like indomethacin) may have a role prior to 28 weeks gestation.

2.1.2 Preferred tocolytic - Nifedipine

Given the efficacy and fetomaternal safety of the various tocolytic agents currently available, nifedipine appears to be the preferred tocolytic (see Appendix 1 for example administration protocol).

The use of nifedipine is well established in clinical practice across NSW having been approved for use through local Drug Committees.

NOTE: Tocolysis is not an approved indication for use for nifedipine. Prior to using any drug for an unapproved (off-label) indication, approval should be sought from the local hospital or Local Health Network Drug Committee and informed patient consent obtained. In the context of this Policy Directive, this means that any drug approvals required should be sought prior to an emergency - i.e. at the time of developing local hospital policies for tocolysis.

2.1.3 Combined tocolytics

The incidence of serious adverse drug reactions in women receiving combined courses of tocolytics is high (1.6 – 2.5%). There is no evidence that treatment with combined tocolytics is superior to single or sequential treatment.

2.1.4 Maintenance tocolysis

There is insufficient evidence for any firm conclusions about whether or not maintenance tocolytic therapy following threatened preterm labour is worthwhile. As such, maintenance therapy cannot be recommended for routine practice.

2.1.5 Contraindications to tocolysis

The administration of tocolytic agents should be restricted to those pregnancies that are at a gestation where benefit may be gained by delaying preterm delivery to allow time for in-utero transfer to a tertiary perinatal centre for multidisciplinary management and/or maternal administration of corticosteroids to enhance fetal lung maturity. Attempts at tocolysis are less likely to be successful with advanced cervical dilatation, particularly in the presence of ruptured membranes. The presence of certain maternal or fetal risk factors may make tocolysis unwise, e.g. active bleeding, evidence of chorioamnionitis, documented intrauterine growth restriction.

Tocolysis is not indicated where delivery is required because of immediate risk to the life of mother or fetus. Tocolysis is not indicated where labour is advanced or where the fetus is sufficiently mature that the fetomaternal risks of tocolysis outweigh the benefits i.e. > 34 weeks gestation. Tocolysis is indicated where benefit may be gained by delaying preterm delivery to allow time for in-utero transfer to a tertiary perinatal centre for multidisciplinary management, and/or maternal administration of corticosteroids to enhance fetal lung maturity.
2.2 Diagnosis of threatened preterm labour

The diagnosis of suspected threatened preterm labour on clinical grounds should include uterine contractions that are painful, palpable, last more than 30 seconds and occur with a frequency of at least 2 every 10 minutes. There may or may not be evidence of cervical change (position, consistency, length or dilatation). Maternal anxiety often causes difficulty with the diagnosis and the absence of cervical change does not mean that the patient’s complaints of pain or the possibility that she is in early labour may be ignored.

On admission a thorough assessment must be made. This includes a detailed history, particularly with respect to uterine activity and any vaginal loss particularly in relation to rupture of the membranes and antepartum haemorrhage. The gestational age must be confirmed by the best available information. Maternal examination must include temperature, uterine tone and tenderness, and clinical assessment of liquor volume, fetal size and presentation.

A speculum examination should be performed utilising an aseptic technique. Genital tract swabs should be taken for microbiological assessment. Digital examination should be avoided unless the cervix cannot be adequately visualised.

Urine microbiology should be undertaken. Cardiotocography (CTG) should also be undertaken if appropriate for the period of gestation.

If the woman is admitted to a non-tertiary hospital and is less than 34 weeks gestation, consideration should be given to transfer. There is clear evidence that neonatal outcomes are improved with in-utero rather than ex-utero transfer. Hospitals must be appropriately networked so that in-utero transfer is both appropriate and timely. In-utero transfer should not be undertaken where there is significant risk of birth occurring during transfer. Consultation with a perinatal advisor through the NSW Newborn & Paediatric Emergency Transport Service (NETS) is available.

Corticosteroids should be administered to accelerate fetal lung maturation. If transfer is indicated because of significant uterine activity or if cervical change has been demonstrated then tocolysis should be commenced unless contraindicated. Abnormalities of the maternal or fetal condition that may contraindicate the use of tocolysis include antepartum haemorrhage, pre-eclampsia, chorioamnionitis, pathological fetal heart rate pattern. Intravenous antibiotics should be given to women with established preterm labour with significant urinary tract sepsis or overt sepsis.

2.3 Algorithm for tocolytic agent use for threatened preterm labour

Repeat cervical assessment prior to transfer should only be undertaken if the clinical condition changes or if uterine activity is unable to be suppressed by tocolysis.
Maternal Assessment:
History – check EDC, ?APH, ?PPROM
Examination – temperature, uterus, fetus, liquor
Speculum examination+
Digital vaginal examination (if cervix not visualised)

Microbiology:
Lower genital tract swab
Mid stream urine

Establish IV access and commence IV fluids.
If no contraindication to tocolysis, then

Nifedipine protocol (Appendix 1).

Contraindication to nifedipine or failed nifedipine tocolysis may need to consider alternate tocolytic agent (Appendix 2). Where in-utero transfer is required discussion regarding further tocolysis should occur with the Perinatal Advisor (available through NETS*).

*Any clinician can contact a perinatal advisor on the NETS Hot Line (1300 36 2500). Call cost are at local call rates from within Australia. Calls to the NETS Line are answered immediately. A list of options is presented and callers are reminded about the fact that calls to NETS are recorded. Option 1 (for emergency retrieval) is answered by the duty ‘clinical coordinator’ who connects the caller (in conference mode) to the duty consultant and then other specialists as required.

REFERENCES
Appendix 1: Nifedipine administration protocol - example

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<th>NOTE:</th>
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<td>• Nifedipine carries the potential for fetal hypoxia associated with maternal hypotension.</td>
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<tr>
<td>• The blood pressure lowering effect of nifedipine may be potentiated by other antihypertensives.</td>
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</tr>
<tr>
<td>• Do not use in women who are hypotensive or in women with established cardiac disease including conduction defects and left ventricular failure.</td>
<td></td>
</tr>
<tr>
<td>• Extreme caution should be exercised if Nifedipine and magnesium sulphate are used concomitantly.</td>
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<table>
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<tr>
<th>PRESENTATION:</th>
<th>20mg Tablets</th>
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<tbody>
<tr>
<td>ADMINISTRATION:</td>
<td>Nifedipine tablets should be swallowed whole. Dose may vary with clinical situation &amp; should be titrated against tocolytic effect. Nifedipine is highly light sensitive. Broken, crushed or chewed tablets result in medication instability.</td>
</tr>
<tr>
<td>INITIAL DOSE:</td>
<td>20mg Nifedipine orally stat (N.B. onset of tocolysis is at 30-60 minutes.)</td>
</tr>
<tr>
<td>If uterine contractions persist after 30 minutes:</td>
<td>Further 20mg Nifedipine orally may be given at 30 minute intervals for two further doses if required.</td>
</tr>
<tr>
<td>If contractions cease:</td>
<td>• A maintenance dose of 20 to 40mg Nifedipine 6 hourly may be given, depending on uterine activity and other clinical circumstances, to a maximum of 160mg in 24 hours • Decisions about cessation of treatment will be on an individual basis and need to take into account location, steroid cover and gestational age</td>
</tr>
<tr>
<td>MAXIMUM DOSE:</td>
<td>160mg in 24 hours</td>
</tr>
<tr>
<td>Side effects:</td>
<td>• Hypotension, especially in hypertensive patients • Tachycardia, palpitations • Flushing • Headaches, dizziness • Nausea</td>
</tr>
<tr>
<td>MATERNAL and FETAL OBSERVATION AND MONITORING:</td>
<td>• Maternal blood pressure, temperature, pulse and respiratory rate hourly during the acute stabilisation phase. Observations may then be recorded less frequently but at least 4 hourly during treatment. • Report systolic BP less than 100 mmHg, temperature greater than 37.5 degrees Celsius or pulse greater than 100. • Report side effects listed above. • If initial cardiotocograph is reactive, record fetal heart rate hourly with doppler during the acute stabilisation phase, then at least 6 hourly for first 48 hrs.</td>
</tr>
<tr>
<td>Overdosage symptoms (observed in cases of severe nifedipine intoxication):</td>
<td>• Disturbed consciousness to the point of coma • A drop in blood pressure • Tachycardic/bradycardic heart rhythm disturbances • Hyperglycaemia • Metabolic acidosis • Hypoxia • Cardiogenic shock with pulmonary oedema</td>
</tr>
</tbody>
</table>

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Appendix 2: Salbutamol infusion protocol - example

<table>
<thead>
<tr>
<th>NOTE:</th>
<th>To prevent hypotension due to aorto-caval compression, the patient should lie on her side during infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRESENTATION:</td>
<td>Ventolin Obstetric 5mg ampoules (1mg per ml)</td>
</tr>
</tbody>
</table>
| ADMINISTRATION: | • Salbutamol should be given by controlled infusion to control dose and fluid volume; a syringe or volumetric infusion pump is the equipment of choice  
  Caution is required when changing to Salbutamol from a vasodilator such as Nifedipine, which has a half-life of 6 to 12 hours. In these circumstances, frequent maternal and fetal observations (as described below) are required. |
| DOSE: | • Draw up 10ml (10mg) of Obstetric Salbutamol in a 10ml syringe.  
  • Withdraw 10ml from a 100ml bag of Normal Saline and replace with the 10ml of Salbutamol. The resulting solution will contain 100 micrograms per ml.  
  • Start the infusion at 6ml per hour.  
  • Increase the rate by 3ml per hour every 10 minutes until there is a suitable response, either cessation of contractions or a reduction in frequency and strength of contractions.  
  • Do not exceed 30ml per hour (equivalent to 50 micrograms per minute). However, the maximum dose is determined by the individual’s response and may be much less than this in some cases. |
| If maternal pulse greater than 140 bpm or sustained fetal tachycardia (greater than 180 bpm) | • Slow infusion rate until pulse or fetal heart rate return below these levels. |
| Side effects: | • Tremor, anxiety, nausea and palpitations are likely and the woman should be warned.  
  • CEASE INFUSION if chest pain, dyspnoea or vomiting occurs. |
| If contractions cease | • Maintain infusion rate for the next 6 hours and then reduce by 3 ml per hour each hour until a maintenance level is reached (3ml per hour).  
  • Decisions about cessation of treatment will be on an individual basis and need to take into account location, steroid cover and gestational age. |
| MATERNAL and FETAL OBSERVATION AND MONITORING | • Maternal blood pressure, pulse and respiratory rate following each increase in the infusion rate during the acute stabilisation phase. Observations may then be recorded less frequently, but at least 4 hourly during treatment.  
  • If initial cardiotocograph is reactive, record fetal heart rate with doppler after each increase in the infusion rate during the acute stabilisation phase, then at least 6 hourly for first 48 hrs.  
  **NB:** Abnormalities detected in the fetal heart rate and/or ongoing uterine activity may require ongoing continuous CTG monitoring. |
<table>
<thead>
<tr>
<th>IMPLEMENTATION REQUIREMENTS</th>
<th>Not commenced</th>
<th>Partial compliance</th>
<th>Full compliance</th>
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<tbody>
<tr>
<td>2. Development of local protocols for the administration of tocolytic agents.</td>
<td>□</td>
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<td>3. Compliance with <em>PD2010_009</em> Critical Care Tertiary Referral Networks (Perinatal).</td>
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<td>4. Compliance with <em>GL2015_004</em> Fetal Heart Rate Monitoring.</td>
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REPORTING OF MATERNAL DEATHS TO THE NSW DEPARTMENT OF HEALTH  
(PD2005_219)

1. A maternal death is defined as any death which occurs during pregnancy, labour or within the 
first year (365 days) following cessation of pregnancy. This includes deaths in the first 
trimester of pregnancy (for example, associated with ectopic pregnancy and following 
termination of pregnancy), deaths due to accidents and deaths of women who are incidentally 
found to be pregnant at post-mortem examination.

Previously in NSW, information on maternal deaths was collected only up to the first 42 days (6 
weeks) following cessation of pregnancy. However, monitoring of maternal deaths nationally 
now includes ‘late maternal deaths’ (from 6 weeks to 12 months after cessation of pregnancy) to 
ensure consistency with international and World Health Organisation guidelines. Information 
on deaths that appear to be incidental (where the pregnancy is unlikely to have contributed to 
the death) is also to be consistently collected up to one year following cessation of pregnancy. 
For example, information on deaths due to suicide have previously been inconsistently reported.

2. Maternal deaths should be reported to the Department of Health within 72 hours of death and 
the following information provided:

- Patient’s name
- Date of birth
- Address
- Hospital of notification
- Hospital medical record number
- Date of death
- Provisional diagnosis of cause of death

Maternal deaths may be notified by mail, phone, fax or email as follows:

Mail: The Secretary, NSW Maternal and Perinatal Committee  
Clinical Excellence Commission  
Locked Bag 8  
Haymarket NSW 1240

Phone: (02) 9269 5500  
Facsimile: (02) 9269 5599  
Email: CEC-Info@health.nsw.gov.au
3. Hospitals and clinicians should note the requirement under the Coroner’s Act 2009 that unnatural deaths be reported to the Coroner. These deaths include accidents, poisonings, violence, death within 24 hours of a anaesthetic or sudden deaths the cause of which is unknown (PD2010_054).

4. All maternal deaths are individually reviewed by the NSW Maternal and Perinatal Committee. The NSW Maternal and Perinatal Committee is an expert committee appointed by the Minister of Health to review maternal and perinatal morbidity and mortality in the State and is privileged from subpoena under the Health Administration Act 1982 for its review of confidential medical information.

5. After notifying the Department of a maternal death, the hospital will receive a letter from the Secretary of the NSW Maternal and Perinatal Committee requesting a copy of the relevant medical and ante-natal record, post-mortem report (if applicable), medical certificate of cause of death, and any other relevant material which the hospital may wish to provide to the Committee for consideration. Hospitals should ensure that a copy of the medical certificate of cause of death is included in the medical record so that it is readily available when requested.

6. The information obtained through the statewide confidential review is used to develop policies aimed at reducing maternal and perinatal mortality in NSW.

Summary information on maternal deaths in NSW is available in the annual NSW Mothers and Babies Report, which is published by the NSW Department of Health and is available on the Department’s web site at http://www.health.nsw.gov.au/bsnsw/Publications/mothers-and-babies-2010.pdf

National information on maternal deaths is available in the Report on Maternal Deaths in Australia, which is published triennially by the National Health and Medical Research Council (NHMRC) and is available from the NHMRC website at: http://www.nhmrc.gov.au/guidelines/publications/wh32

8. To assist with local hospital quality assurance activities, a copy of the Committee’s summary of findings will be returned to the hospital.

9. This circular should be brought to the attention of all staff involved in the administration and delivery of maternity care including intensive care units and emergency wards.
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THE MANAGEMENT AND INVESTIGATION OF A STILLBIRTH (PD2007_025)


This Policy Directive should be read in conjunction with:

- PD2005_341 - Human Tissue - Use/Retention Including Organ Donation, Post-Mortem Examination and Coronial Matters
- PD2005_406 - Consent to Medical Treatment – Patient Information
- PD2007_094 - Client Registration Policy
- PD2011_076 - Deaths - Review and Reporting of Perinatal Deaths

This Policy Directive is based on the Clinical Practice Guideline for Perinatal Mortality Audit produced by the Perinatal Society of Australia and New Zealand. The complete guideline can be found at http://www.stillbirthalliance.org.au/doc/Section_1_Version_2.2_April_2009.pdf

A stillbirth11 is the complete expulsion or extraction from the mother of a product of conception of at least 20 weeks gestation or 400 grams birth weight that did not, at any time after delivery, breathe or show any evidence of life such as a heartbeat (see Glossary Appendix 1).

In the case of a stillbirth where it is unclear whether the gestational age is less than 20 weeks at the time of delivery the fetus is to be weighed. If the weight is 400 grams or greater the fetus must be registered as a stillbirth.

1. General considerations

1.1 Every hospital must have a local policy for the management of the family, care of the stillborn baby and the investigation of the stillbirth.

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11 NSW Health NSW Mothers and Babies 2005 NSW Public Health Bulletin Volume 18 Number S-1 2007
17. OBSTETRICS

1.2 The local policy must clearly articulate the processes for the distinct identification of the body of the stillborn baby and comply with PD2007_094 Client Registration Policy.

1.3 The local policy must include procedures for the transfer of the stillborn baby between and within maternity services and the mortuary. This must be documented in the baby’s medical record.

2. Documentation

1.1 There must be full documentation of the clinical circumstances of the stillbirth.

1.2 Clinicians must undertake and document a comprehensive maternal and family history.

1.3 All clinical examinations of the mother, baby, placenta, membranes and cord must be documented.

2. Consent

2.1 Clinicians must comply with PD2005_406 Consent to Medical Treatment - Patient Information.

2.2 Consent for all investigations must be documented in the maternal record. This includes the histological examination of the placenta and membranes.

2.3 Consent for the post-mortem examination, which clearly outlines the extent of the investigation, must be recorded on an approved consent form.

2.4 Clinicians are also required to ascertain that the other parent has no objections and this must be documented in the maternal record.

3. Respect

3.1 The deceased baby must be treated with the same respect as a live baby.

3.2 The different cultural and religious practices and rituals associated with death must be respected.

3.3 Parents must be given time to make decisions and be informed about how much time can be spent with the baby in keeping with hospital policies and procedures.

4. Information

4.1 Parents must be given:

4.1.1 Written information using parent friendly language (for example to not use terms such as fetus).

4.1.2 Verbal and written information about birth registration.

4.1.3 The leaflet Information for Parents about the Post-mortem Examination of a Stillborn Baby. (Appendix 2). This leaflet is available in print and can be downloaded from the Department of Health website in English and several other languages.
5.1.4 Written information regarding available support services.
- Up-to-date information on genetic counseling services availability, locations, access and educational resources is available from:
  NSW Genetics Education Program
  PO Box 317
  St Leonards NSW 2065
  Ph (02) 9926 7324
  (02) 9906 7529
- Information and support is available from SIDS& Kids NSW
  Phone (02) 9818 8400
- 24 hour bereavement line 1800 651 186 or 
  http://www.sidsandkids.org/bereavement-support/

5.1.5 Information about expectations for their grief. Mothers with mental illness or risk factors for psychological disturbance must have an appropriate mental health referral.

5.1.6 Expectations for a 6 week check up and that there may be other babies present.

6 Birth options

6.1 Caesarean section must only be considered in the presence of compelling maternal risk factors.

7 Creating memories

7.1 Parents must be informed that:

  7.1.5 They can hold, undress and bath their baby.

  7.1.6 Mementos are helpful for long-term grief outcome.

  7.1.7 Baptism or blessing can be arranged through the hospital.

8 Investigation of stillbirths

8.1 The following Investigations must be undertaken where parental consent has been granted, for all stillbirths where there is no obvious cause. Consideration should be given to omitting screening tests when the cause of death is absolutely clear.

  8.1.1 At diagnosis of a fetal death:
  - Ultrasound scan to detect possible fetal abnormalities and to assess amniotic fluid volume.
  - Amniocentesis (where available and warranted) for cytogenetic and infection investigations.
  - A low vaginal and peri-anal swab, to culture for anaerobic and aerobic organisms.
  - Maternal blood must be collected for:
    - Full blood examination
    - Serology for cytomegalovirus, toxoplasmosis parvovirus B19
    - Rubella and syphilis if not already undertaken in the pregnancy
    - Blood group determination and antibody screen if not already undertaken in this pregnancy

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- Kleihauer - Betke test
- Renal function tests including uric acid
- Liver function tests
- Bile acids
- HbA1c
- Anticardiolipin antibodies
- Lupus Anticoagulant; and
- Activated protein C (APC) resistance

8.1.2 Following birth
- External examination of the baby (by a Perinatal pathologist, neonatologist or a paediatrician where possible).
- Clinical photographs.
- Surface swabs (ear and throat) for microbiological cultures.
- Babygram or ultrasound (where an post-mortem is refused).
- Post-mortem examination.
- Blood samples from the cord or cardiac puncture for investigations of infection.
- Blood samples for chromosomal analysis.
- Detailed macroscopic examination of the placenta and cord.
- Placental microbiological cultures.
- Placental and amnion biopsy for chromosomal analysis.
- Placental histopathology.

8.2 Further investigation for thrombophilia must be undertaken 8-12 weeks after the birth where:

8.2.1 fetal death is associated with:
- fetal growth restriction;
- preeclampsia;
- maternal thrombosis and/or there is maternal family history of thrombosis.

8.2.2 the stillbirth remains unexplained following the standard investigations; or

8.2.3 tests for thrombophilia were positive at the time of the intrauterine fetal death (IUFD) as follows:
- Anticardiolipin antibodies; and Lupus anticoagulant repeated if positive at the time of the intrauterine fetal death or initial testing if not previously undertaken;
- APC resistance if it was not undertaken at birth;
- Factor V Leiden mutation if APC resistance was positive at birth;
- Fasting Homocysteine and if there is a positive test for MTHFR gene mutation;
- Protein C and S deficiency;
- Prothrombin gene mutation 20210A.

9 Post-mortem

9.1 Clinicians must discuss the value of a post-mortem examination with the parents in all cases of a perinatal death and seek consent for the procedure. Where possible, this must be a senior clinician who has established a rapport and understanding with the parents.

9.2 The clinician approaching for post-mortem consent must discuss:
9.2.1 the value of the post-mortem examination;  
9.2.2 options for a full, limited or stepwise post-mortem examination;  
9.2.3 the issue of retained tissues;  
9.2.4 the possibility that the information gained may not benefit them but may be of benefit to others.

9.3 When consent has been obtained for specific organ/s to be retained for further examination, the parents must be offered the choice between delaying the funeral until the organs can be returned to the body or specifying their preferred method of organ disposal.

9.4 There must be no charge to a parent where the hospital requests the post-mortem.

9.5 The Guidelines on Autopsy Practice produced by the Royal College of Pathologists[^12] should be used for guidance on minimum standards until guidelines for Australia and New Zealand are developed.

9.6 Guidelines for post-mortem reports produced by the Royal College of Pathologists must be used as a guide for reporting of perinatal post-mortem examinations.

9.7 A request for the General Practitioner to receive a copy of the report (including the PLR if available) must be explicit on the request form, as they are the main care provider on discharge.

9.8 The parents are not to be unduly rushed into making a decision for post-mortem, but should be advised that ideally a post-mortem should take place within 48 hours of birth.

10 Placenta, membrane and umbilical cord

10.1 The placenta, membranes and cord must be examined thoroughly following the birth and findings documented in the mother’s notes.

10.2 Clinicians must discuss the value of pathological examination of the placenta, membranes and cord.

10.3 Where parental consent has been granted, the placenta, membrane and cord must be sent as soon as possible, fresh and unfixed, for pathological examination by the perinatal/paediatric pathologist, once samples have been taken for cytogenetics and microbiology.

10.4 Where parents are ambivalent about pathological examination, the placenta, membrane and cord should not be disposed of immediately in anticipation that they may change their minds.

11 Funeral arrangements

11.1 Parents must be advised that there is no urgency to organise a funeral and that they have continued access to baby prior to the funeral, depending on requested investigations such as post mortem.

17. OBSTETRICS

12 Health professionals

11.2 Clinical leaders must promote formal and informal educational opportunities for clinicians on: post-mortem examination procedures; the potential benefits of an post-mortem examination; compassionate counseling and obtaining parental consent; and address specific local barriers to the conduct of perinatal post-mortem examination.

11.3 Area Health Services should provide all clinicians with specific training in bereavement counselling.

11.4 Area Health Services should make debriefing/support services available to staff working with perinatal death.
Appendix 1

Glossary of Terms

AMNION
A thin but tough extraembryonic membrane of reptiles, birds and mammals that lines the chorion and contains the fetus and the amniotic fluid around it, in mammals it is derived from trophoblast by folding or splitting.

AMNIOTIC FLUID
The fluid that surrounds the developing fetus within the amniotic sac. This environment cushions the baby from injury and plays an important role in fetal development.

APC RESISTANCE
Activated protein C resistance.

AUTOPSY
A surgical procedure post-mortem, which involves the examination of body tissues (including internal organs), often to determine cause of death.

CHORION
Extraembryonic membrane surrounding the embryo of amniote vertebrates. The outer epithelial layer of the chorion is derived from the trophoblast.

CHROMOSOME ANALYSIS (KARYOTYPE)
A picture of the chromosomes of an individual arranged in a standard manner so that abnormalities of chromosome number or form can be identified.

CONFIDENTIAL ENQUIRY
Enquiry by peer groups, including experts in the field, into the cause of, and the factors surrounding, a death, where strict confidentiality is observed at all stages of the process. It is a form of clinical audit, with the important difference that the feedback or ‘closing of the audit loop’ is via reports on the general findings, and not direct feedback to those involved with the individual cases subjected to enquiry.

CESDI
Confidential Enquiry into Stillbirths and Deaths in Infancy.

CMV
Cytomegalovirus.

CONGENITAL ANOMALY
A physical malformation, chromosomal disorder or metabolic abnormality which is present at birth.

CYTOGENETICS
The study of the structure of chromosomes; cytogenetic tests are carried out to detect any chromosomal abnormalities associated with a disease; these help in the diagnosis and selection of optimal treatment.
**DIC**
Disseminated intravascular coagulation is an acquired disorder of clotting characterised by intravascular fibrin formation which occurs in the course of a variety of conditions including sepsis and pre-eclampsia.

**DCT**
Direct Coombs Test.

**FETAL DEATH**
See Stillbirth.

**HAEMOGLOBIN A1C**
The substance of red blood cells that carries oxygen to the cells and sometimes joins with glucose. Because the glucose stays attached for the life of the cell (about 4 months), a test to measure haemoglobin A1C shows what the person’s average blood glucose level was for that period of time.

**HISTOLOGY**
The study of cells and tissue on the microscopic level.

**HISTOPATHOLOGY**
This is the science concerned with the study of microscopic changes in diseased tissues.

**INTRAUTERINE FETAL DEATH (IUFD)**
Death of a fetus in utero after 20 weeks gestation or at birth weighing at least 400gms. See STILLBIRTH.

**IUFD**
See INTRAUTERINE FETAL DEATH.

**KARYOTYPE**
The complete set of chromosomes of a cell or organism; used especially for the display prepared from photographs of mitotic chromosomes arranged in homologous pairs.

**KLEIHHAUER-BETKE**
A blood test performed on the mother’s blood to identify whether substantial bleeding has occurred from the fetus into the mother’s circulation.

**METHYLENETETRAHYDROFOLATE REDUCTASE (MTHFR) GENE**
The MTHFR gene provides instructions for making an enzyme called methylenetetrahydrofolate reductase. This enzyme plays a role in processing amino acids (the building blocks of proteins).

**MTHFR**
Methylenetetrahydrofolate reductase.

**PATHOLOGY**
The branch of medicine concerned with disease, especially its structure and its functional effects on the body.

**PCR**
Polymerase Chain Reaction.
POST-MORTEM
After death. Hence a post-mortem examination may not include an autopsy.

PSANZ
Perinatal Society of Australia and New Zealand.

PSANZ-PDC
Perinatal Society of Australia and New Zealand - Perinatal Death Classification.

PSANZ-NDC
Perinatal Society of Australia and New Zealand - Neonatal Death Classification.

RANZCOG
Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

RCP
Royal College of Pathologists.

RCPA
Royal College of Pathologists of Australasia.

SADFA
Support After Fetal Diagnosis of Abnormality.

SANDS
Stillbirth And Neonatal Death Support Group.

SLE
Systemic lupus erythematosus.

STILLBIRTH (Fetal Death)
Death prior to the complete expulsion or extraction from its mother of a product of conception of 20 or more completed weeks of gestation or of 400 g or more birthweight. The death is indicated by the fact that after such separation the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.
INFORMATION FOR PARENTS ABOUT THE POST-MORTEM EXAMINATION OF A STILLBORN BABY

When your baby is stillborn, expectations, hopes and dreams are shattered and lives are changed. Any parents have initial feelings of shock and confusion when told that their baby has died. Babies are not supposed to die. When they do, it can be devastating, overwhelming, and painful. It is a great sadness that your baby has died.

You may have a lot of questions and there will be decisions to make over the coming days and weeks. Help is available to you; your caregiver(s) will be able to advise you.

This leaflet has been prepared to help you make a decision about a post-mortem examination.

Deciding about a post-mortem can be very difficult. It is important that you make the decision that is right for you and your family. Consider how you and your family will feel in the future. In particular, think about whether a post-mortem would help you and your family to understand why your baby died. Hospital staff will respect and support whatever decision you make about a post-mortem examination.

A post mortem examination of a stillborn baby can only be undertaken with the parent/s consent.

After reading this information, you may find it helpful to discuss the examination with a doctor or midwife who has cared for you during your pregnancy or a counsellor or hospital social worker. You may also ask for more time to think about it and speak with your partner, family, friends or religious leaders.

What is a post-mortem?

The purpose of a post-mortem examination is to find any medical condition which may have contributed to or led to your baby’s death.

A post-mortem, also known as an autopsy, is a medical examination of a body after death. A doctor undertakes the examination (usually a pathologist or a doctor undertaking specialised training in pathology, under the supervision of a pathologist). Pathologists are doctors who specialise in the study of disease. The post-mortem is carried out with utmost respect and care for the baby’s body.

What information can a post-mortem provide?

A post-mortem examination can be a full or a limited post-mortem. These two options will be explained in further detail.

A full post-mortem may:

- Help you to find out more information about medical conditions that may have caused your baby’s death.
- Provide information that may confirm or rule out a suspected or unsuspected medical condition. This may be important for you or other members of your family, particularly if the condition is likely to be inherited.
Provide information to health professionals that may be important in the management of your future pregnancies.

Indicate conditions that may affect other children within the family or future pregnancies.

Contribute to the understanding of those who cared for you and provide knowledge that can be used to help other mothers and babies in the future.

A post-mortem examination does not always provide all the answers about a cause of death.

**What is a limited post-mortem?**

A limited post-mortem may involve either an external examination only; an external examination and some testing on small samples of tissue or blood; or an external examination with an internal examination limited to one particular area.

A limited post-mortem will not provide the same amount of information as a full post-mortem examination and there is always the possibility that something unexpected will be missed. However, a limited post-mortem can provide valuable information.

**What happens to your baby at a post-mortem?**

A doctor, who is usually a specialist pathologist, performs the post-mortem. The doctor will carefully review the medical record and then undertake a thorough examination of your baby. A full post-mortem examination includes a careful external examination, with measurements, as well as an examination of internal organs. X-rays and photographs may also be taken to further assist in making a diagnosis or to determine the cause/s of death.

A full post-mortem examination is undertaken as though the baby was having an operation. The Pathologist will usually make two openings, one across the back of the head, and another on the front of the body. This allows the pathologist to examine all the major organs and look for anything unusual or any clues to the cause of death. Small samples of tissues and fluids will usually be taken for microscopic examination and other tests, such as looking for an infection, or in special cases for genetic testing.

Sometimes it is necessary for the pathologist to retain an entire organ (usually the brain or heart) for further examination in order to test for signs of disease or injury that are not immediately apparent. The importance of retaining a particular organ may not be known until the post-mortem is under way. In some cases, a short delay in the funeral arrangements may be enough to have these organs returned to the body before it is released for burial or cremation. If this is not possible, you can decide whether you would like the baby’s organs returned to you or a person nominated by you for separate burial or cremation or disposed of in a lawful manner by the public health organisation (usually by cremation). Your doctor will explain in further detail what these processes are.

**What happens after the post-mortem?**

Once the examination is complete, the baby is washed and the incisions are closed. In most cases, once the baby has been dressed, the effects of the post mortem are not very noticeable. Normally, after the post-mortem examination you and your family can usually see and hold your baby again. The appearance and colour of your baby’s skin will change after death and the body will feel different to touch. These changes occur naturally after death and are not related to the post-mortem.
Will I have to pay for a post-mortem examination?

There are usually no costs associated with the post-mortem examination. However, it is important that you discuss any potential costs with your doctor or hospital representative before you give consent. If you and not the hospital request the post-mortem, these costs may be related to transport of your baby to a hospital that provides post-mortem examinations for babies. Financial assistance with the funeral costs associated with burial of your baby or of the retained organs may be available through the hospital or Area Health Service.

Why is consent needed for a post-mortem?

Written consent is required from you before a post-mortem of your stillborn baby is carried out. This is a legal requirement. You will be approached by a health professional and asked for your consent to the post-mortem examination. You are free to choose whether or not to give your consent for the post-mortem examination. Your consent must be given in writing.

Because a post-mortem examination may reveal potential genetic information relating to either biological parent, consent also includes a requirement to find out whether the other parent has no objections.

Alternatively, you may prefer someone else to make the decisions on your behalf, regarding consent for the post-mortem and for the use of tissue removed for the purposes of the post-mortem. There is a form you will be asked to complete if you wish to have someone else to make these decisions on your behalf. You must understand that in so doing you are allowing another person to make decisions about your baby in this regard.

What happens after consent is given for a post-mortem?

The post-mortem will be carried out as soon as possible after consent has been given. Occasionally, when certain conditions are suspected, samples need to be taken soon after death to enable the appropriate tests to be done. If this is the case your doctor will discuss this with you. If you wish to see your baby prior to the post-mortem, let your doctor or midwife know and arrangements will be made to delay the post-mortem. The post-mortem can be delayed for a short period, but it is recommended within 48 hours.

When will I know the results of the post-mortem?

A preliminary post-mortem report will be available within a few days of the examination but the results of some tests may not be available for twelve weeks, after which the final report will be prepared.

You should consider whether it is best for you to receive the post-mortem report directly from your primary carer, or to receive a copy through your family doctor, or another doctor who can discuss the report with you. It is suggested that you make a time with one of these doctors to discuss the report and any implications it may have for you or your family, as it may contain technical language.

Retaining and using organs and tissue for use for therapeutic, medical and scientific purposes

When your health professional approaches you to give consent for a post-mortem, you may also be asked to consider allowing the use of your baby’s organs or tissue for other purposes (such as research, medical or therapeutic purposes) that are not part of the post-mortem examination.
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If you consent for your baby’s organs and/or tissue being retained for research, medical or therapeutic purposes, the organ or tissue will usually be retained for the period for which it is considered needed. The period of retention of retained organs or tissue for research may be outlined in the specific information on the research project or you can ask for more information.

You do not have to consent to the use of organs or tissue for therapeutic, medical or scientific purposes. A post-mortem can still be carried out, even if you do not consent to the use of tissue for these purposes. If you do give such consent, it applies only to the tissue that was removed for the purposes of the post-mortem examination. It does not mean that any extra organs or tissue will be removed.

Information and bereavement support

If you have any questions, your doctor, midwife, post-mortem coordinator or social worker will try to answer them for you. Health professionals can provide you with contact details of support groups to help you through this sad time.

SIDS and Kids NSW (incorporating SANDS) provide bereavement support services to families who have experienced the death of their baby, for support and information phone 02 9818 8400, toll free 1800 651 186 or information can be accessed via the website http://www.sidsandkids.org

Summary

- A post-mortem is an important medical examination to help find answers as to why your baby died and to exclude treatable or inherited conditions for future pregnancies.
- It may help to talk to your doctor, midwife, social worker or religious leader or other members of your family, if you have more questions about the post-mortem.
- If you do not want your baby to have a full post-mortem, talk to your doctor about other possible tests, which may give you more information about the cause of the death.
- A post-mortem cannot take place without your written consent.
- The hospital post-mortem will be carried out as soon as possible after consent. Usually this is within 48 hours after death.
- If you wish, you can see and hold your baby again after the post-mortem.
- Results of the post-mortem are usually sent to the doctor within 6-12 weeks

Contact numbers

Post-mortem Coordinator 
Phone ____________________________

Doctor 
Phone ____________________________

Social Worker 
Phone ____________________________

Chaplain 
Phone ____________________________
17. OBSTETRICS

MATERNITY – MANAGEMENT OF PREGNANCY BEYOND 41 WEEKS GESTATION
(GL2014_015)

PURPOSE

The purpose of this document is to provide guidance for the clinical management and provision of evidence based information to women with low risk, singleton pregnancies that extend beyond 41+0 weeks gestation. It is important to assess each woman individually and base the management plan for pregnancy beyond 41+0 weeks on her specific circumstances and preferences.

KEY PRINCIPLES

Effective communication between health care professionals and women is essential. Information should be offered regarding the risks associated with prolonged pregnancies, and the options available. This will help women to make an informed choice, based on her individual preferences and circumstances for either a scheduled induction for a pregnancy beyond 41+0 weeks or expectant management.

Women should be informed that most women will go into labour spontaneously by 42+0 weeks gestation. The use of early gestational scans to calculate the estimated date of birth can lower the rate of pregnancy beyond 41+0 weeks in women. If pregnancy is prolonged, additional fetal surveillance and management plans should be discussed with the woman and clearly documented in the woman’s antenatal record.

The information discussed should include:
- The risks and benefits of membrane sweeping during a vaginal examination, as described in Section 2.2.1 of this document.
- The risks and benefits of expectant management, as described in Section 3.1.1 of this document.
- The need for increased foetal surveillance from 41+0 weeks, as described in Section 3.2 of this document.
- The risks and benefits of induction of labour, as described in Section 3.3.1.

USE OF THE GUIDELINE

This guideline will describe clinical management of pregnancies beyond 41+0 weeks gestation for otherwise low risk women with singleton pregnancies. The terms postdates, post term and overdue will not be used in this document as these terms are often used interchangeably and can be misleading.

ASSISTED REPRODUCTIVE TECHNOLOGY - ETHICAL GUIDELINES (GL2006_011)


NSW Health endorses the NHMRC Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (2004). These guidelines cover activities associated with assisted reproductive technology in clinical practice and research, and were developed through extensive public, community and professional stakeholder consultation. They are primarily intended for assisted reproduction practitioners, researchers, infertility clinic administrators, HRECs, and state and national government officials. They replace the 1996 NHMRC Ethical guidelines on assisted reproductive technology.

Copies can be obtained through National Mailing and Marketing (02) 6269 1000 or http://www.nhmrc.gov.au/guidelines/publications/e78. ISBN Print: 1864962712

GENETIC TESTING INCLUDING DNA DIAGNOSTIC TESTING, DNA TESTING FOR MUTATION CARRIERS AND DNA PREDICTIVE AND PRESYMPTOMATIC TESTING (PD2007_066)

Guidelines for Testing for Genetic Disorders (GL2005_012) has been replaced by two policy directives:

2. Prenatal Testing - including prenatal screening for Down syndrome and other chromosomal abnormalities (PD2007_067)

GENETIC TESTING including DNA diagnostic testing, DNA testing for mutation carriers and DNA predictive and presymptomatic testing

This policy sets out NSW Department of Health requirements for testing for genetic disorders and particularly addresses counselling issues and laboratory requirements associated with genetic testing.

Genetic tests and procedures are available for individuals at high risk for certain genetic disorders and birth defects. Testing may benefit individuals and families in a number of ways but it may also create dilemmas which need sensitive management. Counselling is an essential element of genetic testing. Each test has distinct advantages, disadvantages and limitations and should only be used after the individual being tested has given full consideration to these issues. All testing should be carried out with the informed consent of the person being tested. Health professionals and potential test users need to become familiar with the context in which the tests are used.

See also:

- Prenatal testing - including prenatal screening for Down syndrome and other chromosomal abnormalities - PD2007_067
1. General Information for testing for all genetic disorders

1.1 Professional experience

It is important that health professionals involved with the use of genetic tests and procedures have adequate knowledge and experience to achieve a high standard of service. Health professionals need to be aware of their own professional limitations and of the availability of others with specific expertise. It will sometimes be necessary to transfer responsibility to, or consult with clinical geneticists, cancer geneticists, fetal medicine specialists, obstetricians trained in prenatal diagnosis procedures, genetic counsellors or other appropriate specialists. (See Appendix 1 for Genetics Services contact details.)

1.2 Duty to inform

The outcome of genetic testing can have a significant impact not only on the individual being tested but also on other members of their families. Testing must only be undertaken when the individual has been fully informed about the purpose of the test or the procedure and the possible implications of the results.

1.3 Consent

The person being tested must be legally competent to give consent; must consent freely without coercion by professional staff, family members, employers, insurers or others; and must be adequately informed about all relevant issues including available future options. The person may withdraw consent at any time. (See 2.2 and Appendix 3 for template consent forms.)

1.4 Educational resources

A variety of resources is available to assist with patient education. (See Appendix 2 for details.)

1.5 Pre-test counselling

Testing should be accompanied by pre and post test counselling carried out by a health professional, knowledgeable about:

- the genetic disorder being tested;
- genetic risk assessment and pre-test counselling;
- the features or limitations of the laboratory test;
- interpretation of results and post-test counselling;
- implications of positive and negative results; and
- options available on the outcome of testing.

The way the health professional gives information should help a patient understand the testing process and purpose. The health professional should:

- communicate information and opinions in a form that the patient can understand;
- counsel without coercion; the patient is free to accept or reject the advice or the test;
- allow the patient sufficient time to make a decision, reflect on opinions, ask more questions and consult with the family, within the time constraints of the test;
- encourage the patients to make their own decisions.
17. OBSTETRICS

1.6 Post-test counselling

Careful consideration should be given to the way results are conveyed. The health professional should take this opportunity to explain again the implications of the result. (See also Section 2.1.)

1.6.1 Normal result:

Where the sensitivity of a test is less than 100%, a low risk result will not indicate the absence of a genetic disorder. It is therefore important that health professionals ensure that people are fully informed about their residual risk.

1.6.2 Abnormal result:

Notification of an abnormal result may precipitate a crisis and the person may for some time be unable to absorb any information. Appropriate pre-test counselling will help to reduce post-test anxiety. Post-test counselling must be offered and follow up support may require several consultations. Counselling should be sensitive to the nature of decisions to be taken, should respect individual decisions and allow time to reach decisions. Appropriate follow-up when an abnormality is detected may require referral to genetic counselling services, other professional services or support networks.

When an abnormality is detected women should be offered appropriate follow-up, eg. referral to genetic counselling, family doctor and support networks such as the Association of Genetic Support of Australasia (AGSA).

1.7 Individuals and families from culturally and linguistically diverse backgrounds

Professional interpreter services should be used. The interpreter should not be a member of the family.

1.8 NSW Birth Defects Register

All abnormal results identified by prenatal testing and postnatal testing in the first year of life should be notified to the NSW Birth Defects Register of the NSW Health Department. For further information see http://www.health.nsw.gov.au/policies/pd/2012/PD2012_055.html

1.9 Quality assurance

Quality assurance should be undertaken to achieve optimum results and quality care. (See Section 2.3 and 2.4 for further details.)

1.10 Exception to pre-test counselling requirements

Pre-test counselling requirements are not usually applicable to certain routine haematology, biochemistry, biochemical genetic tests, although testing may lead to diagnosis of a genetic condition. Information should be made available prior to newborn screening and other population screening tests. Counselling should be offered if a result is abnormal.
2. Additional information for DNA diagnostic testing, DNA testing for mutation carriers and DNA predictive and presymptomatic testing

2.1 Clinical and counselling issues in DNA predictive testing

In addition to the general information for testing for all genetic disorders outlined in section 1, the following apply specifically to counselling about DNA predictive testing:

- An abnormal result will indicate the presence of a particular mutation, but the presence of a mutation may not necessarily define the presence or severity of disease;
- Implications for other members of the family including information which changes the risk of other family members who have not requested testing;
- Implications for future reproductive options;
- Availability of treatment;
- Clinical examination by an experienced specialist prior to a test result is encouraged, as knowledge of a normal recent examination in the event of an abnormal DNA test result will be reassuring. If signs of the disorder are present, appropriate further assistance can be obtained.

See also:
Guidelines for predictive and diagnostic DNA testing for serious adult onset neurogenetic disorders with predictive implications for other family members and which are likely to reduce normal life expectancy - (PD2005_303)

2.2 Consent

Different types of genetic testing raise specific issues that need to be discussed as part of the consent process. Template consent forms (Appendix 3) provide direction on particular considerations to be addressed.

- Request Form for Specialised Molecular Genetic/DNA Testing for Genetic Conditions.
- Consent Form for Specialised/DNA Diagnostic Testing/Storage.
- Consent Form for Collection, Testing and Storage of Human Tissue for Research.
- Consent Form for Analysis of Genes Associated with Cancer.
- Consent Form for Pre-symptomatic, Predictive and Diagnostic DNA Testing for Serious Adult Onset Neurogenetic Disorders with Predictive Implications for other Family Members.

2.3 Collection and transport of specimens

- Specimens should be collected under optimum conditions including type of specimen tube, conditions for sample storage during transport, etc.
- DNA predictive testing optimally requires 2 samples from separate blood draws at separate times, with each time recorded on the tube.
- Specimen tubes are to be labelled with the full name and date of birth of the person being tested. The person being tested should sign the specimen tube at the time of collection.
- A copy of the consent form should be forwarded to the testing laboratory with the specimen.
- Patient’s suburb and postcode should be included on the test request form.
- The specimen must be accompanied by a signed referral form that specifies the test(s) to be performed.
- The transport of specimens is to occur at times agreed to by the testing laboratory.
- The time frame for receiving results should be estimated with advice from the testing laboratory.
2.4 Quality assurance

All laboratories providing human diagnostic test results (including both diagnostic and research laboratories) must comply with relevant requirements including:

- **Therapeutic Goods Act of 1989**, its regulations and subsequent amendments, particularly with regard to IVDs
- **NATA/RCPA**

All laboratories should participate in an appropriate quality assurance program (where available) and perform sufficient numbers of tests relevant to the area of investigation in order to maintain reliability and expertise.

