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Patient Matters

CHAPTER 17 - OBSTETRICS

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PUBLIC HOMEBIRTH SERVICES IN NSW (GL2020_022)

GL2020_022 rescinds PD2006_045.

PURPOSE

This document guides NSW maternity services seeking to establish or sustain a public homebirth service (homebirth services).

KEY PRINCIPLES

NSW Health recognises that the place of birth is a decision for women, their partners and their families, and that some women may choose to birth at home with the care of professionals.

Homebirth services align with NSW Health's commitment to the provision of safe, sustainable, high quality, woman-centred maternity care.

Homebirth services should utilise consultation, escalation, referral and transfer processes in line with local guidelines and referral pathways developed in line with NSW Health Policy Directives/ Guidelines and all relevant legislative requirements.

Women should be advised of the health risks and health benefits of all aspects of maternity care, including those associated with their planned place of birth.

Clinical outcomes in all models of care including the homebirth service should be routinely reviewed to identify quality improvement opportunities irrespective of place of birth.

LOCAL HEALTH DISTRICT RESPONSIBILITIES

Local health districts (districts) should consider the needs of their communities when developing models of care. Those districts seeking to establish and or sustain a homebirth service should ensure the following.

- Consumer and other relevant stakeholder participation and involvement at all stages of implementation and ongoing evaluation of a homebirth service.
- Local guidelines for the provision of a homebirth service follow a robust and comprehensive risk assessment process.
- Strong clinical obstetric and midwifery leadership and commitment to establish, support, and maintain a well-functioning and sustainable homebirth service (see Section 2).
- An appropriately skilled and qualified workforce to provide care across the continuum of pregnancy, birth and postpartum care.
- Systems and processes are established to monitor and evaluate the service including workforce management and clinical service provision.

The Public Homebirth Services in NSW guideline can be downloaded from https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2020_022

MANAGEMENT OF THREATENED PRETERM LABOUR (GL2022_006)

GL2022_006 rescinds GL2020_009

GUIDELINE SUMMARY

This Guideline applies to all NSW Health Organisations and/or maternity services where women may present with signs and/or symptoms of threatened preterm labour.

The screening for risk factors associated with prevention and the management of preterm birth are outside the scope of this document.

KEY PRINCIPLES

NSW Health organisations are responsible for the implementation of this Guideline within their services / facilities to ensure local protocols or operating procedures are in place and aligned and consistent with this Guideline.

A comprehensive clinical assessment must be reviewed by the most senior obstetric clinician available and is essential to differentiate threatened preterm labour from preterm labour. The clinician must assess maternal and fetal wellbeing and to develop a comprehensive management plan.

Interventions for threatened preterm labour may include the use of corticosteroids, tocolytics, magnesium sulphate and antibiotics.

The use of tocolytic agents is restricted to when there is benefit from delaying preterm birth. There is greater benefit in delaying birth under **34 weeks' gestation**.

Care at 23-25+6 weeks should be individualised and will depend on the risk to the woman from continuing the pregnancy and the management approach to care of the fetus after birth.

Women and their families must be provided with information and resources to guide shared decision making.

The Maternal Transfer Decision Making Tool is to be used to determine when an in-utero transfer is required and the subsequent process for effective transfer.

The Management of Threatened Preterm Labour: Guideline can be download from:
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2022_006

REPORTING OF MATERNAL DEATHS TO THE CLINICAL EXCELLENCE COMMISSION (PD2021_006)

PD2021_006 rescinds PD2020_043

POLICY STATEMENT

All NSW Health services must report all maternal deaths to the Clinical Excellence Commission (CEC) in addition to other existing reporting obligations.

SUMMARY OF POLICY REQUIREMENTS

For all maternal deaths, the Maternity Unit Manager, Nurse Unit Manager, or Patient Safety Manager is to email CEC-PatientSafety@health.nsw.gov.au, with relevant information.

The death is also to be reported by completing the Admitted Patient Death Screening Tool in the CEC Death Review Reporting System.

Unexpected deaths of women who are either pregnant (any stage) or up to 42 days (6 weeks) postpartum are a reportable incident and must be managed and reported as per NSW Health Policy Directive *Incident Management* ([PD2020_047](#)).

Hospitals must also have effective systems and procedures in place to report deaths to the Coroner in accordance with the Coroners Act 2009; a Reportable death is defined in NSW Health Policy Directive *Coroners Cases and the Coroners Act 2009* ([PD2010_054](#)).

The health facility will be asked to supply the CEC with the following information via a secure file sharing system:

- a copy of the relevant medical records, including medical certificate of cause of death (if applicable)
- post-mortem report (if applicable)
- any other relevant material requested by the Maternal and Perinatal Mortality Review Committee.

The Reporting of Maternal Deaths to the Clinical Excellence Commission Procedures can be download from: https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2021_006

THE MANAGEMENT AND INVESTIGATION OF A STILLBIRTH (PD2007_025)**PD2007_025 rescinds GL2005_013.**

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
- The Australian Health Ministers Advisory Council The National Code of Ethical Autopsy Practice 2002.
- [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 stillbirth¹ is the complete expulsion or extraction from the mother of a product of conception of at least 20 weeks gestation or 400grams 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.

- 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

- Kleihauer - Betke test
- Renal function tests including uric acid
- Liver function tests
- Bile acids
- HbA_{1c}
- 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 Pathologists² 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.

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² The Royal College of Pathologists. Guidelines on Autopsy Practice: report of a working group of the Royal College of Pathologists. In. London: Royal College of Pathologists; 2002

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.

Perinatal Society of Australia and New Zealand Perinatal Mortality Audit Guideline Section 1: Overview and summary of recommendations; Appendix 2.

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.

KLEIHAUER-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.

Appendix 2**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.

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 _____

**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.

To download the Guideline go to http://www.health.nsw.gov.au/policies/gl/2014/GL2014_015.html

ASSISTED REPRODUCTIVE TECHNOLOGY - ETHICAL GUIDELINES (GL2006_011)**GL2006_011 rescinds GL2005_041.**

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:

1. **Genetic Testing – including DNA Diagnostic Testing, DNA Testing for mutation carriers and DNA Predictive and Presymptomatic Testing (PD2007_066)**
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](#)
- 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 - [\(PD2005_303\)](#)
http://www.health.nsw.gov.au/policies/PD/2005/PD2005_303.html

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.

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](#))

http://www.health.nsw.gov.au/policies/PD/2005/PD2005_303.html

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.

General Clinical Genetics and Genetic Counselling Services

Metropolitan Centres

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

Regional Centres

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

Familial Cancer Services

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

Fetal Medicine Services in Public Hospitals Associated with Clinical Genetics Services

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

Genetics Education Services

Centre for Genetics Education	PO Box 317, St Leonards NSW 1590 Ph: (02) 9926 7324, Fax: (02) 9906 7529 Web: http://www.genetics.edu.au/
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Association for Genetic Support of Australasia (AGSA)

AGSA	66 Albion Street, SURRY HILLS NSW 2010 Ph: (02) 9211 1462, Fax: (02) 9211 8077 Email: agsa@ozemail.com.au Web: http://www.agsa-geneticsupport.org.au
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Medications in pregnancy and lactation service (NSW)

Mothersafe	Medications in Pregnancy and Lactation Service, Royal Hospital for Women High St, Randwick, NSW 2031 Ph: (02) 9382 6539 or 1800 647 848
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Birth Defects Register (NSW)

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

GOLD	Hunter Genetics, PO Box 84, WARATAH NSW 2298 Ph: (02) 4985 3131, Fax: (02) 4985 3133
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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.nsw.gov.au/health-public-affairs/publications/genest/>)

<p>Send by courier/express post to:</p> <p>Send samples at room temperature Same day OR overnight</p>	<p>Patient ID MRN</p> <p>Last name</p> <p>First name</p> <p>Address</p> <p>..... Postcode</p> <p>Date of birth/...../..... Sex M F (dd/mm/yyyy)</p>
<p>Sample Date Drawn/...../..... (dd/mm/yyyy)</p> <p>Blood</p> <p><input type="checkbox"/> EDTA mL (room temp)</p> <p><input type="checkbox"/> Lithium heparin..... mL (room temp)</p> <p>Prenatal</p> <p><input type="checkbox"/> amniotic fluid mL (room temp)</p> <p><input type="checkbox"/> cultured amniocytes xT25 Flask(s) (room temp)</p> <p><input type="checkbox"/> CVS sample mg <input type="checkbox"/> on ice <input type="checkbox"/> cleaned <input type="checkbox"/> uncleaned</p> <p>Other</p> <p><input type="checkbox"/> DNAµg</p> <p>Other, specify:</p>	<p>Genetic Counselling</p> <p>Has the individual been offered counselling consistent with Specialised/DNA Testing for Genetic Disorders? http://www.health.nsw.gov.au/health-public-affairs/publications/genest/</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused</p> <p>Consent to Testing</p> <p>Has a Consent Form for Specialised/DNA Testing been completed?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Consent to payment</p> <p><input type="checkbox"/> Public patient, or</p> <p><input type="checkbox"/> Privately referred non-inpatient</p> <p>Payment to be made by Area Health Service by arrangement</p>
<p>Test requested</p> <p>PLEASE ATTACH FAMILY/PEDIGREE INFORMATION</p>	<p>Authorised by.....</p> <p><input type="checkbox"/> Private patient - Payment to be made by patient Consent to payment.....</p>
<p>Purpose of test</p> <p><input type="checkbox"/> Confirm clinical diagnosis</p> <p><input type="checkbox"/> Predictive/presymptomatic testing</p> <p><input type="checkbox"/> Carrier Status</p> <p><input type="checkbox"/> Prenatal Diagnosis - complete box below</p> <p><input type="checkbox"/> Determine feasibility of prenatal Dx</p> <p><input type="checkbox"/> Family study (no report for this individual)</p> <p><input type="checkbox"/> For research (no report for this individual)</p> <p><input type="checkbox"/> Bank DNA until further notice</p> <p><input type="checkbox"/> Other.....</p>	<p>Send Account to:</p> <p>Name.....</p> <p>Address.....</p> <p>.....Postcode.....</p> <p>Test requested by:</p> <p>Name.....Initials.....</p>
<p>Pregnancy Information (if applicable)</p> <p>Is this individual or the partner of this individual currently pregnant</p> <p>L.M.P. (dd/mm/yyyy)</p> <p>Amnio (dd/mm/yyyy)</p> <p>CVS (dd/mm/yyyy)</p>	<p>Address.....</p> <p>..... Postcode.....</p> <p>Telephone No.....</p> <p>Signature.....Date.....</p> <p>Specialty/Appointment.....</p>
<p>Family Information</p> <p>Have samples from this family been sent to a DNA lab before? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If Yes, specify</p> <p>Date of birth or age</p> <p>Ethnic background</p>	<p>Copy of report to:</p> <p>Name.....Initials.....</p> <p>Address.....</p> <p>.....Postcode.....</p> <p>Telephone No.....</p>



(Name of Hospital)

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.

Title	Family Names	MRN		
Given Name		VMO		
Address	Street	DOB	Sex	HIS
Suburb	Postcode	Admission Date		

PROVISION OF INFORMATION TO PATIENT To be completed by Health Professional

I, _____ have informed this patient
 Insert name of Medical Practitioner/Health Professional and designation
 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

_____ and I have discussed diagnostic testing for the
 Insert name of Health Professional
 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
specify
- 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)

Title	Family Names	MRN		
Given Name		VMO		
Address	Street	DOB	Sex	HIS
Suburb	Postcode	Admission Date		

PROVISION OF INFORMATION TO PATIENT **To be completed by Health Professional**

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 **To be completed by Patient/Guardian**

_____ 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 _____
percentage name of disorder
- 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 descendents

- 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/t/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 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 β -hCG and PAPP-A).
- Second trimester screening for women presenting between 15 to 18 weeks of pregnancy, using maternal age, maternal serum screening (free β 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 Register¹ 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

maternal age at delivery	* chance of having a live-born baby with Down syndrome	** chance of having a live-born baby with a chromosomal abnormality
20-24 years	1 in 1411	1 in 506
25 years	1 in 1383	1 in 476
26 years	1 in 1187	1 in 476
27 years	1 in 1235	1 in 455
28 years	1 in 1147	1 in 435
29 years	1 in 1002	1 in 417
30 years	1 in 959	1 in 385
31 years	1 in 837	1 in 385
32 years	1 in 695	1 in 323
33 years	1 in 589	1 in 286
34 years	1 in 430	1 in 244
35 years	1 in 338	1 in 179
36 years	1 in 259	1 in 149
37 years	1 in 201	1 in 124
38 years	1 in 162	1 in 105
39 years	1 in 113	1 in 81
40 years	1 in 84	1 in 64
41 years	1 in 69	1 in 49
42 years	1 in 52	1 in 39
43 years	1 in 37	1 in 31
44 years	1 in 38	1 in 24
45 years	1 in 32	1 in 19

* Morris JK, Mutton DE, and Alberman E (2002). Revised estimates of the maternal age specific live birth prevalence of Down's syndrome. *J Med Screen*, 9, 2-6.

** Hook EB (1981) Rates of chromosomal abnormalities. *Obs Gyn* 58 282-285

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

Maternal age	No.	%
<25	32	7.4
25-29	42	9.7
30-34	79	18.2
35-39	87	20.0
40+	60	13.8
Not Stated	135	31.0
Total	435	100

Source: NSW Birth Defects Register, Centre for Epidemiology and Research, NSW Department of Health¹

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.^{ii,iii,iv,v,vi} 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.^{vii}
- 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 β hCG, AFP and unconjugated estriol).

- 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/>

Prenatal Testing - Special tests for your baby during pregnancy

[http://www.genetics.edu.au/Publications-and-](http://www.genetics.edu.au/Publications-and-Resources/PublicationsBrochuresandPamphlets/PrenatalTestingSpecialTestsforYourBabyDuringPregnancy.pdf)

[Resources/PublicationsBrochuresandPamphlets/PrenatalTestingSpecialTestsforYourBabyDuringPregnancy.pdf](http://www.genetics.edu.au/PublicationsBrochuresandPamphlets/PrenatalTestingSpecialTestsforYourBabyDuringPregnancy.pdf)

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;

- 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 ,eg. 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

<http://www.mhcs.health.nsw.gov.au/>

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

- Prenatal Testing - Special tests for your baby during pregnancy
http://www.mhcs.health.nsw.gov.au/publication_details/7750.asp
- Ultrasound Examination Preparation
http://www.mhcs.health.nsw.gov.au/publication_details/864.asp
- How can Genetic Counselling Help?
http://www.mhcs.health.nsw.gov.au/publication_details/3070.asp
- Bringing up children with Down Syndrome
http://www.mhcs.health.nsw.gov.au/publication_details/3370.asp
- 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>

4. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) <http://www.ranzcog.edu.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.auWeb: <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

<http://www.downsyndromensw.org.au/>



(Name of Hospital)

Consent Form for Prenatal Diagnosis

Appendix 3

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

Genetic File No.		MRN	
Surname		Given Name(s)	
Address			
		Postcode	
Date of Birth		Telephone	

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
Insert name of Health Professional and designation
 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

_____ and I have discussed the consequences and
Insert name of Proceduralist
 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
Insert name of Procedure
 in the procedure.

Signature of Patient Print name of Patient Date

Appendix 4

Fetal Medicine Services in Public Hospitals Associated with Clinical Genetics Services

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

General Clinical Genetics and Genetic Counselling Services**Metropolitan Centres**

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

Regional Centres

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

Familial Cancer Services

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

Genetics Education Services

Centre for Genetics Education	PO Box 317, St Leonards NSW 1590 Ph: (02) 9926 7324, Fax: (02) 9906 7529 Web: http://www.genetics.com.au
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Association for Genetic Support of Australasia (AGSA)

AGSA	66 Albion Street, SURRY HILLS NSW 2010 Ph: (02) 9211 1462, Fax: (02) 9211 8077 Email: agsa@ozemail.com.au Web: http://www.agsa-geneticsupport.org.au
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Medications in pregnancy and lactation service (NSW)

Mothersafe	Medications in Pregnancy and Lactation Service, Royal Hospital for Women High St, Randwick, NSW 2031 Ph: (02) 9382 6539 or 1800 647 848
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Birth Defects Register (NSW)

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

GOLD	Hunter Genetics, PO Box 84, WARATAH NSW 2298 Ph: (02) 4985 3131, Fax: (02) 4985 3133
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References

- ¹ *New South Wales Mothers and Babies 2005*, NSW Public Health Bulletin Supplement, Vol 18, Number S-1. February 2007.
- ¹ 'Best Practice' *Guidelines on antenatal screening for Down syndrome and other fetal aneuploidy* prepared by the Joint Human Genetics Society of Australasia and Royal Australian and New Zealand College of Obstetricians and Gynaecologists
- ¹ *First and second trimester antenatal screening for Down's syndrome: the results of the Serum, Urine and Ultrasound Screening Study (SURUSS)*, Wald NJ, Rodeck C, Hackshaw AK, Walters J, Chitty L, Makinson A, Health Technology Assessment NHS R&D HTA Programme, Vol 7, No 11, 2003.
- ¹ *Nuchal Translucency Measurement in the First Trimester of Pregnancy for Screening of Trisomy 21 and other Autosomal Trisomies*, Medical Services Advisory Committee, Department of Health and Ageing May 2002
- ¹ *Joint estimation of Down syndrome risk and ascertainment rates: a meta-analysis of nine published data sets*. Prenatal Diagnosis 1998;18(1):9-20) Bray I, Wright DE, Davies C, Hook EB
- ¹ *Maternal serum biochemistry at 11-13+6 weeks in relation to the presence or absence of the fetal nasal bone on ultrasonography in chromosomally abnormal fetuses: an updated analysis of integrated ultrasound and biochemical screening*. Prenatal Diagnosis 2005; 25:977-983, Cicero S, Spencer K, Avgidou K, Faiola S, Nicolaidis K.

GENETIC TESTING - GUIDELINES FOR PRIORITISING GENETIC TESTS (GL2007_013)**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

Policy Directive PD2005_335 *Charging Policy for Clinically Required Specialised Genetics Tests which are non-Medicare Benefits Schedule Items*, http://www.health.nsw.gov.au/policies/pd/2005/PD2005_335.html states that:

“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.*

Except where indicated, arrangements are to be consistent with “Principles for Funding of NSW Public Health Sector Pathology Services” PD2005_533 http://www.health.nsw.gov.au/policies/pd/2005/PD2005_533.html

***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 (eg 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 to screening for disease complications.
- To confirm a clinical diagnosis where it is relevant for funding purposes eg 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, ie 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.

