Review of the Safety and Operation of Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018

April 2023

"The purpose of this review is to improve the safety and management of termination of pregnancy services, as provided under Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018"

Contents

Message from Colm Henry, Chief Clinical Officer (CCO)

Termination of Pregnancy (TOP) became legal in Ireland on the 20th December 2018, when the Health (Regulation of Termination of Pregnancy) Act 2018 was enacted. Provision of TOP services commenced across primary and secondary care in January 2019.

The legalisation of abortion within the parameters set out in the Act, required a huge mind-set shift within the healthcare environment. Four years on, the TOP service has evolved and is largely acknowledged as a routine and normal part of healthcare provision.

The HSE is committed to the ongoing provision of high quality, safe abortion care across acute and community settings. The last decade has seen huge advancements in prenatal screening, diagnostics and clinical genetics. Section 11 of the Health Regulation of Termination of Pregnancy Act 2018, provides the legislative framework for provision of termination of pregnancy in circumstances where there is present a condition likely to lead to the death of the fetus.

11. (1) A termination of pregnancy may be carried out in accordance with this section where 2 medical practitioners, having examined the pregnant woman, are of the reasonable opinion formed in good faith that there is present a condition affecting the foetus that is likely to lead to the death of the foetus either before, or within 28 days of, birth.

A diagnosis of a fetal anomaly is often unexpected and causes significant emotional and psychological distress to women/parents. This Review was commissioned to identify what is required to enhance provision of termination of pregnancy under Section 11. As with other areas, we continue to ensure that patient engagement and involvement is at the forefront of all we do and I would like, in particular, to thank Leanbh Mo Chroí for its support in this undertaking and facilitating access to women/parents who have lived experience of fetal anomaly in pregnancy. GPs and various Healthcare specialists across all 19 maternity hospitals/units were consulted with over the course of this Review, their contributions and honest insights have been invaluable in examining the experiences of healthcare professionals in providing termination of pregnancy within the parameters of Section 11 of the Act. This 360-degree view of service user and service provider experience has provided us with a robust, evidence informed baseline of current service provision and helped shape this Review Report and the ensuing recommendations.

I welcome this report and its recommendations which will position us well towards ensuring provision of equitable clinically appropriate, compassionate care in pregnancies complicated by a diagnosis of fetal anomaly, alongside comprehensive supports for the women/parents involved. Finally, I would like to acknowledge the hard work and commitment of members of the Section 11 Review Group who have worked so tirelessly in undertaking this Review and in helping to develop a vision and roadmap for this service into the future.

Foreword – Professor Dame Lesley Regan, Chair of the Review Group

The 25th of May 2018 was a monumental day for reproductive rights and women's health empowerment. The Republic of Ireland voted by a landslide majority to repeal the Eighth Amendment and provide access to abortion. As a long-standing advocate and campaigner for women's health, it was encouraging to learn of the overwhelming vote of the Irish people.

I am delighted to have been approached by Dr Colm Henry, Chief Clinical Officer of the HSE, to Chair this Review of the operation and management of abortion services provided under Section 11 of the Health Regulation of Termination of Pregnancy Act 2018. As we know, one in four pregnancies worldwide will end in abortion. This makes it the most frequent medical procedure that women of reproductive age undergo. Most importantly, safe, high quality abortion care plays an essential role in the health services we offer to women.

Approximately 2-3% of pregnancies will be affected by fetal anomaly. As a practising Obstetrician and Gynaecologist for 40 years, I am acutely aware of the trauma women and their families experience when a much wanted pregnancy is affected by a fetal anomaly. This devastating diagnosis is frequently associated with high levels of fear, depression and traumatic stress. We owe it to the women of Ireland to provide high quality care that is compassionate, dignified, respectful, standardised and person-centred.

This Review has presented us with an opportunity to meaningfully engage with healthcare professionals, women and their families, to plan for, set objectives and implement improved abortion services both now and in the future. Now is the time to introduce change based on experience and informed by evidence. I am confident that the recommendations set out in this review, will ensure the delivery of continuously improving, safe, high quality, compassionate abortion services and will improve the experience for women seeking a termination of pregnancy due to fetal anomaly in Ireland. As I have said many times: *"When we get it right for women, everyone in society benefits."*

It is my strong belief that we must also trust and empower our healthcare staff with the reassurance they need to provide consistent, high quality care by ensuring they receive the appropriate information, education, training and support. The Recommendations arising from this Review will help to achieve this goal.

It has been a pleasure and a privilege to work closely with the many dedicated healthcare professionals who have so generously participated in this Review, alongside the patients and advocacy groups representing the interests and needs of the women and their families who have, or will experience, a diagnosis of fetal anomaly in Ireland. In particular I wish to thank Prof. Keelin O'Donoghue, Ms Fiona Hanrahan and Ms Alison Lynch of Leanbh Mo Chroí, for their commitment to drive this Review forward. Also for their longstanding contributions to the service and their exemplary support for women and families affected by a prenatal diagnosis of fetal anomaly.

Acknowledgements

This Review was commissioned by the HSE's Chief Clinical Officer (CCO) Dr Colm Henry. Dr Henry would like to acknowledge and thank the Members of the Review Group for their guidance, insights and expertise throughout the course of the Review:

Pro. Dame Lesley Regan	Secretary General FIGO (Section 11 Review Group Chair)
Ms Alison Lynch	Patient Representative, Co-Chair, Leanbh Mo Chroi, Bereavement Support
Prof Andrew Green	Consultant Geneticist
Ms Angela Dunne	NWIHP, National Lead Midwife
Dr Aoife Mullally	Consultant Obstetrician & Gynaecologist, Clinical Lead for Termination of Pregnancy
Dr Brendan Fitzgerald	Consultant Perinatal Pathologist
Dr Ciara McCarthy	General Practitioner, Irish College of General Practitioners (ICGP) Representative
Dr Cliona Murphy	NWIHP, Clinical Director
Prof Colm O'Donnell	Consultant Neonatologist
Ms Eileen Ronan	Director of Midwifery
Ms Fiona Hanrahan	Director of Midwifery, Work-stream Chair – Section 11 Review
Ms Fiona Mulligan	Clinical Midwife Specialist in Bereavement and Loss
Ms Jennifer Ryan	Co-Chair, Leanbh Mo Chroí. Bereavement Services
Prof John Morrison	Consultant Obstetrician & Gynaecologist, Maternal Fetal Medicine Specialist
Prof Keelin O'Donoghue	Consultant Obstetrician & Gynaecologist, Maternal Fetal Medicine Specialist, Work-stream Chair – Section 11 Review
Ms Marie Culliton	Medical Scientist, Clinical Lead National Clinical Programme for Pathology
Ms MaryJo Biggs	NWIHP, General Manager
Dr Noirin O'Herlihy	General Practitioner, Irish College of General Practitioners (ICGP) Representative
Mr Robert Kidd	Acute Operations, Assistant National Director
Dr Rosemary Harkin	Consultant Obstetrician & Gynaecologist
Dr Sam Doyle	Consultant Geneticist
Dr Terry Tan	Consultant Anaesthetist

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Executive Summary

The purpose of this National Review was to identify and make recommendations on the structures and supports required to enhance termination of pregnancy services, as provided under Section 11 of the Health Regulation of Termination of Pregnancy Act 2018. The scope of the review spanned screening, diagnosis, management of termination of pregnancy (TOP) due to fetal anomaly, and investigations and follow-up supports. Recommendations are cognisant of the clinical circumstances of the fetus and parent(s), and of the need for provision of compassionate care and emotional supports for families.

An in-depth analysis of current pathways of care available to women/parents seeking to access termination of pregnancy services under Section 11 of the Act was undertaken. The Review was broken down into two distinct phases, the first phase comprising of a detailed service evaluation, mapping services and pathways across primary and secondary care, examining several aspects, including:

- Pre-natal screening services, with specific considerations for fatal fetal anomaly screening;
- Screening and diagnostic services in the context of fatal fetal anomalies/life-limiting conditions;
- Access to multidisciplinary expertise including clinical genetics and other specialties;
- Counselling services, genetic counselling, bereavement and other service user supports;
- Clinical and educational guidance and support; and
- Other service areas where resourcing and sustainability need to be enhanced to improve the quality and safety of services.

Electronic questionnaires were distributed to collect quantitative data, informing a baseline evaluation of termination of pregnancy for fetal anomaly (TOPFA) services. There was positive and proactive engagement from hospital management and healthcare providers in all nineteen maternity hospitals/units with feedback on existing levels of service and pathways provided by senior leaders and relevant clinical specialists. The Irish College of General Practitioners (ICGP) facilitated distribution of an electronic questionnaire to all of its members; whilst the rate of returns was modest, all General Practitioners (GPs) were invited to contribute to the review and all Community Health Organisation (CHO) regions were represented in the final returns.

Across all stages of the pathway, the experience of women/parents was a primary consideration. Information was collated with regard to communication protocols,

provision of information and materials, co-ordination of care and signposting to /availability of support services e.g. counselling and bereavement and loss resources. In order to explore and better understand the lived experience of parents who receive a prenatal diagnosis of fetal anomaly, Leanbh Mo Chroí, on behalf of the Chair of the Review Group, circulated a communication along with the electronic questionnaire to women/parents to whom they had provided support.

The second phase of the Review examined best practice with regard to the diagnosis and management of fetal anomalies in pregnancy. A systematic search for relevant papers was undertaken; citations returned were screened by title and abstract to eliminate clearly irrelevant articles. Selected full text articles from 2000 onwards were reviewed based on inclusion/exclusion criteria and supplemented with guidelines from international professional bodies. This second phase of the review was incorporated to clearly demonstrate existing evidence on the role and responsibilities of relevant clinical specialists in prenatal care and fetal medicine practice, as it relates to prenatal testing, counselling around anomalies, MDT participation, discussions around TOPFA and in pathways of care.

The findings of the Review demonstrate some inconsistency with regard to treatment approaches, care processes and documentation of clinical practices. The Review highlights the need for a) education and training on aspects of the legal framework governing TOPFA service provision; b) development and/or revision of written information and guidance on TOPFA for women/parents; c) more proactive multidisciplinary discussion on cases of fetal anomaly, d) new clinical guidance on TOPFA with all relevant stakeholders involved; e) enhanced focus on the standardisation of clinical pathways for diagnosis and management of fetal anomalies in pregnancy.

The Review also highlights the need for standardised practice (in so far as practicable) across the 6 Fetal Medicine Centres (FMCs) and for Clinicians within to work together to establish consensus in decision making around which fetal anomalies can be offered TOPFA under the Act as well as their operation of the legal review process.

Recommendations

Screening For Fetal Anomaly: Aneuploidy / NIPS, Dating Scans, Anatomy Scans
1. A National Clinical Programme for screening for fetal anomaly, to include screening for fetal aneuploidy (e.g. NIPS), should be established by NWIHP. For example, this might include setting up a working group with all relevant stakeholders to examine ethical issues, relevant legal principles, existing professional guidelines and clinical practice, alongside professional opinion and lived experience. 2. A National Clinical Guideline is to be developed for first trimester fetal ultrasound scanning. 3. A National Clinical Guideline is to be developed for second trimester fetal anatomy ultrasound scanning. 4. The purpose and nature of ultrasound scanning should be clearly explained to women/parents. Informed consent should be obtained prior to undertaking a first trimester fetal/dating ultrasound and second trimester fetal anatomy ultrasound examinations. 5. Each maternity hospital/unit should conduct an annual audit of the first trimester dating and second-trimester anatomy ultrasound scanning service. It is expected this would include numbers referred for scan, gestation that scans are performed, and diagnoses made, as well as intervals to review by Fetal Medicine services. This could be included in each hospital's/unit's annual report.

Management Pathways: Fetal Medicine Centres & Termination of Pregnancy due to Fetal Anomaly
6. Optimal structures for all Fetal Medicine Centres, incorporating infrastructure, resourcing, staffing, skill mix, tests available and referral pathways should be defined by NWIHP. 7. The HSE should develop resource(s) (e.g. a national information pack) providing clinically appropriate, accurate information on major fetal anomalies, tailored to meet the needs of both healthcare providers and women/parents 8. The HSE website should be updated to ensure accurate information is provided to women/parents and clinicians. Updates should include signposting to relevant,

trustworthy information sources and detailed information on termination of pregnancy processes/procedures.

9. All women/parents should be provided with written information on the process for review of a relevant medical opinion (pursuant to section 13 of the Act) should they be advised that they are not deemed eligible for a termination of pregnancy in Ireland.

10. Parental choice with regard to TOP procedures, including feticide, should be respected as far as clinically practicable, should form part of the consultation with the Fetal Medicine Specialist and should be documented.

11. All six Fetal Medicine Centres should have the resource and expertise to provide feticide, if clinically appropriate and based on the preference of the woman/parent.

12. If a woman declines feticide (after 21+6 weeks gestation), it is the responsibility of Fetal Medicine Specialists/Obstetricians and Neonatologists/Paediatricians, before TOPFA, to put in place and appropriately document care plans including where the fetus is born showing signs of life.

13. All women/parents should be facilitated in returning to their local unit, if clinically appropriate, for management of the TOPFA procedure. Factors to take into consideration include: maternal choice, type of anomaly, gestation, maternal co-morbidity and potential predictable complications.

14. Dedicated bereavement teams contribute much to the support offered to parents, where trained professionals provide appropriate person-centred care and follow-up. The HSE should continue to ensure these posts are funded, supported and in place across the maternity infrastructure.

15. The role of the Multidisciplinary team with regard to TOPFA should be clearly defined. A multi-disciplinary learning approach should be adopted at maternity network level with associated MDT Learning events scheduled at regular intervals.