Effective communication between the clinician and the testing laboratory regarding requirements is essential to achieving optimum specimen quality.
### Metropolitan Centres

<table>
<thead>
<tr>
<th>Location</th>
<th>Address</th>
<th>Phone</th>
<th>Fax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Camperdown</td>
<td>Royal Prince Alfred Hospital, Department of Molecular and Clinical Genetics, Missenden Road, Camperdown NSW 2050</td>
<td>(02) 9515 5080</td>
<td>(02) 9550 5389</td>
</tr>
<tr>
<td>Kogarah</td>
<td>St George Hospital, Kogarah NSW 2217</td>
<td>(02) 9113 3635</td>
<td>(02) 9113 3694</td>
</tr>
<tr>
<td>Liverpool</td>
<td>Liverpool Health Services, Clinical Genetics Department, Locked Bag 7103, Liverpool BC 1871</td>
<td>(02) 9828 4665</td>
<td>(02) 9828 4650</td>
</tr>
<tr>
<td>Newcastle</td>
<td>Newcastle Western Suburbs Hospital, Hunter Genetics, PO Box 84, Waratah NSW 2298</td>
<td>(02) 4985 3100</td>
<td>(02) 4985 3105</td>
</tr>
<tr>
<td>Penrith</td>
<td>Nepean Hospital Clinical Genetics Department, Penrith NSW 2750</td>
<td>(02) 4734 3362</td>
<td>(02) 4734 2561</td>
</tr>
<tr>
<td>Randwick</td>
<td>The Sydney Children’s Hospital Department of Medical Genetics, High St, Randwick NSW 2031</td>
<td>(02) 9382 1704</td>
<td>(02) 9382 1711</td>
</tr>
<tr>
<td>St Leonards</td>
<td>Royal North Shore Hospital St Leonards NSW 2065</td>
<td>(02) 9926 6478</td>
<td>(02) 9926 7880</td>
</tr>
<tr>
<td>Westmead</td>
<td>The Children’s Hospital Department of Clinical Genetics, Westmead NSW 2145</td>
<td>(02) 9845 3273</td>
<td>(02) 9845 3204</td>
</tr>
</tbody>
</table>

### Regional Centres

<table>
<thead>
<tr>
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<th>Address</th>
<th>Phone</th>
<th>Fax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bathurst</td>
<td>Community Health Centre PO Box 1479 Bathurst NSW 2795</td>
<td>(02) 6339 5677</td>
<td>(02) 6339 5655</td>
</tr>
<tr>
<td>Broken Hill</td>
<td>Greater Western Area Health Service Community Health Centre, PO Box 457, Broken Hill NSW 2880</td>
<td>(02) 8080 1554</td>
<td>(02) 8080 1611</td>
</tr>
<tr>
<td>Coffs Harbour</td>
<td>Primary Health Service Coffs Harbour Health Campus Locked Mail Bag 812, Cnr High &amp; Boambee Sts, Coffs Harbour NSW 2450</td>
<td>(02) 6656 7200</td>
<td>(02) 6656 7203</td>
</tr>
<tr>
<td>Forster</td>
<td>Forster Community Health Centre Breeze Parade, Forster NSW 2428</td>
<td>(02) 6555 6822</td>
<td>(02) 6554 8874</td>
</tr>
<tr>
<td>Gosford</td>
<td>Child And Family Health Gateway Centre, PO Box 361, Gosford NSW 2250</td>
<td>(02) 4328 7994</td>
<td>(02) 4328 7925</td>
</tr>
<tr>
<td>Goulburn</td>
<td>CIFTS, Locked Bag 15, Goulburn NSW 2580, Ph: (02) 4827 3950, Fax: (02) 4827 3958</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kempsey</td>
<td>C/- North Coast Area Health Service Community Health Centre, Morton Street, Port Macquarie NSW 2444</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mudgee</td>
<td>Macquarie Area Health Service PO Box 29, Mudgee NSW 2850</td>
<td>(02) 6378 6236</td>
<td>(02) 6372 7341</td>
</tr>
<tr>
<td>Muswellbrook</td>
<td>Community Health Centre Brentwood Street, Muswellbrook NSW 2333</td>
<td>(02) 6542 2050</td>
<td>(02) 6542 2005</td>
</tr>
<tr>
<td>North Coast</td>
<td>Lismore Base Hospital PO Box 419, Lismore NSW 2480</td>
<td>(02) 66250 111</td>
<td>(02) 66250 102</td>
</tr>
<tr>
<td>Port Macquarie</td>
<td>North Coast Area Health Service Community Health Centre, Morton Street, Port Macquarie NSW 2444</td>
<td>(02) 6588 2882</td>
<td>(02) 6588 2800</td>
</tr>
<tr>
<td>Tamworth</td>
<td>Community Health Centre 180 Peel Street, Tamworth NSW 2340</td>
<td>(02) 6767 8100</td>
<td>(02) 6766 3967</td>
</tr>
<tr>
<td>Taree</td>
<td>Community Health Centre 22 York Street, Taree, NSW 2430</td>
<td>(02) 6592 9703</td>
<td>(02) 6592 9607</td>
</tr>
<tr>
<td>Wagga Wagga</td>
<td>Wagga Wagga Base Hospital, Cnr Edward and Docker Sts, Wagga Wagga NSW 2650</td>
<td>(02) 6938 6666</td>
<td>(02) 6921 5632</td>
</tr>
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</table>
### Familial Cancer Services

<table>
<thead>
<tr>
<th>Location</th>
<th>Address</th>
<th>Phone</th>
<th>Fax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Camperdown</td>
<td>Royal Prince Alfred Hospital, Department of Molecular and Clinical Genetics, Missenden Rd, Camperdown NSW 2050</td>
<td>(02) 9515 5080</td>
<td>(02) 9550 5389</td>
</tr>
<tr>
<td>Darlinghurst</td>
<td>St Vincent’s Hospital, Family Cancer Clinic, Victoria Rd, Darlinghurst NSW 2011</td>
<td>(02) 8382 3395</td>
<td>(02) 8382 3386</td>
</tr>
<tr>
<td>Kogarah</td>
<td>St George Hospital, Hereditary Cancer Clinic, Cancer Care Centre, Gray St, Kogarah, NSW 2217</td>
<td>(02) 9350 3815</td>
<td>(02) 9350 3958</td>
</tr>
<tr>
<td>Westmead</td>
<td>Westmead Hospital, Familial Cancer Service, Department of Medicine, Westmead NSW 2145</td>
<td>(02) 9845 6947</td>
<td>(02) 9687 2331</td>
</tr>
<tr>
<td>Newcastle</td>
<td>Hunter Family Cancer Service, PO Box 84, Waratah NSW 2298</td>
<td>(02) 4985 3132</td>
<td>(02) 4985 3133</td>
</tr>
<tr>
<td>Penrith</td>
<td>Nepean Hospital, Clinical Genetics Department, Level 5 South Block, PO Box 63, Penrith NSW 2750</td>
<td>(02) 4734 3362</td>
<td>(02) 4734 2567</td>
</tr>
<tr>
<td>Randwick</td>
<td>Prince of Wales Hospital, Hereditary Cancer Clinic, High St, Randwick NSW 2031</td>
<td>(02) 9382 2551</td>
<td>(02) 9382 2588</td>
</tr>
<tr>
<td>St Leonards</td>
<td>Royal North Shore Hospital, Family Cancer Service, Level 2, Vindin House, St Leonards NSW 2065</td>
<td>(02) 9926 5665</td>
<td></td>
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</table>

### Fetal Medicine Services in Public Hospitals Associated with Clinical Genetics Services

<table>
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<tr>
<th>Location</th>
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<th>Phone</th>
<th>Fax</th>
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</thead>
<tbody>
<tr>
<td>Camperdown</td>
<td>Royal Prince Alfred Hospital, Department of Molecular and Clinical Genetics, Building 65, Level 6 Missenden Road, Camperdown NSW 2050</td>
<td>(02) 9515 5080</td>
<td>(02) 9550 5389</td>
</tr>
<tr>
<td>Kogarah</td>
<td>St George Hospital, Women and Children’s Health Gray Street, Kogarah NSW 2217</td>
<td>(02) 9350 3635</td>
<td>(02) 9350 3694</td>
</tr>
<tr>
<td>Liverpool</td>
<td>Liverpool Hospital, Fetal Medicine Unit, Locked Bag 7103 Liverpool BC NSW 1871</td>
<td>(02) 9828 5631</td>
<td>(02) 9828 5570</td>
</tr>
<tr>
<td>Newcastle</td>
<td>John Hunter Hospital, Maternal and Fetal Medicine, Locked Bag 1, Hunter Region Mail Centre Newcastle, NSW 2310</td>
<td>(02) 4921 4694</td>
<td>(02) 4921 3133</td>
</tr>
<tr>
<td>Penrith</td>
<td>Nepean Hospital, Perinatal Ultrasound, Level 3 South Block, Derby Street Penrith NSW 2751</td>
<td>(02) 4734 2578</td>
<td>(02) 4737 3206</td>
</tr>
<tr>
<td>Randwick</td>
<td>Royal Hospital for Women, Maternal/Fetal Medicine, Barker Street, Randwick, NSW 2031</td>
<td>(02) 9382 6098</td>
<td>(02) 9382 6706</td>
</tr>
<tr>
<td>St Leonards</td>
<td>Royal North Shore Hospital, Fetal Medicine Unit, Pacific Highway, St Leonards NSW 2065</td>
<td>(02) 9926 6478</td>
<td>(02) 9926 7880</td>
</tr>
<tr>
<td>Westmead</td>
<td>The Children’s Hospital, Department of Clinical Genetics, Locked Bag 4001, Westmead NSW 2145</td>
<td>(02) 9845 3273</td>
<td>(02) 9845 3204</td>
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### Genetics Education Services

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<th>Service</th>
<th>Address</th>
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<tbody>
<tr>
<td>Centre for Genetics Education</td>
<td>PO Box 317, St Leonards NSW 1590</td>
<td>(02) 9926 7324</td>
<td>(02) 9906 7529</td>
</tr>
<tr>
<td>Web</td>
<td></td>
<td><a href="http://www.genetics.edu.au/">http://www.genetics.edu.au/</a></td>
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</tr>
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</table>

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17. OBSTETRICS

### Association for Genetic Support of Australasia (AGSA)

<table>
<thead>
<tr>
<th>AGSA</th>
<th>66 Albion Street, SURRY HILLS NSW 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ph: (02) 9211 1462, Fax: (02) 9211 8077</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:agsa@ozemail.com.au">agsa@ozemail.com.au</a></td>
</tr>
<tr>
<td></td>
<td>Web: <a href="http://www.agsa-geneticsupport.org.au">http://www.agsa-geneticsupport.org.au</a></td>
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### Medications in pregnancy and lactation service (NSW)

<table>
<thead>
<tr>
<th>Mothersafe</th>
<th>Medications in Pregnancy and Lactation Service, Royal Hospital for Women</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High St, Randwick, NSW 2031</td>
</tr>
<tr>
<td></td>
<td>Ph: (02) 9382 6539 or 1800 647 848</td>
</tr>
</tbody>
</table>

### Birth Defects Register (NSW)

<table>
<thead>
<tr>
<th>NSW Birth Defects Register</th>
<th>Centre for Epidemiology and Research, NSW Health Department</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Locked Mail Bag 961, North Sydney NSW 2061</td>
</tr>
<tr>
<td></td>
<td>Ph: (02) 9424 5829 Fax: (02) 9391 9232</td>
</tr>
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</table>

### Genetics of Learning Disability Service (GOLD)

<table>
<thead>
<tr>
<th>GOLD</th>
<th>Hunter Genetics, PO Box 84, WARATAH NSW 2298</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ph: (02) 4985 3131, Fax: (02) 4985 3133</td>
</tr>
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</table>
Resources

Centre for Genetics Education
PO Box 317
ST LEONARDS NSW 1590

Tel: 02 9926 7324
Fax: 02 9906 7529
http://www.genetics.edu.au/

AGSA
Association of Genetic Support of Australasia Inc.
66 Albion Street
SURRY HILLS NSW 2010

Tel: 02 9211 1462
Fax: 02 9211 8077
Email: agsa@ozemail.com.au
Web: http://www.agsa-geneticsupport.org.au
Appendix 3

Template consent forms

- Request Form for Specialised Molecular Genetic/DNA Testing for Genetic Conditions
- Consent Form for Specialised/DNA Diagnostic Testing/Storage
- Consent Form for Collection, Testing and Storage of Human Tissue for Research
- Consent Form for analysis of Genes Associated with Cancer
- Consent Form for Pre-symptomatic, Predictive and Diagnostic DNA Testing for Serious Adult Onset Neurogenetic Disorders with Predictive Implications for other Family Members
Request Form for Specialised Molecular Genetic/DNA Testing for Genetic Conditions

- Must be used for non-Medical Benefits Schedule Items
- Before testing is commenced, the laboratory may require the following details (see "Guidelines for Specialised DNA Testing for Genetic Disorders" [http://www.health.gov.au/health-public-affairs/publications/genetics/])

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>MBRN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last name</td>
<td></td>
</tr>
<tr>
<td>First name</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>Postcode</td>
<td></td>
</tr>
<tr>
<td>Date of birth</td>
<td>.............</td>
</tr>
<tr>
<td></td>
<td>(dd/mm/yyyy)</td>
</tr>
</tbody>
</table>

**Genetic Counselling**

Has the individual been offered counselling consistent with Specialised/DNA Testing for Genetic Disorders?

- [ ] Yes
- [ ] No
- [ ] Refused

**Consent to Testing**

Has a Consent Form for Specialised/DNA Testing been completed?

- [ ] Yes
- [ ] No

**Consent to Payment**

- [ ] Public patient, or
- [ ] Privately referred non-inpatient

Payment to be made by Area Health Service by arrangement

Authorised by: ____________________________

[ ] Private patient - Payment to be made by patient

Consent to payment: ____________________________

<table>
<thead>
<tr>
<th>Purpose of test</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Confirm clinical diagnosis</td>
</tr>
<tr>
<td>[ ] Predictive/presymptomatic testing</td>
</tr>
<tr>
<td>[ ] Carrier Status</td>
</tr>
<tr>
<td>[ ] Prenatal Diagnosis - complete box below</td>
</tr>
<tr>
<td>[ ] Determine feasibility of prenatal Dx</td>
</tr>
<tr>
<td>[ ] Family study (no report for this individual)</td>
</tr>
<tr>
<td>[ ] For research (no report for this individual)</td>
</tr>
<tr>
<td>[ ] Bank DNA until further notice</td>
</tr>
<tr>
<td>[ ] Other: ____________________________</td>
</tr>
</tbody>
</table>

**Pregnancy Information** (if applicable)

Is this individual or the partner of this individual currently pregnant:

- [ ] L.M.P. (dd/mm/yyyy)
- [ ] Amnio (dd/mm/yyyy)
- [ ] CVS (dd/mm/yyyy)

**Family Information**

Have samples from this family been sent to a DNA lab before?

- [ ] Yes
- [ ] No

If Yes, specify: ____________________________

Date of birth or age: ____________________________

Ethnic background: ____________________________

Send by courier/express post to:

Send samples at room temperature
Same day OR overnight

**Sample Data Drawn** ................./....../...... (dd/mm/yyyy)

**Blood**

- [ ] EDTA .......... mL (room temp)
- [ ] Lithium heparin .......... mL (room temp)

**Prenatal**

- [ ] amniotic fluid .......... mL (room temp)
- [ ] cultured amniocytes x725 Flasks(s) (room temp)
- [ ] CVS sample .......... mg [ ] on ice
  [ ] cleaned
  [ ] uncleansed

**Other**

- [ ] DNA .......... P8

Other, specify: ____________________________

**PLEASE ATTACH FAMILY/PEDIGREE INFORMATION**

Send Account to:

Name: ____________________________

Address: ____________________________

[ ] Postcode: ____________________________

Test requested by:

Name: ____________________________

Initials: ____________________________

Address: ____________________________

[ ] Postcode: ____________________________

Telephone No: ____________________________

Signature: ____________________________

Date: ____________________________

Specialty/Appointment: ____________________________

Copy of report to:

Name: ____________________________

Initials: ____________________________

Address: ____________________________

[ ] Postcode: ____________________________

Telephone No: ____________________________

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Consent Form for Specialised/DNA Diagnostic Testing/Storage

This form has been designed to ensure that your consent is on an informed basis. Please read and consider each section.

<table>
<thead>
<tr>
<th>Genetic File No</th>
<th>MRN</th>
</tr>
</thead>
</table>

**Patient**

<table>
<thead>
<tr>
<th>Surname</th>
<th>Given Name(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Address</th>
<th>Postcode</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date of Birth</th>
<th>Telephone</th>
</tr>
</thead>
</table>

**Parent or Guardian**

<table>
<thead>
<tr>
<th>Surname</th>
<th>Given Name(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Address</th>
<th>Postcode</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date of Birth</th>
<th>Telephone</th>
</tr>
</thead>
</table>

**PROVISION OF INFORMATION TO PATIENT**

To be completed by Health Professional

I, ____________________________ have informed this patient/guardian as detailed below including the nature, likely results, and material risks of DNA diagnostic testing.

Interpreter present Yes/No

<table>
<thead>
<tr>
<th>Signature of Interpreter</th>
<th>Signature of Health Professional</th>
<th>Date</th>
</tr>
</thead>
</table>

**PATIENT CONSENT**

To be completed by Patient

I, ____________________________ and I have discussed the consequences and procedures involved in testing and storage of my tissue/blood/DNA. I have been told that:

- Testing may reveal non-paternity or non-maternity of a presumed natural parent
- Testing may not be informative for some families or family members
- Tissue/blood/DNA will be stored in good faith but may not remain in a suitable state for testing
- The collection of samples of blood/muscle/skin from me

will be used for (tick where applicable):

- [ ] direct testing
- [ ] testing in family studies (indirect testing)
- [ ] storage of cell lines from the sample for

<table>
<thead>
<tr>
<th>Insert period of time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 direct testing: testing of the gene for the disorder to determine whether a mutation is present.</td>
</tr>
<tr>
<td>2 indirect testing (family studies): the tracing through a family of a mutation in a gene using 'markers' to identify the mutation.</td>
</tr>
<tr>
<td>3 cell lines: cells from blood or other tissues kept alive in the laboratory.</td>
</tr>
<tr>
<td>4 DNA (deoxyribonucleic acid): The chemical compound which the genes are made of.</td>
</tr>
</tbody>
</table>

- [ ] storage of the tissue/blood/DNA for

<table>
<thead>
<tr>
<th>Insert period of time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 direct testing: testing of the gene for the disorder to determine whether a mutation is present.</td>
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<tr>
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</tr>
<tr>
<td>4 DNA (deoxyribonucleic acid): The chemical compound which the genes are made of.</td>
</tr>
</tbody>
</table>

- [ ] The information gained from testing may be used to assist the health care of other family members
- [ ] No

- [ ] other family members
- [ ] only the following individual(s)

- [ ] I have been advised to inform other adult family members who may be at risk
- [ ] I request that the sample be stored and retested if testing is inconclusive and future testing may be more informative
- [ ] I understand the potential benefits and adverse consequences involved in testing and storage of this sample
- [ ] I have had the opportunity to ask questions and am satisfied with the explanation and the answers to my questions
- [ ] I understand that consent may be withdrawn

I request and consent to the above

<table>
<thead>
<tr>
<th>Signature of Patient/Guardian</th>
<th>Print name of Patient</th>
<th>Date</th>
</tr>
</thead>
</table>
Consent Form for Collection, Testing and Storage of Human Tissue for Research

This form has been designed to ensure that your consent is on an informed basis. Please read and consider each section.

**Patient**

<table>
<thead>
<tr>
<th>Surname</th>
<th>Given Name(s)</th>
<th>Address</th>
<th>Postcode</th>
<th>Date of Birth</th>
<th>Telephone</th>
</tr>
</thead>
</table>

**Parent or Guardian**

(Patient under age for or unable to consent)

<table>
<thead>
<tr>
<th>Surname</th>
<th>Given Name(s)</th>
<th>Address</th>
<th>Postcode</th>
<th>Date of Birth</th>
<th>Telephone</th>
</tr>
</thead>
</table>

**PROVISION OF INFORMATION TO PATIENT**

To be completed by Health Professional:

I, ___________ have informed this patient as detailed below including the nature, likely results, and material risks of testing and storage of tissue/blood/DNA.

Interpreter present Yes/No

Signature of Interpreter: __________________________ Signature of Health Professional: __________________________ Date: ___________

**PATIENT CONSENT**

To be completed by Patient:

Insert name of Health Professional: __________________________ and I have discussed the consequences and procedures involved in testing and storage of my tissue/blood/DNA. I have been told that:

- The tissue/blood/DNA will be used in a research study entitled __________________________
- The study has been approved by the Institutional Ethics Committee of __________________________
- My tissue/blood/DNA ("cross out two")
  - will be destroyed at the completion of the project
  - will be stored for ______ years after completion of the project
  - may be stored indefinitely
- I will not necessarily receive a report on the outcome of the project
- I or my attending doctor will be advised if the project produces information which could be of value to me or my family
- Testing may reveal non-paternity or non-maternity of a presumed natural parent
- If tissue/blood/DNA is stored it may not remain in a suitable state for testing

I have had the opportunity to ask questions and am satisfied with the explanation and the answers to my questions.

I understand that I may withdraw my consent.

After testing has been completed:

- I consent to my de-identified DNA sample being used for future Institutional Ethics Committee approved research

OR

- My DNA sample may not be used for research without my written consent

I request and consent to the above

Signature of Patient/Guardian: __________________________ Print name of Patient: __________________________ Date: ___________

64(2/08)
Consent Form for analysis of Genes Associated with Cancer

This form has been designed to ensure that your consent is on an informed basis. Please read and consider each section.

(Name of Hospital)

<table>
<thead>
<tr>
<th>Title</th>
<th>Family Names</th>
<th>MRN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Given Name</td>
<td>VMO</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td>Street</td>
<td>DOB</td>
</tr>
<tr>
<td>Suburb</td>
<td>Postcode</td>
<td>Admission Date</td>
</tr>
</tbody>
</table>

PROVISON OF INFORMATION TO PATIENT

To be completed by Health Professional

I, (Insert name of Medical Practitioner/Health Professional and designation)

have informed this patient as detailed below including the nature, likely results, and risks associated with gene testing.

Signature of Medical Practitioner/Health Professional

Signature of Interpreter (if present)

Date

PATIENT CONSENT

To be completed by Patient/Guardian

I, (Insert name of Health Professional)

and I have discussed diagnostic testing for the analysis of genes associated with cancer. He/she has told me that:

TESTING

- The collection of blood/... will be used for testing of genes involved in:

  (Tick the appropriate box)

  - hereditary breast/ovarian cancer
  - hereditary bowel cancer
  - hereditary cancer predisposition (specify)

- The sample will be stored by the laboratory according to regulations.
- The sample will not be used for any purpose other than that agreed upon in this consent.
- Testing is voluntary and it is possible to withdraw from the testing process at any stage.

RESULTS

A Mutation Screen-when a gene change has not been found in any other family member

- A positive test result means that I carry a gene change (mutation) that gives me an increased risk for cancer. Each of my children have a 50% chance of inheriting the same gene change.

- A negative result is uninformative. This may be because
  - We have not been able to find a gene change using current technology or
  - It is possible that changes in other genes may be responsible for the increased risk of cancer in the family.
  - A negative result does not exclude an inherited predisposition in the family.

- Results of unknown significance - Sometimes a gene change is found and we are not sure whether it has caused the increased risk of cancer in the family. This is because the exact effect of this change on the gene is, as yet unknown.

- Other relevant information:

Further testing may be performed in the future as our knowledge of cancer genetics improves.
B. Predictive Test— when a gene change has already been found in another family member

- A **positive** test result means that I carry the gene change that causes an increased risk of cancer in my family. Each of my children have a 50% chance of inheriting the same gene change.
- A **negative** result means that I have **not** inherited the gene change that has caused an increased risk of cancer in my family. As I do not carry this gene change, I cannot pass it on to my children.
- Other relevant information: ........................................................................................................................................

The test result:

- cannot predict whether a cancer will occur.
- cannot predict the age of onset or type of cancer that may develop.
- of one individual can change the estimation of risk for other family members.
- may affect the ability to obtain some types of insurance.
- may reveal non-maternity or non-paternity of a presumed parent.

CONFIDENTIALITY

- The test result will be held by this centre and will be known by those involved in the testing process.
- My test result will be given to me first in person. Other arrangements please specify: ........................................................................................................................................

- In the event of my death, the test results may be made known to:
  - Name: .............................................. Relationship: .............................................. Contact details: ..............................................

  - Name: .............................................. Relationship: .............................................. Contact details: ..............................................

- The fact that I have had a genetic test will not be revealed to any other person or organisation without my written consent except in situations where disclosure is legally required.
- My test result may be revealed to my Doctor(s)  Yes ☐ No ☐
- The information gained from the testing may be used to assist the health care of other family members  Yes ☐ No ☐
- Other relevant Information  ........................................................................................................................................

AFTER TESTING IS COMPLETED:

- [ ] I consent to my de-identified DNA sample being used for future ethics approved research
- [ ] I do not consent to my DNA sample being used for research without my written consent

I request and consent to the test described above.

I understand the potential benefits, potential consequences and limitations involved in testing and the storage of this sample. I have had an opportunity to ask questions and I am satisfied with the explanations and answers to my questions. I understand that genetic counselling will be available for myself and my family.

Signature of person being tested  Print name of person being tested  Date

or

Signature of guardian  Print name of guardian  Date

Signature of guardian  Print name of guardian  Date

Explanation of terms used in this consent form

- Genes associated with cancer: Specific genes in which changes (mutations) are associated with an increased risk of cancer.
- A gene test involves analysis of one or more of those genes to determine whether a mutation is present.
- Cancer predisposition gene mutation: Changed DNA code which gives rise to an increased risk of certain cancers.
- DNA (Deoxyribonucleic acid): The chemical compound of which the genes are made.
Consent Form for Pre-symptomatic, Predictive and Diagnostic DNA Testing for Serious Adult Onset Neurogenetic Disorders with Predictive Implications for other Family Members

This form has been designed to ensure that your consent is on an informed basis. Please read and consider each section.

(Name of Hospital)

<table>
<thead>
<tr>
<th>Title</th>
<th>Family Names</th>
<th>MUH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Given Name</td>
<td></td>
<td>VMO</td>
</tr>
<tr>
<td>Address</td>
<td>Street</td>
<td>DOB</td>
</tr>
<tr>
<td>Suburb</td>
<td>Postcode</td>
<td>Admission Date</td>
</tr>
</tbody>
</table>

PROVISION OF INFORMATION TO PATIENT  

I, ___________________________ have informed this patient as detailed below

Insert name of Health Professional and designation

the nature, likely results, and risks associated with gene testing for ___________________________

name of disorder

Interpreter present Yes/No

Signature of Interpreter ___________________________ Signature of Health Professional ___________________________ Date ___________________________

PATIENT CONSENT  

_____________________________ and I have discussed predictive testing

Insert name of Health Professional

testing for the analysis of the gene fault (mutation) for ___________________________

name of disorder

He/she has told me that:

- The collection of blood will be used to examine my DNA and tested for the gene involved in ___________________________

name of disorder

- A positive test result indicates that I have inherited a faulty gene (mutation). This means that I am at high risk of developing/will develop ___________________________ and my children and siblings have a _________ % chance ___________________________

name of disorder

percentage

- A positive test result cannot accurately predict the age of onset of the disorder.

- A negative test result means that I have not inherited the faulty gene (mutation). I will not develop ___________________________ and cannot pass the faulty gene involved on to my children ___________________________

name of disorder

- An intermediate result means that I may or may not develop ___________________________ name of disorder

- In some instances this may have implications for my siblings and children and their descendants

64(2/08)
• Test results of one individual can change the estimation of risk for other family members and I have been advised to inform other adult family members who may be at risk.
• The test result may impact on obtaining some types of insurance or employment.
• Testing may reveal non-paternity or non-maternity of a presumed natural parent
• Genetic counselling will be available for myself and other family members during the testing process and after the test result has been given.

I have been told about storage of the test results and the DNA sample. I understand the following:
• The test result will be held by this centre and will only be known by those involved in the testing process.
• My own test result, the fact that I have had a test, and my DNA sample will not be revealed or made available to any other person or organisation outside of the testing process, except with my written consent (as detailed below), or in situations where disclosure is required by law.
• The test results will be given to me first.
• The DNA sample will remain the property of the laboratory. It will be stored in good faith; but its suitability for future use cannot be guaranteed. It will be disposed of at a time determined by standard laboratory practices or regulatory requirements.
• My identified DNA sample will not be used for any other purpose except in accordance with my written consent (as detailed below).

I request and consent to the test described above.
I understand the potential benefits of testing and storing this sample and I accept the risks involved. I have had the chance to ask questions and am satisfied with the explanations and the answers to my questions.

I understand that I may withdraw my consent for this test to be processed.

I consent to my test results being revealed at any time to the following people:

☐ Any family member
☐ Only to the following individuals (specify)
☐ My doctor(s) (specify)
☐ No other individual
☐ In the event of my death test results may be made known to:

After testing has been completed:
☐ I consent to my de-identified DNA sample being used for future Institutional Ethics Committee approved research
☐ OR
☐ My DNA sample may not be used for research without my written consent

Signature of Patient/Parent
Print name of Patient
Date

Explanation of terms used in this consent form
• A gene test involves analysis of one or more of those genes to determine whether a mutation is present
• Mutation: Change in the normal DNA code which may cause or increase risk for a condition
• DNA (Deoxyribonucleic acid): The chemical compound of which the genes are made
Prenatal Testing/Screening for Down Syndrome & Other Chromosomal Abnormalities (PD2007_067)

Guidelines for Testing for Genetic Disorders (GL2005_012) has been replaced by two policy directives:

1. Prenatal Testing - including prenatal screening for Down syndrome and other chromosomal abnormalities (PD2007_067)
2. Genetic Testing - including DNA diagnostic testing, DNA testing for mutation carriers and DNA predictive and presymptomatic testing (PD2007_066)

This policy directive addresses:

Prenatal screening tests - these tests may identify a baby as being at an increased risk of having a particular problem and include:
- First trimester screening for women presenting between 10 to 14 weeks of pregnancy using a combination of maternal age, ultrasound nuchal translucency measurement (NTS) and serum screening tests (free $\beta$-hCG and PAPP-A).
- Second trimester screening for women presenting between 15 to 18 weeks of pregnancy, using maternal age, maternal serum screening (free $\beta$hCG, AFP and unconjugated estriol).
- Ultrasound

Prenatal diagnostic tests - these tests may be used following an increased risk result on prenatal screening or independently:
- Ultrasound
- Chorionic villus sampling
- Amniocentesis
- Fetal blood sampling

This policy is directed to NSW Health clinical and care providers involved in prenatal care. It provides direction on access to and provision of prenatal screening and diagnostic tests so pregnant women are informed about screening options and are appropriately directed to services.

See also:

Genetic Testing - including DNA diagnostic testing, DNA testing for mutation carriers and DNA predictive and presymptomatic testing (PD2007_066).

1. Introduction

In recent years, an increasing number of non-invasive biochemical screening tests and ultrasound techniques have been developed which can significantly increase the identification of pregnancies at risk for Down syndrome and other chromosomal abnormalities in women of all ages.

The use of prenatal screening tests has added to the complexity of prenatal care. These screening tests give a risk indication only and are not definitive tests. Use and interpretation are dependent on a number of factors including accurate gestational age, the stage of pregnancy, maternal age, and in the case of ultrasound, operator expertise. They are associated with varying levels of false positive and false negative results, depending on different combinations of tests offered. Women indicated to be at high risk on screening tests should be offered follow-up definitive testing by amniocentesis or chorionic villus sampling.
Each screening test has advantages, disadvantages and limitations. Offers of screening need to be accompanied by sufficient information and counselling, with professional interpreter services if necessary, to help women choose screening on an informed basis. This includes accurate information about the health and development issues for children with Down syndrome and the potential ramifications for women entering into the screening process.

NSW Health’s policy of offering diagnostic testing by chorionic villus sampling and amniocentesis to women at increased risk for chromosome errors through family history or advanced maternal age (35 years and older at estimated date of confinement) remains unchanged (see Section 5).

2. Down syndrome and other chromosomal abnormalities

In NSW, the incidence of Down syndrome in pregnancy is approximately 2.5 per 1000. In 2004, the NSW Birth Defects Register reported 98 births and 132 terminations of pregnancy for Down syndrome, ie a total of 230. The number of livebirths and stillbirths for all chromosomal abnormalities (including Down syndrome) in 2004 was 202 with 243 reported terminations, ie a total of 445.

The risk of having a baby with Down syndrome increases with advancing maternal age. Since 1990 confinements to women 35 years and over have risen from 10.4% to 20.7% in 2005, increasing the potential for more Down syndrome affected pregnancies in this age group.

Table 1 Risk by age of Down syndrome and other chromosomal abnormalities

<table>
<thead>
<tr>
<th>Maternal age at delivery</th>
<th>* Chance of having a live-born baby with Down syndrome</th>
<th>** Chance of having a live-born baby with a chromosomal abnormality</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-24 years</td>
<td>1 in 1411</td>
<td>1 in 506</td>
</tr>
<tr>
<td>25 years</td>
<td>1 in 1383</td>
<td>1 in 476</td>
</tr>
<tr>
<td>26 years</td>
<td>1 in 1187</td>
<td>1 in 476</td>
</tr>
<tr>
<td>27 years</td>
<td>1 in 1235</td>
<td>1 in 455</td>
</tr>
<tr>
<td>28 years</td>
<td>1 in 1147</td>
<td>1 in 435</td>
</tr>
<tr>
<td>29 years</td>
<td>1 in 1002</td>
<td>1 in 417</td>
</tr>
<tr>
<td>30 years</td>
<td>1 in 959</td>
<td>1 in 385</td>
</tr>
<tr>
<td>31 years</td>
<td>1 in 837</td>
<td>1 in 385</td>
</tr>
<tr>
<td>32 years</td>
<td>1 in 695</td>
<td>1 in 323</td>
</tr>
<tr>
<td>33 years</td>
<td>1 in 589</td>
<td>1 in 286</td>
</tr>
<tr>
<td>34 years</td>
<td>1 in 430</td>
<td>1 in 244</td>
</tr>
<tr>
<td>35 years</td>
<td>1 in 338</td>
<td>1 in 179</td>
</tr>
<tr>
<td>36 years</td>
<td>1 in 259</td>
<td>1 in 149</td>
</tr>
<tr>
<td>37 years</td>
<td>1 in 201</td>
<td>1 in 124</td>
</tr>
<tr>
<td>38 years</td>
<td>1 in 162</td>
<td>1 in 105</td>
</tr>
<tr>
<td>39 years</td>
<td>1 in 133</td>
<td>1 in 81</td>
</tr>
<tr>
<td>40 years</td>
<td>1 in 84</td>
<td>1 in 64</td>
</tr>
<tr>
<td>41 years</td>
<td>1 in 69</td>
<td>1 in 49</td>
</tr>
<tr>
<td>42 years</td>
<td>1 in 52</td>
<td>1 in 39</td>
</tr>
<tr>
<td>43 years</td>
<td>1 in 37</td>
<td>1 in 31</td>
</tr>
<tr>
<td>44 years</td>
<td>1 in 38</td>
<td>1 in 24</td>
</tr>
<tr>
<td>45 years</td>
<td>1 in 32</td>
<td>1 in 19</td>
</tr>
</tbody>
</table>

Although the risk to an individual pregnancy increases with age, about half of the occurrences of Down syndrome and other chromosomal abnormalities are in babies of women under the age of 35 who comprise a much greater proportion (80%) of women giving birth.

Table 2  Chromosomal abnormalities among birth defect cases by maternal age, NSW 2002

<table>
<thead>
<tr>
<th>Maternal age</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25</td>
<td>32</td>
<td>7.4</td>
</tr>
<tr>
<td>25-29</td>
<td>42</td>
<td>9.7</td>
</tr>
<tr>
<td>30-34</td>
<td>79</td>
<td>18.2</td>
</tr>
<tr>
<td>35-39</td>
<td>87</td>
<td>20.0</td>
</tr>
<tr>
<td>40+</td>
<td>60</td>
<td>13.8</td>
</tr>
<tr>
<td>Not Stated</td>
<td>135</td>
<td>31.0</td>
</tr>
<tr>
<td>Total</td>
<td>435</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: NSW Birth Defects Register, Centre for Epidemiology and Research, NSW Department of Health
Note: Includes terminations of pregnancy, livebirths and stillbirths

3. Consent and provision of information on prenatal screening and testing

It is recognised that not all women will want to use prenatal screening or diagnostic tests. Any test undertaken should be consented to on the basis of provision of full relevant information. It is important that women/couples considering prenatal screening or diagnostic testing make an informed choice appropriate to them and free from coercion. They should have access to written information on the tests, their implications and their risks (see resources listed in Appendix 2). The relative advantages, disadvantages and limitations of the available tests should be discussed with the woman or couple prior to testing as part of general counselling and support. Discussion should include:

- information on the conditions being screened for
- the timing of testing
- the importance of accurate gestation dates
- the risk to the woman of having an affected offspring
- test performance information based on the audit figures of the local providers of prenatal screening services
- that a screening test alone does not identify any birth defect but indicates a risk only
- interpretation of both increased and low risk screening results. Women must be informed about their residual risk.
- the impact of an increased risk result and the options available for definitive diagnosis, such as amniocentesis.
- the impact on a woman and her family of a false negative or false positive result
- the time frame for receiving results and making further decisions if necessary
- long term implications for the person and their family of having an affected baby and the health and development issues for children with the condition.

Women at increased risk should have access to consultation with an individual or centre able to provide both counselling and prenatal diagnosis procedures. (See Appendix 4 for contact details.) Full information about the risks of amniocentesis and chorionic villus sampling should be provided (See Section 5).
Appendix 1 provides general information for testing for all genetic disorders including:

- Professional experience
- Duty to inform
- Educational resources (listed in Appendix 2)
- Pre-test counselling
- Consent
- Individuals and families from culturally and linguistically diverse backgrounds
- Post-test counselling

4. **Prenatal screening for Down syndrome and other chromosomal abnormalities**

The following policy has been developed to inform health care providers about the tests available and their effectiveness, so that women can be helped to make informed decisions and be given appropriate care.

The policy is based on the data currently available on the performance of screening tests. However, prenatal screening tests continue to evolve and providers need to ensure their information is up-to-date.

4.1 **Women at increased risk**

Women considered at increased risk for chromosome errors, ie those with an indicative previous history or who will be 35 years or older at estimated date of confinement; should be offered prenatal screening or diagnostic testing as an integral part of management. Offers of screening or testing should be accompanied by sufficient information and counselling to help women choose and consent to testing on an informed basis and to be aware of the potential ramifications of entering into the screening process (see Section 3).

**First trimester screening tests for women presenting between 10 to 14 weeks of pregnancy:**

- First trimester screening using combination of maternal age, ultrasound nuchal translucency measurement (NTS) and serum screening tests (free β-hCG and PAPP-A).
- A detection rate of up to 90% with up to 5% false positive results should be achieved.
- Women should be sure of their gestational age based on a known LMP and regular pre-conception menstrual cycle. In the event of any uncertainty about gestational age a pre-test ultrasound examination is optimal.
- Only accredited operators - Fetal Medicine Foundation (FMF) or Nuchal Translucency - Ultrasound, Education and Monitoring Project (NT-UEMP) should perform nuchal translucency (NT) screening (see Section 8).
- The first trimester combined screening risk provided to women is calculated automatically ‘at the gestation at screening’, not ‘at term’, since up to a third of pregnancies affected by Down syndrome spontaneously abort between 10-40 weeks gestation.

**Second trimester screening tests for women presenting between 15 to 18 weeks of pregnancy:**

- Second trimester triple screening using maternal age, maternal serum screening (free βhCG, AFP and unconjugated estriol).
17. OBSTETRICS

- A detection rate of at least 60% with up to 5% false positive results should be achieved. About 40% of babies with Down syndrome will therefore be missed using this test.

Management of high-risk screening results

All women receiving a high-risk test result should be provided with adequate post-test counselling. The level of counselling support needed may vary with the type of result and the resources of the referring practitioner to deal with the issues surrounding an abnormal result. Abnormal screening test results should be dealt with as urgent clinical problems requiring early referral to an individual or centre able to provide both counselling and diagnostic procedures for prenatal diagnosis (see Appendix 3 for a list of services). Full information about the risks of amniocentesis and chorionic villus sampling should be provided (see Section 5). Referral to family doctor, the Association for Genetic Support of Australasia (AGSA) and support networks should be included.

Collection and transport of maternal serum specimens for 1st and 2nd trimester screening

A minimum of 3 mls of serum is required. The blood sample can be drawn at a collecting pathology service and sent immediately to the laboratory. It may be refrigerated for up to 24 hours or frozen if longer.

Laboratories offering maternal serum testing should provide request forms detailing the information that must be provided for accurate interpretation of the test result. This will include at least:

- Gestational age by dating scan.
- Patient’s age - it is most important that this be clearly and correctly stated on the referral form.
- Patient’s weight.
- Patient’s height.
- Whether the patient is an insulin dependent diabetic.
- Previous history of Down syndrome and other chromosomal abnormalities.
- Patient’s suburb and postcode.
- A signed referral form that specifies the test(s) to be performed.

4.2 Women not in the increased risk category (above)

Women not in the increased risk category, ie no previous history and under the age of 35 years at estimated date of confinement should be informed about screening tests and given appropriate risk information by their doctor or midwife (see Section 2, Table 1 - Risk by age of Down syndrome and other chromosomal abnormalities risks) and informed of the availability and potential cost of screening tests.

For further information contact:

Information on prenatal screening for all women is available from:
Centre for Genetics Education
PO Box 317
ST LEONARDS NSW 1590
Tel: 02 9926 7324
Fax: 02 9906 7529
Website: [http://www.genetics.edu.au/](http://www.genetics.edu.au/)

Prenatal Testing - Special tests for your baby during pregnancy
A note on second trimester ultrasound at 18 - 20 weeks gestation

For all women, ultrasound assessment of markers of chromosomal abnormality in the second trimester is not recommended as a primary screening test for Down syndrome (see section 7).

5. Prenatal diagnosis using amniocentesis, chorionic villus sampling and fetal blood sampling to determine the fetal karyotype.

These are invasive tests which pose a risk of miscarriage (of less than 1%) in addition to the “background risk” of miscarriage due to natural causes. It is important to discuss this. After the age of 35 the risk of Down syndrome rises rapidly so the risk of a Down syndrome affected pregnancy becomes greater than the risk of miscarriage associated with amniocentesis and chorionic villus sampling (CVS) procedures.

Prenatal diagnostic services should be made available to:
- Women of 35 years and over at date of confinement.
- Women who have a screening test for Down syndrome which suggests increased risk.
- Women who have had a child with a neural tube defect.
- Women determined to be at high risk for a neural tube defect in light of first or second trimester screening.
- Other women who have a high risk of a fetus with a genetic or chromosomal disorder which may be detectable by prenatal diagnosis.

Additional clinical and counselling issues

It is recommended that where practical patients are counselled face to face at least one day before the procedure with the opportunity to clarify information and options. This may not be possible in some situations. Telephone counselling through the local genetics service may provide an alternative. Counselling should address:
- criteria for access to procedures and choice between CVS and amniocentesis;
- a clear and simple explanation of the probability of an affected fetus;
- stage of pregnancy when the procedure should be undertaken;
- explanation of the process of the procedure:
  - amniocentesis
  - trans-abdominal CVS
  - trans-vaginal CVS
  - fetal blood sampling
- the risk of pregnancy complications including a risk of miscarriage (of less than 1%) in addition to the “background risk” of miscarriage due to natural causes;
- waiting time for results and how they will be conveyed;
- the possibility that the procedure may not be successful;
- the possibility that laboratory testing of specimens obtained may fail;
- the laboratory analysis may not accurately reflect the fetal status and in rare cases this can lead to incorrect interpretation of results;
- options to be considered if the result is abnormal;
- acknowledgement of the individual nature of decisions about continuing or terminating the pregnancy;
- methods of termination of pregnancy;
17. OBSTETRICS

- A normal result on amniocentesis, chorionic villus sampling or fetal blood sampling means that within the diagnostic limitations of the test, the fetus is not affected for the disorder being tested. It does not exclude the possibility that the child may have birth defects and/or mental retardation due to other causes. It is important that health professionals ensure that people are fully informed about their residual risk;
- the implications of a multiple pregnancy;
- the possibility of unexpected results which are difficult to interpret eg a chromosome marker;
- costs involved and how they are to be met.

NB Abnormal results should be reported to the NSW Birth Defects Register (see Appendix 1-1.8).

Consent

A template consent form is attached at Appendix 3.

Collection and transport of specimens:
- Specimens should be collected under optimum conditions including type of specimen tube and conditions for sample storage during transport.
- Specimen tubes are to be labelled with the full name and date of birth of the person being tested. It would be preferable if the patient could sign the tube containing their specimen.
- Patient’s suburb and postcode should be included on the test request form.
- The specimen must be accompanied by a signed referral form that specifies the test(s) to be performed.
- The transport of specimens is to occur at times agreed to by the testing laboratory.
- The time frame for receiving results should be estimated with advice from the testing laboratory.
- DNA testing - A copy of the completed consent form should be forwarded to the testing laboratory with the specimen.

Quality Assurance

- Effective communication between the clinician and the testing laboratory regarding requirements is essential to achieving optimum specimen quality.
- Laboratories should be NATA accredited or should participate in an appropriate quality assurance program performing sufficient numbers of tests relevant to the area of investigation.
- Where prenatal testing is to be performed on DNA from chorionic villus tissue on cells, it would be advisable to also test the sample and parental DNA samples to rule out maternal contamination.

6. Serum alpha fetoprotein testing for neural tube defects

Neural Tube Defects

Neural tube defects (NTD) include anencephaly, spina bifida and encephalocele and occur in about 1 in 800 births. The incidence is increased among women who:
- have a neural tube defect;
- have had a previous child or pregnancy with NTD;
- have a close family history of NTD;
- have insulin-dependent diabetes;
- are taking specific anticonvulsant medications;
- are obese.
These women should be offered genetic counselling.

**Note on Folate**
Approximately 70% of cases of neural tube defects can be prevented by increased folate intake at least one month before and continuing for the first three months of pregnancy. See Appendix 2 for further information on pamphlets.

**Serum Alpha Fetoprotein (AFP) Testing**
AFP testing is a voluntary and optional prenatal test which gives a risk assessment for neural tube defects. **It is not a diagnostic test.** An elevated level of serum AFP signifies an increased risk for neural tube defects. Elevated AFP is also associated with other causes such as multiple gestation or threatened miscarriage and indicates the need for follow up procedures such as ultrasound or an amniocentesis.

**Timing**
The optimal time for AFP testing is between 15 and 18 weeks of gestation.

**Sensitivity and specificity**
The high risk cut off point is normally set at 2.5 MOM so that for every 10 pregnancies identified at high risk, one will have spina bifida.

**Collection and transport of specimens**
A minimum of 3 mls of serum is required. The blood sample can be drawn at a collecting pathology service and sent immediately to the laboratory. It may be refrigerated for up to 24 hours or frozen if longer.