- 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.

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)**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.

Appendix 1**1 BEST PRACTICE GUIDELINES FOR PREDICTIVE AND PRESYMPTOMATIC DNA TESTING**

- 1.1 Genetic Testing, (PD2007_066)
http://www.health.nsw.gov.au/policies/pd/2007/PD2007_066.html
- 1.2 Genetics <http://www.genetics.edu.au/>
- 1.3 Guidelines for predictive testing for genetic disorders; Human Genetics Society of Australasia, available at <http://hgsa.com.au>
- 1.4 Predictive testing in children and adolescents, Human Genetics Society of Australasia, available at <http://hgsa.com.au>
- 1.5 Accreditation Standards for Nucleic Acid Detection Techniques (Section 1.2)
<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-docs-nad.htm>
- 1.6 Ethical Code Governing the Provision of Genetics Services
State Health Publication No (SWS) 980068, ISBN: 0 7313 4036 1
<http://www.health.nsw.gov.au/publications/Pages/genetic-services-ethics.aspx>

2 DISORDER SPECIFIC GUIDELINES

- 2.1 **Huntington Disease**
Guidelines for the molecular genetics predictive test in Huntington disease, Journal of Medical Genetics (1994;31:555-559) and Neurology (1994;44:1533-1536).
<http://www.huntington-assoc.com/>

Appendix 2

Clinical and Genetic Counselling Service Locations

Clinical and Counselling Services

CAMPERDOWN
Department of Molecular and
Clinical Genetics
Royal Prince Alfred Hospital
CAMPERDOWN NSW 2050
Tel: 02 9515 5080
Fax: 02 9515 7595

LIVERPOOL
Department of Clinical Genetics
Health Services Building
Cnr Campbell and Goulburn Sts
LIVERPOOL NSW 2170
Tel: 02 9828 4665
Fax: 02 9828 4650

PENRITH
Nepean Hospital
PENRITH NSW 2750
Tel: 4734 3362
Fax: 4734 2567

RANDWICK
Department of Medical Genetics
Sydney Children's Hospital
RANDWICK NSW 2031
Tel: 02 9382 1708
Fax: 02 9382 1711

WESTMEAD
Department of Clinical Genetics
The New Children's Hospital
WESTMEAD NSW 2145
Tel: 02 9845 3273
Fax: 02 9845 3204

NEWCASTLE
Hunter Genetics
Cnr Turton & Tinonee Sts
WARATAH NSW 2298
Tel: 4985 3100
Fax: 4985 3105

Genetic Counselling Services in conjunction with visiting clinical genetics services

KOGARAH
Women's and Children's Health
2nd Floor Prichard Wing
St George Hospital
Gray Street
KOGARAH NSW 2217
Tel: 02 9350 2315
Fax: 02 9350 3901T

ST LEONARDS
Fetal Medicine Unit
Royal North Shore Hospital
ST LEONARDS NSW 2065
Tel: 02 9926 6478
Fax: 02 9906 1872

BATHURST
Community Health Centre
158 William Street
BATHURST NSW 2795
Tel: 6331 5533
Fax: 6332 2039

BROKEN HILL
Community Health Centre
BROKEN HILL NSW 2880
Tel: 08 8080 1556
Fax: 08 8080 1611

CANBERRA
The Antenatal Clinic
The Canberra Hospital
PO Box 11
CANBERRA ACT 2605
Tel: 6244 4042
Fax: 6244 3422

COFFS HARBOUR
Coffs Harbour Health Campus
Pacific Highway
COFFS HARBOUR 2450
Tel: 6656 7806
Fax: 6656 7817

GOSFORD
Central Coast Health
Public Health Unit
PO Box 361
GOSFORD NSW 2250
Tel: 4337 0207
Fax: 4337 0217

GOULBURN
Child Development Unit
Cnr Albert and Clifford Streets
GOULBURN NSW 2580
Tel: 4827 3951
Fax: 4827 3958

LISMORE
37 Oliver Avenue
GOONELLABAH NSW 2480
Tel: 6625 0111
Fax: 6625 0102

MUDGE/DUBBO
Mudgee Community Health
Centre
MUDGE NSW 2850
Tel: 6372 6455
Fax: 6372 7341

MUSWELLBROOK
Community Health Centre
Brentwood Street
MUSWELLBROOK NSW 2332
Tel: 6542 2083
Fax: 6542 2005

PORT MACQUARIE
Hastings Macleay Community
Health
Morton Street
PORT MACQUARIE 2444
Tel: 6588 2882
Fax: 6588 2800

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 6393
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 647 848 (Other calls)

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

**Prenatal Diagnosis &
Counselling**

Specialised services:

CAMPERDOWN
Fetal Medicine Unit
King George V Hospital
CAMPERDOWN NSW 2050
Tel: 02 9515 8258
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: 02 9845 6802
Fax: 02 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 9687 2331

NEWCASTLE
Hunter Genetics
Cnr Turton & Tinonee 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 317,
ST LEONARDS NSW 2065
Tel: 02 9926 7324
Fax: 02 9906 7529
Web: www.genetics.com.au

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/health-public-affairs/publications/gentest/)

<p>Send by courier/express post to:</p> <p>Send samples at room temperature Same day OR overnight</p>	<p>Patient ID MRN</p> <p>Last name</p> <p>First name</p> <p>Address</p> <p>..... Postcode</p> <p>Date of birth/...../..... Sex M F <small>(dd/mm/yyyy)</small></p>
<p>Sample Date Drawn/...../..... <small>(dd/mm/yyyy)</small></p> <p>Blood</p> <p><input type="checkbox"/> EDTA mL (room temp)</p> <p><input type="checkbox"/> Lithium heparin..... mL (room temp)</p> <p>Prenatal</p> <p><input type="checkbox"/> amniotic fluid mL (room temp)</p> <p><input type="checkbox"/> cultured amniocytes xT25 Flask(s) (room temp)</p> <p><input type="checkbox"/> CVS sample mg <input type="checkbox"/> on ice</p> <p style="padding-left: 150px;"><input type="checkbox"/> cleaned</p> <p style="padding-left: 150px;"><input type="checkbox"/> uncleaned</p> <p>Other</p> <p><input type="checkbox"/> DNAµg</p> <p>Other, specify:</p>	<p>Genetic Counselling</p> <p>Has the individual been offered counselling consistent with Specialised/DNA Testing for Genetic Disorders? www.health.nsw.gov.au/health-public-affairs/publications/gentest/</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused</p> <p>Consent to Testing</p> <p>Has a Consent Form for Specialised/DNA Testing been completed?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Test requested</p> <p>PLEASE ATTACH FAMILY/PEDIGREE INFORMATION</p>	<p>Payment of test cost</p> <p><input type="checkbox"/> Public patient - Payment to be made by Area Health Service by arrangement (see over)</p> <p><input type="checkbox"/> Privately referred non-inpatient - Payment to be made by Area Health Service by arrangement (see over)</p> <p>Name of Area Health Service</p> <p><input type="checkbox"/> Private patient - Payment to be made by patient.</p> <p>Has the patient been advised about the cost of the test and agreed to meet the cost? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>Purpose of test</p> <p><input type="checkbox"/> Confirm clinical diagnosis</p> <p><input type="checkbox"/> Predictive/presymptomatic testing</p> <p><input type="checkbox"/> Carrier Status</p> <p><input type="checkbox"/> Prenatal Diagnosis - complete box below</p> <p><input type="checkbox"/> Determine feasibility of prenatal Dx</p> <p><input type="checkbox"/> Family study (no report for this individual)</p> <p><input type="checkbox"/> For research (no report for this individual)</p> <p><input type="checkbox"/> Bank DNA until further notice</p> <p><input type="checkbox"/> Other.....</p>	<p>Comments</p> <p>Test requested by:</p> <p>Name Initials</p>
<p>Pregnancy Information (if applicable)</p> <p>Is this individual or the partner of this individual currently pregnant</p> <p>L.M.P. (dd/mm/yyyy)</p> <p>Amnio (dd/mm/yyyy)</p> <p>CVS (dd/mm/yyyy)</p>	<p>Address</p> <p>..... Postcode</p> <p>Telephone No</p> <p>Signature..... Date</p> <p>Specialty /Appointment.....</p>
<p>Family Information</p> <p>Have samples from this family been sent to a DNA lab before? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If Yes, specify</p> <p>Date of birth or age</p> <p>Ethnic background</p>	<p>Copy of report to:</p> <p>Name Initials</p> <p>Address</p> <p>..... Postcode</p> <p>Telephone No</p>



Appendix 4

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

(Name of Hospital)

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

Title	Family Names	MRN		
Given Name		VMO		
Address	Street	DOB	Sex	HIS
Suburb	Postcode	Admission Date		

PROVISION OF INFORMATION TO PATIENT

To be completed by Health Professional

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

To be completed by Patient/Guardian

_____ 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 _____ 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 _____ and cannot pass it 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 descendents

- 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 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/UGuardian

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

MATERNITY - MANAGEMENT OF HYPERTENSIVE DISORDERS OF PREGNANCY
(PD2011_064)

PD2011_064 rescinds PD2011_020.

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.³ 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*.⁴ 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.

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³ Centre for Epidemiology and Research, NSW Department of Health. NSW Mothers and Babies Report 2010. NSW Public Health Bulletin 2007; 18(S-1).

⁴ <http://www.health.nsw.gov.au/hnsnw/Publications/mothers-and-babies-2010.pdf>

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 $\geq 30\text{mg}/\text{mmol}$. 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 $> 90 \mu\text{mol}/\text{L}$
 - 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 $> 140 \text{ mmHg}$ systolic and/or $> 90 \text{ mmHg}$ 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).⁽⁸⁻¹⁰⁾ 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⁽¹¹⁾.

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.⁽¹²⁾ 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.^(13,14) 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.^(15,16) 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.⁽⁷⁾ 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.⁽¹⁷⁾ 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.⁽¹⁸⁾

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).⁽¹⁹⁾ 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⁽²⁰⁾ 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
 - $\geq 30\text{mg}/\text{mmol}$. 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 $> 90 \mu\text{mol}/\text{L}$
 - 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^(25,26) although some studies have questioned this.⁽²⁷⁻²⁹⁾ 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,⁽³⁰⁾ 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⁽¹⁹⁾ 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.⁽³¹⁾ 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⁽³²⁾ or an adverse pregnancy outcome.⁽³³⁾ Severe hypertension ($\geq 170/110$ mmHg) is associated with increased risk of adverse outcomes in pregnancy.⁽³³⁾

4.3 Chronic Hypertension

Essential hypertension is defined by a blood pressure > 140 mmHg systolic and/or > 90 mm 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.⁽⁷⁾

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. pheochromocytoma, 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.⁽³⁴⁾

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,^(35,36) 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 pheochromocytoma in pregnancy is potentially fatal and may present as pre-eclampsia.^(37,38) 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

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

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

Maternal	Fetal
Gestational age \geq 37 weeks	Severe fetal growth restriction
Inability to control hypertension	Non-reassuring fetal status
Deteriorating platelet count	
Deteriorating liver function	
Deteriorating renal function	
Placental abruption	
Persistent neurological symptoms Eclampsia	
Persistent epigastric pain, nausea or vomiting with abnormal liver function tests	
Acute pulmonary edema	

The only controlled studies of bed rest for pre-eclampsia have shown no significant maternal or fetal benefit.⁽⁴⁴⁾ 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 \geq 170 mm Hg or a diastolic blood pressure \geq 110 mm Hg because of the risk of intracerebral haemorrhage and eclampsia.⁽⁴⁵⁾ 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.⁽⁴⁶⁾ 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.⁽⁵²⁾ 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 ⁽⁴⁷⁻⁵¹⁾

	Dose	Route	Onset of action
Labetalol	20-50 mg	IV bolus over 2 minutes	5 mins, repeat after 15-30 mins
Nifedipine	10-20 mg	Oral	30-45 mins, repeat after 45 mins
Hydralazine ⁵	5-10 mg	IV bolus	20 mins, repeat after 30 mins
Diazoxide	15-45 mg, max 300mg	IV rapid bolus	3-5 mins, repeat after 5 mins

⁵ 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.⁽⁵³⁾ One small Australian placebo-controlled randomised study examined the role of antihypertensive therapy in the management of mild hypertension.⁽⁵⁴⁾ 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.⁽⁵⁵⁻⁵⁷⁾ Second line agents are hydralazine, nifedipine and prazosin.⁽⁵⁸⁻⁶¹⁾ 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.⁽⁶²⁾

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

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

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.⁽⁶³⁾ 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.⁽⁶⁴⁾

6.2.2 Intravenous Fluids

Although maternal plasma volume is often reduced in women with pre-eclampsia⁽⁶⁵⁾ there is no maternal or fetal benefit to maintenance fluid therapy.⁽⁶⁶⁾ 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⁽⁶⁷⁾ 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.⁽⁶⁸⁾ 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.⁽⁶⁹⁾

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).⁶ 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

⁶ 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.^(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%.⁽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.⁽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 $140 \times 10^9/L$ but the risk of spontaneous bleeding is not significantly increased until the count falls below $50 \times 10^9/L$. Even so, there are concerns with central neuraxial anaesthetic and analgesic techniques at higher levels ($50-75 \times 10^9/L$), 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.⁽⁷³⁾ These abnormalities recover spontaneously postpartum within a few days of delivery, without specific treatment.⁽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

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

7.1 Antenatal Corticosteroid Administration

Contrary to popular belief, accelerated fetal lung maturation does not occur in pre-eclampsia.⁽⁹³⁾ 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.⁽⁹⁴⁾ 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.⁽⁹⁴⁾ A recent randomized trial demonstrated a small benefit of antenatal corticosteroids to mothers undergoing a term (37 to 39 weeks gestation) elective Caesarean section.⁽⁹⁵⁾ 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^(96,97) should be employed.⁽⁹⁸⁾

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.⁽⁹⁹⁾ 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.^(100,101) 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.^(55,68,102-107) The exception to this appears to be uncontrolled hypertension in the first trimester when later fetal and maternal morbidity and mortality are markedly increased.⁽¹⁰⁸⁾ 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.⁽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.^(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.⁽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.⁽¹¹⁵⁾ Relevant issues include anaesthetic risk assessment, blood pressure control, fluid management, eclampsia prophylaxis, and planning of analgesia or anaesthesia.⁽¹¹⁶⁻¹¹⁹⁾

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.^(119,120) 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.⁽¹²¹⁾ 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.⁽¹²²⁾ Fluid loading is not mandatory prior to regional analgesia during labour when low-dose local anaesthetic and opioid methods are used.⁽¹²³⁾ Prior to regional anaesthesia intravenous crystalloid loading is ineffective in preventing hypotension but colloid is effective.⁽¹²⁴⁾ Treatment or prevention of hypotension with drugs such as phenylephrine or metaraminol is effective and appears safe in pre-eclamptic women.^(125,126)

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 remifentanyl patient-controlled intravenous analgesia is preferred. Although ephedrine usually does not cause rebound hypertension⁽¹²⁷⁾ occasionally vasopressors and epidural adrenaline (epinephrine) cause worrisome blood pressure elevation. Other drugs that are best avoided in severe pre-eclampsia include ergometrine⁽¹²⁸⁾, 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.⁽¹⁰¹⁾

10.2.2 Caesarean section

Unhurried preoperative preparation reduces the risk of anaesthesia in women with pre-eclampsia.⁽¹²⁸⁾ Regional anaesthesia is preferred to general anaesthesia (GA) for caesarean section (CS), especially as airway problems including laryngeal oedema may be increased.⁽¹²⁹⁻¹³¹⁾ However, well-conducted GA is also suitable^(132,133) 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.^(134,135) 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.⁽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.^(121,128) Attenuation of this pressor response is best achieved with additional induction drugs such as remifentanyl 1 mcg/kg^(136,137) or magnesium sulphate 40 mg/kg or 30 mg/kg with alfentanil 7.5 mcg/kg.⁽¹³⁸⁾ Neuromuscular block must always be monitored closely after intravenous magnesium administration.⁽¹³⁹⁾ Lignocaine (lidocaine) 1.5 mg/kg is less effective⁽¹³⁷⁾ and fentanyl 2.5-10 mcg/kg or alfentanil 10 mcg/kg of slower onset.⁽¹⁴⁰⁾ Other drug options are beta-blockers (e.g. esmolol)⁽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.^(116,119) Spinal anaesthesia with usual doses is now a recommended technique.^(119,142,143) Cardiac output is well maintained and it is associated with less hypotension and lower vasopressor requirements than among healthy parturients.⁽¹⁴⁴⁾ Combined spinal-epidural anaesthesia appears to offer further advantages in specific cases.⁽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 $> 75 \times 10^9/L$.⁽¹⁴⁵⁾ Platelet counts of $< 50 \times 10^9/L$ are generally considered a contraindication. Within the range $50-75 \times 10^9/L$ 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.⁽¹⁴⁶⁾ Some recommend pulmonary artery catheters for assessment of left ventricular preload⁽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.⁽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⁾

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

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 $\geq 130 \mu\text{mol/L}$) 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.

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APPENDIX 1: PRINCIPLES AND METHOD OF ADMINISTRATION OF INTRAVENOUS HYDRALAZINE FOR SEVERE HYPERTENSION IN PREGNANCY

IV Hydralazine	
<p>AIM: to achieve a gradual reduction in blood pressure to safe levels (90mmHg diastolic), rather than a precipitate drop. NOTE: <i>the risk of sudden hypotension can be greater in women with a contracted plasma volume.</i></p>	
<p>TRADE NAME: PRESENTATION: INCOMPATIBILITIES:</p>	<p>Apresoline® 20mg ampoule aminophylline, ampicillin, hydrocortisone, sulphadiazine, dextrose diluents</p>
<p>DOSE:</p>	<ul style="list-style-type: none"> • Hydralazine 5mg as an intravenous bolus. • Repeat if necessary at 20 minute intervals, up to a maximum of 3 doses.
<p>CONCOMITANT ANTIHYPERTENSIVE THERAPY:</p>	<ul style="list-style-type: none"> • Continue existing oral antihypertensive therapy and review dose regimen; <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • If conscious, commence oral antihypertensive therapy (such as clonidine, labetalol or oxprenolol) in addition to the intravenous hydralazine
<p><i>Persistent hypertension despite 3 boluses of IV hydralazine 5mg may be due to a compensatory reflex tachycardia:</i></p>	<p><i>if heart rate < 125bpm:</i></p> <ul style="list-style-type: none"> • 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. <p><i>if heart rate > 125 bpm:</i></p> <ul style="list-style-type: none"> • Give oral clonidine, labetalol or oxprenolol in addition to hydralazine infusion
<p>MATERNAL and FETAL OBSERVATION AND MONITORING</p>	<ul style="list-style-type: none"> • Continuous CTG throughout administration of hydralazine and until BP is stable (30 minutes after the last dose); • Record BP (Mercury sphygmomanometer, 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.