16. An annual audit of fetal medicine services provided in each Fetal Medicine Centre should be undertaken and reported. This should include staffing compliment and skill-mix, referral numbers and timelines, diagnostic services, termination of pregnancy procedures and investigations after TOPFA.

17. The Interim clinical guidance *"Pathway for Management of Fatal Fetal Anomalies and/or Life Limiting Conditions diagnosed during pregnancy: Termination of Pregnancy"* should be re-written to reflect current best practice and giving considerations to the recommendations arising from this Section 11 Review. This should be managed by NWIHP's Guideline Programme.

Clinical Genetics

18. The HSE should develop a framework for the development of a National Perinatal Genetics service and this should sit within the HSE's recently published National Genetics & Genomics Strategy.

19. Every Fetal Medicine Centre should have structured, protected access to perinatal genetics expertise to support with the evaluation, diagnosis and management of pregnancies with suspected congenital anomalies, chromosome abnormalities, and single gene disorders during pregnancy. The Clinical Genetics team should be part of and available to the Fetal Medicine multi-disciplinary team.

20. A prenatal genetic test directory should be established with supporting guidelines for health professionals from varied disciplines who undertake or refer for prenatal testing and diagnosis. This would include indications for testing and laboratory standards.

21. A standardised consent process should be established for genetic testing to ensure women/parents have a full understanding of testing procedures, benefits, limitations and results.

22. Comprehensive genetic counselling should be available pre-and post- prenatal genetic testing. Genetic Counsellors, working under the direct supervision of a Consultant Geneticist, should deliver this counselling.

23. Ready access to a Perinatal Genetics service should be available to facilitate women/parents to obtain timely information/diagnoses that may affect their decisions regarding the future of their pregnancy and/or subsequent pregnancies.

24. Clinical Guidelines should be developed for prenatal diagnostic testing by Amniocentesis and Chorionic Villus Sampling (CVS). This would include the specific types of tests appropriate in different clinical scenarios and interpretation of results.

Investigation and follow-up: Perinatal Pathology and Bereavement Care

25. All women/parents should be offered timely bereavement supports as per their care needs and individual preferences, in accordance with the National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death. Bereavement supports should be available in all 19 maternity hospitals/units.

26. Consented perinatal post-mortem examination should be offered in instances of TOPFA. This should be facilitated through the maternity networks.

27. Cases of perinatal post-mortem examination after TOPFA should be presented and discussed at relevant perinatal pathology post-mortem multi-disciplinary team meetings.

28. All women/parents should be offered a follow-up appointment with a Senior Obstetrician/Maternal Fetal Medicine Specialist (and other relevant specialists as required), to discuss results of investigations and tests such as post-mortem and to discuss future pregnancy planning. This follow-up may be more clinically appropriate in the Fetal Medicine Centres.

29. Supports should be put in place for subsequent pregnancies incorporating access to appropriate prenatal screening and/or testing, pregnancy counselling and mental health supports.

Professional Development and Peer Support

30. Consideration should be given to establishing an annual academic Fetal Medicine meeting at which complex clinical cases, legislative challenges, annual audits and important clinical updates could be discussed.

31. Specialist trainees in all relevant disciplines (e.g. from Obstetrics, Neonatology, Genetics, Pathology) should be encouraged and facilitated to attend the Fetal Medicine Centres' multi-disciplinary team meetings.

32. Hospital-wide educational events should, where appropriate, include Fetal Medicine services and TOPFA.

33. All Fetal Medicine Centres should be encouraged to seek accreditation (e.g. EBCOG, RCOG) for the provision of sub-speciality training in Fetal Medicine.

34. Staff involved in provision of Fetal Medicine services and TOPFA should be encouraged and facilitated to partake in continuous professional development, reflective practice and peer support networks.

35. NWIHP should consider putting in place mechanisms for ongoing national audit of TOPFA incorporating: indications, gestations, procedures and outcomes.

Background & Context

The Health Regulation of Termination of Pregnancy Act 2018, came into effect on the 20th of December 2018.[1] The Act sets out the grounds and timelines governing access to lawful termination of pregnancy in Ireland. Under the Act, termination of pregnancy is available in both hospital and community settings, with the majority of terminations up to nine weeks gestation taking place in the community. Currently, 11 of the 19 maternity hospitals in Ireland are providing full termination of pregnancy services, as prescribed in the 2018 Act.

While abortion up to 12 weeks' gestation is legal upon request in Ireland, there are limited circumstances under which termination of pregnancy over 12 weeks' gestation is permitted, namely:

Where there is a risk to the life, or of serious harm to the health, of the pregnant woman **(Section 9)**; or

Where there is an immediate risk to the life, or of serious harm to the health, of the pregnant woman **(Section 10)**;

Or

Where there is present a condition affecting the fetus that is likely to lead to the death of the fetus either before, or within 28 days of birth **(Section 11)**

There is no upper gestational limit for termination of pregnancy under Section 11 of the Act.

Planning for termination for reasons of fetal anomaly or maternal medical conditions involves the input of multiple medical specialities in order to provide safe, high quality and appropriate care. Advancements in screening and diagnostic technologies have led to an increase in pre-birth diagnosis of fetal anomalies. Congenital anomalies occur in 2% to 3% of pregnancies with prevalence variance across different populations. Diagnosis of fetal anomaly is an unexpected event for women/parents in pregnancy, often resulting in significant distress and complex emotions.

National Clinical Guidelines[2] were developed in late 2018 by the Institute of Obstetricians and Gynaecologists (IOG) of the Royal College of Physicians of Ireland, to guide and support termination of pregnancy providers to operationalise the service within the legal parameters of the legislation. Membership of the Guideline Development Group included Clinical Contributors from Obstetrics and Gynaecology and collaborators from other relevant clinical areas e.g. general practice, family planning services, pharmacy, anaesthesiology etc. Over the course of the development of the guidelines, there was additional input from legal personnel and the National Women's Council of Ireland.

[1] Health (Regulation of Termination of Pregnancy) Act 2018

[2] INTERIM CLINICAL GUIDANCE Termination of pregnancy under 12 weeks https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/clinical-guidelines/interim-clinical-guidance-termination-of-pregnancy-under-12-weeks-2018-.pdf

However, since services were established in January 2019, there has been evidence of heterogeneity in terms of the operationalisation of the service across the maternity hospitals/units and the specialist Fetal Medicine Centres [3] [4] [5]. It has also been established that some clinicians feel impacted in their ability to provide termination of pregnancy care under threat of prosecution and criminalisation. The criminalisation element of the Act sets abortion apart from other aspects of healthcare and has been cited many times as a challenge with regard to the operationalisation of the service [5] [6]. There is no agreed definition of what constitutes a fatal fetal anomaly (FFA) or agreed list of conditions associated with fatal fetal anomalies.

Section 20 of the Act of 2018 provides for a notification system in relation to all terminations of pregnancy carried out under the legislation. Specifically, it requires that the Minister for Health be notified of each termination of pregnancy no later than 28 days after it has been carried out. For the period 2019-2021 inclusive, there were 250 notifications under Section 11 of the Act. [7] [8] [9] This represents 1.4% of the total notifications for that same period. It should however be noted that due to the impact of the COVID-19 pandemic and the 2021 Cyber-attack, reported figures for 2021 are deemed unreliable.

Between 2019 and 2021, 230 people ordinarily resident in Ireland accessed abortion in England and Wales under 'Ground E' of the Abortion Act 1967. Ground E of the 1967 Act permitted lawful termination *"where there is substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously disabled".*

A recent retrospective service evaluation of fetal medicine clinics in 2 tertiary maternity hospitals in Ireland from 2019-2021, compared pregnancies diagnosed with major fetal anomalies that underwent TOP in Ireland and pregnancies that did not meet the legal criteria, where women travelled abroad for TOP. The most common indication (25/83; 30%) for TOP locally was Trisomy 18, followed by Anencephaly. Travelling to get abortion care was mainly because of the diagnosis of Trisomy 21 (30/56; 53.6%), followed by multiple structural anomalies/syndromes deemed locally as not meeting the legal criteria. The study concluded that legalisation of abortion does not guarantee provision of a standardised or ideal abortion service, and that service evaluation is essential. The findings also emphasised the impact of barriers to abortion care for fetal

[3] Jackson P, Power-Walsh S, Dennehy R, O'Donoghue K. Fatal fetal anomaly: Experiences of women and their partners. Prenat Diagn. 2023 Jan 13. doi: 10.1002/pd.6311. Epub ahead of print. PMID: 36639719

[4] The National Maternity Bereavement Experience Survey

[5] Unplanned Pregnancy and Abortion Care (UnPAC) Study

[6] Mishtal J, Reeves K, Chakravarty D, Grimes L, Stifani B, Chavkin W, Duffy D, Favier M, Horgan P, Murphy M, Lavelanet AF. Abortion policy implementation in Ireland: Lessons from the community model of care. PLoS One. 2022 May 9;17(5):e0264494. doi: 10.1371/journal.pone.0264494. PMID: 35533193; PMCID: PMC9084516.

[7] Notifications in accordance with Section 20 of the Health (Regulation of Termination of Pregnancy) Act 2018: Annual Report 2021

[8] Health (Regulation of Termination of Pregnancy) Act 2018 - Annual Report on Notifications 2019

[9] Health (Regulation of Termination of Pregnancy) Act 2018 - Annual Report on Notifications 2020

anomaly, and the need for legislation and policies that support women's access to TOP. [10]

Challenges in diagnosing and certifying cases of FFA is also the main finding in a recent article that incorporates healthcare professionals and service users' experiences and includes recommendations for policy and legislative change.[11]

Exploring the experiences and establishing the needs of women/parents who experience a prenatal diagnosis of fetal anomaly and of healthcare professionals involved in the care and clinical management of these women/parents following such diagnosis, is key in determining how best to provide and sustain high quality, clinically appropriate and compassionate care.

[10] Miremberg H, Oduola O, Morrison JJ, O'Donoghue K. Fetal anomaly diagnosis and termination of pregnancy in Ireland; evaluation following implementation of abortion services. AJOG 2023, Vol 228 (1): S316

[11] Grimes L, Mishtal J, Reeves K, Chakravarty D, Stifani B, Chavkin B, Duffy D, Horgan T, Favier M, Murphy M, Lavelanet AF. 'Still travelling': Access to abortion post-12 weeks gestation in Ireland. Women's Studies International Forum 2023; 98: 102709 https://doi.org/10.1016/j.wsif.2023.102709

Approach & Methodology

In May 2022, the HSE's Chief Clinical Officer commissioned this Section 11 Review. The aim of the Review was to improve the safety and management of terminations provided under Section 11 of the Health Regulation of Termination of Pregnancy Act 2018. Service providers and special interest groups representing people who had received a fetal diagnosis were invited to participate in the associated Review Group. The Review Group was chaired by Professor Dame Lesley Regan, Professor of Obstetrics & Gynaecology at Imperial College London and former President of the Royal College of Obstetricians and Gynaecologists (RCOG).

The Group comprised of representatives from Obstetrics and Gynaecology, Midwifery, Neonatology, Perinatal Pathology, Clinical Genetics, Anaesthesiology, Medical Science, General Practice, bereavement services, HSE Acute Operations, HSE National Women and Infants Health Programme and groups representing women/parents with lived experience.

Figure 1.1 Methodology Overview

Service Evaluation

A cross-sectional, quantitative service evaluation was undertaken to examine service user-level and service provider-level experiences of the termination of pregnancy service, as provided under Section 11 of the Act. Structured questionnaires were designed in consultation with the Review Group, to gauge common service implementation factors such as acceptability, adoption, appropriateness, fidelity, sustainability, and equity of access.

A speciality specific service evaluation questionnaire was distributed electronically to a range of clinical personnel, including:

- General Practice
- Obstetrics and Gynaecology
- Fetal Medicine
- Perinatal Pathology

- Neonatology
- Midwifery

All members of the Irish College of General Practitioners (ICGP) (n=4,000); hospital management and key personnel across all nineteen maternity hospitals/units (n=72).

A separate questionnaire was developed to evaluate the service from the perspectives of women/parents who had experienced a diagnosis of fetal anomaly. Access to this cohort and dissemination of the questionnaire was facilitated by the organisation Leanbh Mo Chroí (LMC) who provide support and encouragement to parents who receive a fatal or severe fetal diagnosis. [12]

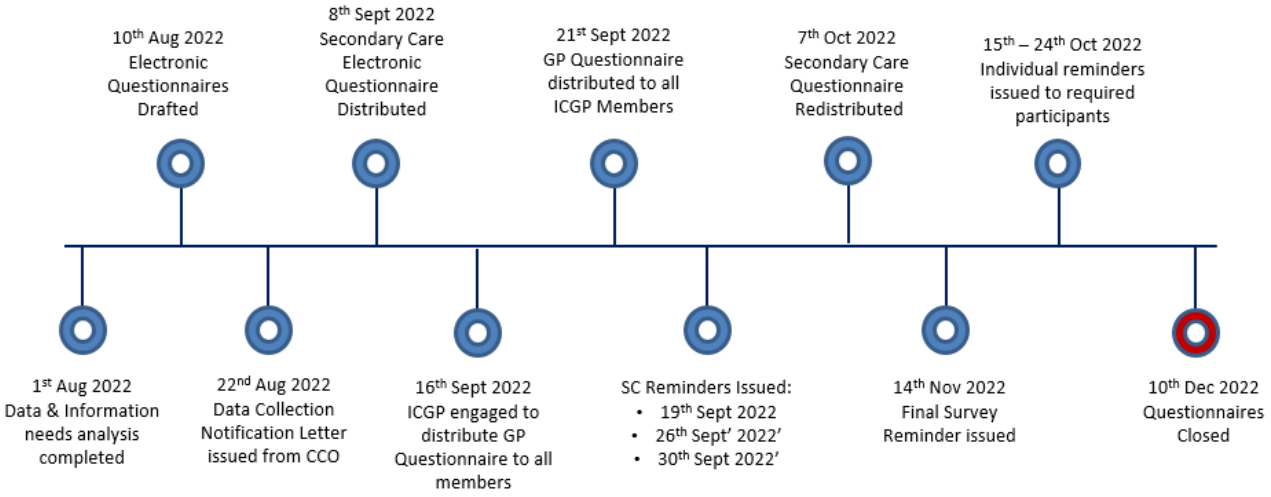

Figure 1.2 – Service Evaluation Timeline & Activities

International Best Practice Review

Good practices and gap analysis were based on desktop review of research and literature using relevant keywords. Due to the timeframe, it was not possible to perform a detailed scoping review or systematic review for each of the topics explored. Searches were restricted to systematic and scoping reviews, national audits and cohort data, randomised control trials, published national clinical guidance and committee opinions and statements. The findings also use the guidelines of other Associations. These included: The International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG); The American Institute of Ultrasound in Medicine (AIUM); The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG); The Society of Obstetricians and Gynaecologists of Canada (SOGC); The National Institute for Health and Care (NICE); The NHS Fetal Anomaly Screening Programme; The Royal College of Obstetricians and Gynaecologists; British Medical Ultrasound Society (BMUS); The International Federation of Gynaecology and Obstetrics (FIGO).

