The Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Excellence in Women's Health

Prenatal assessment of fetal structural conditions

This statement was originally developed by the HGSA/RANZCOG Joint Committee on Prenatal Diagnosis and Screening

The principal authors of this statement were Dr Andrew McLennan and Professor Sue Walker.

A list of members of the HGSA/RANZCOG Joint Committee on Prenatal Diagnosis and Screening can be found in Appendix A and Women's Health Committee in Appendix B.

The Committee acknowledges contributing authorship in Appendix C.

Disclosure statements have been received from all authors and committee members.

Disclaimer This information is intended to provide general advice to practitioners. This information should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The document has been prepared having regard to general circumstances.

First endorsed by RANZCOG: March 2015
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Objectives: This statement is intended to provide advice on the assessment of fetal structural conditions.

Outcomes: Improved understanding regarding effective assessment of fetal structural conditions that are performed at different stages in pregnancy.

Target audience: This statement is intended for use by health professionals providing antenatal care including: Obstetricians, Clinical Geneticists, Radiologists, Obstetricians, Sonologists, Sonographers and GPs, Midwives, Nurses and Genetic Counsellors.

Other audiences: This statement provides useful information for patients and carers, researchers, health policy makers, health regulators and those responsible for quality and safety of healthcare. This statement may also be a valuable resource to State and Federal Government bodies developing guidelines and other documents on prenatal screening and diagnosis.

Values: The evidence was reviewed by the HGSA/RANZCOG Joint Committee on Prenatal Diagnosis and Screening, and applied to local factors relating to Australia and New Zealand.

Background: This statement was originally developed by the HGSA/RANZCOG Joint Committee on Prenatal Diagnosis and Screening in 2015. It adds to the broad statement *Prenatal screening for fetal genetic or structural conditions (C-Obs 35).* More recently the statement was reviewed by Women's Health Committee and approved by RANZCOG Council.

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1. Patient summary

Fetal structural conditions affect 2-3.5% of all pregnancies. Routine screening for FSA by ultrasound has become a part of standard prenatal care throughout the world. The finding of a FSA is usually a devastating event for the patient and her family and has significant implications for the remainder of the pregnancy, for delivery, and for postnatal care. Multidisciplinary input is recommended to provide all the necessary perspectives to optimise management of the pregnancy and to facilitate informed choice for families deciding whether to continue or terminate the pregnancy. The purpose of this document is to provide practitioners with an overview of the role of ultrasound in screening for FSA including information regarding its safety in pregnancy.

2. Summary of recommendations

Recommendation 1	Grade
It is recommended that all consenting patients be offered ultrasound assessment for fetal structural conditions in the mid trimester (generally between 18-22 weeks). Detection of fetal conditions are increasingly being reported in early pregnancy, and it is recognised that many women have an early assessment of anatomy in the first trimester, or as part of aneuploidy screening. Nevertheless, detection rates are optimised with fetal anatomical survey performed in the mid-trimester.	Consensus Based Recommendation References [1-4]
Recommendation 2	**Grade**
At the first contact with a healthcare professional, women should be given information about the purpose and implications of the fetal anatomy ultrasound to enable them to make an informed choice as to whether or not to undertake the examination. The purpose of the ultrasound is to identify fetal conditions and allow parents to access sufficient information regarding the aetiology, associations, and implications of the diagnosis during pregnancy, the newborn period and beyond. Following this, families will be able to make an informed choice about whether to continue or terminate the pregnancy.	Consensus Based Recommendation Reference [5]
Recommendation 3	**Grade**
Credentialed operators should follow appropriate guidelines in the performance of late first trimester ultrasound assessment of fetal structural conditions. While up to 50% of major conditions may be identifiable in the first trimester, many cases will require second trimester review to clarify diagnosis and / or prognosis.	Consensus Based Recommendation References [6-8]
Recommendation 4	**Grade**
All pregnant women should be offered the opportunity to undertake a mid-trimester fetal condition ultrasound assessment. Second trimester ultrasound should screen for the number of fetuses, the gestational age, cervical length, the location of the placenta, and should screen for fetal conditions.	Consensus Based Recommendation Reference [9]

