



National  
Women & Infants  
Health Programme

# National Clinical Practice Guideline The Fetal Anatomy Ultrasound



**INSTITUTE OF  
OBSTETRICIANS &  
GYNAECOLOGISTS**

ROYAL COLLEGE OF  
PHYSICIANS OF IRELAND

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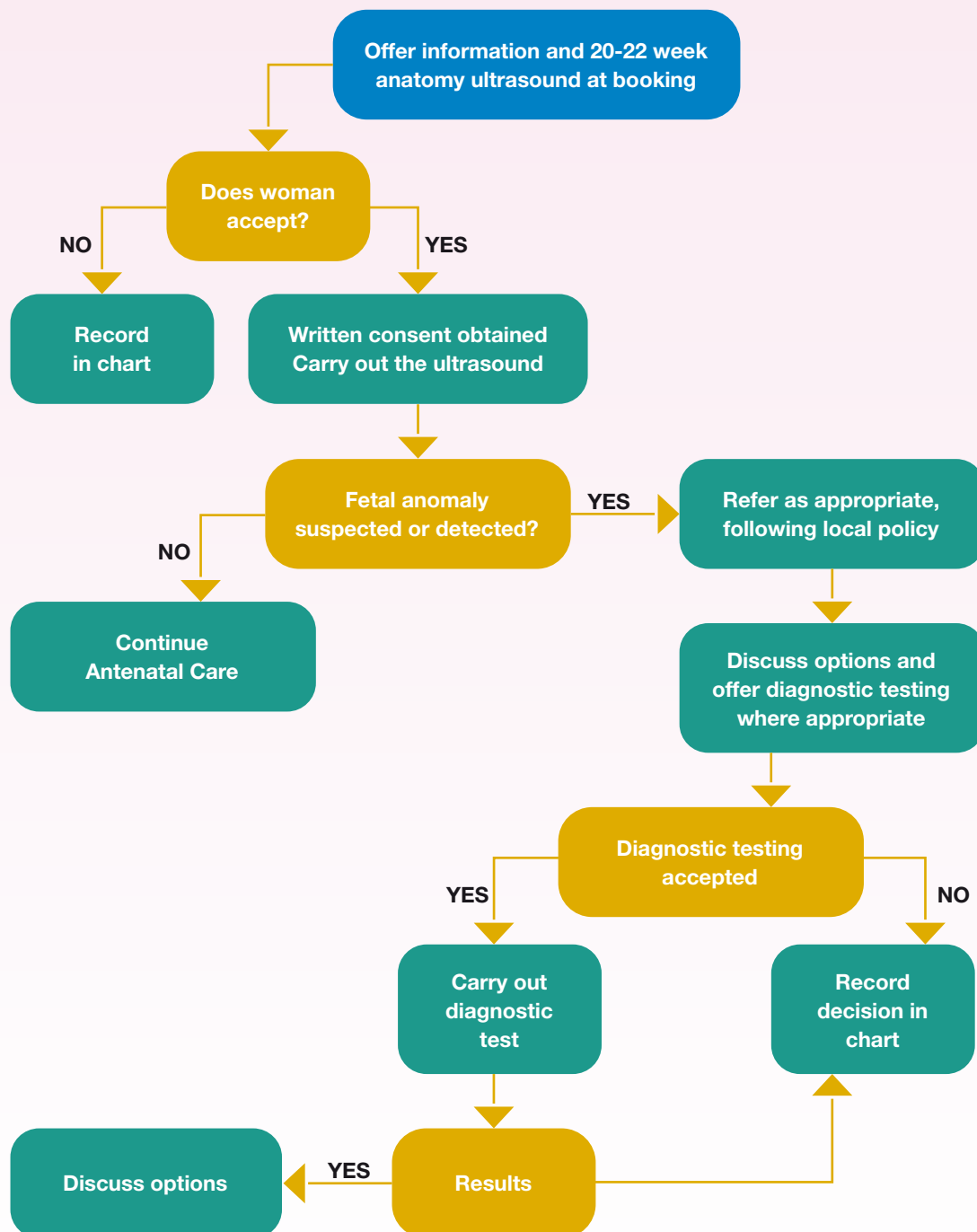
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# Algorithm

## Care Pathway for fetal anatomy ultrasound examination



# Key Recommendations

Number	Recommendation	Grade
1	The aim of the fetal anatomy ultrasound examination is to optimise antenatal care by providing accurate diagnostic information to ensure better outcomes for both the pregnant woman and baby.	<i>Best practice</i>
2	Written information should be provided in a request for a fetal anatomy ultrasound examination, ideally ahead of the ultrasound examination appointment.	<i>Best practice</i>
3	All pregnant women in Ireland should be offered a fetal anatomy ultrasound examination as part of standard antenatal care.	<i>1B</i>
4	Informed written consent should be obtained by the Sonographer prior to proceeding with ultrasound examination.	<i>Best practice</i>
5	It is recommended that the fetal anatomy ultrasound examination be performed after 18 weeks and before 22 weeks' gestation, ideally between 20-22 weeks' gestation. This is of particular relevance in the case of maternal BMI > 30.	<i>Best practice</i>
6	A single repeat ultrasound examination should be offered to complete the screening if the image quality of the first examination is suboptimal e.g. increased BMI, large fibroids, abdominal scarring, and/or suboptimal fetal position. The repeat ultrasound examination should be done as soon as is clinically feasible with the aim to complete the examination by 26 weeks.	<i>1B</i>
7	In the event that the second ultrasound examination is still unable to demonstrate all the required structures the Sonographer should record this on the report and state the reason why. If the key cardiac components cannot be confirmed with two examinations by an experienced Sonographer, the woman should be referred to a Fetal Medicine Specialist.	<i>Best practice</i>
8	A fetal anatomy ultrasound examination should include the assessment of the number of fetuses, cardiac activity, fetal biometry, amniotic fluid and placental location. When clinically indicated the maternal pelvic anatomy should be evaluated.	<i>Best practice</i>
9	The fetal anatomy ultrasound examination should only be used to confirm estimated due date if first trimester ultrasound was not performed.	<i>Best practice</i>
10	If gestational age has not already been established at a first trimester ultrasound examination and the menstrual dates are not reliable, it is recommended the estimated due date should be determined on the basis of fetal head size (biparietal diameter and head circumference) and femur length.	<i>1B</i>

Number	Recommendation	Grade
11	A low-lying placenta <20 mms from the internal cervical os on transabdominal or transvaginal (TAUS/TVUS) ultrasound examination should be followed up with an ultrasound at 32-34 weeks.	1B
12	With a low-lying anterior placenta and suspected features on ultrasound for placenta accreta spectrum (PAS), referral should be made to a Fetal Medicine Specialist prior to 24 weeks' gestation. If this is not available locally, tertiary referral for further assessment is recommended.	1B
13	Placental cord insertion (PCI) should be documented at all fetal anatomy ultrasound examinations.	1B
14	Marginal and velamentous cord insertion may have an association with fetal growth restriction, therefore a fetal growth scan at 32 weeks is recommended.	Best practice
15	In cases with risk factors for vasa praevia e.g., velamentous cord insertion, placental dysmorphism, succenturiate lobed placenta, low lying or bilobed placentas, multiple pregnancies and pregnancies conceived with in vitro fertilisation (IVF) targeted screening with TAUS colour Doppler is recommended. A TVUS is recommended if a TAUS is unclear. A Fetal Medicine opinion should be sought if vasa praevia is suspected.	1C
16	Cervical length and uterine Doppler waveforms should only be measured in specific populations.	1B and 1C
17	The fetal anatomy ultrasound examination should include an assessment of all major fetal organ systems. The minimum images (25) required to complete the fetal anatomy ultrasound examination are set out in the Guideline (Appendix 9).	Best practice
18	Assessment of fetal sex is not the function of the fetal anatomy ultrasound examination and where performed the accuracy of fetal sex determination should be disclosed.	Best practice
19	For fetuses with an isolated echogenic intracardiac focus or choroid plexus cysts (CSP) no further investigation is required and this finding does not need to be recorded.	1B
20	For fetuses with an isolated single umbilical artery (SUA), no additional evaluation for aneuploidy risk is necessary. This finding should prompt a thorough evaluation of the fetal renal anatomy and a third-trimester ultrasound for assessment of growth.	1B
21	For fetuses with renal pelvic dilatation (RPD) >7mms, it is recommended to perform an ultrasound examination at 32 to 34 weeks to reassess the genitourinary tract. Isolated renal pelvic dilatation does not warrant aneuploidy assessment.	1B
22	For pregnant women with low risk NIPS and absent nasal bone no further aneuploidy screening is necessary. If there is no previous screening test (e.g., NIPS), referral for a Fetal Medicine opinion is recommended.	1B



Number	Recommendation	Grade
23	For pregnant women with low risk NIPS and a nuchal fold >6mms detailed cardiac assessment is required. No further aneuploidy screening is necessary. If there is no previous screening test (e.g., NIPS), referral for a Fetal Medicine opinion is recommended.	1B
24	For pregnant women with a low risk NIPS and isolated shortened humerus, femur, or both it is recommended to perform a third-trimester ultrasound for reassessment and evaluation of growth. No further aneuploidy screening is necessary. If there is no previous screening test (e.g., NIPS), referral for a Fetal Medicine opinion is recommended.	1C
25	If there is mild, moderate or severe ventriculomegaly (including low risk NIPS or no previous screening test) referral for a Fetal Medicine opinion is recommended.	1B
26	Pregnant women with low risk NIPS or no previous screening, with fetal echogenic bowel should be referred for a Fetal Medicine opinion for further evaluation for congenital infections and consideration of cystic fibrosis carrier testing on the parents.	1B
27	It is appropriate for experienced Sonographers who perform fetal anatomy ultrasound examinations to impart information when they are confident of the diagnosis.	<i>Best practice</i>
28	Every unit should have referral mechanisms to Fetal Medicine services in place to manage suspected or detected fetal anomalies.	<i>Best practice</i>
29	All women should receive a prompt referral for a Fetal Medicine opinion ideally within 5 working days. When a major fetal anomaly is suspected referral is ideally within 3 days.	<i>Best practice</i>
30	The woman/couple should be kept fully informed throughout the process and have the opportunity to talk fully to any relevant professionals who may be able to offer them information they require.	<i>Best practice</i>
31	Documentation of all findings, counselling and discussion by all clinicians must be clearly documented. Communication with the referring Obstetrician/ Sonographer and GP is of paramount importance for regular updates, in order for them to provide necessary support to the woman/couple.	<i>Best practice</i>
32	Fetal anatomy ultrasound examinations should be performed by healthcare providers with specialised training in the provision of ultrasound screening in the second trimester.	<i>Best practice</i>
33	There must be a permanent record of the ultrasound examination and its findings. Images of all relevant areas defined in the particular examination, both normal and abnormal, should be recorded and should be stored for future reference by the person doing the examination. The responsibility for reporting lies with the person verifying the scan who, ordinarily, should be the person performing the scan.	<i>Best practice</i>

Number	Recommendation	Grade
34	Sonographers performing fetal anatomy ultrasound examination should hold at least one of the following qualifications: Higher Diploma in Diagnostic Imaging / MSc Ultrasound (or equivalent) from a Higher Education Institution relevant to obstetric ultrasound, or Advanced Training Speciality Module (ATSM) in Fetal Medicine.	<i>Best practice</i>
35	Individuals without a recognised qualification, including student Sonographers, should always be supervised by qualified staff. A formal period of monitoring by a senior member of staff should be implemented for all new and temporary staff to confirm their ultrasound interpretation and reporting abilities.	<i>Best practice</i>
36	Ultrasound practitioners should be registered with the relevant statutory body where appropriate. Ultrasound practitioners are required to keep a record of their continuous professional development (CPD) as defined by their registering body.	<i>Best practice</i>
37	It is recommended that a 30 minute time slot is allocated for a singleton pregnancy and a minimum of 45 minute time slot allocated for a multiple pregnancy anatomy ultrasound examination. The ALARA principle regarding output power and duration of ultrasound exposure ('as low as reasonably achievable') should be observed.	<i>Best practice</i>
38	Ultrasound imaging for non-medical reasons is not recommended unless carried out for education, training or demonstration purposes.	<i>Best practice</i>
39	The use of telephone or video recording of the anatomy ultrasound examination is not recommended. However, there may be some situations where it is appropriate and local policies should be in place to determine whether recording of the examination is reasonable.	<i>Best practice</i>
40	Due to the possible sensitive nature of the fetal anatomy ultrasound examination, children should not attend the examination.	<i>Best practice</i>

# Abbreviations of Ultrasound Terms

**3VV** Three vessel view

**AC** Abdominal circumference

**AFI** Amniotic fluid index

**ASD** Atrial septal defect

**AVSD** Atrioventricular septal defect

**BPD** Biparietal diameter

**CCHD** Critical congenital heart disease

**CHD** Congenital heart disease

**CL** Cervical length

**CM** Cisterna magna

**CMV** Cytomegalovirus

**CNS** Central nervous system

**CPC** Choroid plexus cyst

**CRL** Crown rump length

**CSP** Cavum septum pellucidum

**DS** Down syndrome

**DVP** Deepest vertical pool

**EDD** Estimated Due Date

**EIF** Echogenic intracardiac focus

**FFA / LLC** Fatal fetal anomalies / life limiting conditions

**FGR** Fetal Growth Restriction

**FL** Femur length

**GIT** Gastrointestinal tract

**GU** Genitourinary system

**HC** Head circumference

**IUGR** Intrauterine growth restriction

**LVOT** Left ventricular outflow tract

**MHz** Mega hertz

**NF** Nuchal fold

**PCI** Placental cord insertion

**RADIUS** Routine antenatal diagnostic imaging with ultrasound study

**RPD** Renal pelvic dilatation

**RVOT** Right ventricular outflow tract

**SUA** Single umbilical artery

**TAUS** Transabdominal ultrasound scan

**TVUS** Transvaginal ultrasound scan

**UTD** Urinary tract dilation

**VCI** Velamentous cord insertion

**VP** Vasa praevia

**VSD** Ventricular septal defects

# Chapter 1: Initiation

The National Clinical Effectiveness Committee (NCEC) and Health Information and Quality Authority (HIQA) define clinical guidelines as systematically developed statements<sup>1</sup>, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum<sup>1</sup>.

## 1.1 Purpose

The purpose of this Guideline is to review the evidence-based approach to the provision of fetal anatomy ultrasound examination and to outline the benefits of such an approach. This Guideline is intended as a resource and guidance for all providing ultrasound examinations in the second trimester. The aim is to standardise and improve antenatal care for women and infants.

The standards of this document are not rules but are guidelines that attempt to define principles of practice for the performance and recording of high-quality ultrasound examinations. Practices may modify an existing standard as determined by the individual and available resources. The guidelines are not intended to establish a legal standard of care or conduct, and deviation from a Guideline does not, in and of itself, indicate or imply that such practice is below an acceptable level of care.

## 1.2 Scope

There is a clear need for a clinical Guideline for the practice of obstetric ultrasound in Ireland, particularly in the area of anatomy ultrasound examination. This ultrasound examination has been referred to in the literature as a mid-trimester ultrasound/scan, second trimester ultrasound/scan, an anomaly ultrasound/scan, or an anatomy ultrasound/scan. These terms are interchangeable, but for the purpose of this Guideline the term fetal anatomy ultrasound examination will be used.

Ultrasound has been widely practised in Ireland for over 30 years without an agreed approach leading to different units offering ultrasound examinations at varying gestations and to variable degrees of accuracy and detail. In Ireland, the introduction of routine anatomy ultrasound has evolved opportunistically over the last three decades. Analysis of service provision in 2007 showed that 43% (9/21) units were offering anatomy ultrasound but routinely in just 33% of units (7/21). This had not significantly changed by 2013. By 2016, approximately 64% of women received a routine anatomy ultrasound examination<sup>2</sup>.

A national Sonographers survey presented at the National Fetal Echo study day in June 2022 determined that anatomy scans were not routinely offered in 1 unit in 2021 in the second trimester, and 7 out of the 19 units currently did not have formal written anatomy scan protocols<sup>3</sup>.

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1 National Clinical Effectiveness Committee (NCEC) and Health Information and Quality Authority (HIQA) (2015) National quality assurance criteria for clinical guidelines. Version 2. Dublin: NCEC and HIQA. <https://www.hiqa.ie/sites/default/files/2017-01/National-Quality-Assurance-Criteria.pdf>

Currently, there is no recognised screening programme for the detection of fetal anomalies/fetal aneuploidies in Ireland. The recent Health (Regulation of Termination of Pregnancy) Act 2018<sup>4</sup> allows for termination of pregnancy for conditions likely to lead to death of the fetus in utero or within 28 days of birth. Thus it is even more incumbent on health care providers to provide a comprehensive, agreed standard method of diagnosing these and other conditions. More importantly there is an urgent need to ensure the provision of equitable access to a fetal anatomy ultrasound to all who would wish to avail of this examination. The international experience suggests there are many benefits to offering an ultrasound in the mid-trimester.

The evidence to support the recommendations in this Guideline are largely derived from a review of all available international guidelines, in addition to reviewing the recent available literature on ultrasound screening in the mid-trimester and to make recommendations with a pragmatic, evidence-based approach for future practice in Ireland. For further information on the development of this Guideline see chapter 3.

### **Target Users**

This is a clinical practice Guideline commissioned by the National Women and Infants Health Programme (NWHIP). The intended audience encompasses all healthcare providers and healthcare users involved in antenatal care and ultrasonography services in Ireland. This includes Sonographers, Radiographers, General Practitioners, Obstetricians, Midwives, Nurses, Fetal Medicine Specialists, Geneticists and Radiologists and other providers of healthcare for the target population.

### **Target Population**

Most importantly, this Guideline is intended for pregnant women during the second trimester of pregnancy undergoing a fetal anatomy scan.

## **1.3 Objective**

The objective of this Guideline is to summarise the evidence base and generate clinical guidance on the provision of the fetal anatomy ultrasound examination in Irish maternity services.

## **1.4 Guideline development process**

The Guideline Development group (GDG) agreed to undertake this work under the direction of the Guideline Programme Team (GPT). An Expert Advisory Group (EAG) was commissioned by the GPT. Their role was to critically review the Guideline prior to submission to the NWHIP for final approval. See Appendix 18 for EAG Group membership and Appendix 19 for Guideline Programme Process.

The primary writing group members for this Guideline development were as follows:

- Ms Ann Fleming, Midwife Sonographer RCSI, Rotunda hospital, Assistant Professor/Lecturer Obstetrics and Gynaecology Programmes, Radiography and Diagnostic Imaging, School of Medicine, University College Dublin, (UCD).
- Dr Gillian Corbett, Specialist Registrar Obstetrics and Gynaecology (SpR), National Maternity Hospital, Dublin
- Professor Peter McParland, Fetal Medicine Specialist, National Maternity Hospital, Dublin.

This GDG is grateful to Prof Mairead Kennelly (Coombe Women and Infants University Hospital, Dublin), Prof Fionnuala Breathnach (Rotunda Hospital, Dublin), Dr Orla Franklin (Our Lady's Children's Hospital, Crumlin and Coombe Women and Infants University Hospital, Dublin), Dr Etaoin Kent (Rotunda Hospital, Dublin) and Dr Richard Horgan (Cork University Maternity Hospital) for their contribution of expertise in the development of this Guideline.

The GDG is also grateful to Martin Heudan, Education Technologist University College Dublin for providing the schematic images. All ultrasound images were all obtained on GE Healthcare Voluson E10, E8 or 730 ultrasound machines.

## 1.5 Stakeholder involvement

Stakeholders are people who have a common interest in improving health services. This includes persons that are responsible for delivering and those who receive services related to the clinical Guideline.

The GDG would like to acknowledge the following Sonographers for their review and feedback on a draft of the Guideline: Feena Sheeran, Merrion Fetal Health, Dublin, Fiona Cody, RCSI , Rotunda Hospital, Dublin. Sinead Kelleher, Portiuncula Hospital, Galway. Jane Durkin, Coombe Women & Infants University Hospital (CWIUH) Dublin. Elaine McGreevey, CWIUH, Dublin. Christine McLoughlin, CWIUH, Dublin. Valerie Spillane, National Maternity Hospital (NMH), Dublin. Emma Jeffers, Limerick University Maternity Hospital. Limerick (LUMH). Claire Kelliher, University Hospital Kerry (UHK). Liz Cotter, Evie Clinic, Beacon Hospital, Dublin.

The GDG is also grateful to the following stakeholders who reviewed the draft Guideline

- Dr Mary Moran (University College Dublin)
- Prof Aisling Martin (Coombe Women and Infants University Hospital, Dublin)
- Dr Jennifer Walsh (The National Maternity Hospital, Dublin)
- Dr Gillian Ryan (University Hospital Galway)
- Vasa Praevia Support and Awareness Ireland
- Prof Keelin O'Donoghue (Cork University Maternity Hospital).

## 1.6 Disclosure of interests

Guideline developers and reviewers bring a range of experiences and perspectives to the work of the National Guideline Programme. It is likely that both Guideline developers and stakeholders/reviewers will have a variety of interests, arising from different contexts and activities done in a professional or personal capacity. These can include employment and other sources of income, speaking engagements, publications and research, and membership of professional or voluntary organisations. The involvement of individuals with relevant content expertise is essential for enhancing the value of Guideline recommendations, but these individuals may also have interests that can lead to conflicts of interest, as may peer reviewers, patient representatives and researchers.

All interests should be declared if, in the view of a reasonable person, they are relevant, or could be perceived to be relevant, to the work of the clinical practice guideline in question<sup>5</sup>. Declaring an interest does not mean there is a conflict of interest<sup>2</sup>.

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2 NICE (2019) Policy on declaring and managing interests for NICE advisory committees <https://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/declaration-of-interests-policy.pdf>

It is important that interests are openly declared so they can be appropriately managed<sup>3</sup>. Conflicts of interest can bias recommendations and ultimately be harmful to patients and the health system. Disclosures of interests and appropriate management of conflicts of interest, when identified, are therefore essential to producing high-quality, credible health guidelines<sup>6</sup>.

The Guidelines International Network (GIN), a global network of Guideline developers that aims to promote best practices in the development of high-quality guidelines, developed a set of 9 principles to provide guidance on how financial and non-financial conflicts of interest should be both disclosed and managed. It is recommended that Guideline developers follow the GIN principles<sup>7</sup>.

For this National Clinical Practice Guideline, all Guideline developers are asked to complete a conflict of interest declaration form. The response to declared interests will be managed by the Guideline Programme Team, in accordance with GIN principles<sup>4</sup>. Conflicts of interest may be reported in the published Guideline and declarations of interest can be made available.

## 1.7 Disclaimer

These guidelines have been prepared to promote and facilitate standardisation and consistency of good clinical practice, using a multidisciplinary approach. Information in this Guideline is current at the time of publication.

The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the Clinician in light of clinical data presented by the woman and the diagnostic and treatment options available.

Clinical material offered in this Guideline does not replace or remove clinical judgment or the professional care and duty necessary for each specific woman. Clinical care carried out in accordance with this Guideline should be provided within the context of locally available resources and expertise.

This Guideline does not address all elements of standard practice and assumes that individual clinicians are responsible for:

- Discussing care with women in an environment that is appropriate and which enables respectful confidential discussion. This includes the use of interpreter services where necessary
- Advising women of their choices and ensure informed consent is obtained
- Provide care with professional scope of practice, meeting all legislative requirements and maintaining standards of professional conduct
- Applying standard precautions and additional precautions, as necessary, when delivering care
- Documenting all care in accordance with local and mandatory requirements.

3 Traversy G, Barnieh L, Akl EA, Allan GM, Brouwers M, Ganache I, Grundy Q, Guyatt GH, Kelsall D, Leng G, Moore A, Persaud N, Schünemann HJ, Straus S, Thombs BD, Rodin R, Tonelli M. CMAJ. 2021, 193(2):E49-E54. DOI: 10.1503/cmaj.200651 <https://www.cmaj.ca/content/193/2/E49>

4 Holger J, Schünemann, Lubna A, Al-Ansary, Frode Forland, *et al.*; for the Board of Trustees of the Guidelines International Network . Guidelines International Network: Principles for disclosure of interests and management of conflicts in guidelines. Ann Intern Med. 2015;163:548-553. doi:10.7326/M14-1885. <https://www.acpjournals.org/doi/10.7326/m14-1885>

## 1.8 Use of language

Within this guidance we use the terms 'woman' and 'women's health'. However, it is important to acknowledge that people who do not identify as cis-gender women are excluded from this descriptor, including people who identify as transgender, gender diverse and gender non-binary<sup>8</sup>. We also appreciate that there are risks to desexing language when describing female reproduction<sup>9,10</sup>. Services and delivery of care must be appropriate, inclusive and sensitive to the needs of people whose gender identity does not align with the sex they were assigned at birth<sup>5</sup>. This includes training and education regarding diverse pathways to pregnancy and the use of practices which affirm the sexual and gender identities of all people using Obstetrics and Gynaecology services<sup>6 7</sup>.

Language use is key to effectively communicate options, recommendations, and respectfully accept a woman's fully informed decision<sup>8</sup>. With this in mind, the use of birth is preferable to the term delivery in all circumstances and is used consistently where possible throughout the guidelines. It is acknowledged that in some circumstances (e.g., in the case of a medically indicated intervention or surgery) and in some contexts, substituting with the term delivery is considered appropriate and this term may be used instead.

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- 5 Moseson H, Zazanis N, Goldberg E, *et al.* The Imperative for Transgender and Gender Nonbinary Inclusion. *Obstet Gynecol.* 2020;135(5):1059-1068. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7170432/>
  - 6 Brotto LA, Galea LAM. Gender inclusivity in women's health research. *BJOG: An International Journal of Obstetrics & Gynaecology.* <https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.17231>
  - 7 Gribble KD, Bewley S, Bartick MC, *et al.* Effective Communication About Pregnancy, Birth, Lactation, Breastfeeding and Newborn Care: The Importance of Sexed Language. *Frontiers in Global Women's Health.* 2022;3. Accessed 9 June, 2022. <https://www.frontiersin.org/article/10.3389/fgwh.2022.818856>
  - 8 <https://blogs.bmj.com/bmj/2018/02/08/humanising-birth-does-the-language-we-use-matter/>



# Chapter 2: Clinical Practice Guideline

## Background

The fetal anatomy ultrasound examination is an investigation offered to pregnant women during the second trimester of pregnancy. The first screening programme offering systematic fetal examination began in Sweden in 1973 aiming to confirm estimated date of delivery, check viability and detect multiple pregnancy. It showed significant improvement of multiple pregnancy detection, with subsequent reduction in rates of preterm birth and perinatal mortality<sup>11</sup>. Several good quality studies have been performed since then to evaluate outcome benefit. These showed an increased detection of fetal anomalies though there is a lack of data to demonstrate that routine mid-trimester ultrasound examination for pregnant women improves overall outcomes for all pregnant women<sup>11</sup>.

Most countries subsequently adopted a pragmatic approach, given routine ultrasound examination could detect conditions not identified on clinical judgement alone such as placenta praevia, fetal anomalies, multiple pregnancy and abnormal growth patterns. As a result, many national and international professional bodies of Obstetricians and Gynaecologists have generated best practice clinical guidelines on routine mid trimester ultrasound examination in pregnancy using available evidence, consensus and expert opinion to support their clinical recommendations. These include: The International Society of Obstetrics and Gynaecology (ISUOG)<sup>12</sup>; The American Institute of Ultrasound in Medicine (AIUM)<sup>13</sup>; American College of Radiology<sup>13</sup>; College of Obstetricians and Gynaecologists<sup>13</sup>; Society of Maternal and Fetal Medicine (SMFM)<sup>13</sup>; The Society of Radiology<sup>13</sup>; Australia and New Zealand (RANZCOG)<sup>14</sup>; The Society of Obstetricians and Gynaecologists of Canada (SOGC)<sup>15</sup>; The National Institute for Health and Care (NICE)<sup>16</sup>; The National Guideline Clearinghouse; The NHS Fetal Anomaly Screening Programme; The Royal College of Obstetricians and Gynaecologists; The Royal College of Radiologists; British Medical Ultrasound Guidelines<sup>17</sup>; The French College of Gynaecologists and Obstetricians (CNGOF)<sup>18</sup>; The Danish Fetal Medicine Society (DFMS)<sup>19</sup>; Polish Society of Gynaecologists and Obstetricians<sup>20</sup>; Norwegian Society of Gynaecology and Obstetrics<sup>21</sup>; the Swedish Association of Obstetrics and Gynaecology (SFOG)<sup>22</sup> and the Italian Guideline in Obstetrics and Gynaecology<sup>23</sup> (SIEOG).

Recommendations relevant to this Guideline can also be found in:

- National Clinical Practice Guideline: Diagnosis and Management of Placenta Accreta Spectrum<sup>9</sup>
- National Clinical Practice Guideline: Stillbirth - Prevention, Investigation, Management and Care<sup>10</sup>
- National Clinical Practice Guideline: Management of Monochorionic Twin pregnancy (due 2023)
- National Clinical Practice Guideline: Management of Dichorionic Twin pregnancy (due 2023)
- RCPI (2019) INTERIM CLINICAL GUIDANCE. Pathway for management of fatal fetal anomalies and/or life-limiting conditions diagnosed during pregnancy: Termination of pregnancy<sup>11</sup>

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## Section 1: The aim of the fetal anatomy ultrasound examination

### Introduction

Ultrasound is used widely for the prenatal evaluation of fetal anatomy and size, as well as for the management of multiple gestations. The provision, standard and practice of the routine fetal anatomy ultrasound examination varies among different places depending on the availability of qualified personnel, ultrasound machines, local practices and cost<sup>2</sup>.