[12] https://lmcsupport.ie/

Gap Analysis

Using the outputs of both the Service Evaluation and the desktop literature and research review, a gap analysis was undertaken to assess the performance of termination of pregnancy services as provided under Section 11 of the Act against the needs and demands of those seeking to avail of the service, those providing the service and other stakeholders. The purpose of the gap analysis was to identify thematic areas for consideration in the development of national recommendations.

Final Report and Recommendations

Compassionate healthcare professionals who provide non-judgemental and sensitive care can impact positively on parents' satisfaction with the care they receive. A well organised and co-ordinated healthcare system is needed to provide an effective and high-quality service.[13]

The national recommendations set out in this final report are the result of detailed and prolonged engagement and analysis incorporating: desktop research, quantitative analysis and the assimilation of service user expectations and experiences.

The recommendations provide a foundation for the development of an action plan/roadmap for the implementation of evidence-based, best practice service improvements across the continuum of care spanning: prenatal screening, diagnostic testing, termination of pregnancy for fetal anomaly, Investigations and follow-up care and support.

[13] Heaney, S., Tomlinson, M. & Aventin, Á. Termination of pregnancy for fetal anomaly: a systematic review of the healthcare experiences and needs of parents. BMC Pregnancy Childbirth 22, 441 (2022). https://doi.org/10.1186/s12884-022-04770-4

Summary of Findings

Previous studies have shown that in the main, the overall experience of termination of pregnancy services introduced in Ireland in 2019 is frequently described positively by service users. [14] In instances of TOPFA, the needs of women/parents are distinct, varied and complex. Research has helped to identify some common themes such as: the perceived quality of the relationship with healthcare professionals, the quality of information provided, the level and frequency of communication and experiences in terms of co-ordination of care. All of these have been shown to directly impact the perception of the care experience. [15]

Healthcare professionals also need support and appropriate training to meet the needs of women/parents. A study published in 2021, explored the experiences of fetal medicine specialists of providing termination of pregnancy for fetal anomaly. The study identified four themes: 'Not fatal enough', 'Interactions with colleagues', 'Supporting pregnant women' and 'internal conflict and emotional challenges'. Also observed was the fear amongst specialists of getting an FFA diagnosis incorrect and potential associated media scrutiny and/or criminal liability. [16]

This Review and the multiple work-streams thereunder, has, for the first time, provided a complete picture of termination of pregnancy services provided under Section 11 of the Act. By aggregating data and information from women/parents who have received a diagnosis of fetal anomaly, as-well-as from healthcare providers and senior clinical decision makers, we have visibility of the unique relationship each entity has with the service, in-turn providing a platform from which systematic, evidence informed, person centred, service improvements may be made.

Key observations:

The findings of the service evaluation, carried out as part of the Review demonstrate disparity with regard to co-ordination and continuity of care across the maternity infrastructure.

All 19 maternity hospitals/units routinely provide dating/first trimester anatomy and fetal anatomy ultrasound scanning. What constitutes a routine assessment as part of both examinations is not however consistent across sites.

Similarly, from the responses we can conclude that differing levels of information are provided to women/parents before and after routine scanning vis-a-vie the limitations of the scan, possible results, conditions screened for and incidence rates.

There is unregulated, inequitable access to commercially provided screening for aneuploidy by NIPS without appropriate pre and post-test counselling and without the

[14] Unplanned Pregnancy and Abortion Care (UnPAC) Study. July 2022

[15] Heaney, S., Tomlinson, M. & Aventin, Á. Termination of pregnancy for fetal anomaly: a systematic review of the healthcare experiences and needs of parents. BMC Pregnancy Childbirth 22, 441 (2022). https://doi.org/10.1186/s12884-022-04770-4

[16] Power S, Meaney S, O'Donoghue K. Fetal medicine specialist experiences of providing a new service of termination of pregnancy for fatal fetal anomaly: a qualitative study. BJOG. 2021 Mar;128(4):676-684. doi: 10.1111/1471-0528.16502. Epub 2020 Oct 13. PMID: 32935467.

protection of the governance or quality assurance that would come from a structured screening programme.

Findings also demonstrate the impact a lack of information has on the experience of women/parents in receiving a diagnosis of fatal fetal anomaly and emphasises the need for standardised, nationally consistent, clear, clinically sound and un-biased information to enable women/parents to make informed decisions regarding onward care. A determining factor or element in women/parents perceived experience of the service, was their interactions with healthcare professionals and the manner, level and appropriateness of communication regarding their case.

Continuity and co-ordination of care are important aspects of service provision for women/parents. Staffing and skill mix vacillates within maternity units and specialist fetal medicine centres. The need for a consistent and sustainable staffing model is further evidenced in findings with regard to the women's/parents perception of TOPFA services and perceived supports.

Findings of the Review show that demand far outweighs capacity with regard to Clinical Perinatal Genetics services and that at odds with clinical guidance and best practice pathways of care, all fetal medicine centres do not have timely access to clinical genetics specialists to discuss cases and advise on appropriate genetic testing.

The role of Neonatology and level of involvement in review of cases where TOPFA is being considered and in palliative care planning for babies born with signs of life has been observed as varying from site to site, as has the availability and provision of feticide.

Similarly, the role of post-mortem examination (PME) is not uniform with varying policies and practices around provision of PME after TOPFA, PME consent processes and the stage at which PME is discussed with women/parents as part of end-of-life care planning. Access to Perinatal Pathology is still not structured or formalised in some maternity units.

In summary, gaps and deficiencies were observed in services provided across the six Fetal Medicine Centres and nineteen maternity hospitals/units, which is reflected in the lived experience of women/parents and underscores the need to develop a cohesive national approach to fetal medicine and related services.

Section 1

Service Evaluation

Section 1 - Service Evaluation

Section Overview

Evaluation of healthcare services is critical to ensure high quality care and to plan for future service enhancement. The service evaluation undertaken as part of the Review of the Operation and Management of Termination of Pregnancy Services, as provided under Section 11 of the Act, was designed to baseline current service provision and to assess service performance against the intended aims of providing a safe, high quality, termination of pregnancy service, in a co-ordinated, consistent and equitable manner.

The scope of the service evaluation extended to all key touchpoints and pathways across primary and secondary care. This section will describe the current context within Ireland as relevant to prenatal screening, prenatal diagnostic services, termination of pregnancy due to fetal anomaly and support services including bereavement and postnatal care.

About the HSE Maternity Services and Termination of Pregnancy Service Provision

The National Maternity Strategy, Creating a Better Future Together, 2016-2026, provides the strategic roadmap for the development and delivery of maternity services in Ireland around a defined model of care. The model of care comprises of three separate care pathways: Supported Care; Assisted Care and Specialist Care. All pregnant women ordinarily resident in Ireland are entitled to free maternity care. Under the scheme, care is shared between General Practitioners and the hospital/DOMINO services. [17]

Under the 2018 Health Regulation of Termination of Pregnancy Act, termination of pregnancy services are available in both hospital and community settings. The vast majority of terminations of pregnancy up to nine weeks gestation are carried out in the community setting. At the time of writing this report, there are 413 community based providers of termination of pregnancy services, this includes 403 General Practitioners and 10 women's health service contractors.

In Ireland, there are nineteen maternity hospitals/units, configured under six maternity networks, i.e. one per each of the six hospital groups.[18] The maternity networks represent all of the maternity hospital/units within their individual hospital group; act with the authority of the hospital group in interacting with NWIHP and comprise, at a minimum, of a clinical lead, midwifery lead, and quality and safety lead. There are currently 11 maternity hospitals/units providing full termination of pregnancy services as prescribed in the Health Regulation of Termination of Pregnancy Act 2018.[19]

[17] https://www.hse.ie/eng/services/list/3/maternity/combinedcare.html
[18] https://www.hse.ie/eng/services/list/3/maternity/
[19] https://www2.hse.ie/conditions/abortion/how-to-get/in-hospital/

Structural anomalies are usually suspected or diagnosed at routine ultrasound screening in the first or second trimester of pregnancy. Current guidance stipulates that all women should then receive a prompt referral for a fetal medicine opinion, ideally within five working days where a fetal anomaly is suspected, or within 24 to 72 hours where a major fetal anomaly is suspected.[20] The recently published fetal anatomy ultrasound guideline recommends that written information should be provided in a request for a fetal anatomy ultrasound examination; that informed written consent should be obtained by the Sonographer prior to proceeding with ultrasound examination; that fetal anatomy ultrasound examination be performed after 18 weeks and before 22 weeks' gestation, ideally between 20-22 weeks'. In addition, the guideline makes recommendations regarding the scope, extent and limitations of the examination, repeat ultrasound and practices around referral to fetal medicine.[21]

There are six specialist Fetal Medicine Centres attached to tertiary maternity hospitals in Cork (1), Limerick (1), Galway (1) and Dublin (3). The pathways around antenatal diagnosis/initial care, as set out in the Interim Clinical Guidance pathway (published in 2019 and revised in 2020) and agreed through the fetal medicine working group in 2018-2019, are as follows:

- Antenatal diagnosis of a major structural fetal anomaly may be made at the 11-13-week scan, or second trimester anomaly scan at 20-22 weeks, and is ordinarily confirmed by either the local Obstetrician and/or fetal medicine specialist in the tertiary centre (or by a fetal medicine specialist from the tertiary centre who has a sessional commitment in another hospital/unit).
- Where termination of pregnancy is being considered, a fetal medicine specialist should be involved in the antenatal diagnosis and subsequent care of the pregnancy. It is further recommended that a fetal medicine specialist be one of the signatories on the certification documents.
- The majority of pregnant women in this situation will be referred to the tertiary hospital in their area (or to the fetal medicine team in the tertiary hospital) for review and assessment by fetal medicine specialists. This may include additional investigations (e.g. invasive testing for genetic diagnosis or fetal MRI where ultrasound has limitations for full evaluation), and referral to specialist fetal echocardiography for cardiac anomalies. These cases are subsequently discussed by the multi-disciplinary team at the tertiary site to reach a consensus about the diagnosis and prognosis, and to consider the option of TOPFA being discussed with the Parents.
- Some fetal conditions–for which there are simple definitive diagnostic tests and an unequivocal prognosis (e.g. anencephaly)–may be diagnosed and managed at local hospital level, where fetal medicine expertise exists, or where a fetal

[20] INTERIM CLINICAL GUIDANCE PATHWAY FOR MANAGEMENT OF FATAL FETAL ANOMALIES AND/OR LIFE LIMITING CONDITIONS DIAGNOSED DURING PREGNANCY:TERMINATION OF PREGNANCY

[21] Fleming, A., Corbett, G., McParland, P. National Clinical Practice Guideline: The fetal anatomy ultrasound. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. January 2023

medicine specialist from the tertiary centre has a sessional commitment. Invasive testing may occur at the tertiary centre, but results are communicated to local/other units and ongoing care is managed with the local Obstetricians and Neonatologists /Paediatricians, supported as needed by the tertiary site.