Recommendation 5	Grade
Each practice should develop a protocol on the procedure to be followed when a condition is detected. This protocol should include guidelines for the immediate care of the patient and how the referring doctor will be informed.	Consensus Based Recommendation Reference [10]
Recommendation 6	**Grade**
All women should receive timely information following detection of a major fetal structural condition and have the opportunity to undertake counselling about the nature, prognosis, ongoing care pathway and recurrence risk.	Consensus Based Recommendation
Recommendation 7	**Grade**
Depending on the condition, referral to a tertiary centre and involvement of a multidisciplinary team in the management of the pregnancy may be appropriate.	Consensus Based Recommendation
Recommendation 8	**Grade**
When a significant condition has been confirmed by ultrasound examination, all women should be given the time and support they need to decide upon the future of their pregnancy.	Consensus Based Recommendation Reference [2]
Recommendation 9	**Grade**
Routine clinical scanning of every woman during pregnancy using real time B-mode imaging is not contraindicated. The ALARA principle regarding dose and duration of ultrasound exposure ('as low as reasonably achievable') should be observed.	Consensus Based Recommendation Reference [11]
Recommendation 10	**Grade**
Pulsed Doppler ultrasound should not be used routinely in first trimester. If pulsed doppler examination is necessary, the Thermal Index should be <1.0 and exposure time minimised (ideally to 5-10 minutes).	Consensus Based Recommendation Reference [12]
Recommendation 11	**Grade**
Obstetric ultrasound should not be used for non-medical reasons such as sex determination, or solely for the production of photos or videos for commercial purposes.	Consensus Based Recommendation Reference [13]

3. Introduction

The application of fetal ultrasound in obstetrics has revolutionised the management of pregnancy and its potential complications. Access to aneuploidy screening programmes and routine use of ultrasound in the first and second trimester has improved the assignment of gestational age, diagnosis of multiple pregnancy (and chorionicity), placental localisation, prediction of adverse obstetric outcomes in later pregnancy, prenatal diagnosis of structural or karyotypic condition and diagnosis of those conditions which may be amenable to in utero therapy.[1] Normal findings improve positive feelings about the pregnancy and have been shown to promote earlier bonding.[14]

In 2011, 297,126 women gave birth to 301,810 babies in Australia.[15] These pregnancies were largely uncomplicated, with most births resulting in healthy babies at full term. In some cases however, there may be problems with the baby's development. Problems in fetal development may have a genetic origin, or they may be structural conditions. Genetic problems in the fetus are covered in the document, 'Prenatal Screening and Diagnosis of Chromosomal and Genetic Conditions in the Fetus in Pregnancy' (C-Obs 59), whilst this document will address the assessment of structural conditions.

It is estimated that major structural conditions occur in 2-3.5% of pregnancies. Not all conditions can be detected antenatally; detection rates of major structural conditions are reported to be approximately 60% in unselected series, and depend on the anatomical system involved and on the expertise of the ultrasound operator.[16, 17]

The aim of routine screening for fetal structural conditions is primarily to reassure the majority of families that the baby is developing appropriately. In the small number of cases where fetal structural conditions are identified, families are able to receive timely information regarding the condition that has been diagnosed, including the likely aetiology, relevant associations, further investigations required, implications for the remainder of the pregnancy, labour and delivery, and the outlook for their unborn baby as a newborn and beyond. This information is necessary for families as they make decisions regarding the future of the pregnancy, and obstetric caregivers as they plan ongoing care including ongoing surveillance and time, mode and place of delivery.