Laboratories offering serum alpha fetoprotein testing should provide request forms detailing the information that must be provided for accurate interpretation of the test result. This will include at least:
- Gestational age by dating scan.
- Patient’s age - it is most important that this be clearly and correctly stated on the referral form.
- Patient’s weight.
- Patient’s height.
- Whether the patient is an insulin dependent diabetic.
- Whether the patient is taking anticonvulsant medication.
- Multiple pregnancy (if known).
- Previous history of neural tube defects.
- Patient’s suburb and postcode.
- A signed referral form that specifies the test(s) to be performed.

**7. Prenatal screening and diagnosis by fetal imaging**
Ultrasound has become a routine part of prenatal care and may be done at any stage during the pregnancy. It may be used as either a screening or a diagnostic test.

Parents often view the ultrasound as an opportunity to bond with the fetus and may not have given consideration to the prospect of an adverse result. When an abnormality is detected, care should be taken to provide counselling and emotional support to minimise the impact of the result on the woman and her family.
It is recommended that providers of fetal imaging services develop and implement protocols for managing counselling issues associated with the detection of abnormalities. Important elements would include:

- counselling by obstetricians, ultrasound staff, referring doctor and other health professionals prior to routine ultrasound, concerning possible outcomes and management strategies;
- training of ultrasound technologists in management strategies in the event of an abnormality being detected;
- ensuring abnormal results are conveyed in a supportive, informative and timely manner to reduce unnecessary anxiety associated with the diagnosis;
- ensuring appropriate tertiary referral for women when an abnormality is detected, e.g. referral to genetic counselling and fetal medicine units, and follow-up by family doctor and support networks such as the Association of Genetic Support of Australasia (AGSA).

NB Abnormal results should be reported to the NSW Birth Defects Register (see Appendix 1-1.8).

Second trimester ultrasound at 18 – 20 weeks gestation

For all women, ultrasound assessment of markers of chromosomal abnormality in the second trimester is not recommended as a primary screening test for Down syndrome. However, if women have not had the opportunity to have a prior screening test, the second trimester ultrasound may be used to indicate an increased or decreased risk for Down syndrome based on the presence or absence of markers of aneuploidy. This scan has poor sensitivity and specificity for aneuploidy.

8. Professional experience, audit, quality assurance and monitoring

Users of services should be provided with accurate and current information on the numbers of pregnancies screened, the detection rate, and the screen positive rate. Ideally, providers should contribute data to a central body to facilitate pooling of data and allow for external scrutiny of results.

Women’s understanding of and satisfaction with the screening methods, counselling and associated procedures ideally should be assessed so that appropriate information and education can be offered.

Standards for laboratories providing Down Syndrome Screening services

Laboratories should have internal audit and external QA through UK National External Quality Assessment Schemes (UK NEQAS) as well as accreditation with the National Association of Testing Authorities (NATA).

Ultrasound

All procedures should be performed by experienced operators who have appropriate training. Nuchal translucency screening should only be performed by trained operators, using a risk-assessment program that incorporates NT, crown-rump length (CRL) and maternal age. Accreditation should be either through the Fetal Medicine Foundation UK or through the Nuchal Translucency - Ultrasound, Education and Monitoring Project (NT-UEMP) administered through the Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

All ultrasound providers have to be audited at least six monthly by the NT-UEMP.
Providers of prenatal diagnosis by amniocentesis, chorionic villus sampling or fetal blood sampling

Amniocentesis, chorionic villus sampling and fetal blood sampling should be performed in a prenatal diagnosis service where the operator(s) have sufficient training and annual experience of the procedure to keep the complication rate as low as possible. There is evidence that fetal loss rate is multifactorial eg maternal age, gestation and operator experience.

Providers should have an established relationship with a fetal medicine unit, and have ready access to appropriate genetic counselling in the fields of cytogenetics, molecular genetics and biochemical genetics. This association does not necessarily imply that an individual practitioner is geographically located at a hospital containing a fetal medicine unit.

Providers should participate in quality assurance activities and contribute to the statistics of a fetal medicine unit with regard to sampling success rate, proportion of abnormalities detected, fetal loss rate and other complications. They should participate in clinical audit procedures of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

Providers should have demonstrated adequate training and experience in prenatal diagnostic procedures. A minimum level of experience for amniocentesis would be at least 100 procedures in training and 50 per year. A minimum for chorionic villus sampling is at least 100 procedures in training and 50 per year. Fetal blood samplings should only be performed in fetal medicine units.

Minimum qualifications would be FRANZCOG, FRANZCR, DDU or equivalent, with appropriate invasive prenatal diagnosis training.
General information for testing for all genetic disorders

1.1 Professional Experience

It is important that health professionals involved with the use of genetic tests and procedures have adequate knowledge and experience to achieve a high standard of service. Health professionals need to be aware of their own professional limitations and of the availability of others with specific expertise. It will sometimes be necessary to transfer responsibility to, or consult with clinical geneticists, fetal medicine specialists, obstetricians trained in prenatal diagnosis procedures, genetic counsellors or other appropriate specialists.

1.2 Duty to Inform

The outcome of genetic testing can have a significant impact not only on the individual being tested but also on other members of their families. Testing should only be undertaken when the individual has been fully informed about the purpose of the test or the procedure and the possible implications of the results.

1.3 Consent

The person being tested must be legally competent to give consent; must consent freely without coercion by professional staff, family members, employers, insurers or others; and must be adequately informed about all relevant issues including available future options.

The person may withdraw consent at any time.

1.4 Educational Resources

A variety of resources is available to assist with patient education (see Appendix 2 for details).

1.5 Pre-test counselling

Testing should be accompanied by pre and post test counselling carried out by a health professional, knowledgeable about:

- the genetic disorder being tested
- genetic risk assessment and pre-test counselling
- the features or limitations of the laboratory test
- interpretation of results and post-test counselling
- implications of positive and negative results, and
- options available on the outcome of testing.

The way the health professional gives information should help a patient understand the testing process and purpose. The health professional should:

- communicate information and opinions in a form that the patient can understand;
- counsel without coercion; the patient is free to accept or reject the advice or the test;
- allow the patient sufficient time to make a decision, reflect on opinions, ask more questions and consult with the family, within the time constraints of the test;
- encourage the patients to make their own decisions.
1.6 Post-test counselling

Careful consideration should be given to the way results are conveyed. The health professional should take this opportunity to explain again the implications of the result.

1.6.1 Normal Result:

Where the sensitivity of a test is less than 100%, a low risk result will not indicate the absence of a genetic disorder. It is therefore important that health professionals ensure that people are fully informed about their residual risk.

1.6.2 Abnormal Result:

Notification of an abnormal result may precipitate a crisis and the person may for some time be unable to absorb any information. Appropriate pre-test counselling will help to reduce post-test anxiety. Post-test counselling must be offered and follow up support may require several consultations. Counselling should be sensitive to the nature of decisions to be taken, should respect individual decisions and allow time to reach decisions. Appropriate follow-up when an abnormality is detected may require referral to genetic counselling services, other professional services or support networks.

When an abnormality is detected women should be offered appropriate follow-up eg. referral to genetic counselling, family doctor and support networks such as the Association of Genetic Support of Australasia (AGSA).

1.7 Individuals and families from culturally and linguistically diverse backgrounds

Professional interpreter services should be used. The interpreter should not be a member of the family.

1.8 NSW Birth Defects Register

All abnormal results identified by prenatal testing and postnatal testing in the first year of life should be notified to the NSW Birth Defects Register of the NSW Health Department. For further information see http://www.health.nsw.gov.au/policies/pd/2012/PD2012_055.html

1.9 Quality Assurance

Quality assurance should be undertaken to achieve optimum results and quality care.

1.10 Exception to pre-test counselling requirements

Pre-test counselling requirements are not usually applicable to certain routine haematology, biochemistry, biochemical genetic tests, although testing may lead to diagnosis of a genetic condition. Information should be made available prior to newborn screening and other population screening tests. Counselling should be offered if a result is abnormal.
Resources

1. **Centre for Genetics Education**
   PO Box 317
   ST LEONARDS NSW 1590

   Tel: 02 9926 7324
   Fax: 02 9906 7529
   http://www.genetics.edu.au/

   The following publications are available:
   - Prenatal Testing: Special tests for your baby during pregnancy
   - Screening Tests for Your Baby in Early Pregnancy (Consumer and Professional versions available)
   - The Maternal Serum Test
   - Genetic Services and counselling: Why knowing about your genes is important to your future
   - Ultrasound - Obstetric care for pregnant women
   - Prenatal Diagnosis and Counselling - Importance of checking your baby’s health before birth
   - The Importance of Your Family Health Information (Consumer and Professional versions available)
   - When your baby has a problem: How to manage the weeks ahead
   - Diagnosis Of Abnormality In An Unborn Baby, The Impact, Options and Afterwards
   - Folate pamphlet
   - Tests to protect your baby - newborn screening
   - The Genetics Resource Book

2. **Multicultural Resources Available from Multicultural Health Communication Services**

   The following publications available in a variety of languages other than English

   - Prenatal Testing - Special tests for your baby during pregnancy
   - Ultrasound Examination Preparation
   - How can Genetic Counselling Help?
   - Bringing up children with Down Syndrome
   - Questions Women ask about Abortion
     http://www.mhcs.health.nsw.gov.au
3. **The NSW Department of Health**
   - Having a baby - free to all women at their first antenatal booking appointment at a public hospital. Also available on the NSW Health website at [http://www.health.nsw.gov.au](http://www.health.nsw.gov.au)

   - Amniocentesis and Chorionic Villus Sampling (CVS) - a Guide on Prenatal Diagnostic Procedures
   - Antenatal Care and Routine Tests During Pregnancy - a Guide for Women
   - Prenatal Screening Tests for Down Syndrome and Other Conditions
   - Why Aren’t All Babies Perfect?

5. **AGSA**
   **Association of Genetic Support of Australasia Inc.**
   66 Albion Street
   SURRY HILLS NSW 2010
   Tel: 02 9211 1462
   Fax: 02 9211 8077
   Email: agsa@ozemail.com.au
   Web: [http://www.agsa-geneticsupport.org.au](http://www.agsa-geneticsupport.org.au)

6. **The Down Syndrome Association of NSW**
   PO Box 2356
   North Parramatta NSW 1750
   Tel: 02 9683 4333
   Fax: 02 9683 4020
Consent Form for Prenatal Diagnosis

This form has been designed to ensure that your consent is on an informed basis. Please read and consider each section.

(Name of Hospital)

<table>
<thead>
<tr>
<th>Genetic File No.</th>
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**PART A**

PART A of this form must be completed by the health professional for all patients requesting prenatal diagnosis whether they have the procedure or not.

**PROVISION OF INFORMATION TO PATIENT**

To be completed by Health Professional

I, ___________________________ have informed this patient as detailed below including the nature, likely results, and risks of the prenatal diagnosis procedure.

- The procedure involves a risk of causing pregnancy complications including miscarriage.
- There is a possibility that the procedure may not be successful.
- There is a possibility that laboratory testing of specimens obtained may fail.
- The laboratory analysis may not accurately reflect the fetal status and in some instances this can lead to incorrect interpretation of the results.
- A normal result from this test means that, within the diagnostic limitations of the test, the fetus is not affected for the disorder being tested. It does not exclude other abnormalities.
- No assurance has been given that any particular doctor will perform this procedure.

Interpreter present Yes/No

__________________________________________  ___________________________  _____________
Signature of Interpreter                      Signature of Health Professional    Date

**PART B**

**PATIENT CONSENT**

To be completed by Patient

Insert name of Proceduralist and I have discussed the consequences and procedures involved in prenatal diagnosis.

☐ I understand that undergoing the procedure carries risks.
☐ I have had the opportunity to ask questions.
☐ I am satisfied with the explanation and the answers to my questions.
☐ I understand that I may withdraw my consent.

I request and consent to ___________________________ and accept the risks involved in the procedure.

Insert name of Procedure

__________________________________________  ___________________________  _____________
Signature of Patient                          Print name of Patient             Date
### Fetal Medicine Services in Public Hospitals Associated with Clinical Genetics Services

<table>
<thead>
<tr>
<th>Location</th>
<th>Hospital and Department</th>
<th>Address</th>
<th>Phone</th>
<th>Fax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Camperdown</td>
<td>Royal Prince Alfred Hospital, Department of Molecular and Clinical Genetics, Building 65, Level 6 Missenden Road, Camperdown NSW 2050</td>
<td>Ph: (02) 9515 5080, Fax: (02) 9550 5389</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kogarah</td>
<td>St George Hospital, Women and Children’s Health Gray Street, Kogarah NSW 2217</td>
<td>Ph: (02) 9350 3635, Fax: (02) 9350 3694</td>
<td></td>
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</tr>
<tr>
<td>Liverpool</td>
<td>Liverpool Hospital, Fetal Medicine Unit, Locked Bag 7103 Liverpool BC NSW 1871</td>
<td>Ph: (02) 9828 5631, Fax: (02) 9828 5570</td>
<td></td>
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</tr>
<tr>
<td>Newcastle</td>
<td>John Hunter Hospital, Maternal and Fetal Medicine, Locked Bag 1, Hunter Region Mail Centre Newcastle, NSW 2310</td>
<td>Ph: (02) 4921 4694, Fax: (02) 4921 3133</td>
<td></td>
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</tr>
<tr>
<td>Penrith</td>
<td>Nepean Hospital, Perinatal Ultrasound, Level 3 South Block, Derby Street Penrith NSW 2751</td>
<td>Ph: (02) 4734 2578, Fax: (02) 4737 3206</td>
<td></td>
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</tr>
<tr>
<td>Randwick</td>
<td>Royal Hospital for Women, Maternal/Fetal Medicine, Barker Street, Randwick, NSW 2031</td>
<td>Ph: (02) 9382 6098, Fax: (02) 9382 6706</td>
<td></td>
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</tr>
<tr>
<td>St Leonards</td>
<td>Royal North Shore Hospital, Fetal Medicine Unit, Pacific Highway, St Leonards NSW 2065</td>
<td>Ph: (02) 9926 6478, Fax: (02) 9926 7880</td>
<td></td>
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</tr>
<tr>
<td>Westmead</td>
<td>The Children’s Hospital, Department of Clinical Genetics, Locked Bag 4001, Westmead NSW 2145</td>
<td>Ph: (02) 9845 3273, Fax: (02) 9845 3204</td>
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### General Clinical Genetics and Genetic Counselling Services

#### Metropolitan Centres

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<tbody>
<tr>
<td>Camperdown</td>
<td>Royal Prince Alfred Hospital, Department of Molecular and Clinical Genetics, Missenden Road, Camperdown NSW 2050</td>
<td>Ph: (02) 9515 5080 Fax: (02) 9550 5389</td>
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</tr>
<tr>
<td>Kogarah</td>
<td>St George Hospital, Kogarah NSW 2217</td>
<td>Ph: (02) 9113 3635 Fax: (02) 9113 3694</td>
<td></td>
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</tr>
<tr>
<td>Liverpool</td>
<td>Liverpool Health Services, Clinical Genetics Department, Locked Bag 7103, Liverpool BC 1871</td>
<td>Ph: (02) 9828 4665 Fax: (02) 9828 4650</td>
<td></td>
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</tr>
<tr>
<td>Newcastle</td>
<td>Newcastle Western Suburbs Hospital, Hunter Genetics, PO Box 84, Waratah NSW 2298</td>
<td>Ph: (02) 4985 3100 Fax: (02) 4985 3105</td>
<td></td>
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</tr>
<tr>
<td>Penrith</td>
<td>Nepean Hospital Clinical Genetics Department, Penrith NSW 2750</td>
<td>Ph: (02) 4734 3362 Fax: (02) 4734 2561</td>
<td></td>
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</tr>
<tr>
<td>Randwick</td>
<td>The Sydney Children’s Hospital Department of Medical Genetics, High St, Randwick NSW 2031</td>
<td>Ph: (02) 9382 1704 Fax: (02) 9382 1711</td>
<td></td>
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<tr>
<td>St Leonards</td>
<td>Royal North Shore Hospital St Leonards NSW 2065</td>
<td>Ph: (02) 9926 6478 Fax: (02) 9926 7880</td>
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<tr>
<td>Westmead</td>
<td>The Children’s Hospital Department of Clinical Genetics, Westmead NSW 2145</td>
<td>Ph: (02) 9845 3273 Fax: (02) 9845 3204</td>
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### Regional Centres

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<tbody>
<tr>
<td>Bathurst</td>
<td>Community Health Centre PO Box 1479 Bathurst NSW 2795</td>
<td>(02) 6339 5677</td>
<td>(02) 6339 5655</td>
</tr>
<tr>
<td>Broken Hill</td>
<td>Greater Western Area Health Service Community Health Centre, PO Box 457, Broken Hill NSW 2880</td>
<td>(02) 8080 1554</td>
<td>(02) 8080 1611</td>
</tr>
<tr>
<td>Coffs Harbour</td>
<td>Primary Health Service Coffs Harbour Health Campus Locked Mail Bag 812, Cnr High &amp; Boambee Sts, Coffs Harbour NSW 2450</td>
<td>(02) 6656 7200</td>
<td>(02) 6656 7203</td>
</tr>
<tr>
<td>Forster</td>
<td>Forster Community Health Centre Breeze Pde, Forster NSW 2428</td>
<td>(02) 6555 6822</td>
<td>(02) 6554 8874</td>
</tr>
<tr>
<td>Gosford</td>
<td>Child And Family Health Gateway Centre, PO Box 361, Gosford NSW 2250</td>
<td>(02) 4328 7994</td>
<td>(02) 4328 7925</td>
</tr>
<tr>
<td>Goulburn</td>
<td>CIFTS, Locked Bag 15, Goulburn NSW 2580</td>
<td>(02) 4827 3950</td>
<td>(02) 4827 3958</td>
</tr>
<tr>
<td>Kempsey</td>
<td>C/- North Coast Area Health Service Community Health Centre, Morton Street, Port Macquarie NSW 2444</td>
<td>(02) 6588 2882</td>
<td>(02) 6588 2800</td>
</tr>
<tr>
<td>Mudgee</td>
<td>Macquarie Area Health Service PO Box 29, Mudgee NSW 2850</td>
<td>(02) 6378 6236</td>
<td>(02) 6372 7341</td>
</tr>
<tr>
<td>Muswellbrook</td>
<td>Community Health Centre Brentwood Street, Muswellbrook NSW 2333</td>
<td>(02) 6542 2050</td>
<td>(02) 6542 2005</td>
</tr>
<tr>
<td>North Coast</td>
<td>Lismore Base Hospital PO Box 419, Lismore NSW 2480</td>
<td>(02) 66250 111</td>
<td>(02) 66250 102</td>
</tr>
<tr>
<td>Port Macquarie</td>
<td>North Coast Area Health Service Community Health Centre, Morton Street, Port Macquarie NSW 2444</td>
<td>(02) 6588 2882</td>
<td>(02) 6588 2800</td>
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<tr>
<td>Tamworth</td>
<td>Community Health Centre 180 Peel Street, Tamworth NSW 2340</td>
<td>(02) 6767 8100</td>
<td>(02) 6766 3967</td>
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<tr>
<td>Taree</td>
<td>Community Health Centre 22 York Street, Taree, NSW 2430</td>
<td>(02) 6592 9703</td>
<td>(02) 6592 9607</td>
</tr>
<tr>
<td>Wagga Wagga</td>
<td>Wagga Wagga Base Hospital, Cnr Edward and Docker Sts, Wagga Wagga NSW 2650</td>
<td>(02) 6938 6666</td>
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### Familial Cancer Services

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<td>Camperdown</td>
<td>Royal Prince Alfred Hospital, Department of Molecular and Clinical Genetics, Missenden Rd, Camperdown NSW 2050</td>
<td>(02) 9515 5080</td>
<td>(02) 9550 5389</td>
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<tr>
<td>Darlinghurst</td>
<td>St Vincent’s Hospital, Family Cancer Clinic, Victoria Rd, Darlinghurst NSW 2011</td>
<td>(02) 8382 3395</td>
<td>(02) 8382 3386</td>
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<tr>
<td>Kogarah</td>
<td>St George Hospital, Hereditary Cancer Clinic, Cancer Care Centre, Gray St, Kogarah, NSW 2217</td>
<td>(02) 9350 3815</td>
<td>(02) 9350 3958</td>
</tr>
<tr>
<td>Westmead</td>
<td>Westmead Hospital, Familial Cancer Service, Department of Medicine, Westmead NSW 2145</td>
<td>(02) 9845 6947</td>
<td>(02) 9687 2331</td>
</tr>
<tr>
<td>Newcastle</td>
<td>Hunter Family Cancer Service, PO Box 84, Waratah NSW 2298</td>
<td>(02) 4985 3132</td>
<td>(02) 4985 3133</td>
</tr>
<tr>
<td>Penrith</td>
<td>Nepean Hospital, Clinical Genetics Department, Level 5 South Block, PO Box 63, Penrith NSW 2750</td>
<td>(02) 4734 3362</td>
<td>(02) 4734 2567</td>
</tr>
<tr>
<td>Randwick</td>
<td>Prince of Wales Hospital, Hereditary Cancer Clinic, High St, Randwick NSW 2031</td>
<td>(02) 9382 2551</td>
<td>(02) 9382 2588</td>
</tr>
<tr>
<td>St Leonards</td>
<td>Royal North Shore Hospital, Family Cancer Service, Level 2, Vindin House, St Leonards NSW 2065</td>
<td>(02) 9926 5665</td>
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17. OBSTETRICS

Genetics Education Services

<table>
<thead>
<tr>
<th>Centre for Genetics Education</th>
<th>PO Box 317, St Leonards NSW 1590</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ph: (02) 9926 7324, Fax: (02) 9906 7529</td>
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Association for Genetic Support of Australasia (AGSA)

<table>
<thead>
<tr>
<th>AGSA</th>
<th>66 Albion Street, SURRY HILLS NSW 2010</th>
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</thead>
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<tr>
<td></td>
<td>Ph: (02) 9211 1462, Fax: (02) 9211 8077</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:agsa@ozemail.com.au">agsa@ozemail.com.au</a></td>
</tr>
<tr>
<td></td>
<td>Web: <a href="http://www.agsa-geneticsupport.org.au">http://www.agsa-geneticsupport.org.au</a></td>
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Medications in pregnancy and lactation service (NSW)

<table>
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<tr>
<th>Mothersafe</th>
<th>Medications in Pregnancy and Lactation Service, Royal Hospital for Women High St, Randwick, NSW 2031</th>
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<tbody>
<tr>
<td></td>
<td>Ph: (02) 9382 6539 or 1800 647 848</td>
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Birth Defects Register (NSW)

<table>
<thead>
<tr>
<th>NSW Birth Defects Register</th>
<th>Centre for Epidemiology and Research, NSW Health Department, Locked Mail Bag 961, North Sydney NSW 2061</th>
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<tr>
<td></td>
<td>Ph: (02) 9424 5829 Fax: (02) 9391 9232</td>
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Genetics of Learning Disability Service (GOLD)

<table>
<thead>
<tr>
<th>GOLD</th>
<th>Hunter Genetics, PO Box 84, WARATAH NSW 2298</th>
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<tr>
<td></td>
<td>Ph: (02) 4985 3131, Fax: (02) 4985 3133</td>
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References


64(2/08)
Introduction

Many genetic tests provided by NSW public hospital laboratories are non-Medical Benefits Schedule items funded through NSW Health. The charging policy for these tests is addressed in Policy Directive PD2005_335. Further, the Policy Directive requires testing to be assessed and prioritised according to clinical necessity.

The attached guidelines have been developed to assist clinicians/health services to prioritise genetic test requests based on clinical need, equity of access and within available funding levels.

Background


"Area Health Services are to meet the cost of testing from within their global budget allocation for clinically/medically required specialised genetic testing for non-Medicare Benefits Schedule items for:

- admitted public patients;
- non-admitted public patients; and,
- privately referred non-inpatients referred to a public sector specialist clinic.


Specialised tests for genetic disorders refers to tests which are non Medicare Benefits Schedule items performed by public hospital laboratories and funded by the NSW Health System. The costs of tests are generally in the range of $100 to $2000 per test, and more in rare instances. These tests are used to:

- diagnose a genetic disorder, including a prenatal diagnosis;
- determine if a person is a mutation carrier for a disorder; or
- detect an inherited predisposition to a genetic disorder.

Local arrangements are to be negotiated concerning clinical responsibility for authorising testing as well as budget responsibilities for approving test requests. This would most appropriately rest with the head of a clinical genetics unit or delegated staff member. Referral to public sector genetics services will provide the patient with clinical geneticist expertise not generally available in the private sector. It will not guarantee testing, as it will need to be assessed and prioritised according to clinical necessity."

Guidelines for prioritising genetic tests

To assist health services/clinicians prioritise genetic tests within available funding levels, the Genetic Services Advisory Committee (GSAC), NSW Department of Health, in association with Heads of Clinical Genetics Units has developed a priority system as a guide to appropriate genetic testing based on clinical need and equitable access. The charging of genetic tests is to be in accordance with the policy outlined in the above-mentioned policy directives.
High Priority

1. **Prenatal Testing**
   - Where the confirmation of a clinical diagnosis by molecular testing will assist parents who may use the information in making reproductive choices.
   - Where the confirmation of the clinical diagnosis will enable treatment options to be instituted which might be early in the newborn period.
   - Where gonadal mosaicism is recognised to occur frequently (e.g. Osteogenesis Imperfecta with a risk of 3 - 4%)

2. **Diagnostic Testing**
   - When confirmation of a clinical diagnosis will restore reproductive confidence in the family.
   - When confirmation of a clinical diagnosis will lead to changes in management of an affected person.
   - Where a diagnostic test can lead to predictive testing of other at-risk family members.
   - To confirm a clinical diagnosis where it is relevant for screening for disease complications.
   - To confirm a clinical diagnosis where it is relevant for funding purposes e.g. extra aid at school.

3. **Carrier Testing**
   - Where the patient has had genetic counselling and is aware of a high likelihood of being a carrier based on family history or ethnicity and the patient has accepted the advantages and limitations of carrier testing.
   - When there are prenatal diagnosis implications for a family because of a known family history.
   - Where one partner is a known carrier of a recessive condition and carrier testing of the other partner may lead to the possibility of prenatal diagnosis and accurate reproductive counselling.

4. **Presymptomatic and Predictive Testing**
   - Where there is a known family history of a disorder and mutation is known.
   - Where there is definitive testing available and there is a family history of the disorder, i.e. Huntington disease.

Low Priority

1. **Prenatal Testing**
   - Where confirmation of a clinical diagnosis by molecular testing will not alter the reproductive choices or obstetric or perinatal care for the patient.
   - Where there is only a low theoretical risk of gonadal mosaicism.
   - Where there is a recessive condition and there is no need for carrier testing for the new partner who is at a low risk of being a carrier.

2. **Diagnostic Testing**
   - Where the clinical diagnosis is confirmed by other means and genetic testing will not alter the patient’s management or options.
   - Where the test has been requested by the parents or health professionals and the geneticist thinks a diagnosis is unlikely or the test is not clinically indicated.
17. OBSTETRICS

- Where confirmation of the clinical diagnosis by genetic testing will not influence whether prenatal testing is undertaken and or the type of test.
- Where the genetic test will not lead to confirmation or predictive testing of other family members eg no at risk relatives.
- Where confirmation of the clinical diagnosis will not alter screening of potential disease complications.

3. Carrier Testing
- Where the disorder is rare and there is no family history.
- Where the testing will not alter the lifestyle or health options for a person.

4. Presymptomatic and Predictive Testing
- Where there is no family history of the disorder.
- Where the only people to have predictive testing would be children for adult onset disorders.
1. **INTRODUCTION**

Predictive and diagnostic testing using DNA (or sometimes other analytes) is available for a number of adult onset genetic diseases, many of which result in presently incurable illness, dementia and premature death.

**Predictive testing** refers to testing in an individual who currently does not have symptoms or signs of disease, but who may be at risk due to their family history, and who requests more information about their risk.

**Serious adult onset neurogenetic disorders likely to reduce normal life expectancy** include Huntington disease, motor neurone disease, spinocerebellar ataxia and pre-senile dementias.

2. **PREDICTIVE TESTING**

*DNA predictive testing for serious adult onset neurogenetic disorders carried out by NSW Health public hospital laboratories shall only be undertaken when requested by certified clinical geneticists.*

2.1 **Rationale**

This requirement is to ensure that patients receive care according to best practice guidelines (Appendix 1). Taking a predictive DNA test is a major life decision and the results are irreversible. Predictive testing raises a number of complex issues outlined below and it is essential that prior to undertaking testing, the patient is fully informed about the implications of testing and is prepared for the results.

Clinical geneticists requesting predictive testing are required to have expertise in the disorder being tested, the complexities of predictive testing, interpretation of results and their implications and follow-up management strategies. Genetics Service staff work in close liaison with referring practitioners to ensure continuity of care.

2.2 **Offering predictive testing**

Predictive testing is best offered through a team which in addition to a clinical geneticist includes a neurologist, psychiatrist, genetic social worker/genetic counsellor, psychologist and laboratory scientists. A list of genetics services is included as Appendix 2.

The diagnosis in the affected relative should be verified. A baseline neurological consultation should be offered for any person undergoing predictive testing.
2.3 Laboratory requirements

Laboratories will only commence testing on receipt of all information required:

- Information as indicated in the attached request form (Appendix 3).
- A photocopy of the completed consent form (Appendix 4). Completion of the consent form provides the opportunity to address relevant issues in predictive testing.

Laboratories are to keep a list of certified clinical geneticists.

2.4 Results and their implications

A positive test result will indicate that the individual is at high risk of being affected by the disease, although the actual risk varies from disorder to disorder. For example, for Huntington disease a positive test result means that the person will almost definitely develop the condition if they live long enough. The test result may not accurately predict age of onset or severity of the condition. In the case of a positive result, the person should be offered follow-up with the neurologist. Some results are indeterminate or in the intermediate range and require very specialised interpretation. Such results may raise complex psychosocial issues for the individual being tested and their family, and on-going support is often necessary. A positive result may have implications for future reproductive decisions and possible adverse consequences for employment and insurance. The individual should be informed that routine check-ups with an appropriate specialist may be an alternative to a predictive genetic test.

There may be implications for other family members because genetic disorders are inherited. For example, for Huntington disease, a positive predictive test result means that the individual’s children and siblings have a 50% chance of inheriting the mutation. Privacy and confidentiality issues need consideration, particularly the need to balance the right to privacy and confidentiality of the person being tested, with their responsibility to inform other family members, who potentially may suffer harm if their risk status is not disclosed to them.

3. Diagnostic Testing

Neurologists and specialists requesting DNA diagnostic testing for adult onset neurogenetic disorders undertaken by NSW Health Public Hospital Laboratories are reminded that a positive result in diagnostic testing in clinically affected patients will have the same implications for family members as those outlined under predictive testing above. In the case of a positive diagnostic test result it is strongly recommended, that the patient’s family members are offered counselling support and the opportunity for follow-up discussion of their risk with a clinical geneticist (Appendix 2), according to the above guidelines for predictive testing (Appendix 1).

4. Charging Policy

Most of these specialised DNA tests are non Medicare Benefits Schedule Items funded by the NSW Health system. Public or privately referred non-inpatients accessing predictive testing services through a public sector clinical genetics service (Appendix 2), or diagnostic testing through a public sector specialist clinic will be treated as public patients without charge. Private patients will be responsible for their own test costs.
17. OBSTETRICS

Appendix 1

1 BEST PRACTICE GUIDELINES FOR PREDICTIVE AND PRESYMPTOMATIC DNA TESTING

1.1 Genetic Testing, (PD2007_066)

1.2 Genetics http://www.genetics.edu.au/


1.5 Accreditation Standards for Nucleic Acid Detection Techniques (Section 1.2)

1.6 Ethical Code Governing the Provision of Genetics Services
   State Health Publication No (SWS) 980068, ISBN:  0 7313 4036 1

2 DISORDER SPECIFIC GUIDELINES

2.1 Huntington Disease
   http://www.huntington-assoc.com/
Appendix 2

Clinical and Genetic Counselling Service Locations

<table>
<thead>
<tr>
<th>Clinical and Counselling Services</th>
<th>Genetic Counselling Services in conjunction with visiting clinical genetics services</th>
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<tbody>
<tr>
<td><strong>CAMPERDOWN</strong></td>
<td><strong>KOGARAH</strong></td>
</tr>
<tr>
<td>Department of Molecular and</td>
<td>Women's and Children's Health</td>
</tr>
<tr>
<td>Clinical Genetics</td>
<td>2nd Floor Prichard Wing</td>
</tr>
<tr>
<td>Royal Prince Alfred Hospital</td>
<td>St George Hospital</td>
</tr>
<tr>
<td>CAMPERDOWN NSW 2050</td>
<td>Gray Street</td>
</tr>
<tr>
<td>Tel: 02 9315 5000</td>
<td>KOGARAH NSW 2217</td>
</tr>
<tr>
<td>Fax: 02 9315 7595</td>
<td>Tel: 02 9350 2315</td>
</tr>
<tr>
<td></td>
<td>Fax: 02 9350 3901T</td>
</tr>
<tr>
<td><strong>LIVERPOOL</strong></td>
<td><strong>ST LEONARDS</strong></td>
</tr>
<tr>
<td>Department of Clinical Genetics</td>
<td>Fetal Medicine Unit</td>
</tr>
<tr>
<td>Health Services Building</td>
<td>Royal North Shore Hospital</td>
</tr>
<tr>
<td>Cor Campbell and Goulburn Sts</td>
<td>ST LEONARDS NSW 2065</td>
</tr>
<tr>
<td>LIVERPOOL NSW 2170</td>
<td>Tel: 02 9926 6478</td>
</tr>
<tr>
<td>Tel: 02 9828 4665</td>
<td>Fax: 02 9906 1872</td>
</tr>
<tr>
<td>Fax: 02 9828 4650</td>
<td><strong>BATHURST</strong></td>
</tr>
<tr>
<td></td>
<td>Community Health Centre</td>
</tr>
<tr>
<td></td>
<td>138 William Street</td>
</tr>
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<td>BATHURST NSW 2795</td>
</tr>
<tr>
<td></td>
<td>Tel: 6331 5533</td>
</tr>
<tr>
<td></td>
<td>Fax: 6332 2039</td>
</tr>
<tr>
<td><strong>PENRITH</strong></td>
<td><strong>BROKEN HILL</strong></td>
</tr>
<tr>
<td>Nepean Hospital</td>
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<tr>
<td>PENRITH NSW 2750</td>
<td>BROKEN HILL NSW 2880</td>
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<tr>
<td>Tel: 4734 3362</td>
<td>Tel: 08 8080 1556</td>
</tr>
<tr>
<td>Fax: 4734 2567</td>
<td>Fax: 08 8080 1611</td>
</tr>
<tr>
<td><strong>RANDWICK</strong></td>
<td><strong>CANBERRA</strong></td>
</tr>
<tr>
<td>Department of Medical Genetics</td>
<td>The Antenatal Clinic</td>
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<tr>
<td>Sydney Children's Hospital</td>
<td>The Canberra Hospital</td>
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<tr>
<td>RANDWICK NSW 2093</td>
<td>PO Box 11</td>
</tr>
<tr>
<td>Tel: 02 9382 1708</td>
<td>CANBERRA ACT 2605</td>
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<tr>
<td>Fax: 02 9382 1711</td>
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<tr>
<td><strong>WESTMEAD</strong></td>
<td><strong>COFFS HARBOUR</strong></td>
</tr>
<tr>
<td>Department of Clinical Genetics</td>
<td>Coffs Harbour Health Campus</td>
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<td>The New Children's Hospital</td>
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<td>COFFS HARBOUR 2450</td>
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<tr>
<td>Tel: 02 9645 5273</td>
<td>Tel: 6656 7806</td>
</tr>
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<td>Fax: 02 9645 3204</td>
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<td><strong>GOSFORD</strong></td>
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<td>Cor Turton &amp; Tinenee Sts</td>
<td>Public Health Unit</td>
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<tr>
<td>Tel: 4985 3100</td>
<td>GOSFORD NSW 2250</td>
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<tr>
<td>Fax: 4985 3105</td>
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<td><strong>GOUldburn</strong></td>
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<tr>
<td>Child Development Unit</td>
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<td>GOULBURN NSW 2580</td>
<td>GOONELLABAHS NSW 2480</td>
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<td>Tel: 4827 1551</td>
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<td>Tel: 6372 6455</td>
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<td>Tel: 6542 2005</td>
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<tr>
<td><strong>PORT Macquarie</strong></td>
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<tr>
<td>Hastings Macleay Community Health</td>
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</tr>
<tr>
<td>Morven Street</td>
<td>2444</td>
</tr>
<tr>
<td>Tel: 6588 2882</td>
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<td>Fax: 6588 2800</td>
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</table>
TAMWORTH
Community Health Centre
180 Peel Street
TAMWORTH NSW 2340
Tel: 6766 2555
Fax: 6766 3967

TAREE/FORSTER
Community Health Centre
64 Putney Street
TAREE NSW 2430
Tel: 6592 9315
Fax: 6592 9607

WAGGA WAGGA
Wagga Base Hospital
WAGGA WAGGA NSW 2650
Tel: 6938 6303
Fax: 6921 5632

WOLLONGONG
Maternal and Paediatric Services
Wollongong Hospital
Crown Street
WOLLONGONG NSW 2500
Tel: 4222 5216
Fax: 4222 5477

Mothersafe
Statewide Medications in Pregnancy and Lactation Advisory Service
Royal Hospital for Women
RANDWICK NSW 2031
Tel: 02 9382 6539 (Sydney calls)
Tel: 1800 647 648 (Other calls)

AGSA
Association of Genetic Support of Australasia Inc.
66 Allerton Street
SURRY HILLS NSW 2010
Tel: 02 9211 1462
Fax: 02 9211 8077
Email: agsa@ozemail.com.au
Web: www.agsa-geneticsupport.org.au

Prenatal Diagnosis & Counseling
Specialised services:

CAMPERDOWN
Fetal Medicine Unit
King George V Hospital
CAMPERDOWN NSW 2050
Tel: 02 9515 8238
Fax: 02 9515 6579

LIVERPOOL
Fetal Medicine Unit
Liverpool Hospital
Elizabeth Drive
LIVERPOOL NSW 2170
Tel: 02 9828 4145
Fax: 02 9828 4146

RANDWICK
Prenatal Diagnosis
Royal Hospital for Women
RANDWICK NSW 2031
Tel: 9382 6098
Fax: 9382 6706

PENRITH
Fetal Medicine Unit
Nepean Hospital
PENRITH NSW 2750
Tel: 02 4724 3163
Fax: 02 4724 3206

ST LEONARDS
Fetal Medicine Unit
Royal North Shore Hospital
ST LEONARDS NSW 2065
Tel: 02 9926 7280
Fax: 02 9906 1872

WESTMEAD
Fetal Medicine Unit
Westmead Centre
WESTMEAD NSW 2145
Tel: 9845 6802
Fax: 9845 7793

NEWCASTLE
Prenatal Diagnosis Unit
John Hunter Hospital
NEWCASTLE NSW 2310
Tel: 4921 4694
Fax: 4921 3133

Cancer Genetics
Specialised services:

DARLINGHURST
Family Cancer Clinic
Department of Medical Oncology
St Vincent's Hospital
Victoria Street
DARLINGHURST NSW 2010
Tel: 02 8382 3395
Fax: 02 8382 3386

KOGARAH
Cancer Care Centre
St George Hospital
Belgrave Street
KOGARAH NSW 2217
Tel: 02 9350 3815
Fax: 02 9350 3958

LIVERPOOL
Liverpool Hospital
Elizabeth Drive
LIVERPOOL NSW 2170
Tel: 02 9828 4665
Fax: 02 9828 4650

RANDWICK
Hereditary Cancer Clinic
Prince of Wales Hospital
RANDWICK NSW 2031
Tel: 02 9382 2587
Fax: 02 9382 2588

WESTMEAD
Familial Cancer Services
Westmead Hospital
WESTMEAD NSW 2145
Tel: 02 9845 5079
Fax: 02 9617 2221

NEWCASTLE
Hunter Genetics
Cnr Titton & Tionoom Sts
WARATAH NSW 2298
Tel: 4985 3100
Fax: 4985 3105

Further Information:
on services in other areas and newly developed services:
NSW Genetic Education Program
PO Box 217
ST LEONARDS NSW 2055
Tel: 02 9906 7324
Fax: 02 9906 7329
Web: www.genetics.com.au

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**Appendix 3**

**Request Form for Specialised Molecular Genetic/DNA Testing for Genetic Disorders**

- Must be used for non-Medical Benefits Schedule items
- Before testing is commenced, the laboratory may require the following details (see *Guidelines for Specialised DNA Testing for Genetic Disorders* [www.health.nsw.gov.au/publications/publications/pediatric](http://www.health.nsw.gov.au/publications/publications/pediatric))

### Send by courier/express post to:

Send samples at room temperature
Some day OR overnight

### Sample

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Other, specify:

### Test requested

PLEASE ATTACH FAMILY/PEDIGREE INFORMATION

### Purpose of test

- Confirm clinical diagnosis
- Predictive/pre-symptomatic testing
- Carrier Status
- Prenatal Diagnosis - complete box below
- Determine feasibility of prenatal Dx
- Family study (no report for this individual)
- For research (no report for this individual)
- Bank DNA until further notice
- Other, specify:

### Pregnancy Information (if applicable)

- Is this individual or the partner of this individual currently pregnant?
  - L.M.P. (dddd/mm/yyyy)
  - Amino (dddd/mm/yyyy)
  - CVS (dddd/mm/yyyy)

### Family Information

- Have samples from this family been sent to this DNA lab before?
  - Yes
  - No
- Date of birth or age
- Ethnic background

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<td>MRN</td>
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<td>Address</td>
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<tr>
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<td>MRN</td>
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<table>
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</table>

### Genetic Counselling

Has the individual been offered counseling consistent with [Specialised/DNA Testing for Genetic Disorders](http://www.health.nsw.gov.au/publications/publications/pediatric)?
- Yes
- No
- Refused

### Consent to Testing

Has a Consent Form for Specialised/DNA Testing been completed?
- Yes
- No

### Payment of test cost

- Public patient - Payment to be made by Area Health Service by arrangement (see over)
- Privately referred non-patient - Payment to be made by Area Health Service by arrangement (see over)
- Private patient - Payment to be made by patient

### Comments

### Test requested by:

- Name
- Initials
- Address
- Postcode
- Telephone No
- Signature
- Date

### Specialty/Appointment

### Copy of report to:

- Name
- Initials
- Address
- Postcode
- Telephone No
Appendix 4

Consent form for predictive and diagnostic DNA testing for serious adult onset neurogenetic disorders with predictive implications for other family members

This form has been designed to ensure that your consent is on an informed basis. Please read and consider each section.

<table>
<thead>
<tr>
<th>Title</th>
<th>Family Names</th>
<th>MRN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Given Name</td>
<td>VH0</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td>Street</td>
<td>DOB</td>
</tr>
<tr>
<td>Suburb</td>
<td>Postcode</td>
<td>Admission Date</td>
</tr>
</tbody>
</table>

PROVISION OF INFORMATION TO PATIENT

To be completed by Health Professional

I, ___________ have informed this patient as detailed below

the nature, likely results, and risks associated with gene testing for ___________ name of disorder

 Interpreter present: Yes/No

_________________________ Signature of Interpreter
_________________________ Signature of Health Professional
_________________________ Date

PATIENT CONSENT

To be completed by Patient/Guardian

__________ and I have discussed predictive testing

testing for the analysis of the gene fault (mutation) for ___________ name of disorder

He/she has told me that:

- The collection of blood will be used to examine my DNA and tested for the gene involved in ___________

- A positive test result indicates that I have inherited a faulty gene (mutation). This means that I am at high risk of developing ___________ name of disorder and my children and siblings have a ___________% chance of inheriting the mutation ___________ name of disorder percentage

- A positive test result cannot accurately predict the age of onset of the disorder.

- A negative test result means that I have not inherited the faulty gene (mutation). I will not develop ___________ name of disorder and cannot pass it on to my children

- An intermediate result means that I may or may not develop ___________ name of disorder

- In some instances this may have implications for my siblings and children and their descendants
• Test results of one individual can change the estimation of risk for other family members and I have been advised to inform other adult family members who may be at risk.
• The test result may affect the ability to obtain some types of insurance or employment.
• Testing may reveal non-paternity or non-maternity of a presumed natural parent
• Genetic counseling will be available for myself and other family members during the testing process and after the test result has been given.

I have been told about storage of the test results and the DNA sample. I understand the following:
• The test result will be held by this centre and will only be known by those involved in the testing process.
• My own test result, the fact that I have had a test, and my DNA sample will not be revealed or made available to any other person or organisation outside of the testing process, except with my written consent (as detailed below), or in situations where disclosure is required by law.
• The test results will be given to me first.
• The DNA sample will remain the property of the laboratory. It will be stored in good faith, but its suitability for future use cannot be guaranteed. It will be disposed of at a time determined by standard laboratory practices or regulatory requirements.
• My identified DNA sample will not be used for any other purpose except in accordance with my written consent (as detailed below).

I request and consent to the test described above.

I understand the potential benefits of testing and storing this sample and I accept the risks involved. I have had the chance to ask questions and am satisfied with the explanations and the answers to my questions.

I understand that I may withdraw my consent for this test to be processed.

I consent to my test results being revealed at any time to the following people:

☐ Any family member
☐ Only to the following individuals (specify) __________________________________________
☐ My doctor(s) (specify) _________________________________________________________
☐ No other individual
☐ In the event of my death test results may be made known to: __________________________

After testing has been completed:
☐ I consent to my de-identified DNA sample being used for future Institutional Ethics Committee approved research
☐ My DNA sample may not be used for research without my written consent

_____________________________ _______________________________ ________________  
Signature of Patient/Guardian Print name of Patient Date

Explanation of terms used in this consent form
• A gene test involves analysis of one or more of those genes to determine whether a mutation is present
• Mutation: Change in the normal DNA code which may cause disease
• DNA (Deoxyribonucleic acid): The chemical compound of which the genes are made
MOTHERNESS - MANAGEMENT OF HYPERTENSIVE DISORDERS OF PREGNANCY (PD2011_064)


PURPOSE

This policy provides direction to NSW maternity services, Emergency Departments, Ambulance Service of NSW and retrieval services regarding the management of hypertensive disorders of pregnancy. The NSW Maternal and Perinatal Committee and the NSW Maternal and Perinatal Health Priority Taskforce have endorsed The Guidelines for the Management of Hypertensive Disorders of Pregnancy 2008 issued by the Society of Obstetric Medicine of Australia and New Zealand and it is now issued as NSW Health policy.