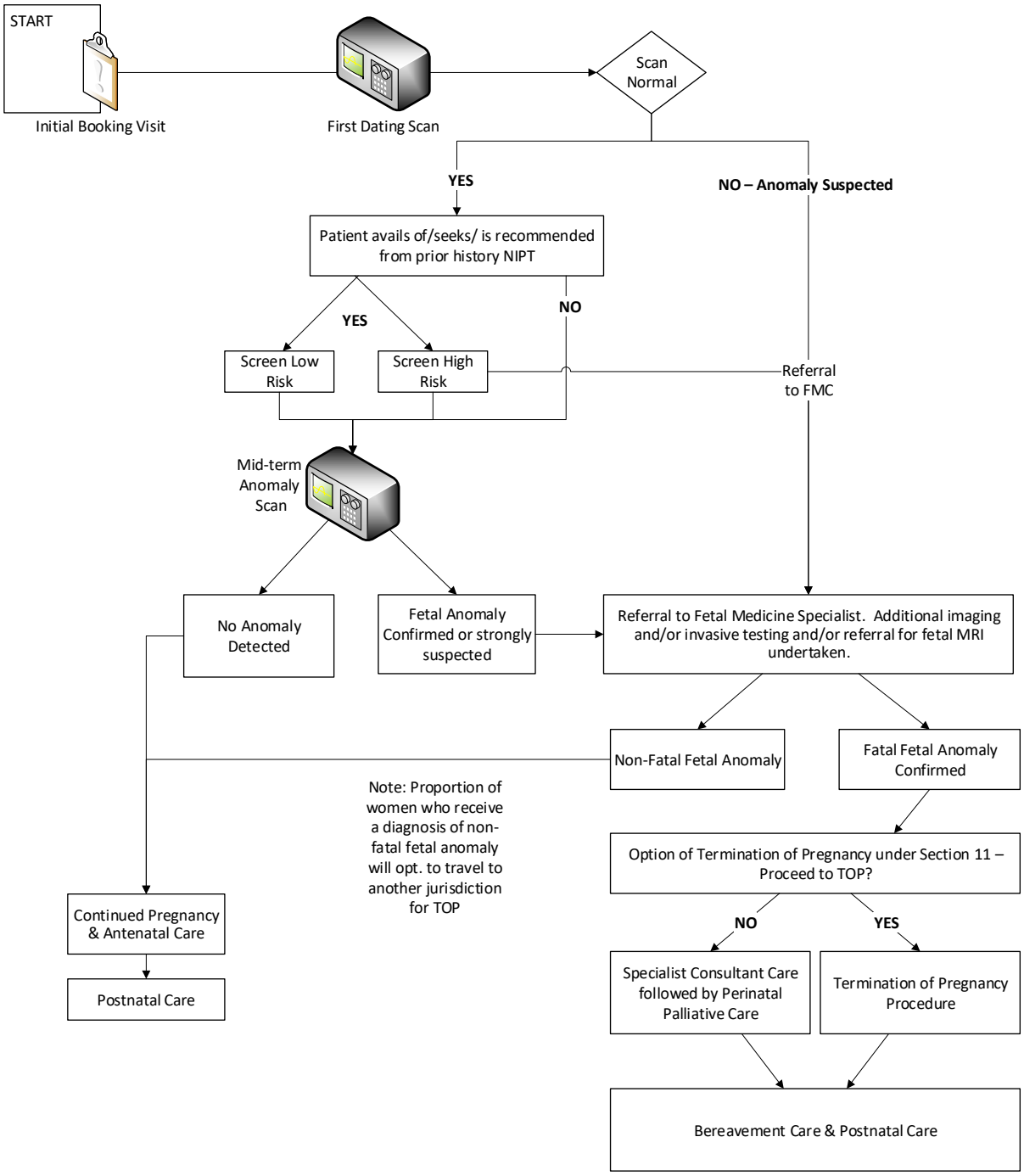

Figure 1.3 Pregnancy Care Pathway – Diagnosis and management of fetal anomaly

Section 1a Service Evaluation - Primary Care

Scope

General practitioners play an important role in maternity care, spanning pre-conception, antenatal and postnatal care, however, as stated earlier, most Structural anomalies are usually suspected or diagnosed at routine ultrasound screening in the first or second trimester of pregnancy in a hospital setting. It was therefore agreed by the Review Group that the scope of the service evaluation with regard to primary care would focus on the current role of GPs in pre-natal screening and diagnostics, considering: provision of information, non-invasive prenatal testing and onward referral pathways to secondary care.

Survey design and distribution

A service evaluation questionnaire (refer to Appendices) was designed in consultation with members of the Review Groups 'Trimester One' working group. The questionnaire incorporated a blend of open-ended, multiple choice and Likert-scale items. The Qualtrics survey platform was used to build and distribute the questionnaire[22]

Data analysis

Quantitative data were analysed within Qualtrics using descriptive statistics. Responses to open-ended questions were imported into NVivo (via Excel) and analysed using content analysis.

Results

An electronic link to the service evaluation questionnaire was distributed to all members of the Irish College of General Practitioners (ICGP; n=4000), with a resulting questionnaire completion rate of 4% (n=163). While the completion rate was relatively modest, the working group was satisfied that all Community Health Organisation (CHO) regions were represented in the returns.

GPs were asked how frequently newly pregnant women enquire about non-invasive prenatal screening (NIPS) or any form of first trimester screening. A high proportion of respondents (86%) selected an option of 'Never' or 'Occasionally'. The questionnaire also asked GPs to consider how frequently they discuss or provide information on NIPS, again a significant majority of respondents selected the options 'Never' or 'Occasionally' for this question (75%). Responses to open-ended questions provided helpful insight as to why some GP providers were adopting a cautious approach with regard to performing or discussing non-invasive prenatal screening and other forms of first trimester screening with patients.

Only 14% of GPs who participated in the service evaluation stated that they routinely provided written information on screening options. Once again, concerns regarding the extent and appropriateness of professional indemnity arrangements were raised. A review of the open-ended comments suggests that GPs are sign-posting to other relevant services.

[22] https://www.qualtrics.com/uk/core-xm/survey-software/

GP's knowledge and awareness of Section 11 of the Act and of the function and limitations of Non-Invasive Pre-natal Screening

61% of GPs who responded to the questionnaire felt that they would not be adequately equipped to discuss NIPS with women routinely were it to be implemented and made publicly available in the first trimester. Just over half of GP respondents felt that their patients had a clear understanding of what NIPS is prior to having it. With regard to follow-up support follow high or low risk NIPS, 74% of those who responded felt that maternity hospitals have a planned pathway of care whilst only one third of GPs felt that private providers have planned care pathways in place.

Three-quarters of participants said that they would participate if NIPS was implemented in the first trimester. Of these, the majority said that the level of involvement would be subject to the required supports being put in place. – primarily, in the form of appropriate funding, reimbursement, resources, and education and training.

Each cohort of clinical specialists surveyed as part of the primary and secondary care service evaluations were to rate, in their professional opinion, the level of awareness of Section 11 of the Act amongst their peer group and provided an opportunity to provide any final comments or observations with regard to the operation of Section 11 of the Act.

Q. In your professional opinion, how would you rate the level of awareness and knowledge of Section 11 of the Health Regulation of Termination of Pregnancy Act 2018 amongst the GP community?

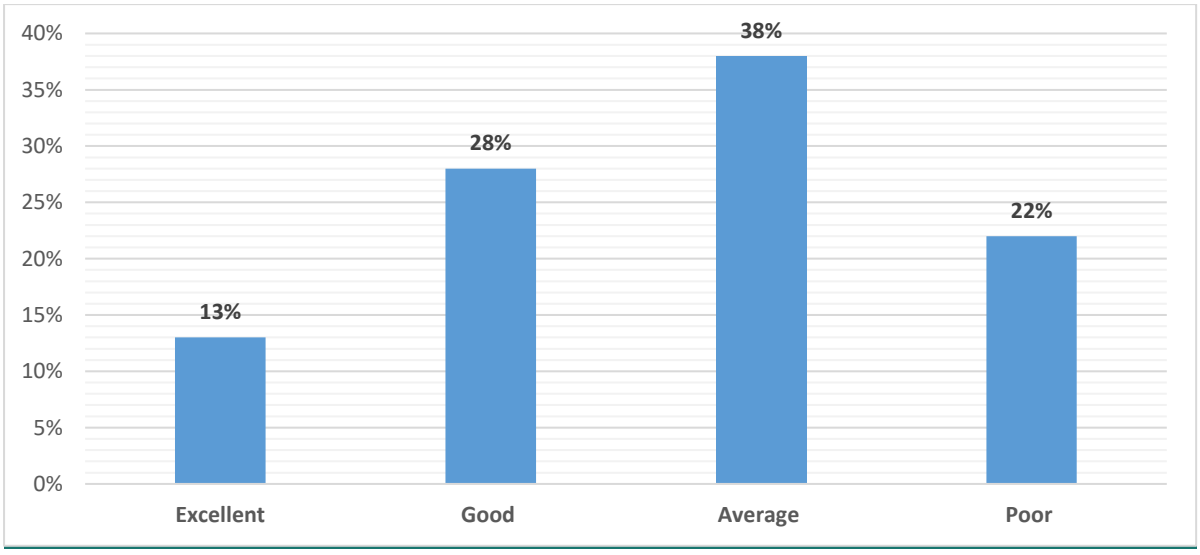

Figure 1.4 GP Level of Awareness of Section 11

Analysis of open-ended questions – Primary Care

Q. In the context of this Review of the operation of Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018, if you have any further comments or observations, please note them here.

Fifty-five people responded to this question, 10 of whom stated no further comments, leaving comments from 45 people for analysis. Responses covered a range of issues.

TOP

Most people provided further comments regarding TOP. The majority of these were regarding the legislation itself and/or how it was operationalised in practice , including knowledge and expertise of service providers.

Many highlighted **barriers to accessing TOP due to the legislation itself (including the three-day wait primarily and also certification/notification) and systemic issues in implementing it**, e.g. access to scans, timely reports, and services, and knowing what services are offered by hospitals or what the pathways are.

"Too rigid at the moment. How terminal is terminal?."

"I would like to see an alternative to current Certification and Notification. I think it is restrictive and can be opaque when supporting women where English is not their first language."

"The 3 day waiting period can be onerous and lead to women struggling with access of dates are late. Also access to scanning varies based on geography. And delays on reports coming back or getting scan lead to woman being over dates and unable to access care."

"I provide abortions and the 12 week limit is very difficult - sometimes women are wrong about their dates and can present at 11 + weeks, the hospitals are hit and miss about accepting referrals, one maternity hospital has caused delay to a patient which resulted in very unfavorable outcome, this was so traumatic for the couple involved. Also, very young women who might be aged 15 or so often present late and are very vulnerable, getting parental consent can take time, and this adds to the delay and puts the young patient at risk- I feel the 12 week limit and the mandatory 3 day wait is not easy to apply clinically - it would be better if there were a clinically relevant guideline such as CRL, for example. Some of the hospital consultants are super and very supportive and helpful, other hospitals are less so. It is awful seeing a patient who is up to the limit and who has been turned away by the hospital, it's very hard. This doesn't happen often, it's a couple of times a year, but I feel there needs to be some clinical flexibility around the 12 week limit and the 3 day mandatory wait. Neither of these legislative restrictions are based on any evidence-based clinical guidelines, they are just numbers that were used to facilitate the legislators. I do think that if these 12 week deadline and 3 day mandatory wait could be removed from the legislation, we could instead apply meaningful clinical guidelines instead that could help to make more clinically

relevant decision making easier for patients. Thanks so much for doing this survey, I really appreciate the work going into this. The patients are very grateful always when we provide this service and so it is an honour to be able to work in this field of medicine."

"Local access to EPU in [Hospital Name] is inadequate, long delays, often have to inappropriately refer to ED due to patient distress over delays/delays in seeing suspected ectopic pregnancies. "

"Our practice sees women from outside CHO [CHO area] for TOP services and their location impacts what services they can avail of."

"opaque system regarding what hospitals provide what."

"No pathway from/to primary care . GPs in the dark about mdt meetings and largely unaware of what reasonably can be expected from service for our patients."

Two participants highlighted issues relating to lack of follow-up following TOP:

"Number of patients have accessed TOP - neighbouring practice/ clinic elsewhere: NO follow up when- had heavy PV Bleed/ cramping. Left to GP (me) to deal with."

One person mentioned that they *"urgently need protection against activists picketing medical premises".*

Many also spoke about issues relating to the **expertise or knowledge required of service providers**. The ambiguity or lack of knowledge around the legislation was mentioned by a few participants.

"The operation of Section 11 is poorly understood, involving inevitable personal perspectives for both patient and professionals that may be converging or diverging, with consequent involvement or inability to be involved on the part of professionals on grounds of freedom of conscience."

"No one would know what the various sections refer to. I'm not sure and I'm a provider."

Some felt that GPs providing TOP were well-informed, whereas GPs who were not had very little knowledge of TOP or referral processes. Some admitted their own lack of knowledge in this area. The value of peer support – within and between practices/individual GPs and also local hospitals - was mentioned.

"think those who are providing are very much up to speed on it TOP logistics etc but those who aren't have very little knowledge on. I haven't provided to date but I would like to get involved but I feel a bit behind now. If there was a system whereby new provider GPs could have an experienced provider GP to call to talk through the first one or two or if queries I think there would be more providing from what colleagues and I have found. We don't want to make a mistake vis a vis the legislation. When it first came in I was abroad so missed the initial training webinars etc."

"Peer support from participating GPs and local hospital back-up has been excellent. This should be emphasised to other GPs who are considering the service."

A few people commented that the service or system was working well.

"I feel the general practice community has upskilled to a very high standard to provide very safe, accessible termination in the community."

"EMA functioning well in [CHO area]."

"Happy to provide top and doing so regularly."

Two people mentioned that people should be presented with all of the options, and details of available supports/counselling, in a non-directive manner and; not offering termination routinely as a first option or allied to the provision of abortion services. Another person mentioned that they felt that people went to My Options as a first port of call as they had not been asked by patients about information around termination since this service became available. One person self-identified as a conscientious objector but left no further comment.

NIPS

Just over a third of people who made further comments in relation to this question, did so regarding NIPS. These mainly focused on the need for training and adequate reimbursement.

"Remuneration for antenatal care for GPs is completely inadequate. I would not take on any additional work in the area of NIPS without additional training, resources and additional remuneration. My GP indemnity does not cover for NIPS and advised against facilitating in GP."

A few also mentioned the need to confirm viability before conducting NIPS and having access to Fetal Medicine services.

"It would be unethical to encourage GPs to perform Harmony/Panorama tests without confirming fetal viability at the time of the test by ultrasound scan, I have experienced many blighted ova as well as patient incorrect date estimation that would cost the patients a lot of money as testing is pointless. As well, prompt fetal medicine access to manage high-risk results as false +ve is much higher than false -ve 1:200 compared to 1:20000, these patients need swift access to amniocentesis and reporting, not accessible in many antenatal centers."