Recommendation 1	Grade and references
It is recommended that all consenting patients be offered ultrasound assessment for fetal structural conditions in the mid trimester (generally between 18-22 weeks). Detection of fetal conditions are increasingly being reported in early pregnancy, and it is recognised that many women have an early assessment of anatomy in the first trimester, or as part of aneuploidy screening. Nevertheless, detection rates are optimised with fetal anatomical survey performed in the midtrimester.	Consensus Based Recommendation References 1-4

4. Discussion and recommendations

4.1 Consent standards and guidance

4.1.1 All pregnant women should be advised of the availability of prenatal ultrasound assessment for fetal structural conditions as early as possible in pregnancy to allow time to discuss the options available and facilitate an informed choice.

4.1.2 Some women may make an informed decision not to proceed with this assessment. Counselling should follow a shared decision-making model, where health professionals discuss information based on their expertise and respect for the woman's values in arriving at an agreed course of action. Women electing not to have ultrasound in pregnancy should be aware of the other important benefits of routine screening, including confirmation of gestational age, excluding multiple pregnancy, placental localisation, cervical length and assessment of fetal growth and welfare.

4.1.3 Information should be communicated using clear, simple and consistent language when discussing the tests, with confirmation that the information has been understood.

4.1.4 Information should be provided in a format that is easy to understand and accessible to pregnant women from culturally and linguistically diverse backgrounds (including Indigenous women) and women with additional needs (such as physical, sensory or learning difficulties). An interpreting service should be made available where it is required (see Appendix E).

4.1.5 If a structural condition is diagnosed, women and their partners should be provided with sufficient information, which often involves a multidisciplinary team, in order to make an informed decision whether to continue the pregnancy or to have a termination. There should be an assurance that regardless of their decision, they will be offered counselling and support. In the case of continuing the pregnancy, women should receive ongoing care and support throughout pregnancy and in preparation for birth and ongoing neonatal management. If they choose termination, they need to know that access to, and mode of termination, may be influenced by gestational age in line with local legal precedents.

Recommendation 2	Grade and references
At the first contact with a healthcare professional, women should be given information about the purpose and implications of the fetal anatomy ultrasound to enable them to make an informed choice as to whether or not to undertake the examination. The purpose of the ultrasound is to identify fetal conditions and allow parents to access sufficient information regarding the aetiology, associations, and implications of the diagnosis during pregnancy, the newborn period and beyond. Following this, families will be able to make an informed choice about whether to continue or terminate the pregnancy.	Consensus Based Recommendation Reference [5]

4.2 Guidelines for first trimester fetal ultrasound (including structural condition)

Ultrasound-based first-trimester aneuploidy screening has resulted in some major structural conditions being diagnosed earlier in pregnancy. It is important that credentialled operators undertaking first trimester ultrasound assessment have a checklist of structures that are usually visualised at this time, and are aware of major structural conditions that should be diagnosed or excluded in the first trimester.

Australian Guidelines for the Performance of First Trimester Ultrasound have been published by the Australian Society for Ultrasound in Medicine (ASUM)[4] and this guideline provides a list of gestational ages at which various fetal structures may be visualised. The ISUOG first trimester fetal ultrasound guidelines[18] provide detailed information about the structures to be identified in first trimester when scanning for fetal structural conditions. Briefly, it is important to identify the following structures: the fetal head (cranium, falx and choroid plexus), chest (lungs, four chamber cardiac view and diaphragm), abdomen (stomach, cord insertion and bladder) and the four limbs (long bones, hands and feet).