MANDATORY REQUIREMENTS

All NSW Public Health Organisations providing maternity services and/or emergency department services must have clinical practice guidelines and protocols for the management of hypertensive disorders of pregnancy based on this policy directive.

Ambulance Service of NSW and all other retrieval services must also have protocols for the management of hypertensive disorders of pregnancy based on this policy directive.

IMPLEMENTATION

The Chief Executives of Local Health Districts and the Ambulance Service of NSW are ultimately responsible for the implementation of this policy directive within their respective facilities.

1. BACKGROUND

1.1 About This Document

Hypertension disorders of pregnancy are common affecting approximately 6% of pregnancies. Hypertensive disorders of pregnancy are associated with increased maternal and perinatal morbidity and mortality. Previous guidance regarding the detection, investigation and management of hypertension, the use of intravenous hydralazine in severe hypertension, and the use of magnesium sulphate for eclamptic seizure prophylaxis was provided in separate policy documents. The primary reference for all three documents was a consensus statement from the Australasian Society for the Study of Hypertension in Pregnancy. This document has since been replaced by the Guidelines for the Management of Hypertensive disorders of Pregnancy 2008 compiled by the Society of Obstetric Medicine of Australia and New Zealand. These guidelines form the basis of this policy directive.

1.2 Key Definitions

Hypertension in pregnancy is defined as:
1. Systolic blood pressure greater than or equal to 140 mmHg and/or
2. Diastolic blood pressure greater than or equal to 90 mmHg (Korotkoff 5)
These measurements should be confirmed by repeated readings over several hours.

Severe hypertension in pregnancy is defined as:
1. Systolic blood pressure greater than or equal to 170 mmHg and/or
2. Diastolic blood pressure greater than or equal to 110 mmHg.

White Coat Hypertension is defined as:
Hypertension in a clinical setting with normal blood pressure away from this setting when assessed by 24 hour ambulatory blood pressure monitoring or home blood pressure monitoring using an appropriately validated device.

Pre-eclampsia is defined as:
Hypertension that arises after 20 weeks gestation and is accompanied by one or more of the following:
- Renal involvement:
  - Significant proteinuria - dipstick proteinuria subsequently confirmed by spot urine protein/creatinine ratio ≥ 30mg/mmol. In view of the close correlation between spot urine protein/creatinine ratio and 24 hour urine excretion, the latter is rarely required.\(^{(21)}\)
  - Serum or plasma creatinine > 90 μmol/L
  - Oliguria
- Haematological involvement
  - Thrombocytopenia
  - Haemolysis
  - Disseminated intravascular coagulation
- Liver involvement
  - Raised serum transaminases
  - Severe epigastric or right upper quadrant pain.
- Neurological involvement
  - Convulsions (eclampsia)
  - Hyperreflexia with sustained clonus
  - Severe headache
  - Persistent visual disturbances (photopsia, scotomata, cortical blindness, retinal vasospasm)
  - Stroke
- Pulmonary oedema
- Fetal growth restriction
- Placental abruption

Gestational hypertension is defined as:
The new onset of hypertension after 20 weeks gestation without any maternal or fetal features of pre-eclampsia, followed by return of blood pressure to normal within 3 months post-partum.

Chronic or essential hypertension is defined as:
A blood pressure > 140 mmHg systolic and/or > 90mm diastolic confirmed before pregnancy or before 20 completed weeks gestation without a known cause.

Pre-eclampsia superimposed on chronic hypertension is diagnosed when:
One or more of the systemic features of pre-eclampsia develop after 20 weeks gestation in a woman with chronic hypertension.
2. DEFINITION OF HYPERTENSION IN PREGNANCY

Normal pregnancy is characterized by a fall in blood pressure, detectable in the first trimester and usually reaching a nadir in the second trimester. Blood pressure rises towards pre-conception levels towards the end of the third trimester.

**Hypertension** in pregnancy is defined as:
1. Systolic blood pressure greater than or equal to 140 mmHg and/or;
2. Diastolic blood pressure greater than or equal to 90 mmHg (Korotkoff 5).

These measurements should be confirmed by repeated readings over several hours.

Elevations of both systolic and diastolic blood pressures have been associated with adverse fetal outcome and therefore both are important.\(^1\) There are several reasons to support the blood pressure readings above as diagnostic of hypertension in pregnancy:
- Perinatal mortality rises with diastolic blood pressures above 90 mmHg;\(^2\)
- Readings above this level were beyond two standard deviations of mean blood pressure in a New Zealand cohort of normal pregnant women\(^3\); and
- The chosen levels are consistent with international guidelines and correspond with the current diagnosis of hypertension outside of pregnancy.

Detecting a rise in blood pressure from ‘booking’ or preconception blood pressure (> 30/15 mmHg), rather than relying on an absolute value, has in the past been considered useful in diagnosing pre-eclampsia in women who do not reach blood pressures of 140 or 90 mmHg. Available evidence however, does not support the notion that these women have an increased risk of adverse outcomes.\(^4,5\) Nevertheless such a rise may be significant in some women, particularly in the presence of hyperuricaemia and proteinuria. Further data are required and in the meantime, closer monitoring of pregnant women with an increment in blood pressure of ≥30 mmHg systolic and/or 15 mmHg diastolic is appropriate.

**Severe hypertension** in pregnancy is defined as a systolic blood pressure greater than or equal to 170 mmHg and/or diastolic blood pressure greater than or equal to 110 mmHg. This represents a level of blood pressure above which cerebral autoregulation is overcome in normotensive individuals. It is generally acknowledged that severe hypertension should be lowered promptly, albeit carefully, to prevent cerebral haemorrhage and hypertensive encephalopathy.\(^6\) This degree of hypertension therefore requires urgent assessment and management. It is important to acknowledge that systolic as well as diastolic hypertension increases the risk of cerebral haemorrhage. Certain experts have recommended lowering the cut-off for the definition of severe systolic hypertension to 160 mmHg. For now, in the absence of definitive data, the above definition should be retained as a clinically useful cut-off value to initiate urgent treatment (see Management of pre-eclampsia and gestational hypertension).

**White Coat Hypertension** is defined as hypertension in a clinical setting with normal blood pressure away from this setting when assessed by 24 hour ambulatory blood pressure monitoring or home blood pressure monitoring using an appropriately validated device. Women with this condition present early in pregnancy with apparent chronic hypertension, but their outcomes are better than those of women with true chronic hypertension. They may generally be managed without medication by using repeated ambulatory or home blood pressure monitoring. A small proportion will go on to develop pre-eclampsia.\(^7\)
3. RECORDING BLOOD PRESSURE IN PREGNANCY

The woman should be seated comfortably with her legs resting on a flat surface. In labour, the blood pressure may be measured in the left arm in lateral recumbency. The supine posture should be avoided because of the supine hypotension syndrome. Measurement of blood pressure should be undertaken in both arms at the initial visit to exclude rare vascular abnormalities such as aortic coarctation, subclavian stenosis and aortic dissection. Generally the variation in blood pressure between the upper limbs should be less than 10 mmHg.

The systolic blood pressure is accepted as the first sound heard (K1) and the diastolic blood pressure the disappearance of sounds completely (K5). Where K5 is absent, K4 (muffling) should be accepted. Correct cuff size is important for accurate blood pressure recording. A large cuff with an inflatable bladder covering 80% of the arm circumference should be used if the upper arm circumference is greater than 33 cm. This helps to minimise over-diagnosis of hypertension during pregnancy.

3.1 Measurement Devices

Mercury sphygmomanometers remain the gold standard for measurement of blood pressure in pregnancy however occupational health concerns are limiting their availability. Automated blood pressure recorders have provided major advantages for treatment and diagnosis of hypertension in the general community and they have been advocated for use in pregnant women. Few studies have compared these self-initiated devices with mercury sphygmomanometry in pregnant women. While such automated devices may give similar mean blood pressure values to those obtained with mercury sphygmomanometry, there is wide intra-individual error and their accuracy may be further compromised in pre-eclamptic women. Aneroid sphygmomanometers are also prone to error. Each unit should maintain a mercury sphygmomanometer for validation of automated and aneroid devices. All devices should be calibrated on a regular basis (ideally monthly), as recommended by the British Hypertension Society.

3.2 Twenty Four Hour Ambulatory Blood Pressure Monitoring (ABPM)

Normal blood pressure values recorded by ABPM have been established for different stages of pregnancy. ABPM is useful in the evaluation of early (< 20 wks gestation) hypertension where approximately one third of these women will be shown to have “white coat” or “office” hypertension. About half of these women will not require antihypertensive medication in pregnancy, while the other half develops true (ABPM confirmed) hypertension. ABPM is less useful in screening for white coat hypertension in the second half of pregnancy. Twenty four hour ABPM has also been shown to predict those women at risk of developing hypertension later in pregnancy but its sensitivity and specificity for this purpose is low.

4. CLASSIFICATION OF HYPERTENSIVE DISORDERS IN PREGNANCY

This classification of the hypertensive disorders in pregnancy reflects the pathophysiology of the constituent conditions as well as the risks and potential outcomes for both mother and baby. The following clinical classification modifies only slightly that proposed in the ASSHP consensus statement of 2000. It has subsequently been adopted by the International Society for the Study of Hypertension in Pregnancy (ISSHP). In endorsing this classification the ISSHP committee examined the classifications proposed by the ASSHP, the National High Blood Pressure Education Programme (NHBPEP) in the United States as well as earlier published criteria.
4.1 Pre-eclampsia

Pre-eclampsia is a multi-system disorder unique to human pregnancy characterised by hypertension and involvement of one or more other organ systems and/or the fetus. Raised blood pressure is commonly but not always the first manifestation. Proteinuria is the most commonly recognised additional feature after hypertension but should not be considered mandatory to make the clinical diagnosis. As this classification is based on clinical data, it is possible that women with another condition will sometimes be classified incorrectly as having pre-eclampsia during pregnancy. This is not usually a clinical problem as the diagnosis of pre-eclampsia should lead to increased observation and vigilance which is appropriate for conditions which may mimic pre-eclampsia. A diagnosis of pre-eclampsia can be made when hypertension arises after 20 weeks gestation and is accompanied by one or more of the following:

- **Renal involvement**
  - Significant proteinuria - dipstick proteinuria subsequently confirmed by spot urine protein/creatinine ratio
  - $\geq 30\, \text{mg/mmol}$. In view of the close correlation between spot urine protein/creatinine ratio and 24 hour urine excretion, the latter is rarely required.\(^{(21)}\)
  - Serum or plasma creatinine $> 90\, \mu\text{mol/L}$
  - Oliguria

- **Haematological involvement**
  - Thrombocytopenia
  - Haemolysis
  - Disseminated intravascular coagulation

- **Liver involvement**
  - Raised serum transaminases
  - Severe epigastric or right upper quadrant pain.

- **Neurological involvement**
  - Convulsions (eclampsia)
  - Hyperreflexia with sustained clonus
  - Severe headache
  - Persistent visual disturbances (photopsia, scotomata, cortical blindness, retinal vasospasm)
  - Stroke

- **Pulmonary oedema**

- **Fetal growth restriction**

- **Placental abruption**

**Notes:**

1. Oedema is not included in the diagnostic features of pre-eclampsia. It is a common feature of normal pregnancy and severe pre-eclampsia may be present in the absence of any oedema. Nevertheless rapid development of generalised oedema should alert the clinician to screen for pre-eclampsia.

2. Other rare disorders may present with some of the features of pre-eclampsia.\(^{(22)}\) Disorders such as acute fatty liver of pregnancy, haemolytic uremic syndrome, thrombotic thrombocytopenic purpura, exacerbation of systemic lupus erythematosus or cholecystitis may need to be excluded.

3. Rarely pre-eclampsia presents before 20 weeks gestation\(^{(23)}\), usually in the presence of a predisposing factor such as hydatidiform mole, multiple pregnancy, fetal triploidy, severe renal disease or antiphospholipid antibody syndrome.

4. Dipstick testing for proteinuria is a screening test with very high false positive and negative rates. The use of automated dipstick readers can significantly improve detection of proteinuria.\(^{(24)}\) Although ideally all women with hypertension should have a urine protein/creatinine ratio performed; in practice, dipstick readings of ‘nil’ or ‘trace’ are unlikely to be significant. The presence of urinary tract infection should also be excluded.
5. Hyperuricaemia is a common but not diagnostic feature of pre-eclampsia; the degree of hyperuricaemia may correlate with fetal risk although some studies have questioned this. A rapidly rising plasma uric acid over a few days in the setting of hypertension usually indicates worsening pre-eclampsia, often in the presence of other markers of deterioration.

6. Serum transaminase levels are reduced in pregnancy (by approximately 20%) and the upper limits of normal should be based on local reference ranges.

7. The HELLP syndrome (Haemolysis, Elevated Liver enzymes and a Low Platelet count) represents a particular presentation of severe pre-eclampsia and separating it as a distinct disorder is not helpful.

8. Microangiopathic haemolysis although infrequent may cause a sudden fall in haemoglobin and the appearance of fragmented red blood cells on the blood film. It is accompanied by a rise in bilirubin and lactate dehydrogenase, as well as thrombocytopenia and elevated liver enzymes, sometimes with the appearance of red or black urine. This diagnosis should be considered after a fall in haemoglobin when there has been insufficient revealed bleeding to account for the anaemia. Despite this, anaemia is more often due to obstetric bleeding in these cases, including occult intra-abdominal haemorrhage.

9. Pre-eclampsia is a frequent cause of migrainous symptoms in pregnancy, the commonest cause in pregnancy of cerebral haemorrhage, and the only cause of eclampsia. Other rare neurological complications include cerebral haemorrhage, cerebral oedema, cortical and sinus vein thrombosis, retinal detachment and central serous retinopathy.

The above classification is a clinical one. Although it is recognised that women with pre-eclampsia may not show proteinuria for research purposes a more homogeneous group will be represented by women with both hypertension and proteinuria as this is less open to clinical interpretation and error.

The ISSHP research definition of pre-eclampsia is as follows:

• De novo hypertension after 20 weeks gestation, returning to normal postpartum; and
• properly documented proteinuria.

4.2 Gestational Hypertension

Gestational hypertension is characterised by the new onset of hypertension after 20 weeks gestation without any maternal or fetal features of pre-eclampsia, followed by return of blood pressure to normal within 3 months post-partum. At first presentation this diagnosis will include some women (up to 25%) who are in the process of developing pre-eclampsia but have not yet developed proteinuria or other manifestations. Some women initially diagnosed in this category will manifest persistent blood pressure elevation beyond 12 weeks post-partum and eventually be classified as having chronic hypertension.

Gestational hypertension near term is associated with little increase in the risk of adverse pregnancy outcomes. The earlier the gestation at presentation and the more severe the hypertension, the higher is the likelihood that the woman with gestational hypertension will progress to develop pre-eclampsia or an adverse pregnancy outcome. Severe hypertension (≥ 170/110mmHg) is associated with increased risk of adverse outcomes in pregnancy.

4.3 Chronic Hypertension

Essential hypertension is defined by a blood pressure > 140 mmHg systolic and/or > 90mm diastolic confirmed before pregnancy or before 20 completed weeks gestation without a known cause. It may also be diagnosed in women presenting early in pregnancy taking antihypertensive medications where no secondary cause for hypertension has been determined. Some women with apparent essential hypertension may have white coat hypertension (raised blood pressure in the presence of a clinical attendant but normal blood pressure otherwise as assessed by ambulatory or home blood pressure monitoring). These women appear to have a lower risk of superimposed pre-eclampsia than women with true essential hypertension but are still at an increased risk compared with normotensive women.
Important secondary causes of chronic hypertension in pregnancy include:

- Chronic kidney disease e.g. glomerulonephritis, reflux nephropathy, and adult polycystic kidney disease.
- Renal artery stenosis.
- Systemic disease with renal involvement e.g. diabetes mellitus, systemic lupus erythematosus.
- Endocrine disorders e.g. phaeochromocytoma, Cushing’s syndrome and primary hyperaldosteronism.
- Coarctation of the aorta.

In the absence of any of the above conditions it is likely that a woman with high blood pressure in the first half of pregnancy has essential hypertension. It is not possible to investigate these disorders fully during pregnancy, and complete appraisal may need to be deferred until after delivery.

4.4 Pre-eclampsia Superimposed on Chronic Hypertension

Pre-existing hypertension is a strong risk factor for the development of pre-eclampsia. Superimposed pre-eclampsia is diagnosed when one or more of the systemic features of pre-eclampsia develop after 20 weeks gestation in a woman with chronic hypertension. In women with pre-existing proteinuria, the diagnosis of superimposed pre-eclampsia is often difficult as pre-existing proteinuria normally increases during pregnancy. In such women substantial increases in proteinuria and hypertension should raise suspicion of pre-eclampsia but the diagnosis is not secure without the development of other systemic features or fetal growth restriction.

5. INVESTIGATION OF NEW ONSET HYPERTENSION IN PREGNANCY

Any woman presenting with new hypertension after 20 weeks gestation should be assessed for signs and symptoms of pre-eclampsia. Initially, assessment and management in a day assessment unit may be appropriate. However, if features of pre-eclampsia are detected, admission to hospital is indicated. The presence of severe hypertension, headache, epigastric pain or nausea and vomiting are ominous signs which should lead to urgent admission and management, as should any concern about fetal wellbeing.

The following investigations should be performed in all patients:

- Urine dipstick testing for proteinuria, with quantitation by laboratory methods if >‘1+’ (30mg/dL)
- Full blood count
- Urea, creatinine, electrolytes
- Liver function tests
- Ultrasound assessment of fetal growth, amniotic fluid volume and umbilical artery Doppler flow

Notes:

1. Blood test abnormalities should be interpreted using pregnancy-specific ranges, some of which are gestation dependent.
2. If features of pre-eclampsia are present, additional investigations should include:
   - Urinalysis and microscopy on a carefully collected mid-stream urine sample.
   - If there is thrombocytopenia or a falling haemoglobin, investigations for disseminated intravascular coagulation (coagulation studies, blood film, LDH, fibrinogen).
3. Patients with severe early onset pre-eclampsia warrant investigation for associated conditions e.g. systemic lupus erythematosus, underlying renal disease, antiphospholipid syndrome or thrombophilias. The timing of these investigations will be guided by the clinical features.
4. Although a very rare disorder, undiagnosed phaeochromocytoma in pregnancy is potentially fatal and may present as pre-eclampsia. Measurement of fasting plasma free metanephrines/normetanephrines or 24 hour urinary catecholamines should be undertaken in the presence of very labile or severe hypertension. Subsequent management will be based on the results of ongoing blood pressure measurement and these investigations (Tables 1 and 5).
Amongst women referred for assessment of new onset hypertension, a number will have normal blood pressure and investigations. These women are considered to have transient or labile hypertension. Repeat assessment should be arranged within 3-7 days as many will subsequently develop pre-eclampsia.

Table 1: Ongoing investigation of women with hypertension in pregnancy

<table>
<thead>
<tr>
<th>Modality</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Hypertension</td>
<td>Urinalysis for protein Preeclampsia bloods Each visit If sudden increase in BP or new proteinuria</td>
</tr>
<tr>
<td>Gestational Hypertension</td>
<td>Urinalysis for protein Preeclampsia bloods 1 - 2 x per week Weekly</td>
</tr>
<tr>
<td>Preeclampsia</td>
<td>Urinalysis for protein Preeclampsia bloods At time of diagnosis: If non-proteinuric, repeat daily Twice weekly or more frequent if unstable</td>
</tr>
</tbody>
</table>

6. MANAGEMENT OF PRE-ECLAMPSIA AND GESTATIONAL HYPERTENSION

Pre-eclampsia is a progressive disorder that will inevitably worsen if pregnancy continues. Current therapy does not ameliorate the placental pathology nor alter the pathophysiology or natural history of pre-eclampsia. Delivery is the definitive management and is followed by resolution, generally over a few days but sometimes much longer. At mature gestational age, delivery should not be delayed. Even so, it is important to control severe hypertension and other maternal derangements before subjecting the woman to the stresses of delivery.

Prolongation of pregnancy in the presence of pre-eclampsia carries no benefit for the mother but is desirable at early gestations to improve the fetal prognosis as in general, fetal outcome is proportional to gestational age at delivery. In cases of preterm pre-eclampsia before 34 weeks, delivery should be delayed for at least 24-48 hours if maternal and fetal status permit, to allow fetal benefit from antenatal corticosteroids administered for lung maturation. A number of trials\(^{(39-42)}\) have shown that 25-30% of women managed expectantly with pre-eclampsia will develop severe morbidity including HELLP syndrome, abruption, pulmonary oedema and eclampsia and that the mean duration of prolongation is less than 12 days. Continuation also carries fetal risk and some stillbirths will occur despite careful monitoring.\(^{(43)}\) These trials have excluded women with the “HELLP” variant of pre-eclampsia and with other evidence of severe morbidity.

The management of women with pre-eclampsia between gestational ages of 24-32 weeks should be restricted to those centres with appropriate experience and expertise. Clear “endpoints” for delivery should be defined for each patient (Table 2), such that the decision to terminate the pregnancy is based on agreed criteria. In many cases, the timing of delivery will be based upon a number of factors, maternal and/or fetal rather than a single absolute indication for delivery.

A team approach, involving obstetrician, midwife, neonatologist, anaesthetist and physician provides the best chance of achieving a successful outcome for mother and baby. Regular and ongoing reassessment of both the maternal and fetal condition is required. Careful daily assessment for clinical symptoms and signs should be complemented by regular blood and urine tests as indicated (Table 1 and 5).
Table 2: Indications for delivery in women with pre-eclampsia or gestational hypertension

<table>
<thead>
<tr>
<th>Maternal</th>
<th>Fetal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age ≥ 37 weeks</td>
<td>Severe fetal growth restriction</td>
</tr>
<tr>
<td>Inability to control hypertension</td>
<td>Non-reassuring fetal status</td>
</tr>
<tr>
<td>Deteriorating platelet count</td>
<td></td>
</tr>
<tr>
<td>Deteriorating liver function</td>
<td></td>
</tr>
<tr>
<td>Deteriorating renal function</td>
<td></td>
</tr>
<tr>
<td>Placental abruption</td>
<td></td>
</tr>
<tr>
<td>Persistent neurological symptoms - Eclampsia</td>
<td></td>
</tr>
<tr>
<td>Persistent epigastric pain, nausea or vomiting with abnormal liver function tests</td>
<td></td>
</tr>
<tr>
<td>Acute pulmonary edema</td>
<td></td>
</tr>
</tbody>
</table>

The only controlled studies of bed rest for pre-eclampsia have shown no significant maternal or fetal benefit. However, admission to hospital allows close supervision of both mother and fetus as progress of the disorder is unpredictable. Outpatient monitoring may be appropriate in milder cases after a period of initial observation.

6.1 Hypertension

6.1.1 Acute Treatment of Severe Hypertension

Antihypertensive treatment should be commenced in all women with a systolic blood pressure ≥ 170 mm Hg or a diastolic blood pressure ≥ 110 mm Hg because of the risk of intracerebral haemorrhage and eclampsia. Whilst there is no controlled trial to determine how long severe hypertension may be left untreated, it is recommended that treatment be administered promptly aiming for a gradual and sustained lowering of blood pressure.

Drugs for the treatment of very high blood pressure in pregnancy have been the subject of a Cochrane review which concluded that no good evidence exists that any short acting antihypertensive is better than another. Several rapidly acting agents are available to control severe hypertension (Table 3).

There is concern that a precipitous fall in blood pressure after antihypertensive treatment, particularly intravenous hydralazine, may impair placental perfusion resulting in fetal distress. This can be prevented by co-administration of a small bolus of fluid e.g. normal saline 250ml at the time of administration of antihypertensive therapy. Continuous CTG monitoring should be considered in these situations, particularly when there is evidence of existing fetal compromise. However, fetal distress as a result of such treatment is rare.

Table 3: Acute blood pressure lowering for severe hypertension

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Onset of action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labetalol</td>
<td>20-50 mg</td>
<td>IV bolus over 2 minutes</td>
<td>5 mins, repeat after 15-30 mins</td>
</tr>
<tr>
<td>Nifedipine</td>
<td>10-20 mg</td>
<td>Oral</td>
<td>30-45 mins, repeat after 45 mins</td>
</tr>
<tr>
<td>Hydralazine</td>
<td>5-10 mg</td>
<td>IV bolus</td>
<td>20 mins, repeat after 30 mins</td>
</tr>
<tr>
<td>Diazoxide</td>
<td>15-45 mg, max 300mg</td>
<td>IV rapid bolus</td>
<td>3-5 mins, repeat after 5 mins</td>
</tr>
</tbody>
</table>

15 See appendix 1 for principles and method of administration of intravenous hydralazine for severe hypertension in pregnancy
Persistent or refractory severe hypertension may require repeated doses of these agents or even an intravenous infusion of labetalol 20-160 mg/hr or hydralazine 5-10 mg/hr, titrated to the blood pressure response. The concurrent administration of longer acting oral agents (see Table 4) will achieve a more sustained blood pressure lowering effect. Infusions of sodium nitroprusside or glyceryl trinitrate are also effective but are recommended rarely, e.g. when other treatments have failed and delivery is imminent. Sodium nitroprusside may cause fetal cyanide and thiocyanate toxicity and transient fetal bradycardia. Such infusions may be considered with intra-arterial blood pressure monitoring in a high dependency care environment if the usual medications have failed to control the blood pressure, but only so as to effect safe operative delivery and not for prolonged use.

The most important consideration in choice of antihypertensive agent is that the unit has experience and familiarity with that agent. It is recommended that protocols for the management of severe hypertension should be readily accessible in all obstetric units.

6.1.2 Ongoing Treatment for Hypertension

Treatment of hypertension in pregnancy does not cure pre-eclampsia but is intended to prevent cerebral haemorrhage and eclampsia and perhaps delay progression of proteinuria. Uncontrolled hypertension is a frequent trigger for delivery and control of hypertension may allow prolongation of pregnancy. There is controversy regarding the need to treat mild to moderate hypertension in women with pre-eclampsia. In favour of treatment is the fact that blood pressure may be extremely labile in pre-eclampsia and treatment at lower blood pressure levels will prevent or attenuate acute and severe rises in blood pressure. In addition, it is possible that pharmacologic arteriolar vasodilatation may help improve organ perfusion. Arguments against treatment include that there is little risk to the mother in having relatively mild hypertension for a short time (usually only a few days or at the most weeks), that fetal perfusion is dependent upon adequate maternal blood pressure and that lowering blood pressure suppresses an important sign of the severity or progression of pre-eclampsia.

There is as yet no controlled trial of the treatment of mild to moderate hypertension in pregnancy, although a pilot trial of such a study has been completed. One small Australian placebo-controlled randomised study examined the role of antihypertensive therapy in the management of mild hypertension. Placebo-treated women were delivered significantly earlier, mainly as a result of severe hypertension or premonitory signs of eclampsia, and there was more neonatal morbidity secondary to prematurity.

In the absence of compelling evidence, treatment of mild to moderate hypertension in the range 140-160/90-100 mm Hg should be considered an option and will reflect local practice. Above these levels, treatment should be considered mandatory.

In terms of lowering blood pressure in pre-eclampsia, a number of drugs have demonstrated safety and efficacy (Table 4). First line drugs include methyldopa, labetalol and oxprenolol. Second line agents are hydralazine, nifedipine and prazosin. Angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers are contraindicated in pregnancy. Their use in the third trimester has been associated with fetal death and neonatal renal failure. All of the drugs in Table 4 along with enalapril, captopril and quinapril are considered compatible with breastfeeding.

It is important to control severe hypertension at any gestation and post partum. Induction of labour or Caesarean section does not control hypertension even though delivery begins the process of resolution of pre-eclampsia. Thus, antihypertensive medication will usually be required even when delivery has been arranged.
6.1.3 Summary

The intention in treating mild to moderate hypertension is to prevent episodes of severe hypertension and allow safe prolongation of the pregnancy for fetal benefit. It is reasonable to consider antihypertensive treatment when systolic blood pressure reaches 140-160 mmHg systolic and/or 90-100 mmHg diastolic on more than one occasion. If the blood pressure exceeds these levels, antihypertensive therapy should be commenced in all women. In view of this uncertainty, each Unit should develop protocols for the management of hypertension and regularly monitor and audit their outcomes.

Table 4. Guidelines for selecting antihypertensive drug treatment in pregnancy

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Action</th>
<th>Contraindication</th>
<th>Practice points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl dopa</td>
<td>250-75mg tds</td>
<td>Central</td>
<td>Depression</td>
<td>Slow onset of action over 24 hour. Dry mouth, sedation, depression, blurred vision. Withdrawal effect with clonidine</td>
</tr>
<tr>
<td>Clonidine</td>
<td>75-300 µg tds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Labetalol</td>
<td>100-400mg tds</td>
<td>β blocker with mild alpha vasodilator effect</td>
<td>Asthma, chronic airways limitation</td>
<td>Bradycardia, bronchospasm, headache, nausea, scalp tingling which usually resolves within 24-48 hours (labetalol only)</td>
</tr>
<tr>
<td>Oxprenolol</td>
<td>20-160mg tds</td>
<td>β blocker with ISA</td>
<td>Heart block</td>
<td></td>
</tr>
<tr>
<td>Nifedipine</td>
<td>20mg bd–60mg SR bd</td>
<td>Ca channel antagonist</td>
<td>Aortic stenosis</td>
<td>Severe headache associated with flushing, tachycardia</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Peripheral edema, consipation</td>
</tr>
<tr>
<td>Prazosin</td>
<td>0.5 - 5mg tds</td>
<td>α blocker</td>
<td></td>
<td>Flushing, headache, nausea, lupus-like syndrome</td>
</tr>
<tr>
<td>Hydralazine</td>
<td>25-50 mg tds</td>
<td>Vasodilator</td>
<td></td>
<td>Flushing, headache, nausea, lupus-like syndrome</td>
</tr>
</tbody>
</table>

6.2 Treatment of Other Manifestations

6.2.1 Thromboprophylaxis

Pre-eclampsia is a risk factor for thrombosis, particularly in the presence of additional risk factors such as obesity, age above 35 years, previous thrombotic event, family history of thrombosis, nephrotic range proteinuria or likely inpatient stay more than a few days. When women are admitted for observation in hospital they will usually be relatively immobile and graduated compression stockings should be considered, with or without prophylactic low molecular weight heparin (LMWH). Postnatal thromboprophylaxis should be administered to women with pre-eclampsia except where there is a surgical contraindication. Units should have clear protocols to deal with the timing of LMWH administration in regard to the insertion and withdrawal of epidural and spinal cannulae.

6.2.2 Intravenous Fluids

Although maternal plasma volume is often reduced in women with pre-eclampsia there is no maternal or fetal benefit to maintenance fluid therapy. Administration of fluid at a rate greater than normal requirements should only be considered for:
1. Women with severe pre-eclampsia immediately prior to parenteral hydralazine, regional anaesthesia or immediate delivery.
2. Initial management in women with oliguria where there is a suspected or confirmed deficit in intravascular volume.

As vascular permeability is increased in women with pre-eclampsia administration of large volumes of intravenous fluid before or after delivery may cause pulmonary oedema and worsen peripheral oedema. This tendency is further aggravated by hypoalbuminaemia. Appropriate blood product replacement is necessary when there has been haemorrhage, as in cases of placental abruption.

Post-partum oliguria is a regular accompaniment of pre-eclampsia and care must be taken to avoid its over-treatment. Persistent oliguria beyond 24 hours post-partum with rising plasma creatinine suggests the possibility of post partum renal failure. There is no evidence that fluid manipulation is able to prevent this rare complication.

Monitoring in a high dependency care unit is ideal for these cases because of the risk of pulmonary oedema as mentioned above. Invasive monitoring should only be considered when there is developing renal failure or pulmonary oedema. In view of the reduced plasma volume in most women with pre-eclampsia, diuretics should not be used in the absence of pulmonary oedema.

6.2.3 Eclampsia

Eclampsia complicates 1 in 200-300 cases of pre-eclampsia in Australia. There are no reliable clinical markers to predict eclampsia and conversely, the presence of neurological symptoms and/or signs is rarely associated with seizures. Seizures may occur antenatally, intra-partum or postnatally, usually within 24 hours of delivery but occasionally later. Hypertension and proteinuria may be absent prior to the seizure and not all women will have warning symptoms such as headache, visual disturbances or epigastric pain.

The further from delivery that the seizure occurs, the more carefully should other diagnoses be considered. Cerebral venous thrombosis in particular may occur in the first few days of the puerperium. It should be remembered that eclampsia is not the commonest cause of seizures in pregnancy and the differential diagnosis includes epilepsy and other medical problems that must be considered carefully, particularly when typical features of severe pre-eclampsia are lacking.

Management of eclampsia

Comprehensive protocols for the management of eclampsia (and severe hypertension) should be available in all appropriate areas. There are four main aspects to care of the woman who sustains eclampsia.

1. Resuscitation:
Resuscitation requires institution of intravenous access, oxygen by mask, assuring a patent airway and removing regurgitated stomach contents from the mouth/pharynx. These seizures are usually self-limiting. Intravenous diazepam (2mg/minute to maximum of 10mg) or clonazepam (1-2mg over 2-5 minutes) may be given whilst the magnesium sulphate is being prepared if the seizure is prolonged.

2. Prevention of further seizures
Following appropriate resuscitation, treatment should be commenced with magnesium sulphate heptahydrate (4g over 10-15 minutes) followed by an infusion (1-2g/hr). In the event of a further seizure, a further 2-4g of magnesium sulphate heptahydrate is given IV over 10 minutes. Magnesium sulphate is usually given as an intravenous loading dose although the intramuscular route is equally

16 See Appendix 2 for magnesium sulphate infusion notes and example infusion protocols
effective. Monitoring should include blood pressure, respiratory rate, urine output, oxygen saturation and deep tendon reflexes. Magnesium sulphate heptahydrate by infusion should continue for 24 hours after the last fit.\(^\text{(70,71)}\) Magnesium sulphate is excreted renally and extreme caution should be used in women with oliguria or renal impairment. Serum magnesium concentration should be closely monitored in this situation. Magnesium is not universally successful and the recurrence rate of seizures despite appropriate magnesium therapy is 10-15\%.\(^\text{(72)}\)

3. **Control of hypertension**

Control of severe hypertension to levels below 160/100 mmHg by parenteral therapy is essential as the threshold for further seizures is lowered after eclampsia, likely in association with vasogenic brain oedema. In addition, the danger of cerebral haemorrhage is real.

4. **Delivery**

Arrangements for delivery should be decided once the woman’s condition is stable. In the meantime, close fetal monitoring should be maintained. There is no role, with currently available treatment, for continuation of pregnancy once eclampsia has occurred, even though many women may appear to be stable after control of the situation has been achieved.

**Prevention of eclampsia in the woman with pre-eclampsia**

The drug of choice for the prevention of eclampsia is magnesium sulphate given as described above.\(^\text{(71)}\) Although there is good evidence for the efficacy of this therapy, the case for its routine administration in women with pre-eclampsia in countries with low maternal and perinatal mortality rates is less than compelling. In some Units, the presence of symptoms or signs such as persistent headache, hyperreflexia with clonus, epigastric pain or severe hypertension are considered indications for prophylaxis with magnesium sulphate. It is appropriate for individual Units to determine their own protocols and monitor outcomes.

**Hepatic and Haematological manifestations**

Epigastric or right upper quadrant pain in a woman with pre-eclampsia often represents hepatic involvement. The pain responds poorly to analgesia but both the pain and associated increases in liver enzymes (AST, ALT) may subside (albeit temporarily) after blood pressure lowering, particularly with vasodilators. If the cause of epigastric or right upper quadrant pain is not clear, close ongoing assessment is required, with careful review of all indicators of maternal and fetal wellbeing (as above) and appropriate imaging of the liver and gallbladder.

Thrombocytopenia is the commonest hematologic abnormality seen in pre-eclampsia; the lower limit of the normal platelet count in pregnancy is approximately 140 x 10^9/L but the risk of spontaneous bleeding is not significantly increased until the count falls below 50 x 10^9/L. Even so, there are concerns with central neuraxial anaesthetic and analgesic techniques at higher levels (50-75 x 10^9 /L), and surgical bleeding may be increased even with moderate thrombocytopenia.

Platelet transfusion is the only rapidly effective treatment for severe thrombocytopenia and this may be necessary at the time of Caesarean delivery or in the case of postpartum haemorrhage, wound or vulval hematoma or other bleeding as sometimes occurs in these cases. Fresh frozen plasma may be required for management of coagulopathy indicated by active bleeding and a prolonged APTT and INR. In this setting, fibrinogen levels should also be measured and cryoprecipitate administered if levels are low.

Steroid therapy (other than for fetal lung maturation) is not indicated for the management of thrombocytopenia or hepatic dysfunction in women with pre-eclampsia.\(^\text{(73)}\) These abnormalities recover spontaneously postpartum within a few days of delivery, without specific treatment.\(^\text{(74-77)}\) If abnormalities worsen or show no improvement after 72 hours post partum, differential diagnoses such as thrombotic thrombocytopenic purpura or antiphospholipid syndrome should be considered, and appropriate therapy instituted.
7. **FETAL SURVEILLANCE**

Adverse perinatal outcome is increased in women with all subcategories of hypertensive disease in pregnancy as compared to normotensive women.\(^{(78)}\) The increase in adverse outcomes is greatest in those with early gestation at onset of disease, severe hypertension and/or chronic hypertension with superimposed pre-eclampsia.\(^{(78-80)}\) Although fetal surveillance is commonly recommended and performed in women with hypertensive disease in pregnancy\(^{(6,81)}\) there is no established consensus on how this should be performed.\(^{(82,83)}\) Frequency, intensity, and modality of fetal evaluation will depend on individual pregnancy (maternal and fetal) characteristics. Individual obstetric units should devise their own protocols for monitoring the fetus in pregnancies complicated by hypertension. In compiling such protocols, the following issues should be considered.

1. **Accurate dating of pregnancy is important for women with chronic hypertension or those at high risk of pre-eclampsia.**

2. **Symphysis-fundal height measurement is a poor screening tool for detection of fetal growth restriction (FGR).**\(^{(84)}\) Therefore, ultrasound should be performed by an experienced operator to assess fetal size, amniotic fluid volume and umbilical artery Doppler flows in such women. Assessing growth trends by serial ultrasound is recommended if pregnancy continues.

   1. **Umbilical artery Doppler flow is the only fetal surveillance modality that has been shown by systematic review to reduce the need for fetal interventions, improve neonatal outcome and predict adverse perinatal outcome.**\(^{(85,86)}\) Severe early onset FGR should be monitored at institutions experienced in advanced fetal Doppler waveform analysis. Absent or reversed end diastolic flow is unlikely to occur within 7-10 days after a normal umbilical artery Doppler waveform analysis. Umbilical artery Doppler flow studies have limited value after 36 weeks gestation.

   2. **Although numerous observational studies have suggested improved outcome in the high-risk pregnancy monitored using protocols that included Biophysical Profile, cardiotocography, and combinations of both,\(^{(87-89)}\) none of these has shown significant benefit in systematic reviews.\(^{(90,91)}\)**

   3. **No fetal testing can predict an acute obstetric event such as placental abruption or cord accident.**

   4. **Fetal Surveillance via a Day Assessment Unit is associated with good perinatal outcome in women with various obstetric complications, including women with well controlled hypertension.**\(^{(92)}\)

   5. **An appropriately grown fetus in the third trimester in women with well-controlled chronic hypertension without superimposed pre-eclampsia generally is associated with a good perinatal outcome. Fetal monitoring using methods other than continued surveillance of fetal growth and amniotic fluid volume in the third trimester is unlikely to be more successful in preventing perinatal mortality/morbidity.**

Table 5 demonstrates commonly used international and national protocols for fetal surveillance in women with hypertensive disease in pregnancy where immediate delivery is deferred. None of these protocols has been tested in prospective randomised trials, thus they are based only on the opinion and experience of the authors. As pre-eclampsia is an ever changing and unpredictable disease, for those women where expectant management is employed, the frequency and modality of fetal surveillance should be adjusted based on the current maternal and/or fetal condition. Each obstetric unit should develop an agreed institutional approach to fetal surveillance and/or fetal medicine referral.
Table 5. Protocol for fetal surveillance in women with hypertension in pregnancy

<table>
<thead>
<tr>
<th>Hypertension</th>
<th>Modality</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Hypertension</td>
<td>Early dating ultrasound</td>
<td>First trimester</td>
</tr>
<tr>
<td></td>
<td>Ultrasound for fetal growth/AFV/Doppler</td>
<td>3rd trimester: 4 - weekly</td>
</tr>
<tr>
<td>Gestational Hypertension</td>
<td>Ultrasound for fetal growth/AFV/Doppler</td>
<td>At time of diagnosis and 3 - 4 weekly</td>
</tr>
<tr>
<td>Preeclampsia</td>
<td>Ultrasound for fetal growth/AFV/Doppler</td>
<td>At time of diagnosis and 2 - 3 weekly</td>
</tr>
<tr>
<td></td>
<td>Cardiotocography</td>
<td>Twice weekly</td>
</tr>
<tr>
<td>Preeclampsia with FGR</td>
<td>Cardiotocography</td>
<td>Twice weekly</td>
</tr>
<tr>
<td></td>
<td>Doppler/AFV/Fetal growth</td>
<td>On admission and 2 weekly</td>
</tr>
</tbody>
</table>

7.1 Antenatal Corticosteroid Administration

Contrary to popular belief, accelerated fetal lung maturation does not occur in pre-eclampsia. A systematic review has shown that a single course of antenatal corticosteroid given to women expected to deliver preterm reduces the risk of neonatal death, respiratory distress syndrome, cerebrovascular haemorrhage, necrotizing enterocolitis, respiratory support, and intensive care admission. This systematic review showed that infants born to pregnancies complicated by hypertension syndromes treated with corticosteroids had significantly reduced risk of neonatal death, RDS, and cerebrovascular haemorrhage. There is insufficient evidence to support antenatal corticosteroids for those pregnancies that have reached 34 weeks gestation. A recent randomized trial demonstrated a small benefit of antenatal corticosteroids to mothers undergoing a term (37 to 39 weeks gestation) elective Caesarean section. In women with hypertensive disorders of pregnancy undergoing planned Caesarean section after 34 weeks gestation, urgent delivery should not be delayed for the benefits of corticosteroid therapy.

The administration of further courses of corticosteroid in women who remain undelivered and still at risk of preterm birth after an initial course of corticosteroids remains controversial. Until further studies are completed and published, repeated doses of corticosteroids should not be prescribed routinely. If they are considered necessary, the protocol described by Crowther et al should be employed.

8. RESOLUTION OF PRE-ECLAMPSIA

After delivery, all clinical and laboratory derangements of pre-eclampsia recover, but there is often a delay of several days, and sometimes longer, in return to normality. On the first day or two after delivery, liver enzyme elevations and thrombocytopenia will often worsen before they reverse. Hypertension may persist for days, weeks or even up to three months and will require monitoring and slow withdrawal of antihypertensive therapy. Resolution is still assured if the diagnosis was pre-eclampsia and there is no other underlying medical disorder. The woman and her family are often overwhelmed and distressed from their experience and appropriate counselling post partum should include psychological and family support.

All women who develop pre-eclampsia and gestational hypertension are at risk of these disorders in future pregnancies and should receive appropriate counselling before embarking upon another pregnancy.
9. MANAGEMENT OF CHRONIC HYPERTENSION IN PREGNANCY

Hypertension affects up to 20% of the Australian adult population, the prevalence increasing with age. Many women of child-bearing age are hypertensive, and of the 10 to 12% of pregnancies affected by elevated blood pressure levels, at least one in five is related to chronic hypertension. The diagnosis can be difficult in women whose blood pressure before pregnancy or early in the first trimester is unknown. Very rarely pre-eclampsia can present before 20 weeks’ gestation and the physiological fall in blood pressure in the second trimester can obscure pre-existing chronic hypertension.

Women with chronic hypertension have an increased risk of accelerated hypertension in the third trimester, superimposed pre-eclampsia, fetal growth restriction, placental abruption, premature delivery and stillbirth. These events are seen more often in women who develop pre-eclampsia and are not correlated with actual blood pressure levels. The exception to this appears to be uncontrolled hypertension in the first trimester when later fetal and maternal morbidity and mortality are markedly increased. Other indicators of poor prognosis include a failure of blood pressure to normalize in the second trimester, the presence of secondary hypertension, a history of longstanding severe hypertension, and concurrent cardiovascular and/or renal disease.

The woman with chronic hypertension, whether essential or secondary, should be observed frequently during pregnancy by an obstetrician and by a physician familiar with the management of hypertension in pregnancy.

9.1 Investigation

A detailed history, physical examination and appropriate laboratory and cardiac testing are essential in seeking a possible cause for hypertension and to ascertain end-organ damage if present.

Investigation of hypertension presenting prior to 20 weeks gestation:
- All patients:
  - Urinalysis for protein, blood and glucose. If proteinuria is evident on dip-stick analysis, a spot urine protein:creatinine ratio.
  - Microscopy of centrifuged urinary sediment for white and red blood cells (including red cell morphology) and for casts.
  - Mid-stream urine culture.
  - Measurement of serum electrolytes, creatinine, uric acid and blood glucose.
  - Full blood examination.
  - ECG.
- Selected patients:
  - Renal Ultrasound should be considered, particularly if the hypertension is severe.
  - Fasting free plasma metanephrines or 24-hour urine collection for estimation of catecholamine excretion if there is concern regarding a possible pheochromocytoma. At least two consecutive collections are advised.

9.2 Clinical and laboratory monitoring

Because women with chronic hypertension are at high risk of developing pre-eclampsia, close monitoring for its maternal and fetal manifestations is necessary. In addition to standard antenatal care, the following additional monitoring is indicated:
- Monitoring for signs of superimposed pre-eclampsia after 20 weeks gestation.
- Assessment for proteinuria at every visit.
- Laboratory assessment (as above) if worsening hypertension or proteinuria.
- Assessment of fetal growth and wellbeing (Table 5).
Admission to hospital or to a day assessment unit is recommended for women with worsening hypertension or proteinuria at any stage of pregnancy. This enables assessment of maternal and fetal welfare and facilitates discussion amongst all involved in the woman’s care. When necessary, pharmacological treatment may be commenced under close supervision.