"Prenatal tests should be arranged at correct stage of pregnancy by hospital services, way above GP level input to refer/ interpret same, that's specialist obstetric work that hospital needs to provide at appropriate early stage, they get referrals quite early from us so they can contact women then. They need to own that service. Incorrect interpretation those results led to a very sad court case."

One participant was unsure of the perceived role of GPs in NIPS, while one was adamant that GPs should not be involved in NIPS:

"NIPS way too complex and medicolegally challenging for us to get involved with. That's for secondary care. Stop trying to offload complex secondary care work to GPs. Won't get involved if foisted on us. Main issue that annoys me is that… Payment for pregnancy combined care utterly appallingly low for responsibility involved, needs to be tripled .. it's a joke…pays way more for top consults which is appaling tbh."

Section 1b Service Evaluation - Secondary Care

Scope

Where a fetal anomaly is suspected or confirmed during pregnancy, a multi-disciplinary approach is recommended to support women/parents in understanding the diagnosis and making informed decisions surrounding onward care. Women/parents need access to clear, accurate and accessible information on all available choices, presented in a non-judgemental, non-directional manner. Women who receive a prenatal diagnosis of fetal anomaly will interact with many clinical specialists and hospital personnel across their care journey. In order to get an accurate, point in time, baseline assessment of service provision and continuity of care in secondary care settings, it was necessary to engage with senior leaders and decision makers across the 19 maternity units as well as those directly involved in providing care around TOPFA to women within each individual maternity hospital/unit.

Survey design and distribution

A service evaluation questionnaire (refer to Appendices) was designed in consultation with members of the Review Groups 'Trimester 2&3' working group. Five speciality/role specific questionnaires were designed, centered around the TOPFA pathway: prenatal screening, diagnosis, management and postnatal follow-up care. The questionnaire incorporated a blend of open-ended, multiple choice and Likert-scale items and were distributed electronically via direct mail to the following personnel across the 19 maternity units and 6 specialist Fetal Medicine Centres. A completion rate of 94% was achieved with all maternity hospitals/units and specialist Fetal Medicine Centres represented.

Role	Total No. Disseminated	Total No. Completed
Consultant Obstetrics & Gynaecology (Lead)	19	17
Director of Midwifery	19	19
Consultant Neonatologist/Paediatrician (Lead)	19	17
Consultant Perinatal Pathologist (Lead)	7	7
Consultant Fetal Medicine Specialist (Lead)	6	6
Total	**70**	**66 (94%)**

Table 1.1 Number of Surveys distributed and completed

Data analysis

Quantitative data were analysed within Qualtrics using descriptive statistics. Responses to open-ended questions were imported into NVivo (via Excel) and analysed using thematic analysis.

Results

1. First Trimester fetal ultrasound and fetal anatomy ultrasound

In accordance with the National Maternity Strategy (NMS) 2016-2026, all women must have equal access to standardised ultrasound services, to accurately date the pregnancy, to assess the fetus for diagnosable anomalies as part of a planned prenatal fetal diagnostic service, and for other indications if deemed necessary during the antenatal period. For many women/parents, the first indications that there may be concern surrounding a pregnancy are identified during routine first trimester fetal ultrasound scanning or fetal anatomy ultrasound scanning.

Technological advancements have allowed for resolution of ultrasound imagining in the first trimester to evolve to a level at which early fetal development can be assessed and monitored in detail. The recently published National Clinical Guideline for Fetal Anatomy Ultrasound provides clear guidance and evidence-based, best practice protocols with regard to the fetal anatomy ultrasound examination. [23]

In order to baseline processes and procedures with regard to first trimester fetal ultrasound scanning and fetal anatomy ultrasound scanning, the service evaluation questionnaire focused on establishing:

- Local compliance with the two-stage ultrasound scanning programme;
- What is assessed routinely as part of both examinations;
- The gestation at which both examinations are undertaken;
- The role and skillsets of the person(s) who perform both examinations;
- The quality and grade of ultra-sonographic equipment being used;

1a. Compliance with the two-stage ultrasound scanning programme:

Responses from all 19 maternity hospitals/units confirmed that all pregnant women are routinely offered first trimester fetal ultrasound (dating scans) and fetal anatomy ultrasound, ordinarily between 11 and 12 weeks and 20 and 21+6 weeks' gestation respectively.

[23] Fleming, A., Corbett, G., McParland, P. National Clinical Practice Guideline: The fetal anatomy ultrasound. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. January 2023

1b. What is assessed routinely as part of both examinations:

Some site-to-site variation was observed as to the scope/extent of first trimester fetal ultrasound scanning and the roles and skill-sets of those undertaking same, for example, 14/19 sites reported that limited fetal anatomy is assessed as part of a routine dating scan. Similarly, 2/19 sites advised that they do not routinely assess chorionicity (if multiple pregnancy) as part of the routine dating scan.

Q. What is assessed as part of a routine dating scan within your hospital/unit? (N=19)

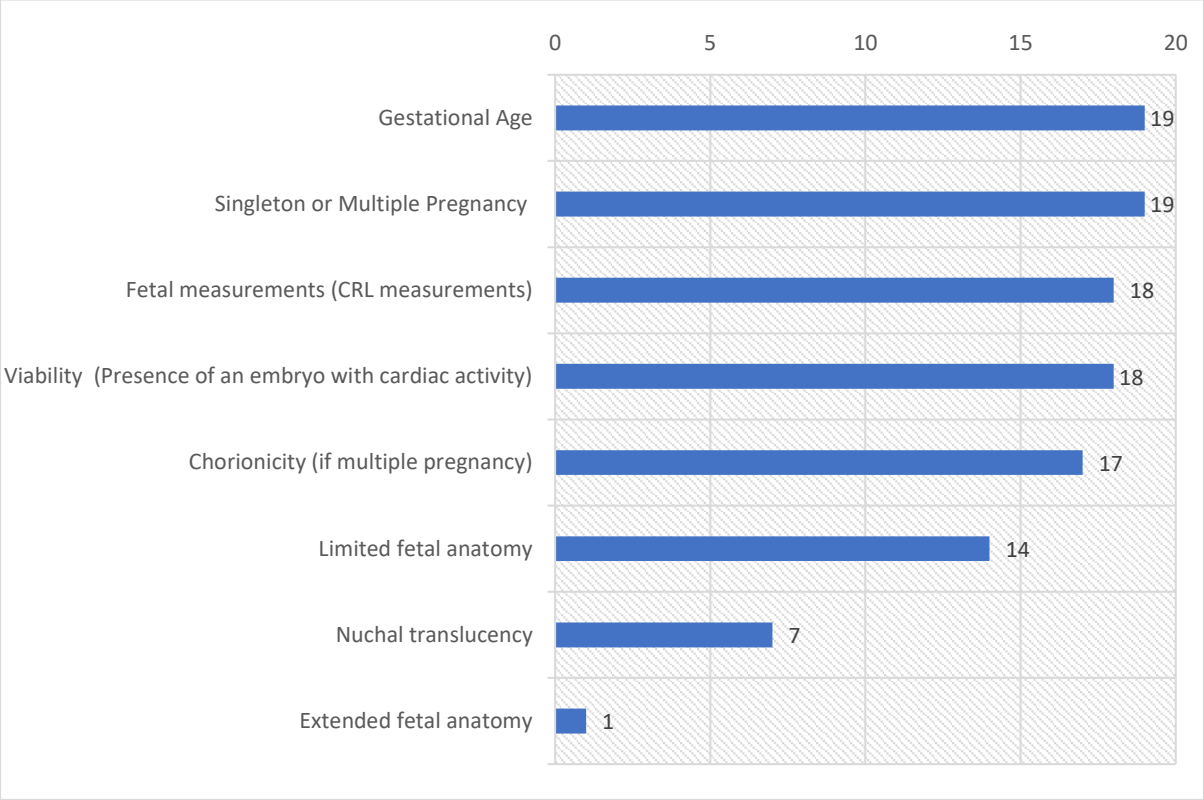

Figure 1.5

1c. Written Information regarding fetal anomalies

It was reported that 32% or 6/19 maternity units provide written information to women/parents regarding fetal anomalies before a dating scan whilst 74% or 14/19 sites reported that they provided written information prior to the fetal anatomy scan.

1d. The role and skillsets of the person(s) who perform both examinations:

Q. Who performs ultrasound examinations in your unit? (Tick all that apply)

Column1	1st Trimester – Fetal Ultrasound	Fetal Anatomy Ultrasound
Midwife Sonographer	n=19/19	n=19/19
Radiographer	n=8/19	n=8/19
Doctor	n=7/19	n=5/19

Table 1.2

1e. Audit of service

The service evaluation also sought to establish whether services were routinely audited and whether particular aspects of the service feature in the hospitals annual report. The Directors of Midwifery responded to this question. 58% or 11/19 sites confirmed that they conduct an audit of the ultrasound services annually. The remainder of the sites do not undertake formal annual audit of ultrasound services.

2. Fetal medicine:

National guidance on TOPFA recommends that a fetal medicine specialist should confirm an antenatal diagnosis of a structural anomaly and a suspected fatal fetal/life limiting condition. In turn, fetal medicine units should have timely access to clinical genetics specialists who may make recommendations and advise on necessary genetic testing.

Within maternity units, fetal medicine specialists play an important role in clinical decision making regarding fetal anomaly and in determining whether a diagnosis satisfies the criteria for lawful termination of pregnancy under Section 11 of the Act. Delayed access to fetal medicine and genetics services, expertise and information can exacerbate an already distressing and traumatic time for women/parents. Lead Maternal Fetal Medicine (MFM) consultants in each of the six Fetal Medicine Centres and the Clinical Leads of all 19 maternity hospitals/units were therefore asked to contribute to the service evaluation around access and appropriateness of services across these two specialist areas.

2a. Referral pathways to fetal medicine

As shown below, survey participants were presented with a list of personnel and asked if any of same co-ordinate referrals to and from fetal medicine services. Results show that roles and responsibilities in co-ordinating and managing referrals where a fetal anomaly is suspected during routine ultrasound examination, are not standardised across the maternity services.

Q. Who usually co-ordinates the referrals to and from the fetal medicine service? (N=19)

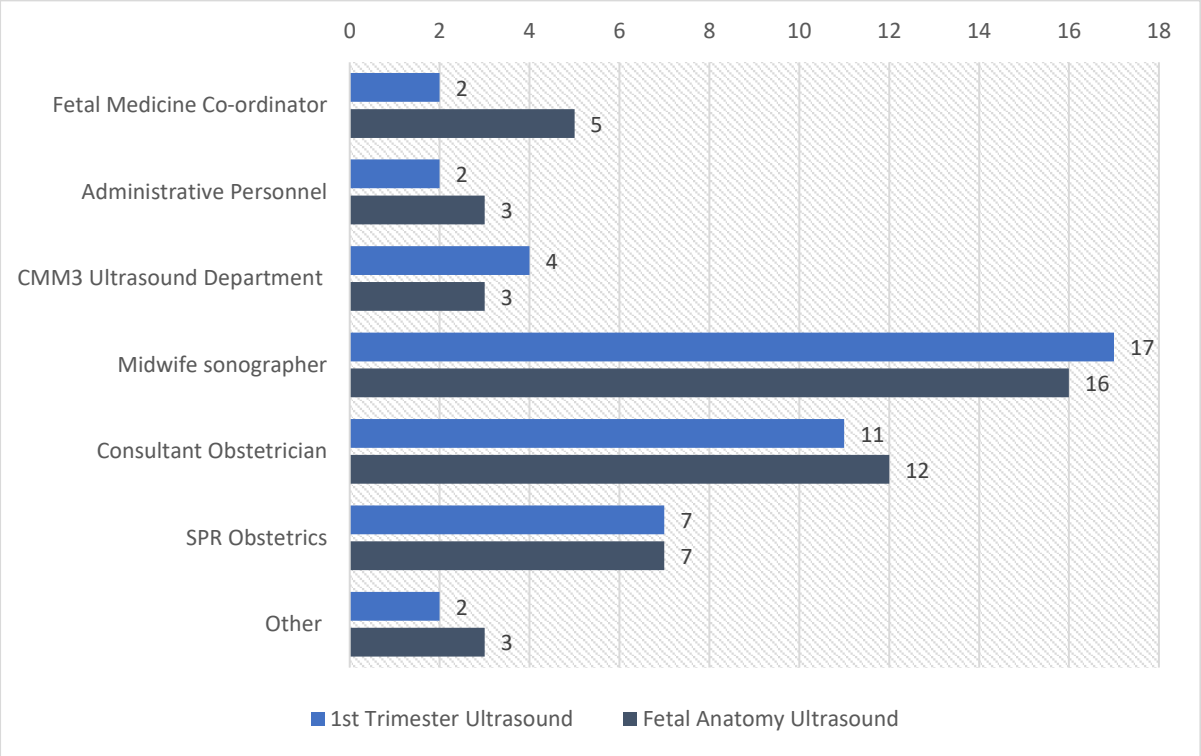

Figure 1.6

2b. Fetal medicine centre resourcing & skill mix

Staffing levels and skill mix also varied from site to site. Only **3** of the **6** fetal medicine centres reported that they had in post a designated, identifiable fetal medicine co-ordinator. Similarly, just **3** of the **6** centres reported that they had a fetal medicine lead midwife/midwife sonographer in post. At time of reporting, none of the 6 Fetal Medicine Centres had in post a dedicated Fetal Medicine Centre manager.