Detection rates of major structural conditions early in pregnancy have increased with improved access to and experience with first trimester ultrasound. In referral centres, detection rates for major conditions and lethal conditions are reported at 40-50% and 75%, respectively. The conditions most likely to be detected in T1 are anencephaly, alobar holoprosencephaly, abdominal wall defects (exomphalos and gastroschisis), univentricular heart; megacystis and body stalk anomalies,[6, 7] while major conditions involving the majority of cardiac, diaphragmatic, skeletal conditions will likely not be diagnosed with certainty until the mid-trimester examination.
Early first-trimester conditions are often diagnosed by chance on clinical indications, whereas late first-trimester diagnoses are the result of systematic screening using ultrasound markers.[19]

Approximately 25% of fetal conditions manifest only in the second and third trimesters and therefore cannot be identified at 11-14 weeks. These include microcephaly, subtle midline brain conditions, echogenic lung lesions and renal structural anomalies and tumours.[6]

Recommendation 3	Grade and references
Credentialled operators should follow appropriate guidelines in the performance of late first trimester ultrasound assessment of fetal structural conditions. While up to 50% of major conditions may be identifiable in the first trimester, many cases will require second trimester review to clarify diagnosis and / or prognosis.	Consensus Based Recommendation References 6-8

4.3 Guidelines for second trimester fetal anomaly ultrasound

The second trimester fetal anomaly ultrasound has been the mainstay for diagnosis of structural conditions over the past 30 years. The examination is generally performed between 18-22 weeks. A systematic approach to the performance of the mid trimester fetal anomaly ultrasound is summarised in the following guidelines: ASUM[4], ISUOG 2011[12], NHS final ultrasound standards 2010[2], NICE clinical guideline 62 2008.[20] These guidelines summarise structures that should be routinely visualised, and the conditions that should generally be excluded. They also indicate appropriate training, governance and audit processes that should be followed in the performance of this widespread screening program.

It is recognised that technical factors including machine capability and sonographer experience, as well as patient factors, including fetal number and increasing maternal BMI can all adversely impact on detection rates. Where

possible, patients with complex scanning needs should be referred to a practice with specific expertise in obstetric ultrasound. In addition, where a condition has been suspected, it is recommended that women are referred to a high risk or tertiary scanning service for confirmation, given the RADIUS study confirmed a relative detection rate of 2.7 (95% CI 1.3-5.8) in tertiary, compared to non-tertiary units.[21]

RANZCOG recommends that all practitioners involved in provision of mid-trimester fetal morphology ultrasound screening must undergo appropriate specific training in this critical and specialised area of practice. Service providers must participate in ongoing professional development, clinical audit, and multidisciplinary review of outcomes specific to their performance of mid-trimester fetal morphology ultrasound screening.

Recommendation 4	Grade and references
All pregnant women should be offered the opportunity to undertake a mid-trimester fetal anomaly ultrasound assessment. Second trimester ultrasound should screen for the number of fetuses, the gestational age, cervical length, the location of the placenta and should screen for fetal conditions.	Consensus-based recommendation Reference [9]
Recommendation 5	**Grade and references**
RANZCOG recommends that all practitioners involved in provision of mid-trimester fetal morphology ultrasound screening must undergo appropriate training and ongoing professional development in this area of practice.	Consensus-based recommendation

4.4 Pathways in the event of a condition

While normal findings promote positive feelings about a pregnancy and improve bonding, the finding of isolated or multiple serious conditionson prenatal ultrasound examination is inevitably stressful.[22] Families require prompt and accurate information, including confirmation of the condition, the likely aetiology, relevant associations, further investigations required (which may involve further imaging or genetic testing), implications for the remainder of the pregnancy, labour and delivery, and the outlook for their unborn baby as a newborn and beyond. This often involves referral to a tertiary unit and a multidisciplinary team. Women regard the speed at which they obtain information regarding the findings as extremely important, even if it means seeing another caregiver with whom they are not familiar.[23] The principles of management include timely review, multidisciplinary input in diagnostic evaluation, detailed counselling of the woman and her family, plans for ongoing care in the pregnancy and timely communication back to the referring practitioner.

Individual units will have their own specific protocols but the following is a suggested approach to the management of families following diagnosis of a structural condition in the fetus;

1. Clinical review

Once a fetal structural condition has been identified, a thorough pregnancy, family and medical history should be performed.