- Recommended loading dose: 4 grams (16 mmol) MgSO₄ heptahydrate over 15-30mins.
- Maintenance infusion: 1gram/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	
<p>1. Loading Dose</p> <p><i>4g MgSO₄ (50% solution) diluted in Normal Saline via infusion pump over 20-30 minutes</i></p> <ul style="list-style-type: none"> • Using a 500ml flask of Normal Saline, run 100ml into a burette; • Add 8ml (4g) of MgSO₄ (50% solution) to the 100ml of Normal Saline in the burette; • Infuse over 20-30 minutes via infusion pump. 	<p>2. Maintenance Infusion</p> <p><i>1 gram MgSO₄ (50% solution) per hour via infusion pump</i></p> <ul style="list-style-type: none"> • Remove 20ml N/Saline from the N/S remaining in the flask and discard. • Add 20ml (10g) of MgSO₄ (50% solution) to the remaining 380ml flask of Normal Saline; • Infuse at 40mls (1g) per hour via infusion pump; • Run maintenance infusion for at least 24hours.
Example 2: Premixed commercial solution (8 grams Magnesium Sulphate in 100 mls water for injection)	
<p>1. Loading Dose</p> <p><i>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)</i></p> <ul style="list-style-type: none"> • Infuse over 15 – 30 minutes 	<p>2. Maintenance Infusion</p> <p><i>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</i></p> <ul style="list-style-type: none"> • Infuse at 12.5 mls per hour
Example 3: Premixed commercial solution (40 grams Magnesium Sulphate in 500 mls water for injection)	
<p>1. Loading Dose</p> <p><i>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)</i></p> <ul style="list-style-type: none"> • Infuse over 15 – 30 minutes 	<p>2. Maintenance Infusion</p> <p><i>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</i></p> <ul style="list-style-type: none"> • Infuse at 12.5 mls per hour

CARE PATHWAY FOR WOMEN CONCERNED ABOUT FETAL MOVEMENTS (GL2021_019)

GL2021_019 rescinded GL2020_017

GUIDELINE SUMMARY

The Guideline will assist clinicians and women to understand the importance of responding to the woman's concerns about fetal movements in a singleton pregnancy. It aims to improve clinical care and standardise management of concerns about fetal movements, to optimise pregnancy outcomes and reduce maternal anxiety.

KEY PRINCIPLES

This Guideline outlines the clinical principles and key actions that will support evidenceinformed practices and improvement in maternity services.

Fetal movements are a reliable indicator of fetal wellbeing. Maternal perception of decreased fetal movements is associated with adverse pregnancy outcomes.

The woman's concerns about fetal movements override any definition of DFM. These concerns may include decreased frequency of movements, changed quality of movements or absent movements.

This Guideline aligns the Perinatal Society of Australia and New Zealand (PSANZ) [*Clinical practice guideline for the care of women with decreased fetal movements for women with a singleton pregnancy from 28 weeks' gestation*](#) (2019), with additional clarification for the NSW context.

The care of a woman concerned about fetal movements from 25 weeks to 28 weeks gestation should use the same care pathway as for a gestation greater than 28 weeks.

Care planning for the fetus less than 25 weeks gestation should be in consultation with a specialist obstetrician or a maternal fetal medicine specialist.

USE OF THE GUIDELINE

The Chief Executives of local health districts are responsible to ensure maternity services have processes in place to:

Routinely provide verbal and written information to pregnant women about normal fetal movements at each point of contact during the antenatal period. This will include actions to take in the event of concerns about fetal movements.

Guide management, escalation and transfer of care if necessary, for women reporting concerns about fetal movements, in line with the relevant Policies and Guidelines.

Implement the Perinatal Society of Australia and New Zealand [*Clinical practice guideline for the care of women with decreased fetal movements for women with a singleton pregnancy from 28 weeks' gestation*](#) (2019) in the NSW context (see Appendix 1).

The complete Guideline is available at:

https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2021_019

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

GL2015_011 rescinds GL2014_017 which rescinded PD2006_074.

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

http://www.health.nsw.gov.au/policies/gl/2015/GL2015_011.html

INVESTIGATION, REVIEW AND REPORTING OF PERINATAL DEATHS (PD2022_046)

PD2022_046 rescinds PD2022_026

POLICY STATEMENT

The NSW Health is committed to review maternal and perinatal morbidity and mortality in the State, through the Perinatal Mortality Review committee (PMRC). The PMRC is a subcommittee of the NSW Maternal and Perinatal Mortality Review Committee (MPMRC), constituted under *Health Administration Act* 1982.

SUMMARY OF POLICY REQUIREMENTS

All NSW Health Services must report and review all perinatal deaths that meets its definition.

Perinatal deaths are defined as stillbirths (fetal deaths) and deaths of infants within the first 28 days of life (neonatal deaths).

Stillbirths include fetuses weighing at least 400 grams or having a gestational age of 20 weeks. Neonatal deaths comprise all deaths of liveborn babies within 28 days of birth, regardless of gestational age at birth.

Perinatal deaths must be managed and reported as per NSW Health Policy Directive *Incident Management* ([PD2020_047](#)) as set out in section 3 Reportable Incident Brief and Appendix D Reportable Incident Definition.

The investigation review and classification of perinatal deaths is based on the Perinatal Society of Australia and New Zealand (PSANZ) [Clinical Practice Guideline for Care Around Stillbirth and Neonatal Death](#) to support a systematic approach to the provision of care.

Each Maternity service is to have a process in place to undertake clinical reviews and the classification of perinatal deaths. These reviews include analysis through a local perinatal morbidity and mortality committee. The chairperson of the committee is responsible for ensuring timely reporting of death classifications to the Clinical Excellence Commission.

From March 1st, 2022, following a review by the local perinatal mortality review committee, all perinatal mortality reports must be submitted to the Clinical Excellence Commission via local public hospital maternity database systems (eMaternity or CernerMaternity).

Private hospitals may access the Clinical Excellence Commission online form for reporting perinatal deaths.

The Clinical Excellence Commission access the reports quarterly and after the completion of a calendar year. Perinatal deaths for the previous year are to be completed by April 1st in the following year.

1. BACKGROUND

Australia is one of the safest places in the world for a baby to be born, yet every day in Australia 6 babies are stillborn and 2 die within 28 days of birth (neonatal death). Each year in NSW over 800 perinatal deaths impact women, families and the healthcare workers providing their care.

Investigation to determine the cause of death and identify contributing factors is important for both families and maternity services to ensure best practice and inform care in future pregnancies. Review of perinatal deaths by hospital and health services is a key opportunity for clinical staff to engage in the processes of patient safety and quality improvement.

Reporting of perinatal deaths on a state-wide basis allows for benchmarking and assessment of trends that inform system improvement.

In all cases of stillbirth and neonatal death, staff are to provide a supportive and safe environment to minimise the stress and trauma parent(s) and family experience.

1.1 About this document

This document describes the procedures for investigation, review, classification and reporting of perinatal deaths to the Clinical Excellence Commission (CEC) and the NSW Perinatal Mortality Review Committee (PMRC).

1.2 Key definitions

Perinatal Period	Pregnancy at or after 20 weeks gestation up to the first 28 days after birth.
Perinatal Death	Perinatal deaths comprise stillbirths (fetal deaths) and deaths of infants within the first 28 days of life (neonatal deaths). Stillbirths are defined to include fetuses weighing at least 400 grams or having a gestational age of 20 weeks. Neonatal deaths comprise all deaths of liveborn babies within 28 days of birth, <i>regardless</i> of gestational age at birth.

1.3 Legal and legislative framework

The NSW Perinatal Mortality Review Committee (PMRC) is a subcommittee of the NSW Maternal and Perinatal Mortality Review Committee (MPMRC). The NSW MPMRC is constituted under Section 20 of the *Health Administration Act* 1982. It has special privilege and is authorised to conduct investigations and research in accordance with section 23 of the *Health Administration Act* 1982.

The members are appointed by the Minister for Health to review maternal and perinatal morbidity and mortality in the State.

2. NSW PERINATAL MORTALITY REVIEW COMMITTEE

The primary purpose of the NSW Maternal and Perinatal Mortality Review Committee is to subject all maternal and perinatal deaths occurring in NSW for peer review. For information relating to the committee, please refer to its [Terms of Reference](#).

The function of the NSW Perinatal Mortality Review Committee in relation to perinatal deaths occurring in NSW is to:

- Review aggregate data on perinatal deaths and identify groups of perinatal deaths which, through detailed inquiry, may provide information for the development of policies designed to reduce perinatal morbidity and mortality
- Identify risk trends or issues of safety and clinical practice which may have contributed to these deaths and/ or any potentially preventable factors
- Provide advice and feedback to the health system with recommendations to improve maternal, neonatal and child health outcomes through annual reports and clinical alerts.

3. INVESTIGATION OF PERINATAL DEATH

Investigation of stillbirths and neonatal deaths is based on the National Perinatal Society of Australia and New Zealand (PSANZ) [Clinical Practice Guideline for Care Around Stillbirth and Neonatal Death](#)² to support a systematic approach to the provision of care.

PSANZ recognises that increased risk of perinatal death exists in Aboriginal and Torres Strait Islander women, some cultural groups and disadvantaged women.

All care is to be culturally responsive, including the provision of Aboriginal Liaison Services, interpreters, religious and cultural supports as required, and private spaces for discussions.

It is recommended that all clinicians providing maternity and newborn care complete the Improving Perinatal Mortality Review and Outcomes Via Education ([IMPROVE](#)) e-learning educational program.

3.1 PSANZ Investigation of Stillbirths

A non-selective approach according to the recommended core investigations is to be adopted for all stillbirths (unless the cause of death has been unequivocally determined antenatally).

Core investigations include:

- Comprehensive maternal (medical, social, family) and pregnancy history
- Kleihauer-Betke test/ Flow cytometry for fetal to maternal haemorrhage
- External examination of the baby performed by a trained clinician
- Clinical photographs of the baby
- Autopsy should be discussed and offered for all unexpected intrauterine fetal deaths/stillbirths (as per the definition in 1.2)
- Detailed macroscopic examination of the placenta and cord
- Placental histopathology
- Cytogenetics (Chromosomal microarray (CMA) or karyotype if CMA is not available).

Further sequential and/ or selective investigations must be undertaken according to the clinical scenario based on a comprehensive history, and information gained from core investigations (PSANZ *Clinical Practice Guideline for Care Around Stillbirth and Neonatal Death*, Appendix A, Stillbirth Investigation Algorithm).

It is recommended that a trained clinician examine the baby to determine the presence of any possible congenital anomalies (refer to PSANZ *Clinical Practice Guideline for Care Around Stillbirth and Neonatal Death*, Appendix D, Clinical examination of baby checklist).

This is particularly important where a post-mortem examination has been declined by the family following an informed consent process.

3.2 PSANZ Investigation of Neonatal Deaths

It is not feasible to have a standardised investigation list that accommodates all neonatal death scenarios. Decisions regarding appropriate investigations must be made by the clinical team in consultation with the parents, based on the individual circumstances and accessing additional specialist expertise as required.

Obstetric and neonatal care teams must collaborate closely to ensure that all relevant maternal (pregnancy and birth) and neonatal factors are considered in the investigation of the neonate.

Recommended core investigations relevant to all neonatal deaths:

- Comprehensive maternal (medical, social, family) and pregnancy history
- Comprehensive neonatal history (including death scene analysis)
- A detailed external examination of the baby
- Accurate anthropometric parameters of birth weight, length and head circumference plotted on appropriate gender specific birth growth charts.
- Newborn screening blood sample
- Autopsy should be discussed and offered to parents in all cases of a neonatal death.

3.3 Perinatal Autopsy Including Placental Assessment

The perinatal autopsy remains the gold standard in diagnostic evaluation of the causes of perinatal death.³ An autopsy can assist to:

- Identify an accurate cause of death
- Exclude some potential causes of death
- Identify disorders that have implications for counselling and monitoring in future pregnancies
- Provide other information related to the death, including excluding possibilities that may alleviate feelings of guilt
- Obtain tissues for genetic tests
- Assist grieving, by helping parents' understanding of the events surrounding the death.

Histopathological examination of the placenta is strongly recommended for all perinatal deaths. Consideration must be given to requests for return of the placenta for cultural reasons.

Pathology of the placenta, cord, or membranes may contribute to stillbirth in 11% to 65% of perinatal deaths.^{4,5}

Consent for autopsy is ideally performed by an experienced senior clinician familiar to the family. The clinician must discuss:

- The value of the post-mortem examination
- Options for a full, or limited post-mortem examination
- The issue of retained tissues
- Implications for the timing of burial or cremation
- The possibility that the information gained may not benefit them but may be of benefit to others.

The [NSW Health Perinatal Post-mortem Service](#) provides support and information to both families and health professionals.

3.3.1 Alternatives to autopsy if declined

If permission for a full autopsy is not obtained, the following investigations are to be considered. Parents must be informed about the possibility of missing an important finding when a full autopsy is not undertaken:

- Formal external examination by pathologist
- X-ray (babygram)
- Clinical photographs
- Magnetic Resonance Imaging (MRI) in limited circumstances
- Small biopsy samples of a single organ via limited incision may be considered in the appropriate clinical setting
- Limited autopsy for focussed investigation of suspected abnormalities.

4. PERINATAL DEATH REVIEW COMMITTEES

Each Maternity service is to have a process in place to undertake clinical reviews and the classification of perinatal deaths. These reviews include analysis through a local perinatal morbidity and mortality committee.

Perinatal morbidity/ mortality review committees within maternity services provide a forum in which the cause of death, other adverse outcomes and their determinants are discussed.

Individual deaths are best reviewed by the local hospital or regional committees that include members who have had contact with the case. This has immediate benefits for participants in providing feedback and enables identification of possible avoidable factors that may be used to improve local services.

Guidelines for conducting Morbidity and Mortality meetings (M&Ms) can be accessed on the CEC website via [CEC M&M meetings guidance](#).

4.1 Membership

Core membership of the committee includes:

- obstetric
- midwifery/nursing
- neonatology/paediatrics.

Additional membership may include representatives from:

- administration
- anaesthetics
- pathology
- clinical genetics
- pharmacy
- epidemiology/ statistics
- social work
- endocrinology/diabetes management
- general practice.

The committee is kept at a reasonable size to ensure a meaningful discussion of the cases can occur.

The chairperson of the committee is responsible for ensuring timely reporting of death classifications to the CEC. They must create a safe, open, and respectful atmosphere for open discussion and learning, allowing all members to contribute.

4.2 Function

The committee may function at hospital or Local Health District level. Maternity services that have insufficient staff to carry out a multidisciplinary review are encouraged to seek support and collaborate with other maternity services within the Tiered Perinatal Network.

Maternity services are authorised to disclose information from one service to another to support the review of perinatal deaths of babies born at their facility but who died elsewhere. This may include confidential sharing of information (results, discharge summaries) or an invitation to the referring site's morbidity/ mortality meeting for the relevant case presentation.

The perinatal morbidity/ mortality (M&M) committee will abide by principles of confidentiality and impartiality and:

- review all perinatal deaths occurring within the maternity service and perinatal deaths who died elsewhere; (where a death has occurred in a Children's Hospital or other maternity service, the service must ensure that the referral hospital is informed, in order to complete this review and provide details or attend M&M as necessary)
- classify perinatal deaths according to the PSANZ Perinatal Death Classification (PDC) and, where appropriate, the PSANZ Neonatal Death Classification (NDC)
- evaluate the circumstances surrounding the death including a consideration of contributing and avoidable factors
- based on such considerations, identify opportunities for improving processes of care, ensuring feedback to families and clinicians; and
- provide a confidential report to the CEC (see section 4 reporting).

5. REPORTING OF PERINATAL DEATHS TO THE CEC

Perinatal deaths must be managed and reported as per NSW Health Policy Directive *Incident Management* ([PD2020_047](#)) as set out in the section 3 Reportable Incident Brief and Appendix D Reportable Incident Definition.

If the death is a sudden unexpected death in infancy (SUDI) this is a reportable death under the *Coroners Act 2009* and management is as per the NSW Health Policy Directive *Management of Sudden Unexpected Death in Infancy (SUDI)* ([PD2019_035](#)).

5.1 Electronic Reporting Process

5.1.1 Public hospitals reporting

From March 1st, 2022, following a review by the local perinatal mortality review committee all perinatal mortality reports which include the PSANZ classification of death must also be electronically submitted by completing the perinatal death report in eMaternity or Cerner PowerChart Maternity.

The CEC will upload/ download the reports quarterly and after the completion of a calendar year.

5.1.2 Private hospitals reporting

From March 1st, 2022, following review by the local perinatal mortality review committee all perinatal mortality reports including the PSANZ classification of death, must be electronically submitted by completing an electronic form.

The link to the electronic form will be provided on a quarterly basis to private hospital maternity unit managers, or the person nominated by the maternity unit manager. If the electronic form is not accessible, a soft copy of the report must be submitted to the CEC (cec-patientsafety@health.nsw.gov.au).

5.1.3 Time Frame for reporting

Perinatal deaths for the previous year must be completed by April 1st in the following year.

5.1.4 Requests for information

For additional assistance or further information contact the CEC:

Phone: CEC Clinical Lead, Maternal and Perinatal Patient Safety, 02 9269 5500.

Email: cec-patientsafety@health.nsw.gov.au

6. REFERENCES

1. Centre for Epidemiology and Evidence. *New South Wales Mothers and Babies 2019*. Sydney: NSW Ministry of Health, 2021.
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FRAMEWORK FOR TERMINATION OF PREGNANCY IN NEW SOUTH WALES (PD2021_018)

PD2021_018 rescinds PD2021_001 and PD2019_048

POLICY STATEMENT

All NSW facilities in which termination of pregnancy services occur are to ensure they have in place protocols that are in accordance with the Abortion Law Reform Act 2019 (the Act).