2c. Counselling and Bereavement support

National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death were developed in response to recommendations in the HSE's Investigation Report into the death of Savita Halappanavar (2013).[24] Following a two year, comprehensive, programme of work the Standards were launched in August 2016, and a revised version was published in 2022. The Standards clearly define the care parents and families can expect to receive following a pregnancy loss or perinatal death and apply to all pregnancy loss situations from early pregnancy loss to perinatal death, including the end of a pregnancy as well as situations where there is a diagnosis of fetal anomaly that will be life-limiting or may be fatal.

As per the standards, anticipatory bereavement support should be offered to all families upon diagnosis of a life limiting condition or a fetal anomaly that may prove

[24] National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death, Version 2, July 2022

fatal. The questionnaire asked each maternity site to advise if dedicated counselling and support was routinely provided to women following a diagnosis of fetal anomaly. 16/19 maternity units (84%) confirmed that they do, while 3/19 (16%) answered 'No' to this question.

The standards also highlight the importance of Bereavement Clinical Midwife Specialist (CMS) role in providing anticipatory bereavement support to those families whose baby is diagnosed with a life-limiting condition, working with the Multidisciplinary Team (MDT) within the Perinatal Palliative Care framework. He/she is an identifiable resource to bereaved mothers, partners and siblings around the time of loss, following discharge home and in subsequent pregnancies.

At time of reporting, dedicated counselling and bereavement resources were reported as in place in **4** of the **6** Fetal Medicine Centres. It is worth noting that a definition of the meaning of a dedicated resource (i.e. in time, WTE or sessional commitment) was not sought or given.

2d. Fetal medicine Multi-disciplinary Team Meetings

A good practice point from the Interim Clinical Guidance on TOPFA states that fetal medicine multidisciplinary team (MDT) discussions should form an important part of the assessment of fetal anomalies, their prognosis and outcomes. The guidance also incorporates suggested membership for fetal medicine MDT meetings and recommends that decisions should be recorded and documented in clinical notes.

Each of the 6 Fetal Medicine Centres was therefore asked about the frequency, mode, membership and decision-making processes and protocols. All sites confirmed that fetal medicine MDT meeting routinely take place in their centre. In 3 of the 6 centres, MDT meetings occur on a weekly basis. One centre reported that the fetal medicine MDT Meeting occurs every 2 weeks and the remaining centre reported that the meeting takes place on a monthly basis. In 4 of the 6 centres the mode of attendance was reported as in-person while 2 centres advised that a hybrid model of in-person and virtual attendance was facilitated.

As illustrated below, variability is observed as to which specialities routinely attend the fetal medicine MDT meetings and in the recording of minutes and decisions across the centres:

Q. Are decisions made at the Fetal Medicine MDT meetings around / in TOPFA recorded? (N=6)

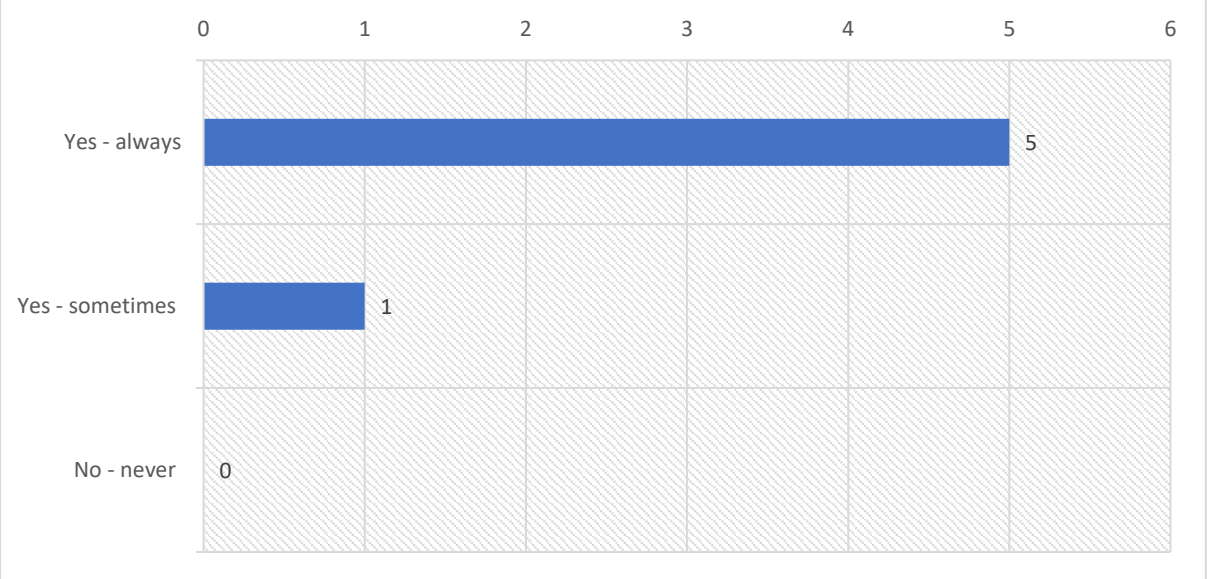

Figure 1.7

Q. Are minutes of the Fetal Medicine MDT meetings routinely recorded? (N=6)

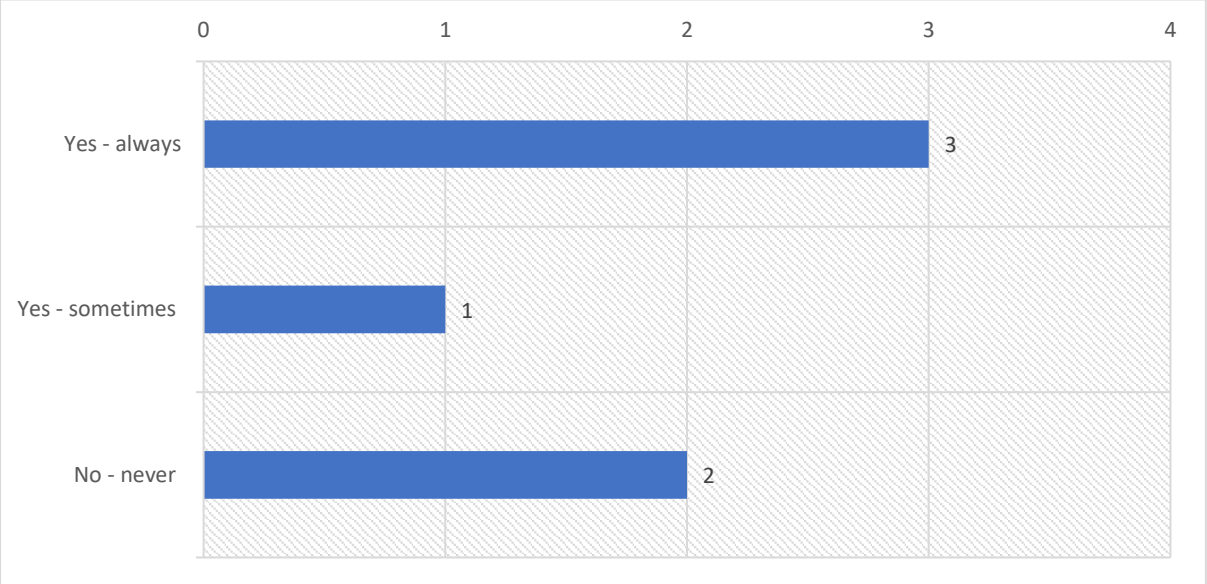

Figure 1.8

Q. What specialities attend the fetal medicine multidisciplinary team meeting ? (N=6)

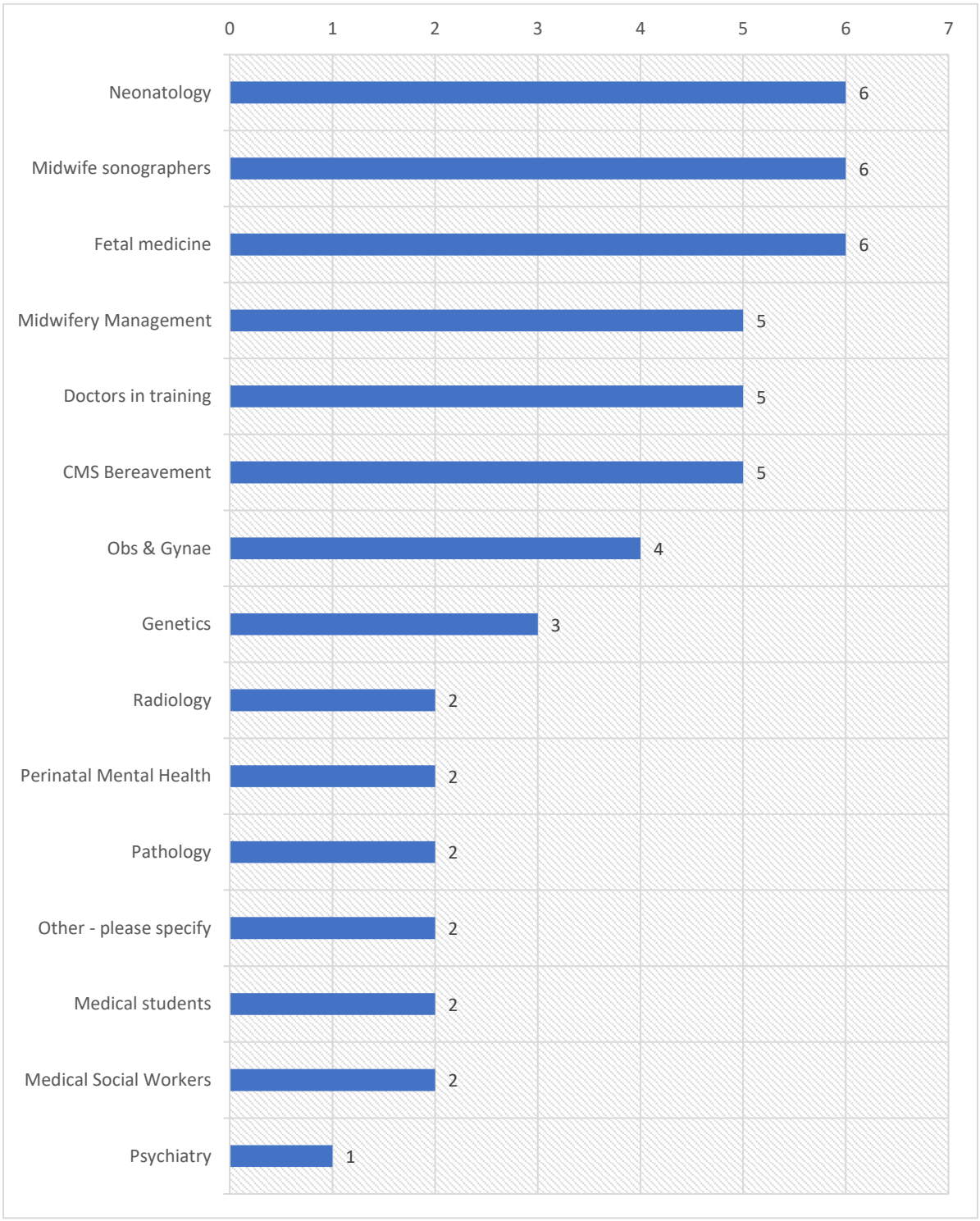

Figure 1.9

2e. Referral for Second Opinion

According to the interim guidance on TOPFA, in instances where either parents or healthcare professionals are uncertain about a diagnosis or prognosis, a second opinion, either internal or external, should be sought.

Each Fetal Medicine Centre was asked whether centre to centre referral takes place in practice and for which conditions a second opinion might be sought internationally. From the results, it can be concluded that processes around referral and frequency of referral for second opinion vary from site to site.

Q. Does your Fetal Medicine Centre refer cases externally, within Ireland?

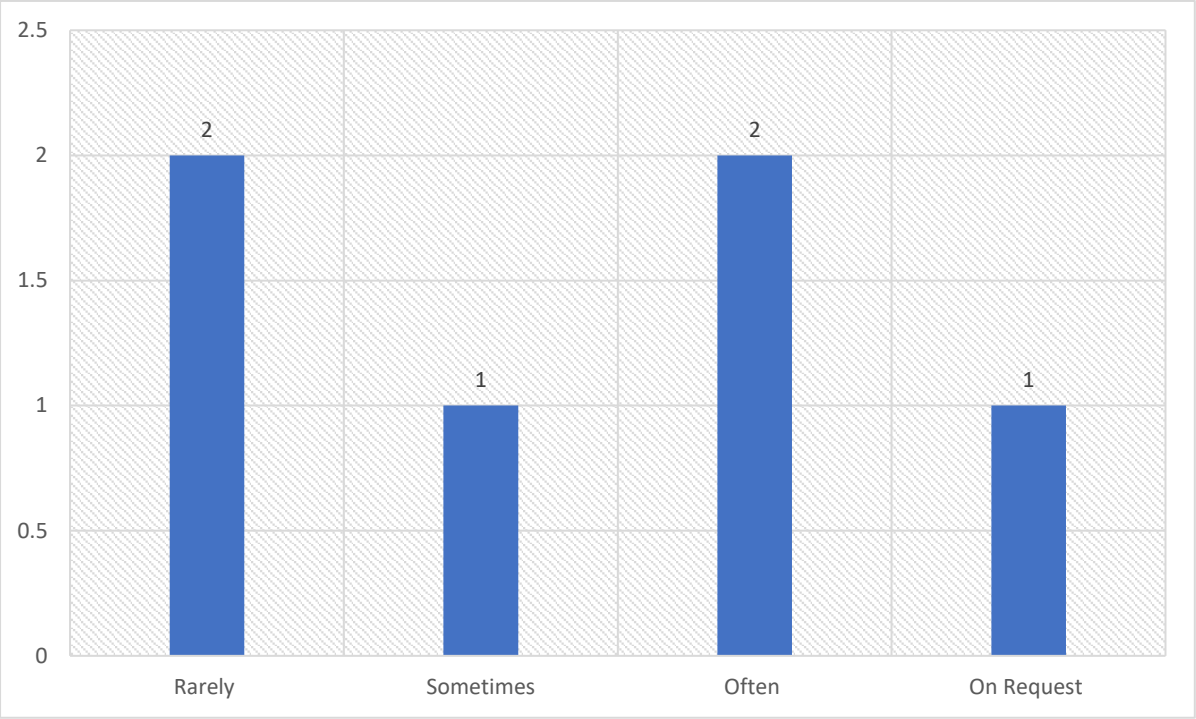

Figure 1.10

Q. Under what circumstances/criteria does your Fetal Medicine Centre refer cases externally, within Ireland? (Tick all that apply)?