2. Further imaging

Confirmation of the condition in a tertiary setting is recommended. Other imaging modalities, such as 3D ultrasound, magnetic resonance imaging (MRI) and parental ultrasound may be appropriate.

3. Additional testing

This may include parental blood testing if a genetic condition or congenital infection is suspected and invasive testing using fluorescent in situ hybridisation (FISH), quantitative fluorescent polymerase chain reaction (QF-PCR), karyotyping or microarray comparative genomic hybridisation depending on the condition identified.

Studies suggest that 1-3% of fetuses with a structural condition will have an irregularity on microarray that would fail to be detected on conventional karyotype24, and so microarray analysis is generally recommended where invasive testing is indicated following diagnosis of a major structural condition.

4. Counselling

Counselling following diagnosis of fetal condition needs to be prompt, comprehensive, accurate, unbiased and compassionate. This counselling should be individualised, mindful of the woman's context in her family and community; her social circumstance, cultural and religious values should be respectfully considered. The engagement of a qualified interpreter, and not a family member, is necessary for families who do not speak English. The information covered will depend on the nature of the condition, but will generally include the potential aetiology and prognosis of the condition, the possible implications for the remainder of the pregnancy, including labour and delivery, consideration for newborn care and recurrence risks in future pregnancies.

5. Subsequent care

Following this initial period of information gathering, families will come to a decision regarding the future of the pregnancy; continuing the pregnancy with specialist support, termination of pregnancy or – less commonly – adoption, or a neonatal palliation pathway in the face of a condition which is lethal.

(i) Continuing pregnancies: Ongoing care of the pregnancy may be able to remain local or it may involve referral to a tertiary centre, depending on the nature of the condition, the presence of other maternal or fetal co-morbidities, the need for ongoing ultrasound surveillance and the need for specialist paediatric medical or surgical services.

(ii) Termination of pregnancy: In the face of prenatal diagnosis of a serious condition, many families will consider termination of pregnancy. Women should be fully informed about the availability of termination of pregnancy, including termination methods available at varying gestational ages. This will vary in differing jurisdictions across Australia and New Zealand.

(iii) Neonatal palliation: Where a lethal condition has been diagnosed, and the woman and her family have decided to continue with the pregnancy, it is essential to consider the implications for the remainder of the pregnancy, and that care plans for paediatric palliation are made and communicated clearly. These plans often evolve during the pregnancy and require multidisciplinary input, with close liaison between the obstetric and paediatric care providers. These plans may include; a) whether any monitoring of fetal well-being is indicated antenatally or intrapartum; b) proposed mode and timing of delivery;
c) documentation on how and where the baby is to be managed in the immediate postpartum period and beyond.

6. Postnatal care

(iv) In the event of fetal death or termination of pregnancy, women and their families should be aware of the value of comprehensive post mortem examination, including imaging and genetic information, which may help in subsequent counselling of the underlying aetiology, and recurrence risk. The family should have the opportunity to meet with the multidisciplinary team postnatally to debrief following delivery, review all postnatal information, and discuss any recurrence risk and implications for future pregnancies.

Recommendation 5	Grade and references
Each practice should develop a protocol regarding the procedure to be followed when a condition is detected. This protocol should include guidelines for the immediate care of the patient and how the referring doctor will be informed.	Consensus Based Recommendation Reference [10]
Recommendation 6	**Grade and references**
All women should receive timely information following detection of a major fetal structural condition and have the opportunity to undertake counselling about the nature, prognosis, ongoing care pathway and recurrence risk.	Consensus Based Recommendation
Recommendation 7	**Grade and references**
Depending on the condition, referral to a tertiary centre and involvement of a multidisciplinary team in the management of the pregnancy may be appropriate.	Consensus Based Recommendation
Recommendation 8	**Grade and references**
When a significant condition has been confirmed by ultrasound examination, all women should be given the time and support they need to decide upon the future of their pregnancy.	Consensus Based Recommendation Reference [2]