SUMMARY OF POLICY REQUIREMENTS

The Policy Directive outlines the legal framework of the Act and associated legislation in relation to termination of pregnancy in NSW.

The Act allows a medical practitioner to undertake a termination of pregnancy on a woman who is not more than 22 weeks pregnant provided that (except in emergencies) informed consent has been obtained.

A termination of pregnancy for a woman who is more than 22 weeks pregnant must only be performed by a specialist medical practitioner at a hospital controlled by a local health district, statutory health corporation or approved health facility (ancillary services, tests or other medical procedures, or the administration, prescription or supply of medication, can be carried out in other places).

If termination of pregnancy is not provided within the local health district, statutory health corporation hospital or approved health facility, then local referral pathways must be developed to support the woman, so she has timely access to termination services.

Procedures for registered health practitioners who have a conscientious objection to termination of pregnancy who are asked to perform or assist in a termination of pregnancy or advise about the performance of a termination are provided.

Before performing a termination of pregnancy, it may be disclosed to the medical practitioner that the reason for the request is for the sole purpose of sex selection. If this is the reason for the request, the practitioner **must not** perform the termination, unless not performing the termination will cause significant risk to the woman's health or safety.

When a termination for the sole purpose of sex selection is refused, the medical practitioner must offer additional support and referral to counselling or other relevant services.

Pre procedural considerations are defined and include counselling for a woman seeking a termination of pregnancy, assessment of the request related to pregnancy gestation and the requirement for informed consent. Post procedural considerations include examination and care of the woman and the fetus/baby.

In accordance with section 15 of the Act, termination of pregnancy must be notified to the Ministry of Health within 28 days. Refer to: www.health.nsw.gov.au/women/pregnancyoptions/Pages/for-health-professionals.aspx for further information.

In addition to routine clinical notes concerning the care and treatment of the woman, her gestational age and weight, signs of life following a termination and the specialist medical practitioners involved in the procedure must also be documented.

Framework for Termination of Pregnancy in New South Wales: Procedure.

1 BACKGROUND

1.1 About this document

This Policy Directive provides a framework to support termination of pregnancy services in accordance with the *Abortion Law Reform Act 2019* (the Act). The Framework aims to provide clarity and safety for registered health practitioners providing terminations of pregnancy.

All facilities in which termination of pregnancy services occur must ensure they have protocols in place that are consistent with and address the content of this policy directive.

For the purpose of section 14 of the Act, the Health Secretary has approved this framework as a guideline that applies to hospitals controlled by local health districts, statutory health corporations and approved health facilities when providing termination of pregnancy services after 22 weeks gestation.

1.2 Key definitions

Approved health facility

A hospital or other facility approved by the Health Secretary under the *Abortion Law Reform Act 2019*.

Gestational age

The number of weeks of pregnancy calculated either from the last menstrual period or using ultrasound dating.

Sex-linked condition

A medical condition that is substantially more common in one sex than another.

Specialist medical practitioner

A medical practitioner who, under the *Health Practitioner Regulation National Law*, holds specialist registration in obstetrics and gynaecology.

This also refers to a medical practitioner who has other expertise that is relevant to the performance of termination of pregnancy, for example a general practitioner who has additional experience or qualifications in pregnancy care. This would include a medical practitioner who has qualifications from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and has pregnancy care in their scope of practice.

Termination of pregnancy

An intentional termination of pregnancy in any way, such as by administering a drug or using an instrument or other thing.

Woman

A pregnant person, regardless of age or identified gender.

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

2 LEGAL CONTEXT

2.1 Abortion Law Reform Act 2019

In New South Wales, the law on termination is governed by the *Abortion Law Reform Act 2019*. The Act amended the *Crimes Act 1900* to repeal the provisions of that Act relating to termination of pregnancy and to abolish the common law offences relating to termination of pregnancy.

The Act establishes a health regime that allows:

- medical practitioners to perform a termination of pregnancy
- certain registered health practitioners (nurses, midwives, pharmacists and Aboriginal and Torres Strait Islander health practitioners) to assist in performing a termination. Assisting a termination includes a pharmacist dispensing medication on prescription of a medical practitioner subject to the requirements of the Act.

The NSW Parliament has opposed the performance of termination of pregnancy for the sole purpose of sex selection. Refer to section 5 of this document.

It is an offence under the Crimes Act 1900 for an unqualified person to perform or assist in performing a termination of pregnancy.

Termination at not more than 22 weeks

The termination of a pregnancy equal to or less than 22 weeks gestation is a decision for the pregnant woman. The Act allows a medical practitioner to undertake a termination of pregnancy on a woman who is not more than 22 weeks pregnant provided that (except in emergencies) informed consent has been obtained. The medical practitioner must also assess whether it would be beneficial to discuss counselling with the woman.

Termination at more than 22 weeks

The decision for termination of pregnancy after 22 weeks is one between an individual woman and her treating specialist medical practitioner. A termination of pregnancy for a woman who is more than 22 weeks pregnant must only be performed:

- by a specialist medical practitioner
- at a hospital controlled by a local health district, statutory health corporation or approved health facility (ancillary services, being tests or other medical procedures or the administration, prescription or supply of medication, can be carried out in other places).

The specialist medical practitioner may request that the hospital or approved health facility make available a hospital advisory committee or multi-disciplinary team to provide advice about the proposed termination. The provision of advice from a multidisciplinary team is not a mandatory component of the assessment of request but serves to assist the treating practitioner in complex clinical situations.

The specialist medical practitioner may perform a termination of pregnancy if:

- the practitioner has obtained informed consent for the procedure
- the practitioner has provided all necessary information to the woman about access to counselling, including publicly funded counselling
- the practitioner considers that in all the circumstances there are sufficient grounds for the termination to be performed. This assessment is to be made after considering:
 - all relevant medical circumstances
 - the woman's current and future physical, psychological and social circumstances
 - the professional standards and guidelines that apply to the practitioner in relation to termination of pregnancy
 - any advice received from the hospital advisory committee or multidisciplinary team.
- the practitioner has consulted with another specialist medical practitioner who also considers that in all the circumstances there are sufficient grounds for the termination to be performed. The second practitioner must also consider:
 - all relevant medical circumstances
 - the woman's current and future physical, psychological and social circumstances
 - the professional standards and guidelines that apply to the practitioner in relation to termination of pregnancy.

In an emergency, to save the woman's life or the life of another fetus, any medical practitioner can perform a termination without meeting the above requirements.

2.2 Births, Deaths and Marriages Registration Act

Under section 12 of the *Births, Deaths and Marriages Registration Act 1995* ("the Registration Act"), a child born alive, irrespective of gestational age, must be registered as a birth. If the child subsequently dies, the death must also 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.

Under the Registration Act, the term "birth" includes a "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.

2.3 Duty of care

This section outlines the legal responsibilities in relation to both adult and child patients in the context of termination of pregnancy.

2.3.1 Duty of care to the woman

A medical practitioner must exercise reasonable care and skill in the provision of professional advice and treatment to a woman undergoing a termination of pregnancy, as with all patients.

Except in an emergency, appropriate and adequate information must be provided to a woman considering a termination of pregnancy in order for her to make an informed choice about treatment.

2.3.2 Duty of care to the child

For the purposes of this section "child" refers to a child who has been expelled or removed from the woman's uterus alive. A fetus in utero is not recognised as a separate legal entity. However, once a fetus has been expelled or removed from the woman's uterus, 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, registered health practitioners have an obligation to work together with families to make medically appropriate and compassionate decisions. A medical practitioner is not obliged to provide medical treatment that is not in the child's best interest or treatment that is considered medically futile.

2.4 Coroners Act

"Death" in the *Coroners Act 2009* is to 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" (that is a stillbirth) after expulsion from the uterus is not a "death" for the purposes of the Coroners Act.

A fetus becomes a person if after expulsion or extraction from the woman and before being determined to be dead, signs of life are exhibited.

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

3 LOCAL CLINICAL PROTOCOLS

Local clinical protocols must be in place for all forms of termination of pregnancy procedures and will include pathways to access counselling for both women, their families and staff. These protocols must incorporate the roles and responsibilities of the relevant professional groups, the variety of medical and surgical procedures available and relevant product information including prescribing, administration, indication of use, contraindications, precautions, adverse reactions and drug interactions for those therapeutic agents used for such procedures.

Local protocols and information must align with the Act and be consistent with any information and guidelines approved by the Secretary, NSW Health.

4 CONSCIENTIOUS OBJECTION

Any registered health practitioner who is asked to perform, assist in or advise on a termination of pregnancy, and who has a conscientious objection to termination of pregnancy must inform the person who made the request that they have a conscientious objection to the performance of a termination of pregnancy and in a timely fashion.

In addition, if a registered health practitioner is asked to perform a termination, or advise about the performance of a termination, the practitioner must, without delay:

1. give information to the woman on how to locate or contact a medical practitioner whom they believe does not have a conscientious objection to the performance of the termination; or
2. transfer the woman's care to another registered health practitioner, or health service provider, who can provide the requested service and does not have a conscientious objection to the performance of the termination.

A registered health practitioner who has a conscientious objection may meet this requirement by providing the woman with the details of a NSW Health supported information service. This service must have capacity to provide information about medical practitioners who do not have a conscientious objection to the performance of termination; as well as general information and support services for reproductive and sexual health (up-to-date information for these services is available at www.health.nsw.gov.au/pregnancyoptions).

Public health organisations and approved health facilities have a duty of care to ensure that women seeking a termination 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 must notify their manager in a timely manner of their conscientious objection. Public health organisations must ensure that no person, either a woman or 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, nurses and other staff must perform a termination of pregnancy, or assist in the termination, in those rare emergency cases where it is necessary to preserve the life of the pregnant woman, regardless of their objection to termination of pregnancy.

5 TERMINATION OF PREGNANCY FOR THE SOLE PURPOSE OF SEX SELECTION

These procedures relate to when a termination of pregnancy is sought for the sole purpose of sex selection. These procedures do not apply to a termination due to the possibility of a sex-linked medical condition in the fetus.

Before performing a termination of pregnancy, it may be disclosed to the medical practitioner that the reason for the request is for the sole purpose of sex selection. If this is the reason for the request, the practitioner **must not** perform the termination, unless not performing the termination will cause significant risk to the woman's health or safety.

These will often be complex clinical and/or ethical scenarios. In all cases, the woman's physical and psychological wellbeing must be the medical practitioner's priority. When a medical practitioner is uncertain about the degree of risk to the woman's health and safety arising from the refusal, further advice and support may be sought from either another medical practitioner, a multidisciplinary team, a hospital advisory committee or the local clinical ethics committee.

When a termination for the sole purpose of sex selection is refused, the medical practitioner must offer additional support and referral to counselling or other relevant services.

Women can be referred to www.health.nsw.gov.au/pregnancyoptions to find the most upto-date information about the NSW pregnancy options helpline. The helpline provides unbiased, non-judgmental information on pregnancy options, including continuing a pregnancy, terminating a pregnancy and seeking pregnancy options counselling.

Further resources and guidance for women and health professionals can be found at: www.health.nsw.gov.au/pregnancyoptions

6 PRE-PROCEDURE ISSUES

6.1 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.

In the context of an anomalous fetus, consideration needs to be given to the immediate and future implications of the range of genetic tests available. 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 requires sensitive management. Pre-test and post-test counselling are an essential element of genetic testing.

Certain test results and fetal conditions must be reported to the NSW Register of Congenital conditions as set out in NSW Health Policy Directive *NSW Register of Congenital Conditions - Reporting Requirements (PD2018_006)*. 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 must 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.

If pre-termination counselling from an appropriately qualified health care professional occurs, documentation of the counselling must be included in the woman's healthcare record.

6.2 Assessment of request

The termination of a pregnancy equal to or less than 22 weeks gestation is a decision for the pregnant woman. The decision for termination of pregnancy after 22 weeks is one between an individual woman and her treating specialist medical practitioner.

For each proposed termination of pregnancy the following criteria must be considered and documented:

- the woman's physical and psychological condition
- accurate assessment of gestational age
- whether the termination is requested solely for the purpose of sex selection
- in cases of congenital condition, the diagnostic probability
- in cases of congenital condition, 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 (see 6.2.1 – 6.2.3) is to be followed.

6.2.1 Less than or equal to 14 weeks gestation

An appropriate health assessment is to be undertaken by the treating medical practitioner in consultation with the woman after appropriate counselling has been offered.

6.2.2 Between 14 weeks (+1 day) to 22 weeks (+0 days) gestation

The assessment of request 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. If termination of pregnancy is not provided within the local health district, statutory health corporation hospital or approved health facility, then local referral pathways must be developed to support the woman, so she has timely access to termination services.

6.2.3 More than 22 weeks gestation

A termination of pregnancy on a woman who is more than 22 weeks pregnant must be performed by a specialist medical practitioner in an appropriate role delineated hospital controlled by a local health district or statutory health corporation that has the appropriate support services available for the procedure proposed, or an approved health facility.

Before performing the termination, the specialist medical practitioner must consider that there are sufficient grounds for the termination, after considering all the circumstances (including the medical circumstances and the woman's current and future physical, psychological and social circumstances and, if requested, any advice of a multidisciplinary team or hospital advisory committee).

The specialist medical practitioner must consult with another specialist medical practitioner who also, after considering all the circumstances, considers that there are sufficient grounds for the termination.

The decision of the treating specialist medical practitioner and the advice of the second specialist medical practitioner must be documented in the woman's file.

The specialist medical practitioner may request that the local health district or statutory health corporation hospital or approved health facility provide opportunity for a case conference with a multidisciplinary team or hospital advisory committee with a mix of skills and experience to provide advice to the treating medical practitioner so that they are able to undertake an informed assessment of request for termination of pregnancy.

The provision of a case conference or multidisciplinary team is not a mandatory component of the assessment of request 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 condition of the woman and fetus.

Such a multidisciplinary team or hospital advisory committee is neither a constituted ethics committee nor does it have clinical decision-making ability. Its sole purpose is to provide the treating specialist medical practitioner with advice of a clinical or technical nature. Consultation and advice are to be documented by the treating practitioner.

A termination of pregnancy at more than 22 weeks must (except in an emergency) be performed in a local health district or statutory health corporation hospital or approved health facility. However, ancillary services to the termination of pregnancy (being tests or other medical procedures and the administration, prescription or supply of medication) are not required to be carried out only at the hospital or approved health facility.

If termination of pregnancy is not provided within the local health district, statutory health corporation hospital or approved health facility then local referral pathways must be developed and operationalised to ensure the woman has timely access to termination of pregnancy services.

6.3 Patient information/informed consent

Women must be provided with sufficient information to be able to make their own decision about undergoing the termination (informed consent). This information will include treatment options, benefits, possible adverse effects or complications, and the likely result if the treatment is not undertaken.

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 baby to be born exhibiting signs of life and the implications should this eventuate.

Informed written consent from the woman is to be obtained by the treating medical practitioner before a termination of pregnancy is performed using the NSW Health *Consent for Medical Procedure/Treatment (Adults and Mature Minors) Form* which can be found in Attachment A of the NSW Health *Consent to Medical and Healthcare Treatment Manual (2020)*.

Unless the woman lacks capacity, only her consent 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.

If the woman lacks capacity, informed consent can be obtained from the relevant substituted decision maker as outlined in section 7 of the NSW Health *Consent to Medical and Healthcare Treatment Manual (2020)*. Health practitioners are to assume that women have capacity to consent to or refuse treatment unless there is evidence to contradict this assumption.

Further information about consent for pregnancy related procedures and refusal of recommended treatment is available in section 10.2 of the NSW Health *Consent to Medical and Healthcare Treatment Manual (2020)*.

7 POST-PROCEDURE CARE

7.1 Care of the woman

Clinical guidelines must be in place regarding immediate post procedure care. This will include clinical observations and frequency required, and management of clinical emergencies in accordance with NSW Health Policy Directive *Recognition and management of patients who are deteriorating (PD2020_018)*.

The medical practitioner responsible for the care of the woman is to be informed of the completion of the procedure, the condition of the woman and, where relevant, the fetus/baby.

The woman must also receive appropriate post procedure information.

The woman's wishes regarding the fetus/baby must be respected and arrangements for viewing and handling of the baby are to accord with her wishes. If an autopsy is considered appropriate, the woman's consent must 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 must also be provided regarding options for future contraception and support services available. A discharge plan is to be developed.

7.2 Care of the fetus/baby

7.2.1 Post-procedure examination and care

Health practitioners have a responsibility to deliver all aspects of healthcare in a compassionate, reasoned and ethical manner. Such responsibility applies to every interaction between a health practitioner and their patient, including post-procedure examination and care following a termination of pregnancy procedure.

Examination of the fetus/baby must occur immediately upon delivery. Where a medical termination of pregnancy results in a baby 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 are to immediately consult a neonatologist.

Where a baby is born alive but medical consensus is that treatment (other than palliative treatment) would be over burdensome and of negligible benefit to the baby (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 baby 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 are to be encouraged to be part of this care.

The requirements of the Registration Act are to be fulfilled. Refer to [section 2.2](#) of this document.

8 NOTIFICATION TO NSW MINISTRY OF HEALTH

In accordance with section 15 of the *Abortion Law Reform Act 2019*, termination of pregnancy must be notified to the Ministry of Health within 28 days.

Information provided to the Ministry of Health must not include any particulars that would allow a woman to be identified. For further information on how to notify the Ministry of Health of a termination of pregnancy, refer to:

www.health.nsw.gov.au/women/pregnancyoptions/Pages/for-health-professionals.aspx Births, perinatal deaths and certain congenital conditions are category 1 conditions under the *Public Health Act 2010* requiring separate notification to the Ministry of Health.

9 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 must also be documented:

1. Gestational age/weight - gestational age is to be recorded where known, including the method used to calculate the gestational age. 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 are to be recorded and what actions were taken.
3. The named specialist medical practitioner who organised the procedure (primary specialist) and the specialist medical practitioner who agreed with the decision to proceed to termination of pregnancy (secondary specialist).