### Clinical Question 2.1: What is the aim of the fetal anatomy ultrasound examination?

#### Evidence Statement

The aim of the fetal anatomy ultrasound examination is to minimise the occurrence of unfavourable obstetric outcomes that may result from undiagnosed fetal anomalies or other intrauterine complications, thus allowing couples to be informed of potential adverse outcomes which may be mild, moderate or severe in nature. This facilitates further antenatal investigations, parental decision making and optimises pregnancy outcome<sup>24 25</sup>. The other proven benefits of routine anatomy ultrasound examination include an improved estimation of gestation, increased detection of multiple pregnancy, a reduction in the rate of induction for post-term and a probable reduction of maternal anxiety<sup>25</sup>.

The benefits which accrue from timely prenatal diagnosis and subsequent management are as follows:-

#### Detection of congenital anomalies:

- Allowing timely diagnosis to facilitate multidisciplinary discussion and anticipatory management at delivery<sup>24</sup>
- Allowing birth in a setting with optimal resources – tertiary centre, neonatal intensive care, access to adjacent paediatric surgical or cardiothoracic services
- Reduction in perinatal morbidity and mortality due to timely diagnosis and optimal care provision after birth<sup>26</sup>
- Informed decision making with regard to continuing or termination of pregnancy, within the legislative framework.<sup>27</sup>

#### In the absence of ultrasound in the first trimester, to confirm:

- Viability
- Estimated due date for accurate detection of growth restriction, as well as birth planning and reduction of post-term morbidity and mortality in the setting of inaccurate dates<sup>16</sup>
- Detection of multiple pregnancy.<sup>28</sup>

#### Accurate placental localisation:

- Identification of women with low-lying placentas at high risk of developing placenta praevia / placenta-accreta spectrum and vasa praevia (VP)
- This allows streamlining of care of these women into multidisciplinary services, associated with lower fetal and maternal morbidity/mortality.<sup>29,30</sup>

There are additional benefits of routine anatomy ultrasound examination outside of its diagnostic role in antenatal care including:

- Bonding between mother and fetus<sup>31 32</sup>
- Health-improvement motivation<sup>33</sup>
- Engaging partners in the antenatal care experience
- Major pregnancy milestone.

### **Clinical Practice**

An ultrasound examination provides the pregnant woman and her care provider with information about multiple aspects of her pregnancy.

The fetal anatomy ultrasound examination will inform them of viability, confirm the gestational age, establish fetal wellbeing, determine the location of the placenta and can identify maternal pelvic pathology.

The routine anatomy ultrasound examination can diagnose fetal anomalies and intrauterine complications, allowing women/couples to be informed of potential outcomes which may be mild, moderate or severe in nature. This facilitates further antenatal investigations, parental decision making and optimises pregnancy outcome.

### **Recommendations**

1. The aim of the fetal anatomy ultrasound examination is to optimise antenatal care by providing accurate diagnostic information to ensure better outcomes for both the pregnant woman and baby.
2. Written information should be provided in a request for a fetal anatomy ultrasound examination, ideally ahead of the ultrasound examination appointment.

## **Section 2: Who should have a fetal anatomy ultrasound examination**

### **Introduction**

Examination of fetal wellbeing throughout the pregnancy is an integral part of maternity care throughout the world. In the late 1970s, routine fetal ultrasound examination became established. Early randomised controlled trials (RCTs) demonstrated that the management of various pregnancy disorders, such as incorrect assessment of the gestational age, placenta praevia, multiple pregnancy, congenital anomalies, and growth restriction were improved with the use of prenatal ultrasound<sup>34,35</sup>.

## Clinical Question 2.2: Who should be offered a fetal anatomy ultrasound examination?

### Evidence Statement

The World Health Organization (WHO) recommends one ultrasound examination before 24 weeks' gestation as part of routine antenatal care<sup>36</sup>. There is considerable variance between countries and international bodies, from one ultrasound examination to a two to three stage approach and in varying detail. As one example, an imaging workshop organized by the Eunice Kennedy Shriver National Institute of Child Health and Human Development in the United States reached a consensus that all pregnant women should be offered an ultrasound examination at 18 to 24 weeks' gestation for the detection of fetal anomalies and pregnancy complications<sup>16</sup>. Recommendations for this clinical question are generated in keeping with international consensus statements<sup>12-23</sup>.

### Clinical Practice

All pregnant women in Ireland should be offered a fetal anatomy ultrasound examination. There are limitations to performing the fetal anatomy ultrasound examination to the same standard in every woman. These include anatomical variances that make ultrasonographic views more challenging to obtain. Increased maternal weight, particularly abdominal obesity, decreases sensitivity, specificity and detection rates of anatomical surveys<sup>37</sup>. Scarring of the anterior abdominal wall from previous surgeries can also interfere with sonographic frequency and alter view quality<sup>38,39</sup>. Other anatomical variations including uterine fibroids or abdominal masses can make obtaining optimum ultrasound images additionally challenging. Specific recommendations around these special populations will be discussed in subsequent questions, but the limitations of the ultrasound examination based on woman-related factors should be acknowledged.

### *Request for the fetal anatomy ultrasound examination*

A request form should be completed before the ultrasound examination. The written or electronic request for the examination should provide sufficient information to allow for the appropriate performance and interpretation of the examination. The request for the examination must be originated by a health care provider i.e., doctor or midwife. The accompanying clinical information should provide the woman's last menstrual period and significant medical and obstetric history to include the woman's BMI. It is recognised that some units may accommodate self-referrals, and in these cases, it is incumbent on the ultrasound provider to obtain all the relevant clinical details.

### Recommendations

3. All pregnant women in Ireland should be offered a fetal anatomy ultrasound examination as part of standard antenatal care.

## Section 3: Informed consent

### Introduction

Consent is an essential component to any medical investigation or intervention. Consent is defined as the giving of permission or agreement for an intervention, receipt or use of a service or participation in research following a process of communication in which the service user has received sufficient information to enable him/her to understand the nature, potential risks and benefits of the proposed intervention or service. Informed consent can only be obtained after adequate counselling and with discussion of the benefit-risk ratio<sup>40</sup>. Consent must be obtained from a woman before any medical intervention or procedure can be carried out on them, with the central ethos being to prioritise and preserve the woman's autonomy in guiding their own care<sup>41</sup>.

### Clinical Question 2.3: What are the prerequisites to informed consent for the fetal anatomy ultrasound examination?

### Evidence Statement

The Royal College of Radiologists (RCR) UK, states that informed consent should be obtained for each ultrasound from the woman prior to commencing an examination. They recommend that clear guidance, which is grounded in principles of person-centred care, is provided to support Sonographers in facilitating a discussion about the examination prior to the ultrasound<sup>42</sup>. This is supported by the National Health Service (NHS) Fetal Anomaly Screening Programme (FASP)<sup>17</sup>, in the UK, who aims to ensure equal access to uniform and quality assured screening across England. They state that fetal anomaly screening should be described as a choice rather than an inevitable aspect of routine antenatal care. If the process of seeking consent is to be meaningful, it must be clear that refusal is an option. If a woman declines fetal anatomical screening, all other appropriate care must still be provided. If a woman consents to ultrasound examination, but refuses certain aspects of the screening programme, the possible consequences and other available options must be explained<sup>43</sup>.

The more recent ISUOG guidelines recommend that before starting the ultrasound examination, the ultrasound practitioner should counsel the woman/couple regarding the potential benefits and limitations of a routine fetal ultrasound examination<sup>12</sup>. It is not stated if this discussion should be documented or not.

The Royal Australia and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) Joint Committee on Prenatal Diagnosis and Screening recommends that 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<sup>14</sup>.

### Clinical Practice

All women should receive adequate counselling and information regarding the fetal anatomy ultrasound examination prior to their appointment. The purposes of the anatomy ultrasound including its role as a screening tool, its sensitivity and accuracy and its limitations should be highlighted to the woman<sup>43</sup>.

Consent should acknowledge factors that can influence the image quality of the anatomy ultrasound examination. These include, but are not limited to maternal BMI, position of fetus, fibroids, abdominal scarring and oligohydramnios<sup>44</sup>. Maternal obesity lowers the image quality, sensitivity and detection

rates in anatomical ultrasound. There may be clinical situations that necessitate (with consent) a TVUS ultrasound approach to optimise visualisation of the fetal anatomy or placental relationship within the lower segment of the uterus<sup>45</sup>.

This information should be provided to the woman in written form, ideally prior to the date of ultrasound appointment date (e.g., at booking as part of the antenatal information package or by email). Nationally, it was previously reported that just 57% (8/19) units were previously providing verbal and written information prior to fetal anatomy ultrasound<sup>2</sup>. It is recommended that all maternity units offer this standard of counselling and information in advance to commencing the fetal anatomy ultrasound examination.

A sample patient leaflet encompassing this information is included in Appendix 1 and can be adapted by each unit based on local service delivery. It is important to emphasise the limitations of the examination and that there is always a chance that a baby may be born with a condition that could not be seen on ultrasound.

It is acknowledged that there are circumstances in which the goals of the fetal anatomy ultrasound examination can be more challenging to achieve. Discussion of the nuances, functions and limitations of this ultrasound can be challenging in situations where the woman's first language is not English. Efforts should be made to ensure a formal translator for discussion and consent. For some more common languages, institutions could consider providing direct translations of the information leaflets for the woman.

Prior to proceeding with the fetal anatomy ultrasound examination, Sonographers should invite discussion from the woman on the pre-ultrasound information and answer any questions the woman may have. After discussion with the woman, written informed consent should be obtained and documented on the ultrasound clinical report. (example of information leaflet and consent Appendix 1)

In the event that a woman does not consent to a fetal anatomy ultrasound for congenital anomalies, this should be documented in the ultrasound report. The other components of the ultrasound examination including cardiac activity, fetal biometry and placental localisation should be performed, with the omission of the full anatomical survey.

## Recommendations

4. Informed written consent should be obtained by the Sonographer prior to proceeding with ultrasound examination.

## Section 4: Optimal gestation for fetal anatomy ultrasound

### Introduction

With the aim of detecting the full range of fetal anomalies at the earliest possible gestation, recommendations for the timing of the fetal anatomy ultrasound examination range between 18 and 24 weeks' gestation with no absolute consensus on what is the optimal time. Ideally the ultrasound examination should be completed in a single visit, if possible. It should also be done at a gestational age which ensures adequate time for any referral, counselling or additional investigations that may be indicated and to ensure women can make timely decisions regarding pregnancy management.

### Clinical Question 2.4: What is the optimal gestation at which to perform the routine fetal anatomy ultrasound examination?

### Evidence Statement

The Eunice Kennedy Shriver National Executive Institute of Child Health and Human Development, recommends a single obstetric ultrasound at 18-24 weeks' gestation as an optimal time to assess fetal anatomy<sup>16</sup>. The International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG) Clinical Standards Committee recommends performance of the mid-trimester ultrasound examination between 18 and 24 weeks<sup>12</sup>. The Royal College of Obstetricians and Gynaecologists in the United Kingdom and the National Health Service (NHS) state an anatomy ultrasound should be performed between 18+0-20+6 weeks' gestation<sup>17</sup>. RANZCOG recommends ultrasound assessment for fetal structures between 19-22 weeks to optimise detection rates<sup>14</sup> while the Society of Obstetricians and Gynaecologists of Canada (SOGC) advocate for a slightly earlier gestational age of 18-20 weeks<sup>15</sup>.

There is increasing evidence in the literature that virtually all relevant fetal anatomy can be visualised as early as 15-16 weeks of gestation due to the advances in ultrasound technology and that 30 to 70% of congenital anomalies can be diagnosed prior to 14 weeks<sup>46</sup>. However later ultrasound examinations provide improved anatomical detail and greater sensitivity for anomaly detection.

Gupta *et al* recommend an early comprehensive fetal anatomic ultrasound examination at 13-16 weeks' gestation to be considered for women in whom it is anticipated that a mid-trimester examination will be technically challenging or who have a higher risk for significant fetal anomalies<sup>47</sup>. A subsequent study of pregnant women with a BMI  $\geq 35$  kg/m<sup>2</sup> demonstrated that using TVUS assessment at 13-15 weeks improved anatomic survey completion, which could lead to the early detection of fetal anomalies in this group<sup>45</sup>. A more recent systematic review determined the sensitivity of first trimester ultrasound in the detection of fetal anomalies was 32% in low risk women and more than 60% in high risk women<sup>46</sup>. However, these results are achievable and reproducible only by highly skilled operators in specialised centres. Frequently, structural anomalies diagnosed prior to 14 weeks will require a second trimester ultrasound examination to confirm the findings.

Many studies have examined detection rates for fetal anomalies at the time of second trimester ultrasound examinations and there is a wide variation in reported rates. A 2008 NICE systematic review of 17 studies reported an overall sensitivity of 24% for detection of fetal anomalies prior to 24 weeks. However, the range was between 13.5% and 87.5%. Of note there was no difference in detection rates at different gestational ages<sup>48</sup>.



A more recent large study performed between 2006 and 2013 evaluated routine second trimester ultrasound in 10,414 fetuses. Ultrasounds were all performed between 18 and 22 weeks' gestation. They reported an overall sensitivity for the detection of fetal anomalies of 44%, specificity of 99.9 % and a negative predictive value of 98.7%. Of note, only an additional 4% of anomalies were detected between 22 weeks and birth<sup>49</sup>.

Although ultrasound in the second trimester has become a routine part of antenatal care, the sensitivity and specificity of the ultrasound examination remains unclear to many women and healthcare providers. Most centres that perform ultrasound do not have their own statistics regarding detection rates. This necessitates reliance on past studies, and recent trials are lacking.

The clinical utility of follow up ultrasound examination of low risk women when fetal anatomy has not been well visualised in an otherwise normal ultrasound has not been established<sup>16</sup>. Therefore, the Eunice Kennedy Shriver National Institute of Child Health and Human Development Fetal Imaging Workshop consensus states that it may be reasonable to repeat depending on the limitations and findings on the initial examination. Studies since then have shown the addition of a follow up scan did improve the overall anomaly detection over a single scan on its own, 71.3% versus 65.9%, ( $P=.03$ )<sup>50</sup>. These findings are supported by two further studies<sup>51,52</sup>.

## Clinical Practice

Factors that influence ultrasound examination timing include optimal organ development, maternal BMI and technical ability to allow for a reliable diagnosis or reassurance to be given, against a timely diagnosis.

It is recommended that the fetal anatomy ultrasound examination be performed after 18 weeks and before 22 weeks' gestation. It is ideally performed in the 20-22 week window. This is particularly relevant in the case of maternal BMI > 30. Additional examinations are less likely to be required to complete the anatomical survey in the 20-22 week window compared to the 18-20 week window<sup>53</sup>. This will avoid the unnecessary anxiety of the woman and cost associated with an incomplete examination. An upper limit of 22 weeks was selected to allow sufficient time for referral onwards and subsequent ultrasound examination to be undertaken.

### Repeat Examination:

A single repeat ultrasound examination should be offered to complete the screening if the image quality of the first examination is affected by BMI, fibroids, abdominal scarring, and/or suboptimal fetal position. If the examination cannot be performed completely in accordance with the guidelines, this also mandates a repeat ultrasound examination. The repeat ultrasound should be done as soon as is clinically reasonable with the aim to complete the examination by 26 weeks (although this is not always achievable in practice). This is to minimise unnecessary anxiety for the woman and unnecessary delay in the potential diagnosis of congenital anomalies.

At the repeat examination all anatomy should be checked. Biometry is only necessary if there is a gap of more than 14 days. In the event that the second examination is still unable to demonstrate all the required structures, the Sonographer should record this on the report and state the reason why. The woman is given an explanation and why it is not possible. For an example of documentation of incomplete examination see Appendix 2.

It may be prudent to consider in some women, with a previous history of a fetal anomaly (one relatively easy to diagnose on ultrasound) or other relevant risk factor, to offer an anatomy ultrasound examination earlier (e.g., 14-18 weeks) than the preferred 18-22 weeks window, avoiding the prolonged stress by waiting. Consideration may also be given to including an early TVUS at 13- 15 weeks in women with a BMI >35<sup>45</sup>.

Other possible indications for an earlier ultrasound include:

- Abnormal first trimester ultrasound
- Parent with congenital anomaly
- Previous fetal anomaly
- Teratogenic drugs - e.g., carbamazepine (Tegretol) or Isotretinoin (Roaccutane)
- High risk first trimester screening results, without invasive testing
- Consanguinity
- Two inconclusive attempts at NIPS (Non-Invasive Prenatal Screening)

### Recommendations

5. It is recommended that the fetal anatomy ultrasound examination be performed after 18 weeks and before 22 weeks' gestation, ideally between 20-22 weeks' gestation. This is of particular relevance in the case of maternal BMI > 30.
6. A single repeat ultrasound examination should be offered to complete the screening if the image quality of the first examination is suboptimal e.g. by increased BMI, large fibroids, abdominal scarring, and/or suboptimal fetal position. The repeat ultrasound examination should be done as soon as is clinically feasible with the aim to complete the examination by 26 weeks.
7. In the event that the second ultrasound examination is still unable to demonstrate all the required structures the Sonographer should record this on the report and state the reason why. If the key cardiac components cannot be confirmed with two examinations by an experienced Sonographer, the woman should be referred to a Fetal Medicine Specialist.

## Section 5: What is assessed in a fetal anatomy ultrasound examination

### Introduction

In addition to an assessment of the fetal anatomy a routine examination includes assessment of the number of fetuses, fetal cardiac activity, fetal size, maternal anatomy, amniotic fluid and placental localisation.

### Clinical Question 2.5: What assessments are included in the fetal anatomy ultrasound examination?

### Evidence Statement

There is international consensus that assessment of fetal biometry and the placental site should be performed at the anatomy ultrasound examination<sup>12-23</sup>.

### Estimating gestational age

First trimester ultrasound is more effective than second trimester ultrasound in decreasing post-term pregnancy and to establish accurate dating<sup>54</sup>. The estimated due date (EDD) should not be adjusted if it has been established by an ultrasound prior to 14 weeks' gestation with an optimally performed ultrasound examination. In cases where the EDD is required to be determined at the anatomy ultrasound examination, the fetal head size (BPD and HC) and FL should be utilised. Combining all three components improves precision, however, there is no significant benefit using more than three measurements<sup>55</sup>.

### Biometry assessment

Ultrasound assessment of fetal size at the anatomy ultrasound examination serves to confirm the gestational age but also enables early detection of growth anomalies. Hadlock 4 charts are widely used as they have the best performance according to the bias and precision methods<sup>55</sup>. Estimated fetal weight should be numerically reported in grams.

### Amniotic fluid volume

Amniotic fluid volume can be estimated subjectively or by using semi quantitative indicators. The SAFE trial demonstrated that neither Amniotic fluid Index (AFI) or single deepest vertical pool (DVP) was superior in predicting adverse pregnancy outcomes<sup>56</sup>. AFI has been shown to increase the diagnosis of oligohydramnios<sup>56</sup> and DVP may be the favourable method to estimate amniotic fluid volume. The amniotic fluid should be only reported numerically, in centimetres, to one decimal place. It should be reported as normal, increased (DVP>8cms/AFI polyhydramnios), decreased (DVP<2cm / AFI oligohydramnios), or absent (anhydramnios).

### Multiple Pregnancy

Multiple gestation is increasingly common, owing in part to advances in reproductive technology. Twin births currently represent approximately 1.8% of all births in Ireland<sup>57</sup>. Ultrasound plays a key role in management of these high-risk pregnancies. Determination of chorionicity is preferably performed in the first trimester, if an ultrasound examination is done at that time, and is paramount to deciding on the appropriate frequency of ultrasound surveillance in multiple gestations.

### Placental Site

Placental localisation via the transabdominal route at the anatomy examination is the main screening test for placenta praevia. A low lying placenta lies less than 2 cm from the internal cervical os<sup>58</sup>. The incidence of a low-lying placenta is 5% in the second trimester which decreases to 0.3-0.9% in the third trimester as the placenta migrates with advancing gestation<sup>59</sup>. A transvaginal ultrasound examination at 18-22 weeks, although more invasive, provides a more accurate determination of the placenta to cervical internal os distance and therefore can reduce the number of women called for a repeat assessment in the third trimester. TVUS examination has been shown to reclassify 26–60% of placentas diagnosed as low lying at the routine fetal anatomy ultrasound examination as upper<sup>60</sup>.

The probability of resolution of a low lying placenta is inversely proportional to the distance from the internal os. Durst *et al* (2018) noted the resolution of a low lying placenta to be 99.5% in women with an initial distance of leading edge of placenta to the internal os of 10 to 20mm or greater, 95.4% with a distance between 0.1 and 10 mm, and 72.3% when the placenta totally covered the cervix internal os<sup>59</sup>. These findings are supported by two other studies which recommend routinely following up all women with a low placenta less than two centimetres from the internal cervical os at the fetal anatomy ultrasound examination at a further ultrasound examination at 32-34 weeks<sup>60,61</sup>.

A more recent study has recommended lowering the cut-off value of the distance between the edge of an anterior low lying placenta to the internal cervical os to 5mms using a TVUS. This would decrease the number of unnecessary follow up examinations. For posteriorly located placentae it remains at 20mm<sup>62</sup>. Further confirmatory research in this area is needed.

## Cord Insertion

Abnormal placental cord insertions such as velamentous (VCI) or marginal cord insertions can be associated with adverse pregnancy outcomes (placenta praevia, fetal growth restriction, abruption, vasa praevia)<sup>63</sup>. The RANZCOG issued a statement regarding vasa praevia on screening and management in 2016 advocating the examination of the placental cord insertion site on all singleton pregnancies. The AIUM recommends that the placental cord insertion be identified whenever technically feasible. Placental cord insertion has been shown that it is achievable in between 99% and 100% of second trimester ultrasound examinations and takes very little time, making no extra demand on personnel and equipment<sup>64-65</sup>.

## Screening for Vasa Praevia at the anatomy ultrasound examination

It is beyond the scope of this Guideline to discuss vasa praevia but as it is an important and preventable condition with emerging evidence of the benefits of screening. We wish to highlight the main issues.

Vasa praevia (VP), a relatively rare condition (1: 1275-2500 pregnancies), occurs when the fetal blood vessels that are unprotected by the umbilical cord or placenta run through the amniotic membranes and traverse the cervix.

Risk factors for vasa praevia are low lying placenta, placenta praevia, bilobed placenta, twin gestations, assisted reproduction techniques (IVF 1:260), antepartum haemorrhage (APH) and velamentous cord insertion<sup>66</sup>. As unprotected by placental tissue or Wharton's jelly, a vasa praevia may rupture in active labour or when an amniotomy is performed, in particular when located near or over the cervix, under the fetal presenting part. There are no standardised criteria for how close the fetal vessels must be to the internal os to constitute vasa praevia, but a threshold of 2cm has been proposed. Due to growth of the lower uterine segment, vasa praevia may resolve in up to 40% of pregnancies in whom it is diagnosed in the second trimester<sup>67</sup>.

A review of international guidelines highlights varying approaches with the Society of Obstetricians and Gynaecologists of Canada (SOGC) recommending a TVUS ultrasound should be considered for all women at high risk for vasa praevia<sup>68</sup>. In 2004 a multicentre study conducted in the US, of 155 cases of VP, reported 97% survival in cases of antenatal diagnosis VP compared to 44% not diagnosed<sup>63</sup>. More recently, the RANZCOG issued a revised statement regarding vasa praevia on screening and management in 2016. They acknowledge that even with a standard screening technique not all cases will be detected and that universal TVUS screening is not a cost-effective method for screening for vasa praevia. They do however advocate the examination of the placental cord insertion site on all singleton pregnancies, and the use of targeted screening of the lower uterine segment with colour flow Doppler to assess for vasa praevia in those pregnancies in the high-risk category<sup>69</sup>.

The 2017 UK National Screening Committee (UK NSC) external review of the 2013 screening policy concluded that there appears to be little benefit in attempting to identify cases of vasa praevia in the second trimester and that this strategy could be associated with a high false-positive rate. The analysis of the literature included in this external review of the 2013 UK NSC policy indicated that up to 80% of vasa praevia cases have one or more identifiable prenatal risk factors. There is no UK data on the epidemiology of velamentous cord insertion and no studies on screening for vasa praevia have reported outcomes (benefits and harms) from identifying velamentous cord insertion in the absence of vasa praevia. Overall, the UK NSC recommendation on screening for vasa praevia is that screening for velamentous cord insertion as a means of identifying vasa praevia should not be implemented<sup>70</sup>. This recommendation has been criticised on the basis that vasa praevia is not rare and may be underestimated, that ultrasound imaging is efficient in screening and diagnosis, and accurate diagnosis lead to a 97% survival by performing a caesarean section at approximately 36 weeks<sup>71</sup>.

It is noted in all guidelines that even with the most standardised screening protocol, cases of vasa praevia will be missed and not making the diagnosis is acceptable.

## Clinical Practice

### *Fetal biometry*

The following sonographic parameters can be assessed to estimate fetal size and confirm gestational age: Biparietal diameter (BPD), Head circumference (HC), Abdominal circumference (AC), Femur length (FL), Humeral length (HL) and Cerebellum (TCD). Please refer to Appendix 10 for measurement techniques and interpretation.

### *Estimating gestational age*

It is anticipated that the majority of women attending for a fetal anatomy ultrasound examination, will have had a dating ultrasound examination performed earlier in the pregnancy. Ideally the dating ultrasound is performed after 7 weeks' gestation or with a CRL of 10 mm or greater. Factors to consider include the quality of the ultrasound examination, ultrasound method, and all available clinical information. The estimated due date should not be adjusted if it has been established by an ultrasound prior to 14 weeks' gestation with an optimally performed ultrasound.

If gestational age has not already been established at a first trimester ultrasound examination and menstrual dates are not reliable, it is recommended the EDD should be determined at the anatomy ultrasound examination on the basis of fetal head size (BPD and HC) and FL. Up to 22 weeks, the 95% confidence range is  $\pm 7-10$  days with the use of composite fetal biometry (head circumference, biparietal diameter, and femur length) for predicting EDD<sup>72</sup>. The earlier in the second trimester that an ultrasound is performed, the more accurate the gestational age.

### *Fetal size*

With a discrepancy of more than 10-14 days between ultrasound estimated, IVF, or optimal menstrual dating, a repeat ultrasound in approximately two weeks should be performed after the anatomy ultrasound. A review of the dating ultrasound examination and assessment of potential factors that may have resulted in the abnormal biometry to include maternal medical disorders and related treatment (hypertension, diabetes, infectious exposure) should be carried out. If there remains a significant difference in size, referral to a Fetal Medicine Specialist is advised.

A discrepancy of more than 14 days or fetal growth significantly less than the 5<sup>th</sup> centile with a suspicion for a fetal anomaly should be referred for a Fetal Medicine opinion (see flow chart Appendix 4).

- The fetal anatomy ultrasound examination will assess fetal size by comparing the fetal biometry with the agreed EDD from the booking ultrasound.
- Fetal biometry measurements should be numerically reported in millimetres corrected to the first decimal point (e.g., 290.3mm or 290.7mm). They should not be rounded up to the nearest millimetre (e.g., 290mm or 291mm).
- For all measurements, clear images with sufficient magnification and correct depiction of landmarks are needed to allow precise calliper placement. It is recommended to use the ellipse method for HC and AC as using this method was found to be associated with slightly better interobserver reproducibility<sup>73</sup>
- All biometry measurements should be plotted on their respective charts. It is recommended that departments check that any data programmed into their ultrasound and computerised patient management systems use the gestational age and reference charts that correspond with the measurement technique.
- It is recommended that Hadlock charts for BPD, HC, AC and FL are chosen as it is a widely accepted method and appears to be more accurate across the entire gestational spectrum, and these are conventional population-based reference charts<sup>74</sup>.

### Amniotic fluid

- Amniotic fluid volume can be estimated subjectively, defined as 'normal' 'oligohydramnios' 'polyhydramnios' or 'anhydramnios' or by using semi quantitative indicators.
- It is recommended that DVP technique is the favoured method to measure amniotic fluid. Please refer to Appendix 10 for measurement techniques and interpretation.
- $DVP \leq 2.0$  cm is considered as oligohydramnios,  $DVP > 2$ cm and  $\leq 8.0$ cm as normal amniotic fluid volume, and  $DVP > 8$  cm as polyhydramnios. Pregnant women with abnormal amounts of amniotic fluid (after an SROM has been excluded as a cause of oligohydramnios) should be referred for a Fetal Medicine opinion (see Appendix 3 for referral criteria).

### Multiple pregnancy

In cases of multiple pregnancies when no first trimester ultrasound examination has been performed and it is not possible to identify two separate placentae and the fetal sex is the same, the pregnancy should be considered as monochorionic and referred or followed as a high-risk pregnancy<sup>12</sup>.

Additional information required at the anatomy ultrasound examination when a multiple pregnancy is present:

- The anatomy of each fetus is demonstrated as in a singleton.
- Comparison of fetal size and amniotic fluid volume of each sac should be made.
- Placental number and the presence or absence of interposed membrane should be recorded.
- An attempt should be made to confirm or determine chorionicity. Identifying the sex of each fetus may assist in determining the chorionicity.

It is important to recognise signs of Twin-To-Twin Transfusion Syndrome (TTTS) early to improve the management of monochorionic twin pregnancies. Presence of bladder, amniotic fluid and weight should be assessed and therefore any suspicion of TTTS should be referred directly to the Fetal Medicine team and seen appropriately.

Follow-up of multiple pregnancies should be arranged in accordance with national guidelines, noting the updates are due in 2023.<sup>75</sup>

### Placenta

The placenta should be reported as 'upper' when its leading edge is more than 20 mms from the internal os. The ultrasound report should also provide the best estimate of placental location *i.e.*, anterior or posterior, fundal, right lateral or left lateral.