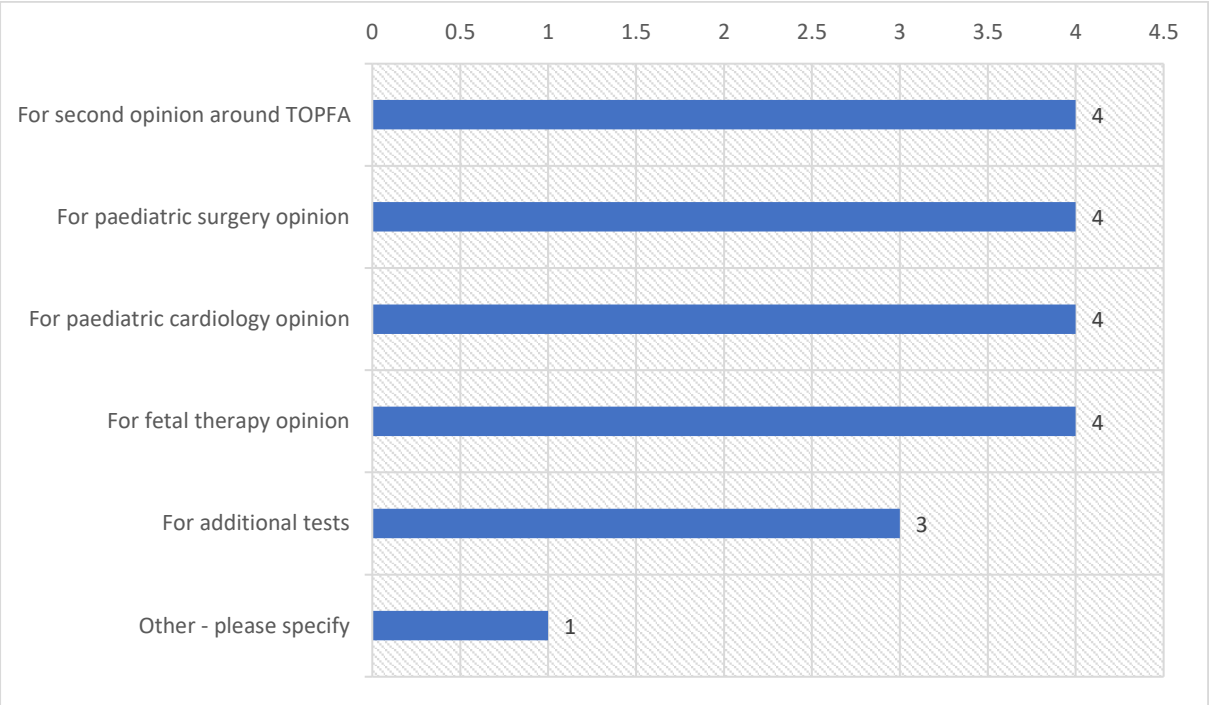

Figure 1.11

Q. Does your Fetal Medicine Centre refer cases outside of Ireland for the following Indications

Figure 1.12

2f. Clinical Guidelines & sub-speciality training (accreditation)

Clinical practice guidelines assist healthcare practitioners, service users, policymakers and other stakeholders to make informed decisions about healthcare practice, public health and health policy. Clinicians also need up-to-date and reliable resources to keep up their knowledge, and guidelines are important to address this need.

With this in mind, Fetal Medicine Centres were asked about access to and knowledge and awareness of clinical guidelines across a range of areas. Illustrated below and of concern, is that not all sites reported having national and/or local guidelines across all clinical areas:

Q. Does your Fetal Medicine Centre have guidelines on the following (N=6)

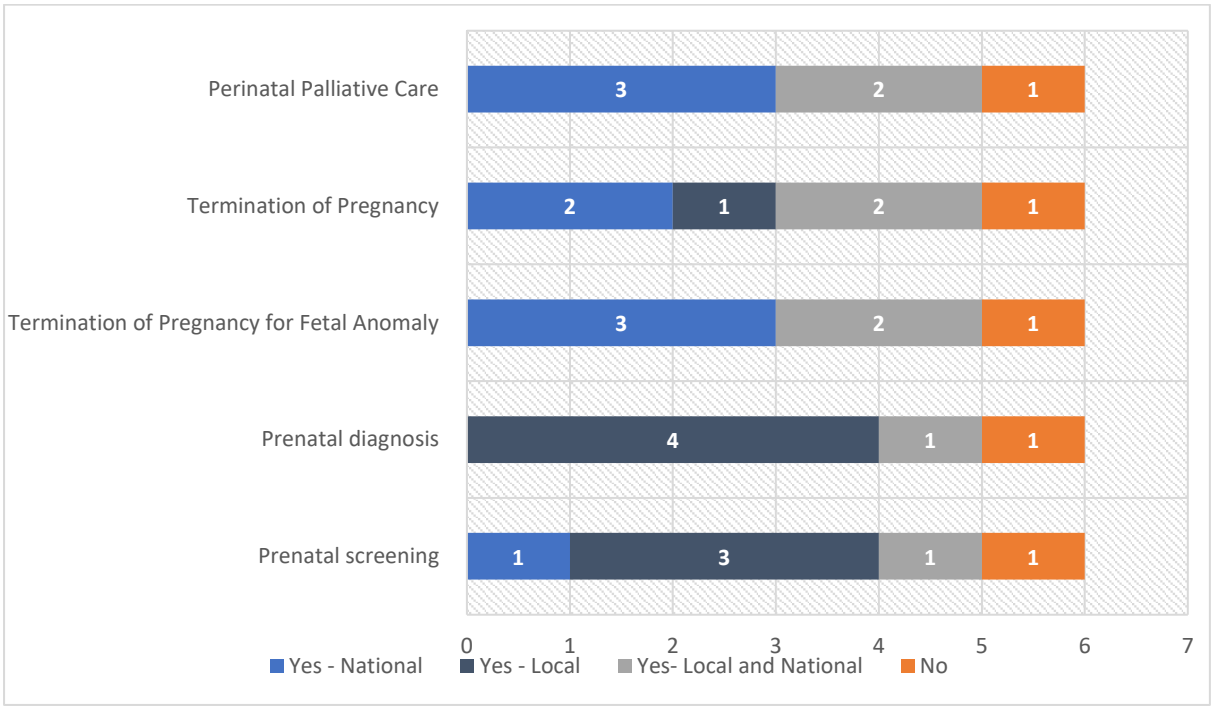

Figure 1.13

Two Fetal Medicine Centres reported that they were recognised for sub-speciality training (Accreditation) with both sites recognised by the Royal College of Obstetricians and Gynaecologists in the UK.

2g. Annual Audit

As part of the service evaluation, Fetal Medicine lead consultants were asked what aspects of service provided in their respective fetal medicine centres are audited on an annual basis. Results show that not all sites are routinely auditing various aspects of the service.

Q. Does your Fetal Medicine Centre routinely audit the following? (N=6)

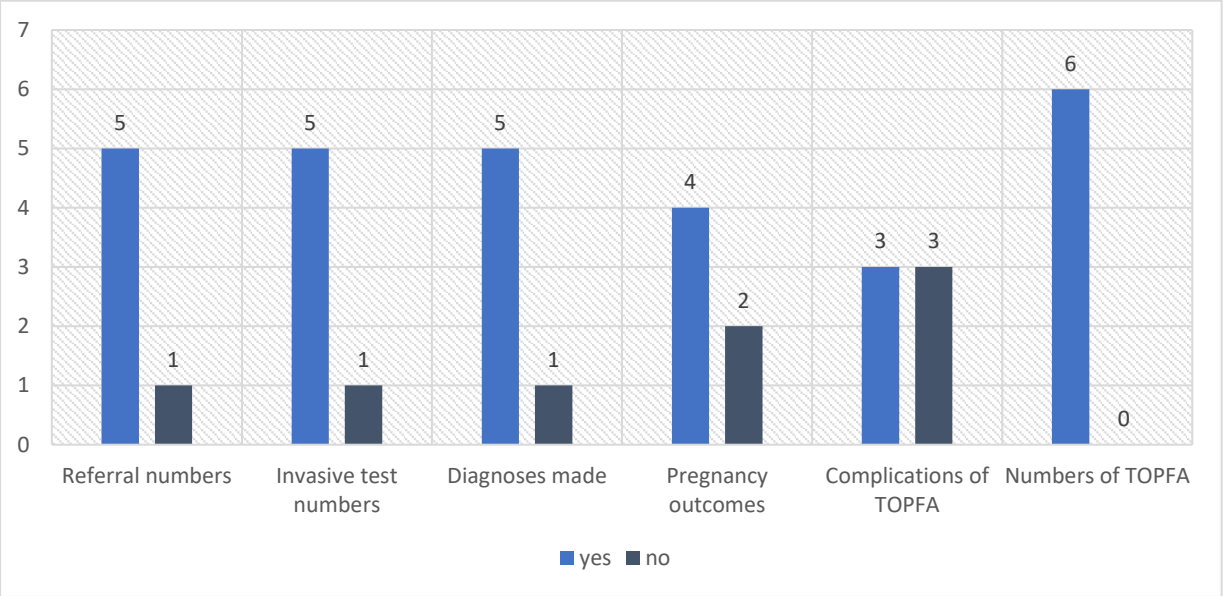

Figure 1.14

3. TOPFA

Each Fetal Medicine Centre was asked about TOPFA services available to women/parents attending their respective centres.

All sites (6/6) confirmed that they provide a full suite of TOPFA Services incorporating: antenatal care, antenatal scans, management of complications post TOP, medical induction/delivery after certification and post termination consultant review.

3a. Right to Apply for a Review of Relevant Medical Opinion

Where a pregnant woman is deemed not to meet the criteria for termination under Section 11 (Condition likely to lead to death of foetus) of the TOP Act, the woman must (under law):

a) Be informed of that decision in writing; and

b) Be advised of her right to apply (this is to NWIHP) for a review of said medical opinion.

Fetal medicine centres were asked about practices in relaying information to women on clinical decisions around TOP requested under Section 11 of the Act and in relation to advising women of their right to make an application for a review of a relevant clinical decision in instances where they have been refused a termination. Findings are illustrated below.

Q. Do you routinely provide written information to women on clinical decisions made around TOPFA? (N=6)

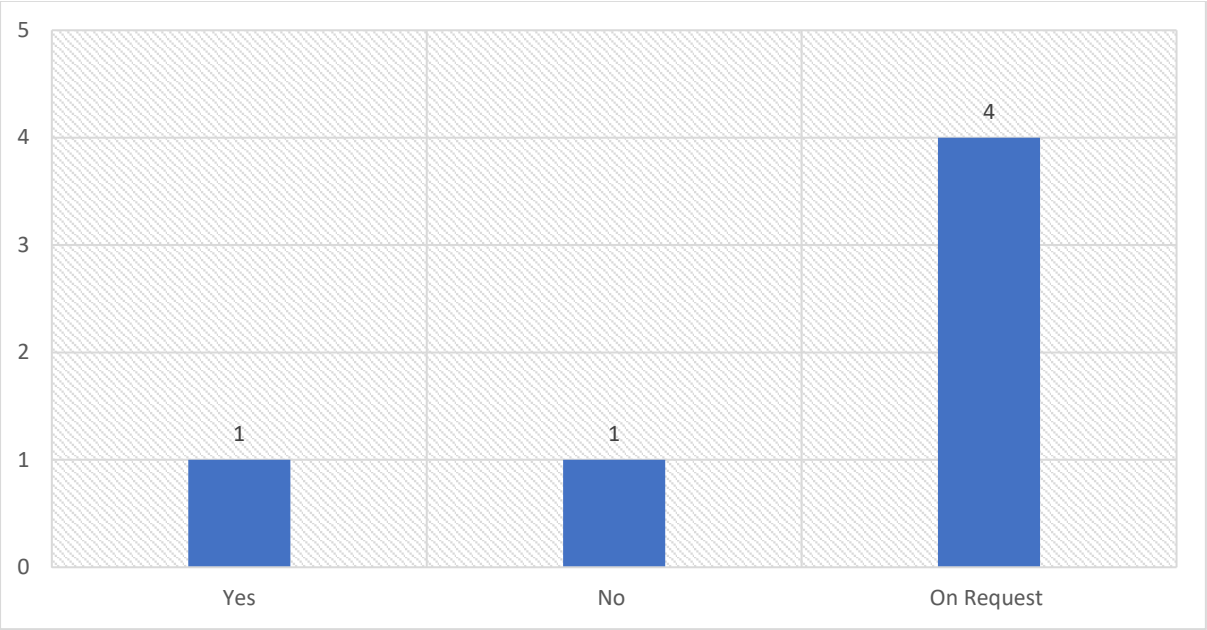

Figure 1.15

Q. Do you routinely provide written information to women in relation to the Review Process (as per Section 13 of the Health Regulation of Termination of Pregnancy Act 2018? (N=17)