10 RELATED DOCUMENTS

This Policy Directive is intended to be read in conjunction with the following NSW Health Policy Directives:

PD2007_066	Genetic Testing
PD2007_094	Client Registration Policy
PD2010_054	Coroners Cases and the Coroners Act 2009
PD2011_076	Deaths - Review and Reporting of Perinatal Deaths
PD2012_069	Health Care Records - Documentation and Management
PD2015_025	NSW Perinatal Data Collection (PDC) Reporting and Submission Requirements from 1 January 2016
PD2016_001	Donation, Use and Retention of Tissue from Living Persons
PD2017_013	Infection Prevention and Control Policy
PD2017_044	Interpreters - Standard Procedures for Working with Health Care Interpreters
PD2018_006	NSW Register of Congenital Conditions - Reporting Requirements
PD2020_011	Verification of Death and Medical Certificate of Cause of Death
PD2020_014	Tiered Networking Arrangements for Perinatal Care in NSW
PD2020_018	Recognition and Management of Patients who are Deteriorating
Consent to Medical and Healthcare Treatment Manual (2020)	

PREVENTION OF TERMINATION OF PREGNANCY FOR THE SOLE PURPOSE OF SEX SELECTION (GL2021_008)

GUIDELINE SUMMARY

This Guideline has been issued under s14 of the Abortion Law Reform Act 2019 for practitioners who perform termination of pregnancy in NSW and provides guidance for these practitioners when a termination of pregnancy is sought for the sole purpose of sex selection.

Under section 14 of the NSW Abortion Law Reform Act 2019 (the Act), a registered health practitioner performing a termination of pregnancy or assisting in the performance of a termination of pregnancy, must practice in accordance with this Guideline.

Further information can be found in NSW Health Policy Directive: *Framework for Termination of Pregnancy in New South Wales* ([PD2021_018](#))

KEY PRINCIPLES

In NSW, the law on termination of pregnancy is governed by the Act. The Act amended the Crimes Act 1900 to repeal the provisions relating to termination of pregnancy and to abolish the common law offences relating to termination of pregnancy.

The NSW Parliament has opposed the performance of termination of pregnancy for the sole purpose of sex selection.

This Guideline relates to when a termination of pregnancy is sought for the sole purpose of sex selection. This Guideline does not apply to a termination due to the possibility of a sex-linked medical condition in the fetus.

Before performing a termination of pregnancy, it may be disclosed to the medical practitioner that the reason for the request is for the sole purpose of sex selection. If this is the reason for the request, the practitioner **must not** perform the termination, unless not performing the termination will cause significant risk to the woman's health or safety.

These will often be complex clinical and/or ethical scenarios. In all cases, the woman's physical and psychological wellbeing must be the medical practitioner's priority.

When a medical practitioner is uncertain about the degree of risk to the woman's health and safety arising from the refusal, further advice and support may be sought from either another medical practitioner, a multidisciplinary team, a hospital advisory committee or the local clinical ethics committee.

When a termination for the sole purpose of sex selection is refused, the medical practitioner must offer additional support and referral to counselling or other relevant services.

Women can be referred to www.health.nsw.gov.au/pregnancyoptions to find the most up-to-date information about the NSW pregnancy options helpline. The helpline provides unbiased, non-judgmental information on pregnancy options, including continuing a pregnancy, terminating a pregnancy and seeking pregnancy options counselling.

Further resources and guidance for women and health professionals can be found at: www.health.nsw.gov.au/pregnancyoptions

Notification to NSW Ministry of Health

In accordance with section 15 of the Act, all terminations of pregnancy must be notified to the NSW Ministry of Health within 28 days. Information provided to the Ministry must **not** include any particulars that would allow a woman to be identified.

For further information on how to notify the NSW Ministry of Health of a termination of pregnancy, refer to www.health.nsw.gov.au/women/pregnancyoptions/Pages/for-healthprofessionals.aspx

USE OF THE GUIDELINE

This Guideline is intended for use by all termination of pregnancy providers in NSW in line with:

1. [NSW Abortion Law Reform Act 2019](#)
2. NSW Health Policy Directive *Framework for Termination of Pregnancy in New South Wales* (PD2021_018)
3. [Preventing gender-biased sex selection: An Interagency statement OHCHR, UNFPA, UNICEF, UN Women and WHO](#)

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 \(2016- 17\)](#)¹ 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
- endorses ANZCOR Guidelines (2016-2017) Section 13 - Neonatal guidelines 13.1-13.10 and the Newborn Life Support algorithm (Attachment 1)
- outlines local health district responsibilities to develop systems to ensure:
 - clinicians are appropriately targeted to complete mandatory and recommended newborn basic life support education, training and proficiency requirements
 - 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
 - standardised newborn resuscitation equipment is available and operational and clinicians are familiar with the equipment
 - local procedures are in place to review resuscitation interventions and outcomes to monitor patient

To download the Guideline please go to:

https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2018_016

POSTPARTUM HAEMORRHAGE (PPH) (GL2021_017)

GL2021_017 rescinds GL2021_010

GUIDELINE SUMMARY

This Guideline outlines the roles and responsibilities of NSW Health organisations and health practitioners in the prevention, early detection, escalation and management of postpartum haemorrhage (PPH). NSW Health places a high priority on health practitioners working collaboratively with woman and their families, as well as each other, throughout all phases of maternity care.

KEY PRINCIPLES

The key principles that support prevention, early detection, escalation and management of PPH include, identification of women with risk factors and the development of strategies to prevent and/or manage PPH. These strategies include prompt, appropriate clinical and pharmacological management of women experiencing a PPH, and development of a Maternity Massive Transfusion Protocol (MTP) for managing obstetric critical bleeding in local Maternity Services.

USE OF THE GUIDELINE

This Guideline is designed for use by NSW Health staff who are part of the maternity care team. This Guideline should form the basis for:

- 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 this Guideline
- Provision of culturally safe and responsive maternity care services
- Access to education and training in relation to PPH for clinicians who may be required to care for women before, during and after birth. 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 Postpartum Haemorrhage (PPH): Guideline please go to:

https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2021_017

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

MATERNITY - SAFETY AND QUALITY ESSENTIALS (PD2023_031)**PD2023_031 replaced PD2009_003****POLICY STATEMENT**

NSW Health is committed to the implementation of safe, reliable, and resilient safety systems across all maternity services in NSW.

This Policy Directive outlines a clinical governance framework for maternity services, derived from the NSW Health Safety Systems Model and aligned with the National Safety and Quality Health Service (NSQHS) Standards.

SUMMARY OF POLICY REQUIREMENTS**Embedding Safety Strategically**

All local health district (District) maternity services are to implement governance structures that promote safety and quality. Districts require managerial and clinical leadership positions that are responsible for operational and strategic aspects of maternity services. Regular monitoring, evaluation and reporting of the key deliverables assigned to maternity leadership positions are essential.

Collaborative agreements are required to enable shared leadership across the Tiered Perinatal Networks (TPN).

Consumers are to be supported and encouraged to be actively involved in maternity service activities.

Accountable Leadership and Culture

Accountable leadership plays a crucial role in driving improvements in safety and quality and extends beyond the sole responsibility of maternity leaders. Districts are required to:

- Ensure all staff are informed and aware of the importance of safety and quality, and their individual roles and responsibilities in safety improvement.
- Ensure safety and quality behaviour and capability is included in performance review discussions for all maternity staff.
- Implement the Clinical Excellence Commission Safety Culture Framework, undertake regular safety culture measurements, and utilise the [Aboriginal Cultural Engagement Self-Assessment](#) tool to ensure delivery of culturally safe and accessible maternity services for Aboriginal women and women having an Aboriginal baby (sections 3.1 Patient Safety Culture and 3.2 Organisational Safety Culture).
- Districts are required to ensure allocation of resources that support staff self-care and emotional and psychological support (section 3 Accountable Leadership and Culture).

Safety Governance

Districts are required to:

- Complete the Governance and Accountability in NSW Health Maternity Services – Self-Assessment Tool annually and associated monitoring and reporting (section 4 Safety Governance).
- Implement a clearly defined and documented governance structure (section 4.1 Maternity Safety Governance Structure).
- Establish multidisciplinary Maternity Safety and Quality Committees with clearly defined and articulated reporting lines.

Safety Intelligence

Districts are required to:

- Ensure the development, implementation and utilisation of a maternity safety and quality surveillance strategy and have dedicated data and analytics support and resources for maternity services (section 5.2 Data Surveillance Strategy).
- Ensure near real time data is accessible to clinicians to support women to make informed decisions through the continuum of their pregnancy, birth, and the postnatal period.

Safety and Improvement Capability

Ensuring safety and quality improvement capability requires Districts to have clear executive sponsorship, and a collective governance commitment across maternity services.

Districts are to ensure that the healthcare safety and quality capabilities are included in position descriptions for all maternity leadership positions, recruitment selection criteria, professional career development goals and to guide safety and quality capability development of other clinicians.

It is recommended that all District and facility maternity leaders complete the Safety and Quality Essentials Pathway.

Safety Improvement

Embedding safety and quality improvement as business as usual is pivotal to improving the safety and quality of maternity services.

Districts are required to implement a number of processes to achieve this including identifying quality improvement opportunities and having clear quality improvement goals, ensuring regular auditing processes, implementing morbidity and mortality review meetings, and disseminating outcomes and lessons learnt from these processes (section 7 Safety Improvement).

The full Maternity - Safety and Quality Essentials policy is available at:

https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2023_031

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 is based on *Management of Early Pregnancy Loss Clinical Practice Guideline* (2008). The complete guideline can be found at

<https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg25/>

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.^{2,3,4}

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.⁽¹²⁾

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.

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 pregnancies⁵ 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,⁸¹ 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 ago^{9,10} 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 recommended medical term for pregnancy loss less than 20 weeks in Australia and New Zealand is ‘miscarriage’. The word miscarriage should be used in clinical practice.

C

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

**Evidence
Level IV**

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?

All maternity services must provide or be networked to a dedicated outpatient early pregnancy assessment service (EPAS). There are clinical benefits associated with this type of service.

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

**Evidence
Level IV**

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%).¹⁴ 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'.



'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.

**Evidence
Level IV**

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."¹³ In specialised scanning services, the overall incidence of pregnancy of unknown location is as low as 8 - 10%.

**Evidence
Level IV**

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.¹⁷ 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.

**Evidence
Level IV**

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.^{13,18}

**Evidence
Level IV**

Serial serum hCG assay is particularly useful in the diagnosis of asymptomatic ectopic pregnancy.

B

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).¹⁹ 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.¹³ 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.¹³ 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.²⁰

**Evidence
Level III**

Early ectopic pregnancy can be difficult to diagnose and access to serial serum hCG estimation is essential, with results available within 24 hours.⁷ 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.

B

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.^{13,21–24} 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.

C

Rh D Immunoglobulin (Anti-D) must be administered in accordance with [GL2015_011](#).

The National Blood Authority guidelines⁷⁷ 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.

**Evidence
Level I**

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.

Protocols must be developed locally with selection criteria, therapeutic regimens, and arrangements for follow-up.

A

Concerns have been raised about the infective risks of non-surgical management⁵⁸ but published data suggest a reduction in clinical pelvic infection and no adverse effects on future fertility.^{28,57,66}

Evidence
Level Ia

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.

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 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.

A

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.

Observational and controlled trials of expectant compared with surgical management also show wide variations in reported efficacy (25-100%).⁵⁵⁻⁶⁴ 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.⁶⁵

Evidence
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%),⁵⁵ while another included all those with an 'AP tissue diameter < 50mm' and reviewed patients clinically on three occasions up to 6 months (efficacy 100%).⁵⁷ 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.¹⁴ 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%, $P = 0.06$).⁵⁹

Evidence
Level Ib

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).⁶¹ After seven days, 37% of women managed expectantly had achieved a complete miscarriage. A meta-analysis of 13 trials comparing expectant with medical management⁶³ 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%).

**Evidence
Level Ia**

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.

C

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.²⁷ At least 34% of women express a 'strong' preference for a surgical approach to uterine evacuation.²⁸

**Evidence
Level IV**

4.3 How should surgical uterine evacuation be performed?

Surgical uterine evacuation for miscarriage should be performed using suction curettage.

A

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).²⁹ 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).³⁰ Where infection is suspected, delaying surgical intervention for 12 hours is recommended to allow intravenous antibiotic administration.

**Evidence
Level Ia**

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%³¹ with a mortality of 0.5/100 000.³²

**Evidence
Level III**

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 USA³³ 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 high³⁴

**Evidence
Level III**

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.

C

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;²⁶ until further research is published, no definitive recommendations can be made for women undergoing surgical evacuation for miscarriage management.

**Evidence
Level IV**

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.

A

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.

**Evidence
Level Ib**

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.

C

Heath, et al., suggested that there is no obvious benefit in routine histological investigation of tissue obtained from cases of pregnancy termination and miscarriage.⁶⁸ 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.⁷

**Evidence
Level IV**

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.

C

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.

Evidence
Level III

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.

Evidence
Level III

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.

A

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
Small Miracles Foundation, <http://www.smallmiraclesfoundation.org/>
SIDS and Kids, www.sidsandkids.org
Stillbirth and Neonatal Death Support, www.sands.org.au
Bears of Hope, <http://www.bearsofhope.org.au>
Stillbirth Foundation, <http://www.stillbirthfoundation.org.au>

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9. APPENDICES

Appendix A Evidence levels

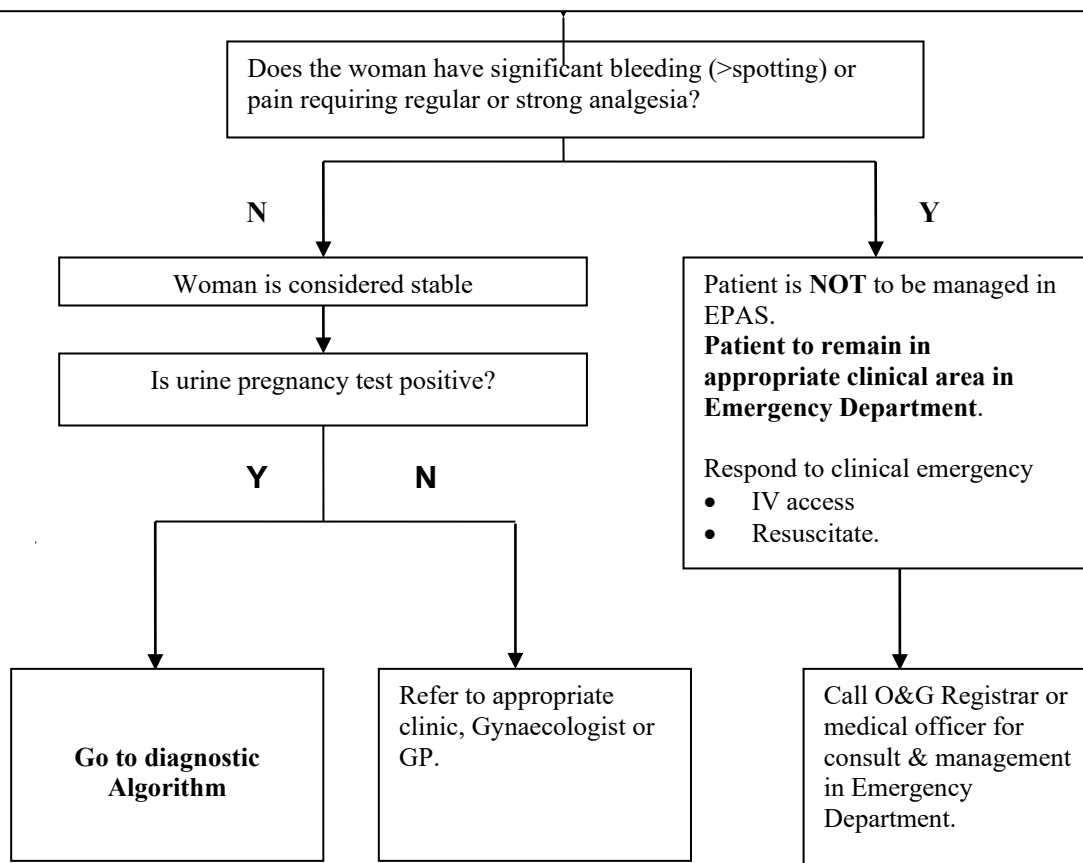
Classification of evidence levels	Grades of recommendations
<p>Ia Evidence obtained from meta-analysis of randomised controlled trials</p> <p>Ib Evidence obtained from at least one randomised controlled trial</p> <p>IIa Evidence obtained from at least one well-designed controlled study without randomisation</p> <p>IIb Evidence obtained from at least one other type of well-designed quasiexperimental study</p> <p>III Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies</p> <p>IV Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities</p>	<p>A 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)</p> <p>B Requires the availability of well controlled clinical studies but no randomised clinical trials on the topic of recommendations. (Evidence levels IIa, IIb, III)</p> <p>C 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)</p> <p>√ Good practice point Recommended best practice based on the clinical experience of the guideline development group.</p>

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

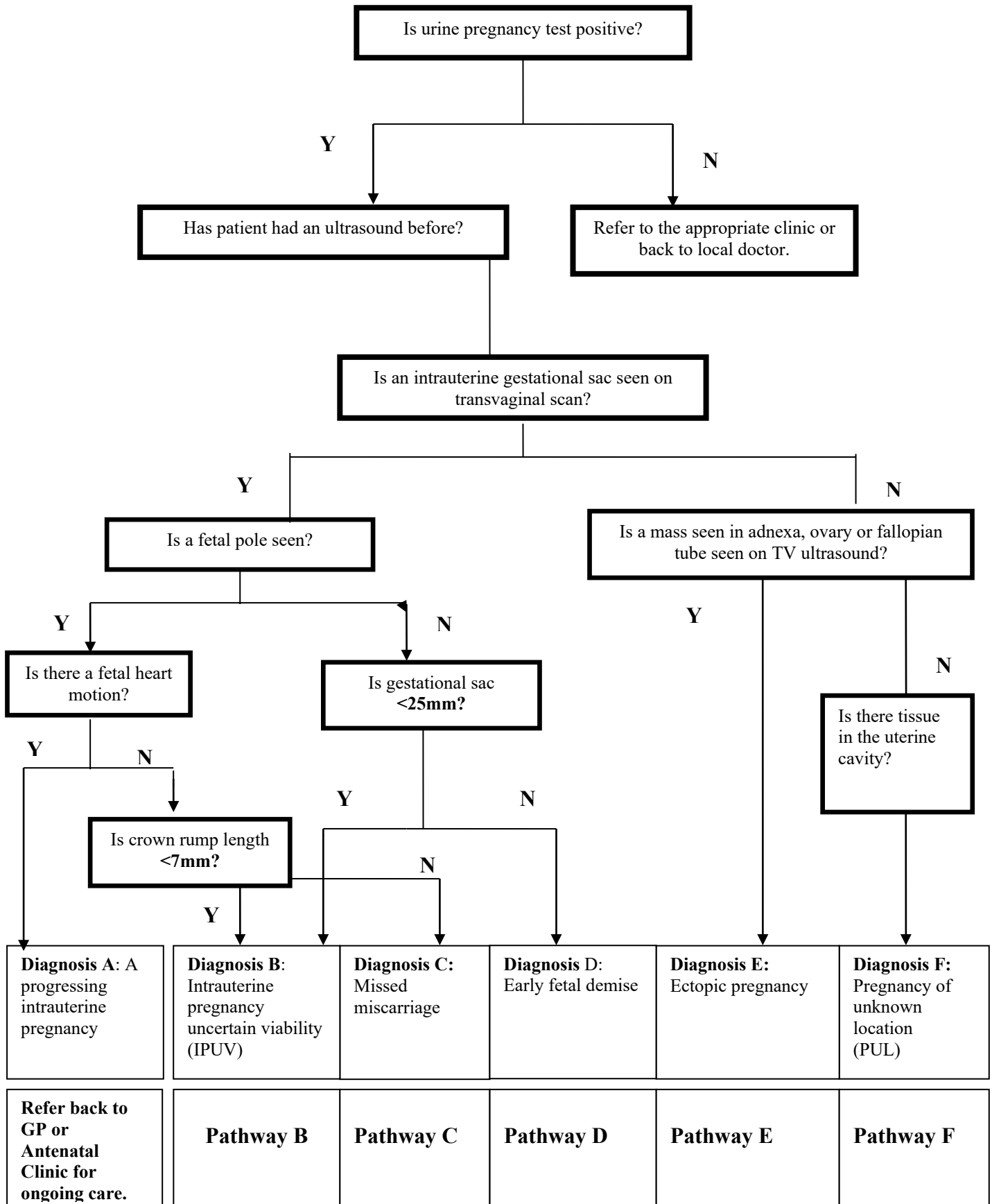
- History
- Current contraception/pap smear
- Vital signs
- Urinary pregnancy test (unless results already confirmed)
- Establish gestation based on LMP
- Abdominal palpation
- Speculum/bimanual assessment if significant bleeding (POC to histology, unless woman wants to retain).