- If the TAUS is unclear, due to maternal obesity, posterior placenta, or large fibroids a TVUS should be considered.
- If the leading edge of a placenta is less than 20 mm from the internal os or covering the internal os, it should be reported as 'low lying'. Ideally, a TVUS should be performed at this visit, if acceptable to the women to reduce false positives. If still low-lying after TVUS reassessment at 32 -34 weeks is recommended. For further management of low-lying placenta, please see Appendix 8.
- Diagnosis of placenta praevia should not be made at the fetal anatomy ultrasound examination. The provisional diagnosis must be confirmed after 32 weeks' gestation or earlier if the clinical situation warrants<sup>60</sup>
- In addition to noting the placental edge in relation to the cervical os, the position should be noted in relation to the low transverse uterine incision in cases of previous caesarean section.

### **Placenta accreta spectrum**

Women who have been diagnosed with an anterior low-lying placenta who have had a previous caesarean section should have an ultrasound performed by an experienced operator where features of PAS are clearly documented as being present or absent. Where no features of PAS are identified on ultrasound by a skilled operator, can be managed as per usual obstetric care for women with placenta praevia. Healthcare providers should be aware of the limitations of ultrasound and that PAS cannot be completely excluded on imaging.

Women with a low-lying anterior placenta and suspected features on ultrasound for placenta accreta, referral should be made to Fetal Medicine Specialist prior to 24 weeks' gestation. If this is not available locally, tertiary referral for further assessment is recommended (see PAS criteria Appendix 7). Women with a diagnosis of placenta accreta spectrum disorder should be referred to a Tertiary centre dedicated to the multi-disciplinary management of this condition<sup>76</sup>. Evaluation and management of placenta accreta spectrum is considered in a separate guideline<sup>29</sup>.

### **Cord insertion**

- Placental cord insertion should be documented at the anatomy ultrasound examination (see Appendix 10).
- If the placental cord insertion is normal and in the absence of a succenturiate lobe, vasa praevia usually can be excluded<sup>77</sup>.
- Marginal and velamentous cord insertion may have an association with fetal growth restriction, therefore a fetal growth scan at 32 weeks is recommended.

### **Vasa praevia**

- Routine screening for vasa praevia of singleton pregnancies is not recommended.
- Targeted screening using TAUS colour flow Doppler of the lower uterine segment is recommended in cases with risk factors for vasa praevia. A TVUS is recommended if a TAUS is unclear. Risk factors include: velamentous cord insertion, placental dysmorphology, succenturiate lobed placenta, low lying or bilobed placentas, multiple pregnancies and IVF pregnancies.
- In cases where vasa praevia is suspected on colour flow Doppler, referral to Fetal Medicine for management is recommended (see flowchart Appendix 4)

### **Maternal anatomy**

It is not the purpose of the fetal anatomy ultrasound examination to assess the uterus or adnexa but when uterine or adnexal masses (fibroids or ovarian cyst) are seen or follow up required they should be reported and images saved.

## **Recommendations**

8. A fetal anatomy ultrasound examination should include the assessment of the number of fetuses, cardiac activity, fetal biometry, amniotic fluid and placental location. When clinically indicated the maternal pelvic anatomy should be evaluated.
9. The fetal anatomy ultrasound examination should only be used to confirm estimated due date if first trimester ultrasound was not performed.

10. If gestational age has not already been established at a first trimester ultrasound examination and the menstrual dates are not reliable, it is recommended the estimated due date should be determined on the basis of fetal head size (biparietal diameter and head circumference) and femur length.
11. A low-lying placenta <20 mms from the internal cervical os on transabdominal or transvaginal (TAUS/TVUS) ultrasound examination should be followed up with an ultrasound at 32-34 weeks.
12. With a low-lying anterior placenta and suspected features on ultrasound for placenta accreta spectrum (PAS), referral should be made to a Fetal Medicine Specialist prior to 24 weeks' gestation. If this is not available locally, tertiary referral for further assessment is recommended.
13. Placental cord insertion (PCI), should be documented at all fetal anatomy ultrasound examinations.
14. Marginal and velamentous cord insertion may have an association with fetal growth restriction, therefore a fetal growth scan at 32 to 34 weeks is recommended.
15. In cases with risk factors for vasa praevia e.g. velamentous cord insertion, placental dysmorphism, succenturiate lobed placenta, low lying or bilobed placentas, multiple pregnancies and pregnancies conceived with in vitro fertilisation (IVF) targeted screening with TAUS colour Doppler is recommended. A TVUS is recommended if the TAUS is unclear. A Fetal Medicine opinion should be sought if vasa praevia is suspected.

## Section 6: Specific clinical situations

### Introduction

These guidelines refer to routine ultrasound evaluation of pregnant women who have no maternal, fetal or obstetric risk factors identified. However, in select populations, additional, more comprehensive, detailed ultrasound examinations in response to specific clinical situations should be performed.

### Clinical Question 2.6: When should cervical length and uterine artery Doppler examination be performed at the fetal anatomy ultrasound?

#### Evidence Statement

##### Cervical Length

Cervical length (CL) measured by TVUS in the mid-trimester based on a risk profile assessment has been shown to be an effective predictor of spontaneous preterm birth (PTB)<sup>78</sup>. Screening for PTB aims to identify women at risk in early pregnancy so that they can be targeted for preventative interventions. A short mid-trimester cervical length is one of the strongest risk factors for spontaneous PTB, as studies have consistently shown that the risk of PTB is inversely proportional to the length of the cervix<sup>79</sup>. TVUS ultrasound measurement of cervical length is safe, reliable, and highly reproducible when performed by trained Sonographers. Many organisations and groups have issued policy statements and



recommendations on the use of universal cervical length screening. The UK NSC (National Screening Committee 2020) does not recommend a population screening programme for low risk asymptomatic pregnant women in keeping with international experience and recommendations<sup>80</sup>.

### **Uterine Artery Doppler Examination**

Doppler velocimetry has been used to assess the uterine circulation for over 30 years and is useful in predicting pregnancies at risk of developing complications related to abnormal placentation. An abnormal uterine circulation is associated with a risk of pre-eclampsia, IUGR, preterm birth, fetal demise and placental abruption. Assessing the uterine artery alone at the anatomy ultrasound examination has limited clinical value. Studies suggest the effectiveness in risk assessment and screening should be combined with other screening tests, for example ethnicity, body mass index and previous/family history of eclampsia, biomarkers and measurement of mean arterial pressure<sup>81</sup>.

## **Clinical Practice**

### ***Cervical length***

Cervical length measurement is not indicated in a low risk pregnancy. It is anticipated that cervical length screening will have been performed on women who are at high risk of PTB prior to the anatomy scan.

In the event that this has not occurred cervical length screening should be considered when clinically appropriate to include the following scenarios:

- Previous preterm birth or mid-trimester loss (16 to 34 weeks' gestation)
- Previous use of cervical cerclage
- Known uterine anomalies (i.e., unicornuate, bicornuate uterus or uterine septum)
- Intrauterine adhesions (Asherman's syndrome)
- Two previous Large Loop Excision of the Transformation Zone (LLETZ) or Cone Biopsy
- Large LLETZ excisions, over 15 mm or 2.66 cm<sup>3</sup> (these are associated with a doubling of the risk of preterm birth)
- History of trachelectomy

In general, the cervix should be assessed by TVUS. A measurement of less than 25mms at less than 24 weeks is considered to be a short cervix and has a higher risk of preterm birth<sup>82</sup>. For more detail on obtaining a cervical length see Appendix 5.

### ***Uterine artery doppler***

Uterine Artery Doppler screening is not indicated in a low risk pregnancy as the application of this test on its own fails to improve short term neonatal and maternal morbidity and mortality. There is still insufficient data to support its routine implementation in clinical practice as a standalone test as it would not change care<sup>81</sup>. Uterine artery Doppler screening may be considered in cases of unexplained growth restricted pregnancies (less than the 5th centile) or if requested by the Obstetrician.

Where uterine artery Dopplers are being performed, the technique is described in Appendix 6.

## **Recommendations**

16. Cervical length and uterine Doppler waveforms should only be measured in specific populations.

## Section 7: Anatomical structures

### Introduction

Many clinically important anatomical anomalies can be detected at the fetal anatomy ultrasound. Detection of lethal or serious life limiting anomalies facilitates discussion of pregnancy options, such as pregnancy termination or perinatal hospice care. In the case of other anomalies, it facilitates treatment planning and appropriate timed intervention. This helps to optimise antenatal care to improve outcomes for mothers and babies. Major congenital anomalies remain the most common cause of stillbirth, early neonatal and late neonatal death in 2020. The leading cause of early neonatal death in Ireland in 2019 is reported as congenital anomalies (54.2%) with 30.6% of stillbirths due to congenital anomalies<sup>83</sup>.

### Clinical Question 2.7: What are the anatomical structures to be examined at the fetal anatomy ultrasound?

### Evidence Statement

Many organisations have called for standardisation of the fetal anatomy ultrasound, as currently detection rates vary between centres and operators<sup>84</sup>. The use of a standardised anatomical protocol improves the sensitivity of the anatomy ultrasound examination<sup>85</sup>. Areas evaluated with this imperative include the cranium, cerebral ventricles, midline falx, the choroid plexuses, cisterna magna, cerebellum, orbits, upper lip, chest, diaphragm, cord insertion, stomach, kidneys, urinary bladder, fetal spine, and the presence of upper and lower extremities to include hands and feet. The fetal heart should be evaluated, noting its position and the position of the cardiac axis. Imaging of the four chamber view and the right and left outflow tract is necessary. These standards for the basic examination have been adapted worldwide. However, the requirements regarding saved images of fetal anatomic regions vary considerably from 7 (FASP, UK<sup>17</sup>) to 24 views (Canada<sup>15</sup>).

It is widely acknowledged that ultrasound examination will not identify all congenital anomalies even with the most experienced examiners using the best ultrasound equipment and obtaining optimal views. An example is when the condition causes no structural changes in the fetus, such as autism or cerebral palsy, or when the anomaly only develops later in pregnancy.

### Clinical Practice

It is recommended to examine fetal anatomy in a systematic manner. The structures are presented in cephalic to caudal order, but where possible are grouped by organ system. Before starting an ultrasound examination it is necessary to check the position of the fetal head and spine allowing the identification of the left and right side of the fetus (See Appendix 10 for establishing situs). Unfavourable fetal position can be overcome by changing maternal position or transducer orientation.

Each organ system is discussed in detail below to aid in the identification of the important features and is worth careful consideration during a second trimester anatomy examination.

Appendix 10 provides details of the techniques and landmarks used to obtain components of the fetal anatomy examination set out below.

### Fetal head

**Skull:** The shape, integrity, and bone density of the fetal skull should be assessed while measuring the head size. The normal skull has an oval shape and appears as a continuous white echogenic structure interrupted only by cranial sutures. Standard ultrasound planes for the basic examination of the fetal brain have been adapted from the ISUOG Guideline document<sup>86</sup> which can be downloaded from the Society's website <http://www.isuog.org> or the ISUOG Guideline document.

**Brain structures:** Brain structures, including lateral ventricles, choroid plexus, midline falx, cavum septum pellucidum, thalamus, cerebellum and cisterna magna, can be examined through transventricular plane, transthalamic, and transcerebellar planes, see Appendix 10.

**Cavum septum pellucidum:** The cavum septum pellucidum (CSP) is seen as a fluid-filled structure anterior to the thalami on axial views. Just anterior to the CSP there is often a fine hypoechoic 'U' shaped structure representing the anterior leaflets of the corpus callosum. The CSP is an important landmark for development of the corpus callosum<sup>87</sup>.

**Lateral ventricles:** Measurement of the atrium is recommended because several studies suggest that this is the most effective approach for assessing the integrity of the ventricular system<sup>86</sup>. The atrium is characterised by the presence of the glomus of the choroid plexus, which is brightly echogenic, while the occipital horn is fluid filled. **Measurement:** The atrial width should be measured inner-to-inner and should be <10mm throughout pregnancy<sup>86</sup>. See Appendix 10.

**Cerebellum:** In the transcerebellar plane, the presence and shape of the cerebellum should be assessed and documented. The cerebellum appears as a figure of eight formed by the round cerebellar hemispheres joined in the middle by the slightly more echogenic cerebellar vermis. **Measurement:** should be plotted on the relevant centile chart. A cerebellum less than the 5th centile or 2 mms less than gestational age should be referred for a Fetal Medicine opinion<sup>88</sup>. See Appendix 10 .

**Cisterna Magna:** The cisterna magna can be measured in the midline from the cerebellar vermis to the occipital bone. The callipers should be positioned in a correct transcerebellar plane, between the outer edge of the most dorsal point of the cerebellar vermis and the internal side of the occipital bone. **Measurement:** The cisterna magna should measure 2 - 10 mm in the second trimester.

**Nuchal fold:** Nuchal fold measurements should be performed on the transcerebellar image using internal landmarks including the cavum septum pellucidum, cerebral hemispheres, cerebellar peduncles, and cisterna magna. **Measurement:** A thickened nuchal fold is defined as greater or equal to 6mm before 22 weeks' gestation<sup>89</sup>. See Appendix 10 for technique.

### Fetal face

Imaging of the fetal face can be accomplished through a combination of coronal, axial and sagittal views, to determine the presence of mouth and both orbits, to evaluate nose/nostrils and integrity of upper lip and exclude cleft lip and other facial anomalies.

**Facial Profile:** A midsagittal facial profile should be obtained if technically feasible. The tip of the nose, upper lip, lower lip, and chin should line up along the same imaginary line.

**Nasal bone:** Nasal bone measurements vary according to race and ethnicity. The recommended method to measure the nasal bone is that of the method described by Sonek<sup>90</sup>. For further information see Section 8 on soft markers. Examination of the nasal bone is optional and the measurement is not required routinely.

**Intraorbital distance:** This can be seen in a coronal view of the fetal face. The orbits should be approximately equal size and should be evenly spaced. The lenses can be seen as central circles that should not have internal echogenicity. This is an optional view and this view is not required as part of the basic anatomy ultrasound examination. **Measurement:** The width of the nasal bridge between each orbit is approximately the same as the size of each orbit – dividing the upper face into thirds.

**Lips and nose:** This image is obtained by moving the probe forward from the coronal orbital view to the very front of the face. This image demonstrates two nostrils and a separate intact upper lip.

**Upper lip and palate:** This is a transverse image used to obtain a cross section through the upper lip and hard palate. It demonstrates an intact skin line of the upper lip (no cleft). Behind this is an echogenic intact hard palate; this confirms the correct plane, and is useful to distinguish palate involvement if a cleft lip is present. This image does not exclude clefts of the soft palate or secondary hard palate. This is an optional view and this view is not required as part of the basic anatomy ultrasound examination.

### *Fetal neck*

The neck normally appears as cylindrical in a transverse plane with no protuberances, masses or fluid collections. Obvious neck masses such as cystic hygromas or teratomas should be documented.

### *Fetal thorax*

The shape of the thorax should be regular with a smooth transition to the abdomen. The ribs should have normal curvature without deformities.

### *Fetal lungs*

The fetal lungs are homogeneous in echotexture and become more echogenic as gestation progresses. The fetal lungs are usually more echogenic than the liver and separated from the abdominal contents by the diaphragm. Deviation of the heart from its normal position or axis may provide important clues to the presence of a chest mass even if the echotexture appears normal. Deviation of the normal cardiac axis may be the first clue to the presence of a fetal lung mass.

### *Fetal diaphragm*

The diaphragmatic interface can be visualised through sagittal and coronal views as a hypoechoic dividing line with the heart above and stomach below. The heart and the stomach are observed on the left side of the fetus.

### *Fetal cardiac examination*

Congenital heart disease (CHD) accounts for the majority of deaths from congenital defects in childhood. The overall prevalence of CHD is estimated at 8 per 1000 live births. Critical defects are classified as those that are lethal or require intervention in infancy or on long term follow up. The estimated prevalence of such major anomalies is 4 per 1000 live births. CHD can occur in isolation or as part of a genetic syndrome or chromosomal anomaly. The techniques required for confirming fetal cardiac normality are described in Appendix 10.

The primary purpose of fetal cardiac examination at the fetal anatomy ultrasound examinations is to exclude Critical Congenital Heart Disease (CCHD). Prenatal diagnosis is known to confer survival advantage for babies with arterial duct-dependent cardiac anomalies, owing to the resultant opportunity for delivery planning and optimisation of perinatal care. It has been universally established that the introduction of a screening protocol increases the diagnostic rate of cardiac anomalies<sup>91,92</sup>. In a selected example, an Irish study in which a prenatal screening protocol was instituted found that the detection rate of major CHD increased from 31% to 91%<sup>93</sup>.

**Key components of the fetal cardiac examination**

The heart rhythm should be regular and the rate measuring between 110 and 180 beats per minute. A four-chamber view that demonstrates left and right ventricles of approximately equal size and with forward flow across two separate atrio-ventricular valves. Great vessels of approximately equal size, with the aorta seen to arise from the left ventricle and the main pulmonary artery arising from the right ventricle. There is no requirement to measure cardiac size, individual valves, chambers or vessels for the purposes of a screening examination if the captured views are considered by the Sonographer to demonstrate normal heart size and proportion between right and left-sided cardiac structures. Colour Doppler may facilitate imaging of the various cardiac structures<sup>94</sup>. It may also constitute a valuable tool in the evaluation of cardiac anatomy in women with increased BMI and may further improve detection rates of major CHD in low-risk pregnancies<sup>97</sup>. For ultrasound techniques and optimal machine settings as well as additional components of the cardiac examination see Appendix 10 and 11. Referral Criteria for Fetal Echocardiography following a fetal anatomy ultrasound is set out in Appendix 14.

**Fetal abdomen**

**Situs:** Abdominal organ situs should be determined by obtaining a transverse section through the upper abdomen just below the four-chamber view of the heart. It is the same section or just above the level of the abdominal circumference. The aorta sits just in front of the spine, slightly to the left of the spine. The inferior vena cava (IVC) is anterior to the aorta and right sided. The fetal stomach should be identified in its normal position on the left side. A 'J' shaped hypoechoic structure is seen in the midline; it should be 1/3 of the way across the abdomen and represents the internal portion of the umbilical vein branching to the right portal vein.

**Bowel:** Bowel should be contained within the abdomen and should not be dilated and its echogenicity is less than bone. Echogenic fetal bowel is a sonographic finding, in which the fetal bowel appears to be brighter than normal. For further information see soft marker (question 7). The diameter of the lumen of the small bowel and colon increases as gestational age increases. The fetal small bowel lumen rarely exceeds 6 mm in diameter. Small bowel peristalsis can be seen with increasing frequency with increasing gestational age<sup>95</sup>.

**Gallbladder:** Aside from the left-sided stomach, a fetal gallbladder may be seen in the right upper quadrant next to the liver as a tear shaped hypoechoic structure situated to the right anterior of the umbilical vein.

**Umbilical cord insertion:** The fetal umbilical cord insertion site should insert into an intact abdominal wall. The best views are obtained with the cord insertion near the three or nine o'clock position on the screen. The skin line should be clearly visualised on both sides of the insertion. The base of the cord should insert cleanly into the abdominal wall with no evidence of a mass to suggest gastroschisis or omphalocele.

**Fetal kidneys and bladder**

**Kidneys:** Both kidneys should be assessed in two planes. However, selecting a representative image in one plane is sufficient. It is not essential to measure the kidneys unless there is suspicion of a renal anomaly. Normal kidneys measure 20-30 mms in the second trimester with no renal cysts present<sup>96</sup>.

**Renal pelvis:** The size of the renal pelvis should be measured and reported in mms by placement of the callipers on the inner border of the renal pelvis and measured in the anterior to posterior direction. A measurement of  $\leq 7$ mm is normal in the second trimester<sup>97</sup>.

**Renal arteries:** This is a coronal section through the back just anterior to the fetal spine, in the same view as the coronal view of kidneys. Low flow settings are needed to detect both arteries. The arteries should extend all of the way into the renal pelvis to distinguish the renal arteries from the mesenteric artery.

**Bladder:** Fluid should be seen within the bladder at some stage during the examination. A large bladder >23mm may indicate bladder outlet obstruction (partial or complete)<sup>98</sup>.

**Umbilical arteries:** Colour or power Doppler is used to identify the two umbilical arteries that surround the bladder and then are directed towards the cord insertion. The presence of a single umbilical artery should be an indication for a thorough reassessment of the fetal anatomy especially the kidneys<sup>99</sup>. For further information see question 8 dealing with soft markers.

### *Fetal spine*

Complete evaluation of the fetal spine is from the cervical to sacral region by the transverse, sagittal and coronal planes. The choice of plane depends on the fetal position. A full detailed examination of the spine from every projection is not part of the basic examination. In a low risk women, if the transcerebellar and transventricular plane are obtained satisfactorily and the head size is within normal limits more than 97% of spina bifida can be ruled out.

However, a longitudinal section of the fetal spine should always be obtained because it may reveal, at least in some cases, other spinal anomalies including vertebral anomalies and sacral agenesis. Although sacral agenesis may be challenging even in expert hands due to the physiological non-ossification of the caudal spine in the second trimester<sup>100</sup>. The intactness of the skin overlying the spine either on transverse view or longitudinal view should be attempted.

### *Fetal limbs and extremities*

The presence or absence of both arms/hands and both legs/feet should be assessed. The four limbs should be assessed to confirm the presence of all three segments of both upper and lower limbs (e.g., femur, tibia, fibula and foot). The symmetry in length, shape and density of the bones on each side should be observed.

**Lower Limbs:** The femur and the two long bones should be seen in each leg. A sagittal view of each leg will demonstrate the ankle to be correctly orientated. In order to exclude talipes the sole of the foot and the length of tibia and fibula should not be able to be seen in the same image.

**Upper Limbs:** The humerus and the 2 long bones should be seen in each upper limb. Hands need to be seen to open fully at least once during the ultrasound examination.

Counting of fingers or toes is not required as part of the routine anatomy ultrasound examination.

### **Sex**

It is not the function of the fetal anatomy ultrasound examination to diagnose the fetal sex. An ultrasound examination will not be performed for this reason, unless at the request of a referring health care provider for a sex linked condition. However, the fetal sex may be visible during the ultrasound. At the request of the women the Sonographer may disclose this information. The examination should not be prolonged or repeated if no structural anomalies are seen but sex determination is inconclusive. The sex cannot be stated with absolute certainty. Prospective parents should be made aware of the risk of error with the disclosure<sup>101</sup>. 8 per 1,000 fetuses are incorrectly assigned sex. This is more common in females<sup>102</sup>. Therefore the 99.2% accuracy of fetal sex determination should be disclosed to the parents.

Local policy with regard to providing this information should be clearly displayed in the ultrasound department and service users advised of the policy. On occasion, Sonographers may be requested to write the gender of the fetus on a piece of paper and place it in an envelope. Whether or not this is facilitated may be determined locally.

### Recording of images

The selection of the minimum number of images which are suitable for a comprehensive screening examination, are included in Appendix 9. This can be removed from the document as a summary of the requirements for the Fetal Anatomy ultrasound examination.

All images should be archived in a retrievable format for subsequent review and interpretation. All images should be easily identifiable from the section of the anatomy being studied but if not, obvious images should be annotated to facilitate interpretation.

Other images will be required if an anomaly is suspected or detected. The following images outlined in Table 1 are required to be taken and stored.

**Table 1. Images required to be taken and stored. Clips/ sweeps is the preferred method for cardiac examination.**

- Transthalamic plane BPD/ HC demonstrating measurement.
- Transventricular plane- Measurement at the Atrium of the lateral ventricle
- Transcerebellar plane /Measurement of Cerebellum/ Cisterna Magna/ Nuchal Fold
- Coronal view of lips with nasal tip
- Cardiac situs
- FH rate and rhythm
- Four chamber view with/ without colour Doppler (split screen)
- LVOT with/ without colour Doppler (split screen)
- RVOT with/ without colour Doppler (split screen)
- 3VV OR 3VT
- AC with measurement
- Fetal Cord insertion
- Kidney (1)
- Kidney (2)
- Bladder with 2 umbilical arteries
- Femur length demonstrating measurements
- Humeral Length demonstrating measurement.
- Sagittal view of spine to include skin covering lumbar sacral region (more than one image may be required).
- Hand (1)
- Hand (2)
- Foot (1)
- Foot (2)
- Placental site in relation to cervix
- Placental cord insertion/ Colour flow
- Amniotic fluid

#### **Optional images to include, but are not limited to**

- Both fetal orbits
- Midsagittal facial profile, normal in appearance
- Nasal bone normal in appearance
- Three vessel and Trachea view
- Diaphragm
- Right radius and ulna
- Left radius and ulna
- Right tibia and fibula
- Left tibia and fibula
- Male or Female image if disclosing sex

#### **Recommendations**

17. The fetal anatomy ultrasound examination should include an assessment of all major fetal organ systems. The minimum images (25) required to complete the fetal anatomy ultrasound examination are set out in the Guideline (Appendix 9).
18. Assessment of fetal sex is not the function of the fetal anatomy ultrasound examination and, where performed, the accuracy of fetal sex determination should be disclosed.

## **Section 8: Soft markers**

### **Introduction**

Soft markers were originally introduced to prenatal ultrasonography to improve the detection of trisomy 21 over that achievable with age-based and serum screening strategies. As prenatal genetic screening strategies have greatly evolved in the last 20 years, the relative importance of soft markers has shifted. The purpose of this section is to discuss the recommended evaluation and management of isolated soft markers in the context of increasing non-invasive screening options (NIPS) and to assist clinicians with counselling and appropriate referral.

### **Clinical Question 2.8: What is the significance of an isolated soft marker?**

#### **Evidence Statement**

Soft markers are minor ultrasound findings identified in the mid trimester of pregnancy that most commonly do not represent a structural anomaly and may be normal variants but are noteworthy because of their association with an increased aneuploidy risk<sup>103</sup>. Soft markers that are commonly noted at the time of anatomy ultrasound examination include echogenic bowel, echogenic intracardiac focus, choroid plexus cysts, renal pelvic dilation absent nasal bone, enlarged nuchal fold, short



femur, short humerus, ventriculomegaly and single umbilical artery. Approximately 10% of fetuses will have an isolated soft marker identified in the mid-trimester and the vast majority of these will be chromosomally normal<sup>104</sup>. The finding of a soft marker can create significant unnecessary anxiety but this negative must be balanced against the diagnosis of a fetus with aneuploidy and should be handled with great sensitivity.

Individual soft markers will vary in the degree of association with fetal aneuploidy. In 1998, Nyberg *et al.* suggested reassessing the initial risk of aneuploidies by developing likelihood ratios (LRs) for each marker as an isolated finding<sup>103</sup>. It has become practice in some countries to estimate the degree of association as a likelihood ratio (LR) by which the a priori background risk is altered. The LR is defined as sensitivity/false positive rate. An LR of > 1 suggests a positive association with a particular finding. A meta-analysis evaluating sonographic markers for Trisomy 21 has suggested that the most powerful predictors of Trisomy 21 (i.e. those with pooled positive LR>0) were mild cerebral ventriculomegaly (LR=27.5), increased nuchal fold (LR=23.2), hyperechoic bowel (LR=11.4), absent or hypoplastic nasal bone (LR=23.3), and aberrant right subclavian artery (LR=21.5). Absence of the most commonly evaluated sonographic markers lowers the risk of Trisomy 21 to about half the a priori risk<sup>103</sup>.

With increasing numbers of women availing of NIPS the significance of soft markers has diminished<sup>108</sup>. It should be noted that the vast majority of women in 2022 in Ireland do not have access to NIPS and NIPS still remains cost prohibitive for most of the population. It is important to acknowledge that only diagnostic testing will remove residual risk of aneuploidy irrespective of any screening test.

Non-invasive prenatal screening (NIPS) is reliant on laboratory assessment of cell-free fetal DNA from maternal plasma and is the single best screening test for the common trisomies (T21, T18, and T13)<sup>105</sup>. The introduction of NIPS has greatly improved the ability to screen for aneuploidies over and above maternal age or soft marker screening<sup>106</sup>. The International Society for Prenatal Diagnosis (ISPD) considered it appropriate to offer NIPS as a first choice screening test for all pregnant women<sup>107</sup>.

When counselling a woman regarding the significance of the finding of a soft marker, the magnitude of risk associated with the soft marker in question should be addressed taking into consideration whether the mother has undergone NIPS or first trimester screening.

Several organisations have recommendations on the role of soft markers in assessing the risk of aneuploidy, including SMFM, ACOG, the International Society of Ultrasound in Obstetrics and Gynaecology, the National Institute for Health and Care Excellence, and the Society of Obstetricians and Gynaecologists of Canada<sup>48 109,110,111</sup>.

The SMFM have produced a very comprehensive Guideline on the evaluation and management of isolated soft ultrasound markers for aneuploidy in the second trimester in October 2021 which reflects the changed thinking on this difficult area and is highly recommended reading<sup>111</sup>. Appendix 12 has been adapted from this Guideline.

ISUOG have previously recommended the so-called 'genetic sonogram', which includes looking for soft markers of trisomy 21. This should not be performed in women with a normal NIPS result due to its high false-positive rate and poor positive predictive value<sup>105</sup>. Similarly the SOGC state in women with a low risk of aneuploidy following first trimester aneuploidy screening (e.g. NIPS), the presence of specific ultrasound "soft markers" associated with fetal trisomy 21 (echogenic intracardiac focus) or trisomy 18 (choroid plexus cysts) identified during the second trimester ultrasound (18 to 22 weeks) are not clinically relevant due to poor predictive value and do not warrant further testing, with the exception of an increased nuchal fold<sup>112</sup>.

The Fetal Anomaly Screening Programme guidelines have recommended that an established screening result (based on an approved screening test which in the UK entails first trimester screening with biochemistry and NT, and NIPS) should not be recalculated at the second trimester ultrasound examination. These guidelines encourage the use of the term 'normal variants' rather than 'soft markers'. It recommends that in women given a 'low-risk' result, neither choroid plexus cysts, dilated cisterna magna, echogenic foci in the heart or two-vessel cord should be routinely reported and no further assessment of the risk of trisomy 21 should be made. However, for the following findings it is agreed that further assessment is required: nuchal fold greater than 6mm, ventriculomegaly (atrium greater than 10 mm), echogenic bowel (with density equivalent to bone), renal pelvic dilatation (AP measurement greater than 7 mm) or small fetal size measurements compared to dating ultrasound (significantly less than 5th centile)<sup>17</sup>.