9.3 Antihypertensive therapy

The continued administration or initiation of antihypertensive therapy in women with chronic hypertension in pregnancy (except for the acute treatment of severe hypertension) remains controversial. Most women manifest a physiological fall in blood pressure in the first half of pregnancy that may allow withdrawal or a reduction of antihypertensive medication. Although treatment of chronic hypertension is associated with a significant reduction in severe hypertension, it has not been shown to alter the risk of superimposed pre-eclampsia, preterm delivery, placental abruption or perinatal death.\textsuperscript{(109-111)}

There is insufficient evidence upon which to base a definite recommendation for the levels of blood pressure at which antihypertensive drug treatment should commence. We recommend that such treatment should definitely be started when the blood pressure consistently reaches or exceeds 160 mmHg systolic and/or 100 mmHg diastolic.

Treatment at BP levels between 140 and 160 mmHg systolic and/or 90 - 100 mmHg diastolic is also common practice, with good documented outcomes. It is therefore reasonable to treat with antihypertensive medications at these levels, but not below these levels. In the third trimester of pregnancy an increase in the requirement for antihypertensive therapy should be anticipated. The drugs used for treatment of chronic hypertension are the same as those recommended for pre-eclampsia and gestational hypertension (Table 4).

Atenolol and other highly selective beta blocker drugs are not recommended for prolonged use in pregnancy as they have been associated with fetal growth restriction.\textsuperscript{(57,112-113)} The use of ACE-inhibitors and angiotensin receptor blockers is contraindicated in pregnancy. They have been associated with an increased risk of fetal, particularly cardiovascular, malformations in early pregnancy in one study and are known to cause adverse sequelae for the fetus in late pregnancy.\textsuperscript{(114)} Diuretics, although not teratogenic, may restrict the natural plasma volume expansion of pregnancy and are not recommended for the treatment of hypertension.

9.4 Post partum management of women with chronic hypertension

In many women with chronic hypertension or superimposed pre-eclampsia, blood pressure is unstable for 1-2 weeks after delivery and may be difficult to control. It may be particularly high on the third to the sixth day after delivery and it is often necessary to increase or commence antihypertensive medication at that time. All of the agents mentioned earlier are compatible with breast feeding, as are the ACE inhibitors enalapril, captopril and quinapril.

9.5 Chronic hypertension with superimposed pre-eclampsia

As already mentioned, the main risk of chronic hypertension in pregnancy is the development of superimposed pre-eclampsia in the second half of pregnancy which occurs in about 20% of women. This is of considerable concern as the risks to both mother and fetus are greater than those of chronic hypertension alone. Management of superimposed pre-eclampsia should be as outlined above for pre-eclampsia unless specific diagnostic issues, such as some secondary causes of hypertension, are present.
10. ANAESTHETIC CONSIDERATIONS IN HYPERTENSIVE DISORDERS OF PREGNANCY

Whenever possible an anaesthetist should be informed about a woman with severe pre-eclampsia well prior to labour or operative delivery, because appropriate anaesthetic management is associated with reduction in both fetal and maternal morbidity. Relevant issues include anaesthetic risk assessment, blood pressure control, fluid management, eclampsia prophylaxis, and planning of analgesia or anaesthesia.

10.1 Fluid management

Fluid management is a challenging area in pre-eclampsia and there is no clear evidence regarding optimal type or volume of fluid. Fluid therapy aims to maintain organ perfusion in the setting of vasoconstriction, endothelial dysfunction and in some parturients severe left ventricular diastolic dysfunction. Intravenous fluid should be administered incrementally in small volumes (e.g. crystalloid 250 mL) with monitoring of maternal haemodynamics, urine output and fetal heart rate, because overhydration contributes to maternal mortality from pulmonary oedema and adult respiratory distress syndrome. Particular caution is necessary in women with oliguria, renal impairment or pulmonary oedema, in whom the left ventricle may adapt less well to volume load. Fluid loading is not mandatory prior to regional analgesia during labour when low-dose local anaesthetic and opioid methods are used. Prior to regional anaesthesia intravenous crystalloid loading is ineffective in preventing hypotension but colloid is effective. Treatment or prevention of hypotension with drugs such as phenylephrine or metaraminol is effective and appears safe in pre-eclamptic women.

10.2 Anaesthetic technique

10.2.1 Vaginal delivery

For labour and delivery, epidural analgesia is a useful adjunct to antihypertensive therapy for blood pressure control and improves renal and uteroplacental blood flow. When relatively contraindicated (e.g. severe thrombocytopenia, coagulopathy or sepsis), fentanyl or remifentanil patient-controlled intravenous analgesia is preferred. Although ephedrine usually does not cause rebound hypertension occasionally vaspressors and epidural adrenaline (epinephrine) cause worrisome blood pressure elevation. Other drugs that are best avoided in severe pre-eclampsia include ergometrine, ketamine (hypertension); and the non-steroidal anti-inflammatory drugs and COX-2 specific inhibitors (impaired renal function and hypertension). Oxytocin should be given slowly in small doses to minimise its significant hemodynamic effects.

10.2.2 Caesarean section

Unhurried preoperative preparation reduces the risk of anaesthesia in women with pre-eclampsia. Regional anaesthesia is preferred to general anaesthesia (GA) for caesarean section (CS), especially as airway problems including laryngeal oedema may be increased. However, well-conducted GA is also suitable and may be indicated in the presence of severe fetal compromise; pulmonary oedema; hemodynamic instability; intraspinal haematoma risk (e.g. placental abruption; severe thrombocytopenia); or after eclampsia where altered consciousness or neurological deficit persists.

Emergency CS confers increased maternal morbidity, so early anaesthetic notification by the obstetrician and in-utero resuscitation provide additional time for assessment, planning and establishment of regional anaesthesia. When a well-functioning epidural catheter is in situ, GA is achieved only marginally more rapidly than conversion to epidural anaesthesia. Prophylaxis against pulmonary aspiration is recommended using clear antacid and ranitidine, with or without metoclopramide. Skilled anaesthetic assistance is mandatory, as is left lateral tilt on a pelvic displacement wedge or table tilt to minimise aortocaval compression.
Attenuation of pressor responses at general anaesthesia for caesarean section

Laryngoscopy and tracheal intubation present a particularly dangerous time for the pre-eclamptic woman, especially if the intracranial pressure is elevated or the blood pressure is inadequately controlled.\(^\text{128}\) The transient but severe hypertension that usually accompanies intubation can cause myocardial ischemia, cerebral haemorrhage or pulmonary oedema, all being important causes of maternal death.\(^\text{121,128}\) Attenuation of this pressor response is best achieved with additional induction drugs such as remifentanil 1 mcg/kg\(^\text{136,137}\) or magnesium sulphate 40 mg/kg or 30 mg/kg with alfentanil 7.5 mcg/kg.\(^\text{138}\) Neuromuscular block must always be monitored closely after intravenous magnesium administration.\(^\text{139}\) Lignocaine (lidocaine) 1.5 mg/kg is less effective\(^\text{137}\) and fentanyl 2.5-10 mcg/kg or alfentanil 10 mcg/kg of slower onset.\(^\text{140}\) Other drug options are beta-blockers (e.g. esmolol)\(^\text{141}\), hydralazine, glyceryl trinitrate, sodium nitroprusside and diazoxide.

Regional anaesthesia for caesarean section and pre-eclampsia

All the regional anaesthetic techniques (spinal, epidural or combined spinal-epidural) appear safe provided meticulous attention is paid to fluid management, preventing aortocaval compression and dealing with hypotension.\(^\text{116,119}\) Spinal anaesthesia with usual doses is now a recommended technique.\(^\text{119,142,143}\) Cardiac output is well maintained and it is associated with less hypotension and lower vasopressor requirements than among healthy parturients.\(^\text{144}\) Combined spinal-epidural anaesthesia appears to offer further advantages in specific cases.\(^\text{119}\)

Low dose aspirin therapy is not a contraindication to regional techniques, which in the absence of bleeding are considered safe when the platelet count is > 75 x 10⁹/L.\(^\text{145}\) Platelet counts of < 50 x 10⁹/L are generally considered a contraindication. Within the range 50-75 x 10⁹/L an individual assessment (considering patient risks; coagulation tests and thermoelastography or platelet function if available) and risk reduction strategies (experienced operator; single-shot spinal anaesthesia or flexible tip epidural catheter) are encouraged.

10.3 Critical Care

10.3.1 Admission to an Intensive Therapy Unit

Anaesthetists form an important part of the critical care team. Women who develop organ failure require intensive monitoring and medical management, either within a high dependency or intensive care setting. Indications for admission to an intensive therapy unit include severe pulmonary oedema or sepsis; intractable hypertension; anuria or renal failure; repeated convulsions; massive blood loss with disseminated intravascular coagulation; neurological impairment requiring ventilation (e.g. intracerebral haemorrhage or infarction; cerebral oedema); and critical intra-abdominal pathology (e.g. acute fatty liver; liver or arterial aneurysm rupture; adrenal haemorrhage).

10.3.2 Invasive monitoring

Direct intra-arterial blood pressure monitoring is often useful, including during anaesthesia and operative delivery. However, establishing an arterial line should not delay treatment for acute severe hypertension. Central venous pressure correlates poorly with pulmonary capillary wedge pressure and although it may provide trend monitoring it is infrequently used to complement clinical indicators of intravascular volume.\(^\text{116}\) Some recommend pulmonary artery catheters for assessment of left ventricular preload\(^\text{147}\) but they can cause serious complications and are not of proven outcome benefit in pre-eclampsia. The increasing use of echocardiography and pulse contour or pulse power algorithms for cardiac output monitoring appears promising.\(^\text{119}\)
11. PRECONCEPTION MANAGEMENT AND PROPHYLAXIS FOR WOMEN AT RISK OF PRE-ECLAMPSIA

11.1 Recurrence and prevention of pre-eclampsia

It is likely that development of pre-eclampsia requires a combination of underlying susceptibility and a triggering event. Many susceptibility factors for pre-eclampsia have been identified (see Table 6) but to date no accurate predictive tool, using either clinical or laboratory markers, has been developed.(148) Such a tool applied early in pregnancy would allow intervention that might modify outcomes.

A number of other factors are also associated with an increased risk of pre-eclampsia including chronic hypertension, pre-existing renal disease, autoimmune disease, > 10 years since previous pregnancy, short sexual relationship prior to conception, other thrombophilias e.g. Factor V Leiden and possibly periodontal disease.(148)

Table 6: Risk factors associated with pre-eclampsia(149)

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Relative risk [95%CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous history of preeclampsia</td>
<td>7.19 [5.85, 8.83]</td>
</tr>
<tr>
<td>Antiphospholipid antibodies</td>
<td>9.72 [4.34, 21.75]</td>
</tr>
<tr>
<td>Pre-existing diabetes</td>
<td>3.56 [2.54, 4.99]</td>
</tr>
<tr>
<td>Multiple pregnancy</td>
<td>2.91 [2.04, 4.21]</td>
</tr>
<tr>
<td>Nulliparity</td>
<td>2.91 [1.28, 6.61]</td>
</tr>
<tr>
<td>Family history of pre-eclampsia</td>
<td>2.90 [1.70, 4.93]</td>
</tr>
<tr>
<td>Elevated BMI &gt; 25</td>
<td>2.47 [1.66, 3.67]</td>
</tr>
<tr>
<td>Maternal Age ≥ 40</td>
<td>1.96 [1.34, 2.87]</td>
</tr>
<tr>
<td>Diastolic BP ≥ 80 mmHg at booking</td>
<td>1.38 [1.01, 1.87]</td>
</tr>
</tbody>
</table>

11.2 Recurrence of pre-eclampsia

Studies of the risk of recurrent pre-eclampsia in women with a history of a hypertensive pregnancy disorder in a prior pregnancy show variable results. A number of factors appear to influence this risk including severity and gestation at onset of the initial episode and the presence of additional maternal risk factors such as chronic hypertension or diabetes. Recurrence rates vary from 6% to 55% with the greatest risk in women with early onset pre-eclampsia and chronic hypertension.(150) Data from one Australian centre suggest that women with pre-eclampsia have an overall 14% risk of pre-eclampsia and the same risk of developing gestational hypertension in their next pregnancy.(151)

11.3 Preventing pre-eclampsia

A number of agents have been studied for their ability to reduce the risk of pre-eclampsia and improve maternal and fetal outcomes. These include antiplatelet agents, vitamins, calcium and heparin.

Antiplatelet agents

Prophylactic therapy with antiplatelet agents has been the subject of a large number of studies and various statistical reassessments. They demonstrate that the use of aspirin in doses between 50-150mg daily is associated with a reduction in the recurrence rate of pre-eclampsia, delivery prior to 34 weeks as well as preterm birth and perinatal death. There was a reduction in the rate of small-for-gestational age (SGA) infants but this failed to reach statistical significance. Risk reduction was greater if the antiplatelet agent was started before 20 weeks and if doses > 75mg were taken. Of importance, there was no difference in the rate of bleeding complications such as antepartum and postpartum haemorrhage or placental abruption between treatment and placebo groups.
In translating these results into clinical practice, the underlying risk of pre-eclampsia in the population being treated must be taken into consideration. If the baseline risk is 8%, treating 114 women will prevent one case of pre-eclampsia. In a population with a 20% risk of pre-eclampsia, the number needed to treat to prevent one case of pre-eclampsia is 50. In view of this potential benefit, and the relative absence of maternal or neonatal complications, low dose aspirin is indicated for the secondary prevention of pre-eclampsia in women at increased risk. In most cases, aspirin may be ceased at 37 weeks gestation although continuation beyond this period is not unsafe.\(^{152}\)

**Calcium supplements**

The use of calcium supplementation has been demonstrated to reduce the risk of pre-eclampsia, particularly in high risk women and those with low dietary calcium intake. However there was no significant effect on fetal and neonatal outcomes including preterm birth, low birth weight, fetal growth restriction, stillbirth or death before discharge from hospital. Calcium supplementation (1.5g/day) should therefore be offered to women at increased risk of pre-eclampsia, particularly in those women with a low dietary calcium intake.\(^{153}\)

**Other therapies**

Randomised, placebo controlled trials of antioxidants Vitamins C and E failed to demonstrate any significant effect on the incidence of pre-eclampsia. Of concern, a number of adverse effects were seen including an increased risk of stillbirth and of birthweight < 2.5kg but there were fewer fetal deaths due to immaturity. Prophylactic antioxidant therapy with vitamins C and E is therefore not recommended.\(^{154,155}\)

To date, there are no large randomised trials assessing the effect of heparin with or without aspirin in prevention of pre-eclampsia.\(^{156}\) As discussed above, women with thrombophilias have an increased incidence of pre-eclampsia and there has been enthusiasm for prophylactic treatment with anticoagulants, particularly low molecular weight heparin, with or without aspirin. Other than in the specific case of antiphospholipid antibody syndrome, there is no randomised study to support this practice.\(^{157}\)

Recent observational studies have suggested that supplementation with multivitamins containing folic acid during pregnancy is associated with a reduced risk of pre-eclampsia. Folic acid may reduce the risk of pre-eclampsia by improving placental and systemic endothelial function or by lowering blood homocysteine levels. Randomized, controlled trials are still required to address this potential therapy.\(^{158,159}\)

**Preconception counselling for women with chronic hypertension**

Ideally, the woman with pre-existing hypertension and/or renal disease should be seen, investigated and a diagnosis established prior to a planned pregnancy. This also allows discussion of the potential risks and estimation of the prognosis. Women with significant prenatal renal dysfunction (serum creatinine ≥ 130 μmol/L) should have the risks of perinatal morbidity/mortality and of deterioration of their underlying renal disease fully explained at this time.\(^{160}\) Antihypertensive drugs contra-indicated in pregnancy such as angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers and diuretics may be ceased and more appropriate therapy instituted. In women with mild-moderate chronic hypertension, the physiological fall in blood pressure that occurs in the first half of pregnancy may allow the discontinuation of antihypertensive therapy, at least temporarily.
12. AUDITING OUTCOMES IN WOMEN WITH HYPERTENSIVE DISORDERS OF PREGNANCY

The preceding guidelines aim to optimise the outcome of pregnancies complicated by pre-eclampsia and other hypertensive disorders of pregnancy. To quantify these outcomes, it is appropriate for all hospitals managing such patients to monitor and review their outcome data. Rigorous data collection is required to ensure the reliability of reported results. Strict diagnostic criteria for the diagnosis of pre-eclampsia/eclampsia, gestational hypertension and chronic hypertensive disorders should be utilised as defined in this document.

13. LONG-TERM CONSEQUENCES OF HYPERTENSIVE DISORDERS OF PREGNANCY

Women who have been diagnosed with either pre-eclampsia or gestational hypertension are at increased risk of subsequent cardiovascular morbidity including hypertension and coronary heart disease. A recent systematic review and meta-analysis[162] determined that the relative risks for hypertension were 3.70 after 14 years follow-up, for ischemic heart disease 2.16 after 12 years, for stroke 1.81 after 10 years, and for venous thromboembolism 1.87 after 5 years. Overall mortality after pre-eclampsia was increased 1.5 fold after 14 years.

These associations are likely to reflect a common cause for pre-eclampsia and cardiovascular disease, or an effect of pre-eclampsia on vascular disease development, or both. It is reasonable to counsel patients who develop hypertension in pregnancy that they will benefit from avoiding smoking, maintaining a healthy weight, exercising regularly and eating a healthy diet. It is recommended that all women with previous pre-eclampsia or hypertension in pregnancy have an annual blood pressure check and regular (5 yearly or more frequent if indicated) assessment of other cardiovascular risk factors including serum lipids and blood glucose.

14. REFERENCES

5. Levine RJ. Should the definition of preeclampsia include a rise in diastolic blood pressure ≥15 mm Hg? (abstract) Am J Obstet Gynecol 2000;182:225.


25. Roberts JM, Bodnar LM, Lain KY et al. Uric acid is as important as proteinuria in identifying fetal risk in women with gestational hypertension.[see comment]. Hypertension 2005;46(6):1263-9.


17. OBSTETRICS


64. Gallery EDM, Hunyor SN, Györy AZ. Plasma volume contraction: a significant factor in both pregnancy-associated hypertension (pre-eclampsia) and chronic hypertension in pregnancy. Quart J Med 1979;192:593-602.


### IV Hydralazine

**AIM:** to achieve a gradual reduction in blood pressure to safe levels (90mmHg diastolic), rather than a precipitate drop.  
*NOTE: the risk of sudden hypotension can be greater in women with a contracted plasma volume.*

| TRADE NAME: | Apresoline®  
20mg ampoule  
aminophylline, ampicillin, hydrocortisone, sulphadiazine, dextrose diluents |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PRESENTATION:</td>
<td></td>
</tr>
<tr>
<td>INCOMPATIBILITIES:</td>
<td>Apresoline® 20mg ampoule aminophylline, ampicillin, hydrocortisone, sulphadiazine, dextrose diluents</td>
</tr>
<tr>
<td>DOSE:</td>
<td></td>
</tr>
</tbody>
</table>
• Hydralazine 5mg as an intravenous bolus.  
• Repeat if necessary at 20 minute intervals, up to a maximum of 3 doses. |
| CONCOMITANT ANTIHYPERTENSIVE THERAPY: |  
• Continue existing oral antihypertensive therapy and review dose regimen;  
• If conscious, commence oral antihypertensive therapy (such as clonidine, labetalol or oxprenolol) in addition to the intravenous hydralazine |
| Persistent hypertension despite 3 boluses of IV hydralazine 5mg may be due to a compensatory reflex tachycardia: |  
**if heart rate < 125 bpm:**  
• Commence hydralazine infusion of 10mg/hr.  
• Load 50 mg of IV hydralazine into 50ml of normal saline (not glucose sol.);  
• Run the infusion through an infusion pump at a rate of 10ml/hr;  
• Increase rate by 5ml/hr every 15 minutes until blood pressure is controlled.  
**if heart rate > 125 bpm:**  
• Give oral clonidine, labetalol or oxprenolol in addition to hydralazine infusion |
| MATERNAL and FETAL OBSERVATION AND MONITORING |  
• Continuous CTG throughout administration of hydralazine and until BP is stable (30 minutes after the last dose);  
• Record BP (Mercury sphygmanometer, Korotokoff V) and pulse every 5 minutes after each bolus dose;  
• Continue 5 minute BP and pulse until stable, thence measure hourly;  
• Record BP every 15 minutes for the first hour of a continuous infusion, thence measure hourly if stable. |
APPENDIX 2: MAGNESIUM SULPHATE HEPTAHYDRATE INFUSION NOTES AND EXAMPLE INFUSION PROTOCOLS

Indications for magnesium sulphate infusion:
1. seizure prophylaxis in a woman who has already had an eclamptic seizure;
2. seizure prophylaxis in a woman with severe pre-eclampsia who is at risk of eclampsia (although the efficacy for this is less certain).

Relative contraindications:
NOTE: Magnesium sulphate can be extremely hazardous in the following circumstances:
• renal failure, severe renal compromise or if oliguria is present (magnesium concentration can reach toxic levels as elimination is predominantly renal). Half dose magnesium sulphate should be considered if there is renal compromise;
• in association with hypocalcaemic states;
• myasthenia gravis;
• cardiac conditions, in particular conduction problems or myocardial damage.

Other considerations:
Magnesium sulphate:
• may lower blood pressure (secondary to vasodilatation). Dose of any current antihypertensive medication may require adjustment;
• may have some tocolytic effect;
• may decrease fetal heart rate variability;
• may cause loss of reflexes (patellar reflexes will be absent well before toxic serum levels of magnesium are reached);
• should be used with caution in the presence of calcium antagonists or other respiratory depressants (e.g. valium).

Common maternal side effects:
• Sensation of pain and warmth in arm;
• Flushing of hands, face and neck;
• Nausea.

Signs of maternal toxicity:
• Loss of patellar reflexes;
• Respiratory rate < 10;
• Slurred speech, weakness, feeling extremely sleepy, double vision;
• Muscle paralysis;
• Respiratory/cardiac arrest.

Antidote for magnesium toxicity:
Calcium chloride or calcium gluconate (10ml of 10% solution) by slow intravenous injection over 3 minutes.

Protocol for magnesium sulphate heptahydrate (MgSO4) infusion:
• Administration of magnesium sulphate heptahydrate should always be via an infusion pump;
• The intravenous line should not be used to inject other drugs;
• Presentation of magnesium sulphate is most commonly a 50% solution in 5mls of H2O.
• Undiluted this is 10mmol of magnesium in 5mls, or a 2mmol per ml solution. Magnesium sulphate is administered intravenously or intramuscularly. Intravenous doses should be diluted to a concentration of magnesium 20% or less.

N.B. Pre-mixed solutions of magnesium sulphate heptahydrate are commercially available for infusion pump use. These preparations are preferred as pre-mixed solutions confer considerable safety benefits over manually prepared solutions. In the event that a maternity service elects not to use pre-mixed solutions, a drug protocol for the manual mixing of the solutions should be developed and approved by the local drug committee. This should then be available and clearly communicated to all staff involved in the use of magnesium sulphate heptahydrate solutions.
17. OBSTETRICS

- Recommended loading dose: 4 grams (16 mmol) MgSO4 heptahydrate over 15-30mins.
- Maintenance infusion: 1 gram/hour for at least 24 hours.

Care and observations during infusion
Close observation and assessment (maternal and fetal) is required for the duration of the infusion. Where patient condition is unstable, the frequency of observation will need to be increased.

Routine observations:
- 1-2 hourly recording of maternal blood pressure, respiratory rate, heart rate and urine output. (Cease infusion if respiratory rate is < 10 per minute or if urine output is < 80mls over four hours);
- Patellar reflexes at completion of loading dose and then 2 hourly. (Cease infusion if unable to elicit reflexes.);
- Fetal heart rate monitoring as clinically indicated;
- Serum magnesium levels may be measured 60 minutes after commencing the infusion and thereafter as clinically indicated. Normal therapeutic levels are 1.5-3.5 mmol/L. (Blood for serum levels should not be collected from the limb receiving the infusion.)

Example 1: Mixing solution for infusion pump use

<table>
<thead>
<tr>
<th>1. Loading Dose</th>
<th>2. Maintenance Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>4g MgSO4 (50% solution) diluted in Normal Saline via infusion pump over 20-30 minutes</td>
<td>1 gram MgSO4 (50% solution) per hour via infusion pump</td>
</tr>
<tr>
<td>• Using a 500ml flask of Normal Saline, run 100ml into a burette;</td>
<td>• Remove 20ml N/Saline from the N/S remaining in the flask and discard.</td>
</tr>
<tr>
<td>• Add 8ml (4g) of MgSO4 (50% solution) to the 100ml of Normal Saline in the burette;</td>
<td>• Add 20ml (10g) of MgSO4 (50% solution) to the remaining 380ml flask of Normal Saline;</td>
</tr>
<tr>
<td>• Infuse over 20-30 minutes via infusion pump.</td>
<td>• Infuse at 40mls (1g) per hour via infusion pump;</td>
</tr>
<tr>
<td></td>
<td>• Run maintenance infusion for at least 24hours.</td>
</tr>
</tbody>
</table>

Example 2: Premixed commercial solution (8 grams Magnesium Sulphate in 100 mls water for injection)

<table>
<thead>
<tr>
<th>1. Loading Dose</th>
<th>2. Maintenance Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mls (4 grams) Magnesium Sulphate premixed solution (8 grams magnesium sulphate heptahydrate in 100 mls water for injection; each 100 mls contains approximately 32 millimoles magnesium and 32 millimoles sulphate)</td>
<td>12.5 mls (1 gram) Magnesium Sulphate premixed solution (8 grams magnesium sulphate heptahydrate in 100 mls water for injection; each 100 mls contains approximately 32 millimoles magnesium and 32 millimoles sulphate) per hour</td>
</tr>
<tr>
<td>• Infuse over 15 – 30 minutes</td>
<td>• Infuse at 12.5 mls per hour</td>
</tr>
</tbody>
</table>

Example 3: Premixed commercial solution (40 grams Magnesium Sulphate in 500 mls water for injection)

<table>
<thead>
<tr>
<th>1. Loading Dose</th>
<th>2. Maintenance Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mls (4 grams) Magnesium Sulphate premixed solution (40 grams magnesium sulphate heptahydrate in 500 mls water for injection; each 500 mls contains approximately 162 millimoles magnesium and 162 millimoles sulphate)</td>
<td>12.5 mls (1 gram) Magnesium Sulphate premixed solution (40 grams magnesium sulphate heptahydrate in 500 mls water for injection; each 500 mls contains approximately 162 millimoles magnesium and 162 millimoles sulphate) per hour</td>
</tr>
<tr>
<td>• Infuse over 15 – 30 minutes</td>
<td>• Infuse at 12.5 mls per hour</td>
</tr>
</tbody>
</table>
MATERNITY – DECREASED FETAL MOVEMENTS IN THE THIRD TRIMESTER
(GL2011_012)

PURPOSE

These guidelines provide direction to NSW maternity services regarding the management of pregnant women who report decreased fetal movements (DFM) in the third trimester of pregnancy.

KEY PRINCIPLES

Analysis of adverse perinatal events in NSW has identified considerable variations in both clinical practice and information provided to women regarding DFM. This guidance is provided to improve consistency in the management of women with DFM through defining DFM and maternal perception of fetal activity, clarifying the role of formal fetal movement counting, standardising the investigation of DFM, and the management of ongoing maternal concern regarding DFM.

USE OF THE GUIDELINE

Maternity services should use the information in these guidelines as practical guidance to manage pregnant women who report decreased fetal movements.

MATERNITY – Rh (D) IMMUNOGLOBULIN (ANTI-D) (GL2015_011)


PURPOSE

This guideline provides direction to NSW maternity service providers, emergency departments and general practitioners regarding the care of rhesus (Rh) (D) negative women and the use of Rh (D) Immunoglobulin (Anti-D).

Rh (D) Immunoglobulin is used as prophylaxis treatment and or treatment for potential sensitising events for Rh negative women who are pregnant or recently pregnant (up to 10 days post pregnancy cessation).

KEY PRINCIPLES

All pregnant women should be typed for ABO and Rh (D) as early as possible during each pregnancy.

All Rh negative women who are pregnant or recently pregnant (up to 10 days post pregnancy cessation), should be provided with information both verbal and written on their rhesus status and Rh (D) Immunoglobulin.

All Rh negative women who are pregnant or recently pregnant (up to 10 days post pregnancy cessation), should be offered Rh (D) Immunoglobulin prophylactically and or for potential sensitising events.

All Rh negative women should sign the consent/decline to treatment form.

USE OF THE GUIDELINE

The guideline for the use of Rh (D) Immunoglobulin should be used by general practitioners and all staff working in NSW Health Maternity Services or Emergency Departments who are providing care to Rh negative women who are pregnant or recently pregnant (up to 10 days post pregnancy cessation).

• Midwives
• Nurses
• Obstetricians
• Medical Officers
• General Practitioners

To download the Guidelines please go to

252(17/09/15)
DEATHS - REVIEW AND REPORTING OF PERINATAL DEATHS (PD2011_076)


PURPOSE

The policy describes the procedures for review of perinatal deaths occurring in NSW hospitals and for reporting of these deaths to the NSW Maternal and Perinatal Committee. The Maternal and Perinatal Committee is a quality assurance committee established by the Minister for Health to review maternal and perinatal morbidity and mortality in the State, and is privileged under the *Health Administration Act 1982* for its review of confidential medical information.

This Policy Directive supersedes PD2006_006 (previously PD2005_228).

MANDATORY REQUIREMENTS

Each maternity service will have a perinatal morbidity/mortality committee. The committee may function at hospital or local health district level. All perinatal deaths will be reviewed by the committee, including infants born within the service who died elsewhere. Maternity services may choose to combine the functions of the perinatal morbidity/mortality committee with a hospital or Local Health District morbidity/mortality review committee.

The perinatal morbidity/mortality committee will:

i) work with (or as part of) the Maternity Clinical Risk Management Committee;

ii) review all neonatal deaths, regardless of gestational age at birth, and stillbirths of at least 20 weeks gestation or 400 grams birth weight;

iii) classify perinatal deaths according to the Perinatal Society of Australia and New Zealand (PSANZ) - Perinatal Death Classification (PDC) and Neonatal Death Classification (NDC) where appropriate;

iv) evaluate the circumstances surrounding the death including a consideration of contributing factors;

v) on the basis of such considerations, develop recommendations for improving processes of care, ensuring feedback to clinicians;

vi) review the coordination of care for parents following a perinatal death including follow-up; and

vii) provide a confidential case summary to the NSW Ministry of Health.

IMPLEMENTATION

The review process should be multidisciplinary. Membership of the committee should, at a minimum, include key clinical representatives of medical, nursing and midwifery staff. In addition, where possible and relevant, membership should include representatives from the disciplines of: obstetrics, neonatology/paediatrics, pathology, neonatal nursing, independent midwives accredited to the service, general practitioners with a shared antenatal care arrangement, allied health professionals and staff representing relevant cultural groups. Hospitals that have insufficient staff to carry out a multidisciplinary review are encouraged to seek advice and support from other maternity services.

The functioning of the perinatal morbidity/mortality committee should be in accordance with Section 3 of the attached Procedures.
After consideration by the local perinatal death review committee, the following information on all neonatal deaths, regardless of gestational age at birth, and stillbirths of at least 20 weeks gestation or 400 grams birth weight:

1. Copy of a completed Confidential Report Form (Appendix 1).
2. Copy of the post mortem report and report of histopathological examination of the placenta, if applicable.
3. Any other information which the local perinatal death review committee may wish to provide for consideration by the NSW Maternal and Perinatal Committee.

should be forwarded to the Secretary of the NSW Maternal and Perinatal Committee Perinatal Outcomes Working Party at the following address:

The Secretary
Perinatal Outcomes Working Party
NSW Maternal and Perinatal Committee
Centre for Epidemiology and Research
Locked Bag 961
NSW Ministry of Health
North Sydney NSW 2059
Telephone: 9391 9223
Facsimile: 9391 9232

1. BACKGROUND

1.1 About this document

Each year, there are over 800 perinatal deaths in NSW. This document describes the procedures for review of perinatal deaths occurring in NSW hospitals and revises the process for classifying perinatal deaths and reporting of these deaths to the NSW Maternal and Perinatal Committee to be implemented from 1 January 2012. Information obtained through these reviews is used to develop policies aimed at reducing maternal and perinatal mortality in NSW.

The procedures described in this document are based on the Clinical Practice Guideline for Perinatal Mortality produced by the Perinatal Society of Australia and New Zealand (PSANZ).\(^1\)

This policy directive should be brought to the attention of all staff involved in the administration and delivery of maternity and neonatal care including intensive care units, emergency departments, and medical records departments.

1.2 Key definitions

Perinatal deaths comprise all deaths of liveborn babies within 28 days of birth, regardless of gestational age at birth, and stillbirths of at least 20 weeks gestation or 400 grams birth weight.

1.3 Legal and legislative framework

The NSW Maternal and Perinatal Committee is an expert committee appointed by the Minister of Health to review maternal and perinatal morbidity and mortality in the State and is privileged from subpoena under the *Health Administration Act 1982* for its review of confidential medical information.
Under certain circumstances the death of a neonate may be reportable to the Coroner: for example, where the infant died a sudden death the cause of which is unknown, or the infant died under suspicious or unusual circumstances. Further information on requirements for reporting deaths to the Coroner is included in NSW Ministry of Health Policy Directive PD2010_054 Coroners Cases and the Coroners’ Act 2009.

2. INVESTIGATION OF PERINATAL DEATH

In addition to investigations relevant to the particular circumstances of the death, clinicians should consider the value of a post-mortem examination in every instance of perinatal death and discuss this with the parents. In some cases a limited post-mortem may be of assistance.

It is recommended that a trained clinician examine the baby to determine the presence of any possible congenital anomalies. This is particularly important where a post-mortem examination has been refused by the family. A trained clinician may be a clinician specialising in paediatrics or a generalist clinician who has undergone specific training, such as a perinatal loss workshop, or who has a working knowledge of the PSANZ Clinical Practice Guideline for Perinatal Mortality.

Clinicians are encouraged to carry out alternative procedures, such as radiological examination, if a post-mortem is refused.

Histopathological examination of the placenta is recommended. If the death is a stillbirth, guidelines for investigation of a stillborn should be followed as described in PD2007_025 Stillbirth - Management and Investigation.

3. PERINATAL DEATH REVIEW COMMITTEES

3.1 Purpose and composition

Perinatal morbidity/mortality review meetings within maternity services provide a forum in which the cause of death, other adverse outcomes and their determinants are discussed. This has immediate benefits for participants in providing feedback, and enables identification of possible avoidable factors that may be used to improve local services. The process provides a mechanism for continuous improvement of services as described in PD2009_003 Maternity - Clinical Risk Management Program.

Individual deaths are best reviewed by local hospital or regional committees that include members who have had contact with the case. Aggregation of information derived from these case reviews provides an important resource for planning of services and prevention programs at a State level.

The review process should be multidisciplinary. Membership of the committee should, at minimum, include key clinical representatives of obstetrics, neonatology/paediatrics, nursing and midwifery staff. In addition, where possible and relevant, membership should include representatives from the disciplines of: pathology, general medicine, endocrinology, genetics, neonatal nursing, privately practicing midwives accredited to the service, general practitioners with a shared antenatal care arrangement, social workers, allied health professionals and staff representing relevant cultural groups. Hospitals that have insufficient staff to carry out a multidisciplinary review are encouraged to seek advice and support from other maternity services.
3.2 Operation

Each maternity service will have a perinatal morbidity/mortality committee. The committee may function at hospital or local health district level. Maternity services may choose to combine the functions of the perinatal morbidity/mortality committee with a hospital or local health district morbidity/mortality review committee.

The perinatal morbidity/mortality committee will abide by principles of confidentiality and impartiality.

The perinatal morbidity/mortality committee will:
(i) work with (or as part of) the Maternity Clinical Risk Management Committee (see PD2009_003 Maternity - Clinical Risk Management Programme);
(ii) review all perinatal deaths occurring within the maternity service and perinatal deaths of babies born at the maternity service who died elsewhere;
(iii) classify perinatal deaths according to the PSANZ Perinatal Death Classification (PDC) and, where appropriate, the PSANZ Neonatal Death Classification (NDC);
(iv) evaluate the circumstances surrounding the death including a consideration of contributing factors;
(v) on the basis of such considerations develop recommendations for improving processes of care, ensuring feedback to clinicians; and
(v) provide a Confidential Report to the NSW Ministry of Health (Appendix 1).

The PSANZ PDC and NDC classifications are shown in abbreviated form in the Attachment to Appendix 1 and reproduced in full in Appendix 2.

Potentially avoidable or preventable factors should be assessed. The determination that potentially avoidable factors were present does not imply that the death was certainly avoidable. The presence of contributing factors in the following areas should be considered:
   i) maternal/social - factors relating to the woman including her social situation;
   ii) infrastructure/service organisation - factors relating to the setting in which the care was provided; and
   iii) professional care delivery – factors relating to the clinical care provided.

Information on potentially avoidable or preventable factors which have implications for policy concerning local health service provision should be referred to the relevant hospital/local health district manager or manager of clinical services.

3.3 Qualified privilege

Committees may wish to apply to the Minister for Health for qualified privilege under the NSW Health Administration Act 1982, section 20E. The provision of qualified privilege for quality assurance committees is designed to encourage health professionals to participate in quality assurance activities by providing for:
- The confidentiality of the documents and the proceedings of quality assurance committees.
- The protection of the quality assurance committee’s documents and proceedings from being used in legal actions.
- The protection from liability and indemnity for present and former members of the Committee who were acting in good faith in carrying out their responsibilities.

Information for quality assurance committees seeking qualified privilege is available on the NSW Ministry of Health website at:
3.4 Review of arrangements for coordination of care for parents

The perinatal morbidity/mortality committee should verify that arrangements are in place for coordination of care, including follow-up, for parents following a perinatal death.

4. REPORTING OF PERINATAL DEATHS TO THE MINISTRY OF HEALTH

From 1 January 2012, after consideration by the local perinatal death review committee, a completed Confidential Report Form (Appendix 1) on each perinatal death should be forwarded to the Secretary of the NSW Maternal and Perinatal Committee Perinatal Outcomes Working Party at the following address:

The Secretary
Perinatal Outcomes Working Party
NSW Maternal and Perinatal Committee
Centre for Epidemiology and Research
 Locked Bag 961
NSW Ministry of Health
North Sydney NSW 2059
Telephone: 9424 5829
Facsimile: 9391 9232

Following notification, the Committee secretariat may make a written request for copies of the medical record, antenatal record, postmortem report, report of a root cause analysis (where applicable) and any other information that is relevant to the circumstances of the death. The health service should provide this information when requested.

Copies of Confidential Report Forms may be obtained from the Secretary, are available from the Ministry’s website under the Policy Directive or a photocopy of the Confidential Report Form shown at Appendix 1 may be used. Hospitals wishing to submit data electronically should contact the Secretary.

5. REFERENCES


PURPOSE
This Policy Directive provides a framework to support the review and development of appropriate local protocols for terminations of pregnancy undertaken in public hospitals. It clarifies the assessment of need, consent and the responsibilities of each public health organisation in the provision of this procedure. All public health organisations that manage facilities in which terminations occur are to ensure they have in place protocols that are consistent with and address all the issues referred to in this Policy Directive.

MANDATORY REQUIREMENTS
All NSW Public Health Organisations are to ensure they have in place protocols that are consistent with and address all the issues referred to in this Policy Directive.

IMPLEMENTATION
The Chief Executives of NSW Local Health Districts are ultimately responsible for the implementation of this Policy Directive within their services/facilities.

1. BACKGROUND

1.1 About this document

This Policy Directive provides a framework to support the review and development of appropriate local protocols for terminations of pregnancy undertaken in public hospitals. It clarifies the assessment of need, consent and the responsibilities of each public health organisation in the provision of this procedure. All public health organisations that manage facilities in which terminations occur are to ensure they have in place protocols that are consistent with and address all the issues referred to in this Policy Directive including the use of health care interpreters where required or requested.

1.2 Key definitions

In this document the term:
- **must** – indicates a mandatory action required by a NSW Health Policy Directive, law or industrial instrument; and
- **should** – indicates an action that should be followed unless there are justifiable reasons for taking a different course of action.

Please note that the definitions used for the purposes of public health data collections such as the NSW Midwives Data Collection, may differ from reporting requirements under the *Births, Deaths and Marriages Registration Act 1995*.

1.3 Related Documents

This Policy Directive should be read in conjunction with the following Policy Directives:

- Client Registration Policy PD2007_094
- *Coroners Cases and the Coroners Act 2009* PD2010_054
17. OBSTETRICS

- Death - Extinction of Life and the Certification of Death - Assessment PD2012_036
- Consent to Medical Treatment - Patient Information PD2005_406
- Human Tissue-Use/Retention Including Organ Donation, Post-Mortem Examination and Coronial Matters PD2005_341
- Infection Control PD2007_036
- Deaths - Review and Reporting of Perinatal Deaths PD2011_076
- NSW Perinatal Data Collection (PDC) Reporting and Submission Requirements from 1 January 2016 PD2015_025
- Congenital Conditions Register - Reporting Requirements PD2012_055
- Health Care Records - Documentation and Management PD2012_069
- Genetic Testing PD2007_066

2. LEGAL CONTEXT

The legal framework in relation to termination of pregnancy is set out below.

2.1 Criminal Law

In New South Wales, the law on termination is governed by the NSW Crimes Act 1900 as interpreted by relevant case law. In summary, termination is lawful if:

- The procedure is performed with the consent of the woman and by a registered medical practitioner.
- The medical practitioner procuring the termination has an honest belief based on reasonable grounds that the procedure is necessary to preserve the woman from serious danger to her life, or physical or mental health. These grounds may be medical, economic or social.
- In the circumstances, the operation is not out of proportion to the danger intended to be avoided.

2.2 Births, Deaths and Marriages Registration Act

Under the Births, Deaths and Marriages Registration Act 1995 (“the Registration Act”) there is a requirement to register all births.

2.2.1 Stillbirth

“Birth” includes “stillbirth”, which means the birth of a “stillborn child” (a fetus of at least 20 weeks gestation or, if the gestational age is not known, having a body mass of at least 400 grams at birth). If the gestational age of the fetus is not accurately known, the weight of the fetus becomes relevant. When notice of a stillbirth is given, the responsible person must also give a doctor’s certificate certifying the cause of fetal death. No registration of “death” is required in respect of stillborn children.

2.2.2 Neonatal birth and death

A child born alive, irrespective of gestational age, must be registered as a birth - see section 12 of the Registration Act. If the child subsequently dies it must be registered and notified to the Registrar together with the cause of death in accordance with the Registration Act or alternatively reported to the Coroner.

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17 see Sections 82 to 84 of the Crimes Act
2.3 **Duty of Care**

This section outlines the legal responsibilities in relation to both adult and child patients in the context of terminations of pregnancy. Both the civil and criminal law is relevant.

2.3.1 **Adult patient**

The law imposes on a medical practitioner a duty to his/her patient to exercise reasonable care and skill in the provision of professional advice and treatment. Appropriate and adequate information must be provided to patients in order for the patient to make an informed choice about treatment.

In relation to the actual performance of the termination, a duty of care is owed to the patient and the standard of reasonable care and skill required is that of a medical practitioner experienced in that area of practice. Negligence may be established where the standard of care falls below that which could be reasonably expected in the circumstances.

2.3.2 **Child**

For the purposes of this section “child” refers to a child who has been expelled or removed from the mother’s womb alive. It should be noted that a fetus in utero is not recognised as a separate legal entity. However, once a fetus has been expelled or removed from the mother’s womb, and is born alive, the child has the legal status of a person whose rights exist independently of the rights of the parents.

Where a child is born alive and a responsible body of medical opinion considers that the burden of medical treatment is such that it would not benefit the child, because of pre-viability of the child, prematurity, or the effect of a disease or condition - then a medical practitioner is under no duty to render overburdensome treatment. Healthcare professionals have an obligation to work together with families to make compassionate decisions. Conversely, where the likelihood of treatment will be of benefit, there is an obligation to render life-saving medical treatment.

2.4 **Coroners Act**

“Death” in the *Coroners Act 2009* should be construed in the same way as “death” in the Registration Act. The delivery of a fetus that “exhibits no sign of respiration or heartbeat, or other sign of life” which does not include a stillbirth after expulsion from the womb is not a “death” for the purposes of the *Coroners Act*. A fetus becomes a person if after expulsion or extraction from the mother and before being determined to be dead, signs of life are exhibited.

The reporting obligations are set out in the *Coroners Act* and Policy Directive *Coroners Cases and the Coroners Act 2009* (PD2010_054).

3. **PRE-PROCEDURE ISSUES**

3.1 **Counselling**

All women seeking a termination of pregnancy are to be offered counselling. This counselling does not replace but is additional to any genetic counselling that may be indicated.
17. OBSTETRICS

Before considering consent to the termination, consideration needs to be given to the immediate and future implications of the range of genetic tests available to pregnant women. Testing may benefit women and their families in a number of ways but it may also create dilemmas for the woman being tested and other members of their families that need sensitive management. Pre-test and post-test counselling is an essential element of genetic testing.

Each test has distinct advantages, disadvantages and limitations and should only be used after the woman being tested has given full consideration to these issues. All testing should be carried out with the consent of the woman being tested. The woman must be provided with comprehensive information as to the purpose of the test or the procedure and the possible implications and consequences of those results, before being asked to give consent. Careful consideration should be given to the way results are conveyed to ensure this is done sensitively.

Certain results must be reported to the NSW Register of Congenital conditions as set out in PD2012_055 Congenital Conditions Register - Reporting Requirements. Where there is prenatal diagnosis using amniocentesis, chorionic villus sampling or fetal blood sampling it is recommended that where possible women are counselled face-to-face at least one day before the procedure. Counselling should address a clear and simple explanation of the probability of an affected fetus, explanation of the process of the procedure, options to be considered if the result is abnormal, acknowledgment of the individual nature of decisions about continuing or terminating the pregnancy and methods of termination of pregnancy.

Ultrasound has become a routine part of prenatal care. Parents may not have given consideration to the prospect of an adverse result. When an abnormality is detected, care should be taken to provide counselling and emotional support to minimise the impact of the result on the woman and her family.

Maternal serum screening alone, or in combination with ultrasound, is an optional and voluntary prenatal test for women of any age, which, when combined with age and other factors, can provide an assessment of risk for Down syndrome and other abnormalities. The test alone does not identify any birth defect. An increased risk result indicates the need to consider definitive prenatal diagnostic tests such as amniocentesis. It is important that women consider all aspects of such screening before agreeing to have it done.