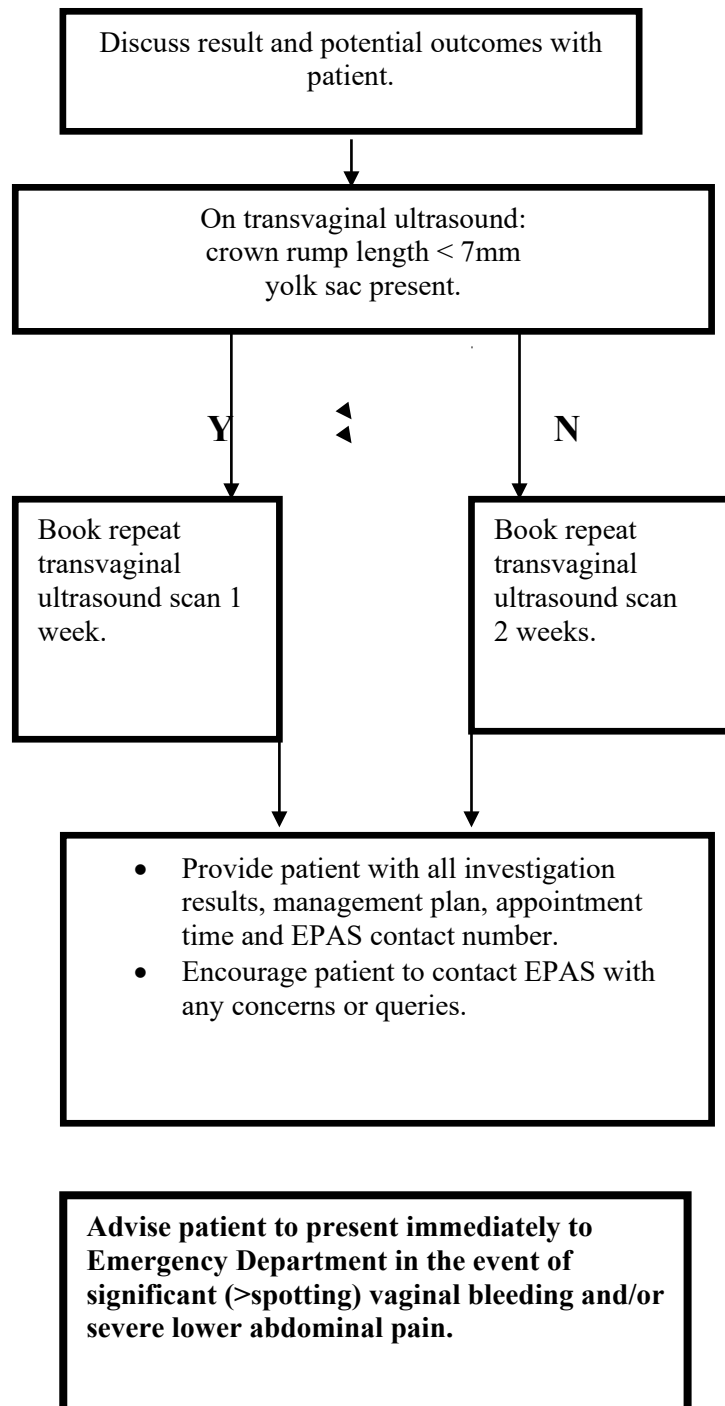
When referring to EPAS:

- 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.

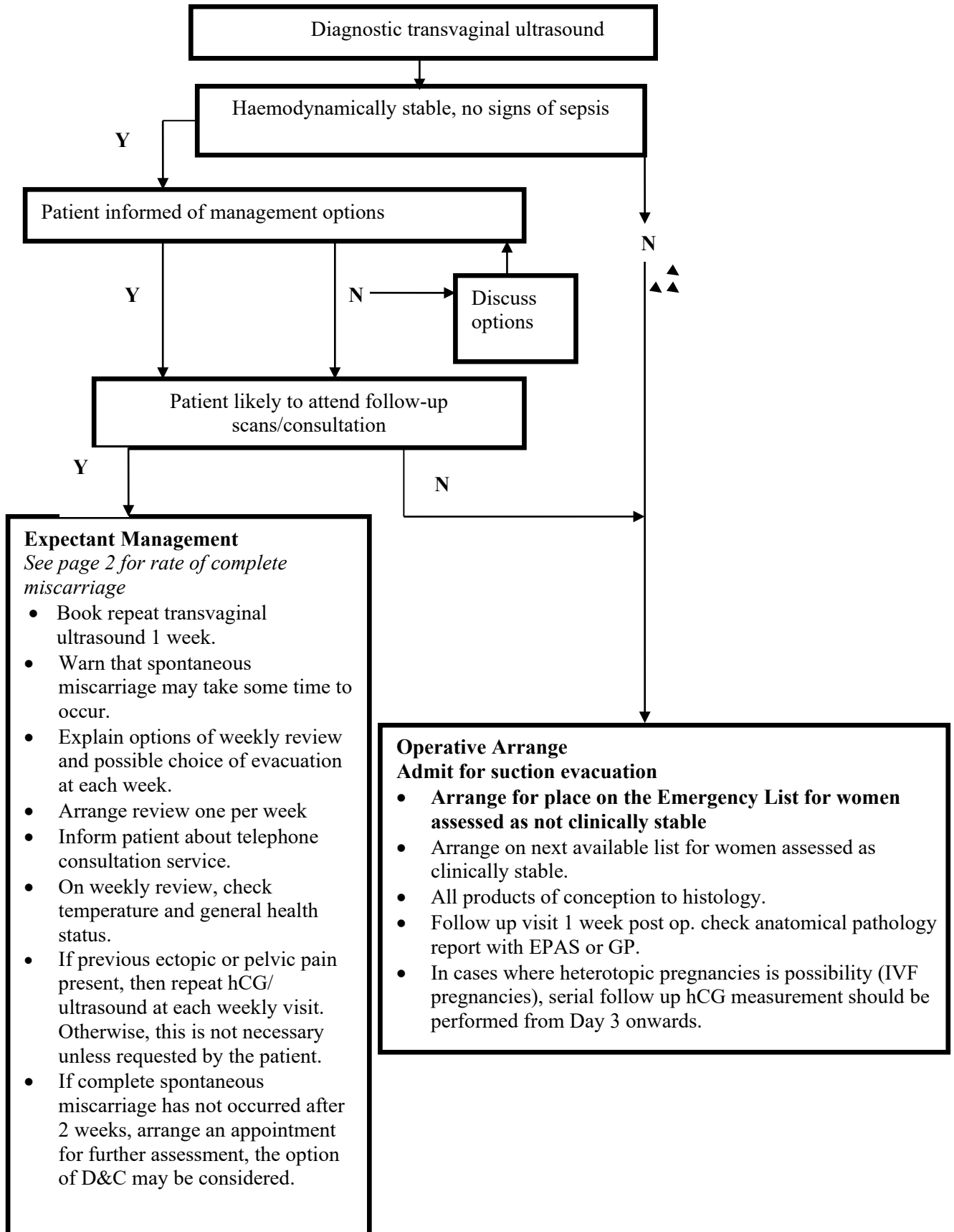
EPAS Diagnostic Algorithm

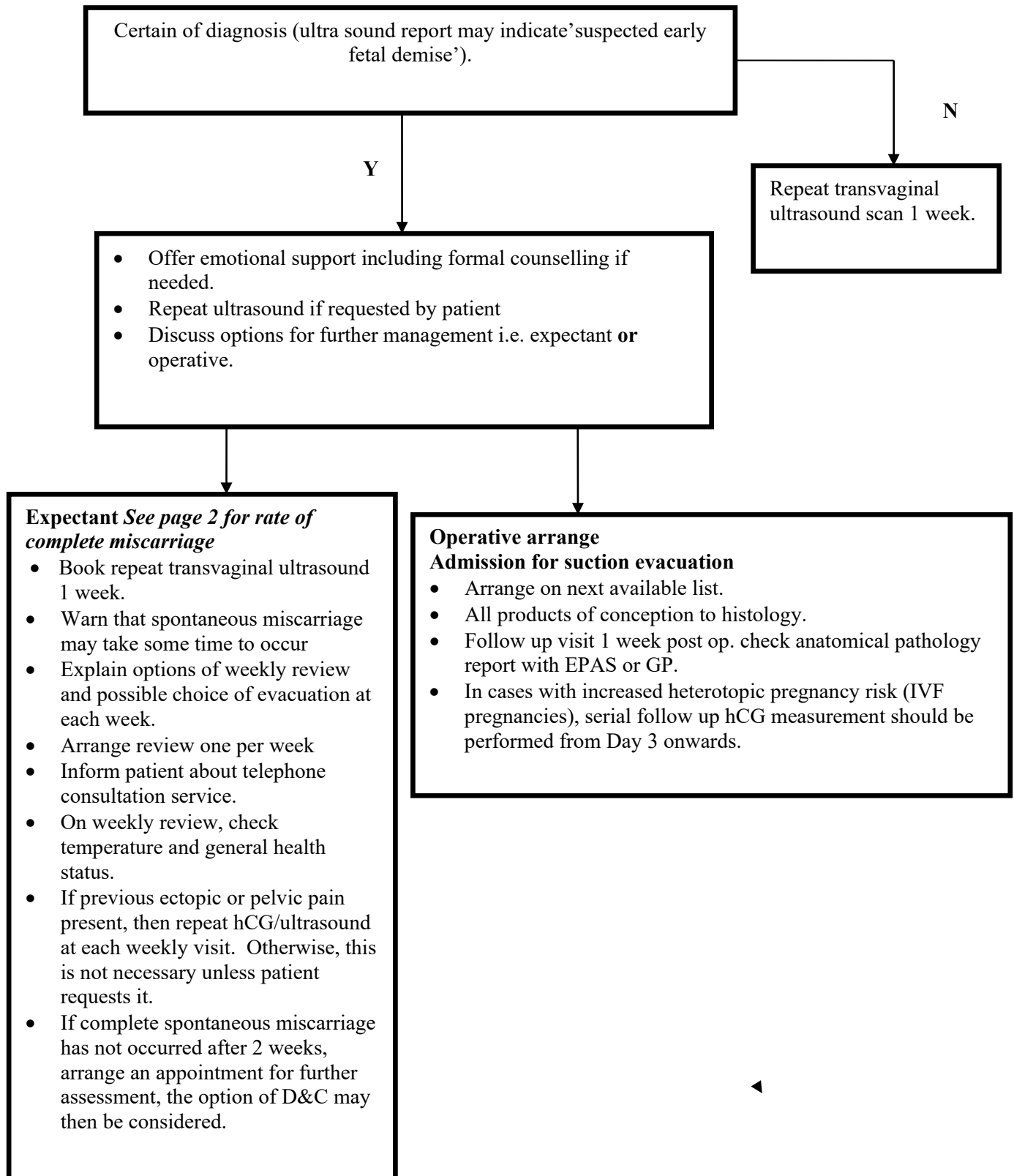


EPAS Algorithm: Pathway B
Intrauterine Pregnancy Uncertain Viability (IPUV)
Gestational sac < 20mm