4.5 Ultrasound safety and bioeffects

Medical ultrasound has a high level of safety and routine clinical scanning of every woman during pregnancy using real time B-mode imaging is not contraindicated.[11] There have been no proven adverse biological effects associated with obstetric ultrasound. Ultrasound can produce bioeffects (e.g. heating of tissue and cavitation) at levels used in clinical ultrasound. There is potential for subtle, low incidence, delayed and, as yet, unrecognised effects, thus a prudent and responsible approach to its use is important. This is embodied in the "ALARA" ("as low as reasonably achievable") principle - utilising the lowest amount of power exposure necessary to achieve the diagnostic purpose in clinical practice. This entails using ultrasound only if there is an appropriate clinical indication, minimising exposure time, using the lowest power and optimal gain settings to obtain the desired image, being mindful of operating modes which increase the potential for bioeffects (e.g. power or pulse wave doppler) and being aware of the Thermal Index (TI) and Mechanical Index (MI) on the ultrasound machine.

It is widely accepted that ultrasound that induces a temperature rise in tissue of less than 1.5 degrees Celsius is not associated with harmful sequelae. Some clinical situations entail an increased risk of inducing a temperature rise beyond this limit and particular care must be taken when scanning febrile patients, fragile tissues of early gestation, poorly perfused tissues (e.g. eyes), or tissues with a high absorption co-efficient (e.g. bone). It is for this reason that

pulsed Doppler should not be used routinely during the first trimester. If it is necessary, the TI should be <1.0 and exposure time minimised (ideally to 5-10 minutes).[12]

Recommendation 9	Grade and references
Routine clinical scanning of every woman during pregnancy using real time B-mode imaging is not contraindicated. The ALARA principle for duration of ultrasound exposure ('as low as reasonably achievable') should be observed.	Consensus Based Recommendation Reference [11]
Recommendation 10	**Grade and references**
Pulsed Doppler ultrasound should not be used routinely in first trimester. If it is necessary, the TI should be <1.0 and exposure time minimised (ideally to 5-10 minutes).	Consensus Based Recommendation Reference [12]

4.6 Non-medical use of ultrasound

Ultrasound for non-medical purposes, such as the production of images or videos of the fetus for the sole purpose of providing souvenirs or to determine fetal gender is not recommended by the majority of governing bodies (ISUOG, WFUMB, SOGC).[25, 26] As described in Section 4.5, US produces bioeffects in tissue and the potential for subtle, low-incidence and delayed effects cannot be absolutely excluded. Other potential adverse consequences from non-medical use of ultrasound arise from the unregulated nature of such commercial practices. Technical safeguards, operator training, qualifications and expertise are not regulated and staff may not be adequately trained to recognise fetal and placental conditions.

Recommendation 11	Grade and references
Obstetric ultrasound should not be used for non-medical reasons such as sex determination, or solely for the production of photos or videos for commercial purposes.	Consensus Based Recommendation Reference [13]

5. Conclusion

The application of ultrasound in obstetrics has dramatically improved care of pregnant women and their fetuses. The mid trimester routine scan provides important information regarding plurality of the pregnancy, gestational age, cervical length, placental site, and assessment of fetal anatomy to detect fetal structural conditions. While it is important to note that not all conditions can be detected prenatally, the increasing ability to detect fetal structural conditions with ultrasound means that families can obtain important information about the nature of the condition so that they can make an informed decision regarding the future of the pregnancy. For ongoing pregnancies, knowledge of the presence of a structural condition provides an opportunity to institute appropriate fetal therapy and/ or surveillance during the pregnancy and optimise the circumstances of delivery and newborn care. International expert groups have provided guidelines on first and second trimester FSA screening, as well as safety and good practice recommendations.