Evidence of pre-termination counselling from an appropriately qualified health care professional must be documented as having been offered and a copy of the counsellor’s report provided to the treating medical practitioner. Where the medical practitioner provides counselling, documentation of the counselling must be included in the medical record.

3.2 Assessment of Need

The decision for termination of pregnancy is one between an individual woman and her treating practitioner.

For all proposed terminations the following criteria should be considered and documented:
1. The woman’s physical and psychological condition
2. Accurate assessment of gestational age
3. In cases of birth defect, the diagnostic probability
4. In cases of birth defect, the prognosis for the fetus.

Except where there is an imminent threat to the life or physical health of a woman necessitating a termination as a matter of urgency, the following process is to be followed:
17. OBSTETRICS

- <13 weeks gestation - The assessment of need is to be undertaken by the treating medical practitioner in consultation with the woman after appropriate counselling has been offered.

- 13 - 20 weeks gestation - The assessment of need is to be undertaken by the treating medical practitioner in consultation with the woman after appropriate testing and counselling has been offered and the results/reports provided to the treating practitioner. The treating practitioner may need to consult further with other relevant specialists as part of the assessment.

- > 20 weeks gestation - In the assessment of need the treating practitioner should seek appropriate consultation and advice as dictated by the individual clinical scenario. Such consultation and advice should be documented by the treating practitioner. In some circumstances the Local Health Districts may provide opportunity for a case conference or multidisciplinary team, with a mix of skills and experience to provide advice to the treating medical practitioner so that he/she is able to undertake an informed assessment of need for termination of pregnancy. The provision of a case conference or multidisciplinary team is not a mandatory component of the assessment of need but serves to assist the treating practitioner in complex clinical situations. The multidisciplinary team may include experts in the areas of psychiatry or specialist mental health, fetal medicine, neonatology and the other specialty or specialties relevant to the woman’s and fetus’ condition.

Such a multidisciplinary team is neither a constituted ethics committee nor does it have clinical decision making ability. Its sole purpose is to provide the treating medical practitioner with advice of a clinical or technical nature.

If the clinical decision is made by the treating medical practitioner that a termination is to occur up to 22 weeks gestation, this service should be provided within the facility. If the clinical decision is made between a woman and a treating medical practitioner that a termination is required after 22 weeks gestation and the facility is not in a position to offer a termination as outlined in this policy, the treating practitioner must provide appropriate information and refer the woman to another facility within their tiered maternity network which does have the expertise and capacity to undertake this procedure.

3.3 Patient Information/Consent

Written consent of the woman is to be obtained by the treating medical practitioner before a pregnancy termination is performed. Hospital protocols should give guidance to clinicians on providing appropriate patient information. Women must be provided with sufficient information about the treatment options, benefits, possible adverse effects or complications, and the likely result if the treatment is not undertaken, in order to be able to make their own decision about undergoing the termination.

A medical practitioner has a legal duty to warn a woman of any material risks to her physical or mental health from the proposed termination. Where applicable, the woman is to be informed of the potential for the infant to be born exhibiting signs of life and the ramifications should this eventuate. Consent to the proposed procedure must be obtained from the woman. Only the consent of the pregnant woman is required before a termination may be performed (not the consent of other family members, even though on many occasions the woman may choose to discuss the matter with other family members).

The requirements for valid consent are:
1. The person must have the capacity to give consent.
2. The consent must be freely given.
3. The consent must be specific and is valid only in relation to the treatment or procedure for which the patient has been properly informed and has agreed to.

4. The patient must be informed in broad terms of the procedure that is intended, in a way the patient can understand.

Capacity to give consent implies that the person must be able to comprehend and retain relevant information, and understand the implications sufficiently to reach a decision about termination. Examples of patients who are not considered as having this capacity would include: a child under the age of fourteen, and some people affected by mental illness, intellectual disability or cognitive impairment (PD2005_406).

The woman’s wishes regarding contact with the fetus/child following termination should be documented to ensure appropriate arrangements are made where requested by the woman.

3.3.1 Consent form

The Policy Directive Consent to Medical Treatment - Patient Information (PD2005_406) Section 34: Consent for procedures that a medical practitioner does not “recommend”, provides an alternatively worded consent form for some procedures, such as termination of pregnancy. This is in recognition that some medical procedures, such as terminations of pregnancy are performed which may not be “recommended” by a medical practitioner, or whereby a medical practitioner may feel uncomfortable about recommending the procedure. Public health organisations may adopt the alternatively worded consent form as in PD2005_406 - Section 34.

4. PROCEDURE

4.1 Clinical protocols

Clinical protocols are to be in place for all forms of termination procedures and should include the provision of counselling for staff if required. These protocols should incorporate the roles and responsibilities of the relevant professional groups and relevant product information including prescribing, administration, indication of use, contraindications, precautions, adverse reactions and drug interactions.

4.2 Conscientious objection

Any medical practitioner who is asked to advise a woman about termination of pregnancy, or perform, direct, authorise or supervise a termination of pregnancy, and who has a conscientious objection to termination of pregnancy must:

1. Inform the woman that they have a conscientious objection and that other practitioners may be prepared to provide the health service she seeks; and

2. Take every reasonable step to direct the woman to another health practitioner, in the same profession, who the practitioner reasonably believes does not have a conscientious objection to termination of pregnancy.

The term ‘direct’ is to be understood in its ordinary sense, that is, to direct or point to another source, rather than the requirement of a written referral as part of an ongoing working relationship. It may be as simple as directing the woman to another practitioner who they know has no such objection. This is to ensure that women receive timely, accurate information from a professional who does not hold an objection to the health service she seeks.
Any health practitioner having a conscientious objection to termination of pregnancy should notify their manager in a timely manner of his/her conscientious objection. Public health organisations must ensure that no staff member is disadvantaged because of a conscientious objection to termination of pregnancy.

The exception to this is termination of pregnancy in emergency situations. Medical practitioners, midwives and nurses must perform a termination of pregnancy in those rare emergency cases where it is necessary to preserve the life of the pregnant woman, regardless of their objection to abortion.

5. POST-PROCEDURE ISSUES

5.1 Woman

Clinical guidelines should be in place regarding immediate postpartum care. These should include clinical observations and frequency required, and management of clinical emergencies.

The medical practitioner responsible for the care of the woman should be informed of the completion of the procedure, the condition of the woman and, where relevant, the child.

The woman should also receive appropriate post procedure information.

The woman’s wishes regarding the fetus should be respected and arrangements for viewing and handling of the fetus should accord with her wishes. If an autopsy is considered appropriate, the woman’s consent should be sought.

The woman must be informed of any further requirements that may be necessary, and provided with assistance in fulfilling these, for example, funeral arrangements and birth registration.

Counselling is to be offered to the woman, and as appropriate to the family, after the procedure. Information should also be provided regarding support services available. A discharge plan should be developed.

5.2 Fetus/Child

5.2.1 Post-procedure examination and care

Examination of the fetus/child should occur immediately upon delivery. Where a medical termination of pregnancy results in a fetus/child showing signs of life it is important that staff involved are aware of their responsibilities and duty of care toward the child. This includes assessment of the condition of the child at birth and any abnormalities present. If upon examination the condition of the child warrants further specialist examination, staff should immediately consult a neonatologist.

Where a child is born alive but medical consensus is that treatment (other than palliative treatment) would be over burdensome and of negligible benefit to the child (futile), whether due to pre-viability, prematurity, the effect of a disease or condition or some other reason, the medical practitioner has no legal obligation to provide that treatment. Healthcare professionals have an obligation to work together with families to make compassionate decisions.

Any child born with signs of life as a result of a termination of pregnancy, irrespective of gestation or condition, must be afforded the right of dignity, maintenance of privacy and physical comfort whilst signs of life exist. Parents should be encouraged to be part of this care.
5.2.2 Registration requirements

The requirements of the Registration Act are to be fulfilled. Refer to Section 2 of this document.

In the case of a stillbirth, where it is unclear whether the gestational age is less than 20 weeks at the time of delivery, the fetus is to be weighed. If the weight is 400 grams or greater the fetus must be registered as a stillbirth. If the gestational age is less than 20 weeks or the weight is less than 400 grams then no birth or death registration is required.

All live births and all deaths following a live birth must be registered.

5.2.3 Appropriate disposal/transfer

Local guidelines should be developed for the appropriate transfer and disposal of the fetus and products of conception following termination of pregnancy.

5.2.4 Notification to Ministry of Health

Birth, perinatal death and birth defects are category 1 conditions under the Public Health Act 2010 requiring notification to the Ministry of Health.

6. RECORDS MANAGEMENT

Health professionals are required to keep accurate health care records of patients. In addition to routine clinical notes concerning the care and treatment of the woman the following information should also be documented:

1. Gestational age/weight
   Gestational age is to be recorded where known. The method used to calculate the gestational age should be documented. If appropriate, weight should be recorded.

2. Signs of life following a medical termination
   Where a medical termination is performed the extent and duration of any signs of life should be recorded and what actions were taken.
MATERNITY – RESUSCITATION OF THE NEWBORN INFANT (GL2018_016)

GL2018_016 rescinds PD2008_027

PURPOSE
This Guideline aims to optimise, facilitate and standardise newborn resuscitation by endorsing the Australian and New Zealand Committee on Resuscitation (ANZCOR) Guidelines - Section 13: Neonatal Guidelines (2016-17) for use by NSW Health.

KEY PRINCIPLES
This Guideline applies to all clinicians who care for newborn infants in maternity and related environments and to the resuscitation of the newborn immediately following birth and during the birth admission.

USE OF THE GUIDELINE
This Guideline:

• replaces the Policy Directive PD2008_027 Maternity - Clinical Care and Resuscitation of the Newborn Infant
• outlines local health district responsibilities to develop systems to ensure:
  o clinicians are appropriately targeted to complete mandatory and recommended newborn basic life support education, training and proficiency requirements
  o locally determined clinicians complete newborn advanced life support education, training and proficiency requirements, and are in attendance at the birth of newborn infants who are at higher risk of requiring resuscitation at birth
  o standardised newborn resuscitation equipment is available and operational and clinicians are familiar with the equipment
  o local procedures are in place to review resuscitation interventions and outcomes to monitor patient

To download the Guideline please go to:
MATERNITY - PREVENTION, DETECTION, ESCALATION & MANAGEMENT OF POSTPARTUM HAEMORRHAGE (PPH) (GL2017_018)

GL2017_018 rescinds PD2010_064

PURPOSE

This Guideline provides direction to NSW Public Health Organisations (PHOs) regarding the prevention, early detection, escalation and management of postpartum haemorrhage (PPH).

KEY PRINCIPLES

This document applies to all NSW PHOs and guides the:

- Identification of women with risk factors for PPH and the development of strategies to prevent and/or manage PPH

Prompt, appropriate management of women experiencing a PPH

USE OF THE GUIDELINE

The Chief Executives of NSW PHOs are responsible for:

- Implementation of this Guideline within their services/facilities
- Development and implementation of evidenced based local procedures and escalation plans for the prevention, detection, escalation and management of primary PPH that are aligned and consistent with the Guideline
- Development of a Maternity Massive Transfusion Protocol (MTP) for use in obstetric critical bleeding

Ensuring that all clinicians who may be required to care for women before, during and after birth have access to education and training in relation to PPH. This may be mandatory or targeted education and training at the discretion of the health entity, based on its assessment of local needs.

To download the Maternity – Prevention, Detection, Escalation and Management of Postpartum Haemorrhage (PPH): Guideline please go to: 
MATERNITY – TIMING OF PLANNED OR PRE-LABOUR CAESAREAN SECTION AT TERM (GL2016_015)

GL2016_015 rescinds PD2007_024

PURPOSE
The purpose of this document is to provide guidance for the timing of planned or pre-labour caesarean section at term. Where there are no identified maternal, fetal or obstetric risks, it is advised that a planned or pre-labour caesarean section at term should not routinely take place prior to 39 weeks gestation (39+0 weeks).

KEY PRINCIPLES
The risks of maternal and neonatal morbidity incurred by planned caesarean section birth prior to 39+0 weeks should be weighed carefully on a case by case basis, against the risks of spontaneous labour occurring prior to the planned procedure.

The risks of maternal and neonatal morbidity include a higher risk of neonatal respiratory distress syndrome, transient tachypnoea of the newborn, mechanical ventilation, transfer and admission to neonatal intensive care units, breastfeeding difficulties, increased maternal blood loss, and longer hospital stay.

Clinical decision-making about the timing of a planned caesarean section at term should follow a discussion with the woman and her family about the risks and benefits of all options for birth, and include information about the risks and benefits of birth after 39+0 weeks.

USE OF THE GUIDELINE
The Chief Executives of NSW PHOs are responsible for the implementation of this Guideline within their services / facilities to ensure that local protocols or operating procedures are in place, aligned and consistent with this Guideline. All maternity services staff should be aware of the Guideline and actively participate in its implementation.

To download the Maternity – Timing of Planned or Pre-Labour Caesarean Section at Term guideline please go to:  https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2016_015

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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.\(^\text{18}\)

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
- PD2007_075 Lookback Policy
- PD2014_028 Open Disclosure Policy
- PD2014_004 Incident Management Policy
- PD2005_219 Deaths - Reporting of Maternal Deaths to the NSW Department of Health
- PD2008_070 Death – Management of Sudden Unexpected Death In infancy
- PD2011_076 Deaths - Review and Reporting of Perinatal Deaths

The Maternity Clinical Risk Management Committee will assume the responsibilities set out in PD2011_076 Deaths - 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.

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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.

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>
<thead>
<tr>
<th>Table 1 Risk identification – possible sources of information</th>
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</thead>
<tbody>
<tr>
<td><strong>Internal</strong></td>
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<tr>
<td>Risk assessment</td>
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<tr>
<td>Incident reporting</td>
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<tr>
<td>Trigger reporting</td>
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<tr>
<td>Complaints and claims</td>
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<tr>
<td>Staff consultation</td>
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<tr>
<td>Clinical audit</td>
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<tr>
<td>Clinical indicators</td>
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</tbody>
</table>
Principles that govern these activities are:

- Wherever possible a multidisciplinary approach be taken.
- 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 Policy. 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 PD2014_004 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 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.

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PD2014_004 Incident Management Policy
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.

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 monthly\(^20\) 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.

\(^20\)This may vary according to the volume of clinical activity but no less than quarterly.
Appendix 1 Maternity Clinical Risk Management process

Data Sources (Risk identification)

- Standards
- IIMS
- Complaints
- Triggers
- Coroner
- HCCC

Analysis and Action Strategies (Risk assessment, analysis and evaluation)

- Maternity Clinical Risk Management Committee

Outcomes (Risk control)

- Make recommendations to the maternity managers about system improvements.
- Make recommendations to the Chief Executive through the Clinical Stream about system improvements.
- Provide reports about outcomes from the activities undertaken.

Lessons learned

- Feedback
Appendix 2 Maternity Risk Management Governance Structure

Department of Health

Chief Executive

Executive Director Clinical Governance

Executive Director Clinical Operations

Area/Cluster Director

Network Director

Facility
Maternity Services Management

Maternity Clinical Risk Management Committee
Clinical Director
Midwifery Manager
Clinicians

Maternity Service

Adapted from Dr Charles Pain, Director of Clinical Governance Sydney West AHS
## Appendix 3 Triggers and incidents that must be reported on IIMS.

<table>
<thead>
<tr>
<th>Maternal</th>
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<tbody>
<tr>
<td>Severe postpartum haemorrhage &gt;1500 mls</td>
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<tr>
<td>Peripartum blood product transfusion</td>
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<tr>
<td>Unplanned return to theatre</td>
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<tr>
<td>Anaesthetic complications</td>
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<tr>
<td>Admission to a critical care area outside of</td>
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<tr>
<td>the maternity unit'</td>
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<tr>
<td>Thromboembolic events</td>
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<tr>
<td>Caesarean section at full dilatation (all</td>
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<tr>
<td>presentations)</td>
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<tr>
<td>3rd/4th degree tears</td>
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<tr>
<td>Uterine rupture</td>
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<tr>
<td>Unplanned readmission</td>
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<tr>
<td>Transfer to a higher level facility</td>
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<tr>
<td>Maternal death</td>
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<tr>
<th>Fetal/neonatal</th>
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<tbody>
<tr>
<td>Shoulder dystocia where more than positioning</td>
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<tr>
<td>and/or McRobertts manoeuvre are required</td>
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<tr>
<td>to effect delivery</td>
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<tr>
<td>Apgar score &lt;7 at 5 minutes</td>
</tr>
<tr>
<td>Cord ph &lt;7.10 arterial or cord lactate &gt;5.2</td>
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<tr>
<td>Term baby admitted to NICU</td>
</tr>
<tr>
<td>Transfer to a higher level facility</td>
</tr>
<tr>
<td>Stillbirth</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Organisational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unavailability of health record</td>
</tr>
<tr>
<td>Delay in responding to call for assistance</td>
</tr>
<tr>
<td>Faulty equipment</td>
</tr>
<tr>
<td>Conflict over case management</td>
</tr>
<tr>
<td>Potential patient complaint</td>
</tr>
<tr>
<td>Failure to follow local protocol</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Process step</th>
<th>Proposed change in service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Career Medical Officer (CMO) Coverage</td>
<td>All midwives and Doctors involved in labour and birthing will be required to have training in Advanced Life Support Obstetrics (ALSO).</td>
</tr>
</tbody>
</table>

Step Two: Identifying risks

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

<table>
<thead>
<tr>
<th>Process step</th>
<th>Proposed change in service</th>
<th>Threat/risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMO Coverage</td>
<td>All midwives and Doctors involved in labour and birthing will be required to have training in ALSO</td>
<td>Maintaining competence in ALSO training requires time &amp; budget allocation</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Process step</th>
<th>Proposed change in service</th>
<th>Threat/risk</th>
<th>C</th>
<th>L</th>
<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMO Coverage</td>
<td>All midwives and Doctors involved in labour and birthing will be required to have training in ALSO</td>
<td>Maintaining competence in ALSO training requires time &amp; budget allocation</td>
<td>A</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>
Table 3 SAC matrix

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Serious A</th>
<th>Major B</th>
<th>Moderate C</th>
<th>Minor D</th>
<th>Minimum E</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Frequent</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>2 Likely</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3 Possible</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4 Unlikely</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>5 Rare</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Process step</th>
<th>Proposed change in service</th>
<th>Threat</th>
<th>C</th>
<th>L</th>
<th>R</th>
<th>Current controls</th>
<th>Possible additional controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMO Coverage</td>
<td>All midwives and Doctors involved in labour and birthing will be required to have training in ALSO</td>
<td>Maintaining competence in ALSO training requires time &amp; budget allocation</td>
<td>A</td>
<td>3</td>
<td>1</td>
<td>* ALSO training completed for all currently employed midwives</td>
<td>* Budget allocation needed to support ongoing training for new recruits and refresher training for all staff every 5 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Informal regular skill drills</td>
<td>* One VMO has received ALSO training</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Current CMO booked in for ALSO training</td>
<td>* Formalise skill drills</td>
</tr>
</tbody>
</table>

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.

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

70(2/09)
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 Standards

**Standard 1: Organisation**

*Local arrangements and accountability for implementing Risk Management and risk management are clearly defined.*

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>There is a written maternity services Risk Management strategy that has been approved by the Area Health Service Quality Committee.</td>
</tr>
<tr>
<td>1.2</td>
<td>A nominated professional lead(s) has the responsibility for overseeing Risk Management throughout the maternity service.</td>
</tr>
<tr>
<td>1.3</td>
<td>There is a lead obstetrician and clinical midwife manager for labour and birthing matters.</td>
</tr>
<tr>
<td>1.4</td>
<td>Each maternity service or facility has a formal group, the MCRMC, in which Risk Management and risk related issues are discussed.</td>
</tr>
</tbody>
</table>

**Standard 2: Learning from experience**

*The maternity service proactively uses internal and external information to improve clinical care.*

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Incidents, near misses and trigger events are reported in all areas of the maternity service by all staff groups.</td>
</tr>
<tr>
<td>2.2</td>
<td>Summarised incident reports are provided regularly to the Area Health Service Quality Committee.</td>
</tr>
<tr>
<td>2.3</td>
<td>The maternity service applies policy directives issued by the Department of Health.</td>
</tr>
<tr>
<td>2.4</td>
<td>The maternity services consider and apply recommendations from Area Health Service, State and national reports.</td>
</tr>
<tr>
<td>2.5</td>
<td>There is evidence of lessons learned and action arising from Risk Management activities.</td>
</tr>
</tbody>
</table>

**Standard 3: Communication**

*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.*

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>There is information available to women and their partners, which is dated and describes the risks, benefits and alternatives of their proposed treatment throughout maternity care.</td>
</tr>
<tr>
<td>3.2</td>
<td>The arrangements are clear concerning which named professional is responsible for planning and managing the woman’s care at all times.</td>
</tr>
<tr>
<td>3.3</td>
<td>There is an agreed mechanism for direct referral and consultation to an obstetrician by a midwife at all stages of care.</td>
</tr>
<tr>
<td>3.4</td>
<td>There is a personal handover of care on labour ward when midwifery and medical shifts change.</td>
</tr>
</tbody>
</table>

---

22 Adapted from Clinical Negligence Scheme for Trusts Maternity Clinical Risk Management Standards April 2006 NHS Litigation Authority
### Standard 4: Clinical care

**There are clear guidelines for the management of general clinical care.**

| 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

**There are management systems in place to ensure the competence and appropriate training of all professional staff.**

| 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

*A comprehensive system for the completion of health records is in place. Documentation standards are completed as part of clinical audit activities.*

| 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. |

### Standard 7: Staffing levels

*Maternity services provide safe care for mothers and babies at all times.*

| 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

*A system to monitor and evaluate the risk management program is in place.*

| 8.1 | Compliance with polices 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.
- 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.
MATERNITY - MANAGEMENT OF EARLY PREGNANCY COMPLICATIONS
(PD2012_022)

**PD2012_022 rescinds PD2009_058.**

**PURPOSE**
This is a policy for maternity services with respect to the management of early pregnancy complications in Early Pregnancy Assessment Services (EPAS). It also acts as a guide as to what is deemed suitable for ambulatory management.

This policy provides information related to the diagnosis and clinical management of women with early pregnancy loss, defined as a loss within the first 12 completed weeks of pregnancy. It mainly addresses the management of spontaneous miscarriage, but is also relevant to women affected by ectopic pregnancy and gestational trophoblastic disease, although specific guidelines for these conditions should be examined separately.

This policy recognises the importance and value of a dedicated outpatient EPAS within hospitals, as the EPAS has been shown to provide clinical benefits.

It is recognised that EPAS may care for women between 12 to 20 weeks gestation. However, the clinical and psychological needs of such women are often different compared to those with early pregnancy complications. Consideration needs to be given to a lower threshold for admission to hospital to ensure that such clinical and psychological needs can be met. The carers in environments to which such women are admitted need to be cognisant of the particular clinical and psychological needs of these women.

**MANDATORY REQUIREMENTS**

The place of the different diagnostic modalities must be clearly defined within service-specific algorithms (Appendix B), and the full range of therapeutic options (expectant and surgical) must be available to women who miscarry whenever possible. Apart from certain specific clinical circumstances, women should be able to choose their preferred method of management.

All maternity services must provide or be networked to a dedicated outpatient Early Pregnancy Assessment Service (section 2).

**IMPLEMENTATION**

Chief Executives or delegated officers are to ensure a written local protocol is in place and implemented as described in this policy.

Health professionals in all relevant health care settings must be familiar with the various diagnostic tools necessary to help delineate viable from non-viable pregnancy and ectopic from intrauterine pregnancy.

Maternity services and Emergency Departments must ensure that there are appropriate local policies and algorithms for each therapeutic intervention with clearly outlined pathways for each of the options available.

All health professionals must be aware of the psychological sequelae associated with pregnancy loss and must provide support, follow-up and access to formal counselling when necessary (section 5).
1. INTRODUCTION


This policy directive should be read in conjunction with:
- **PD2005_406** Consent to Medical Treatment - Patient information
- **PD2005_341** Human Tissue - Use/Retention, including Organ Donation
- **GL2015_011** Rh (D) immunoglobulin (Anti D)

The Woman’s Hospitals of Australasia Clinical Practice Guideline (2008) was adapted from the Green-top Guideline No. 25, Management of Early Pregnancy Loss, October 2006, produced by the Royal College of Obstetricians and Gynaecologists (RCOG) of the United Kingdom. This policy has been recommended for use in NSW by the Maternal and Perinatal Health Priority Taskforce and the Early Pregnancy Assessment Service Clinical Advisory Group.

1.1 Types of Evidence defined

The definitions of the types of evidence used in the original RCOG Guideline, come from the US Agency for Health Care Policy and Research (AHCPR). Where possible, recommendations are based on, and explicitly linked to, the evidence that supports them. Areas lacking evidence are annotated as ‘good practice points. Refer Appendix A.

1.2 Purpose and scope

This is a policy for maternity services with respect to the management of early pregnancy complications in Early Pregnancy Assessment Services (EPAS). It also acts as a guide to Emergency Departments as to what is deemed suitable for ambulatory management.

This policy provides information related to the diagnosis and clinical management of women with early pregnancy loss, defined as a loss within the first 12 completed weeks of pregnancy. It mainly addresses the management of spontaneous miscarriage, but is also relevant to women affected by ectopic pregnancy and gestational trophoblastic disease, although specific guidelines for these conditions should be examined separately.

This policy recognises the importance and value of a dedicated outpatient Early Pregnancy Assessment Service (EPAS) within hospitals, as the EPAS has been shown to provide clinical benefits.

It is recognised that EPAS may care for women between 12 to 20 weeks gestation. However, the clinical and psychological needs of such women are often different to those with early pregnancy complications. Consideration needs to be given to a lower threshold for admission to hospital to ensure that such clinical and psychological needs can be met. The health professionals in the environment in which such women are admitted must be cognisant of the particular clinical and psychological needs of these women.

The place of the different diagnostic modalities must be clearly defined within service-specific algorithms (refer Appendix B), and the full range of therapeutic options (expectant and surgical) must be available to women who miscarry whenever possible. And apart from certain specific clinical circumstances, women should be able to choose their preferred method of management.

152(03/05/12)
Chief Executives or delegated officers are to ensure a written local protocol is in place and implemented as described in this policy.

Health professionals in all relevant health care settings must be familiar with the various diagnostic tools necessary to help delineate viable from non-viable pregnancy and ectopic from intrauterine pregnancy.

Maternity services must ensure that there are appropriate local policies and algorithms as above for each therapeutic intervention with clearly outlined pathways for each of the options available.

All health professionals must be aware of the psychological sequelae associated with pregnancy loss and must provide support, follow-up and access to formal counselling when necessary (section 5).

It is acknowledged that Specialist Obstetricians & Gynaecologists and GP Obstetricians have been and will continue to provide such services. The algorithms in this document are also appropriate for their use.

1.3 Background

Miscarriage occurs in 10 to 20% of clinical pregnancies and accounts for 55,000 couples experiencing early pregnancy loss each year in Australia.6

While the rate of miscarriage has remained fairly predictable, better diagnostic and therapeutic interventions have changed standard treatments; what once was ‘routine surgical evacuation’ has become less so.1 In the last five years, with the advent of more refined diagnostic techniques and therapeutic interventions, treatment is now provided more and more on an outpatient basis, in both GP and outpatient hospital settings.7

In addition to the obvious medical (and possibly surgical) implications of miscarriage, research over the last two decades indicates that significant psychological effects can occur in women who suffer a miscarriage,8,1 while further research has shown that appropriate support during and after the event can have positive, lasting effects.8

Changes in medical terminology for miscarriage were recommended as early as ten years ago9,10 however many textbooks and research articles continue to use terminology which women find distressing. In this policy the medical terminology has been reviewed and the preferred terminology has been recommended.

This policy is primarily aimed at health professionals from all disciplines and managers who support women at the time of pregnancy loss.
1.4 Appropriate terminology

The inadvertent use by health professionals of inappropriate terms such as 'pregnancy failure', or 'incompetent cervix' can contribute to women's negative self-perceptions and worsen any sense of failure, shame, guilt and insecurity related to the miscarriage.9

It is important to note that the terminology that describes different types of clinical miscarriage (e.g. 'incomplete' or 'missed') remains relevant, as medical interventions vary depending on the type of miscarriage. Appendix C outlines both revised terms and terms recommended for use with women experiencing an early pregnancy loss.

2. SERVICE PROVISION

2.1 What is the ideal setting for assessment of women with possible diagnosis of early pregnancy loss?

Management of women with threatened or actual early pregnancy loss can be streamlined with the implementation of EPAS, with improvement in the efficiency of the service and quality of care. Admission to hospital was shown to be avoided in the UK by 40% of women, with a further 20% requiring shorter hospital stay.12

Dedicated EPAS have been established in various locations across NSW. These services in general augment existing hospitals and non hospital services for women with early pregnancy problems. It is acknowledged that Specialist Obstetricians & Gynaecologists and GP Obstetricians have been and will continue to provide such services. It is recognised that lower role delineated facilities across the State will have established pathways for dealing with early pregnancy problems. For such services networking to a dedicated EPAS for consultation is recommended with referral only where required.

2.2 What are the requirements for running an effective early pregnancy assessment service (EPAS)?

To be effective, an EPAS requires the following:
- an appointments system;
- a discrete waiting area and appropriate consultation room;
- ultrasound equipment (including transvaginal probes) or access to ultrasound evaluation;
- easy access to laboratory facilities for rhesus antibody testing, selective serum human chorionic gonadotrophin (hCG), and ideally progesterone estimation.13
The EPAS should be available on a daily basis during the normal working week, and if possible, services available on weekends and after hours.

There must be written pathways for clinical management, clearly defined lines of communication, governance, and accountability for clinical practice.

Inclusion and/or exclusion criteria for the EPAS should be delineated by the facility and should include guidance for appointment booking (i.e. with referral only or self-referral).

Standardised patient information leaflets, referral and transfer of care (discharge) letters must also be readily available, utilised, and regularly reviewed.

3. DIAGNOSIS AND INVESTIGATION

Diagnosis is made through a combination of patient history, physical examination and clinical investigation.

3.1. What is the role of transvaginal ultrasound in the EPAS setting?

EPAS should have access to transvaginal ultrasound with staff appropriately trained and credentialed in its use.

Transvaginal scanning will be required in the majority of women referred to an EPAS. Ultrasound assessment is particularly reliable in confirming the diagnosis of complete miscarriage (positive predictive value 98%). The sonographer should be formally trained in the use of both transabdominal (TAS) and trans-vaginal ultrasound (TVS), as TAS and TVS are complementary and the appropriate modality should be used.

Ideally, ultrasound reports should use standardised documentation (see Appendix D for sample report). Ultrasound practice is guided by the Australian Society of Ultrasound in Medicine, RANZCOG, other professional bodies, and local governance policies.

Appropriate infection control measures must be taken when disinfecting transvaginal ultrasound probes and facilities must ensure that there is strict adherence to current standards for disinfection.

3.2. How should cases of suspected early pregnancy loss be managed in the EPAS?

EPAS must use diagnostic and therapeutic algorithms of care. In particular, these must be available for the management of suspected ectopic pregnancy, intrauterine pregnancy of uncertain viability and for pregnancy of unknown location.

The use of the term ‘indeterminate’ is confusing and more specific definitions should be used, that is, ‘pregnancy of unknown location’ and ‘pregnancy of uncertain viability’. 

152(03/05/12)
‘Indeterminate’ is a term used in clinical practice that has led to confusion. Some practitioners have used the term to mean ‘pregnancy of indeterminate site’ or ‘pregnancy of indeterminate viability’. Therefore the term ‘indeterminate’ should no longer be used, and replaced with the two separate terms “pregnancy of unknown location” and “pregnancy of uncertain viability” (see table 1 for definitions). Both terms should only be used after assessment by TVS.

Even with expert use of TVS using agreed criteria, it may not be possible to confirm if a pregnancy is intrauterine or extra uterine in 8 - 31% of cases in the first visit. These women should be classified as having a “pregnancy of unknown location.” In specialised scanning services, the overall incidence of pregnancy of unknown location is as low as 8 - 10%.

The number of cases falling into these two groups can be kept to a minimum by using a thorough and critical approach to TVS in conjunction with strict diagnostic criteria. The sonographer should record whether an ‘apparently empty’ sac is eccentrically placed in the fundus, whether it exhibits a ‘double-ring’ pattern, and so on. These findings will help to delineate whether this is likely to be an intra- or extra uterine pregnancy.

A basic ultrasound diagnostic algorithm can be found in Appendix B. It includes terminology described above, with the aim of encouraging a consistent approach across EPAS. TVS is only one part of the diagnostic process in the assessment of potential early pregnancy loss. Women should be managed within a service-specific policy that includes the use of serum hCG assay. Several published guidelines for the diagnosis, management, and treatment of early pregnancy are available on which to base clinical practice.

A basic ultrasound diagnostic algorithm can be found in Appendix B. It includes terminology described above, with the aim of encouraging a consistent approach across EPAS. TVS is only one part of the diagnostic process in the assessment of potential early pregnancy loss. Women should be managed within a service-specific policy that includes the use of serum hCG assay. Several published guidelines for the diagnosis, management, and treatment of early pregnancy are available on which to base clinical practice.

3.3. What is the role of serial hCG assessment in predicting pregnancy outcome?

Modern monoclonal antibody based kits can detect hCG at 25 iu/l, a level reached nine days post conception (day 23 of a 28-day cycle). Service-specific discriminatory zones for serum hCG should be defined to help exclude possible ectopic pregnancy. At levels above 1500 iu/l, an ectopic pregnancy will usually be visualised with TVS. However, the importance of levels that plateau below 1000 iu/l must be recognised. In these cases, pregnancy of unknown location and miscarriage are both possible outcomes. The potential for rarer diagnoses, such as gestational trophoblastic disease or cranial germ cell tumour, must be considered although, in these cases, serum hCG levels are likely to be greater than 1000 iu/l. In a study of 152 women with a history and TVS findings suggestive of complete miscarriage, serial hCG assessment revealed a 5.9% incidence of ectopic pregnancy.

Early ectopic pregnancy can be difficult to diagnose and access to serial serum hCG estimation is essential, with results available within 24 hours. Staff must be familiar with what is an acceptable normal rise in 48 hours. Although a doubling of hCG titre is often expected, this can vary depending on gestation.

Serum hCG levels need caution in interpretation. In cases of twin pregnancy or heterotopic pregnancy, a suboptimal rise may be misleading.

Women with miscarriage or ectopic pregnancy who are managed expectantly may also require serial serum hCG monitoring.
3.4. Does serum progesterone assay have a role in predicting pregnancy outcome?

Serum progesterone can be a useful adjunct when ultrasound suggests pregnancy of unknown location. TVS, serial serum hCG levels and progesterone may all be required in order to establish a definite diagnosis.

When ultrasound findings suggest pregnancy of unknown location, serum progesterone levels below 25 nmol/l are associated with pregnancies subsequently confirmed to be non-viable. However, care must be taken in terms of active intervention, and uterine evacuation should not be undertaken based on a low initial progesterone. Viable pregnancies have been reported with initial levels less than 15.9 nmol/l. In the presence of pregnancy of unknown location, a serum progesterone less than 20 nmol/l predicts spontaneous pregnancy resolution with a sensitivity of 93% and specificity of 94%. One advantage is that the need for formal uterine evacuation can be reduced if a policy of expectant management is adopted.

Levels above 25nmol/l are ‘likely to indicate’ and above 60 nmol/l are ‘strongly associated with’ pregnancies subsequently shown to be normal. Overall, it is not possible to define a specific discriminatory value for a single serum progesterone result that will allow absolute clinical confirmation of viability or non-viability.

If the pregnancy test is positive yet ultrasound is unable to visualize the pregnancy, this is by definition a “pregnancy of unknown location.” There are threshold hCG levels whereby an intrauterine pregnancy would not be expected to be seen with ultrasound (approximately 1500i/u for T/V and 2000i/u for T/A) and the role of progesterone in the assessment of pregnancy nonviability is less important than hCG in the acute setting.

3.5. Should all women with early pregnancy loss receive anti-D immunoglobulin?

Non-sensitised rhesus (Rh) negative women must receive anti-D immunoglobulin in the following situations: ectopic pregnancy and any miscarriage, regardless of gestational age of the fetus or uterine evacuation method.

Rh D Immunoglobulin (Anti-D) must be administered in accordance with GL2015_011.

The National Blood Authority guidelines on the prophylactic use of Rh D immunoglobulin (anti-D) in obstetrics recommends the following:

General

For successful immunoprophylaxis, Rh D immunoglobulin should be administered as soon as possible after the sensitising event, but always within 72 hours. If Rh D immunoglobulin has not been offered within 72 hours, a dose offered within 9-10 days may provide protection. Blood should be taken from the mother before administration of the Rh D immunoglobulin to assess the magnitude of fetomaternal haemorrhage (FMH). Where FMH quantitation shows that FMH greater than that covered by the dose already administered has occurred, administration of an additional dose/s sufficient to provide immunoprophylaxis must be administered and preferably within 72 hours.
17. OBSTETRICS

Sensitising events in the first trimester

- A dose of 250 IU (50 μg) Rh D immunoglobulin should be offered to every Rh negative woman with no preformed anti-D to ensure adequate protection against immunisation for the following indications up to and including 12 weeks gestation (Level IV evidence):
  - miscarriage; (Level IV)
  - termination of pregnancy; (Level IV)
  - ectopic pregnancy; and (Level IV)
  - chorionic villus sampling. (Level III)
- A dose of 250 IU (50 μg) Rh D immunoglobulin is sufficient to prevent immunisation by a fetomaternal haemorrhage of 2.5 ml of fetal red cells (5 ml whole blood) (Level IV evidence).
- There is insufficient evidence to support the use of Rh D immunoglobulin in bleeding prior to 12 weeks gestation in an ongoing pregnancy, although if the pregnancy then requires curettage, Rh D immunoglobulin should be given. If miscarriage or termination occurs after 12 weeks gestation, 625 IU (125 μg) Rh D immunoglobulin should be offered.

Sensitising events beyond the first trimester

- Although some of the recent evidence related to the use of immuno-prophylaxis is based upon studies of potentially sensitising events occurring up to 20 weeks gestation, for practical purposes the working party recommends that a dose of 250 IU (50 μg) be used for first trimester events (up to and including 12 weeks gestation) and 625 IU (125 μg) be used beyond first trimester. Future revisions of these guidelines may, in the face of further recommendations, extend the use of the 250IU (50μg) dose beyond 12 weeks gestation.
- A dose of 625 IU (125 μg) Rh D immunoglobulin should be offered to every Rh D negative woman with no preformed anti-D to ensure adequate protection against immunisation for the following indications after 12 weeks gestation (Level IV evidence):
  - Genetic studies (chorionic villus sampling, amniocentesis, cordocentesis);(Level III)
  - Abdominal trauma considered sufficient to cause fetomaternal haemorrhage; (Level IV)
  - Each occasion of revealed or concealed antepartum haemorrhage (where the patient suffers unexplained uterine pain the possibility of concealed antepartum haemorrhage should be considered, with a view to immunoprophylaxis); (Level IV)
  - External cephalic version (performed or attempted); (Level III)
  - Miscarriage or termination of pregnancy. (Level IV)
- As evidence for the efficacy of this dose for these indications is not available, it is recommended that the magnitude of fetomaternal haemorrhage be assessed and further doses of Rh D immunoglobulin administered if required, especially where transplacental access or puncture of fetal blood vessels occurs.

Upon transfer of care (discharge) from the EPAS, documentation that clearly states whether or not anti-D was given and the dosage must be annotated.

4. TREATMENT

The options for treatment include: expectant management and/or surgical uterine evacuation. To the fullest extent possible, a woman should be given the choice of treatment option.
Concerns have been raised about the infective risks of non-surgical management but published data suggest a reduction in clinical pelvic infection and no adverse affects on future fertility.

Expectant management may be followed by minimal bleeding, as any retained tissue will usually undergo reabsorption. Occasionally, the passage of tissue may be associated with significant bleeding (ie >spotting). It is important that all women undergoing expectant management have direct telephone access to staff for advice and support. Hospital beds must be available should admission be required.

Evidence Level IV

Expectant management should be offered by EPAS where women have access to a telephone and emergency hospital admission, if required. A plan to access medical assistance when required, should be developed in consultation with each woman in areas where there is geographical and/or social isolation.

Evidence Level Ia

Expectant management is an effective method to use in selected cases of confirmed first-trimester miscarriage. This means no specific intervention is undertaken and allows spontaneous passage of fetal tissue.

Evidence Level Ia

4.1 Expectant Management

Expectant management is an effective and acceptable method to offer women who miscarry. Patient counselling is particularly important for those women with an intact sac who wish to take an expectant approach. They should be aware that complete resolution may take several weeks and that overall efficacy rates are lower. They may wish to consider a medical approach or to commence expectant management with the option of surgical evacuation at a later date, if required. Expectant management for incomplete miscarriage is highly effective.

Evidence Level Ib

Observational and controlled trials of expectant compared with surgical management also show wide variations in reported efficacy (25-100%). Similar factors affect the success rates; these factors include the type of miscarriage, duration of follow-up, and whether ultrasound or clinical assessment was used for review. A low serum progesterone level can be used to predict those pregnancies which are most likely to resolve spontaneously.

Evidence Level Ib

Ultrasound criteria used to define ‘retained products’ varies between studies. One study included patients with an ‘AP tissue diameter of 15-50mm’ with ultrasound review at 3 days (efficacy 71%), while another included all those with an ‘AP tissue diameter < 50mm’ and reviewed patients clinically on three occasions up to 6 months (efficacy 100%). The mean anteroposterior (AP) diameter of tissue in those managed expectantly in the latter study was only 11 mm, which would have been defined as ‘complete miscarriage’ by the former study and therefore would have been excluded. When ultrasound assessment of the uterine cavity shows heterogenous shadows with a maximum AP diameter of 15 mm or less, genuine retained products are less likely to be confirmed histologically. These could, of course, include some cases of ‘incomplete miscarriage’ but are best managed conservatively as there is a trend towards a lower complication rate compared with surgical management (3.0 versus 5.8%, P = 0.06).
Several randomised trials have compared expectant with surgical management. In a trial with 122 women, efficacy rates were confirmed at six weeks of 47% (expectant) and 95% (surgical). After seven days, 37% of women managed expectantly had achieved a complete miscarriage. A meta-analysis of 13 trials comparing expectant with medical management showed that the type of miscarriage was a significant factor affecting the efficacy with an expectant approach. For missed miscarriage, complete evacuation rates for expectant versus surgical management were 28% (49/173, range 14-47%) and 81% (242/298, range 60-83%), respectively. For women with incomplete miscarriage, the rates were 94% (31/33, range 80-100%) and 99% (75/76, range 99-100%).

4.2 When should surgical uterine evacuation be used?

Clinical indications for offering surgical evacuation include: persistent excessive bleeding, haemodynamic instability, evidence of infected retained tissue and suspected gestational trophoblastic disease. Surgical uterine evacuation should be offered to women who prefer that option.

Surgical uterine evacuation (ERPC) has been the standard treatment offered to women who miscarry. Until recently, up to 88% of women who miscarried were offered ERPC. This was based on an assumption that retained tissue increases the risks of infection and haemorrhage and would not be passed spontaneously. It remains the treatment of choice if there is excessive and persistent bleeding, if vital signs are unstable or in the presence of retained infected tissue. Studies suggest that these complications affect less than 10% of women who miscarry. At least 34% of women express a ‘strong’ preference for a surgical approach to uterine evacuation.

4.3. How should surgical uterine evacuation be performed?

Vacuum aspiration has been used as the method of choice for management of miscarriage where there is an intact intrauterine sac. A Cochrane review concluded that vacuum aspiration is preferable to sharp curettage in cases of incomplete miscarriage. Two trials were included: vacuum aspiration was associated with statistically significantly decreased blood loss (mean difference -17 ml, 95%CI -24 to -10ml), less pain (RR 0.74, 95% CI 0.61 to 0.90) and shorter duration of procedure (mean difference -1.2 minutes,95% CI -1.5 to -0.87 minutes). Routine use of a metal curette after suction curettage is not required. Use of oxytocin is associated with a statistically significant (but not clinically significant) difference in median blood loss (17.6 ml versus 24.5 ml). Where infection is suspected, delaying surgical intervention for 12 hours is recommended to allow intravenous antibiotic administration.

Reported serious complications of surgery include perforation, cervical tears, intra-abdominal trauma, intrauterine adhesions and haemorrhage. The incidence of serious morbidity using a similar surgical technique in induced pregnancy termination is 2.1% with a mortality of 0.5/100 000. The advantages of prostaglandin administration prior to surgical evacuation are well established, with significant reductions in dilatation force, haemorrhage and uterine/cervical trauma. There is no randomised evidence to guide practice in cases of first-trimester miscarriage, particularly in the presence of an intact sac. Practitioners may consider oral or vaginal cervical preparation based on individual patient circumstance. ‘Timing’ of the administration should be considered to allow for maximum effect whilst minimizing the possibility of the loss of uterine contents into the bed or toilet.
Curettage under local anaesthesia is well described. It is used commonly in the USA and many European, Asian and African countries. In a UK study of 58 women with incomplete and missed miscarriage, uterine evacuation was achieved in all cases using a manual vacuum aspiration technique under systemic analgesia or patient-controlled anaesthesia. Levels of patient satisfaction and acceptability were high.

4.4 Which women should be screened for genital tract infection?

Screening for infection, including *Chlamydia trachomatis*, should be considered in women undergoing surgical uterine evacuation.

Consider vaginal swabs to diagnose bacterial vaginosis if clinically indicated or population prevalence dictates.

Women with *C. trachomatis*, *Neisseria gonorrhoea* or bacterial vaginosis in the lower genital tract at the time of induced pregnancy termination are at an increased risk of subsequent pelvic inflammatory disease; until further research is published, no definitive recommendations can be made for women undergoing surgical evacuation for miscarriage management.

4.5 Should prophylactic antibiotics be given prior to surgical evacuation?

There is insufficient evidence to recommend routine antibiotic prophylaxis prior to surgical uterine evacuation.

Antibiotic prophylaxis must be given based on individual clinical indications.

A randomised trial of prophylactic doxycycline in curettage for incomplete miscarriage did not demonstrate an obvious benefit but the study was of insufficient power to detect a clinically meaningful change in infectious morbidity. Until further research is available, antibiotic prophylaxis should only be given based on individual clinical indications.

4.6 What are the advantages of arranging histological examination of tissue passed at the time of miscarriage?

Tissue obtained via surgical evacuation should be histologically examined/evaluated to confirm pregnancy and to exclude ectopic pregnancy or unsuspected gestational trophoblastic disease.