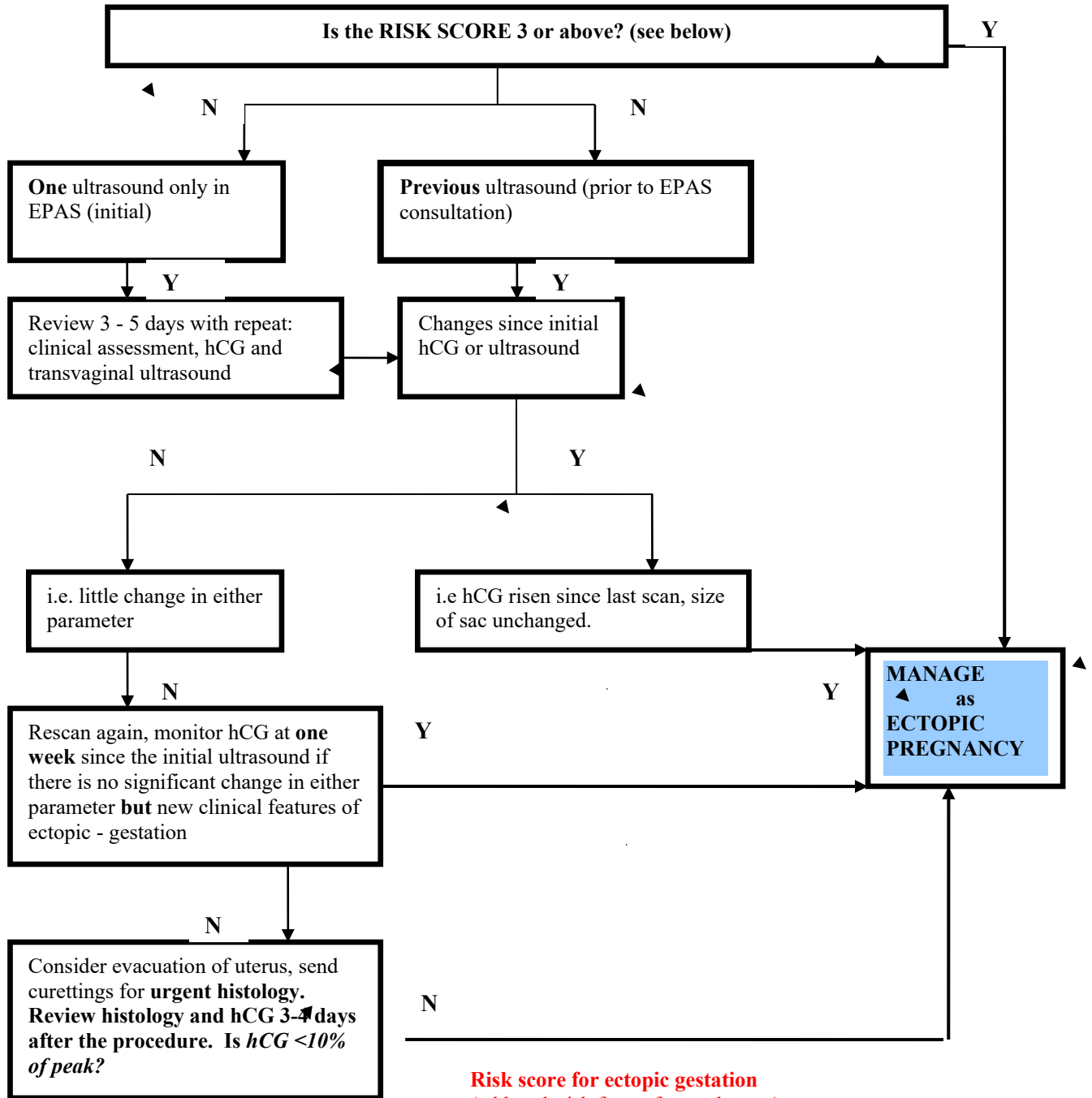


EPAS ALGORITHM: PATHWAY C
Missed Miscarriage



EPAS ALGORITHM: PATHWAY D**Early fetal demise**

EPAS ALGORITHM: PATHWAY E
Management of Ectopic Pregnancy



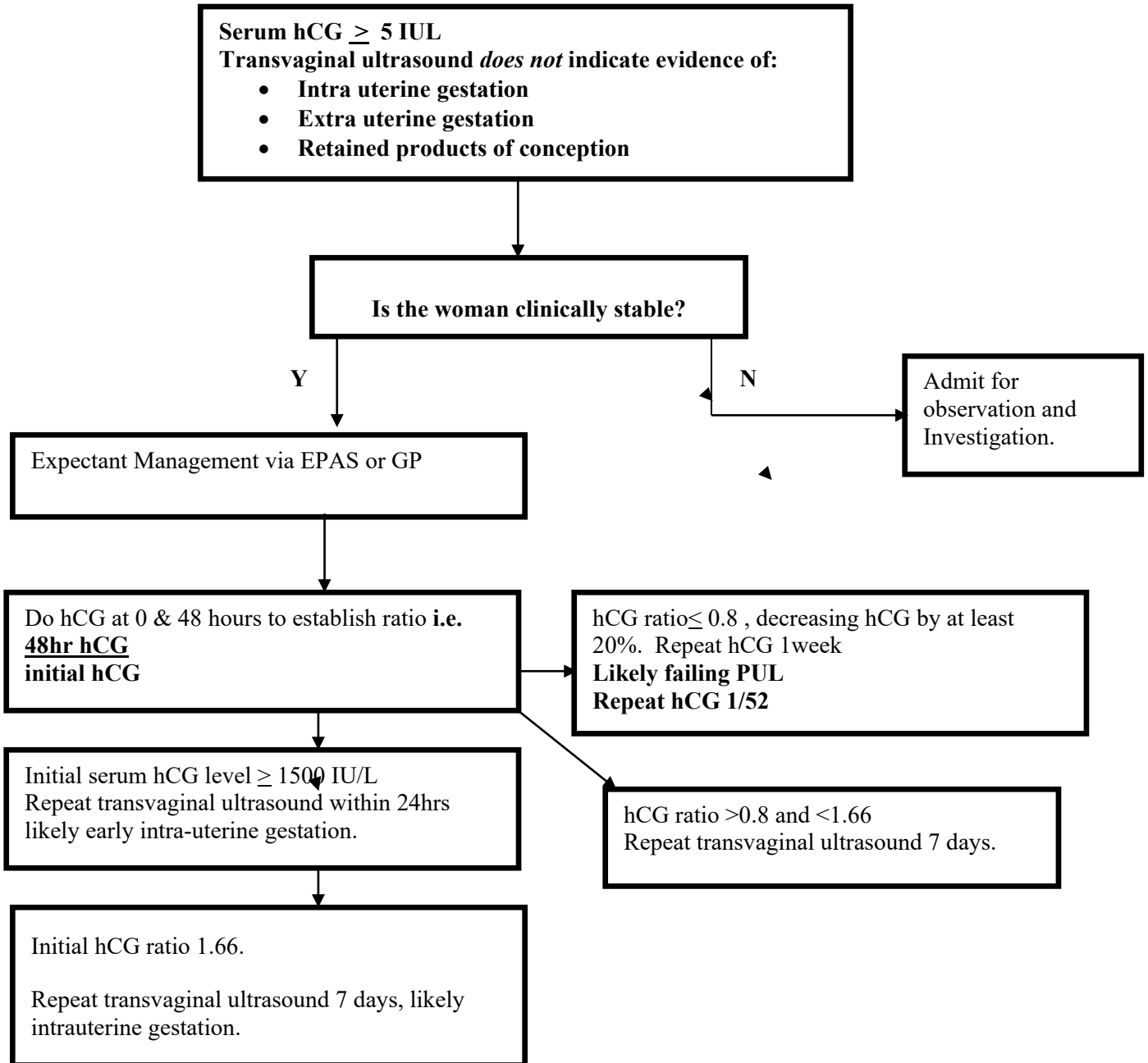
Risk score for ectopic gestation
 (add each risk factor for total score)

Risk	Score
Previous ectopic gestation	2
History of tubal surgery	2
IUCD in situ	2
History PID, Chlamydia or gonorrhoea	1
Documented tubal pathology (i.e. hydrosalpinx at ultrasound or laporotomy)	1
Assisted conception	1

**EPAS Algorithm: Pathway F
Pregnancy of unknown location
(PUL)**

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



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.

Laparotomy 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/m^2 is well tolerated and effective.

Indications for Methotrexate use:

- Haemodynamically stable.
- Baseline serum hCG $< 5,000\text{IU/L}$.
- Ectopic pregnancy $< 3\text{cm}$ 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

- 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

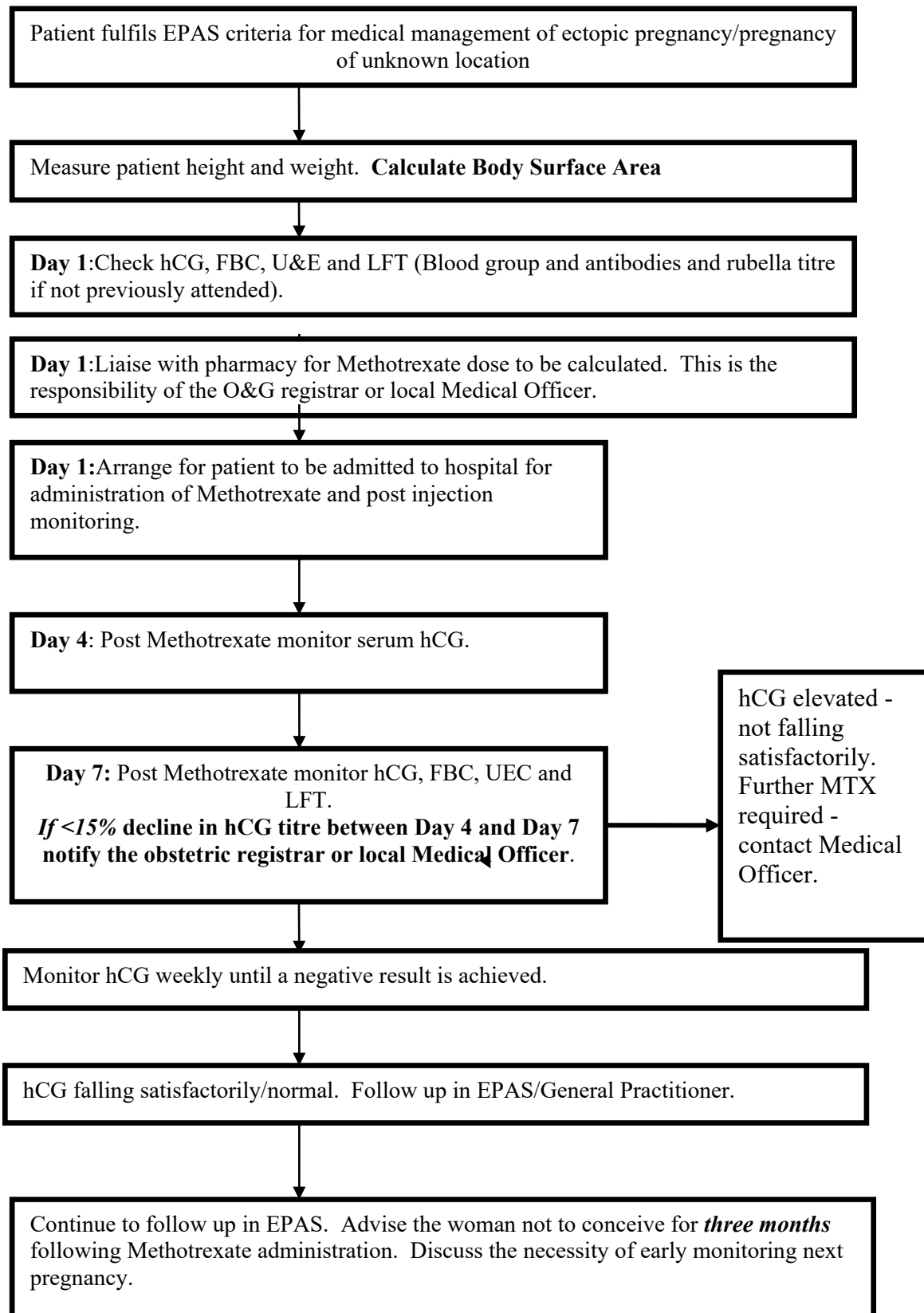
- Patient is potentially non compliant or not motivated to long term recovery.

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



References for algorithms:

Association of Early Pregnancy Units: Guidelines 2007. Organisational, Clinical & supportive. Cardiff 2007

Condous G, Bleeding and pain in early pregnancy: what are the likely problems. Handbook for Early Pregnancy Care pp19-26 Chapter 3. Taylor and Francis London 2006

Condous G, Okaro E, Bourne T. The conservative management of early pregnancy complications: a review of literature. Ultrasound Obstet Gynaecol. 2003;22:420-430

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Luise C, Outcome of expectant management of spontaneous first trimester miscarriage: observational study. 2002 April 13;324 (7342): 873-5.

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 Prince Alfred Hospital: Early Pregnancy Assessment Service: Management Protocol for Early Pregnancy Assessment Service. November 2004.

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

Sairam S, The role of ultrasound in the expectant management of early pregnancy loss. Ultrasound Obstet Gynaecol. 2001 Jun; (6) 506-9

Stovall and Ling. Single dose Methotrexate: An Expanded clinical trial. American Journal of O&G 1993.

Western Sydney Area Health Service (WSAHS): Registrars Guide for Bleeding in Early Pregnancy. 2003

Women's Hospitals Australasia: Management of Early Pregnancy Loss. Clinical Practice Guideline 2008

Appendix C Terminology

Table of appropriate terminology

Previous Term	Recommended Term	Definition	Notes
Spontaneous abortion	Miscarriage	Pregnancy loss occurring before 20 completed weeks of gestation or of a fetus less than 400gm weight if gestation is unknown [#]	
Threatened abortion	Threatened miscarriage	Any vaginal bleeding other than spotting before 20 completed weeks of gestation [#]	
Inevitable abortion	Inevitable miscarriage	Miscarriage is imminent or is in the process of happening [#] Threatened miscarriage with an open cervical os and/or rupture of the membranes [#]	
Incomplete abortion	Incomplete miscarriage	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 [#]	
Complete abortion	Complete miscarriage	A miscarriage needing no medical or surgical interventions [#] Products of conception have been passed; USS shows no apparent products; bleeding generally settles [#]	
Missed abortion	Missed miscarriage or Silent miscarriage	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 [#]	A '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 [#]

Previous Term	Recommended Term	Definition	Notes
Anembryonic pregnancy* or Blighted ovum*	Early fetal demise or Delayed miscarriage	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 [#]	*these reflect different stages in the same process
Septic abortion	Miscarriage with infection (sepsis)	A miscarriage complicated by a pelvic infection [#]	
Recurrent abortion	Recurrent miscarriage	3 or more consecutive miscarriages by the same woman [#]	
	Biochemical pregnancy loss ¹¹	Pregnancy not located on scan ⁺	
	Empty sac ¹¹	Sac with absent or minimal structures ⁺	
	Fetal loss ¹¹	Previous CRL measurement with subsequent loss of fetal heart activity (FHA) ⁺	
	Early pregnancy loss ¹¹	Confirmed empty sac or sac with fetus but no FHA <12 weeks ⁺	
	Delayed miscarriage ¹¹	As 'early pregnancy loss' ⁺	
	Late pregnancy loss ¹¹	Loss of FHA >12 weeks ⁺	
Suspected ectopic	Pregnancy of unknown location ¹¹ (PUL)	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 ⁺	
	Viable pregnancy	Live ongoing embryonic pregnancy ⁺	
	Pregnancy of uncertain viability	Intrauterine sac (<25mm mean diameter) with no obvious yolk sac or fetus or Fetal echo <7mm crown-rump length with no obvious fetal heart activity.	In order to confirm or refute viability, a repeat scan at a minimal interval of 1 week is necessary. ¹⁶

Previous Term	Recommended Term	Definition	Notes
	Ectopic pregnancy	A pregnancy located outside the uterus, usually in the fallopian tubes, but may be ovarian. #	
	Molar pregnancy	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. #	
Incompetent cervix	Cervical weakness	The opening of the cervix before a fetus is mature enough to be born. It may lead to miscarriage or premature delivery.	Cervical weakness is not routinely evaluated and therefore not usually diagnosed until after a second trimester loss has occurred.
	Expectant miscarriage management	No specific intervention; allows spontaneous passage of fetal tissue. ⁷⁸	
	Surgical miscarriage management	Surgical evacuation (with or without curettage) of the retained fetal tissue. ⁷⁸	
Heterotopic pregnancy	Heterotopic pregnancy	Concurrent/simultaneous intra-uterine and extra uterine pregnancies	

Definitions from the Health Data Standards Committee. 2006. National Health Data Dictionary Version 13.2. <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

MATERNAL & 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 responsibility 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**.

- PD2010_016 SAFE START Strategic Policy available at: http://www.health.nsw.gov.au/policies/pd/2010/PD2010_016.html
- GL2010_004 SAFE START Guidelines: Improving mental health outcomes for parents and infants available at: http://www.health.nsw.gov.au/policies/gl/2010/GL2010_004.html

The Maternal & Child Health Primary Care Policy can be downloaded from http://www.health.nsw.gov.au/policies/pd/2010/PD2010_017.html

MATERNITY- NATIONAL MIDWIFERY GUIDELINES FOR CONSULTATION AND REFERRAL (PD2020_008)

PD2020_008 rescinded PD2010_022

POLICY STATEMENT

This is a Policy Directive for maternity services with respect to appropriate consultation and referral by midwives.

This Policy establishes the requirement that all midwives providing midwifery care utilise the *Australian College of Midwives (ACM) National Midwifery Guidelines for Consultation and Referral*©1. The ACM Guidelines provide an evidenced-based framework to support midwives in their clinical decision making across all practice areas and facilitate appropriate consultation and referral to peer midwives, medical and allied health staff during pregnancy, birth and the postnatal period.

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.

SUMMARY OF POLICY REQUIREMENTS

Local Health Districts:

- 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.
- Provide ongoing education on the use of the *ACM National Midwifery Guidelines for Consultation and Referral*©.
- Are to 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.

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.

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
- Privately Practicing Endorsed Midwives with access rights.

Instructions for accessing the ACM National Midwifery Guidelines for Consultation and Referral© can be found at the Australian College of Midwives website.

Local Health Districts should have in place a local implementation plan for education in the use of the *ACM National Midwifery Guidelines for Consultation and Referral*©

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
- facilitates standardisation of clinical management, consultation and escalation of abnormal FHR features in line with Policy Directive PD2013_049 Recognition and Management of Patients who are Clinically Deteriorating and the GL2016_018 NSW Maternity and Neonatal Service Capability Framework.

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:

https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2018_025

CONNECTING, LISTENING AND RESPONDING: A BLUEPRINT FOR ACTION – MATERNITY CARE IN NSW (IB2023_006)**IB2023_006 rescinded PD2010_045****PURPOSE**

This Information Bulletin is to notify the NSW Health system of the release of [Connecting, Listening and Responding: A Blueprint for Action – Maternity Care in NSW](#) (the Blueprint).

KEY INFORMATION

The Blueprint is guided by the [Woman-centred care: Strategic directions for Australian maternity services](#) and aligns with the NSW Health Policy Directive First 2000 Days Framework ([PD2019_008](#)). It has been developed in consultation with local health districts, NSW Health pillars, consumers and key stakeholders.

The Blueprint aims to strengthen maternity care services to ensure they are collaborative, equitable and woman-centred, while acknowledging and striving to address the contemporary organisational challenges for maternity care in NSW.

The Blueprint's vision is that 'all women in NSW receive respectful, evidence-based and equitable maternity care that improves experiences and health and wellbeing outcomes'. The Blueprint is supported by 10 goals:

1. Women receive maternity care that is socially and culturally respectful
2. Women's views actively inform improvements to maternity care
3. Women have enough information before conception to optimise their health, pregnancy experience and outcomes
4. Women are connected to information and care early in pregnancy
5. Antenatal care reflects the individual preferences and needs of women, babies and families
6. Women are offered different care options, are actively involved in decision-making about their care and their choices are respected
7. Women with additional needs during pregnancy are connected to appropriate services
8. Women are informed of the possible outcomes of all aspects of care during labour and birth
9. Women receive safe, high quality, evidence-based care that is appropriate to their individual needs and expectations
10. Women are connected to the care and support they need after the birth.

The NSW Ministry of Health will work with key stakeholders to develop an implementation plan for the Blueprint. The implementation plan will set out the short, medium and long-term priorities and further guide decisions on actions required to strengthen implementation.

Key actions

All local health districts and speciality health networks are to:

- promote and utilise the Blueprint for ongoing system reform and service redesign to strengthen maternity care across NSW including preconception, antenatal, labour, birth, postnatal care and transition to care in the community.
- promote the use of the Blueprint to inform direction and local actions to ensure all women in NSW receive respectful, evidence-based and equitable maternity care that improves experiences and health and wellbeing outcomes.
- provide input to the NSW Health implementation plan and to support local implementation of the goals, objectives and actions documented in the Blueprint.

Further information

For further information, contact the Health and Social Policy Branch, NSW Ministry of Health at MOH-HSPB@health.nsw.gov.au.

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.

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^{3,4,5} 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®) gel or Cervidil® 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[®]) 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[®]). 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[®]).

3.2.3 Concentration

To reduce error, a standard concentration must always be used regardless of parity. The recommended concentration is:

- 10iu oxytocin (Syntocinon[®]) in 1000ml infusion fluid; **OR**
- 5iu oxytocin (Syntocinon[®]) 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[®]) 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

Time	Milliunits per minute	Mls per hour
Start	2.5	15
Min 30 mins	5	30
½ hourly	10	60
	15	90
	20	120
	25	150
	30	180
Medical Review		
½ hourly	35	210
	40	240

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.² 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

1. Swift, J. (2002). Routine induction of labour at 41 weeks gestation: nonsensus consensus *British Journal Obstetrics and Gynaecology: an International Journal of Obstetrics and Gynaecology* May 2002, Vol. 109, pp.485-491
2. National Collaborating Centre for Women's and Children's Health. *Induction of Labour - Clinical Guideline*. July 2008. RCOG Press.
3. Government of South Australia, Department of Health. Perinatal Practice Guidelines. Available at URL: <http://www.health.sa.gov.au/ppg>
4. British Columbia Reproductive Program. Obstetric Guideline 1: Cervical Ripening and Induction of Labour. (2005)
5. Royal Women's Hospital, Melbourne. Guidelines for Induction of Labour, 2007. Available at URL: [http://www.thewomens.org.au/InductionoflabourFactSheet?searchTerms\[\]=induction&searchTerms\[\]=of&searchTerms\[\]=labour](http://www.thewomens.org.au/InductionoflabourFactSheet?searchTerms[]=induction&searchTerms[]=of&searchTerms[]=labour).
6. Calder AA, Embrey MP, Hillier K. Extra-amniotic prostaglandin E2 for the induction of labour at term. *Journal of Obstetrics & Gynaecology of the British Commonwealth* 1974; 81(1); 39-46

6. APPENDIX A

Modified Bishop⁶ Cervical Score System

Characteristic	0	1	2	3	Score
Dilatation (cm)	< 1	1-2	2-4	> 4	
Length (cm)	> 4	2-4	1-2	< 1	
Consistency	firm	average	soft	-	
Position of cervix	posterior	middle/anterior	-	-	
Station	-3	-2	-1 to 0	+1 to +2	
					Total =

Attachment 1: Implementation checklist

Assessed by:		Date of Assessment:		
IMPLEMENTATION REQUIREMENTS	Not commenced	Partial compliance	Full compliance	
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<u>Notes:</u>			
2. All medical, midwifery, nursing and other staff must be educated about the content of this policy directive within 12 months of issue.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<u>Notes:</u>			

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^{\(1\)}](#), 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.