## Clinical Practice

An 'isolated soft marker' is used to describe a single soft marker that has been identified in the absence of any fetal structural anomaly, growth restriction or any other feature that raises a concern for aneuploidy (e.g., polyhydramnios, abnormal/absent fetal movement) following an ultrasound examination. Summary table for management of soft marker, see appendix 15

If more than one marker is identified in the absence of NIPS, then a Fetal Medicine opinion is also recommended though the combination of echogenic intracardiac focus and choroid plexus cyst does not increase the risk of Down Syndrome (DS) in a low risk unscreened woman<sup>103, 112, 113</sup>.

**Certain soft markers, if isolated, require no further evaluation, these are as follows (see Appendix 15):**

### *Echogenic intracardiac focus*

An echogenic intracardiac focus (EIF) is defined as a small (<6mm) echogenic lesion in either ventricle which is visualised in at least 2 planes, EIF are present in 3 – 5% of fetuses<sup>112</sup>. They do not represent a structural or functional cardiac anomaly. Studies have reported an increased incidence of EIF in fetuses with Trisomy 21, however, this association has not been consistently found and reported LRs for T21 vary from 0.95 – 1.8 with a confidence interval extending to or lower than 1, suggesting a minimal risk<sup>113</sup>.

Therefore, an isolated single EIF may be considered a normal variant that does not need to be acknowledged or discussed and should not be recorded in the anatomy ultrasound examination report.

### *Choroid plexus cysts*

Choroid Plexus cysts (CPCs) appear as echolucent cysts within the choroid of the lateral ventricle and are not considered to be a structural or functional brain anomaly and nearly all resolve by 28 weeks<sup>114</sup>. The size, complexity, laterality and persistence do not affect the risk. They may be single or multiple and are seen in 1 – 2% of fetuses in the second trimester. They are associated with trisomy 18, being present in up to 50% of fetuses with this condition. They are not seen any more frequently in T21 than in euploid fetuses and its presence does not alter the background risk of T21. The presence of CPCs should prompt a careful evaluation for other structural findings associated with Trisomy 18 such as cardiac defects, clenched hands, abnormal positioning of the feet or polyhydramnios. If a structural anomaly is present the positive LR is 66 and referral to Fetal Medicine is recommended.

If CPCs are an isolated finding no further investigation is required and do not need to be discussed or recorded in the ultrasound report. However, the findings must be interpreted in the context of a priori risk such as maternal age (and in the absence of NIPS).

### Urinary tract dilation

Several terms have been used to describe urinary tract dilation (UTD), including pyelectasis and hydronephrosis. UTD is defined by the Society of Urology as mild when the renal pelvic diameter measurement is 4mm to < 7mm, moderate 7 to 10 mm, and severe >10mm<sup>97</sup>. Renal pelvic dilation is found in 1-2% of fetuses and may be a transient finding or can be due to underlying urinary tract obstructive pathology. For details on measuring the renal pelvic diameter please see Appendix 10. An association between UTD and Trisomy 21 has been observed although the LR is only 1.5. Therefore, in isolation, renal pelvic dilation does not warrant any further investigation for aneuploidy. However, the findings should be interpreted in the context of the priori risk.

A renal pelvis diameter of >7mm should be followed up in the third trimester to monitor progression and need for postnatal imaging. In approximately 80% of cases it will have resolved at a later ultrasound examination. A renal pelvic diameter  $\geq$  10 mms at the routine anatomy scan should be referred for Fetal Medicine opinion.

### Single umbilical artery

An umbilical cord with a single umbilical artery (SUA) following agenesis or atrophy of the second umbilical artery is found in up to 1% of singleton pregnancies. The frequency is higher in twin gestations particularly in monochorionic twin pairs. This finding should prompt an evaluation of the fetal renal and cardiac anatomy as SUA is frequently associated with structural anomalies of these systems. If either/both of these are present the risk of aneuploidy ranges from 4 to 50% and as such will require further Fetal Medicine evaluation. In isolation a SUA is not associated with an increased risk of aneuploidy and does not warrant any further evaluation for aneuploidy risk in this regard.

There is conflicting evidence regarding the association between single umbilical artery and fetal growth restriction or other adverse outcomes including stillbirth. A study of 243 fetuses with SUA showed higher rates of FGR, placental abruption and perinatal mortality<sup>115</sup>. In contrast, a systematic review by Voskamp *et al* found no association between SUA and FGR<sup>116</sup>. Given these conflicting results it is prudent to offer a third trimester ultrasound examination to evaluate fetal size/growth with this finding.

**Soft markers which confer an increase in the risk of aneuploidy should be referred for a Fetal Medicine opinion. The aim of this referral is to evaluate further and discuss/offer aneuploidy screening or invasive testing as appropriate. These are discussed below in the context of no prior screen testing and with prior screen testing (see Appendix 15).**

### Echogenic bowel

Echogenic bowel is present when the echogenicity of the fetal bowel is equal to or greater than the echogenicity of fetal bone typically the iliac wing. The ultrasound gain should be minimised and tissue harmonics turned off (and if possible using a low frequency probe) to avoid overdiagnosis of echogenic bowel.

It is seen in up to 1.8% of fetuses in the mid trimester, echogenic bowel can be associated with a range of underlying pathologies including aneuploidy, cystic fibrosis, fetal growth restriction, infection, gastrointestinal pathology and intra-amniotic bleeding<sup>117-119</sup>. The estimated incidence of aneuploidy with isolated echogenic bowel ranges from 3 to 5%. Most positive LRs for trisomy 21 for a fetus with isolated echogenic bowel range between 6 and 8 suggesting a moderately increased risk. The risk of cystic fibrosis in the presence of isolated echogenic bowel ranges from zero to 13% increasing to 17% if dilated loops of bowel are present. The risk of congenital infection is 2 to 4%.

This finding at an anatomy ultrasound examination should prompt referral to a Fetal Medicine Specialist for further evaluation and consideration of additional investigations including invasive testing for aneuploidy, screening for congenital infections and cystic fibrosis carrier testing on the parents (with appropriate clinical genetics input) in addition to a third trimester ultrasound examination.

### **Absent/hypoplastic nasal bone**

It is not essential to measure the nasal bone at the fetal anatomy ultrasound examination but if viewed and appears small it may be prudent to measure the nasal bone (See Appendix 16 for technique). The finding of a hypoplastic nasal bone in the absence of NIPS does significantly increase the possibility of Trisomy 21 with reported LRs of 6.6 – 23.

This finding should therefore prompt referral for a Fetal Medicine opinion. For pregnant women with a low risk screening result and isolated absent or hypoplastic nasal bone, no further aneuploidy evaluation is warranted and is most likely a normal variant<sup>111</sup>.

### **Enlarged nuchal fold**

A commonly accepted definition of a thickened nuchal fold is defined as greater or equal to 6mm before 22 weeks' gestation<sup>120</sup>. It is one of the more significant soft markers and has a significant association with Trisomy 21 with reported LRs varying from 11 – 23. As an isolated finding it has a LR of approximately 3.8 and should be referred for a Fetal Medicine Opinion.

Whilst an increased first trimester nuchal translucency is associated with an increased risk of congenital cardiac anomalies, this association is less clear for a second trimester finding of an enlarged nuchal fold, therefore if the cardiac anatomy has been adequately visualised no further cardiac imaging is indicated<sup>16,111</sup>.

### **Short femur and/or short humerus**

Shortened humerus and femur are defined as bone length below the 5th percentile for gestational age<sup>121</sup>. Fetal short long bones have been associated with aneuploidy, skeletal dysplasia, fetal structural anomalies, preeclampsia, stillbirth and fetal growth restriction (FGR). The association is greater for short humerus with an approximate LR of 5.1 to 7.5 suggesting a moderate risk. A short femur carries a LR of 1.5 to 2.7 with the CI of the lower estimate falling below 1 suggesting a minimal risk<sup>103</sup>. Parental race and ethnicity can lead to constitutionally short bones and should be considered in the differential diagnosis.

If NIPS has been performed and is screen negative, there is no need for further aneuploidy evaluation. It is important to consider other possibilities when short long bones are identified such as an underlying skeletal dysplasia (especially if measurements fall below the 3rd centile) or early onset fetal growth restriction. Follow up ultrasound examination to assess fetal growth should be arranged for the third trimester<sup>121</sup>. In the absence of screening the finding of either a short femur or a short humerus Fetal Medicine opinion should be considered.

### **Ventriculomegaly**

Ventriculomegaly has an overall prevalence estimated to be about 1 per 1000 birth<sup>122</sup>. It is extremely important to measure the lateral ventricle correctly to avoid over diagnosis and considerable resultant anxiety. This is described in Appendix 10. The normal width of the lateral ventricle is <10 mm. Ventriculomegaly is categorised as mild 10–11.9 mm, moderate 12–14.9 mm, or severe  $\geq 15$  mm<sup>123</sup>.

Mild ventriculomegaly is considered a soft marker. According to the meta-analysis carried out by Agathokleios *et al*, the LR is 3.8 for T21<sup>119</sup>. If ventriculomegaly is present it can also be caused by structural anomalies of the central nervous system such as haemorrhage, Toxoplasmosis, Rubella, CMV, Herpes Virus Serology infections (TORCH), or hypoxic fetuses. Finally, if identified in the low risk woman in the absence of any other soft marker or fetal structural anomaly, mild fetal ventriculomegaly may represent a normal variant.

Findings of mild, moderate or severe ventriculomegaly warrant a Fetal Medicine opinion for further evaluation and consideration for specific aneuploidy screening and investigations

### Recommendations

19. For fetuses with an isolated echogenic intracardiac focus or choroid plexus cysts (CSP) no further investigation is required and this finding does not need to be recorded.
20. For fetuses with an isolated single umbilical artery (SUA), no additional evaluation for aneuploidy risk is necessary. This finding should prompt a thorough evaluation of the fetal renal anatomy and a third-trimester ultrasound for assessment of growth.
21. For fetuses with renal pelvic dilatation (RPD) >7mms, it is recommended to perform an ultrasound examination at 32 to 34 weeks to reassess the genitourinary tract. Isolated renal pelvic dilatation does not warrant aneuploidy assessment.
22. For pregnant women with low risk NIPS and absent nasal bone no further aneuploidy screening is necessary. If there is no previous screening test (e.g. NIPS), referral for a Fetal Medicine opinion is recommended. Grade 1B
23. For pregnant women with low risk NIPS and a nuchal fold > 6mm detailed cardiac assessment is required. No further aneuploidy screening is necessary. If there is no previous screening test (e.g. NIPS), referral for a Fetal Medicine opinion is recommended.
24. For pregnant women with a low risk NIPS and isolated shortened humerus, femur, or both it is recommended to perform a third-trimester ultrasound for reassessment and evaluation of growth. No further aneuploidy screening is necessary. If there is no previous screening test (e.g. NIPS), referral for a Fetal Medicine opinion is recommended.
25. If there is mild, moderate or severe ventriculomegaly (including low risk NIPS or no previous screening test) referral for a Fetal Medicine opinion is recommended.
26. Pregnant women with low risk NIPS or no previous screening, with fetal echogenic bowel should be referred for a Fetal Medicine opinion for further evaluation for congenital infections and consideration of cystic fibrosis carrier testing on the parents.

## Section 9: Diagnosis of fetal anomaly

### Introduction

The vast majority of babies are born healthy. However, fetal structural anomalies are found in up to 3% of pregnancies with 75% of anomalies occurring in low or normal risk women<sup>124</sup>. Prenatal ultrasound offers instantaneous information in real time. When an anomaly is suspected, the Sonographer should continue and complete the examination or seek another opinion. This situation needs to be handled with heightened sensitivity.

### Clinical Question 2.9: What should happen when a fetal anomaly is suspected/diagnosed?

### Evidence Statement

Fetal ultrasounds are performed by a variety of health care professionals including Fetal Medicine consultants, midwives, radiologists, and Sonographers, all with different training paths and levels of experience. There is a variance around the world with regard to who provides the news of a suspected anomaly with UK Sonographers and ultrasound practitioners delivering news as standard<sup>125</sup>. In other countries such as the US and Australia, policies differ according to the healthcare discipline of the ultrasound practitioner, their relationship with the referring doctor and the type of anomaly which has been identified<sup>126</sup>.

A recent systematic review explored the views, experiences and preferences of expectant parents and Sonographers when a fetal anomaly or unexpected finding was identified during an antenatal ultrasound examination<sup>127</sup>. Amongst many findings this review showed that parents needed to be able to speak to appropriate personnel and to ask questions in a timely fashion. Parents appreciated it when visual aids were used and having the correct terminology was important, as it helped parents to communicate the type of anomaly to others and to search the internet more effectively. Short time intervals between appointments were important; even brief delays were distressing. Parents wanted the phone number of a healthcare professional they could contact with questions. This review also supported the practice of disclosing news of unexpected findings immediately in the ultrasound room where appropriate.

These findings support an Irish study which highlighted that women reported rapid access for a Fetal Medicine opinion, (preferably within 24 hours of the initial ultrasound examination), was desirable. Women experienced most distress when waiting longer than this period and especially if the wait spanned a weekend, when they believed access to information was hindered<sup>128</sup>. In the UK, the FASP standard is to see a Fetal Medicine Consultant/Specialist within 5 working days<sup>17</sup>.

It is acknowledged that delivering bad news is a uniquely demanding situation which puts a strain on healthcare professionals.<sup>129</sup> Terms such as: *distressing, constant pressure, awkward position, upsets me, impossible situation, complicated, difficult, professional reputation* were used to display levels of stress, and also the resilience of Sonographers.

### Clinical Practice

#### *Anomaly is suspected/detected at an ultrasound examination*

When a fetal anomaly is detected or suspected, the situation should be dealt with sensitively and the woman and her partner should be informed, in an appropriate and private environment. If the partner

is not present it may be reasonable to wait until he/she is present before imparting this information. It may be reasonable to impart information in the absence of a partner and for the information and/or ultrasound to be repeated when the partner is in attendance.

If there is a reasonable degree of certainty of the diagnosis and the Sonographer is suitably qualified it is reasonable that this information is imparted in the ultrasound room by the Sonographer. The level of awareness and understanding of the woman should be taken into account. The Sonographer may request a second Sonographer to confirm findings and then should refer the woman to the Fetal Medicine midwife/consultant and an appointment made for follow up ideally before the woman has left the department. Every effort should be made to ensure the woman has a direct contact number of a suitable contact (e.g., a Midwife, Sonographer, clinician or co-ordinator depending on the unit) and a Fetal Medicine appointment prior to leaving the ultrasound appointment. The woman should have a full understanding of why she is being referred to Fetal Medicine services and be provided with appropriate information leaflets/reading material if deemed appropriate.

If the referring clinician (Midwife, Sonographer, or Obstetrician) does not have enough information to answer the parent's questions, they should say so, to avoid being led into answering inappropriately. Unless there is high confidence about the exact diagnosis the specific information about the significance of an anomaly should not be given until the diagnosis is clarified or confirmed. Misleading information can be particularly frustrating for the parents especially when there are subsequently significant differences between the initial diagnosis and the subsequent diagnosis.

The processes underlying news delivery in obstetric ultrasound are beyond the scope of these guidelines. Therefore, it is recommended that all Sonographers undertaking fetal anatomy ultrasound be familiar with the *Consensus Guidelines for the Communication of Unexpected news via ultrasound* by ScOR and Leeds university (Improving News Delivery in Ultrasound (INDira) and also the Australian guidelines on parent centred communication in obstetrics, <https://www.asum.com.au/standards-of-practice/obstetrics-and-gynaecology><sup>126</sup>.

### **Referral to Fetal Medicine Specialist**

It is the responsibility of the Sonographer or consultant to initiate referral to a Fetal Medicine Consultant within their own unit or if the hospital does not have an appropriately qualified person, the woman/couple should be referred to a tertiary centre. Prenatal diagnosis of a congenital anomaly ranges from being very mild with little clinical significance to severe anomalies leading to a perinatal death.

Ideally all suspected anomalies should be seen within five working days by a Fetal Medicine consultant and in cases where a major anomaly is suspected within 3 days.

This should be qualified by a degree of clinical discretion whereby a suspicion of a mild/insignificant anomaly would not require immediate referral and some anomalies should be seen as soon as possible, sometimes within 24 to 72 hours for those anomalies suspected to be fatal/lethal or life limiting, for example, with mild hydronephrosis, appropriate follow might be a repeat ultrasound at 28-32 weeks, whilst hydrops with a correctable cause should be seen as soon as is practical.

A referral form (example in Appendix 17) which can be locally adapted) should be completed. The referral should be marked routine, urgent, or very urgent. Very urgent cases should be discussed by phone with the accepting Fetal Medicine Unit (FMU) prior to sending the referral.

Women should be informed that the FMU in the tertiary hospital will contact her by telephone with an appointment with clear directions to the location in the hospital and a specific time. The accepting unit should make every effort to see women and their partners at the appointed time.

### **Communication**

Women and their partners should be offered compassionate support by experienced clinicians and must receive appropriate information and time to enable them to come to an informed decision.

This will include time to:

- Make decisions after the antenatal testing process
- Come to terms with the fact that their unborn baby has an anomaly
- Make decisions about continuing the pregnancy
- Make decisions about ending the pregnancy
- Cope with complex and painful issues after a decision, including bereavement
- Decide to have a diagnostic test.

### **Documentation**

The fetal anomaly (actual or suspected) should be documented on the ultrasound report. A clear plan with follow up appointment times and location should be outlined. Documentation of all counselling and discussions, should be clearly recorded as well as documentation of any patient information leaflets that are issued to the woman. Documentation of the anomaly and its clinical implications should also be highlighted in the main clinical notes in addition to the ultrasound report which may be overlooked.

## **Recommendations**

27. It is appropriate for appropriately experienced Sonographers who perform fetal anatomy ultrasound examinations to impart information when they are confident of the diagnosis.
28. Every unit should have referral mechanisms to Fetal Medicine services in place to manage suspected or detected fetal anomalies.
29. All women should receive a prompt referral for a Fetal Medicine opinion ideally within 5 working days. Where a major fetal anomaly is suspected referral is ideally within 3 days.
30. The woman/couple should be kept fully informed throughout the process and have the opportunity to talk fully to any relevant professionals who may be able to offer them information they require.
31. Documentation of all findings, counselling and discussion by all clinicians must be clearly documented. Communication with the referring Obstetrician/ Sonographer and GP is of paramount importance for regular updates, in order for them to provide the necessary support to the woman/couple.



## Section 10: Performing the anatomy scan

### Introduction

Adequate specialised training, accreditation and regulation is critical as part of delivery of any high-quality service.

### Clinical Question 2.10: Who should perform the fetal anatomy scan?

#### Evidence Statement

Ultrasonography is a medical procedure that should only be carried out in the clinical setting where there is a medical indication and when carried out is under the supervision of a physician or an appropriately trained expert in diagnostic ultrasound<sup>130</sup>. The Society and College of Radiographers (ScOR) and the British Medicine Ultrasound Society (BMUS) guidelines for professional practice 2019 state that 'Ultrasound equipment should only be used by people that are fully trained in its safe and proper operation' because ultrasound is highly operator dependent, requiring specialist skills and knowledge<sup>125</sup>.

The person performing ultrasound in obstetrics varies. In some countries ultrasound examinations are performed mainly by medically trained staff such as Obstetricians or Radiologists; in others, the majority are performed by technicians, Ultrasonographers, Nurses and Midwives<sup>125</sup>. It is difficult to define the optimal time needed for learning how to perform an ultrasound examination safely or the minimum number of examinations required before a trainee is able to perform an ultrasound examination without supervision.

ISUOG recommends that trainees perform at least 100 hours of supervised training to be a certified Sonographer, and the supervised training should include at least 100 obstetric ultrasound examinations and 100 gynaecology<sup>131</sup>. RCR have recommended that the trainee should perform at least 30 sessions of ultrasound in obstetrics and gynaecology within six months, each session involving three to eight supervised ultrasound examinations as a minimum<sup>42</sup>. The European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) have indicated that the trainee should perform a minimum 300 ultrasound examinations in gynaecology and a minimum 500 ultrasound examinations in obstetrics and all under supervision<sup>132</sup>.

The AIUM recommends that the trainee is required to perform at least 300 supervised ultrasound examinations within three years for each of obstetrics and gynaecology<sup>133</sup>. Although such guidelines were written for medical trainees, they are not limited to the medical field. Still, they are further recommended by the UK Consortium for the Accreditation of Sonographic Education to be included within training programmes for other disciplines such as radiography, midwifery and nursing<sup>134</sup>.

#### Reporting

The process of reporting varies internationally. Some countries, such as the United Kingdom, have a long tradition of Sonographer practice that includes the provision of a formal report<sup>17</sup>. BMUS believes that the two elements of acquiring and reporting of an ultrasound examination are interdependent and should not be separated. BMUS acknowledges that the quality of the report is paramount in ensuring clinical effectiveness of the investigation. As such BMUS (in partnership with the Society of Radiographers) has published tools to support Sonographers in producing high quality diagnostic reports<sup>125</sup>.

In Australia and New Zealand, the practice of Sonographer reporting varies considerably between individual Sonographers and between different departments<sup>135</sup>. Some Sonographers are not involved in reporting and others report all their ultrasound examinations. In the United States also, some Sonographers perform the ultrasound examinations and the physicians review the images and finalise the report. Some Sonographers/Advanced Practitioners fulfil both ultrasound examination and reporting roles and are recognised for such roles in their contracts.

## **Clinical Practice**

Sonographers are qualified healthcare professionals who undertake, report and take responsibility for the conduct of diagnostic, screening ultrasound examinations. Their individual scope of practice can be wide and varied. For those who use the professional title of 'sonographer', ultrasound is their daily work and their primary profession. Sonography is not a regulated profession and 'sonographer' and 'ultrasonographer' are not protected titles, therefore it is essential for all practitioners to be registered with a statutory regulator such as the Nursing and Midwifery Board of Ireland (NMBI), CORU or the Irish Medical Council (IMC).

Trained healthcare providers should be performing fetal ultrasounds on a regular basis with adequate case volume in order to maintain competency. They have a responsibility to be involved in professional development endeavours and medical education within their departments. Providers should also be involved in quality improvement and assurance within their departments.

Individuals without a recognised qualification, including student Sonographers, should always be supervised by qualified staff.

## **Training requirements**

Currently in Ireland, medical ultrasound is taught at postgraduate level with the majority of Sonographers entering from a healthcare background such as medicine, radiography, nursing or midwifery<sup>3</sup>. The most common pathway for Sonographers is an undergraduate degree in radiography, midwifery or nursing followed by a period of practical experience as a qualified member of staff before the individual joins a post graduate programme to undertake their ultrasound training<sup>136</sup>.

The vast majority of Sonographers across Ireland have a Master's Degree (MSc) or a Higher Diploma in Diagnostic Imaging (HDDI). The MSc Ultrasound programme develops professional competencies by integrating clinical skills with specialist theoretical knowledge. It incorporates in excess of 1000 clinical hours and has an immersive, innovative blended learning curriculum, based on continuous assessment. It should be acknowledged that there are some experienced and competent ultrasound practitioners in Ireland who may have commenced their practice before formal training and accreditation was available.

In Ireland, the MSc ultrasound course at UCD was accredited by the Consortium for the Accreditation of Sonographic Education (CASE) for a period of five years with effect from July 2019. CASE is an organisation which traditionally accredits sonographic courses delivered within the UK and this is the first time courses from outside the UK have been accredited. CASE works closely with universities and other higher-education institutions to ensure the highest standards in ultrasound education are met.

Training for medical practitioners is delivered through medical training programmes, later complemented by subspecialist training in ultrasonography and maternal Fetal Medicine, such as fellowships accredited by the Royal College of Physicians of Ireland and the Royal College of Obstetricians and Gynaecologists, UK.

**Reporting**

The responsibility for reporting lies with the person verifying the ultrasound examination who, ordinarily, should be the person performing the ultrasound. There must be a permanent record of the ultrasound examination and its findings. Images of all relevant areas defined in the particular examination, both normal and abnormal, should be recorded by the person doing the examination. However, report templates can be designed locally in collaboration with referring clinicians to ensure that the required information is given consistently and in a clear and concise manner.

Retention of the ultrasound images and report should be consistent both with clinical needs and with relevant legal and local requirements. Communication between the interpreting provider and the referring provider should be clear, timely, and in a manner that minimises potential errors. All communication should be performed in a manner that respects the woman's confidentiality.

Whether still images or cine images (or both) are captured, the archived images should contain the following:

- Woman's name, hospital number and other identifying information
- Facility's identifying information
- Date and time of the ultrasound examination
- Output display standard (thermal index and mechanical index)
- Label of the anatomic structure if not obvious.

An ultrasound examination report should be produced. Table 3 lists the information a report should contain, at a minimum.

**Table 3: Information to include in ultrasound report**

1.	The number of fetuses
2.	Cardiac activity (present or absent)
3.	Fetal size recorded on appropriate centile charts
4.	The 25 images outlined in Appendix 9
5.	Placental site in relation to the cervix
6.	Amniotic Fluid (normal, polyhydramnios, oligohydramnios or anhydramnios)
7.	Technical factors, such as increased BMI affecting the resolution and image quality, should be recorded on the report
8.	An ultrasound report filed in the woman's chart
9.	An electronic copy of the report should be stored and archived
10.	Communication of the report and images must comply with local policy

### **Continuous professional development**

It is essential that Sonographers continue to maintain and update their knowledge and skills in obstetric ultrasound examinations. As doctors, radiographers, nurses and midwives it is a requirement for them to keep a record of their CPD. This is achieved through participation in audits, internal and external training events and self-learning and study days. Professional development review (PDR) should be encouraged for each health professional performing ultrasound screening.

### **Preceptorship**

A recently published *Preceptorship and Capability Development Framework for Sonographers* by BMUS, provides guidance on preceptorship of Sonographers. They recommend that a preceptorship period should be a formal programme with clear expectations of both the preceptor, preceptee and the employing organisation. There should be a written agreement between the preceptor and preceptee to provide clarity of roles and responsibilities within the preceptorship timeframe. This will help the newly qualified Sonographer to cope more effectively with these challenges. This will help to maintain wellbeing and build resilience among newly qualified Sonographers<sup>13,7</sup>.

## **Recommendations**

32. Fetal anatomy ultrasound examinations should be performed by healthcare providers with specialised training in the provision of ultrasound screening in the second trimester.
33. There must be a permanent record of the ultrasound examination and its findings. Images of all relevant areas defined in the particular examination, both normal and abnormal, should be recorded and should be stored for future reference by the person doing the examination. The responsibility for reporting lies with the person verifying the scan who, ordinarily, should be the person performing the scan.
34. Sonographers performing fetal anatomy ultrasound examination should hold at least one of the following qualifications: Higher Diploma in Diagnostic Imaging/ MSc Ultrasound (or equivalent) from a Higher Education Institution relevant to obstetric ultrasound, or Advanced Training Speciality Module (ATSM) in Fetal Medicine.
35. Individuals without a recognised qualification, including student sonographers, should always be supervised by qualified staff. A formal period of monitoring by a senior member of staff should be implemented for all new and temporary staff to confirm their ultrasound interpretation and reporting abilities.
36. Ultrasound practitioners should be registered with the relevant statutory body where appropriate. Ultrasound practitioners are required to keep a record of their continuous professional development as defined by their registering body.

## Section 11: Factors affecting the quality of fetal anatomy ultrasound

### Introduction

There are many factors affecting the quality of ultrasound examinations, including personnel expertise, ultrasound equipment, time allowed for examination<sup>138</sup>. The role of clinical audit and leadership is also important.

### Clinical Question 2.11: What factors affect the quality of the fetal anatomy ultrasound examination?

#### Evidence Statement

The 2005 RCR in the UK Standards for ultrasound equipment stated that a formally agreed equipment review and replacement programme is highly desirable because of rapid changes in technology and changing clinical expectations and needs. High-specification ultrasound machines will often have a longer useful life than basic- or middle-range equipment. In the UK these assessments are typically undertaken between four to six years following installation. Depending on the outcomes of this review, a decision can then be made whether to continue to use the equipment or to obtain a replacement system<sup>139</sup>.

The American Institute of Ultrasound in Medicine (AIUM) states that ultrasound equipment must meet *all* state and federal guidelines. Studies must be conducted with real-time equipment, and transducers must be available with a frequency range that will optimize beam penetration and resolution. The equipment used for diagnostic imaging must be maintained in good operating condition and undergo routine quality assurance at least once a year or more frequently if problems arise. Regular assessment of transducer operation and quality control of repaired transducers are critical for optimal patient care. Practices must follow recommendations from manufacturers regarding transducer testing and repair<sup>133</sup>.

#### Safety

There is no evidence that diagnostic ultrasound has produced any harm to the fetus in the time it has been in use. However, the acoustic output of modern equipment is generally much greater than that of the early equipment and, in view of the continuing progress in equipment design and applications, outputs may be expected to continue to be subject to change. Also, investigations into the possibility of subtle or transient effects are still at an early stage. Consequently, diagnostic ultrasound should only be considered safe if used prudently.

The most reassuring data regarding long-term development have been from follow-up evaluation of children whose mothers participated in the Norwegian and Swedish randomised trials. Hoglund Carlsson *et al* analysed school performance, as assessed by the children's teachers, of children aged 8 to 9 years from the Norwegian trials. There were no differences in various measures, ranging from test scores to the proportion classified as dyslexic, between children exposed to ultrasound as a routine versus those who received usual care. Also, there is no independently confirmed peer-reviewed published evidence that a cause-effect relationship exists between in utero exposure to clinical ultrasound and development of ASD in childhood from recent high-quality studies<sup>140</sup>. However, BMUS states that "all unnecessary exposure to the human body should be avoided as it provides no medical benefit to outweigh any potential harm. In particular, ultrasound should not be used on pregnant women solely for 'entertainment' or 'bonding' purposes"<sup>125</sup>.