6. References

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7. Other suggested reading

Australian Guidelines for the Performance of First Trimester Ultrasound have been published by the Australian Society for Ultrasound in Medicine (ASUM)[4]

International Society of Ultrasound in Obstetrics and Gynecology (ISUOG). First trimester guidelines[18]

8. Links to other College statements

HGSA/RANZCOG Prenatal Assessment of Fetal Structural Conditions (C-Obs 60)

Prenatal Screening for Adverse Pregnancy Outcomes (C-Obs 61)

Prenatal Screening for Fetal Conditions(C-Obs 35)

Pre-pregnancy Counselling (C-Obs 3(a))

Routine Antenatal Assessment in the Absence of Pregnancy Complications (C-Obs 3 (b))

Diagnostic Ultrasound, Position Statement on the Appropriate Use of (C-Gen 10)

9. Patient information

A range of RANZCOG Patient Information Pamphlets can be ordered via:
https://www.ranzcog.edu.au/Womens-Health/Patient-Information-Guides/Patient-Information-Pamphlets

Appendices

Appendix A

Human Genetics Society of Australia (HGSA) and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) Joint Committee on Prenatal Diagnosis and Screening Membership

Name	Expertise	Role
Dr Agnes Wilson – RANZCOG member	RANZCOG Guideline developer Research Scientist	Committee Chair. RANZCOG Senior Coordinator, Guideline development and Women's Health
A/Professor Michael Gabbett – HGSA member	Paediatrics and Epidemiology	Senior Staff Specialist in Clinical Genetics, Genetic Health Queensland, Associate Professor, Griffith University, Senior Lecturer, The University of Queensland
Professor Jane Halliday – HGSA member	Epidemiology and Research	Head, Public Health Genetics Genetics Theme, Murdoch Childrens Research Institute
Clinical Professor Jon Hyett – RANZCOG member	Obstetrics and Gynaecology	Head of High Risk Obstetrics, Royal Prince Alfred Women and Babies. Clinical Professor, Obstetrics and Gynaecology University of Sydney
Dr Natalie Kiesey-Calding – RANZCOG member	Obstetrics and Gynaecology	Private Consultant, Cairns Obstetrics & Gynaecology
Ms Pauline McGrath – HGSA member	Genetic Counselling and Prenatal Screening and Diagnosis	HGSA Certified Genetic Counsellor at Queensland Health
Dr Andrew McLennan – RANZCOG member	Obstetrics and Gynaecology	Consultant to the Maternal Fetal Medicine Unit at Royal North Shore Hospital and a Partner at Sydney Ultrasound for Women
A/Professor Ricardo Palma-Dias – RANZCOG member	Obstetrics and Gynaecology	Clinical Director - Ultrasound Services, Royal Women's Hospital, Victoria. Clinical Associate Professor at University of Melbourne
Dr Jason Pinner – HGSA member	Medical Geneticist	University of Sydney (member to January 2014)
Professor Peter Stone – RANZCOG member	Obstetrics and Gynaecology Professor of Maternal Fetal Medicine	The University of Auckland
Dr Marleen Susman – HGSA member	Public Health Geneticist	Murdoch Childrens Research Institute (member to January 2014)
Professor Susan Walker – RANZCOG member	Obstetrics and Gynaecology Professor of Maternal Fetal Medicine	Shiela Handbury Chair of Maternal Fetal Medicine, Director Perinatal Medicine, Mercy Hospital for Women
Dr Dianne Webster – HGSA member	Laboratory Science	Lead Clinical Scientist, LabPlus, Auckland City Hospital, New Zealand

Appendix B Women's Health Committee Membership

Name	Position on Committee
Professor Yee Leung	Chair
Dr Joseph Sgroi	Deputy Chair, Gynaecology
Associate Professor Lisa Hui	Member
Associate Professor Ian Pettigrew	EAC Representative
Dr Tal Jacobson	Member
Dr Ian Page	Member
Dr John Regan	Member
Dr Craig Skidmore	Member
Associate Professor Janet Vaughan	Member
Dr Bernadette White	Member
Dr Scott White	Member
Associate Professor Kirsten Black	Member
Dr Greg Fox	College Medical Officer
Dr Marilyn Clarke	Chair of the ATSI WHC
Dr Martin Byrne	GPOAC Representative
Ms Catherine Whitby	Community Representative
Ms Sherryn Elworthy	Midwifery Representative
Dr Amelia Ryan	Trainee Representative