To download the Guideline please go to http://www.health.nsw.gov.au/policies/gl/2014/GL2014_004.html

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.

To download the Guideline please go to

http://www.health.nsw.gov.au/policies/gl/2014/GL2014_006.html

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.

USE OF THE GUIDELINE**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

http://www.health.nsw.gov.au/policies/gl/2014/GL2014_016.html

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

http://www.health.nsw.gov.au/policies/gl/2014/GL2014_022.html

NEONATAL AND INFANT HEPATITIS B PREVENTION AND VACCINATION PROGRAM (PD2023_032)

PD2023_032 replaced PD2017_036

POLICY STATEMENT

NSW Health is committed to reducing the risk of hepatitis B transmission to neonates born in NSW. This Policy Directive focuses on the screening of all pregnant women for hepatitis B disease, appropriate referral to a specialist hepatology service/ specialist hepatologist as required, and the follow-up and management of all infants born to hepatitis B surface antigen (HBsAg) positive women.

SUMMARY OF POLICY REQUIREMENTS

This Policy Directive must be read in conjunction with the current edition of The Australian Immunisation Handbook.

The Policy Directive aims to ensure consistent implementation of the NSW Neonatal and Infant Hepatitis B Prevention and Vaccination Program in all local health districts; and applies to NSW ante- and post-natal services, maternity hospitals, and public health units within the local health district.

All maternity facilities must offer hepatitis B surface antigen (HBsAg) screening and referral where appropriate to all pregnant women. HBsAg positive pregnant women with a high viral load (>200,000 or 5.3 log₁₀ IU/mL) are recommended to be referred to a hepatology service/ specialist hepatologist for management and follow up. HBsAg positive pregnant women with a low viral load (≤200,000 or 5.3 log₁₀ IU/mL) can be managed by either their general practitioner or hepatology service.

All maternity facilities are required to offer Hepatitis B immunoglobulin (HBIG) to all neonates born to HBsAg positive mothers within 12-hours of birth. In addition, all neonates regardless of mothers HBsAg status must be offered the hepatitis B vaccine within 7-days of birth.

For reporting requirements, all maternity facilities are required to enter hepatitis B data onto eMaternity or Cerner as appropriate and report regularly to their Local Health District

The Neonatal Hepatitis B Hospital Coordinator must forward a copy of the Neonatal and Infant Hepatitis B Follow Up Letter to the LHD Neonatal and Infant Hepatitis B Lead and the mother's nominated doctor, if known to assist with following up babies born to a HBsAg positive mother.

In addition, the Neonatal Hepatitis B Hospital Coordinator must complete the Maternity Unit Record Form for every infant born to a HBsAg positive mother. The completed form must be sent to the LHD Neonatal and Infant Hepatitis B Lead to ensure all reporting and monitoring responsibilities are met.

The LHD Neonatal and Infant Hepatitis B Lead is required to send a copy of the *Neonatal and Infant Hepatitis B Follow Up Letter to General Practitioners* and the *Maternity Unit Record Form* to the local PHU Immunisation Coordinator for monitoring and follow up of vaccination course completion.

All neonates born to HBsAg positive mothers outside of NSW Health facilities should be notified to the local public health unit to assist with monitoring the completion of their primary hepatitis B vaccination course.

Following collection of the data, the local health district is responsible for reporting program performance and follow-up all neonates born to HBsAg positive mothers who are overdue for vaccination.

The full Neonatal and Infant Hepatitis B Prevention and Vaccination Program policy is available at https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2023_032

MATERNITY – 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.

To download the full Maternity – External Cephalic Version guideline go to:

https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2017_007

MATERNITY – 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.

Download the Maternity – Supporting Women Planning a Vaginal Breech Birth guideline at:

https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2017_008

VISITING ENDORSED MIDWIFE PRACTICE (PD2023_036)**PD2023_036 replaced PD2022_018****POLICY STATEMENT**

NSW Health is committed to facilitating women's options for maternity care. NSW Health also supports public hospitals to enable admitting and practice rights for Visiting Endorsed Midwives (VEMs), in accordance with Commonwealth maternity reforms.

SUMMARY OF POLICY REQUIREMENTS

This Policy Directive provides options for endorsed midwives to apply for an Access Agreement with an NSW Public Health Organisation (PHO). These options include in the capacity as a VEM who provides private midwifery services in NSW Health facilities in an individual capacity, or as a VEM who is separately employed by a midwifery practice or Health Care Service.

Planned births at home that require escalation or transfer of care to a public maternity facility is not included in the scope of this Policy Directive.

An Access Agreement outlines the terms and conditions under which a PHO agrees to grant a VEM the right of access to NSW Health facilities operated by that organisation.

A collaborative arrangement must be agreed and in place between the VEM and either a NSW Health maternity service, or an Obstetric Specified Medical Practitioner who also has rights of practice at the same service.

PHOs must establish Verification Committees to assess applications for Access Agreements from VEMs, and applications from midwifery practices or Health Care Services that employ a VEM requesting an Access Agreement. Verification Committees make recommendations to the Chief Executive (or their delegate) of the PHO to approve or decline applications. Verification Committees are also responsible for credentialing and determining the scope of practice of VEMs. Verification Committees verify, cite and authenticate relevant documents supplied by a VEM to validate their professional qualifications and experience, and also validate the endorsement of VEMs for use of scheduled medicines.

Verification Committees also consider and approve amendments to Collaborative Arrangements. Verification Committees review the right of access of the VEM, midwifery practice or Health Care Service at one year from the commencement date of the Access Agreement, and then each 12-month period thereafter (a new application for an Access Agreement is required every five years).

Download the complete Visiting Endorsed Midwife Practice policy at:

https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2023_036

347(30/10/23)

NAUSEA AND VOMITING IN PREGNANCY AND HYPEREMESIS GRAVIDARUM (GL2022_009)

GUIDELINE SUMMARY

Nausea and vomiting in pregnancy and hyperemesis gravidarum can cause significant emotional, psychological, physical and financial distress for women and their families.

This Guideline provides evidenced-based guidance to support consistency of practice, decision-making and care coordination for the diagnosis and management of nausea and vomiting in pregnancy and hyperemesis gravidarum.

This Guideline applies to NSW Health and non-NSW Health clinicians (such as general practitioners) who provide care to pregnant women.

KEY PRINCIPLES

This Guideline reflects evidence based best clinical practice and expert consensus opinion to standardise the diagnosis and management of nausea and vomiting in pregnancy and hyperemesis gravidarum.

The Guideline provides recommendations for the care of priority populations including the care of Aboriginal and/or Torres Strait Islander families, culturally and linguistically diverse families and care of LGBTIQ+ people.

Comprehensive assessment, including the Pregnancy Unique Quantification of Emesis (PUQE-24) scoring index, will assist with defining the severity of illness and to guide care pathways which promote community and ambulatory care settings.

Holistic and multidisciplinary care must consider the woman's social and emotional wellbeing. Individual care plans are to be developed in partnership with the woman and must include advice on how to adjust treatment if symptoms improve, fluctuate or deteriorate, and how to access care if required.

Continuity of care models, including access to specialist care, must be developed to support women accessing care closer to home. This may include community or ambulatory care for women with mild to moderate severity; Hospital in the Home for women with more severe symptoms; and virtual care as appropriate.

Transfer of care between maternity services and community-based services is to be coordinated, ensuring that women receive consistent information, assessment, management, treatment, and continuity of care.

Pre-conception support, counselling and early or pre-emptive treatment, including an early pregnancy booking, is to be offered to women who have experienced hyperemesis gravidarum in a previous pregnancy.

Local Health Districts and Specialty Health Networks must ensure:

- implementation of this Guideline
- relevant staff receive education and training based on the Guideline
- local protocols or operating procedures are in place and consistent with this Guideline
- monitoring of practice.

Download the Nausea and Vomiting in Pregnancy and Hyperemesis Gravidarum guideline at:
https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2022_009

REDUCING THE EFFECTS OF SMOKING AND VAPING ON PREGNANCY AND NEWBORN OUTCOMES (PD2022_050)

POLICY STATEMENT

NSW Health services and clinical staff are committed to provide evidence-based and high-quality smoking and vaping cessation support to women before, during and after pregnancy.

Smoking during pregnancy is the most significant preventable cause of complications for pregnant women and their children, and is associated with preterm birth, low birth weight, babies who are small-for-gestational-age and perinatal death.

SUMMARY OF POLICY REQUIREMENTS

All clinicians working in Maternity and Newborn, Child and Family Health, Perinatal Infant Mental Health Services (PIMHS), Aboriginal Maternal and Infant Health Services (AMIHS), Building Strong Foundations for Aboriginal Children, Families and Communities (BSF), Oral Health Services, Primary Care and Aboriginal Community Controlled Health Services (ACCHSs), and other relevant services are to be appropriately skilled in the management of smoking and vaping in pregnancy.

Carbon monoxide (CO) monitoring is to be offered to all women before asking about smoking status:

- at first pregnancy visit and at the 28 weeks gestation visit.
- at every health visit for women who are known to smoke, or who have recently quit (i.e., in the last 12 months).

The carbon monoxide measurement is to be used as a tool to engage in discussion on smoking status, avoiding second-hand smoke, and to motivate quitting. The expired carbon monoxide reading is to be recorded in the woman's health care record.

Clinicians are to use a sensitive and empathetic approach when discussing smoking and vaping with pregnant women. The 'Ask, Advise, Help' smoking and vaping cessation brief intervention model must be used at every health visit.

Clinicians are to ask and record the smoking and vaping status of all pregnant women and that of their partner and/or household members at all health visits. Clinicians are to advise on the short and long term benefits of quitting and effective ways to quit, and offer culturally appropriate support (help) and resources to assist their attempts to quit.

Clinicians are to provide all Aboriginal women with care that is safe, respectful and trauma informed. A comprehensive, holistic approach must be taken when addressing smoking and/or vaping. This includes the physical, spiritual, cultural, emotional, and social wellbeing of women. This is especially important for Aboriginal women and women having an Aboriginal baby.

Clinicians are to offer consultation with an Aboriginal health worker that the woman is comfortable with, or referral to a culturally safe service, such as Aboriginal Quitline (accessed by calling Quitline and asking to speak to an Aboriginal Advisor).

Support and interventions to quit smoking and vaping are to be self-determined and adopt a strengths-based approach to ensure women and their families feel supported in their progress to quit. A strengths-based approach acknowledges the strengths of Aboriginal people, their families, and their communities, including connection to culture, resilience, and a holistic view of health, and moves away from deficit discourse.

People who smoke or vape may have complex needs associated with their nicotine/tobacco use, including psychosocial issues, trauma, mental health conditions, and drug and alcohol related health issues. Clinicians are to provide smoking and vaping cessation support that is safe, respectful and trauma informed.

Clinical staff are to document carbon monoxide readings, smoking and vaping status, support offered, and outcomes of discussions in the woman's health care record to ensure continuity of care and appropriate follow-up.

Download the complete Reducing the effects of Smoking and Vaping on Pregnancy and Newborn Outcomes policy at:

https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2022_050

344(14/10/22)

CARE OF WOMEN WITH SUSPECTED OR CONFIRMED FETAL GROWTH RESTRICTION (GL2023_004)

GUIDELINE SUMMARY

Fetal growth restriction is a common complication in pregnancy that is associated with adverse perinatal and neurodevelopmental outcomes including stillbirth, neonatal mortality and short- and long-term morbidity. This Guideline provides evidence-based guidance to support maternity services in the care planning for pregnant women with suspected or confirmed fetal growth restriction, ensuring women and their families are fully informed of risks, potential outcomes and their options of care.

This Guideline applies to all NSW Health maternity services.

KEY PRINCIPLES

This Guideline reflects evidence based clinical practice for the screening, management, and escalation of Fetal Growth Restriction (FGR) during pregnancy. Women with confirmed FGR require as a minimum, a multidisciplinary collaborative care plan in line with the Tiered Perinatal Networks.

Throughout all pregnancy and perinatal care, women and their families must be fully informed of risks, potential outcomes and their options of care. Women and their support person(s) are always included in care planning and decision making, and consent for healthcare treatment must be established.

Throughout the antenatal period, all women must be assessed for risk factors associated FGR in line with the [NSW Fetal Safety Risk Assessment Pathway](#) and an appropriate care plan developed in collaboration with the woman.

FGR is associated with adverse perinatal outcome including stillbirth. Aboriginal and Torres Strait Islander women experience higher rates of stillbirth. Risk factor identification is vital to support perinatal risk reduction and reduce adverse outcomes for Aboriginal and Torres Strait Islander women.

Serial plotting of symphysis fundal height (SFH) measurements on the NSW Health [International Symphysis-Fundal Height Standards](#) chart are to be conducted as part of routine antenatal care starting from 24 to 28 weeks gestation, to monitor for potential FGR.

Women who are unsuitable for symphysis fundal height measurements or have FGR risk factors as per the NSW Fetal Safety Risk Assessment Pathway will require growth ultrasound assessments.

Where FGR is identified, consultation and referral for specialist obstetric care must be offered and arranged as appropriate.

346(24/02/23)

In the presence of FGR, decisions for planning birth should include consideration of the gestational age and be balanced against the benefits of ongoing pregnancy, in collaboration with the woman.

Optimal care planning includes ensuring the availability of multidisciplinary team members including the neonatal team, to support stabilisation and potential admission of the baby to a neonatal unit.

For future pregnancies, women with a history of FGR require as a minimum, multidisciplinary collaborative care planning involving midwifery and medical consultation.

All women should be provided the opportunity to debrief with clinicians about their pregnancy and birth experience and appropriate follow up support be made available. This should include psychosocial support where indicated with appropriate wellbeing support made available.

Download the complete Care of women with suspected or confirmed Fetal Growth Restriction guideline at:

https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2023_004

DOMESTIC VIOLENCE ROUTINE SCREENING (PD2023_009)**POLICY STATEMENT**

NSW Health is committed to early identification of domestic violence and promoting awareness of the health impacts of violence. Domestic violence routine screening is mandatory for all women and girls accessing maternity and child and family services, and women 16 years and over accessing mental health and alcohol and other drug services.

Other appropriate NSW Health services, following NSW Ministry of Health approval, can implement domestic violence routine screening with all women 16 years and over in line with this Policy Directive.

SUMMARY OF POLICY REQUIREMENTS

Domestic violence routine screening is conducted through five phases: delivering the domestic violence routine screening preamble; asking the screening questions; taking appropriate actions in response to the woman's answers; explaining and offering the domestic violence Z-card; and documenting screening and outcomes in medical records.

Health workers are to take account of clients' broader social context and be responsive to clients' needs, including by addressing additional barriers that women from priority populations may face.

All clinical staff and Aboriginal Health Workers who conduct screening must complete the four-hour mandatory face-to-face Domestic Violence Routine Screening Training. In participating health services, staff must complete the training before conducting screening.

Screening must occur with all eligible women, except in the following circumstances: others are present; the woman is not well enough to answer the screening questions; or the woman has made a recent disclosure of domestic violence.

Where domestic violence is identified prior to screening health workers are to respond in line with the requirements of this Policy and related NSW Health policies.

Domestic violence routine screening must be conducted at face-to-face appointments in a safe and private space, not via telehealth. Where privacy cannot be assured, domestic violence routine screening is not to proceed. Where health services are delivering services through a mix of face-to-face and telehealth, health services must prioritise domestic violence routine screening at face-to-face appointments.

If domestic violence routine screening cannot be conducted when initially scheduled, attempts must be made at subsequent appointments or on subsequent occasions of service until the domestic violence routine screening is completed.

Health workers must read out the preamble on the Domestic Violence Routine Screening form before asking the screening questions and then ask the screening questions, in full and as instructed, on the Domestic Violence Routine Screening form.

Responses to disclosures of domestic violence must include risk assessment and safety planning.

All women who disclose domestic violence are to be offered a referral to a counsellor, social worker, or other appropriate trained psychosocial worker within NSW Health or relevant specialist services.

Health workers must also address the safety, health, and wellbeing needs of children and young people. Workers are to respond to suspected risk of significant harm and take action that promotes the safety of both adult and child victims of domestic violence. This includes identifying responses to assist women to continue to care for their children in a safer environment where possible.

Where a woman or where children are identified as being at serious threat, workers must prioritise action to reduce the threat.

All women must be offered a Z-card, and have its contents explained, regardless of the outcome of the domestic violence routine screening.

Where a woman discloses other forms of violence and abuse, including family violence, health workers will respond in line with this Policy's procedures and other relevant NSW Health policies.

Responses to screening questions and subsequent actions must be documented in the woman's medical record, including if they do not disclose violence. This includes completing the Domestic Violence Routine Screening form. Domestic Violence Routine Screening forms must be completed in the electronic medical record where available.

Local Health Districts and Specialty Health Networks are to support health workers to deliver domestic violence routine screening by:

- Ensuring that Domestic Violence Routine Screening Training is provided to clinical staff and Aboriginal Health Workers whose role involves delivery of domestic violence routine screening.
- Identifying appropriate staff to complete the Domestic Violence Routine Screening Facilitator Training so that they can deliver the Domestic Violence Routine Screening Training within their Local Health District or Specialty Health Network.
- Ensuring workers who conduct screening and respond to disclosures have access to support. This includes promoting awareness of and access to domestic and family violence leave provisions, and other supports for workers who may themselves be experiencing domestic and family violence.
- Promoting screening practices that are accessible, safe and respectful to all women, including women from priority populations.
- Establishing and maintaining consultation and referral pathways from screening services to specialist violence, abuse and neglect practitioners and services both within and beyond NSW Health.
- Monitoring and reporting on the implementation of domestic violence routine screening and training as required.

The full Domestic Violence Routine Screening policy is available at:

https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=pd2023_009