ISUOG mandates that ultrasound be performed by health professionals trained in its clinical use and bioeffects while disapproving of the use of US for the sole purpose of souvenir images<sup>141</sup>. This is also supported by The World Federation of Ultrasound in Medicine and Biology (WFUMB)<sup>130</sup>. The AIUM states the use of a diagnostic ultrasound machine for entertainment purposes, without a medical request, may be in violation of state laws or regulations<sup>133</sup>.

### **Examination times**

The time allowed for an ultrasound examination should take into account the fact that the actual transducer time is only a component of the overall examination. Time needs to be allowed for room preparation, assessing the ultrasound request, introductions and explanations, obtaining valid consent and assisting the woman when necessary onto and off the examination couch.

Post-procedure time is required to discuss the findings with the woman, write the report, archive the images and attend to the after-care of the woman, including making arrangements for further appointments and/or further investigations. Equipment will also need cleaning and disinfecting as required post examination.

An ultrasound practitioner has a professional responsibility to ensure that the time allocated for an examination is sufficient to enable it to be carried out and reported safely and competently, with critical and urgent findings dealt with appropriately. The allocated appointment time will vary depending on the type and complexity of the ultrasound examination. It may also be influenced by the expertise of the ultrasound practitioner and training commitments within the department. In addition, the duration of the examination will be influenced by the ultrasound findings. The quality of equipment and general support available to the Sonographer are also relevant.

Scheduling must take other considerations into account, including the impact of women arriving late for appointments, discovery of unexpected anomalies, and women not attending their scheduled appointments.

There is no universally accepted duration for the routine anatomy ultrasound and examination times are not reported by most authors. Some studies have shown that in a 30-minute examination, Sonographers succeeded in obtaining visualization of cranial anatomy including lips, face, midline, ventricles, choroid plexus, and cerebellum in 98% of women<sup>142</sup>. The corresponding figures for spine, cardiac screening (four chamber, aortic, and pulmonary outflow views) and for abdominal anatomy (stomach, kidneys, bladder, ventral wall, and three-vessel cord) were 91%, 91%, and 99%, respectively. Other studies recommending 30 minute appointments for the anatomy ultrasound examination found an average examination time of 23 min and mean examination time for the heart structures was 4 min<sup>138</sup>. The duration of the ultrasound was influenced by the maternal BMI and the fetal position. The most difficult organs to visualise were the heart and the face with optimal visualisation rates of less than 80%.

Published times by the Fetal Anomaly Screening Programme (FASP) and the National Institute for Health Care and Excellence (NICE) recommend 30 minutes for a singleton pregnancy and 45 minutes for a multiple pregnancy anatomy ultrasound examination<sup>17</sup>.

The BMUS Guideline sets out image quality requirements, quality assurance and equipment replacement in the RCR/SCoR document "Standards for the provision of an ultrasound service"<sup>139</sup>.

### **Clinical Practice**

An ultrasound examination should be performed by using real time scanning with TAUS and TVUS capabilities, on an appropriate ultrasound machine. The choice of transducer is a trade-off between beam penetration and resolution. Generally, probes of 3-9MHz allows sufficient penetration in most women whilst providing adequate resolution. In obese women, a lower frequency probe may be needed

to provide increased penetration. There must be adequate display/screen size for sufficient clear visualisation. The availability of M mode, colour, harmonics; Power and spectral Doppler is advisable as well as Tissue-specific pre-sets for individual clinical applications e.g., cardiac. Adjustable acoustic power output controls with output display should be standard. Freeze frame capabilities; electronic callipers; and capacity to print and or store images should be available.

All ultrasound equipment should undergo regular planned preventative maintenance by qualified personnel and there should be an agreed quality assurance programme in place that incorporates the regular inspection of ultrasound machines and ancillary equipment.

The safety issues require an appreciation of the potential thermal and mechanical bioeffects of ultrasound, a full awareness of equipment settings and an understanding of the effects of machine settings on power levels. Whilst users may not have a full understanding of the physical properties of ultrasound imaging, they must be aware of the need to limit examination times and only use equipment for the proposed medical purpose. Ultrasound exposure depends on many factors, including the examination type, the woman's body habitus and equipment settings. Some modes, such as B-mode have a lower potential for tissue damage than Doppler, with pulsed Doppler techniques having the potential for the highest exposure levels. Examination times should be kept as short as is necessary to produce a useful diagnostic result. Output levels should be kept as low as is reasonably achievable (ALARA principle) while producing a useful diagnostic result.

Ultrasound imaging for non-medical reasons is not recommended unless carried out for education, training or demonstration purposes.

### **Scheduling**

It is recommended that a 30-minute time slot is allocated for a singleton pregnancy, to include time allowed for generation of a report for the woman's medical record. A twin anatomical survey should be allocated 45 minutes at a minimum.

### **Archiving and storage**

Ultrasound images should be captured, stored and archived on an electronic reporting system. There should be a permanent electronic record of all imaging studies. All imaging studies should be accompanied by an electronic report available with the images. Every obstetric ultrasound service should be able to upload ultrasound reports and images on an auditable electronic hospital reporting system in order to provide audit data. All required images should be captured, stored and archived for the purposes of a complete maternal record and to fulfil medico-legal requirements. Maternity care providers should be supported with sufficient clerical support, appropriate information technology (IT), equipment and software.

### **Video recording**

Video recording by a third party during the examination can be very distracting for Sonographers. These distractions can lead to errors being made when they might not otherwise have been<sup>102</sup>. Therefore under normal circumstances when a partner or support person can be in attendance at the ultrasound examination we do not recommend the use of telephone or video recording of the examination. To minimise distractions for both Sonographer and the woman, children should not attend the examination.

Clear signage indicating that video recording and attendance by children is strongly discouraged in all departments.

There may be some situations when additional support is needed and local policies should be in place to determine whether recording of the examination is appropriate.

## Recommendations

37. It is recommended that a 30 minute time slot is allocated for a singleton pregnancy and a minimum of 45 minute time slot allocated for a multiple pregnancy anatomy ultrasound examination. The ALARA principle regarding output power and duration of ultrasound exposure ('as low as reasonably achievable') should be observed.
38. Ultrasound imaging for non-medical reasons is not recommended unless carried out for education, training or demonstration purposes.
39. The use of telephone or video recording of the anatomy ultrasound examination is not recommended. However, there may be some situations where it is appropriate and local policies should be in place to determine whether recording of the examination is reasonable.
40. Due to the possible sensitive nature of the fetal anatomy ultrasound examination, children should not attend the examination.



# Chapter 3: Development of Clinical Practice Guideline

## 3.1 Literature search strategy

A comprehensive literature review was undertaken which included national and international publications.

The methodology is described in detail in The National Clinical Effectiveness Committee (NCEC) 2019 for guideline development<sup>143</sup>.

To formulate the clinical questions they were broken down into their component parts using the PICO framework:

- Participant/Population
- Intervention/Exposure
- Control/Comparison
- Outcome

Published literature was retrieved through searches of PubMed or MEDLINE and The Cochrane Library in September 2021. Date restrictions were applied to the last 5 years. The keywords used to create the search were:

- Second Trimester OR Midtrimester OR Mid Trimester OR mid-trimester OR Second Pregnancy Trimester OR “Pregnancy Trimester”
- Ultrasound OR sonogram OR Level 2 scan OR fetal anomaly scan OR fetal anatomy scan OR foetal anomaly scan OR foetal anatomy scan OR diagnostic scan OR fetal assessment scan OR foetal assessment scan OR midtrimester scan OR ultrasonography OR screening scan OR obstetric scan OR fetal examination OR foetal examination OR routine ultrasound

MeSH terms were also applied: (Fetal OR Foetal OR fetus\* OR Foetus\* OR “Fetus” AND Ultrasound\* OR screen\* OR structural assessment\* OR Structural survey\* OR ultra-sound OR ultra-sonogra\* or ultrasonography OR sonogra\* OR echography OR Scan\*.

## 3.2 Appraisal of evidence

The evidence which addressed each clinical question, both from international guidelines and primary literature, was extracted. Recommendations were formulated through a formal structured process. A ‘considered judgment form’ (adapted from SIGN; see NCEC) Methodology Manual 2019) was completed for each clinical question<sup>144</sup>.

The following items were considered:

- What evidence is available to answer the clinical question?
- What is the quality of the evidence?
- Is the evidence consistent?

- Is the evidence generalisable to the Irish population?
- Is the evidence applicable in the Irish context?
- What is the potential impact on the health system?
- What is the potential benefit versus harm to the woman?
- Are there resource implications?

### 3.3 AGREE II process

While being developed, the Guideline was assessed using the AGREE II checklist (Appendix 20) as recommended by the Department of Health<sup>12</sup> in the 'How to Develop a National Clinical Guideline Manual', 2019<sup>143</sup>.

The purpose of AGREE II is to provide a framework to:

1. Assess the quality of guidelines;
2. Provide a methodological strategy for the development of guidelines; and
3. Inform what information and how information ought to be reported in guidelines

### 3.4 Literature review

The GDG met to consider the clinical questions to be addressed. A scoping review of the literature was undertaken in January 2022 using the key word outlined in 3.1. Searches were restricted to systematic reviews, meta-analyses, randomized control trials and clinical trials. Due to the time frame it was not possible to perform a systematic review for each of the topics explored. The search was also restricted to humans and the English Language. Literature searches were conducted by Ann Fleming and an Endnote library was set up for each database. They were combined to one library where duplicates were removed using Endnote software and also by hand. The titles were screened for relevance to the review. Of the relevant articles the abstract was screened. From the selected articles relevant data was extracted from the studies which fulfilled the requirements of each clinical question. Evidence was appraised according to study design, study sample size, methodology, primary and secondary outcomes, applicability, and relevance to the PICO question.

A lack of high quality data on outcomes following fetal anatomy ultrasound examination from randomised controlled trials (RCTs) was observed. Where evidence is lacking, these guidelines utilise the experience and constructed Guidelines of other Associations. These include: The International Society of Obstetrics and Gynaecology (ISUOG); The American Institute of Ultrasound in Medicine (AIUM); Australia and New Zealand College of Obstetricians and Gynaecologists (RANZCOG); American College of Radiology; The Society of Radiology; The Society of Obstetricians and Gynaecologists of Canada (SOGC); The National Institute for Health and Care (NICE); The National Guideline Clearinghouse; The NHS Fetal Anomaly Screening Programme; The Royal College of Obstetricians and Gynaecologists; The Royal College of Radiologists; British Medical Ultrasound Guidelines; The International Federation of Gynaecology and Obstetrics (FIGO); The French College of Gynaecologists and Obstetricians; The Danish Fetal Medicine Society (DFMS); Polish Society of Gynaecologists and Obstetricians; Norwegian Society of Gynaecology and Obstetrics; Society of Maternal and Fetal Medicine (SMFM) and the German Society of Obstetrics and Gynaecology.

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12 Department of Health (2019). How to develop a National Clinical Guideline: a manual for guideline developers. Available at: <https://www.gov.ie/en/collection/cd41ac-clinical-effectiveness-resources-and-learning/>

Further studies were identified through a bibliography search and referred where appropriate throughout the document.

### 3.5 Grades of recommendation

GRADE<sup>13,14</sup> offers a transparent and structured process for developing and presenting evidence summaries and for carrying out the steps involved in developing recommendations<sup>145,146</sup> While we acknowledge that for this particular work an extensive approach is not possible, we have used the suggested language set out in the table when making recommendations<sup>147</sup>. (Appendix 21)

Due to the number of international guidelines used in these guidelines and the variation in how the evidence and strength of recommendations were graded, it was decided by the GDG to retain the grading as per original documents. The GDG accepts that this translation is limited in its accuracy. Best Practice points were developed by the GDG to provide guidance on important aspects of fetal anatomy ultrasound examination that had little existing evidence base but were agreed by GDG consensus.

### 3.6 Future research

An important outcome of the guideline development process is in highlighting gaps in the evidence base.

The questions of relevance to this Guideline include the following examples

- Evaluation of the woman's understanding of fetal anatomy ultrasound
- The natural history of vasa praevia in an unselected population
- The usefulness of a Fetal Medicine opinion after two attempts resulting in suboptimal ultrasound where all required anatomical pictures have not been seen/obtained
- Performance of routine TVUS at the fetal anatomy ultrasound when the placental edge is within 2 cms of the internal cervical os
- Optimal ultrasound duration for singleton and multiple examinations
- Usefulness of captured cardiac videos versus still images
- Strategies to improve the performance of the fetal anatomy ultrasound in women with a high BMI.

13 Guyatt, Gordon, *et al.* "Guidelines: 1. Introduction—Evidence Profiles and Summary of Findings Tables." *Journal of Clinical Epidemiology*, vol. 64, no. 4, 2011, pp. 383–94, <https://doi.org/10.1016/j.jclinepi.2010.04.026>

14 SMFM adopts (Grading of Recommendations Assessment, Development, and Evaluation) for clinical guidelines. Society for Maternal-Fetal Medicine (SMFM), Chauhan SP, Blackwell SC. *Am J Obstet Gynecol.* 2013 Sep;209(3):163-5. doi: 10.1016/j.ajog.2013.07.012. PMID: 23978245 <https://pubmed.ncbi.nlm.nih.gov/23978245/>

# Chapter 4: Governance and Approval

## 4.1 Formal governance arrangements

This Guideline was written by the Guideline Developers under the direction of the Guideline Programme Team. An Expert Advisory Group was formed to review the Guideline prior to submission for final approval with the National Women and Infants Health Programme. The roles and responsibilities of the members of each group and their process were clearly outlined and agreed.

## 4.2 Guideline development standards

This Guideline was developed by the Guideline Developer Group (GDG) within the overall template of the HSE National Framework<sup>148</sup> or developing Policies, Procedures, Protocols and Guidelines (2016) (Appendix 23) and under supervision of the Guideline Programme Team (GPT)<sup>15</sup>.

A review was conducted by a group of experts, specialists and advocates (EAG) prior to approval by the Clinical Advisory Group (CAG) of the National Women and Infants Health Programme (NWIHP) with final sign off for publication by CAG Co-Chairs, the Clinical Director of NWIHP and the Chair of the IOG. See appendix 22 for list of CAG members.

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15 Health Service Executive (2016). National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs). Available from: <https://www.hse.ie/eng/about/who/qid/nationalframeworkdevelopingpolicies/>

# Chapter 5: Communication and Dissemination

A communication and dissemination plan for this Guideline has been developed by the GPT and endorsed by NWIHP.

Effective ongoing clear communication is essential in explaining why the guideline is necessary and securing continued buy-in<sup>16</sup>. It provides an opportunity to instil motivation within staff, helps overcome resistance to change and gives an opportunity for feedback<sup>144</sup>.

The Clinical Guideline will be circulated and disseminated through the Guideline Programme Team as well as through the professional networks who participated in developing and reviewing the document.

Senior management within the maternity units are responsible for the appropriate dissemination of new and updated guidelines. Local hospital groups including guideline committees are also instrumental in the circulation of new and updated guidelines and promoting their use in the relevant clinical settings.

The HSE will make this Guideline available to all employees through standards networks as well as storing it in the online PPPG repository. Electronic versions available on the NWIHP and RCPI websites (<https://www.rcpi.ie/faculties/obstetricians-and-gynaecologists/national-clinical-guidelines-in-obstetrics-and-gynaecology/>) and other communication means can be used to maximise distribution. The NWIHP website will also provide a training webinar introducing each Guideline and where relevant a downloadable version of the recommended algorithm will be available.

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16 Department of Health (2018). NCEC Implementation Guide and Toolkit. Available at: <https://health.gov.ie/national-patient-safety-office/ncec/>

# Chapter 6: Implementation

## 6.1 Implementation plan

Implementation was considered at the beginning, and throughout the Guideline development process. The local multidisciplinary clinical team, senior executive and clinical management in each maternity and gynaecology unit are ultimately responsible for the appropriate structured adoption and implementation of the guidelines within their area of responsibility. They must ensure that all relevant personnel under their supervision have read and understood the Guideline and monitor both its effectiveness and adoption.

Within each site, local multidisciplinary teams are responsible for the clinical implementation of Guideline recommendations, and ensuring that their local clinical practices and processes reflect and are aligned with the Guideline recommendations.

In the case of this Guideline senior management teams should support ultrasound services by ensuring that there is adequate staffing, ultrasound examination rooms and ultrasound machines to provide the recommended standards for the fetal anatomy ultrasound examination to every woman engaging in the service.

The following have been put in place to help facilitate the implementation of this Guideline.

- Quick Summary Document (QSD) for clinical staff (includes key recommendations, auditable standards, and recommended reading)
- Clinical Guideline mobile application
- Plain language summary

## 6.2 Education plans required to implement the Guideline

It is acknowledged that this Guideline should be complemented by ongoing education, training and assessment where required. We acknowledge that access to scanning simulators to optimise training opportunities is of value in maintaining sonography skills. It is also essential to provide support for ongoing professional development.

## 6.3 Barriers and facilitators

To ensure successful implementation of guidelines, it is first necessary to look at potential barriers and facilitators. Taking these into account when developing the implementation plan should improve levels of support from relevant users <sup>143,144</sup>.

Barriers may be categorised as internal (specific to the Guideline itself) or external (specific to the clinical environment).

The Guideline Development Group has aimed to address any internal barriers during the development of this Guideline.

Potential external barriers include:

- Structural factors (e.g., budget or service redesign)
- Organisational factors (e.g., lack of facilities or equipment)
- Individual factors (e.g., knowledge, skills, training)
- Patient perceptions

In the case of this Guideline it will be necessary to examine possible barriers and consider implementation strategies to address them. By example, this may include discussion with relevant management groups with regards budgetary impact or providing training to or upskilling the relevant staff.

## **6.4 Resources necessary to implement recommendations**

The implementation of this Guideline should be undertaken as part of the quality improvement of each hospital. Hospitals should review existing service provision against this Guideline, identifying necessary resources required to implement the recommendations in this Guideline.

Of note are the following issues:

### **Ultrasound equipment**

Ultrasound machinery used for the fetal anatomy ultrasound scan should be capable of producing images of diagnostic quality and include the following features:

- adequate display/screen size for sufficient clear visualisation
- magnification facility
- Freeze frame capabilities
- cineloop function
- callipers that have a precision to one decimal point
- adjustable signal processing facilities
- tissue-specific pre-sets for individual clinical applications (e.g., cardiac)
- adjustable acoustic power output controls with output display
- appropriate transducers (including 3-D) relevant to gestational age
- Doppler (Colour, Power, spectral), M-mode and harmonic function
- capacity to print and or store images

All ultrasound equipment should undergo regular planned preventative maintenance by qualified personnel and there should be an agreed quality assurance programme in place in each maternity unit/hospital that incorporates the regular inspection of ultrasound machines and ancillary equipment<sup>17,133</sup>.

Ultrasound images should be captured, stored and archived on an electronic reporting system. There should be a permanent electronic record of all imaging studies. All imaging studies should be accompanied by an electronic report available with the images. Every obstetric ultrasound service should be able to upload ultrasound reports and images on an auditable electronic hospital reporting system in order to provide audit data<sup>138,139</sup>.

### **Ultrasound training**

Fetal anatomy ultrasound examinations should be performed by healthcare providers with specialised training in the provision of ultrasound screening in the second trimester. Sonographers performing fetal anatomy ultrasound examination should hold at least one of the following qualifications: Higher Diploma in Diagnostic Imaging / MSc Ultrasound (or equivalent) from a Higher Education Institution relevant to obstetric ultrasound, or Advanced Training Speciality Module (ATSM) in Fetal Medicine.

Trained healthcare providers should also be performing fetal ultrasounds on a regular basis with adequate case volume in order to maintain competency. They have a responsibility to be involved in professional development endeavours and medical education within their departments. Providers should also be involved in quality improvement and assurance within their departments<sup>131,132</sup>.

CPD should be achieved through participation in audits, internal and external training events and self-learning and study days in each hospital/unit or hospital group. Professional development review (PDR) should be encouraged for each health professional performing ultrasound screening<sup>134</sup>.

### **Screening for aneuploidy**

This Guideline discusses the role of NIPS in management of soft markers detected at the fetal anatomy ultrasound. The introduction of NIPS has greatly improved the ability to screen for aneuploidies over and above maternal age or soft marker screening, and it is offered as a first-choice screening test for all pregnant women in many high-income countries<sup>107</sup>.

With increasing numbers of women availing of NIPS the significance of soft markers has diminished. However, it should be noted that the vast majority of women in Ireland do not have access to NIPS, as there is no national screening programme for fetal anomaly or fetal aneuploidy, and NIPS still remains cost-prohibitive for most of the population<sup>109, 110</sup>.



# Chapter 7: Audit and Evaluation

## 7.1 Introduction to audit

It is important that both implementation of the Guideline and its influence on outcomes are audited to ensure that this Guideline positively impacts on patient care. Institutions and health professionals are encouraged to develop and undertake regular audits of Guideline implementation. Personnel tasked with the job of conducting the audit should be identified on receipt of the most recent version of the Guideline.

## 7.2 Auditable standards

Audit using the key recommendations as indicators should be undertaken to identify where improvements are required and to enable changes as necessary. Audit should also be undertaken to provide evidence of continuous quality improvement initiatives.

Suggestions of auditable standards might include:

- The number of hospitals providing pregnant women the opportunity to have an anatomy ultrasound examination
- The number of hospitals providing pregnant women written information in advance of the ultrasound examination
- The number of hospitals obtaining written informed consent to perform the anatomy ultrasound examination
- The number of hospitals allocating a 30 minute slot for each ultrasound appointment for a singleton and a 45 minute slot for a twin pregnancy
- The number of examinations that are completed according to the required checklist for the fetal anatomy ultrasound (Appendix 9)
- The number of pregnant women that are recalled for a second anatomy ultrasound examination
- The number of women where the ultrasound examination remains incomplete following a second examination
- The number of hospitals that have a policy in place for referral when an anomaly is suspected/ diagnosed on the fetal anatomy ultrasound examination
- The number of pregnant women that are seen within 5 working days of a suspected or confirmed anomaly and within 3 working days for a major fetal anomaly
- The number of hospitals that audit images from the fetal anatomy ultrasound examination
- The number of hospitals that audit and report the numbers and types of fetal anomalies detected at fetal anatomy ultrasound examinations
- The number of hospitals that have clear guidelines for managing clinical incidents relating to fetal anatomy ultrasound.

### **7.3 Evaluation**

Evaluation is defined as a formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved <sup>149</sup>. Implementation of this Guideline will be audited periodically at national level, with standards for this set by the NWIHP. Evaluation of the auditable standards should also be undertaken locally by senior hospital clinical management to support implementation.

# Chapter 8: Revision Plan

## 8.1 Procedure for the update of the Guideline

It may be a requirement to amend, update or revise this Guideline as new evidence emerges. This Guideline will be reviewed at national level every three years, or earlier if circumstances require it, and updated accordingly<sup>14</sup>.

The Guideline Development Group will be asked to review the literature and recent evidence to determine if changes are to be made to the existing Guideline. If the Guideline Development Group are unavailable, the GPT along with the NWIHP senior management team will select a suitable expert to replace them.

If there are no amendments required to the Guideline following the revision date, the detail on the revision tracking box must still be updated which will be a new version number and date.

The recommendations set out in this Guideline remain valid until a review has been completed.

## 8.2 Method for amending the Guideline

As new evidence becomes available it is inevitable that Guideline recommendations will fall behind current evidence based clinical practice. It is essential that clinical guidelines are reviewed and updated with new evidence as it becomes available.

In order to request a review of this Guideline one of the following criteria must be met:

- a. 3 years since the Guideline was published
- b. 3 years since last review was conducted
- c. Update required as a result of new evidence

Correspondence requesting a review of the Guideline should be submitted to the National Women and Infants Health Programme. Any such requests should be dealt with in a timely manner.

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# Glossary

## (for the purpose of this Guideline)

**ACOG** American College of Obstetricians and Gynaecologists

**AGREE** Appraisal of Guidelines for Research and Evaluation

**AEDs** Anti-Epileptic Drugs

**AIUM** American Institute of Ultrasound in Medicine

**APH** Antepartum Haemorrhage

**ASUM** Australasian Society for Ultrasound in Medicine

**ATSM** Advanced training specialty module

**BCCA** British Congenital Cardiac Association

**BMI** Body Mass Index

**BMUS** British Medicine Ultrasound Society

**CAG** Clinical Advisory Group

**CASE** Consortium for the Accreditation of Sonographic Education

**CPD** Continuous Professional Development

**DoH** Department of Health

**EAG** Expert Advisory Group

**EFSUMB** European Federation of Societies for Ultrasound in Medicine and Biology

**EUROCAT** European Registration of Congenital Anomalies and Twins

**FASP** Fetal Anomaly Screening Programme

**FIGO** International Federation of Gynaecology and Obstetrics

**FMF** Fetal Medicine Foundation

**FMU** Fetal Medicine Unit

**GP** General Practitioner

**GPT** Guideline Programme Team

**GRADE** Grading of Recommendations, Assessments, Developments and Evaluations

**HIQA** Health Information and Quality Authority

**HSE** Health Service Executive

**IMC** Irish Medical Council

**IOG** Institute of Obstetricians and Gynaecologists

**ISUOG** International Society of Ultrasound in Obstetrics and Gynaecology

**IVF** In-vitro fertilisation

- LLETZ** Large Loop Excision of the Transformation Zone
- LR** Likelihood Ratio
- MEDLINE** Medical literature Analysis and Retrieval System Online
- MeSH** Medical subject heading
- MFM** Maternal Fetal Medicine
- NCEC** National Clinical Effectiveness Committee
- NHS** National Health Service
- NHS FASP** National Health Service Fetal Anomaly Screening Programme
- NICE** National Institute of Clinical Excellence
- NICE** National Institute for Health and Clinical Excellence
- NICU** Neonatal Intensive Care Unit
- NIPS** Non-Invasive Prenatal Screening
- NMBI** Nursing and Midwifery Board of Ireland
- NWIHP** National Women and Infants Health Programme
- PICO** Population, Intervention, Comparison and Outcome
- PPPG** Policy, Procedures, Protocols and Guidelines
- PTB** Preterm Birth
- RANZCOG** Royal Australia and New Zealand College of Obstetricians and Gynaecologists
- RCOG** Royal College of Obstetrics and Gynaecologists
- RCPI** Royal College of Physicians of Ireland
- RCR** Royal College of Radiologists
- RCSI** Royal College of Surgeons in Ireland
- RCT** Randomised controlled trial
- ROB** Risk of Bias
- ROBINS** Risk of Bias in Nonrandomised studies of intervention
- SCoR** Society and College of Radiographers
- SMFM** Society for Maternal-Fetal Medicine
- SOGC** The Society of Obstetricians and Gynaecologists of Canada
- SPR** Society for Paediatric Radiology
- SRU** Society of Radiologists in Ultrasound
- ToRCH** Toxoplasmosis, Rubella, CMV, Herpes Virus Serology
- TTTS** Twin-To-Twin Transfusion Syndrome
- UK** United Kingdom
- UK NSC** United Kingdom National Screening Committee
- WHO** World Health Organisation

# Appendix 1: Information Leaflet and Consent on the Fetal Anatomy Ultrasound (sample)

Congratulations and Welcome to the [name of hospital]

We offer all pregnant women an ultrasound scan at approximately 20-22 weeks. This leaflet aims to explain the benefits and the limitations of this routine anatomy ultrasound scan.

## The Scan

Ultrasound is performed using high frequency sound waves that bounce off the body structures to form a picture of your baby. By 20 weeks, your womb is normally big enough that the scan can be done without a full bladder. The scan is safe and painless but the sonographer might need to apply slight pressure to get clear views of your baby. The appointment usually takes up to 30 minutes. You may find the sonographer is quiet during the scan; it is important for them to be able to concentrate on this detailed examination.

## What will happen?

- You will be asked to lie on a couch.
- You will be asked to raise your top to your chest and lower your skirt/trousers to your hips. Tissue paper will be tucked into your clothes to protect them from the ultrasound gel. The gel is put on your tummy and may be cold.
- The sonographer will move a hand-held device, called a probe, over your tummy to carefully examine your baby's body.
- The gel makes sure there is good contact between the probe and your skin.

This scan at 20-22 weeks is a screening test to check the anatomy of your baby. The size of the baby's head, tummy and thigh bone are measured. The internal organs including the brain, heart, stomach, kidneys and bladder are examined. We also try to image the baby's spine, limbs and face. The placenta (afterbirth) and the amniotic fluid ('waters') are examined.

## What affects the Quality of the Scan?

Sometimes, because of the position of the baby and/or due to conditions like fibroids or increased weight in the mother, we may not achieve the best image. We occasionally recommend an internal (vaginal) scan depending on the issues in a particular pregnancy. A woman's weight has a major influence on the ability to see the baby, as the sound waves don't penetrate as well, giving less clear images. Many studies have shown less accuracy in identifying fetal anomalies in mothers with higher weight.



## Possible results of the anatomy scan

In up to 15% of cases, we need to repeat the scan to get a better view of a particular part of the baby. This does not mean that there is something wrong but a repeat scan will be booked for you to complete the examination. The vast majority of pregnancies are normal and most scans show that the baby appears to be developing as expected. You will be told if something unexpected is found during your scan. Should there be a concern on your scan, we will arrange a timely review with a Fetal Medicine Specialist.

It is important to note that scans cannot diagnose or detect all conditions. There is always a chance that a baby may be born with a condition that could not be seen on scan.