Appendix C Contributing Author

Name	Role
Dr Anna Lee	COGU Subspecialist and Consultant, Fetal Diagnostic Unit, Monash Medical Centre

Appendix D Overview of the Development and Review Process for this Statement

i. Steps in developing and updating this statement

This statement was originally developed in August 1991 and was re-developed during 2015. The statement was reviewed by the Women's Health Committee in March 2018. The WHC carried out the following steps in reviewing this statement:

- Declarations of interest were sought from all members prior to reviewing this statement.
- Structured clinical questions were developed and agreed upon.
- An updated literature search to answer the clinical questions was undertaken.
- At the March 2018 face-to-face committee meeting, the existing consensus-based recommendations were reviewed and updated (where appropriate) based on the available body of evidence and clinical expertise. Recommendations were graded as set out below

in Appendix B part iii).

ii. Declaration of interest process and management

Declaring interests is essential in order to prevent any potential conflict between the private interests of members, and their duties as part of the Committee.

A declaration of interest form specific to guidelines and statements was developed by RANZCOG and approved by the RANZCOG Board in September 2012. All members were required to declare their relevant interests in writing on this form prior to participating in the review of this statement.

Members were required to update their information as soon as they become aware of any changes to their interests and there was also a standing agenda item at each meeting where declarations of interest were called for and recorded as part of the meeting minutes.

There were no significant real or perceived conflicts of interest that required management during the process of updating this statement.

iii. Grading of recommendations

Each recommendation in this College statement is given an overall grade as per the table below, based on the National Health and Medical Research Council (NHMRC) Levels of Evidence and Grades of Recommendations for Developers of Guidelines. Where no robust evidence was available but there was sufficient consensus within the HGSA/RANZCOG Joint Committee on Prenatal Diagnosis and Screening Committee, consensus-based recommendations were developed or existing ones updated (and are identifiable as such). Consensus-based recommendations were agreed to by the entire Committee. Good Practice Notes are highlighted throughout and provide practical guidance to facilitate implementation. These were also developed through consensus of the entire Committee.

Recommendation category		Description
Evidence-based	A	Body of evidence can be trusted to guide practice
	B	Body of evidence can be trusted to guide practice in most situations
	C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
	D	The body of evidence is weak and the recommendation must be applied with caution
Consensus-based		Recommendation based on clinical opinion and expertise as insufficient evidence available

Good Practice Note	Practical advice and information based on clinical opinion and expertise

Appendix E Full Disclaimer

This information is intended to provide general advice to practitioners, and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient.

This information has been prepared having regard to general circumstances. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual patient and the particular circumstances of each case.

This information has been prepared having regard to the information available at the time of its preparation, and each practitioner should have regard to relevant information, research or material which may have been published or become available subsequently.

Whilst the College endeavours to ensure that information is accurate and current at the time of preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become subsequently available.

Appendix F Considerations for Indigenous and Culturally and Linguistically Diverse Populations

4.2.1 There should be appropriate communication with all women. Particular care should be taken to ensure that communication is clear and understood by women who are from culturally and linguistically diverse populations (including women from an Indigenous background).

4.2.2 In Australia, the Department of Immigration and Citizenship offers Free Interpreting Services through TIS National for private medical practitioners (defined as General Practitioners and Medical Specialists) providing Medicare rebate-able services and their reception staff to arrange appointments and provide results of medical tests. Free interpreters are also available in New Zealand.

4.2.3 A resource developed especially for Indigenous women by the Menzies School of Health Research is available on line at this link: - Fetal Anomaly Screening Resource "Take Home Booklet" Menzies School of Health Research.