Heath, et al., suggested that there is no obvious benefit in routine histological investigation of tissue obtained from cases of pregnancy termination and miscarriage. However, within a subgroup of 468 undergoing surgical evacuation for miscarriage, there were two cases of ectopic pregnancy diagnosed 25 and 28 days post-evacuation (an incidence of 0.42%). Neither was suspected on scan, but histology had reported ‘decidua only’. In view of the maternal risks associated with ectopic pregnancy and molar pregnancy, it is recommended that practitioners send tissue obtained at the time of surgical uterine evacuation for histological examination. This may confirm the diagnosis of miscarriage and can help to exclude ectopic pregnancy or gestational trophoblastic disease.
Practitioners must be aware of their local public health requirements or guidelines related to the appropriate disposal of fetal remains, should the woman request to take the remains home. Medical, nursing and midwifery staff must provide current and sensitive information to ensure proper burial or cremation.

5. PSYCHOLOGICAL ASPECTS OF EARLY PREGNANCY LOSS

5.1 Is there potential benefit from support and follow-up after pregnancy loss?

All professionals must be aware of the psychological sequelae associated with pregnancy loss and must provide support, follow-up and access to formal counselling when necessary. Appropriate support can result in significant positive psychological gain.

Plans for follow-up must be clearly recorded in the referral or transfer of care (discharge) letter from the EPAS or ward.

A system must be in place for informing all relevant primary health care professionals in cases of pregnancy loss.

The negative psychological impact of early pregnancy loss can be both severe and protracted and affects both women and their families71-73 and may be different for every couple. Information should be made available which highlights the options available for appropriate and sensitive disposal of fetal tissue.69 Each woman’s (and couple’s, as appropriate) needs should be identified and acknowledged, assistance and referral given to facilitate the grieving process. The provision of information on miscarriage should be offered to each woman or couple.

A randomised trial assessing the effects of caring-based counselling on women’s emotional wellbeing in the first year after miscarriage found a significant beneficial effect with reduction in overall emotional disturbance, anger and depression.8 A continuing awareness of the potential effects of miscarriage is required, with a willingness to involve appropriate support and counselling services when needed. The needs of the partner should also be considered. The opportunity for follow-up should be offered to all women after pregnancy loss but unfortunately this does not always occur. In a recent national audit study in the UK, 38% of women reported that there had been no offer of or arrangement for follow-up.74 Follow-up can involve any member of the multidisciplinary team based in hospital or community practice.

5.2 Should informed choice be encouraged in deciding which intervention to use to achieve uterine evacuation?

In terms of therapeutic intervention, the woman’s choice should be encouraged, as it is associated with positive quality-of-life outcomes.

Objective assessment of psychological morbidity in a controlled trial of expectant versus surgical management of miscarriage revealed no differences related to the procedure itself.75 However, women with miscarriage who chose their own treatment had the best health-related quality-of-life (HRQL) assessments compared with women who were randomised to one or other treatment modality.76 This confirms the importance of allowing and encouraging patient choice in the management of early miscarriage.
6. **RECOMMENDED AUDITABLE STANDARDS**

- Patient satisfaction with elements of the EPAS.
- Appropriate use of anti-D prophylaxis.
- Appropriate screening for genital tract infection.
- Appropriate use of serial serum hCG/serum progesterone assessment.
- Uptake rates for expectant, and surgical interventions.
- Complications of the various interventions (including failure rates).
- Involvement of patient in choice of treatment.
- Number of visits required to reach definitive diagnosis.
- Standards of documentation.

7. **SUPPORT GROUP WEBSITES**

Association of Early Pregnancy Units, [www.earlypregnancy.org.uk](http://www.earlypregnancy.org.uk)
SIDS and Kids, [www.sidsandkids.org](http://www.sidsandkids.org)
Bears of Hope, [http://www.bearsofhope.org.au](http://www.bearsofhope.org.au)

**REFERENCES**


17. OBSTETRICS


47. Ngoc NT, Blum J, Westheimer E, Quan TT, Winkoff B. Medical treatment of missed abortion using misoprostol. Int J Gynecol Obstet 2004;87:138–42.


17. OBSTETRICS


77. National Blood Authority, Guidelines on the prophylactic use of Rh D immunoglobulin (anti-D) in Obstetrics, Approved by the National Health and Medical research Council, 6 June, 2003, revision of guidelines funded by the Australian Government Department of Health and Ageing.


### Appendix A Evidence levels

<table>
<thead>
<tr>
<th>Classification of evidence levels</th>
<th>Grades of recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ia</strong> Evidence obtained from meta-analysis of randomised controlled trials</td>
<td><strong>A</strong> Requires at least one randomized controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)</td>
</tr>
<tr>
<td><strong>Ib</strong> Evidence obtained from at least one randomised controlled trial</td>
<td><strong>B</strong> Requires the availability of well controlled clinical studies but no randomised clinical trials on the topic of recommendations. (Evidence levels IIa, IIb, III)</td>
</tr>
<tr>
<td><strong>IIa</strong> Evidence obtained from at least one well-designed controlled study without randomisation</td>
<td><strong>C</strong> Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)</td>
</tr>
<tr>
<td><strong>IIb</strong> Evidence obtained from at least one other type of well-designed quasiexperimental study</td>
<td><strong>√</strong> Good practice point Recommended best practice based on the clinical experience of the guideline development group.</td>
</tr>
<tr>
<td><strong>III</strong> Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies</td>
<td></td>
</tr>
<tr>
<td><strong>IV</strong> Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities</td>
<td></td>
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</tbody>
</table>

Good practice point

Recommended best practice based on the clinical experience of the guideline development group.
Appendix B Algorithms

Algorithms
Initial assessment and triage of women with bleeding/pain in early pregnancy less than 12 weeks gestation

Initial assessment: presentation to GP, Emergency Department (in an appropriate clinical area/Early Pregnancy Unit) Or Early Pregnancy Assessment Service
- History
- Current contraception/pap smear
- Vital signs
- Urinary pregnancy test (unless results already confirmed)
- Establish gestation based on LMP
- Abdominal palpation
- Speculum/bimanual assessment if significant bleeding (POC to histology, unless woman wants to retain).

Does the woman have significant bleeding (>spotting) or pain requiring regular or strong analgesia?

N

Woman is considered stable

Is urine pregnancy test positive?

Y

Go to diagnostic Algorithm

N

Refer to appropriate clinic, Gynaecologist or GP.

Y

Patient is NOT to be managed in EPAS.
Patient to remain in appropriate clinical area in Emergency Department.

Respond to clinical emergency
- IV access
- Resuscitate.

Call O&G Registrar or medical officer for consult & management in Emergency Department.

When referring to EPAS:
- Ensure that findings from initial assessment are documented and made available to EPAS. If possible, commence documentation on the EPAS record.
- Advise woman:
  - what time to attend EPAS and where to go
  - that she is likely to have a vaginal ultrasound scan
  - if possible to come with partner or friend/relative
  - if possible avoid bringing children to EPAS.
  - to be prepared to stay for up to 3 hours in the EPAS, as blood tests may be required
- Provide EPAS information leaflet.
EPAS Diagnostic Algorithm

Is urine pregnancy test positive?

Y → Has patient had an ultrasound before?

N → Refer to the appropriate clinic or back to local doctor.

Y → Is an intrauterine gestational sac seen on transvaginal scan?

Y → Is a fetal pole seen?

Y → Is there a fetal heart motion?

N → Is gestational sac <25mm?

N → Is a mass seen in adnexa, ovary or fallopian tube seen on TV ultrasound?

N → Refer back to GP or Antenatal Clinic for ongoing care.

Diagnosis A: A progressing intrauterine pregnancy

Diagnosis B: Intrauterine pregnancy uncertain viability (IPUV)

Diagnosis C: Missed miscarriage

Diagnosis D: Early fetal demise

Diagnosis E: Ectopic pregnancy

Diagnosis F: Pregnancy of unknown location (PUL)

Pathway B

Pathway C

Pathway D

Pathway E

Pathway F

Y → Is crown rump length <7mm?

Y → Is there tissue in the uterine cavity?

N → Refer back to GP or Antenatal Clinic for ongoing care.

Pathway F

152(03/05/12)
EPAS Algorithm: Pathway B
Intrauterine Pregnancy Uncertain Viability (IPUV)
Gestational sac < 20mm

Discuss result and potential outcomes with patient.

On transvaginal ultrasound:
crown rump length < 7mm
yolk sac present.

Y

Book repeat transvaginal ultrasound scan 1 week.

N

Book repeat transvaginal ultrasound scan 2 weeks.

- Provide patient with all investigation results, management plan, appointment time and EPAS contact number.
- Encourage patient to contact EPAS with any concerns or queries.

Advise patient to present immediately to Emergency Department in the event of significant (>spotting) vaginal bleeding and/or severe lower abdominal pain.
EPAS ALGORITHM: PATHWAY C
Missed Miscarriage

Diagnostic transvaginal ultrasound

Haemodynamically stable, no signs of sepsis

Patient informed of management options

Discuss options

Patient likely to attend follow-up scans/consultation

Expectant Management
See page 2 for rate of complete miscarriage
- Book repeat transvaginal ultrasound 1 week.
- Warn that spontaneous miscarriage may take some time to occur.
- Explain options of weekly review and possible choice of evacuation at each week.
- Arrange review one per week
- Inform patient about telephone consultation service.
- On weekly review, check temperature and general health status.
- If previous ectopic or pelvic pain present, then repeat hCG/ultrasound at each weekly visit. Otherwise, this is not necessary unless requested by the patient.
- If complete spontaneous miscarriage has not occurred after 2 weeks, arrange an appointment for further assessment, the option of D&C may be considered.

Operative Arrange
Admit for suction evacuation
- Arrange for place on the Emergency List for women assessed as not clinically stable
- Arrange on next available list for women assessed as clinically stable.
- All products of conception to histology.
- Follow up visit 1 week post op. check anatomical pathology report with EPAS or GP.
- In cases where heterotopic pregnancies is possibility (IVF pregnancies), serial follow up hCG measurement should be performed from Day 3 onwards.
EPAS ALGORITHM: PATHWAY D
Early fetal demise

Certain of diagnosis (ultrasound report may indicate ‘suspected early fetal demise’).

Y

- Offer emotional support including formal counselling if needed.
- Repeat ultrasound if requested by patient
- Discuss options for further management i.e. expectant or operative.

N

Repeat transvaginal ultrasound scan 1 week.

Expectant See page 2 for rate of complete miscarriage
- Book repeat transvaginal ultrasound 1 week.
- Warn that spontaneous miscarriage may take some time to occur
- Explain options of weekly review and possible choice of evacuation at each week.
- Arrange review one per week
- Inform patient about telephone consultation service.
- On weekly review, check temperature and general health status.
- If previous ectopic or pelvic pain present, then repeat hCG/ultrasound at each weekly visit. Otherwise, this is not necessary unless patient requests it.
- If complete spontaneous miscarriage has not occurred after 2 weeks, arrange an appointment for further assessment, the option of D&C may then be considered.

Operative arrange
Admission for suction evacuation
- Arrange on next available list.
- All products of conception to histology.
- Follow up visit 1 week post op. check anatomical pathology report with EPAS or GP.
- In cases with increased heterotopic pregnancy risk (IVF pregnancies), serial follow up hCG measurement should be performed from Day 3 onwards.
EPAS ALGORITHM: PATHWAY E
Management of Ectopic Pregnancy

Is the RISK SCORE 3 or above? (see below)

N

One ultrasound only in EPAS (initial)

Y

Review 3 - 5 days with repeat: clinical assessment, hCG and transvaginal ultrasound

N

Y

Changes since initial hCG or ultrasound

i.e. little change in either parameter

N

Rescan again, monitor hCG at one week since the initial ultrasound if there is no significant change in either parameter but new clinical features of ectopic - gestation

N

Consider evacuation of uterus, send curettings for urgent histology. Review histology and hCG 3-5 days after the procedure. Is hCG <10% of peak?

Y

Arrange follow up in EPAS to discuss histology and planning next pregnancy.

Y

MANAGE as ECTOPIC PREGNANCY

Risk score for ectopic gestation
(add each risk factor for total score)

<table>
<thead>
<tr>
<th>Risk</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous ectopic gestation</td>
<td>2</td>
</tr>
<tr>
<td>History of tubal surgery</td>
<td>2</td>
</tr>
<tr>
<td>IUCD in situ</td>
<td>2</td>
</tr>
<tr>
<td>History PID, Chlamydia or gonorrhoea</td>
<td>1</td>
</tr>
<tr>
<td>Documented tubal pathology (i.e. hydrosalpinx at ultrasound or laparotomy)</td>
<td>1</td>
</tr>
<tr>
<td>Assisted conception</td>
<td>1</td>
</tr>
</tbody>
</table>
Pregnancy of unknown location can be defined when:
- Serum hCG is positive i.e. ≥ 5 IU/L
- Transvaginal ultrasound (performed by a Senior Sonographer or Trained Sonologist) indicates no sign of either intra or extra uterine gestation or evidence of retained products of conception

**EPAS Algorithm: Pathway F**

Pregnancy of unknown location (PUL)

**Serum hCG ≥ 5 IU/L**

Transvaginal ultrasound *does not* indicate evidence of:
- Intra uterine gestation
- Extra uterine gestation
- Retained products of conception

---

**Is the woman clinically stable?**

- **Y**
  - Expectant Management via EPAS or GP

  **Do hCG at 0 & 48 hours to establish ratio i.e.**
  **48hr hCG**
  **initial hCG**

  **Initial serum hCG level ≥ 1500 IU/L**
  Repeat transvaginal ultrasound within 24hrs likely early intra-uterine gestation.

  **Initial hCG ratio 1.66.**
  Repeat transvaginal ultrasound 7 days, likely intrauterine gestation.

- **N**
  - Admit for observation and investigation.

  **hCG ratio < 0.8**, decreasing hCG by at least 20%. Repeat hCG 1 week
  **Likely failing PUL**
  **Repeat hCG 1/52**

  **hCG ratio >0.8 and <1.66**
  Repeat transvaginal ultrasound 7 days.

---

All women must be advised to contact EPAS or present to Emergency Department if an increase in lower abdominal pain and/or vaginal bleeding, experiences faintness or shoulder tip pain.
Management of Ectopic Pregnancy

Ectopic pregnancy affects approximately 1 in 80 pregnancies. Statistics indicate the incidence is rising, however the associated mortality is decreasing due to improved diagnostic performance of transvaginal sonography and biochemical sensitivity and establishment of Early Pregnancy Services and Clinics.

Ectopic pregnancies are most commonly situated in the fallopian tube (approximately 95%). Less common sites are: interstitial, cervix, ovary, caesarean scar or rarely abdomen.

Risk factors may only be present in 25% - 50% of patients diagnosed with an ectopic pregnancy. These include:
- Previous ectopic pregnancy.
- Tubal surgery.
- Assisted reproductive technology.
- Intra uterine contraceptive device in situ.
- Use of emergency contraception.
- History pelvic inflammatory/sexually transmitted disease.
- Documented Tubal Pathology.

Management

Will depend on:
- clinical state of the woman;
- size ectopic visualised on transvaginal ultrasound;
- presence/absence of haemoperitoneum;
- serum hCG level;
- patient choice and potential compliance.

Surgical Management

**Laparoscopy** is the method of choice for stable women who are medically fit and of appropriate BMI.

**Laporotomy** is preferred in cases of haemorrhagic shock or:

*If the surgeon has insufficient experience of operative laparoscopy or suboptimal quality of laparoscopic equipment.*

Medical Management: Systemic Methotrexate

Methotrexate is an anti-metabolite which prevents the growth of rapidly dividing cells by interfering with DNA synthesis. A single intramuscular dose of Methotrexate 50mg/m² is well tolerated and effective.

**Indications for Methotrexate use:**
- Haemodynamically stable.
- Baseline serum hCG < 5,000IU/L.
- Ectopic pregnancy < 3cm diameter on transvaginal ultrasound.
- Absence of fetal heart motion on transvaginal ultrasound.
- No significant haemoperitoneum.

**Exclusion criteria**
- Evidence of significant haemoperitoneum on transvaginal ultrasound.
- Presence of fetal heart motion.
17. OBSTETRICS

- Active liver disease, aplastic anaemia, thrombocytopenia.
- Women on concurrent corticosteroids.
- Contraindications to Methotrexate.
- Woman potentially non compliant to prolonged follow up (35 – 109 days).
- Ectopic mass > 3.0cm.

**Expectant Management**
Spontaneous resolution will occur in approximately 18% of all ectopic pregnancies. This has been well documented in numerous reports.

**Indications for Expectant Management**
- Serum hCG < 1000IU/L and declining.
- Tubal mass less than 3cm.
- No signs of tubal rupture or haemoperitoneum on transvaginal ultrasound.
- Patient clinically stable.

**Exclusion criteria**
- Patient is potentially non compliant or not motivated to long term recovery.

**Follow up**
- Monitor serum hCG every 48 - 72 hrs until less than 20 IU/L.
- Once hCG levels less than 20 IU/L monitor once a week until negative.
- Repeat transvaginal ultrasound if clinically indicated.

*Rupture of ECTOPIC PREGNANCY can occur until hCG < 15 IU/L following expectant, medical or surgical management.*
EPAS Algorithm: Methotrexate (MTX) Protocol

Patient fulfils EPAS criteria for medical management of ectopic pregnancy/pregnancy of unknown location

Measure patient height and weight. **Calculate Body Surface Area**

**Day 1:** Check hCG, FBC, U&E and LFT (Blood group and antibodies and rubella titre if not previously attended).

**Day 1:** Liaise with pharmacy for Methotrexate dose to be calculated. This is the responsibility of the O&G registrar or local Medical Officer.

**Day 1:** Arrange for patient to be admitted to hospital for administration of Methotrexate and post injection monitoring.

**Day 4:** Post Methotrexate monitor serum hCG.

**Day 7:** Post Methotrexate monitor hCG, FBC, UEC and LFT. 
*If* <15% decline in hCG titre between Day 4 and Day 7 notify the obstetric registrar or local Medical Officer.

Monitor hCG weekly until a negative result is achieved.

hCG falling satisfactorily/normal. Follow up in EPAS/General Practitioner.

Continue to follow up in EPAS. Advise the woman not to conceive for three months following Methotrexate administration. Discuss the necessity of early monitoring next pregnancy.
References for algorithms:


Nepean Hospital Department of Obstetrics and Gynaecology: Acute Gynaecology Unit (AGU) Protocols, 2006

Royal College of Obstetricians and Gynaecologists (RCOG) The management of early pregnancy loss. (Green-top guideline: no 25) 2006


Royal Women’s Hospital: Algorithm: Initial assessment and triage of women with bleeding and pain in early pregnancy. Melbourne 2007

Royal Women’s Hospital Early Pregnancy Assessment Service (EPAS) assessment, diagnosis, and management planning. Melbourne 2007


Western Sydney Area Health Service (WSAHS): Registrars Guide for Bleeding in Early Pregnancy. 2003

### Appendix C Terminology

#### Table of appropriate terminology

<table>
<thead>
<tr>
<th>Previous Term</th>
<th>Recommended Term</th>
<th>Definition</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spontaneous abortion</td>
<td>Miscarriage</td>
<td>Pregnancy loss occurring before 20 completed weeks of gestation or of a fetus less than 400gm weight if gestation is unknown</td>
<td></td>
</tr>
<tr>
<td>Threatened abortion</td>
<td>Threatened miscarriage</td>
<td>Any vaginal bleeding other than spotting before 20 completed weeks of gestation</td>
<td></td>
</tr>
<tr>
<td>Inevitable abortion</td>
<td>Inevitable miscarriage</td>
<td>Miscarriage is imminent or is in the process of happening; threatened miscarriage with an open cervical os and/or rupture of the membranes</td>
<td></td>
</tr>
<tr>
<td>Incomplete abortion</td>
<td>Incomplete miscarriage</td>
<td>A miscarriage where some of the fetus or placenta are unable to be naturally expelled by the mother; a confirmed non-viable pregnancy on ultrasound with bleeding. Some products of conception remain in the uterus</td>
<td></td>
</tr>
<tr>
<td>Complete abortion</td>
<td>Complete miscarriage</td>
<td>A miscarriage needing no medical or surgical interventions; products of conception have been passed; USS shows no apparent products; bleeding generally settles</td>
<td></td>
</tr>
<tr>
<td>Missed abortion</td>
<td>Missed miscarriage</td>
<td>A confirmed, non-viable pregnancy on USS with no bleeding; signs of this would be a loss of pregnancy symptoms and the absence of fetal heart tones found on an ultrasound</td>
<td>‘missed miscarriage’ is when the fetus dies but the woman’s cervix stays closed, there is no bleeding and the fetus continues to stay inside the uterus</td>
</tr>
</tbody>
</table>

152(03/05/12)
<table>
<thead>
<tr>
<th>Previous Term</th>
<th>Recommended Term</th>
<th>Definition</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anembryonic pregnancy* or Blighted ovum*</td>
<td>Early fetal demise or</td>
<td>Also called an anembryonic pregnancy. A fertilized egg implants into the uterine wall, but fetal development never begins. Often there is a gestational sac with or without a yolk sac, but there is an absence of fetal growth</td>
<td>*these reflect different stages in the same process</td>
</tr>
<tr>
<td></td>
<td>Delayed miscarriage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Septic abortion</td>
<td>Miscarriage with infection (sepsis)</td>
<td>A miscarriage complicated by a pelvic infection</td>
<td></td>
</tr>
<tr>
<td>Recurrent abortion</td>
<td>Recurrent miscarriage</td>
<td>3 or more consecutive miscarriages by the same woman</td>
<td></td>
</tr>
<tr>
<td>Biochemical pregnancy loss*</td>
<td>Pregnancy not located on scan</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Empty sac*</td>
<td>Sac with absent or minimal structures</td>
<td></td>
</tr>
<tr>
<td>Fetal loss*</td>
<td>Previous CRL measurement with</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>subsequent loss of fetal heart</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>activity (FHA)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Early pregnancy loss*</td>
<td>Confirmed empty sac or sac with</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>fetus but no FHA &lt;12 weeks*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Delayed miscarriage*</td>
<td>As ‘early pregnancy loss’</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Late pregnancy loss*</td>
<td>Loss of FHA &gt;12 weeks*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suspected ectopic</td>
<td>Pregnancy of unknown location*</td>
<td>No signs of either intra- or extra uterine pregnancy or retained products of conception in a woman with a positive pregnancy test. No identifiable pregnancy on scan with positive hCG</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(PUL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viable pregnancy</td>
<td>Live ongoing embryonic pregnancy*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy of uncertain viability</td>
<td>Intrauterine sac (&lt;25mm mean</td>
<td>In order to confirm or refute viability, a repeat scan at a minimal interval of 1 week is necessary.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>diameter) with no obvious yolk sac</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>or fetus or</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fetal echo &lt;7mm crown-rump length</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>with no obvious fetal heart</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>activity.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous Term</td>
<td>Recommended Term</td>
<td>Definition</td>
<td>Notes</td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Ectopic pregnancy</td>
<td></td>
<td>A pregnancy located outside the uterus, usually in the fallopian tubes, but may be ovarian.</td>
<td></td>
</tr>
<tr>
<td>Molar pregnancy</td>
<td></td>
<td>The result of a genetic error during the fertilization process that leads to growth of abnormal tissue within the uterus. Molar pregnancies rarely involve a developing embryo, but often entail the most common symptoms of pregnancy including a missed period, positive pregnancy test and severe nausea.</td>
<td></td>
</tr>
<tr>
<td>Incompetent cervix</td>
<td>Cervical weakness</td>
<td>The opening of the cervix before a fetus is mature enough to be born. It may lead to miscarriage or premature delivery.</td>
<td>Cervical weakness is not routinely evaluated and therefore not usually diagnosed until after a second trimester loss has occurred.</td>
</tr>
<tr>
<td>Expectant miscarriage</td>
<td></td>
<td>No specific intervention; allows spontaneous passage of fetal tissue.</td>
<td></td>
</tr>
<tr>
<td>Surgical miscarriage</td>
<td></td>
<td>Surgical evacuation (with or without curettage) of the retained fetal tissue.</td>
<td></td>
</tr>
<tr>
<td>Heterotopic pregnancy</td>
<td>Heterotopic pregnancy</td>
<td>Concurrent/simultaneous intra-uterine and extra uterine pregnancies</td>
<td></td>
</tr>
</tbody>
</table>

http://meteor.aihw.gov.au/content/index.phtml/itemId/357718

*Definitions from The European Society for Human Reproduction Special Interest Group for Early Pregnancy, who have revised the nomenclature for use in early pregnancy loss in order to improve clarity and consistency.*11
Appendix D Sample ultrasound report form

This example has been kindly provided by Gold Coast Health Service, Queensland Health

---

<table>
<thead>
<tr>
<th>Patient History</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LNMP :</td>
<td></td>
</tr>
<tr>
<td>PREVIOUS U/S :</td>
<td>Yes □ No □</td>
</tr>
<tr>
<td>BHCG :</td>
<td>DATE TAKEN :</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ULTRASOUND FINDINGS</th>
<th>T/A</th>
<th>T/V</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intrauterine sac</td>
<td>Yes □ No □</td>
<td>Single □ Multiple □</td>
</tr>
<tr>
<td>Mean Sac Diameter</td>
<td>mm</td>
<td></td>
</tr>
<tr>
<td>Yolk sac seen</td>
<td>Yes □ No □</td>
<td>Gestation =</td>
</tr>
<tr>
<td>Fetal Pole</td>
<td>Yes □ No □</td>
<td>Length =</td>
</tr>
<tr>
<td>FHM seen</td>
<td>Yes □ No □</td>
<td></td>
</tr>
<tr>
<td>FHR</td>
<td>bpm</td>
<td></td>
</tr>
<tr>
<td>Peri gestational bleed</td>
<td>Yes □ No □</td>
<td>Size =</td>
</tr>
<tr>
<td>Gestational age by this u/s</td>
<td>Weeks</td>
<td>days</td>
</tr>
<tr>
<td>EDD by this u/s</td>
<td>/</td>
<td>/</td>
</tr>
<tr>
<td>? RPOC</td>
<td>Yes □ No □ N/A □</td>
<td>Size =</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BODY</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>RIGHT OVARY:</td>
<td>……………………………………………</td>
</tr>
<tr>
<td>LEFT OVARY:</td>
<td>……………………………………………</td>
</tr>
<tr>
<td>RIGHT ADNEXA:</td>
<td>……………………………………………</td>
</tr>
<tr>
<td>LEFT ADNEXA:</td>
<td>……………………………………………</td>
</tr>
<tr>
<td>FREE FLUID:</td>
<td>Yes □ No □ Minimal □ Moderate □ Extensive □</td>
</tr>
</tbody>
</table>

Signature: ____________________________________________________________________________
Sonographer: Reporting Radiologist: O&G/A&E Medical Officer

PLEASE TURN OVER

152(03/05/12)
COMMENTS/DIAGNOSIS:

_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

SIGNED: ____________________________________________

DESIGNATION: ______________________________________

DATE:  __________________________________________

152(03/05/12)
MATERIAL & CHILD HEALTH PRIMARY HEALTH CARE POLICY (PD2010_017)

(A component of the NSW Health/Families NSW Supporting Families Early Package)

PURPOSE

This policy is to ensure a consistent statewide approach to the provision of primary health care and health home visiting to parents expecting or caring for a new baby is implemented throughout NSW.

The policy identifies a primary health model of care for the provision of universal assessment, coordinated care, and home visiting, by NSW Health’s maternity and community health services, for all parents expecting or caring for a new baby.

MANDATORY REQUIREMENTS

All Area Health Services (AHS) are to ensure that:

- a comprehensive assessment process, consistent with the SAFE START model, is implemented in both maternity and early childhood health services (Reference: Policy Section 3)
- risk factors and vulnerabilities are determined using a team-management approach to case discussion and care planning (Reference: Policy Section 3)
- the continuity-of-care model is implemented in accordance with this policy (Reference: Policy Section 3)
- effective communication systems from maternity services to early childhood health services are established (Reference: Policy Section 3)
- Universal Health Home Visiting (UHHV) is implemented and that every family in NSW is offered a home visit by a child and family health nurse within two weeks of the baby’s birth (Reference: Policy Section 4)
- Sustained Health Home Visiting (SHHV) is implemented in accordance with this policy (Reference: Policy Section 4) NB: SHHV is not provided in all AHS and is not mandatory.

IMPLEMENTATION

Chief Executives are to ensure this policy is implemented in accordance with the Implementation Requirements (Reference: Policy Section 5) and personnel, resources and the assignment of responsibly is adequate to effectively implement the policy.

AHS are to provide to NSW Department of Health data as requested on UHHV and SHHV (from those AHS funded to implement SHHV).

This policy must be read in conjunction with the following documents that comprise the NSW Supporting Families Early Package.


82(04/03/10)
MATERNITY – NATIONAL MIDWIFERY GUIDELINES FOR CONSULTATION AND REFERRAL (PD2010_022)

PURPOSE

This is a policy for maternity services with respect to appropriate consultation and referral by midwives.

This policy establishes the requirement that all midwives providing maternity care utilise the Australian College of Midwives (ACM) National Midwifery Guidelines for Consultation and Referral. The ACM Guidelines describes the parameters for identifying normal risk pregnancy and supports midwives to make appropriate consultation and referral to other clinicians and allied health staff if risk factors arise in pregnancy.

It is recognised that safe maternity care is reliant on robust systems and processes. This includes careful risk assessment with pathways for escalation to an appropriately role delineated service.

MANDATORY REQUIREMENTS

The NSW Department of Health and the Maternal and Perinatal Health Priority Taskforce have endorsed the Australian College of Midwives (ACM) National Midwifery Guidelines for Consultation and Referral for use by all midwives in the provision of maternity care.

Area Health Services:
• Must ensure that all midwives who are providing maternity care refer to and use the Australian College of Midwives (ACM) National Midwifery Guidelines for Consultation and Referral©.
• Must ensure the availability of the ACM National Midwifery Guidelines for Consultation and Referral© to all midwives within their maternity services.
• Should provide ongoing education on the use of the ACM National Midwifery Guidelines for Consultation and Referral©.
• Should include an audit of the usage of the ACM National Midwifery Guidelines for Consultation and Referral© in their quality framework.

Maternity services must be aware of their designated higher level maternity service for consultation and/or referral and transfer. Equally, higher designated maternity services must be aware of their obligations and responsibilities for lower level maternity services.

IMPLEMENTATION

Chief Executives or delegated officers are to ensure a written local protocol is in place within maternity services and is implemented as described in this policy.

Health professionals in all relevant health care settings must be familiar with and use the ACM National Midwifery Guidelines for Consultation and Referral©.

Maternity services must ensure that the ACM National Midwifery Guidelines for Consultation and Referral© are available to all midwives in all areas of maternity care within one month of the release date of this Policy Directive.

86(08/04/10)
17. OBSTETRICS

These areas include but are not limited to:
- Antenatal Clinics, both medical and midwifery.
- Antenatal inpatient units.
- Postnatal inpatient units.
- Day Assessment Units.
- Delivery Suites/Birthing Centres.
- Community Midwifery Programs.
- Midwifery Continuity of Care Programs.

Area Health Services should develop a local implementation plan for education in the use of the ACM National Midwifery Guidelines for Consultation and Referral© within three months of the release date of this Policy Directive.

This Policy Directive should be fully implemented by Area Health Services within six months of the release date.

The ACM National Midwifery Guidelines for Consultation and Referral are appropriate for use by other clinicians when providing maternity care.
MATERNITY - FETAL HEART RATE MONITORING (GL2018_025)

GL2018_025 rescinds GL2016_001

PURPOSE

This Guideline provides guidance for fetal heart rate (FHR) monitoring using intermittent auscultation (IA), antenatal and intrapartum electronic fetal heart rate monitoring (EFM), and fetal blood scalp sampling (FBS) to monitor fetal wellbeing.

KEY PRINCIPLES

This Guideline applies to all NSW Public Health Organisations (PHOs) providing maternity services where fetal welfare assessment is conducted. The Guideline:

- clarifies the indicators for FHR assessment, monitoring and FBS
- defines the terms used to describe FHR features used by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), and the International Federation of Gynaecologists and Obstetricians (FIGO)
- clarifies the features of the preterm FHR response compared to the term fetus
- introduces new assessment tools (algorithms and documentation labels) for the interpretation of antenatal and intrapartum FHR features

USE OF THE GUIDELINE

The Chief Executives are responsible for:

- the implementation of this Guideline in NSW PHO maternity services
- the development of local protocols, pathways and Clinical Emergency Response Systems (CERS) to facilitate consultation and escalation of concern where abnormal FHR features are identified
- monitoring patient safety and quality outcomes related to fetal monitoring, particularly for women with identified risks
- processes are in place to ensure that all relevant maternity services staff (this includes permanent, casual staff, agency and locum staff) receive appropriate education.

To download the Guideline please go to:
MATURETY – TOWARDS NORMAL BIRTH IN NSW (PD2010_045)

PURPOSE

This policy provides direction to NSW maternity services regarding actions to increase the vaginal birth rate and decrease the caesarean section operation rate; to develop, implement and evaluate strategies to support women and to ensure that midwives and doctors have the knowledge and skills necessary to implement this policy.

The NSW Maternal and Perinatal Health Priority Taskforce have endorsed *Towards Normal Birth in NSW* and it is now issued as NSW Health policy.

MANDATORY REQUIREMENTS

All NSW Public Health organisations providing maternity services must implement the ten steps to providing woman centred labour and birth care.

IMPLEMENTATION

The Chief Executives or delegated officers of all NSW Public health organisations providing maternity services are ultimately responsible for the implementation of this policy directive and must ensure that it is implemented in accordance with this policy directive.

All maternity services staff must be made aware of the ten steps to providing woman centred labour and birth care and actively participate in its implementation.
## Attachment 1: Implementation checklist

<table>
<thead>
<tr>
<th>IMPLEMENTATION REQUIREMENTS</th>
<th>Not commenced</th>
<th>Partial compliance</th>
<th>Full compliance</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. All Area Health Services must establish the baseline performance of each maternity service against every measure by December 2010.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>2. All Area Health Services must identify year on year incremental targets to achieve the measures by June 2011.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>3. All Area Health Services must provide annual reports against every measure commencing June 2011.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>5. All Area Health Services must achieve the measures by December 2015.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>

MATERNITY - OXYTOCIN FOR THE INDUCTION OF LABOUR AT OR BEYOND TERM
(PD2011_075)

PURPOSE

This Policy Directive was developed to ensure safe and uniform clinical practice in relation to the use of oxytocin (Syntocinon®) for the induction of labour at or beyond term in maternity hospitals throughout NSW. It applies to induction of labour at or beyond term with a live baby. It is acknowledged that fetal death in utero at any stage of pregnancy may require induction of labour with similar or alternative agents acting upon the uterus not mentioned in the policy directive.

This policy directive provides direction to NSW maternity services regarding safe and uniform practice in relation to the induction of labour. It follows an audit of NSW maternity services undertaken in 2008 that demonstrated a wide variation in clinical practice. This policy directive should help inform maternity services in the development and implementation of local clinical practice guidelines and protocols.

MANDATORY REQUIREMENTS

All NSW Public Health Organisations providing maternity services must have clinical practice guidelines and protocols for the use of oxytocin for the induction of labour at or beyond term. Such clinical practice guidelines and protocols must reflect a Local Health District wide, standardised, evidence based policy for the induction of labour. The Local Health District policy must have statements that reflect the appropriateness of the procedure for the role level of maternity services.

All appropriately role delineated NSW public hospitals providing maternity services must have clinical practice guidelines for the induction of labour at term. Such guidelines must include a clear local plan of action for all clinicians to follow with appropriate early involvement of senior consultants in obstetrics in the event of uterine hyperstimulation (tachysystole), unsuccessful induction of labour, cord prolapse, uterine rupture and maternal collapse.

Health services and hospitals should comply with the educational program components as outlined in IB2008_002 Fetal Welfare, Obstetric Emergency, Neonatal Resuscitation Training (FONT). In particular, fetal welfare and maternity emergencies education days must include cord prolapse and maternal collapse/resuscitation in the program content. All clinicians working in maternity units are expected to complete the various components of the FONT program.

This policy directive must be read in conjunction with:
- PD2009_003 Maternity - Clinical Risk Management Program.
- GL2015_004 Maternity - Fetal Heart rate Monitoring.
- PD2010_045 Maternity - Towards normal Birth in NSW.

IMPLEMENTATION

The Chief Executives of Local Health Districts are ultimately responsible for the implementation of this policy directive within their respective facilities.
17. OBSTETRICS

1. BACKGROUND

1.1 About this document

This Policy Directive was developed to ensure safe and uniform clinical practice in relation to the use of oxytocin (Syntocinon®) for the induction of labour at or beyond term in maternity hospitals throughout NSW. It applies to induction of labour at or beyond term with a live baby. It is acknowledged that fetal death in utero at any stage of pregnancy may require induction of labour with similar or alternative agents acting upon the uterus not mentioned in the policy directive.

The development of this policy has been undertaken following:

- Literature review on induction of labour.
- An audit of clinical practice for induction of labour undertaken in NSW maternity services in role delineated levels 3, 4, 5 and 6.

An audit of maternity services undertaken in 2008 identified variance in practice in relation to induction of labour and the use of oxytocin for induction and augmentation of labour.

A review of the literature found a range of research papers, systematic reviews and evidence-based clinical practice guidelines describing international best practice for induction of labour. Relevant references are provided at the end of this Policy Directive.

This Policy Directive has been endorsed by the Maternal and Perinatal Committee and the Maternal and Perinatal Health Priority Taskforce.

1.2 Key Definitions

In this document the term:

- **must** – indicates a mandatory action required by a NSW Health policy directive, law or industrial instrument; and
- **should** – indicates an action that should be followed unless there are justifiable reasons for taking a different course of action.

1.3 Local Health District Requirements

Local Health Districts (LHD) must have a LHD wide, standardised, evidence based policy for Induction of Labour. The LHD policy must have statements that reflect the appropriateness of the procedure for the role level of the maternity service.

1.4 Woman Centred Care

Induced labour has an impact on the birth experience for women. Labour is often more painful than spontaneous labour, and epidural analgesia and assisted delivery are more likely to be required.

Treatment and care should take into account a woman’s individual needs and preferences. Women who are having, or being offered, induction of labour must have the opportunity to receive accurate information and make informed decisions about their care and treatment, in partnership with their health care professionals.
Effective communication between health care professionals and women is essential. Communication should be supported by evidence-based written information, where possible, tailored to the needs of the individual woman. Treatment and care, and the information provided should be culturally appropriate. It should also be accessible to women, their partners and families, taking into account any additional needs such as physical or cognitive disabilities, and inability to speak or read English.

1.5 Information and decision making

Only GP Obstetricians and Specialist Obstetricians who have been credentialed and have these procedures in their scope of practice may supervise induction or augmentation of labour including the use of oxytocin. It is recommended that scheduling of inductions should be by arrangement with the Birthing Unit Manager, in order to take into account the availability of staff, equipment, support services and expertise.

Women should be informed that most women will go into labour spontaneously by 42 weeks gestation. The median and mode for uncomplicated singleton pregnancy are 40 weeks two days and 40 weeks three days, respectively, not ‘40 weeks’, and two standard deviations beyond that is approximately 13 days. Approximately one-quarter of pregnant women may not have laboured by 41 weeks.1

At term, women must be offered information about the risks associated with prolonged pregnancies, and the options available to them.2

The information must cover:
• The risks and benefits of membrane sweeping during a vaginal examination:
  ▪ what a membrane sweep is;
  ▪ that membrane sweeping makes spontaneous labour more likely, and so reduces the need for induction of labour to prevent prolonged pregnancy;
  ▪ that discomfort and slight vaginal bleeding are possible from the procedure;
• The risks and benefits of induction of labour from 413 weeks gestation; and
• The risks and benefits of expectant management (waiting for labour to start).

**Induction of labour must not routinely be offered on maternal request alone.**

Health care professionals must explain the following points to women being offered induction of labour:2
• the reasons for induction being offered;
• when, where and how induction could be carried out;
• the arrangements for support and management of pain in labour (recognising that women are likely to find induced labour more painful than spontaneous labour);
• the alternative options if the woman chooses not to have induction of labour;
• the risks and benefits of induction of labour in specific circumstances and the proposed induction methods; and
• that induction may not be successful and what the woman’s options would be in this situation.

Health care professionals offering induction of labour must:
• provide the woman with adequate time to discuss the information with her partner/support person before coming to a decision;
• encourage the woman to access a variety of sources of information;
• invite the woman to ask questions, and encourage her to think about her options; and
• support the woman in whatever decision she makes.
1.6 Special Considerations

Induction of labour carries inherent risk and must be exercised with caution. There needs to be clear benefits for the mother and/or the fetus.

Induction of labour may lead to further interventions hence consideration of the context must be undertaken in line with the designated role delineated level of the maternity service. Such interventions may include the necessity to perform an emergency caesarean section.

Local Health Districts are required to provide guidance for clinicians in circumstances where clinical decision making is particularly difficult such as breech presentation, pre-labour rupture of membranes at term, multiple pregnancy, and previous caesarean section.

Women with a history of previous caesarean section must be informed of the following risks with induction of labour:
- an increased risk of need for emergency caesarean section during induced labour; and
- an increased risk of uterine rupture.

In the case of women with a history of previous caesarean section, Local Health Districts must ensure that medical induction of labour or augmentation with oxytocin (Syntocinon®) does not occur at role delineated level 3, 2 or 1 maternity services.

2. PRIOR TO INDUCTION OF LABOUR WITH OXYTOCIN

2.1 Membrane Sweeping

Membrane sweeping involves the examining finger passing through the cervix to rotate against the wall of the uterus, to separate the chorionic membrane from the decidua. If the cervix will not admit a finger, massaging around the cervix in the vaginal fornices may achieve a similar effect.

For the purpose of this policy directive, membrane sweeping is regarded as an adjunct to induction of labour rather than an actual method of induction.

2.2 Modified Bishop’s Score

Before induction of labour is carried out, a modified Bishop’s score\(^3\) must be assessed and recorded to assist with decision making about the best approach. The recommended modified Bishop’s score assessment tool is found in Appendix A.

2.3 Prostaglandins for Cervical Ripening

Prostaglandins like dinoprostone (Prostin\(^8\)) gel or Cervidil\(^9\) pessary) are widely used throughout many countries for both cervical ripening and induction of labour. In Australia, prostaglandins are promoted for cervical ripening with intact membranes and a modified Bishop Score <5. Health care professionals must comply with the requirements of PD2005_406 Consent to Medical treatment – Patient Information.

Before induction of labour is carried out, modified Bishop’s score must be assessed and recorded, and a normal fetal heart rate pattern must be confirmed using electronic fetal monitoring. After administration of vaginal PGE2, when contractions begin, fetal wellbeing should be assessed with continuous electronic fetal monitoring. Once the CTG is confirmed as normal, intermittent auscultation should be used unless there are clear indications for continuous electronic fetal
monitoring as described in GL2015_004 Maternity - Fetal Heart Rate Monitoring. If the fetal heart rate is abnormal after administration of vaginal PGE2, management of fetal compromise should be attended as per the recommendations in GL2015_004 Maternity - Fetal Heart Rate Monitoring.

For Prostin® gel:
- 1 or 2mg for the initial dose. If Prostin® gel is used and a second dose is required, it must not be given within 6 hours of the first dose.
- For Prostin® gel, the maximum dose, regardless of parity, is 3mg for all women in a 12 hour period.
- There is no evidence that further doses of Prostin® gel have any benefit.
- Oxytocin (Syntocinon®), if used, must not be started for six hours following the administration of the last insertion of Prostin® gel.
- Amniotomy may be attended four hours following the administration of the last insertion of Prostin® gel.

For Cervidil®:
- 1 x 10mg pessary is inserted and removed at or before 12 hours has passed depending on uterine activity. At 12 hours after insertion, approximately 4mg of dinoprostone has been absorbed.
- Oxytocin (Syntocinon®) must not be commenced less than 30 minutes after removal of the pessary.

The optimal timing of the doses of prostaglandins needs to be determined locally.

It is recognised that there is ongoing research into other regimes for both Prostin® gel and Cervidil® and that maternity services may be participating in clinical trials that cause variation from this policy directive.

The use of misoprostol for cervical ripening as outlined in this PD is not supported.

NB: Cervical ripening is not an approved indication for the use of misoprostol. Prior to using any drug for an unapproved (off-label) indication, approval should be sought from the local hospital or LHD Drug Committee, and informed patient consent obtained.

2.4 Mechanical Methods for Cervical Ripening

Mechanical methods used for induction of labour include various types of balloon catheters introduced via the cervical canal into the extra-amniotic space. There is emerging evidence favouring the use of balloon catheters for cervical ripening in women with an unfavourable cervix. Mechanical methods of cervical ripening must be supported by local evidence-based guidelines to support staff in their proper use.

3.  INDUCTION OF LABOUR

3.1 Surgical Methods of Induction of Labour

Amniotomy is often used in conjunction with methods of cervical ripening and/or oxytocin (Syntocinon®) to effect the initiation of labour. Amniotomy alone may be appropriate in some circumstances. In the absence of contractions, and with a high presenting part, amniotomy carries inherent risk such as compound presentation and/or cord prolapse. Appropriate risk management procedures must be in place to deal with such clinical scenarios.
3.2 Medical Methods of Induction of Labour - Oxytocin

In women with intact membranes, amniotomy should be performed where feasible prior to commencement of an infusion of oxytocin.\(^{2,3}\) Even in the situation where induction of labour is being undertaken for prelabour rupture of membranes a vaginal examination should be performed to ensure that any forewaters are ruptured. With intact membranes intravenous oxytocin alone should not be used for induction of labour.

It must be noted that water intoxication is a rare but recognised complication of synthetic oxytocin (Syntocinon\(^{\textregistered}\)) infusion. Care must be exercised with the solution used, the concentration and the total volume infused.

A fluid balance chart must be accurately maintained for women receiving this infusion. Careful review of fluid status needs to be undertaken after 2 litres of solution have been administered.

3.2.1 Solution

A non-dextrose solution must be used as the vehicle for delivering oxytocin (Syntocinon\(^{\textregistered}\)). The solutions of choice are normal saline or Hartmann’s solution.

3.2.2 Administration

Oxytocin must be administered with an infusion pump to ensure accurate administration.\(^{2,11}\) It is not acceptable to use visual methods such as counting drops or utilising a burette to administer oxytocin (Syntocinon\(^{\textregistered}\)).