## Limitations of the Scan

2-3% of babies are born with a birth defect. The scan can detect some but not all of these defects. Many conditions like autism and cerebral palsy cannot be detected by ultrasound. Down Syndrome may be associated with heart and bowel problems but many cases of Down Syndrome present for the first time late in pregnancy or after birth.

**Overall the anatomy scan detects two thirds of problems in the baby and does not detect one third.**

## Frequently asked questions

### Can I find out if I am having a girl or a boy?

The fetal sex is often seen on the scan but it is not always possible to tell for sure. The baby may be lying in a position where the genital area is not visible. We do not offer repeat scans for the sole purpose of identifying the gender of the baby.

### Can I have a picture of my baby?

Yes of course, but this depends on the baby being in the right position to get a good picture! We try our best to give you good pictures to take home as mementos of your scan.

### Can I record the scan?

Mobile phones or other recording devices are not usually permitted. Recording devices can divert the sonographer's attention when they most need to concentrate. We very much appreciate your understanding and cooperation

**For further information or advice, please contact...**

**Conditions we screen for and detection rates we expect to identify before the birth of a Baby**

Condition	Explanation	Chance of being seen (%)
Open Spina Bifida	Lesion in the spinal cord	90
Anencephaly	Absence of the top of the head	99
Hydrocephalus	Excess fluid in the brain	60
Major congenital heart disease	Heart defects that are likely to need surgery soon after birth	60
Diaphragmatic hernia	A defect in the muscle that separates the chest and the abdomen	60
Exomphalos/Gastroschisis	Defects of the abdominal wall	90
Major kidney problems	Missing or very abnormal kidneys	75
Major limb problems	Missing bones or very short limbs	15
Cleft lip	A separation in the upper lip	75
Cerebral Palsy		Cannot be seen
Autism		Cannot be seen
Down Syndrome	This condition may be suspected on ultrasound but diagnosis is confirmed by genetic tests. About 40% of cases will be known before birth	

**Consent**

Below is an example of written consent that can be added to the information leaflet. It is recommended that consent is obtained by the person responsible for the ultrasound examination. The woman should read the information leaflet and sign the form if she agrees with them.

I have read the provided information leaflet and understand the reason for performing the fetal anatomy ultrasound examination and the limitations of this test.

I agree to have the Fetal Anatomy ultrasound examination on:

Date:

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Signature

---

Print name:

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Date:

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## Appendix 2: Documentation for incomplete anatomy ultrasound examination

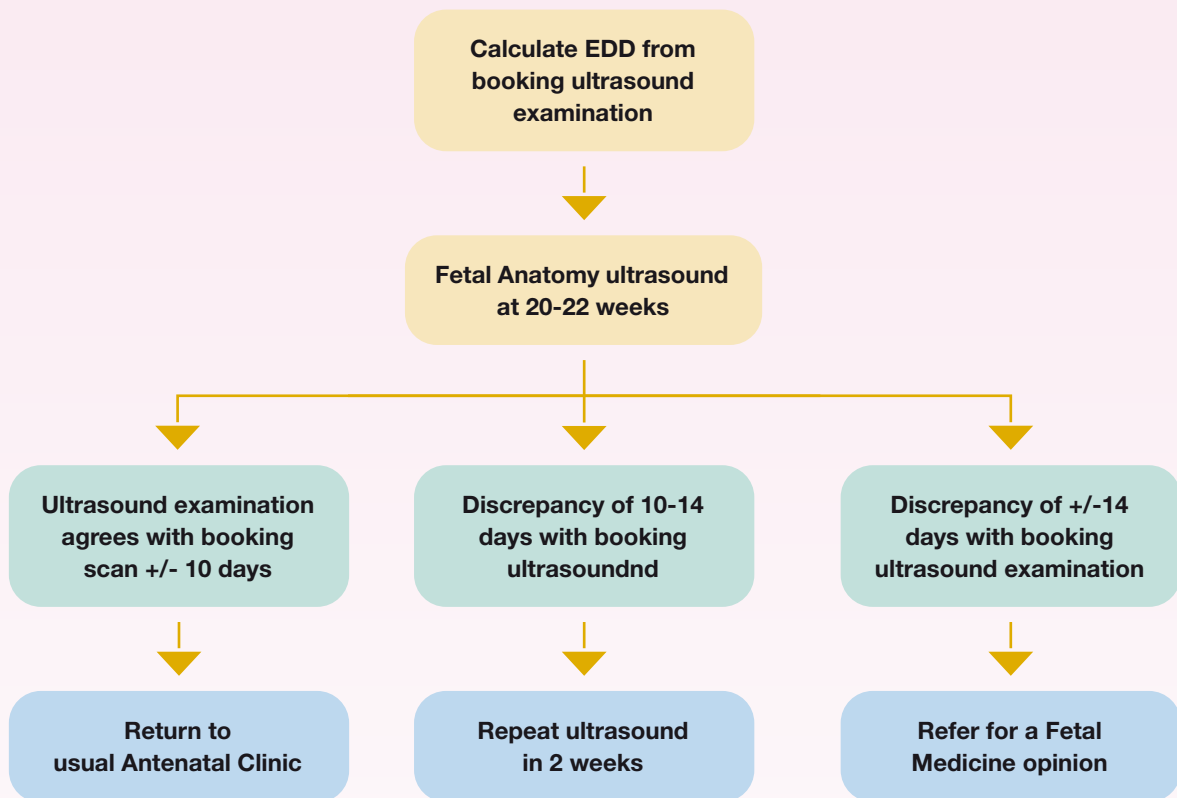
This woman has undergone two successive attempts at acquiring detailed views of the mid trimester fetal anatomy. Owing to the maternal habitus, these examinations have not successfully confirmed normality for the following key anatomical structures: (list structures).

This limitation reflects failure to obtain satisfactory views rather than a suspicion of an anomaly and has been explained to the woman. The limited nature of fetal anatomy examination in this case should be borne in mind in the event of clinical concerns in the neonatal period.

## Appendix 3: Referral criteria for Fetal Medicine opinion following a fetal anatomy ultrasound examination

1. Structural fetal anomaly identified.
2. Nuchal fold (equal to or greater than 6mm).
3. Ventriculomegaly (posterior horn equal to or greater than 10mm).
4. Echogenic bowel (density equal to bone).
5. Inability to confirm normality for key cardiac components on 2 serial examinations with a sonographer.
6. More than one ultrasound soft marker is identified in the absence of NIPS.
7. Anhydramnios < 2cms
8. Polyhydramnios >8cm deepest vertical pocket in the setting of a negative GTT and non-macrosomic fetus, or in the absence of a GTT/ fetal macrosomia if there are additional ultrasound features of fetal anomaly.
9. Sonographic evidence of morbid placental adherence.
10. Suspected fetal growth restriction (Discrepancy of +/- 14 days with booking ultrasound examination, or less than 5<sup>th</sup> centile).
11. Cases of suspected Vasa Previa

# Appendix 4: Discordance of ultrasound-based dating between anatomy ultrasound and booking ultrasound



## Appendix 5: Cervical length technique

Cervical length can be measured using various sonographic approaches including transvaginal, transabdominal and transperineal assessment. Transvaginal approach is recommended as the gold standard in high-risk patients<sup>78</sup>.

Regardless of the sonographic approach to imaging the cervix, the core principles and landmarks are similar. The cervix should occupy a large portion of the image (for transvaginal sonography, 66% to 75% of the image). The following landmarks are sought: (i) internal os, (ii) external os, (iii) the full length of endocervical canal in sagittal view, (iv) body of the corpus, and (v) the cervical/vaginal interface (marked by a border of increased echogenicity). The anterior and posterior cervical thicknesses should be similar.

Correct calliper placement is important. Callipers should be placed where the anterior and posterior cervical walls touch the internal and external cervical os and should not extend beyond these points. A minimum of 3 measurements are taken over several minutes, and the shortest image should be used to determine the cervical length. The cervical length should be noted along with the presence or absence of funnelling. Studies have compared the straight and segmental techniques and noted that they both had excellent agreement in identifying a short cervical length.

A cervix of less than 25mm long is associated with an increased risk of miscarriage or preterm labour.

A short cervical length should instigate prompt referral to a Fetal Medicine Specialist with clinical experience in preterm birth preventative management or indeed a specialist preterm birth service if accessible.

## Appendix 6: Uterine artery Doppler technique

The transabdominal technique is similar to that of the first trimester, the main difference being that right and left uterine arteries are identified at the apparent crossover with the external iliac arteries, rather than paracervically.

After the arteries are identified, pulsed-wave Doppler is used to obtain the waveforms.

When at least three similar consecutive waveforms are obtained, the PI is measured, and the presence or absence of early diastolic notching is recorded.

Detailed methodology for obtaining uterine artery Dopplers can be found in the ISUOG Practice Guidelines: Role of ultrasound in screening for and follow-up of pre-eclampsia at <https://www.isuog.org/resource/practice-guidelines-role-of-ultrasound-in-screening-for-pe-pdf.html>.

## Appendix 7: Ultrasound features for Placenta Accreta Spectrum (PAS)

- Loss of clear zone
- Myometrial thinning
- Uterine bulge
- Focal exophytic placental mass - through serosa, parametrium
- Bladder wall interruption
- Lacunae

### Colour Doppler

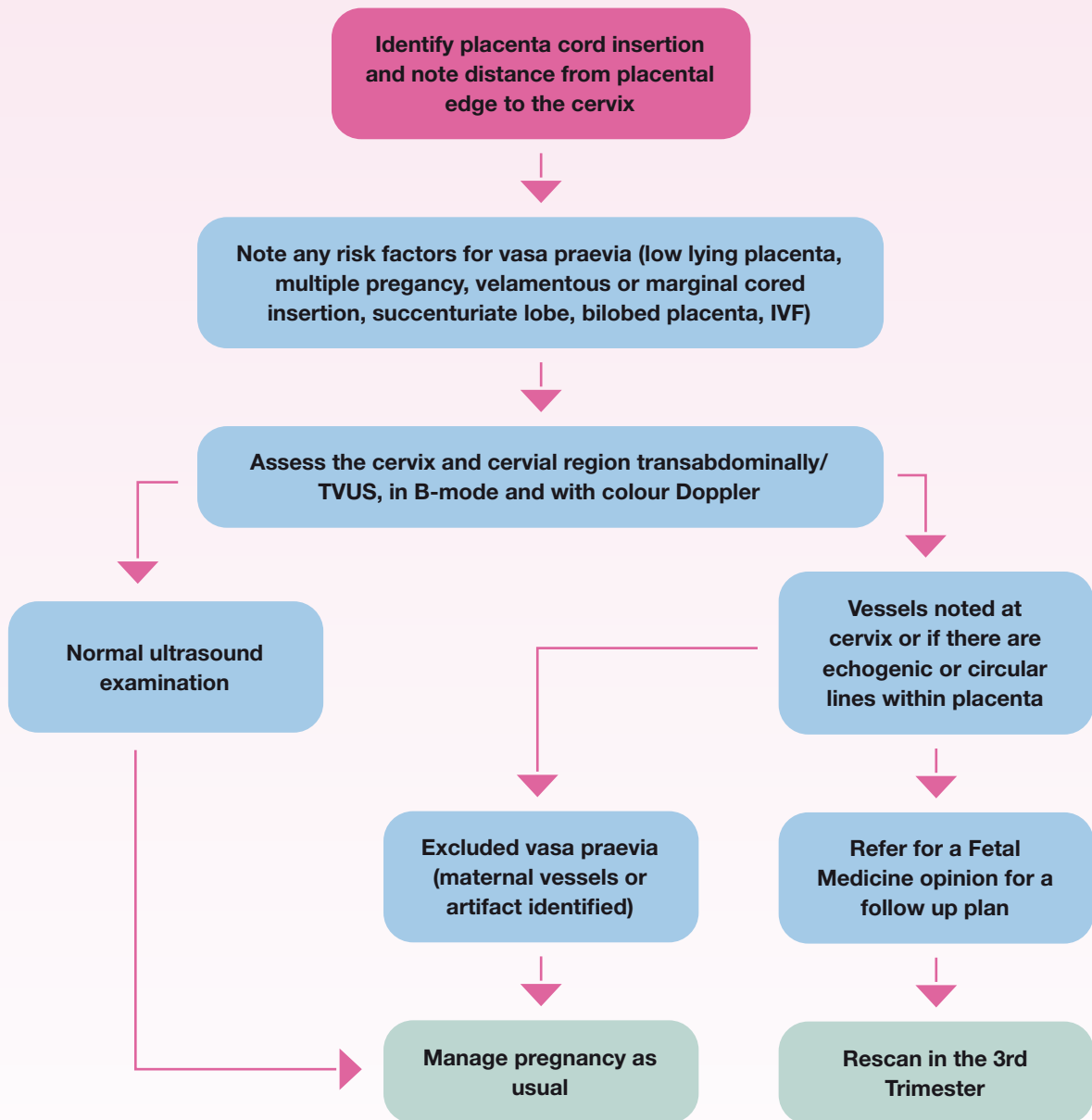
- Placenta lacunae feeder vessels
- Abnormal vasculature at placental-myometrial interface

Refer to:

Bartels H.C, Walsh J.M, Ní Mhuirheartaigh R, Brophy D, Moriarty J, Geoghegan T, O'Leary M, Donnelly J. C, Colleran, G.C, Thompson, C, Cooney, N, Byrne, B, Downey, P, Greene, R, Higgins, S, Brennan, D.J. National Clinical Practice Guideline: Diagnosis and Management of Placenta Accreta Spectrum. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. December 2022



# Appendix 8: Diagnosis of Vasa Praevia (Flowchart)



## Appendix 9: Minimum (and \*optional) image requirements for Fetal Anatomy Ultrasound

Clips/sweeps is the preferred method for the cardiac examination to be archived.

Structure/Area	Detail	Fetal Measurements	Images/measurements to capture/archive
<b>Head and neck</b> • Skull • Brain • Neck	Head shape	Biparietal Diameter Head circumference	Yes. Transthalamic view
	Cavum septum (CSP)	Measurement not required	
	Lateral ventricle (Vp)	Measurement of the Vp at the glomus	Yes
	Cerebellum	Transcerebellar diameter	Yes [+ measurement of TCD]
	Nuchal Fold	Distance between the outer border of the occipital bone and the outer skin edge.	Yes (included in TCD image)
<b>Facial features</b>	Both orbits and bulbi present*	Measurement not required	Image optional
	Coronal view of lips and nose	Measurement of nasal bone not required	Yes
	Mid sagittal* facial profile		Image optional

Structure/Area	Detail	Fetal Measurements	Images/measurements to capture/archive
<b>Lungs</b> <b>Heart</b>	Visceral situs/laterality of heart	Measurement not required	Yes, image to demonstrate assessed visceral situs/orientation of the heart using a split screen.
	Four chamber view		Yes- Spilt screen with and without colour
	FH rate and rhythm		Yes
	Aorta arising from the left ventricle		Yes, Spilt screen with and without colour
	Pulmonary artery (PA) arising from right ventricle, or the three vessel view.		Yes. Spilt screen with and without colour
	3 vessel 3V / 3 vessel* trachea view (3VT)		Yes
<b>Abdominal content</b>	Stomach and position	Measurement not required	Yes (may be included in AC image below)
	Short intra-hepatic section of the umbilical vein (UV)	AC Measurement is required.	Yes
	Abdominal wall and cord insertion		Yes
	Diaphragm*	Measurement not required	Image optional
	Kidneys X2	Measurement of renal pelvis not required unless it appears > 7mm.	Yes
	Bladder	Measurement not required  Colour Doppler to demonstrate 2 umbilical arteries	Yes
<b>Spine</b> <ul style="list-style-type: none"> <li>• Cervical</li> <li>• Thoracic</li> <li>• Lumbar Sacral</li> </ul>	Vertebrae	Measurement not required	Yes, image either sagittal or coronal to include lower spine
	Skin covering		

Structure/Area	Detail	Fetal Measurements	Images/measurements to capture/archive
<b>Limbs</b> • Upper and lower	Femur, tibia and fibula (both legs)	Femur length	should be visualised with an image and measurement of a single femur.  Tibia/ Fibula Image optional*
	Both feet	Digit count not required	Yes
	Radius Ulna, humerus (both arms)	Humerus length	should be visualised with an image and measurement of a single humerus.  Radius/Ulna image optional*
	Both hands	Digit count not required	Yes
<b>Genitalia</b>	Male or Female		Image if disclosing gender
<b>Uterine cavity</b> • Uterine content	Placenta	Assess relationship between lower placental edge and the internal os.	Yes
		Measure and report if leading edge is less than 2cm from the internal os.	Yes
		Cord insertion	Yes
	Amniotic fluid		Yes

# Appendix 10: Technique and images for components of the fetal anatomy ultrasound

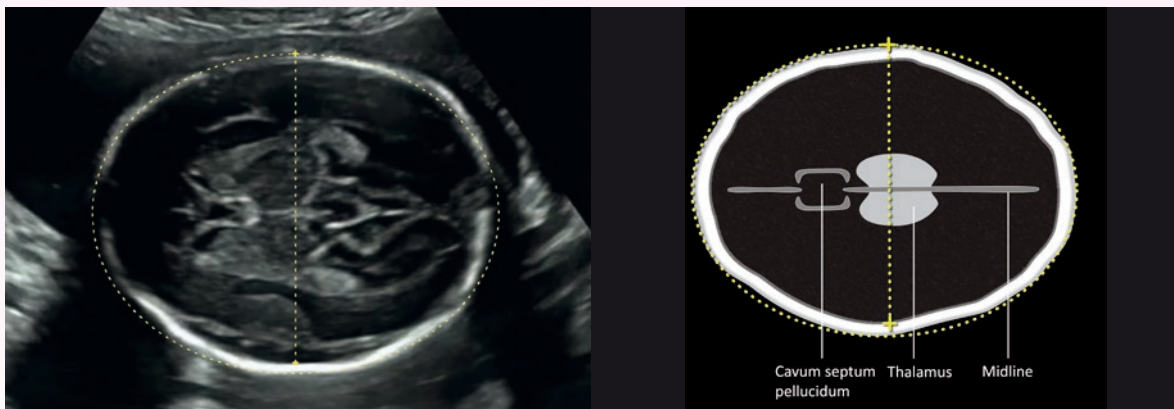
## Transthalamic plane

**Biparietal Diameter and Head Circumference (BPD/HC)** It is recommended that the standard fetal head biometry is measured using the transthalamic plane and not the transventricular plane based on the reproducibility evidence<sup>150</sup>. This is a cross-sectional view of the fetal head at the level of the thalami and cavum septi pellucidum without visualisation of the cerebellum. The image should occupy more than half of the monitor screen with the optimal machine settings.

**Calliper placement** BPD is measured from the leading edge (outer edge of proximal skull) to the inner edge. With modern transducers artefact is now avoided so the outer to inner technique is less relevant. However because Hadlock charts have been designed using an outer to inner approach, it is recommended to use this technique for the calliper placement<sup>151</sup>.

The HC is measured around the outside of the skull bone echoes with the ellipse method, by placing the ellipse around the outer outline of the calvarium echoes. Using this method also enables direct comparisons to be made between antenatal and postnatal measurements and is also clinically useful for monitoring growth from 'the womb to the classroom'<sup>26</sup>.

When head shape is flattened (dolichocephaly) or round (brachycephaly), HC is more reliable than BPD. Provided a technically good image is obtained, a single measurement is adequate.



Transverse views of the fetal head, demonstrating transthalamic scanning plane.

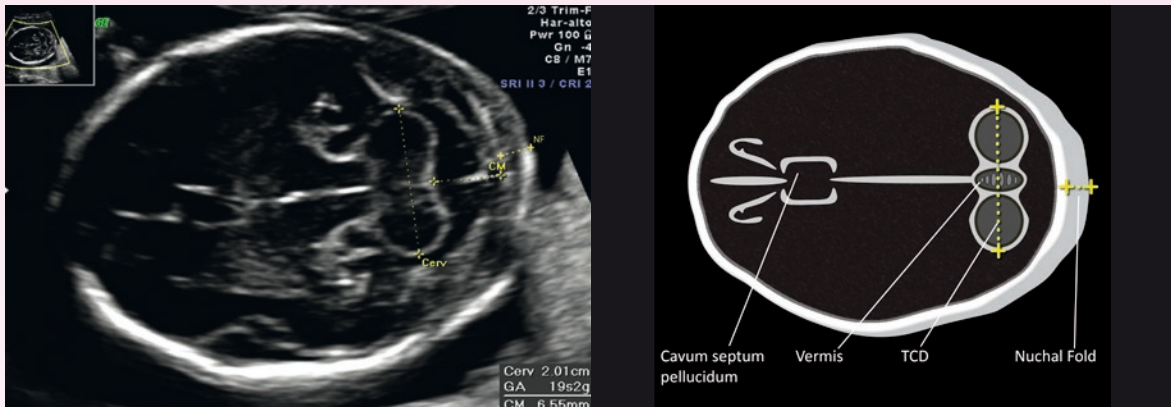
## Transcallebellar plane

**Cerebellum** Measurement of the cerebellum (TCD) is detailed in the next section under 'fetal brain'. The fetal cerebellum from the second trimester grows with a linear correlation with gestational age. It is the least affected by external factors because it is surrounded by dense bone which allows it to be used for assessing or confirming gestational age. Therefore in the clinical setting for women who present to a hospital for the first time in the second trimester, measurement of the cerebellum is helpful to assess the gestational age, particularly where there is a discrepancy between different measurements. TCD is an accurate parameter in estimation of gestational age in second trimesters as its values are in close relation with that of GA by LMP.

**Calliper placement** The calliper placement should be positioned on the other edge to the outer edge.

### Nuchal fold measurements taken in the same plane

**Calliper placement:** The callipers should be placed from the occipital bone to the outer surface of the skin. When measuring the nuchal fold, angling the probe to place the falx at 15° to horizontal may provide a sharper image of skin line and bone. This may minimise the chance of beam width artefact causing a thickened nuchal fold measurement.



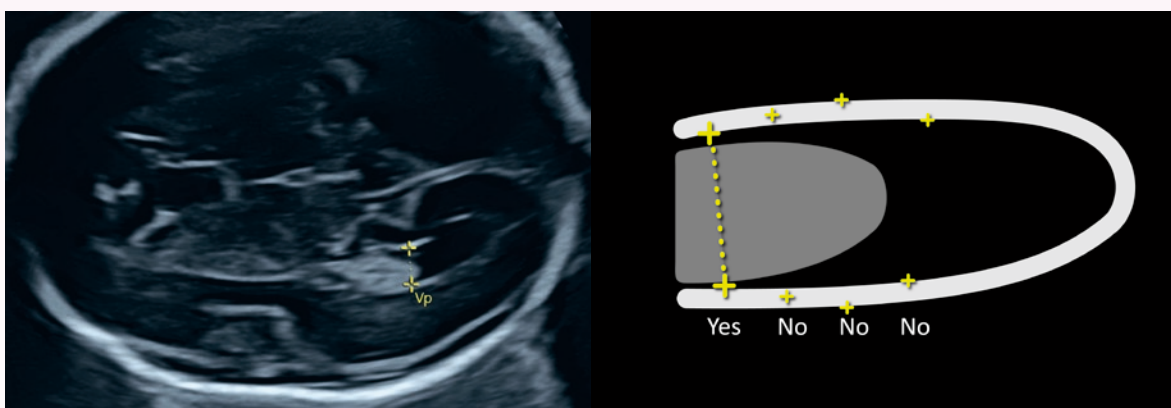
Transverse views of the fetal head, demonstrating transcerebellar scanning planes.

### Tranventricular plane

#### Lateral ventricles

Due to artifacts in the near field of the image, caused by shadowing from the proximal parietal bone, in the standard transventricular plane, only the hemisphere and the lateral ventricle on the far side of the transducer are measured.

**Calliper placement:** Callipers are positioned at the level of the glomus of the choroid plexus opposite the parieto occipital sulcus<sup>86</sup>. Callipers are placed correctly when touching the inner edge of the ventricular wall at its widest part and aligned perpendicular to the long axis of the ventricle. Due to artifacts in the near field of the image, caused by shadowing from the proximal parietal bone, in the standard transventricular plane, only the hemisphere and the lateral ventricle on the far side of the transducer are measured.

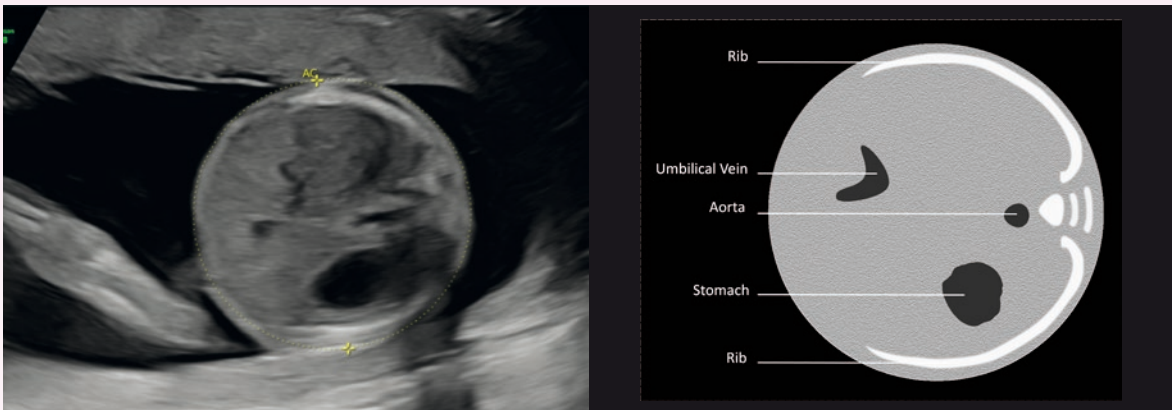


Adapted from the ISUOG Practice Guidelines of the fetal central nervous system 2020. Callipers are positioned at the level of the glomus of the choroid plexus opposite the parieto occipital sulcus (POS)

## Abdominal content

**Abdominal Circumference (AC)** is measured at the outer surface of the skin on a transverse section of the fetal abdomen as close to circular as possible. The fetal stomach should be identified in its normal position on the left side. A 'J' shaped hypoechoic structure is seen in the midline; it should be 1/3 of the way across the abdomen and represents the internal portion of the umbilical vein branching to the right portal vein. The kidneys should not be visible in the section; the cord insertion should not be visible; and the 'J' should not extend all of the way to the skin line anteriorly. Ensure not to distort the circular shape of the fetal abdomen by applying too much pressure with the transducer. The cross section of the abdomen should occupy at least 50% of the screen.

**Caliper placement:** The AC is measured with the ellipse method. The callipers are placed on the outer border of the body outline from the anterior surface to the posterior surface and across the abdomen at the widest point.

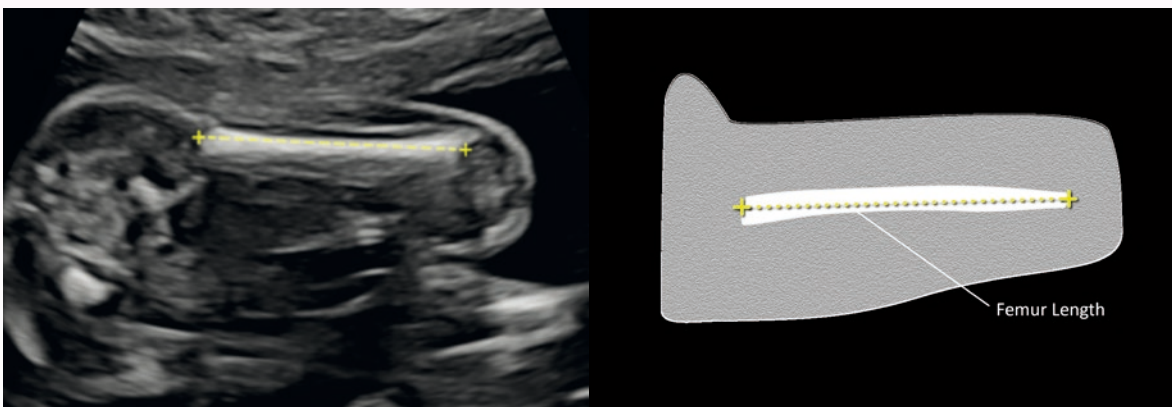


Ultrasound image of a standard abdominal circumference

## Limbs

**Femur Length (FL)** is measured using a longitudinal view of the thigh that is closest to the probe and with the femur as close as possible to the horizontal plane such that the angle of insonation of the ultrasound beam is 90 degrees. Both ends of the bone are clearly visible<sup>12</sup>. Provided a technically good image is obtained, a single measurement is adequate. The femur closest to the transducer should be measured. The femur should occupy at least 50% of the screen<sup>15</sup>.

**Calliper placement:** The callipers should be placed at the outer borders of the edges of the diaphysis (outer to outer) ensuring clear femoral edges. Ultrasound artifacts of the femoral edges such as the proximal trochanter or pointed femoral spurs are not included in the measurement.



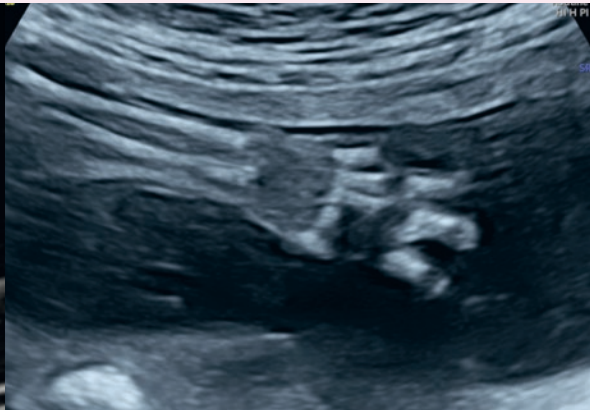
Ultrasound image of a standard femur length

**Humeral Length (HL)** should be performed in a standardized manner on the basis of strict quality criteria with the humerus as close as possible to the horizontal plane such that the angle of insonation of the ultrasound beam is 90 degrees. Image should be well magnified and occupy at least 50% of the screen. The humerus closest to the transducer should be measured. Provided a technically good image is obtained, a single measurement is adequate.

**Calliper placement:** The callipers should be placed at the furthest ends of the bone, not including cartilage if visible. The longest axis is determined by the strong acoustic shadow and visualisation of both cartilaginous ends.



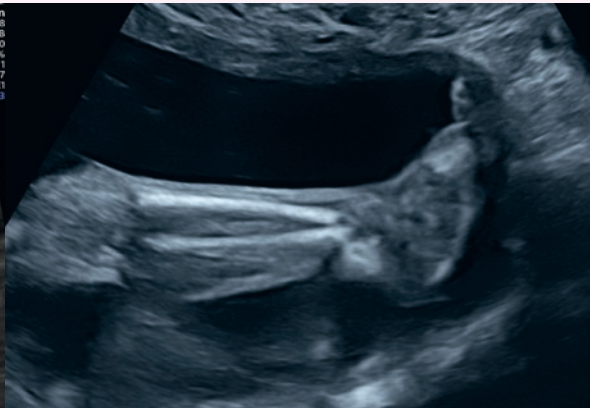
**Humeral length**



**Ultrasound image of radius, ulnar and hand**



**Ultrasound image of 2 feet**



**Ultrasound image of tibia and fibula**

## Face

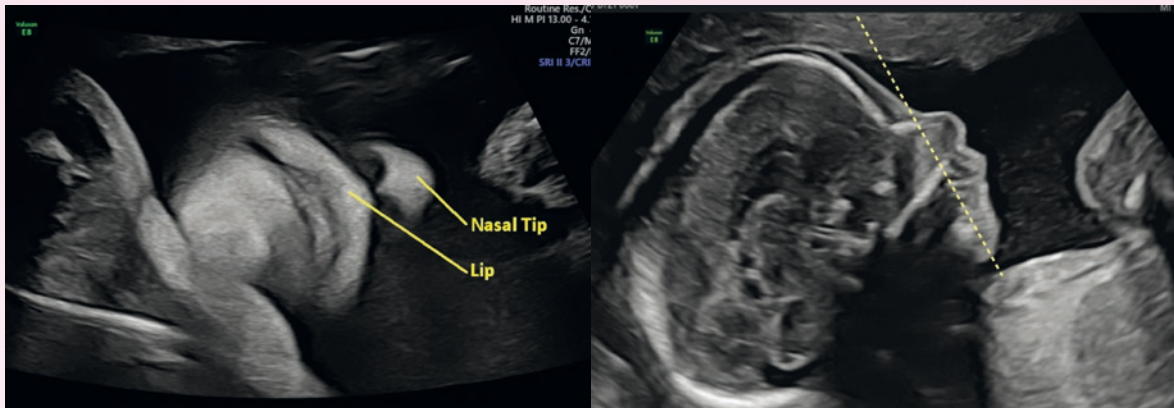
### Lips and nose

This image is obtained by moving the scanner forward from the coronal orbital view to the very front of the face.

### Facial profile

This is a mid-sagittal image best taken with the angle of the face at about 45°. The skin line over the nose should be close to horizontal. There should be no frontal bossing of the forehead. If the chin is significantly behind this imaginary line then micrognathia is suspected.





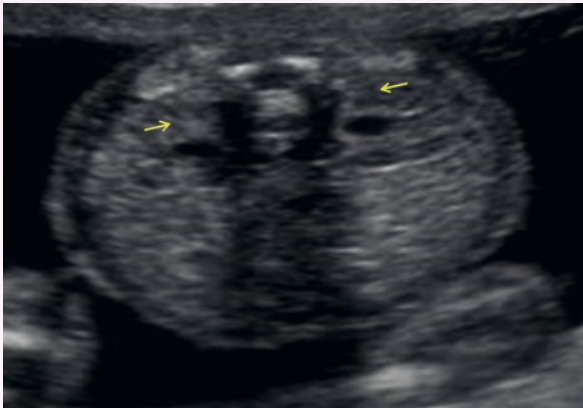
**Ultrasound image of two nostrils and a intact lip.**

**Ultrasound image of a Facial profile**

### Fetal kidneys

Examination of the fetal kidneys in two planes is essential.

**Transverse plane:** Placing the spine in the uppermost position obtains the best image. The kidneys can be seen on either side of the spine. They appear as round structures on either side of the spine and at mid gestation have a hypoechoic area centrally that represents the renal pelvis.



#### Right and left kidney

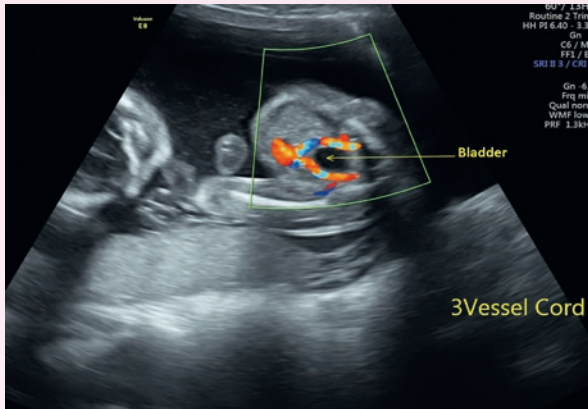
**Coronal plane:** This is a coronal section through the back just anterior to the fetal spine. A kidney should be seen on each side of the aorta. Each kidney is 'C' shaped around a single renal pelvis. The axis of each kidney is roughly parallel to the aorta; if they angle towards each other at the caudal ends then this may indicate a horseshoe kidney. Each kidney should be similar sized.

#### Measurement of kidneys if required

The callipers are placed on the inner borders of the renal tissue in the transverse section. The transducer is then rotated to identify the kidney in the longitudinal section. Measurements of kidney length are then made with the longitudinal axis of the kidney as close as possible to a right angle of the ultrasound beam. Care is taken to ensure that the full length of the kidney is visualised and the callipers are placed on the lower edge of the kidney and then on the superior border. It is important to avoid inclusion of the adrenal gland.

## Umbilical Arteries

These arteries need to be traced around the bladder towards the cord insertion to differentiate them from the iliac vessels that are seen more laterally in the pelvis directed towards the thighs. It is important to ensure that the Doppler settings are set at low flow by decreasing the PRF to maximise the ability to detect both arteries.



**Umbilical arteries around the bladder**

## Sex

**Male sex:** The male genitalia are best assessed by taking two images. Firstly a mid-sagittal image of the lower abdomen below the cord insertion demonstrates penis and scrotum caudally to the cord insertion. Secondly a transverse image, just below the level of the bladder, best taken with the knees separated. Penis and scrotum are seen between the thighs in this image.



**Male genitalia**

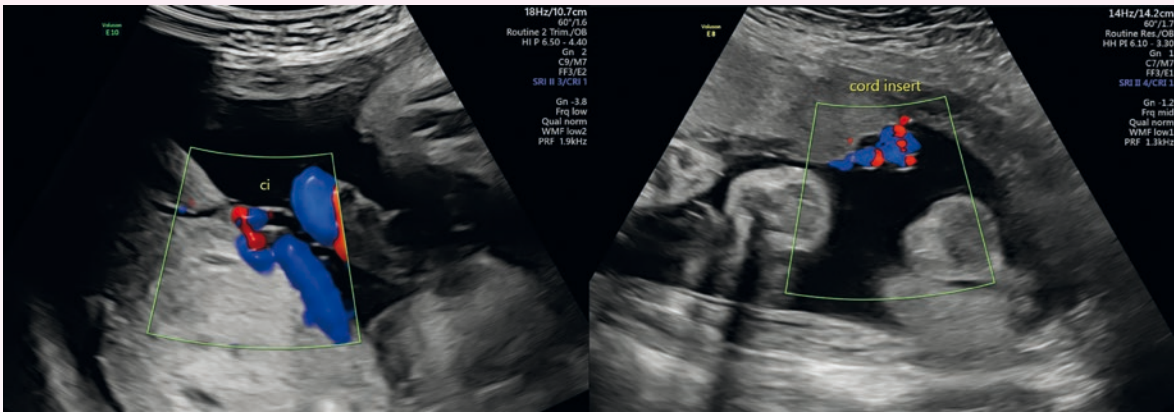
**Female sex:** As with the male genitalia the female external genitalia are best assessed by looking from two directions. The first image is a mid-sagittal image of the lower abdomen demonstrating the flat mons pubis caudal to the cord insertion. Secondly a transverse image, just below the level of the bladder, best taken with the knees separated. There are three lines representing the labia



**Female genitalia**

**Placental cord insertion**

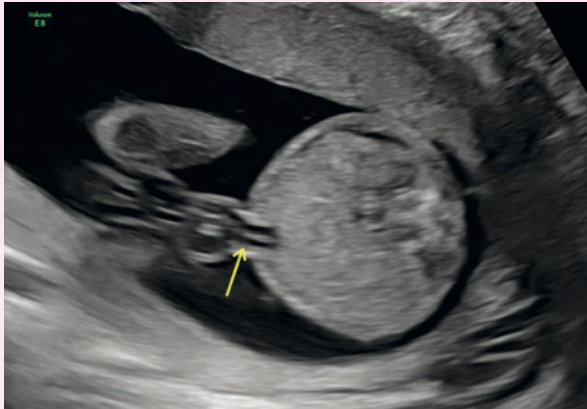
The placental cord insertion is imaged by visualising with B mode imaging the entry of the umbilical vessels into the fetal surface of the placenta, noting the continuity of the cord sheath with the chorionic plate. Colour Doppler ultrasound should be used to aid assist localisation.



**Normal cord insertion**

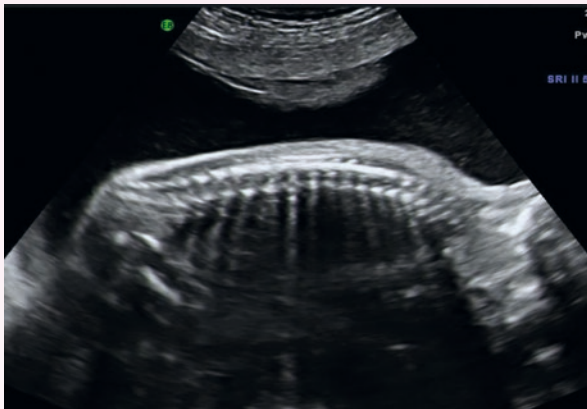
**Marginal cord insertion**

## Fetal Cord Insertion



Ultrasound images of fetal spine with skin covering and fetal cord insertion.

## Fetal spine



Ultrasound images of fetal spine with skin covering and fetal cord insertion.

# Appendix 11: Technique to assess the fetal heart

Standard scanning planes for the examination of the fetal heart have been adopted from the ISUOG guideline document **ISUOG Practice Guidelines : sonographic screening of the fetal heart**, AIUM and FASP.

Cardiac screening examination is best done in real time and saved as a video clip.

- **Cardiac Imaging Planes** An axial thoracic view should be captured that establishes the following:
  - Normal Situs –It should be confirmed that the heart and the stomach are both on the left side of the fetus.
  - The apex of the heart pointing leftward with its long axis at 45°.
  - The heart occupying no more than 1/3 of the total area of the fetal thorax
- **Machine settings:** All ultrasound machines have cardiac pre-sets which optimise resolution and persistence. It is important to have a high resolution available to obtain optimal views of the heart. Higher frame rate and contrast is also of importance for cardiac imaging. A single acoustic focal zone and relatively narrow field of view can help to maximize frame rates. An intact rib should be present.

The following strategies should be used to optimise image resolution and persistence.

- Reduce the image depth to the minimum value that includes the area of interest
- Use the time Gain Compensation (TGC) or 2D gain control to amplify incoming sound waves,
- Adjust the image focus to the area of interest
- Aim to keep the frame rate as high as possible by restricting the image width to the narrowest value that allows the heart to be imaged
- When using colour Doppler reduce the size of the colour box to the minimum that covers the area of interest.
- Images should be magnified until the heart fills 75% of the screen
- Cardiac screening examination is best done in real time and saved as a video clip

For further cardiac pre-sets, see Appendix 12.

- **Rate and Rhythm:** A normal regular rate ranges from 110 to 180 beats per min. Heart rate can be measured with M-mode or pulse wave Doppler. A regular rhythm should be demonstrated. If bradycardia or tachycardia is documented, or if the rhythm is noted to be irregular, a detailed assessment of atrial and ventricular contractions should be performed.
- **Position:** The heart should be located in the left chest (same side as the fetal stomach), if the *situs* is normal. There are many ways to establish situs. One method to confirm visceral situs is the Cordes technique. This technique has been useful in normal and abnormal situations<sup>152</sup>. The technique is to orientate the fetal head to the right side of the ultrasound screen with the fetus lying horizontally across the screen. From this starting position, rotate the transducer 90° clockwise to obtain a transverse image of the fetus through the fetal heart. If the left hand of the operator is

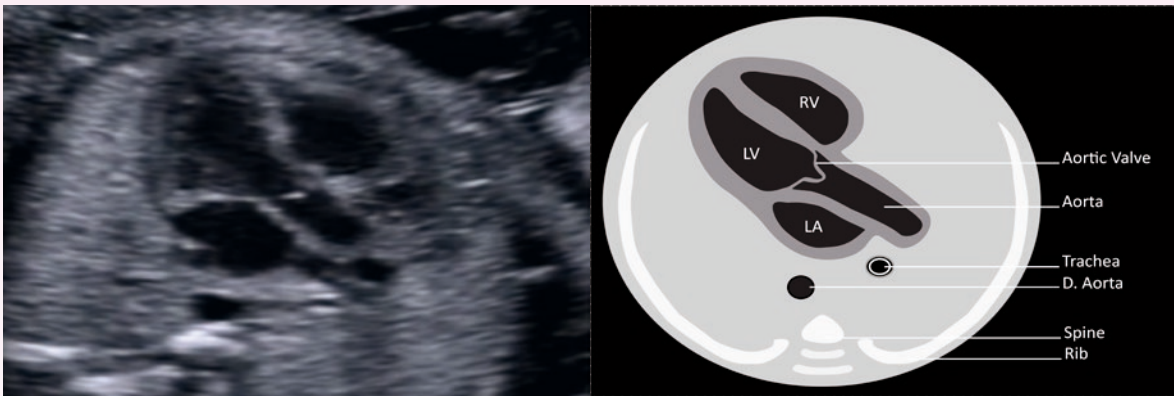
placed in front of the ultrasound screen positioned as an 'L' shape with the tips of fingers pointing towards the fetal sternum and the palm placed on the fetal spine, the thumb will now be pointing towards the left side of the fetus. Others may want to imagine themselves within the uterus.

- **Size:** A normal heart is usually no larger than one-third of the area of the chest. The heart is normally deviated by about  $45 \pm 20$  degrees towards the left side of the fetus
- **Four chamber view:** An apical 4-chamber view should be captured, that demonstrates the following:
  - Left and right sides of the heart should be approximately equal in size. Both left and right ventricles should extend to the apex of the heart and should be approximately equal in width at the level of the atrio-ventricular (AV) valves.
  - The crux of the heart demonstrates an offset cross arrangement of the AV valves. The right valve (tricuspid) is closer to the apex than the left (mitral).
  - Normal valve opening and closing with echogenicity or thickening. The right ventricle has the moderator band at the apex, closest to the sternum. The left atrium has pulmonary veins entering it.
  - The foramen ovale leaflet is visible opening from the right atrium to the left atrium, There is occasionally some fluid in the pericardial sac where a thin rim is likely to be physiological (up to 2 mm)<sup>146</sup>.
- **Ventricular septum:** The ventricle septum should be intact from crux to apex.
  - An impression of an inlet ventricular septal defect (VSD) is commonly perceived in the apical 4-chamber view, as the septum thins out toward the crux or as dropout if the ventricular wall is imaged parallel to the ultrasound beam.
  - A true VSD has bright margins ('T-sign')
  - Colour Doppler flow should be used to demonstrate bidirectional flow across a VSD
- **Outflow tracts:**
  - It is recommended to evaluate the aortic and pulmonary outflow tracts, which can increase the detection rates for major cardiac anomalies above those achievable by the four-chamber view alone. These additional views are more likely to identify conotruncal anomalies such as tetralogy of Fallot, transposition of the great arteries, double outlet right ventricle and truncus arteriosus.
  - Normal great vessels are approximately equal in size and should cross each other as they exit from their respective ventricular chambers.
  - In addition, the use of 'three-vessels and trachea view' can increase the detection of congenital heart disease<sup>153</sup>. This view is a transverse plane in the upper mediastinum showing simultaneously the course and the connection of both the aortic and ductal arches, their relation to the trachea and the visualization of the superior vena cava. In 99% of patients this view was quickly and easily obtained from the familiar four-chamber view. Its use shortened the time required to examine the aortic arch, the most time-consuming aspect of examining the heart<sup>154</sup>
  - There is no requirement to measure cardiac size, individual valves, chambers or vessels for the purposes of a screening examination if the captured views are considered by the sonographer to demonstrate normal heart size and proportion between right and left-sided cardiac structures.

Representative scanning planes for fetal cardiac screening at the ultrasound examination. Clips /sweeps is the preferred method for the cardiac examination to be archived.



The four-chamber view



LVOT



RVOT



**3VV**



**3VVT**

**Colour Doppler** Colour flow mapping is an integral part of performing the cardiac examination and its role in the diagnosis of CHD cannot be underestimated. Doppler settings need to be sufficient to demonstrate the physiological atrial septal defect of the foramen ovale and complete filling of the ventricles. Colour Doppler is best performed with the septum between 45° and horizontal. This allows for improved Doppler detection of flow <sup>155</sup>. Optimal colour Doppler settings include the use of a narrow colour box (region of interest) as this has the greatest impact on frame rate, appropriate pulse repetition frequency, low colour persistence and adequate gain settings to display flow across valves and vessels (See ISUOG Practice guidelines on use of Doppler)<sup>156</sup>.



**Additional components of the fetal cardiac examination that may be seen at 18-22 weeks.**

Once normality has been confirmed for the key components described above cardiac examination can identify additional features that may indicate non-critical congenital heart disease or may indicate a functional/ vascular problem of cardiac/non-cardiac aetiology.

Such additional features are listed below:

- AV valve regurgitation
- Stenosis or regurgitation of the aortic or pulmonary valves on colour flow doppler assessment
- A right-sided aortic arch (right of trachea)
- Bilateral Superior Venae Cavae
- Evidence of cardiac failure (pericardial/ pleural effusions, cardiomegaly, atrio-ventricular valve regurgitation)
- Sustained fetal bradycardia or tachycardia

The above list is not exhaustive, but represents the most common cardiac anomalies identified that are not in the CCHD (single ventricle/ outflow tract anomaly) category.

If normality for the key components cannot be confirmed with two examinations by an experienced sonographer, the woman should be referred to a Fetal Medicine Specialist.

## Appendix 12: Optimal cardiac settings during fetal anatomy ultrasound examination

<b>Frequency</b>	Highest possible between 5-7 mhz recognising the trade off between penetration and resolution.
<b>Depth</b>	Adjust for body habitus.
<b>Cine loop</b>	Because the heart is small and moves very quickly. When possible the image should be frozen and each frame be observed individually.
<b>Focus</b>	Adjust to level for the required plane of the heart. Single focal zone.
<b>Persistence</b>	Should be turned off or low.
<b>Frame rate</b>	Minimum frame rate is between 20/s and 40/s.
<b>Gain</b>	35-45db
<b>Video</b>	Because the heart is a moving organ, still pictures alone cannot record clinically important findings. Moving images could be recorded and compared with previous ones.

Adapted from: ISUOG Practice Guidelines (updated): sonographic screening examination of the fetal heart (2013).<sup>154</sup>

# Appendix 13: Doppler settings

Settings	Cardiac Scanning	Uterine / Renal and Umbilical Artery Doppler
<b>Mode</b>	Colour (consider Power Doppler for very slow flow)	Colour
<b>Steer of Box</b>	<60 degrees towards flow	<60 degrees towards flow
<b>Size of Box</b>	Narrow colour box to encompass heart. Increasing the size increases processing time and thus the frame rate	Narrow colour box to Increasing the size increases processing time and thus the frame rate
<b>High pass filter</b>	To climate wall movement and low velocity vessels	
<b>PRF</b>	2-3.5 kHz	3-4 kHz
<b>Velocity scale</b>	40- 70 cms/sec for AV semilunar and great vessels.	20 cm/s for smaller vessels
<b>Gain</b>	Enough to fill the chambers and avoid blooming. Too high gain settings leads to artefact	Enough to fill the lumen and avoid blooming
<b>Colour Persistence</b>	Low colour persistence to eliminate superimposing colour signal form different phases of the cardiac cycle	
<b>Safety</b>	ALARA principle.  The TI should be $\leq 1.0$ and the exposure time should be kept as short as possible, usually no longer than 5-10mins and not exceeding 60 mins	

Adapted from: ISUOG Practice Guidelines: use of Doppler ultrasonography in obstetrics (2021).<sup>156</sup>

# Appendix 14: Referral criteria for Fetal Echocardiography following a fetal anatomy ultrasound

The majority of cases of CHD occur in the low risk population<sup>157</sup>. However, it is also known that there are risk factors associated with CHD and the following criteria are accepted as referral criteria for those patients at a higher risk of fetal CHD. These criteria also adhere to the British Congenital Cardiac Association (2021) guidance<sup>158</sup>.

## Maternal Indications

1. Maternal congenital heart disease (CHD) or congenital complete heart block (CHB)
  - A. NB Only lesions where surgery or interventional procedures required
  - B. NB Not PDA, ASD
2. Maternal metabolic disorders, if poor control in early pregnancy
  - A. diabetes mellitus
  - B. phenylketonuria
3. Maternal exposure to known cardiac teratogens:
  - A. anticonvulsant, retinoic acid, lithium
  - B. viral infection (rubella, CMV, coxsackie, parvovirus) and toxoplasma
4. Maternal collagen disease with anti Ro/SSA and/or and La/SSB

## Familial Indications

1. Paternal CHD/Previous child or fetus with CHD/CHB
  - A. First degree relatives to this fetus
  - B. NB Only lesions where surgery or interventional procedures required
  - C. NB Not PDA, ASD
2. Family history of genetic disorders/Chromosomal anomalies/ syndromes associated with CHD or cardiomyopathy

### **Fetal Indications for Fetal Echocardiography**

1. Suspicion of fetal cardiac anomaly during an obstetric scan
2. Nuchal translucency >3.5mm at first trimester screening
3. Nuchal Pad thickening of >6mm at anatomy ultrasound examination
4. Fetal hydrops
5. Pericardial effusion
6. Pleural effusion
7. Extra-cardiac malformation which is associated with CHD
8. Chromosomal anomalies/genetic syndromes which are associated with CHD
9. Fetal arrhythmias
  - A. sustained bradycardia heart rate <110 beats per minute
  - B. tachycardia – heart rate >180 beats per minute
  - C. Not atrial ectopic beats or “irregular heartbeat”
10. Other states with known risk for fetal heart failure:
  - A. twin-twin transfusion syndrome
  - B. absence of ductus venosus
  - C. fetal anaemia
  - D. tumours with a large vascular supply
  - E. arteriovenous fistulas
  - F. acardiac twin

# Appendix 15: Management of isolated soft markers in the second trimester

Soft marker	Screening test	No previous screening	Antenatal management	Follow-up imaging
<b>Echogenic intracardiac focus</b>	NIPS – if negative no further screening	None required	Routine care	N/A
<b>Choroid plexus cyst</b>	NIPS – if negative no further screening	None required	Routine care	N/A
<b>Single umbilical artery</b>	NIPS – if negative no further screening	None required	Routine care	Third-trimester ultrasound examination for evaluation of growth
<b>Urinary tract dilation</b>	NIPS – if negative no further screening	None required	Evaluation for persistence, with frequency of evaluation dependent on initial findings	Third-trimester ultrasound examination to determine whether postnatal paediatric urology or nephrology follow-up is needed
<b>Echogenic bowel</b>	NIPS – if negative no further screening	Refer for FM opinion	Evaluation for cystic fibrosis, congenital viral infection, intra-amniotic bleeding	Third-trimester ultrasound examination for reassessment and evaluation of growth
<b>Ventriculomegaly</b>				
<b>Mild</b>	NIPS – if negative refer for FM opinion	Refer for FM opinion		Third-trimester ultrasound examination for reassessment
<b>Moderate</b>	NIPS – if negative refer for FM opinion	Refer for FM opinion	Diagnostic testing	

<b>Soft marker</b>	<b>Screening test</b>	<b>No previous screening</b>	<b>Antenatal management</b>	<b>Follow-up imaging</b>
<b>Shortened humerus, femur, or both</b>	NIPS – if negative no further screening	Refer for FM opinion	Evaluation for skeletal dysplasia	Third-trimester ultrasound examination for reassessment and evaluation of growth
<b>Thickened nuchal fold</b>	NIPS – if negative no further screening	Refer for FM opinion	Detailed anatomic survey especially cardiac	N/A
<b>Absent or hypoplastic nasal bone</b>	NIPS – if negative no further screening	Refer for FM opinion	Routine care	N/A

## Appendix 16: Nasal bone measurement

The fetal profile is viewed in the mid-sagittal plane. The fetal nasal bone is identified and measured at the level of the synostosis. Care is taken to keep the angle of insonation close to 45 degrees or 135 degrees. If this angle is less than 45 degrees or greater than 135 degrees, the nasal bone may artificially appear to be absent.

**Measurement:** The full length of the nasal bone can be measured and plotted on the Sonek centile chart. The 2.5th centile for the nasal bone measurement has been reported as 4.4 mm at 18 weeks and 5 mm at 20 weeks. For management of absence or nasal hypoplasia (see soft markers Section 8)



# Appendix 17: Referral Form to Tertiary Service

This form should be completed for all referrals to tertiary centres. Urgent referrals can be telephoned prior to email. The email account is checked regularly throughout the day during office hours. You will receive confirmation of the referral by email.