3.2.3 Concentration

To reduce error, a standard concentration must always be used regardless of parity. The recommended concentration is:

- 10iu oxytocin (Syntocinon\(^{\textregistered}\)) in 1000ml infusion fluid; **OR**
- 5iu oxytocin (Syntocinon\(^{\textregistered}\)) in 500ml infusion fluid.

This equates to 10 milliunits per ml.

3.2.4 Starting dose

The same starting dose must be initiated regardless of parity, i.e. 15ml per hour or 150 milliunits per hour.

3.2.4.1 Increments

The rate must not be increased less than 30 minutes following the commencement of the regimen.

The purpose of the administration of oxytocin (Syntocinon\(^{\textregistered}\)) infusion is to achieve 4 to 5 contractions every 10 minutes. In normal circumstances, this would mean contractions that are 50-70 seconds in duration, and with a minimum resting tone of 90 seconds.

Incremental increases must occur as follows until this is achieved.
Table 1 - Incremental Regimen

<table>
<thead>
<tr>
<th>Time</th>
<th>Milliunits per minute</th>
<th>Ms per hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start</td>
<td>2.5</td>
<td>15</td>
</tr>
<tr>
<td>Min 30 mins</td>
<td>5</td>
<td>30</td>
</tr>
<tr>
<td>½ hourly</td>
<td>10</td>
<td>60</td>
</tr>
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<tr>
<td></td>
<td>30</td>
<td>180</td>
</tr>
<tr>
<td>Medical Review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>½ hourly</td>
<td>35</td>
<td>210</td>
</tr>
<tr>
<td></td>
<td>40</td>
<td>240</td>
</tr>
</tbody>
</table>

It is reasonable to consider reduction or cessation of the infusion in circumstances where spontaneous uterine activity is apparent particularly in multiparous women.

If ceased for an insertion of an epidural, recommence at the rate being infused at cessation unless otherwise indicated by the uterine activity.

3.2.4.2 Maximum dose

The maximum dose must not exceed 40 milliunits per minute or 240 ml per hour.

Once the dose has reached 30 milliunits/minute (180ml/hour), a medical reassessment must be undertaken before any further increase is undertaken. The management plan must be clearly documented in the health record.

3.2.4.3 Fetal Heart Rate Monitoring

Medical induction of labour must only occur where there are facilities for continuous external uterine contraction and fetal heart rate monitoring.²

For women who are healthy and have had an otherwise uncomplicated pregnancy, fetal wellbeing should be established before and after the administration of prostaglandins. Once a reassuring fetal heart rate is shown, intermittent auscultation should be used.²

When oxytocin is being infused continuous electronic fetal monitoring should be used as per GL2015_004 Maternity - Fetal Heart Rate Monitoring.

Local Health Districts must establish district wide procedures to assess and document the following:

- Maternal Blood Pressure, pulse and temperature.
- Maternal uterine contractions.

Local Health Districts must establish district wide procedures in the event of the following:

- Tachysystole (uterine hyperstimulation).
- Unsuccessful Induction of Labour.
- Cord prolapse.
- Uterine rupture.
- Maternal Collapse.
4. OTHER CONSIDERATIONS

4.1 Mobility

Women should be offered the opportunity to ambulate throughout the induction of labour.

4.2 Managing pain

Women should be informed of the different ways to manage and cope with pain in labour in different settings.

Women should be offered support and analgesia as required, and staff should encourage women to use their own coping strategies for pain relief. This includes the opportunity to labour in water.

4.3 Failed induction

If induction fails, clinicians must discuss this with the woman and provide support. The woman’s condition and the pregnancy in general should be fully reassessed and fetal wellbeing should be assessed using electronic fetal monitoring. If induction of labour fails, subsequent management options should be discussed with the woman. Such options may include a further attempt to induce labour, the timing of which will be dependent on the clinical situation and woman’s wishes. Caesarean section operation may be appropriate in some circumstances.

4.4 Evaluation

In accordance with PD2009_003 Maternity - Clinical Risk Management Program, the local Maternity Clinical Risk Management Committees are charged with auditing the following on an annual basis:

- Gestational age less than 39 weeks for elective induction of labour.
- Documentation of modified Bishop’s Score.
- Documentation of fetal welfare.
- Recognition and management of uterine hyperstimulation (tachysystole).

5. REFERENCES

17. OBSTETRICS

6. APPENDIX A

Modified Bishop\textsuperscript{6} Cervical Score System

<table>
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<tr>
<th>Characteristic</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>Score</th>
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<td>Dilatation (cm)</td>
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<td>1-2</td>
<td>2-4</td>
<td>&gt; 4</td>
<td></td>
</tr>
<tr>
<td>Length (cm)</td>
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<td>2-4</td>
<td>1-2</td>
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<td></td>
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<tr>
<td>Consistency</td>
<td>firm</td>
<td>average</td>
<td>soft</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Position of cervix</td>
<td>posterior</td>
<td>middle/anterior</td>
<td>-</td>
<td>-</td>
<td></td>
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<tr>
<td>Station</td>
<td>-3</td>
<td>-2</td>
<td>-1 to 0</td>
<td>+1 to +2</td>
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</tr>
</tbody>
</table>

Total =

Attachment 1: Implementation checklist

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<th>Partial compliance</th>
<th>Full compliance</th>
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</thead>
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<tr>
<td>1. A Local Health District standardised local practice procedure, based on this policy directive, must be implemented within 6 months of issue of this policy directive.</td>
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</tr>
<tr>
<td>Notes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. All medical, midwifery, nursing and other staff must be educated about the content of this policy directive within 12 months of issue.</td>
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<td>☐</td>
<td>☐</td>
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MATERNITY – SUPPORTING WOMEN IN THEIR NEXT BIRTH AFTER CAESAREAN SECTION (NBAC) (GL2014_004)

PURPOSE

The Guideline: Maternity - Supporting Women in their Next Birth After Caesarean Section (NBAC) provides direction to the NSW maternity services staff to provide consistent, evidence-based information to women. This information will support pregnant women in their decision making about their next birth after caesarean section.

This Guideline should be read in conjunction with PD2010_045 Maternity - Towards Normal Birth in NSW, which aims to increase the vaginal birth rate in NSW.

KEY PRINCIPLES

This Guideline applies to all NSW Public Health Organisations (PHOs) providing maternity services. It guides all NSW PHOs to support women in their decision making around their NBAC which includes ensuring that:

- Women are provided with access to vaginal birth after caesarean section (VBAC) services.
- Women are provided with consistent evidence-based information regarding NBAC.
- Clinicians have access to consistent evidence-based information in order to support women to make informed choices about birth after a previous caesarean section.

IMPLEMENTATION

The Chief Executives of NSW PHOs are responsible for the implementation of this Guideline within their services/facilities to ensure that local VBAC protocols or operating procedures are in place, aligned and consistent with the Guideline.

All maternity services staff should be aware of the Guideline and actively participate in its implementation to support pregnant women who have had a previous caesarean section in their decision making around their NBAC.


MATERNITY – INDICATIONS FOR PLACENTAL HISTOLOGICAL EXAMINATION (GL2014_006)

PURPOSE

This guideline describes indications for placental histological examination for births occurring in NSW hospitals as well as recommendations for storage, transport and submission of placentas for pathological review.

This document is intended to support clinical practice. The information provided in this document has been guided by the Clinical Practice Guideline for Perinatal Mortality produced by the Perinatal Society of Australia and New Zealand (PSANZ).
KEY PRINCIPLES

Within NSW, all placentas should be grossly examined at the time of birth. Specialist medical practitioners and midwives present at the time of delivery who have knowledge of placental anatomy and pathology as well as an understanding of the abnormalities and variations that affect the placenta may carry out the examination.

As the vast majority of pregnancies, newborns and placentas are normal, formal pathological examination of all placentas is neither required nor feasible for many institutions. Therefore, only a subset of placentas requires submission for histological examination. Formal histological examination of the placenta may provide valuable explanation for pregnancies affected by medical complications, pregnancy loss or neonatal death, as well as information relevant to the management of the infant and/or subsequent pregnancies.

USE OF THE GUIDELINE

This guideline should be brought to the attention of staff involved in the delivery of maternity and neonatal care including maternity services units, neonatal intensive care units and general and specialist pathology departments.

The decision regarding the indications for referral of placenta for histological examination should be agreed at a local level by obstetricians, neonatologists, midwives and other relevant maternity services staff. Further advice can be found in Appendix 1 of the Guideline - Guide to Indications for Placental Histological Examination. Submission of placentas following other pregnancy complications or adverse outcomes that are not listed in the guide at Appendix 1, may depend on local resources and availability of pathology services.


MATERNITY – PREGNANCY AND BIRTHING CARE FOR WOMEN AFFECTED BY FEMALE GENITAL MUTILATION/CUTTING (GL2014_016)

PURPOSE

The purpose of this document is to assist health care professionals within NSW Public Health Organisations to provide sensitive and culturally appropriate, evidence-based antenatal, intrapartum and postnatal care for women and their families affected by Female Genital Mutilation/Cutting (FGM/C). It is an expectation that clinical care provided to women with FGM/C will be provided in accordance with these guidelines.

KEY PRINCIPLES

Women with FGM/C are significantly more likely than those without FGM/C to have adverse obstetric outcomes. As more women from these countries settle in Australia, clinicians working within maternity services will increasingly need to become familiar with the skills required to optimise the health of women affected by FGM/C during pregnancy and childbirth.
Tiered Maternity Networks (Section 1.5.1)

Delivering best practice care will require a coordinated approach within NSW public hospitals for women affected by FGM/C, including support, counselling and related surgery.

Consultation and referral pathways should also be in place to facilitate the woman’s movement between services within her tiered maternity network, to enable her to access skilled care. Local Health Districts (LHDs) should ensure that local guidelines for referral and transfer remain current and are in line with State policy.

Maternity Units in LHDs with a high population of women from countries that practice FGM/C (section 1.5.2)

These facilities should consider establishing an experienced designated team specialising in FGM/C issues, potentially comprising the following staff:

- Midwife
- Doctor
- Nurses, including women's health nurse, child and family health nurse
- Mental Health workers.

The designated team members should:

- Have a sound knowledge of FGM/C and understand the cultural and social complexities around the practice of FGM/C and its health effects through established contact with the NSW Education Program on FGM (SWLHD)²
- Undertake regular clinical education/training on FGM/C. More information can be obtained through the NSW Education Program on FGM (SWLHD)²
- Act in an advisory capacity or a referral point for maternity units that see fewer affected women.

Maternity Units in LHDs with a low population of women from countries that practice FGM/C

Although all LHDs should be familiar with guidance provided in this guideline it may not be practical for facilities to establish or maintain substantial local expertise. This may be due to factors such as low incidence of FGM/C, staff turnover and difficulty in accessing clinical education/training on FGM/C. In such instances, it will be necessary for these hospitals to establish and maintain links with hospitals that have staff with the required expertise in their tiered maternity network or source the nearest facility that offers FGM/C expertise. These arrangements will be best determined locally. Advice on appropriate contacts and clinical education/training can be sourced from the NSW Education Program on FGM.

To download the Guidelines please go to
GUIDELINES FOR THE MANAGEMENT OF SUBSTANCE USE DURING PREGNANCY, BIRTH AND THE POSTNATAL PERIOD (GL2014_022)

PURPOSE

These clinical guidelines are intended to support a range of health care workers who care for pregnant and breastfeeding women with substance use issues, and their infants and families.

KEY PRINCIPLES

The guidelines emphasise the importance of establishing a sound therapeutic relationship with the woman based on respect and non-judgmental attitudes, of engaging the woman into adequate antenatal care through this relationship, and of maintaining continuity of care and of carers throughout the pregnancy and postnatal period.

The guidelines recommend that pregnant women with significant problematic substance use will benefit from an appropriate referral for specialist drug and alcohol assessment (in addition to midwifery and obstetric care), appointment of a consistent and continuous case manager and care team who use effective communication systems, and specific treatments for their substance use, which may include counselling, pharmacotherapies and relapse prevention strategies.

USE OF THE GUIDELINE

These guidelines are intended for use by all health care practitioners in NSW working with pregnant women who are using substances during pregnancy, and the postnatal period. Substances refers to both licit purposes, such as those prescribed for pain relief, substance use treatment or other issues, and illicit purposes, which can include prescribed substances used for purposes other than that prescribed, and illicit substances.

Substances discussed in these guidelines include the licit substances of alcohol and tobacco; illicit substances of opioids, amphetamine-type stimulants (ATS), cocaine, cannabis and inhalants; and prescription medication which can be used licitly or illicitly. Other topics covered include breastfeeding, vertical transmission of blood-borne viruses, obstetric implications, pain management during labour, psychosocial issues, the management of Neonatal Abstinence Syndrome and early childhood development. This NSW revision of the guidelines has chapters specifically addressing the needs of women who are incarcerated or at risk of incarceration, women who live in rural and/or remote locations, and Aboriginal women. New legislation pertaining to child protection in NSW is also covered in detail.

The Guideline can be downloaded at
NEONATAL HEPATITIS B PREVENTION AND VACCINATION PROGRAM
(PD2017_036)

PURPOSE
This policy aims to ensure consistent implementation of the NSW Neonatal Hepatitis B Prevention and Vaccination Program in all Local Health Districts (LHDs). The policy focuses on screening of all pregnant women for hepatitis B disease and their referral to a specialist hepatology service and the follow-up and management of all infants born to hepatitis B surface antigen (HBsAg) positive women.

MANDATORY REQUIREMENTS
All pregnant women must be offered HBsAg screening and provided with verbal and written communication about hepatitis B disease and the neonatal hepatitis B vaccination program. All infants must be offered hepatitis B vaccine at birth (within 7 days) and all infants born to HBsAg positive women must also be offered hepatitis B immunoglobulin (HBIG) within 12 hours of birth. All infants born to HBsAg positive women must also be followed-up to ensure completion of their primary hepatitis B vaccination course and subsequent serology.

IMPLEMENTATION
Local Health Districts will:
- Establish definitive governance pathways to ensure that all implementation responsibilities (Sections 2, 3, 4 and 5) are assigned to the relevant staff to meet the requirements of this policy directive. This will require extensive consultation, collaboration and agreement within each LHD.
- Report to Health Protection NSW as specified in Section 6.
- Report to Health Protection NSW on the program’s Key Performance Indicators (Section 7).
- Manage Incident Information Management System reporting as detailed in Section 8.

Health Protection NSW will:
- Collate LHD quarterly and KPI reports and report on program performance to the Deputy Secretary Population and Public Health and Chief Health Officer.
- Provide support to LHDs regarding program implementation as required.

1 BACKGROUND

1.1 About this policy
This policy specifies the requirements for neonatal hepatitis B vaccination and reporting with regard to:
- Screening of pregnant women for hepatitis B surface antigen (HBsAg);
- Referral of HBsAg positive women to specialist services;
- Treatment of neonates born to HBsAg positive mothers;
- Follow-up of infants born to HBsAg positive mothers;
- Vaccination of all infants;
- Neonatal hepatitis B vaccination program data.
This policy relates only to neonatal hepatitis B vaccination recommendations and should be read in conjunction with the current edition of *The Australian Immunisation Handbook*. The National Health and Medical Research Council’s hepatitis B vaccination recommendations for additional groups of people (i.e. Aboriginal people, health care workers and child care workers) should be followed as specified in the current edition of *The Australian Immunisation Handbook*.

Each Local Health District must have definitive governance pathways established to ensure that responsibilities are assigned to the relevant staff to meet the requirements of this policy directive.

1.2 Prevalence, Risk and Prevention

Hepatitis B virus is transmitted through contact with blood or body fluid of an infectious person, and is commonly acquired either perinatally, by sexual contact, by sharing injecting equipment or by exposure to infectious fluids. In NSW in excess of 2,000 new hepatitis B diagnoses are made each year and newly acquired cases of hepatitis B virus (HBV) mostly occur in young adults. Vaccination is the best way to prevent hepatitis B. A strategy for the prevention of hepatitis B through immunisation commenced in Australia in the early 1980’s and a universal infant hepatitis B program commenced nationally in 2000. In NSW an adolescent hepatitis B vaccination program commenced in 2004 and continued until 2013, when all infants vaccinated in the universal program reached adolescence. Currently all infants in NSW are offered four doses of hepatitis B vaccine, at birth, 6 weeks, 4 and 6 months of age. The rationale for recommending the birth dose for all newborn infants is not only to prevent vertical transmission from a mother with chronic hepatitis B infection (there may be incomplete or delayed maternal testing, reporting, communication or appropriate response), but also to prevent horizontal transmission to the infant in the first months of life from persons with chronic hepatitis B infection who are household or other close contacts. NSW Health has released its inaugural *NSW Hepatitis B Strategy 2014-2020* which details the priorities to reduce the transmission of hepatitis B in NSW.

1.3 Key definitions

**Australian Immunisation Register (AIR)** – a system that records the information about vaccinations given to all persons in Australia. The AIR was previously known as the Australian Childhood Immunisation Register (ACIR) which was established in 1996 and held the information about vaccinations given to children from birth up to seven years of age. The ACIR transitioned to the AIR in September 2016 and records information about vaccinations given at any age.

**Follow-up** – involves reasonable attempts (up to six attempts are considered reasonable) to contact a hepatitis B positive mother and provide advice on the importance of completing her infant’s primary hepatitis B vaccinations (if they are overdue) and serological testing requirements following completion of the primary hepatitis B vaccinations.

**Hepatitis B surface antigen** (HBsAg) – a protein on the surface of the hepatitis B virus. It can be detected in high levels in serum during acute or chronic hepatitis B virus infection.

**HBsAg positive serology result** – the presence of HBsAg indicates active hepatitis B infection which can be spread to others.

**Hepatitis B Immunoglobulin** – a protein extract from blood that provides temporary immunity to hepatitis B disease.

**Hepatitis B vaccination schedule** – the National Health and Medical Research Council (NH&MRC) recommends a birth dose of hepatitis B vaccine (administered within 7 days of birth) followed by three further doses at 6 weeks, 4 and 6 months of age.
Incident Information Management System (IIMS) – a state-wide system that records all healthcare incidents for follow-up by the relevant manager to minimise the clinical risks in health services through the management of health care incidents as they occur.

Incidents – refers to instances where the requirements of this policy have not been met and as specified in Section 8 Incident Information Management System.

Hospital Neonatal Hepatitis B Coordinator – a person who has been nominated by the hospital as an appropriate staff member with the knowledge and skills to coordinate the neonatal hepatitis B vaccination program and report to the local Public Health Unit (PHU) Immunisation Coordinator monthly and as specified in Section 6.

LHD Immunisation Coordinator – a senior public health unit officer responsible for liaising with the private and public hospitals in their local health district regarding implementation of the neonatal hepatitis B vaccination program and reporting to Health Protection NSW as specified in Attachment 4.

Lost to follow-up – an infant is considered ‘lost to follow up’ when they are overdue one month after their scheduled due date of their fourth dose of hepatitis B vaccine (includes birth dose) and their mother is not contactable by the Local Health District (LHD) Coordinator. This includes children who were born in Australia but have moved overseas. Children should only be classified as lost to follow-up when all reasonable attempts have been undertaken to contact the mother or their primary health care provider. A child who is lost to follow-up must not be counted in the ‘overdue for completion of hepatitis B’ reporting. Should an Aboriginal child be at risk of being lost to follow up, a referral should be made to the Aboriginal Immunisation Health Worker at the PHU to facilitate further follow up.

Neonate – a live newborn infant from birth to 28 days old.

Overdue for completion of hepatitis B vaccination course – an infant is considered overdue for completion of their hepatitis B vaccination course one month after the scheduled due date of the fourth dose (includes birth dose) of vaccine, however for reporting purposes, only infants who are three months overdue are counted in the ‘overdue for completion of hepatitis B course’ report and not counted in the lost to follow-up data.

1.4 Legal and legislative framework

Under the NSW Public Health Act 2010, hepatitis B disease is a Schedule 1 Category 3 notifiable medical condition, for example, laboratories are required to notify detection of viral antigen or of HBV deoxyribonucleic acid (DNA).

2. SCREENING AND REFERRAL

All pregnant women

• All pregnant women must be offered screening for hepatitis B surface antigen (HBsAg) and provided with verbal and written information about hepatitis B disease and the neonatal hepatitis B vaccination program (refer to the NSW Health Hepatitis B Vaccination for your Newborn Baby brochure). HBsAg positive women must be offered further testing to determine staging of disease and risk of infectivity, including viral load and history of prior maternal infant transmission.

• The screening results must be entered into the eMaternity or Cerner Maternity databases according to whichever system is used in the LHD. The results should also be recorded on the NSW Health Antenatal Card in case the woman delivers outside the LHD.

• Women who do not have a known HBsAg status at the time of admission to hospital or labour ward should have urgent HBsAg testing to determine their hepatitis B status as soon as possible.
• HBsAg positive pregnant women with a high viral load (>200,000IU/ml) or liver function test ALT result ≥40IU/L or higher must be referred to a liver clinic/specialist hepatologist (unless they are already under the care of a specialist) for an appointment to enable sufficient time for assessment and commencement of antiviral therapy according to local and/or international guidelines as anti-viral medication administered in the third trimester may further reduce the risk of transmission of hepatitis B to the neonate. Commencement of treatment will be at the discretion of the treating specialist.

• Management of all other HBsAg positive women (with a viral load ≤200,000IU/ml or liver function test ALT less than 40IU/L) must include monitoring of their hepatitis B disease and their infant’s screening and vaccination by either their GP or specialist liver service.

• An interpreter service must be used where there is any doubt about the woman’s English comprehension.

• An incident information management system (IIMS) report must be submitted according to the circumstances specified in section 8.

3 VACCINATION

All neonates

• Parents of all neonates should be given the Hepatitis B Vaccination for your Newborn Baby brochure to ensure informed decision making when consenting to the neonatal hepatitis B vaccination program.

• All neonates (regardless of the HBsAg status of the mother), must be offered hepatitis B vaccine preferably within 24 hours and definitely within 7 days of birth, and recorded in the eMaternity or Cerner Maternity database and the neonate’s Personal Health Record.

• The birth dose of hepatitis B vaccine must be given no later than 7 days of age, based on the expected period that the vaccine may be effective as prophylaxis, should an undetected exposure have occurred at birth, and to prevent interference with the next dose due at 6 weeks of age. Therefore, catch-up of the birth dose is not recommended if it has not been administered within 7 days of birth.

• Following the birth dose of hepatitis B vaccine, all infants require a three-dose course of hepatitis B-containing combination vaccine at 6 weeks, 4 and 6 months of age.

• Low birth weight and preterm newborn neonates do not respond as well to hepatitis B-containing vaccines as full-term infants. Thus, for low birth weight neonates (<2000g) and/or those born at <32 weeks gestation (irrespective of weight), it is recommended that the vaccine is given in a 4-dose schedule at 0 (birth), 2 (can be given as early as 6 weeks of age if infant’s weight is ≥1.5kg, seek specialist advice as necessary), 4 and 6 months of age, followed by either:
  • measuring the anti-HBs antibody level at 7 months of age, and if the antibody titre is <10 mIU/mL, giving a booster at 12 months of age (due to a better immunogenic response at this age compared with a younger age); or
  • giving a booster of a hepatitis B vaccine at 12 months of age (without measuring the antibody titre).

• The infant’s Personal Health Record must be updated at each encounter to ensure completeness of information to inform all clinicians involved in their care.
Neonates born to HBsAg positive mothers

Refer Section 5 for detailed information on screening and vaccination.

- Neonates born to HBsAg positive mothers must be offered hepatitis B immunoglobulin (HBIG) within 12 hours of birth and a total of four doses of hepatitis B vaccine at birth, 6 weeks, 4 and 6 months of age. The birth dose of hepatitis B vaccine can be given concurrently with HBIG using a different thigh.

- Counselling regarding the risks of contracting hepatitis B disease and its consequences should be provided by staff (with expertise in hepatitis B disease) to HBsAg positive mothers who refuse HBIG and/or hepatitis B vaccination for their infant. A report should be forwarded to the child protection services at Family and Community Services regarding HBsAg positive women who refuse HBIG and the birth dose of hepatitis B vaccine for their infant.

- An incident information management system (IIMS) report must be submitted according to the circumstances specified in section 8. All incidents must be discussed with the Nursing Unit Manager/Midwifery Unit Manager of the ward prior to maternal discharge.

4 IMPLEMENTATION RESPONSIBILITIES

- Each hospital maternity unit must designate one person as the Hospital Neonatal Hepatitis B Coordinator (‘Hospital Coordinator’) and forward their contact details to their LHD Immunisation Coordinator at the local PHU.

- Each LHD must designate one person as the neonatal hepatitis B vaccination program LHD Immunisation Coordinator.

- Within each LHD, collaboration between all relevant staff must occur to ensure that responsibilities are appropriately designated to ensure that:
  - pregnant women with a high viral load are referred to a liver specialist;
  - infants born to HBsAg positive women are followed up to check for timely completion of their primary hepatitis B vaccination course and subsequent serology, and;
  - infants with an anti-HBs level <10IU/mL or who are HBsAg positive are referred to the Paediatric Viral Hepatitis Network (at The Children’s Hospital, Westmead) or a local specialist service (e.g. Infectious Diseases Clinic at Sydney Children’s Hospital, Randwick) for ongoing management (see Section 11 ‘Resources’ for more information).

- Refer to Attachments 2-4 for reporting requirements and documentation.

5 FURTHER TESTING AND FOLLOW-UP OF INFANTS BORN TO HBsAg POSITIVE MOTHERS

- Attachment 5 provides a clinical pathway for the management of an HBsAg positive woman and her infant. The pathway may be adapted according to the model of care in each LHD, for example, in some LHDs all HBsAg positive women are referred to the liver clinic/specialist for assessment, treatment and management.

- All women with a high viral load must be referred (according to LHD policy) to a liver clinic/specialist for ongoing management. Her infant’s vaccination record must be checked to ensure timely completion of the primary hepatitis B vaccination schedule. Where a child is found to be late with their scheduled vaccinations, the woman should be prompted to make arrangements to have her child vaccinated.
17. OBSTETRICS

- All infants born to a HBsAg positive woman are to be monitored for completion of their primary hepatitis B vaccination course (refer to the flowchart in Attachment 5).
- All infants born to HBsAg positive mothers require follow-up serology 3-12 months after completion of their primary hepatitis B vaccination course (and not before nine months of age) to check if they are protected. Mothers of infants born to HBsAg positive mothers must be educated prior to discharge about their infant’s requirement for follow-up serology as even optimal preventive measures fail in some cases.
- Each maternity unit must complete a neonatal hepatitis B follow-up letter (refer to the template in Attachment 1) for neonates born to HBsAg positive mothers and forward this letter to the mother’s doctor upon discharge from hospital (this could be the mother’s doctor or in their absence, it could be the mother’s obstetrician). The letter should be generated from the template in eMaternity or Cerner Maternity and amended as appropriate.
- A copy of the neonatal hepatitis B follow-up letter must be given to the mother upon discharge from hospital along with a full explanation regarding the infant’s follow-up requirements and documented in the infant’s Personal Health Record. Translation services should be used as required.

5.1 Infants born to HBsAg positive women with a high viral load

- Women with a high viral load >200,000IU/ml or liver function test ALT greater than 40IU/L, must be referred to a liver clinic/specialist for an appointment to enable sufficient time for assessment and commencement of antiviral therapy according to local and/or international guidelines
- A mechanism must be in place within each LHD to check that referred women have been booked in and attended the liver clinic for assessment.
- The liver clinic/specialist will decide on each woman’s requirement for treatment and management, including anti-viral treatment to prevent perinatal transmission, and according to current evidence and best practice guidelines.
- Each infant’s hepatitis B vaccination record must be checked for completion of the primary course and where a child has been identified as being not up to date, the mother must be prompted to make arrangements to have her child vaccinated.
- The mother’s GP must be provided with a letter recommending an infant serology test three months following completion of the infant’s primary hepatitis B vaccination course (not before nine months of age). Refer to Section 6 Reporting Requirements.
- Infants with an anti-HBs level <10IU/mL or who are HBsAg positive must be referred to the Paediatric Viral Hepatitis Network (at The Children’s Hospital, Westmead) or a local specialist service (e.g. Infectious Diseases Clinic at Sydney Children’s Hospital, Randwick) for ongoing management (see Section 11 ‘Resources’ for more information). The referral details must be documented in the records section of the infant’s Personal Health Record.

5.2 Infants born to HBsAg positive women with a low viral load

- Women with a viral load ≤200,000IU/ml and liver function test ALT less than 40IU/L, may be managed under the care of their GP or specialist liver clinic, according to LHD policy.
- Infants must be followed up to ensure timely completion of their hepatitis B vaccination course. The AIR overdue reports and/or hospital records and GP records may be used for this purpose. If a mother is unable to be contacted her infant should be considered as ‘lost to follow up’.

310(09/10/17)
• Infants with an anti-HBs level <10IU/mL or who are HBsAg positive must be referred to the Paediatric Viral Hepatitis Network (at The Children’s Hospital, Westmead) or a local specialist service (e.g. Infectious Diseases Clinic at Sydney Children’s Hospital, Randwick) for ongoing management (see section 11 ‘Resources’ for more information).

• All attempts to contact the mother (and outcomes) must be documented and retained as specified in the State Records Authority of New South Wales (2004) General Retention and Disposal Authority Public Health Services: Patient/Client Records. Refer to Section 6 Reporting Requirements.

6 REPORTING REQUIREMENTS

• The Hospital Coordinator must:
  o Collate the Maternity Unit Record Form (Attachment 2) for every infant born to a HBsAg positive mother, provide a copy to the LHD Coordinator monthly and store the original report in the infant’s medical record. Ensure that the mother’s doctor details are complete;
  o Complete the Hospital Coordinator Monthly Report Form (Attachment 3), and;
  o Forward Attachments 2 and 3 to the LHD Immunisation Coordinator monthly.

• Should a neonate who is born to an HBsAg positive mother be transferred to another hospital, local processes must be determined to ensure they are included in the delivery unit’s monthly report to the LHD Immunisation Coordinator as appropriate.

• A neonatal hepatitis B follow-up letter (refer to the template in Attachment 1) must be forwarded to the mother’s doctor which includes a full explanation of the infant’s follow-up requirements.

• The LHD Immunisation Coordinator is responsible for collating the neonatal hepatitis B vaccination program data from their maternity units and must report quarterly to the Manager of the NSW Health Immunisation Unit (Attachment 4) by the specified reporting timeframes as follows:

<table>
<thead>
<tr>
<th>Birth Cohort</th>
<th>Report Form Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>Births Jan, Feb, March</td>
<td>the following 31 December</td>
</tr>
<tr>
<td>Births April, May, June</td>
<td>the following 31 March</td>
</tr>
<tr>
<td>Births July, Aug, Sept</td>
<td>the following 30 June</td>
</tr>
<tr>
<td>Births Oct, Nov, Dec</td>
<td>the following 30 Sept</td>
</tr>
</tbody>
</table>

• While the LHD Immunisation Coordinator reporting schedule incorporates timeframes to allow follow up of infants at 9 months of age, the Hospital Coordinator reporting to the LHD Immunisation Coordinator should be monthly, due the 8th working day of the following month. The LHD Immunisation Coordinator must report to the AIR (via secure email) on children identified as having moved overseas.
7 KEY PERFORMANCE INDICATORS

The LHD Immunisation Coordinator must also report annually on hospital performance against the following indicators:

- 100% of women screened for hepatitis B during pregnancy or up to 2 hours following delivery (if no antenatal care was received);
- 100% of HBsAg positive women tested for viral load and liver function
- 100% of infants born to HBsAg+ women administered HBIG within 12 hours of birth;
- 100% of infants born to HBsAg+ women administered hepatitis B vaccine within 7 days of birth;
- 100% of women with a high viral load >200,000IU/ml or liver function test ALT 40IU/L or higher referred to a liver clinic/specialist hepatologist for an appointment prior to 32 weeks gestation;
- 100% of infants born to HBsAg positive women recommended for completion of serology three months after primary hepatitis B vaccination course, and;
- 100% of incidents (as specified in Section 8) are entered onto the Incident Information Management System.

8 INCIDENT INFORMATION MANAGEMENT SYSTEM (IIMS)

An IIMS report must be submitted by the person that identifies an incident when:

- A pregnant women has not been screened for hepatitis B during pregnancy or up to 2 hours after delivery;
- A neonate born to a HBsAg positive mother has not received hepatitis B immunoglobulin within 12 hours of birth;
- A neonate born to an HBsAg positive mother has not received hepatitis B vaccine within 7 days of birth;
- A HBsAg positive mother is not provided with a copy of the infant’s follow-up letter to the GP;
- An infant born to an HBsAg positive mother has not been followed-up (refer to “follow-up” in section 1.3 Key Definitions) to ensure completion of the hepatitis B vaccination course and follow-up serology recommended (does not include ‘lost to follow-up’ infants).

9 LIST OF ATTACHMENTS

1. Neonatal Hepatitis B Follow up Template Letter to GPs
2. Maternity Unit Record Form
3. Hospital Coordinator Monthly Report Form
4. LHD Immunisation Coordinator Quarterly Report Form
5. Flowchart Referral and Management of HBsAg+ women and infants in NSW

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10 REFERENCES


11 RESOURCES

Hepatitis B Vaccination for your Newborn Baby Brochure

Pregnancy – Protection & Vaccination from Preconception to Birth

*Both brochures are available in 23 community languages on the NSW Health website at* www.health.nsw.gov.au/immunisation

Paediatric Viral Hepatitis Network – Gastroenterology services including liver clinics

Infectious Diseases and Microbiology at Sydney Children’s Hospital, Randwick:
Follow up of babies born to hepatitis B surface antigen positive (HBsAg) mothers

Baby of [Insert First name] [Insert Last name]

DOB: [Insert date of birth] Time of birth: [Insert time] MRN: [Insert MRN] Gender: [Insert sex]

This baby’s mother was HBsAg positive, accordingly the baby was given:

- Hepatitis B immunoglobulin (HBIG) within 12 hrs of birth [insert date/time]:
- Hepatitis B vaccine within 7 days of birth [insert date/time]:

What to do next:

1. Vaccinate the infant on time with Infanrix-hexa® at 2 months (can be given as early as 6 weeks), 4 and 6 months of age.
2. Serologically test the infant for confirmation of immunity 3 to 12 months after completing the vaccination course (and not before 9 months of age). Anti-HBs and HBsAg should be measured.

It is estimated that up to 90% of infants infected with hepatitis B virus (HBV) as neonates become chronic HBV carriers. Therefore, preventing neonates becoming HBV carriers can avoid the serious complications associated with hepatitis B infections.

For neonates born to HBsAg positive mothers, the NH&MRC recommends that following the birth dose of hepatitis B vaccine and HBIG, three subsequent doses of Infanrix-hexa® vaccine should be administered at 6 – 8 weeks, 4 and 6 months of age. There is no need to catch-up the birth dose of hepatitis B vaccine if it is not administered within the first 7 days of life.

Serologic confirmation of post-vaccination immunity of all infants born to HBsAg positive mothers is required 3 to 12 months after completion of the primary vaccination course (and not before 9 months of age). Hepatitis B surface antigen antibody (Anti-HBs) and HBsAg levels should be measured. Children who have Anti-HBs antibody levels ≥ 10 mIU / mL and are HBsAg negative are considered to be protected.

If the Anti-HBs antibody level is < 10mIU/mL, the possibility of hepatitis B infection should be investigated and expert advice sought regarding revaccination and/or further testing. Children who test HBsAg positive should be referred to a paediatrician experienced in viral hepatitis.

Additional important considerations include:

- Specialist assessment of HBsAg positive mothers.
- Hepatitis B vaccination is recommended for any susceptible household contacts.

Please do not hesitate to contact the immunisation team at your local Public Health Unit on 1300 066 055 if you require any additional advice regarding the management of this infant.

[insert name] Hospital
[Insert date] printed
Order this form via the Stream Direct Catalogue as a POD item number NH700268
Attachment 3
HOSPITAL COORDINATOR MONTHLY REPORT FORM

NAME OF HOSPITAL: _______________________________________

REPORT FOR MONTH: ____________________ YEAR: ____________

<table>
<thead>
<tr>
<th>INDICATORS</th>
<th>MONTHLY TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Number of women who birthed (live births)</td>
<td></td>
</tr>
<tr>
<td>2. Number of women who birthed and had been screened for HBsAg</td>
<td></td>
</tr>
<tr>
<td>3. Number of women who birthed and tested HBsAg positive</td>
<td></td>
</tr>
<tr>
<td>4. Number of HBsAg+ Indigenous women</td>
<td></td>
</tr>
<tr>
<td>5. Number of women with viral load &gt;200,000IU/mL or liver function test ALT 40IU/L or higher</td>
<td></td>
</tr>
<tr>
<td>6. Number of all live neonates</td>
<td></td>
</tr>
<tr>
<td>7. Number of neonates born to HBsAg positive mothers</td>
<td></td>
</tr>
<tr>
<td>8. Number of neonates born to HBsAg positive mothers who received HBIG</td>
<td></td>
</tr>
<tr>
<td>9. Number of neonates born to HBsAg positive mothers who received HBIG within 12 hours of birth</td>
<td></td>
</tr>
<tr>
<td>10. Number of neonates born to HBsAg positive mothers who received hepatitis B vaccine within 7 days of birth</td>
<td></td>
</tr>
<tr>
<td>11. Number of all neonates who received hepatitis B vaccine within seven days of birth</td>
<td></td>
</tr>
<tr>
<td>12. Number of incidents identified (refer to section 8 IIMS)</td>
<td></td>
</tr>
<tr>
<td>13. Number of incidents reported in IIMS</td>
<td></td>
</tr>
</tbody>
</table>

Completed by (print name):____________________________________________________________________________

Contact phone number: (    ) _____________________________________________________________

Forward this form monthly to the Neonatal Hepatitis B Vaccination Program LHD Immunisation Coordinator

310(09/10/17)
## LHD QUARTERLY REPORT FORM

### LOCAL HEALTH DISTRICT: ________________________________

### SUBMITTED BY (please print name): __________________________

Forward this form quarterly to the Manager Immunisation Unit, Health Protection NSW at: 
vaccreports@doh.health.nsw.gov.au

* Infants are overdue one month after the scheduled date of their 4th dose of hepatitis B however for reporting purposes, only infants who are three months overdue are counted in the ‘overdue for completion of hepatitis B course’ report and not counted in the lost to follow-up data. Attempts to contact with the mother must be ongoing.

** Infants are ‘lost to follow-up’ when all reasonable attempts to contact the mother are exhausted – these infants are not counted in the overdue report.

### PERFORMANCE INDICATOR

<table>
<thead>
<tr>
<th>Birth Cohort</th>
<th>Report Form Due</th>
<th>Date Report Submitted</th>
</tr>
</thead>
<tbody>
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<td>Births Jan, Feb, March</td>
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</tbody>
</table>

<table>
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<tr>
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<th></th>
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<td>10. Number of neonates born to HBsAg positive mothers who received hepatitis B vaccine within 7 days of birth</td>
<td></td>
</tr>
<tr>
<td>11. Number of all neonates who received birth dose hepatitis B vaccine within 7 days of birth</td>
<td></td>
</tr>
<tr>
<td>12. Number of neonates born to HBsAg positive mothers who are more than 3 months overdue for their six month [i.e. 4th dose] hepatitis B vaccination*</td>
<td></td>
</tr>
<tr>
<td>13. Number of infants born to HBsAg positive mothers who are lost to follow-up**</td>
<td></td>
</tr>
<tr>
<td>14. Number of incidents identified (refer to section 8 IIMS)</td>
<td></td>
</tr>
<tr>
<td>15. Number of incidents reported in IIMS</td>
<td></td>
</tr>
</tbody>
</table>

310(09/10/17)
ATTACHMENT 5

REFERRAL & MANAGEMENT OF HBsAg+ WOMEN & INFANTS

1. Pregnant woman screened for HBsAg

   1. HBsAg+
      - High viral load (>200,000 IU/ml or ALT ≥ 40 IU/L)
        - Adult referred to liver clinic/specialist for appointment to enable sufficient time for assessment and commencement of antiviral therapy according to local or international guidelines
        - Liver clinic/specialist assumes clinical management including anti-viral treatment (AVT) to prevent perinatal transmission if appropriate
        - Infant’s record of vaccination monitored for completion of primary hepatitis B vaccination at 6 weeks, 4 and 6 months
        - Advise woman on timing of ceasing AVT
        - Continue with routine antenatal care
        - Letter to GP recommending infant serology 3 months following completion of primary hepatitis B vaccination course
        - Infant referred to specialist paediatric service for ongoing management
        - END

   2. HBsAg-
      - At birth, infant offered birth dose hepatitis B vaccine followed by primary vaccination schedule at 6 weeks, 4 and 6 months
      - Infants discharged from hospital with advice regarding importance of completion of primary hepatitis B vaccination course and serology 3 months following completion of primary course (and not before 9 months of age)
      - Anti-HBs level <10 IU/mL or HBsAg+
        - Infant referred to specialist paediatric service for ongoing management
        - END

3. Letter to GP re: infant’s serology

   - Infant referred to specialist paediatric service for ongoing management
   - END

References:
1. Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) Management of Hepatitis B in pregnancy (July 2016)
*This clinical pathway may be adapted according to the model of care with each LHD i.e. where all HBsAg+ women are referred to the liver clinic/specialist for assessment

NOTE: Women who do not have a known HBsAg status at the time of admission to hospital or labour ward should have urgent HBsAg testing to determine their hepatitis B status and infants born to HBsAg+ women must be managed as specified in this policy. The infant’s Personal Health Record must be updated at each encounter.

310(09/10/17)
MATERINITY – EXTERNAL CEPHALIC VERSION (GL2017_007)

GL2017_007 rescinds GL2016_024

PURPOSE
This Guideline describes the procedure for external cephalic version (ECV) and clinical care required when a woman presents at or near term with a singleton breech presentation.

KEY PRINCIPLES
ECV should be an option for women who have a baby that is in a breech presentation and meet criteria for the procedure to be undertaken safely.

USE OF THE GUIDELINE
This Guideline recommends consistent, evidence-based information regarding the option of ECV be provided to the woman by experienced clinicians.

ECV should be offered as noted in GL2016_018 NSW Maternity and Neonatal Service Capability Framework. Each Tiered Maternity Network in NSW should have consultation, referral and transfer processes in place to ensure all women are provided with the option of ECV in the presence of a term singleton breech presentation. The woman’s management plan should be documented in her medical record.


MATERINITY – SUPPORTING WOMEN PLANNING A VAGINAL BREECH BIRTH (GL2017_008)

PURPOSE
This Guideline provides guidance to Local Health Districts (LHDs) to establish a planned vaginal breech birth service in order to ensure all women have access to this birth option. Alternatively, LHDs are encouraged to ensure that a consultation and referral process is in place for access to vaginal breech birth within their Tiered Maternity and Neonatal Network.

KEY PRINCIPLES
Local and international guidelines support the provision of vaginal breech birth in selected circumstances. For women with a singleton breech presentation at term, research has demonstrated that in maternity units with policies and guidelines to direct clinical care, there is no significant excess additional risk associated with planned vaginal birth compared with planned caesarean section.
USE OF THE GUIDELINE

Access to a supportive vaginal breech birth service within NSW is limited. It is an obligation of NSW Health to provide women with birthing options that offer appropriate safety controls and processes within a tiered network of maternity services.

Consultation, referral and transfer processes should be in place to ensure all women are provided with the option of vaginal breech birth.

To ensure the best outcomes for mothers and babies, vaginal breech birth should be managed in services with expertise in this birth option, including support for informed decision making. Information should be provided on the benefits and risks, both for current and future pregnancies, of planned caesarean section versus planned vaginal birth for breech presentation at term.

To download the full Maternity – Supporting Women Planning a Vaginal Breech Birth guideline go to:


310(04/05/17)

PROVISION OF PRIVATE MIDWIFERY SERVICES BY ELIGIBLE MIDWIVES IN NSW PUBLIC HOSPITALS

PURPOSE

This Guideline describes the process for the provision of private midwifery services by eligible midwives in NSW public hospitals. The document provides advice related to the types of Collaborative Arrangements recognised by NSW Health and outlines the requirements and responsibilities of the privately practising midwife and the maternity service in the granting of right of access to a NSW public hospital via an Access Agreement.

KEY PRINCIPLES

• Under Commonwealth legislation an eligible midwife must have a collaborative arrangement in place with a medical practitioner in order to access the Medicare Benefits Scheme (MBS), Pharmaceutical Benefits Scheme (PBS) and any government subsidised Professional Indemnity Insurance (PII).
• The eligible midwife is required to have a Medicare provider number, which currently is only available to midwives in private practice.
• The collaborative arrangement must include provision for the transfer of patient care to the collaborating medical practitioner/s as clinically relevant, to ensure safe, high quality maternity care.
• The process of providing access to a NSW PHO only applies to midwives in private practice and who are not employees, either casual, permanent, or part time in the NSW Health Service.
• Eligible midwives wishing to be granted the right of access to a NSW PHO must apply to the PHO.
• Prior to entering into an Access Agreement with a PHO, an eligible midwife must have his or her application assessed by a Verification Committee established by the PHO.
• If approved by the Chief Executive (or delegate), the applicant will be notified, in writing, regarding the outcome of the application.

310(16/11/15)
• The privately practising eligible midwife will be able to book in and admit women to the PHO as private patients under her/his care, and provide midwifery care whilst an inpatient. Normal admission procedures and processes will apply when the woman books into the PHO.

Terms and conditions under which right of access is granted to NSW public hospitals includes obligations to be fulfilled by the midwife and responsibilities of the NSW PHO in granting right of access.

At the expiration or termination of the Access Agreement, the privately practising eligible midwife’s access rights will cease.

If the privately practising eligible midwife wishes to continue to have access rights to the hospital, the midwife is required to make fresh application to the Verification Committee, and if approved, a new Access Agreement needs to be entered into between the parties.

The PHO may withdraw access rights by terminating the Access Agreement if the PPEM in the circumstances set out in the Access Agreement. Incidents, concerns or complaints will be managed in accordance with NSW Health guideline and any locally applicable policies.

**USE OF THE GUIDELINE**

This Guideline should be used by Chief Executives of NSW PHOs, or their delegates, when considering granting right of access to a NSW public hospital by a privately practising eligible midwife so that local procedures are in place, aligned and consistent with the Guideline.

To download the full Provision of Private Midwifery Services by Eligible Midwives in NSW Public Hospitals guideline go to:  