Patient and Referral Details			
Name	ID number		
Address	GP details		
DOB /age	Telephone number		
Next of Kin (name, role)	Next of Kin (Tel. No.)		
Details of Referring Clinician / Hospital			
Healthcare provider making referral: (Name, role, hospital, contact details)			
Referring hospital at which woman is booked			
Consultant under whom patient is booked in referring hospital			
Date of Referral			
Pregnancy Details			
Name	ID number		
EDD by scan:	Gestation at date of referral		
Parity	Gravidity		
Blood Group/HIV status			
Significant obstetric/ medical history			
Reason for referral			
Is the patient aware of indication for referral?			
Urgency	Routine (at appropriate gestation)	Urgent (within 2 working days)	Very Urgent (same or next day)
Is an Interpreter required			

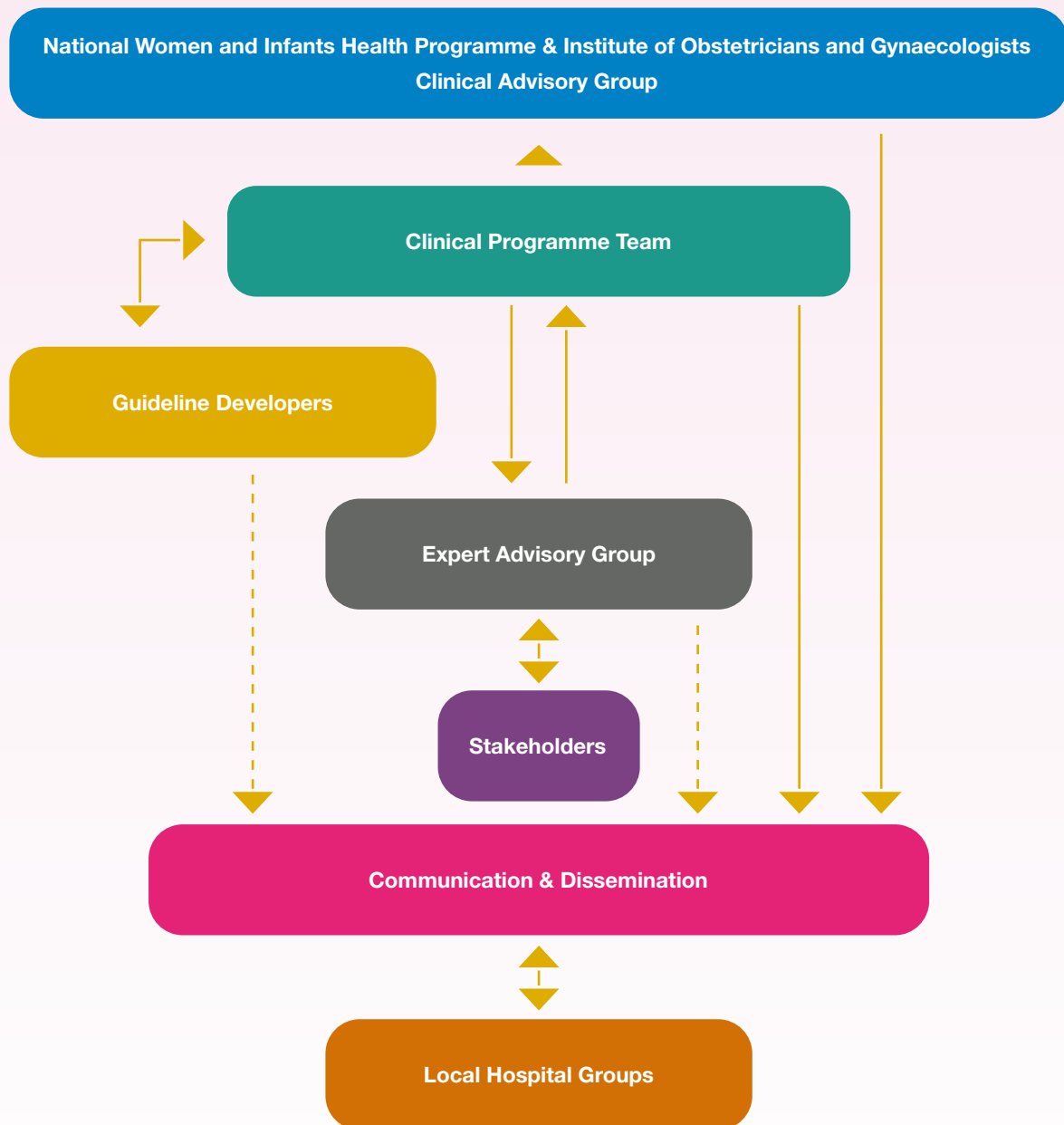
# Appendix 18: Expert Advisory Group Membership 2021-

Name	Profession	Location (2021)
Dr Fergus McCarthy	Consultant Obstetrician, Gynaecologist, Senior Lecturer and Maternal-Fetal Medicine Sub-specialist	Cork University Maternity Hospital, University College Cork
Dr Mairead Butler	Consultant Obstetrician and Gynaecologist	University Hospital Waterford
Prof Declan Keane	Professor of Obstetrics and Gynaecology	National Maternity Hospital Dublin, Royal College of Surgeons in Ireland
Dr Katherine Astbury	Consultant Obstetrician and Gynaecologist Gynaecology Oncology Sub-specialist	University Hospital Galway
Dr Sarah Petch	Specialist Registrar, Obstetrics and Gynaecology	National Maternity Hospital Dublin
Dr Orla Donohoe	Specialist Registrar, Obstetrics and Gynaecology	Sligo University Hospital
Prof John Murphy	Consultant Neonatologist and Clinical Lead for the National Clinical Programme for Paediatrics and Neonatology	National Women and Infants Health Programme
Ms Siobhan Canny	Group Director of Midwifery	Saolta University Health Care Group
Ms Fiona Hanrahan	Director of Midwifery and Nursing	Rotunda Hospital Dublin
Ms Margaret Quigley	National Lead for Midwifery	Office of Nursing and Midwifery Services Director
Prof Valerie Smith	Professor of Midwifery	School of Nursing and Midwifery, Trinity College Dublin
Ms Triona Cowman	Director of the Centre for Midwifery Education	Centre for Midwifery Education, Coombe Women & Infants University Hospital
Ms Janet Murphy	Advanced Midwifery Practitioner	University Hospital Waterford

Attendee	Profession	Location (2021)
Dr Ciara McCarthy	General Practitioner and ICGP Women's Health Lead	Irish College of General Practitioners
Mr Fergal O'Shaughnessy <i>And</i> Dr Brian Cleary <i>(Shared nomination)</i>	Senior Pharmacist, Honorary Lecturer <i>And</i> Chief Pharmacist, Honorary Clinical Associate Professor and Medications Lead, Maternal & Newborn Clinical Management System	Rotunda Hospital Dublin Royal College of Surgeons in Ireland
Ms Marie Finn	Medical Social Work Counsellor	Saolta University Health Care Group
Ms Marie Culliton	Lab Manager/Chief Medical Scientist	National Maternity Hospital Dublin
Ms Marita Hennessy	Post-Doctoral Researcher	Pregnancy Loss Research Group, INFANT Centre, University College Cork
Ms Niamh Connolly-Coyne <i>And</i> Ms Mandy Daly <i>(Shared nomination)</i>	Board of Directors	Irish Neonatal Health Alliance
Ms Caroline Joyce	Principal Clinical Biochemist PhD Candidate	Cork University Hospital University College Cork
Dr Richard Duffy	Consultant Perinatal Psychiatrist	Rotunda Hospital Dublin
Ms Clare Farrell	Physiotherapy Manager	Coombe Women & Infants University Hospital
Ms Fiona Dunlevy <i>And</i> Ms Sinéad Curran <i>(Shared nomination)</i>	Dietician Manager	Coombe Women & Infants University Hospital National Maternity Hospital
Dr Nicholas Barrett	Lead for Obstetric Anaesthesiology services	Limerick University Hospital
Dr Brendan Fitzgerald	Consultant Perinatal Pathologist	Cork University Hospital
Dr Niamh Conlon	Consultant Histopathologist	Cork University Hospital
Ms Georgina Cruise	Service Manager	Patient Advocacy Ireland

# Appendix 19: Guideline Programme Process

## Guideline Programme Process



# Appendix 20: AGREE II Checklist<sup>17</sup>

## AGREE Reporting Checklist 2016

This checklist is intended to guide the reporting of Clinical Practice Guidelines.

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
<b>DOMAIN 1: SCOPE AND PURPOSE</b>		
<p><b>1. OBJECTIVES</b> <i>Report the overall objective(s) of the guideline. The expected health benefits from the guideline are to be specific to the clinical problem or health topic.</i></p>	<input type="checkbox"/> Health intent(s) (i.e., prevention, screening, diagnosis, treatment, etc.) <input type="checkbox"/> Expected benefit(s) or outcome(s) <input type="checkbox"/> Target(s) (e.g., patient population, society)	
<p><b>2. QUESTIONS</b> <i>Report the health question(s) covered by the guideline, particularly for the key recommendations.</i></p>	<input type="checkbox"/> Target population <input type="checkbox"/> Intervention(s) or exposure(s) <input type="checkbox"/> Comparisons (if appropriate) <input type="checkbox"/> Outcome(s) <input type="checkbox"/> Health care setting or context	
<p><b>3. POPULATION</b> <i>Describe the population (i.e., patients, public, etc.) to whom the guideline is meant to apply.</i></p>	<input type="checkbox"/> Target population, sex and age <input type="checkbox"/> Clinical condition (if relevant) <input type="checkbox"/> Severity/stage of disease (if relevant) <input type="checkbox"/> Comorbidities (if relevant) <input type="checkbox"/> Excluded populations (if relevant)	
<b>DOMAIN 2: STAKEHOLDER INVOLVEMENT</b>		
<p><b>4. GROUP MEMBERSHIP</b> <i>Report all individuals who were involved in the development process. This may include members of the steering group, the research team involved in selecting and reviewing/rating the evidence and individuals involved in formulating the final recommendations.</i></p>	<input type="checkbox"/> Name of participant <input type="checkbox"/> Discipline/content expertise (e.g., neurosurgeon, methodologist) <input type="checkbox"/> Institution (e.g., St. Peter's hospital) <input type="checkbox"/> Geographical location (e.g., Seattle, WA) <input type="checkbox"/> A description of the member's role in the guideline development group	

17 AGREE Reporting Checklist is available on the AGREE Enterprise website, a free and open access resource to support the practice guideline field ([www.agreetrust.org](http://www.agreetrust.org))

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
<p><b>5. TARGET POPULATION PREFERENCES AND VIEWS</b>  <i>Report how the views and preferences of the target population were sought/considered and what the resulting outcomes were.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Statement of type of strategy used to capture patients'/publics' views and preferences (e.g., participation in the guideline development group, literature review of values and preferences)</li> <li><input type="checkbox"/> Methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups)</li> <li><input type="checkbox"/> Outcomes/information gathered on patient/public information</li> <li><input type="checkbox"/> How the information gathered was used to inform the guideline development process and/or formation of the recommendations</li> </ul>	
<p><b>6. TARGET USERS</b>  <i>Report the target (or intended) users of the guideline.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> The intended guideline audience (e.g. specialists, family physicians, patients, clinical or institutional leaders/administrators)</li> <li><input type="checkbox"/> How the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care)</li> </ul>	
<b>DOMAIN 3: RIGOUR OF DEVELOPMENT</b>		
<p><b>7. SEARCH METHODS</b>  <i>Report details of the strategy used to search for evidence.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL)</li> <li><input type="checkbox"/> Time periods searched (e.g., January 1, 2004 to March 31, 2008)</li> <li><input type="checkbox"/> Search terms used (e.g., text words, indexing terms, subheadings)</li> <li><input type="checkbox"/> Full search strategy included (e.g., possibly located in appendix)</li> </ul>	
<p><b>8. EVIDENCE SELECTION CRITERIA</b>  <i>Report the criteria used to select (i.e., include and exclude) the evidence. Provide rationale, where appropriate.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Target population (patient, public, etc.) characteristics</li> <li><input type="checkbox"/> Study design</li> <li><input type="checkbox"/> Comparisons (if relevant)</li> <li><input type="checkbox"/> Outcomes</li> <li><input type="checkbox"/> Language (if relevant)</li> <li><input type="checkbox"/> Context (if relevant)</li> </ul>	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
<p><b>9. STRENGTHS &amp; LIMITATIONS OF THE EVIDENCE</b></p> <p><i>Describe the strengths and limitations of the evidence. Consider from the perspective of the individual studies and the body of evidence aggregated across all the studies. Tools exist that can facilitate the reporting of this concept.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Study design(s) included in body of evidence</li> <li><input type="checkbox"/> Study methodology limitations (sampling, blinding, allocation concealment, analytical methods)</li> <li><input type="checkbox"/> Appropriateness/relevance of primary and secondary outcomes considered</li> <li><input type="checkbox"/> Consistency of results across studies</li> <li><input type="checkbox"/> Direction of results across studies</li> <li><input type="checkbox"/> Magnitude of benefit versus magnitude of harm</li> <li><input type="checkbox"/> Applicability to practice context</li> </ul>	
<p><b>10. FORMULATION OF RECOMMENDATIONS</b></p> <p><i>Describe the methods used to formulate the recommendations and how final decisions were reached. Specify any areas of disagreement and the methods used to resolve them.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered)</li> <li><input type="checkbox"/> Outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified Delphi technique, outcome of voting procedures)</li> <li><input type="checkbox"/> How the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote)</li> </ul>	
<p><b>11. CONSIDERATION OF BENEFITS AND HARMS</b></p> <p><i>Report the health benefits, side effects, and risks that were considered when formulating the recommendations.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Supporting data and report of benefits</li> <li><input type="checkbox"/> Supporting data and report of harms/side effects/risks</li> <li><input type="checkbox"/> Reporting of the balance/trade-off between benefits and harms/side effects/risks</li> <li><input type="checkbox"/> Recommendations reflect considerations of both benefits and harms/side effects/risks</li> </ul>	
<p><b>12. LINK BETWEEN RECOMMENDATIONS AND EVIDENCE</b></p> <p><i>Describe the explicit link between the recommendations and the evidence on which they are based.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> How the guideline development group linked and used the evidence to inform recommendations</li> <li><input type="checkbox"/> Link between each recommendation and key evidence (text description and/or reference list)</li> <li><input type="checkbox"/> Link between recommendations and evidence summaries and/or evidence tables in the results section of the guideline</li> </ul>	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
<p><b>13. EXTERNAL REVIEW</b>  <i>Report the methodology used to conduct the external review.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence)</li> <li><input type="checkbox"/> Methods taken to undertake the external review (e.g., rating scale, open-ended questions)</li> <li><input type="checkbox"/> Description of the external reviewers (e.g., number, type of reviewers, affiliations)</li> <li><input type="checkbox"/> Outcomes/information gathered from the external review (e.g., summary of key findings)</li> <li><input type="checkbox"/> How the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations)</li> </ul>	
<p><b>14. UPDATING PROCEDURE</b>  <i>Describe the procedure for updating the guideline.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> A statement that the guideline will be updated</li> <li><input type="checkbox"/> Explicit time interval or explicit criteria to guide decisions about when an update will occur</li> <li><input type="checkbox"/> Methodology for the updating procedure</li> </ul>	
<b>DOMAIN 4: CLARITY OF PRESENTATION</b>		
<p><b>15. SPECIFIC AND UNAMBIGUOUS RECOMMENDATIONS</b>  <i>Describe which options are appropriate in which situations and in which population groups, as informed by the body of evidence.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> A statement of the recommended action</li> <li><input type="checkbox"/> Intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects)</li> <li><input type="checkbox"/> Relevant population (e.g., patients, public)</li> <li><input type="checkbox"/> Caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply)</li> <li><input type="checkbox"/> If there is uncertainty about the best care option(s), the uncertainty should be stated in the guideline</li> </ul>	
<p><b>16. MANAGEMENT OPTIONS</b>  <i>Describe the different options for managing the condition or health issue.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Description of management options</li> <li><input type="checkbox"/> Population or clinical situation most appropriate to each option</li> </ul>	



CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
<p><b>17. IDENTIFIABLE KEY RECOMMENDATIONS</b>  <i>Present the key recommendations so that they are easy to identify.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms</li> <li><input type="checkbox"/> Specific recommendations grouped together in one section</li> </ul>	
<b>DOMAIN 5: APPLICABILITY</b>		
<p><b>18. FACILITATORS AND BARRIERS TO APPLICATION</b>  <i>Describe the facilitators and barriers to the guideline's application.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Types of facilitators and barriers that were considered</li> <li><input type="checkbox"/> Methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation)</li> <li><input type="checkbox"/> Information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography)</li> <li><input type="checkbox"/> How the information influenced the guideline development process and/or formation of the recommendations</li> </ul>	
<p><b>19. IMPLEMENTATION ADVICE/TOOLS</b>  <i>Provide advice and/or tools on how the recommendations can be applied in practice.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Additional materials to support the implementation of the guideline in practice.  For example: <ul style="list-style-type: none"> <li>• Guideline summary documents</li> <li>• Links to check lists, algorithms</li> <li>• Links to how-to manuals</li> <li>• Solutions linked to barrier analysis (see Item 18)</li> <li>• Tools to capitalize on guideline facilitators (see Item 18)</li> <li>• Outcome of pilot test and lessons learned</li> </ul> </li> </ul>	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
<p><b>20. RESOURCE IMPLICATIONS</b>  <i>Describe any potential resource implications of applying the recommendations.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs)</li> <li><input type="checkbox"/> Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.)</li> <li><input type="checkbox"/> Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course)</li> <li><input type="checkbox"/> How the information gathered was used to inform the guideline development process and/or formation of the recommendations</li> </ul>	
<p><b>21. MONITORING/ AUDITING CRITERIA</b>  <i>Provide monitoring and/or auditing criteria to measure the application of guideline recommendations.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Criteria to assess guideline implementation or adherence to recommendations</li> <li><input type="checkbox"/> Criteria for assessing impact of implementing the recommendations</li> <li><input type="checkbox"/> Advice on the frequency and interval of measurement</li> <li><input type="checkbox"/> Operational definitions of how the criteria should be measured</li> </ul>	
<b>DOMAIN 6: EDITORIAL INDEPENDENCE</b>		
<p><b>22. FUNDING BODY</b>  <i>Report the funding body's influence on the content of the guideline.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> The name of the funding body or source of funding (or explicit statement of no funding)</li> <li><input type="checkbox"/> A statement that the funding body did not influence the content of the guideline</li> </ul>	
<p><b>23. COMPETING INTERESTS</b>  <i>Provide an explicit statement that all group members have declared whether they have any competing interests.</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Types of competing interests considered</li> <li><input type="checkbox"/> Methods by which potential competing interests were sought</li> <li><input type="checkbox"/> A description of the competing interests</li> <li><input type="checkbox"/> How the competing interests influenced the guideline process and development of recommendations</li> </ul>	

From: Brouwers MC, Kerkvliet K, Spithoff K, on behalf of the AGREE Next Steps Consortium. The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. *BMJ* 2016;352:i1152. doi: 10.1136/bmj.i1152.

For more information about the AGREE Reporting Checklist, please visit the AGREE Enterprise website at <http://www.agreertrust.org>.

# Appendix 21: Grades of Recommendation<sup>18</sup>

Grade of recommendation	Clarity of risk/benefit	Quality of supporting evidence	Implications	Suggested Language
<b>1 A.</b> Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Consistent evidence from well-performed randomised, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk	Strong recommendations can apply to most patients in most circumstances without reservation. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present	<p>We strongly recommend...</p> <p>We recommend that ...should be performed/ administered...</p> <p>We recommend that ... is indicated/ beneficial/ effective....</p>

18 SMFM adopts GRADE (Grading of Recommendations Assessment, Development, and Evaluation) for clinical guidelines. Society for Maternal-Fetal Medicine (SMFM), Chauhan SP, Blackwell SC. Am J Obstet Gynecol. 2013 Sep;209(3):163-5. doi: 10.1016/j.ajog.2013.07.012. PMID: 23978245 <https://pubmed.ncbi.nlm.nih.gov/23978245/>

Grade of recommendation	Clarity of risk/benefit	Quality of supporting evidence	Implications	Suggested Language
<b>1 B.</b> Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Evidence from randomised, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate	Strong recommendation and applies to most patients. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present	We recommend... We recommend that ... should be performed/ administered... We recommend that ... is (usually) indicated/ beneficial/ effective...
<b>1 C.</b> Strong recommendation, low-quality evidence	Benefits appear to outweigh risk and burdens, or vice versa	Evidence from observational studies, unsystematic clinical experience, or from randomised, controlled trials with serious flaws. Any estimate of effect is uncertain	Strong recommendation that applies to most patients. Some of the evidence base supporting the recommendation is, however, of low quality	We recommend... We recommend that ... should be performed/ administered... We recommend that ... is (maybe) indicated/ beneficial/ effective...
<b>2A.</b> Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	Consistent evidence from well-performed randomised, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk	Weak recommendation: best action may differ depending on circumstances or patients or societal values	We suggest... We suggest that ... may/might be reasonable...

Grade of recommendation	Clarity of risk/benefit	Quality of supporting evidence	Implications	Suggested Language
<b>2B.</b> Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burdens, some uncertainty in the estimates of benefits, risks and burdens	Evidence from randomised, controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate	Weak recommendation; alternative approaches likely to be better for some patients under some circumstances	We suggest... We suggest that ... may/might be reasonable...
<b>2C.</b> Weak recommendation, low-quality evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens	Evidence from observational studies, unsystematic clinical experience, or from randomised, controlled trials with serious flaws. Any estimate of effect is uncertain	Very weak recommendation: other alternatives may be equally reasonable.	We suggest... is an option We suggest that ... may/might be reasonable.
<b>Best practice</b>	A recommendation that is sufficiently obvious that the desirable effects outweigh undesirable effects, despite the absence of direct evidence, such that the grading of evidence is unnecessary			We recommend... We recommend that ... should be performed/ administered... We recommend that ... is usually indicated/ beneficial/effective

## Appendix 22: NWIHP/IOG CAG membership 2022

Dr Cliona Murphy (Chair). Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Director, National Women and Infants Health Programme.

Dr Sam Coulter-Smith. Consultant Obstetrician and Gynaecologist, Rotunda Hospital. Chair, Institute of Obstetricians and Gynaecologists.

Angela Dunne. Director of Midwifery, National Women and Infants Health Programme.

Kilian McGrane. Director, National Women and Infants Health Programme.

Dr Peter McKenna. Clinical Lead, Obstetric Event Support Team, National Women and Infants Health Programme.

Prof John Murphy. Clinical Lead Neonatology, National Women and Infants Health Programme.

Prof Maeve Eogan. Consultant Obstetrician and Gynaecologist, Rotunda Hospital. Clinical Lead, Sexual Assault Treatment Units, National Women and Infants Health Programme.

Dr Aoife Mullaly. Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital. Clinical Lead, Termination of Pregnancy Services, National Women and Infants Health Programme.

Prof Keelin O'Donoghue. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Lead, National Guidelines, National Women and Infants Health Programme.

Prof Nóirín Russell. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Director, Cervical Check.

Prof Richard Greene. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Clinical Director, National Perinatal Epidemiology Centre, University College Cork.

Prof John Morrison. Consultant Obstetrician and Gynaecologist, University Hospital Galway. Clinical Director, Saolta Maternity Directorate.

Dr Suzanne O'Sullivan. Consultant Obstetrician and Gynaecologist, Cork University Maternity Hospital. Director of Education and Training, Obstetrics and Gynaecology, Institute of Obstetricians and Gynaecologists.

Prof Fergal Malone. Master, Consultant Obstetrician and Gynaecologist, Rotunda Hospital.

Prof John Higgins. Cork University Maternity Hospital, Consultant Obstetrician and Gynaecologist, Clinical Director, Ireland South Women and Infants Directorate.

Dr Mendinaro Imcha. Clinical Director, Consultant Obstetrician and Gynaecologist, University Maternity Hospital Limerick.

Prof Shane Higgins. Master, Consultant Obstetrician and Gynaecologist, National Maternity Hospital.

Prof Mike O'Connell. Master, Consultant Obstetrician and Gynaecologist, Coombe Women and Infants University Hospital.

Dr Brian Cleary. Chief Pharmacist, Rotunda Hospital. Medications Lead, Maternal and Newborn Clinical Management System Project.

# Appendix 23: Policies, Procedures, Protocols and Guidelines checklist

The PPPG Checklists were developed to assist staff to meet standards when developing Clinical PPPGs.

Standards for developing clinical PPPG	
Stage 1 initiation	Checklist
The decision making approach relating to the type of PPPG guidance required (policy, procedure, protocol, guideline), coverage of the PPPG (national, regional, local) and applicable settings are described.	<input type="checkbox"/>
Synergies/co-operations are maximised across departments/organisations (Hospitals/ Hospital Groups/Community Healthcare Organisations (CHO)/National Ambulance Service (NAS)), to avoid duplication and to optimise value for money and use of staff time and expertise.	<input type="checkbox"/>
The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.	<input type="checkbox"/>
The target users and the population/patient group to whom the PPPG is meant to apply are specifically described.	<input type="checkbox"/>
The views and preferences of the target population have been sought and taken into consideration (as required).	<input type="checkbox"/>
The overall objective(s) of the PPPGs are specifically described.	<input type="checkbox"/>
The potential for improved health is described (e.g. clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).	<input type="checkbox"/>
Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.	<input type="checkbox"/>
Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.	<input type="checkbox"/>
The PPPG is informed by the identified needs and priorities of service users and stakeholders.	<input type="checkbox"/>
There is service user/lay representation on PPPG Development Group (as required).	<input type="checkbox"/>
Information and support is available for staff on the development of evidence-based clinical practice guidance.	<input type="checkbox"/>

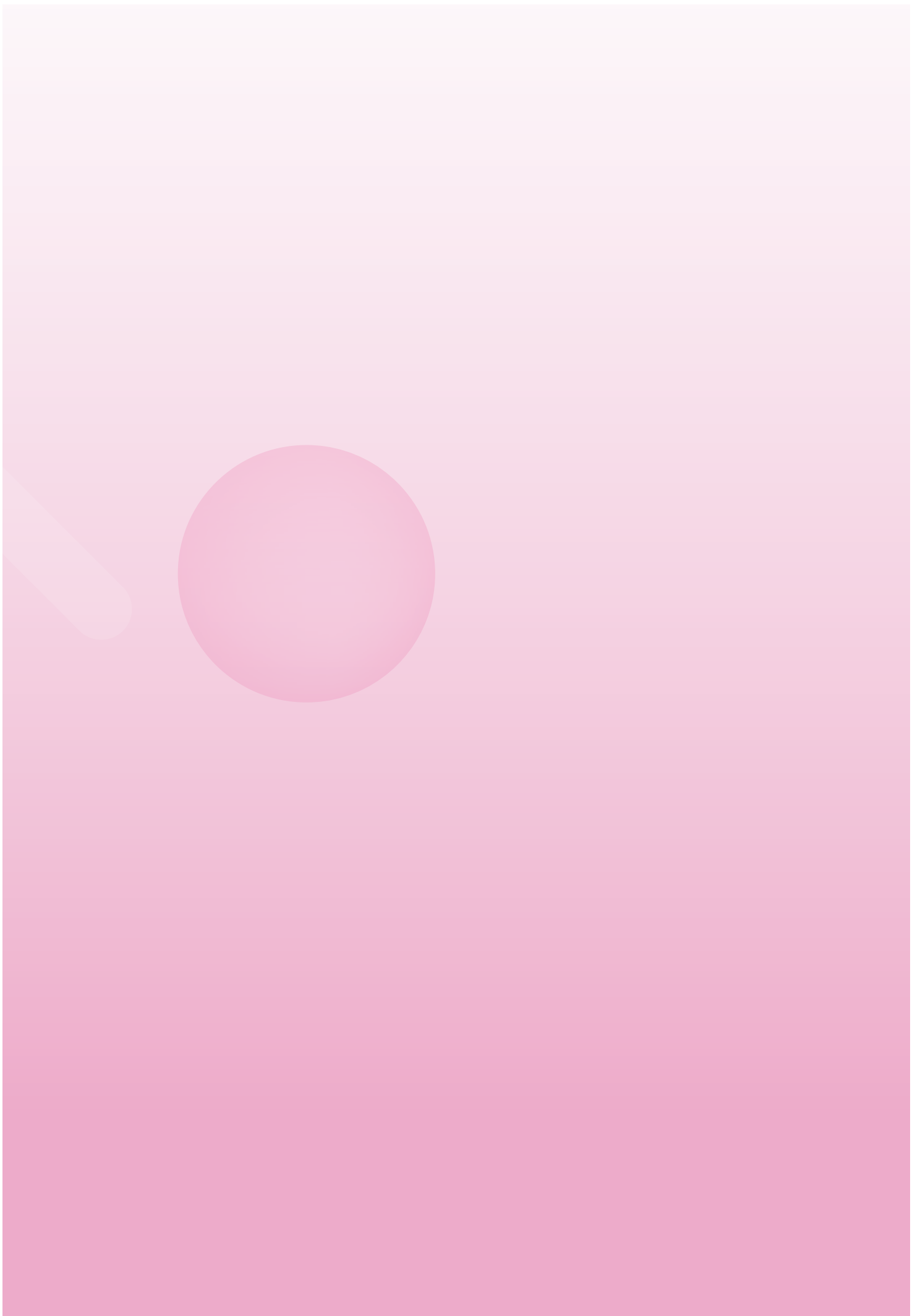
<b>Stage 2 development</b>	<b>Checklist</b>
The clinical question(s) covered by the PPPG are specifically described.	<input type="checkbox"/>
Systematic methods used to search for evidence are documented (for PPPGs which are adapted/ adopted from international guidance, their methodology is appraised and documented).	<input type="checkbox"/>
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).	<input type="checkbox"/>
The health benefits, side effects and risks have been considered and documented in formulating the PPPG.	<input type="checkbox"/>
There is an explicit link between the PPPG and the supporting evidence.	<input type="checkbox"/>
PPPG guidance/recommendations are specific and unambiguous.	<input type="checkbox"/>
The potential resource implications of developing and implementing the PPPG are Identified e.g. equipment, education/training, staff time and research.	<input type="checkbox"/>
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	<input type="checkbox"/>
Budget impact is documented (resources required).	<input type="checkbox"/>
Education and training is provided for staff on the development and implementation of evidence- based clinical practice guidance (as appropriate).	<input type="checkbox"/>
Three additional standards are applicable for a small number of more complex PPPGs:	<input type="checkbox"/>
Cost effectiveness analysis is documented.	<input type="checkbox"/>
A systematic literature review has been undertaken.	<input type="checkbox"/>
Health Technology Assessment (HTA) has been undertaken.	<input type="checkbox"/>
<b>Stage 3 governance and approval</b>	<b>Checklist</b>
Formal governance arrangements for PPPGs at local, regional and national level are established and documented.	<input type="checkbox"/>
The PPPG has been reviewed by independent experts prior to publication (as required).	<input type="checkbox"/>
Copyright and permissions are sought and documented.	<input type="checkbox"/>
<b>Stage 4 communication and dissemination</b>	<b>Checklist</b>
A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	<input type="checkbox"/>
Plan and procedure for dissemination of the PPPG is described.	<input type="checkbox"/>
The PPPG is easily accessible by all users e.g. PPPG repository.	<input type="checkbox"/>



<b>Stage 5 implementation</b>	<b>Checklist</b>
Written implementation plan is provided with timelines, identification of responsible persons/ units and integration into service planning process.	<input type="checkbox"/>
Barriers and facilitators for implementation are identified, and aligned with implementation levers.	<input type="checkbox"/>
Education and training is provided for staff on the development and implementation of evidence- based PPPG (as required).	<input type="checkbox"/>
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	<input type="checkbox"/>
<b>Stage 6 monitoring, audit, evaluation</b>	<b>Checklist</b>
Process for monitoring and continuous improvement is documented.	<input type="checkbox"/>
Audit criteria and audit process/plan are specified.	<input type="checkbox"/>
Process for evaluation of implementation and (clinical) effectiveness is specified.	<input type="checkbox"/>
<b>Stage 7 revision/update</b>	<b>Checklist</b>
Documented process for revisions/updating and review, including timeframe is provided.	<input type="checkbox"/>
Documented process for version control is provided.	<input type="checkbox"/>

To view in full refer to website: <https://www.hse.ie/eng/about/who/qid/nationalframeworkdevelopingpolicies/>





the 1990s, the UK has experienced a period of rapid economic growth, and the government has introduced a number of measures to encourage investment in research and development (R&D). The R&D tax credit is a key element of this policy, and is designed to encourage companies to invest in R&D by providing a tax credit for a proportion of their R&D expenditure.

The R&D tax credit is a tax credit that is available to companies that are engaged in R&D. It is calculated as a percentage of the company's R&D expenditure, and is available to companies of all sizes. The rate of the credit is 20% for companies that are engaged in R&D that is classified as 'qualifying R&D'. This rate is higher than the 10% rate that applies to companies that are engaged in R&D that is not classified as 'qualifying R&D'. The R&D tax credit is available to companies that are engaged in R&D that is classified as 'qualifying R&D' for a period of 12 months. This period is known as the 'qualifying period'. The R&D tax credit is available to companies that are engaged in R&D that is classified as 'qualifying R&D' for a period of 12 months. This period is known as the 'qualifying period'. The R&D tax credit is available to companies that are engaged in R&D that is classified as 'qualifying R&D' for a period of 12 months. This period is known as the 'qualifying period'.

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