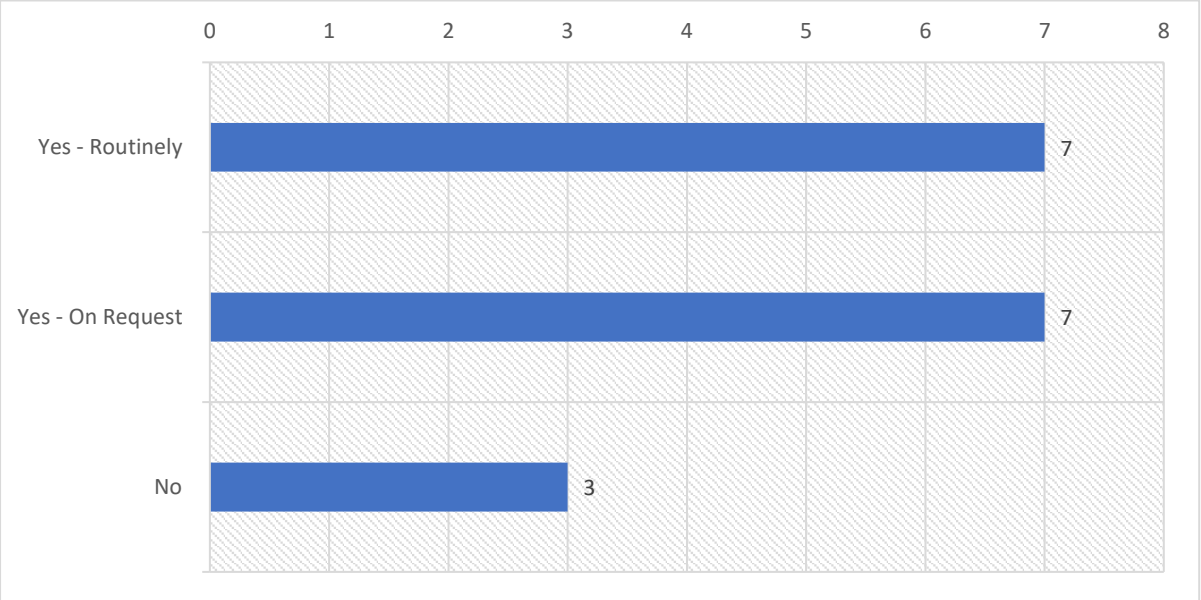

Figure 1.16

The above is in contradiction with what is set out in Section 13 of the Health Regulation of Termination of Pregnancy Act 2018, which states that:

Application for review of medical opinion

13. *(1) Where a medical practitioner, who has been requested to give an opinion in respect of a pregnant woman in the circumstances referred to in section 9 (1) or 11(1)—*

(a) does not give an opinion, or

(b) gives an opinion but not such as would be required for the purposes of a section 9 certification or section 11 certification, as the case may be,

(in this Part referred to as a "relevant decision") he or she shall inform the pregnant woman in writing that an application may be made in accordance with subsection (2) to review the relevant decision.

(2) A pregnant woman, or a person acting on her behalf, may make an application in the prescribed form and manner to the Executive for a review of a relevant decision.

3b. Feticide

As per international guidance at later gestations of pregnancy, feticide should be available and considered as part of termination of pregnancy procedure. Each site was asked if feticide is available to women/parents attending their centre. At time of reporting, 3/6 or (50%) of sites confirmed that feticide is available as an option. The most common method of feticide reported was by intracardiac injection of potassium chloride (3/3).

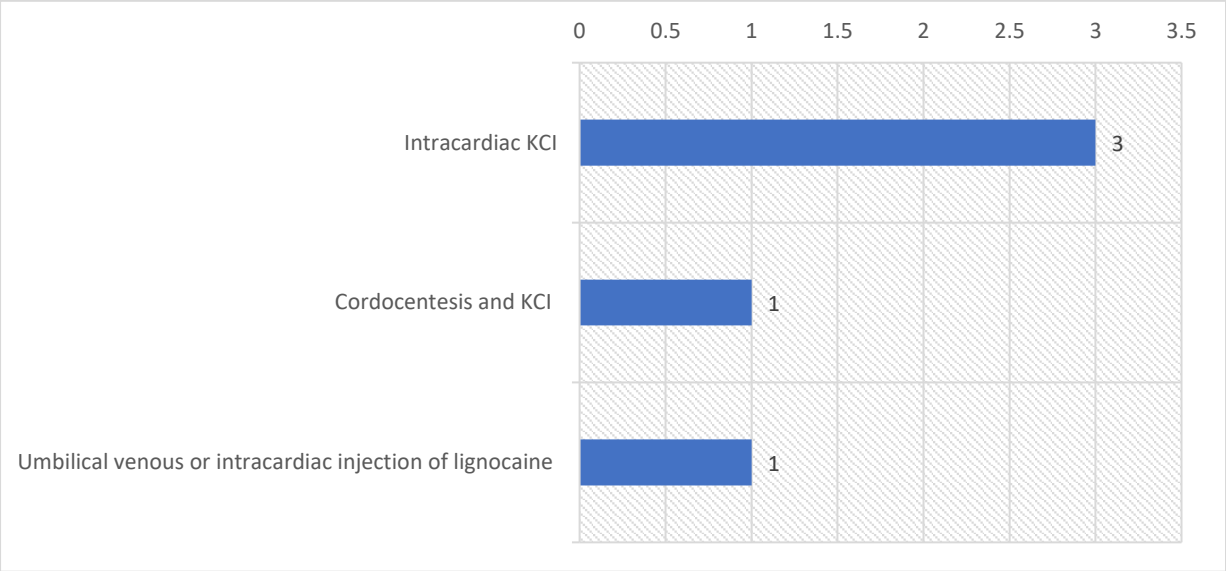

Figure 1.17 Method of Feticide

Fetal Medicine Centres were also asked whether women/parents are routinely referred back to their local hospital/unit from the tertiary Fetal Medicine Centre for delivery post feticide. Of the 3 sites who confirmed the availability of feticide in their centre, 1/3 'always' refer back, 1/3 'sometimes' refer back and 1/3' 'rarely' refer back. This again is suggestive practice inconsistency regarding referrals from and to local maternity units after feticide.

3c. The role of Neonatology & Perinatal Palliative Care in TOPFA

The probability of death prior to delivery or in the early neonatal period in instances of TOPFA (without prior feticide) is high however, there will be babies who survive longer than expected during end of life care. Care plans should allow for scenarios where perinatal palliative care is provided. It is the responsibility of Fetal Medicine Specialists/Obstetricians and Neonatologists/Paediatricians to plan care in cases where there is a probability of survival in the early neonatal period. Perinatal pathology specialists also play an important role with regard to options around post-mortem investigations and examination.

Lead Consultant Neonatologists within the maternity hospitals/units and Lead Consultant Perinatal Pathologists provided insights and clarifications with regard to the level of involvement of each Specialty in review and discussion of cases where TOPFA is sought and in care after delivery following TOPFA.

Q. Do Neonatology / Paediatric personnel participate in antenatal consultations for major fetal anomaly, where the plan is TOPFA?? (N=16)

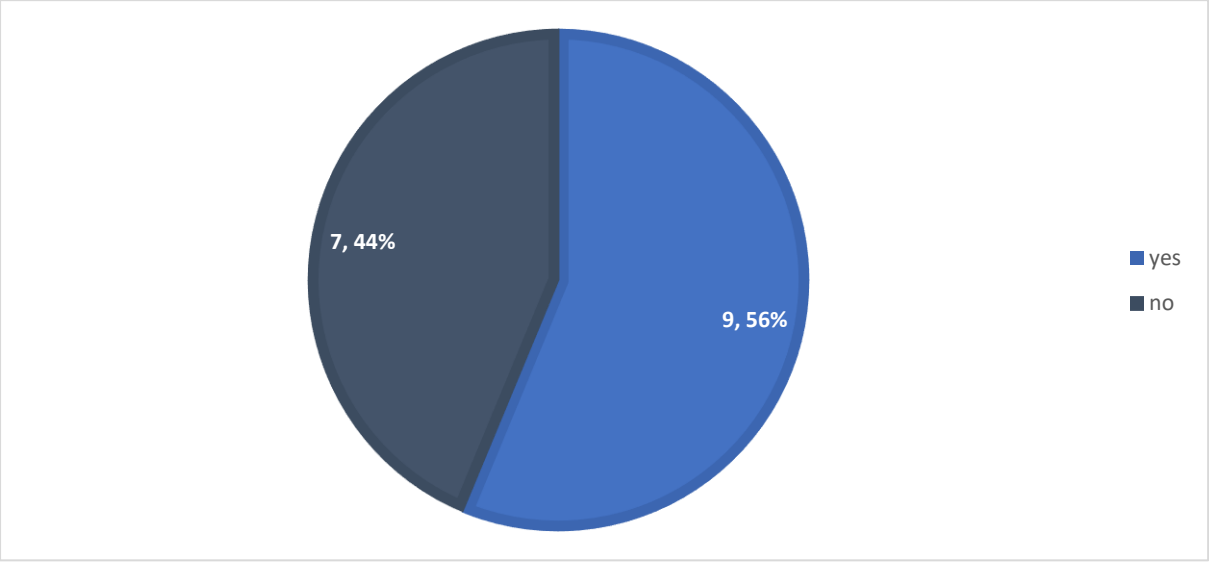

Figure 1.18

Neonatologists/Paediatricians who participated in the service evaluation were also asked if Neonatology/Paediatric personnel attend the fetal medicine MDT meetings in the designated Fetal Medicine Centre for their service. 5/15 or 33% answered No, while 9/15 or 60% answered 'Yes-Routinely' and 1 site advised that they attended only for specific cases. Those who responded 'Yes – Routinely' or 'Yes – only for specific cases' where requested to provide further information as to the capacity in which they attend.

Q. In what capacity do Neonatology / Paediatric routinely attend the fetal medicine MDT meetings? (N=10)

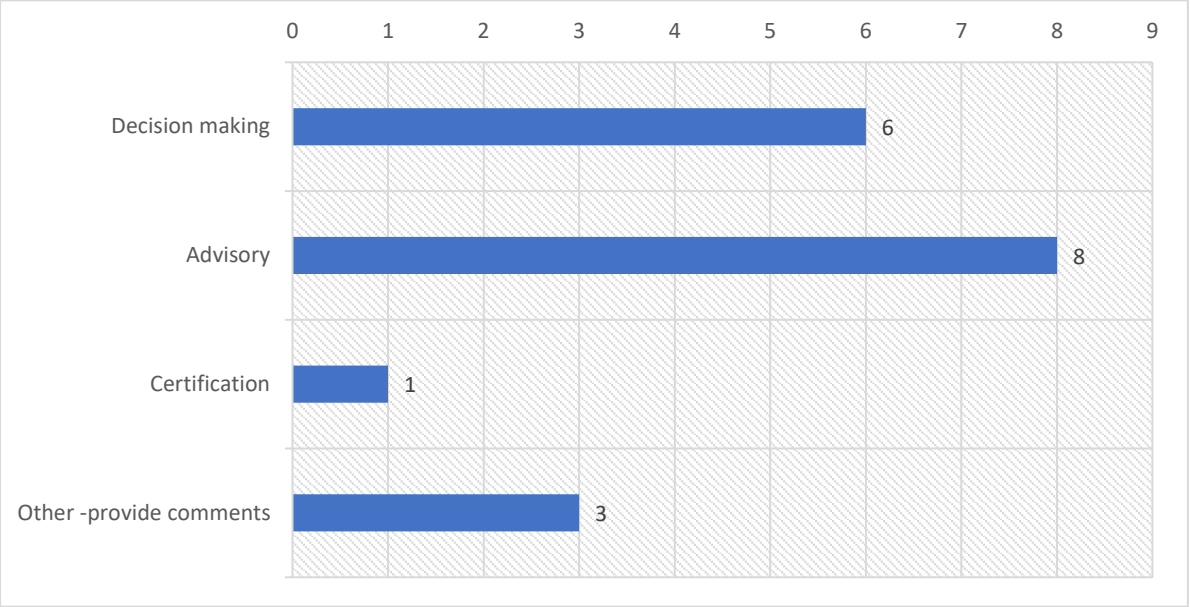

Figure 1.19

As referenced earlier, a small proportion of termination procedures will result in a live birth. In instances where babies are born with signs of life, it is expected that a care plan should be in place and overseen by the Neonatology team.

Neonatologists/Paediatricians who completed the service evaluation questionnaire were asked if Neonatal/Paediatric consultants are involved in neonatal palliative care after birth where an infant is born alive. 5/15 responded 'Always' to this question, 3/15 and 3/15 advised that Neonatology/Paediatric Consultants are 'Sometimes' or 'Rarely' involved with the remaining 4 sites stating that Neonatology/Paediatrics are never involved in providing care in instance of live birth following TOPFA. The questionnaire also enquired as to whether Neonatology teams have any involvement with pregnancies returning to the local maternity hospital/unit for delivery or TOPFA: 2/15 responded 'Yes' to this question but a significant majority 13/15 or 87% responded 'No'.

Clinical leads in each of the 19 maternity sites were asked a series of questions in relation to perinatal pathology services covering: access, post-mortem investigation and consent processes for same and policies in relation to reporting perinatal deaths after TOPFA to the local coroner. Consultant perinatal pathology leads (N=7) also provided responses to a suite of questions relating to their experiences of and involvement in cases of TOPFA. The responses, visualised below, demonstrate some variability between and within sites.

Q. In your hospital/unit, is a post-mortem service routinely available if requested for infants born after TOPFA? (N=7)

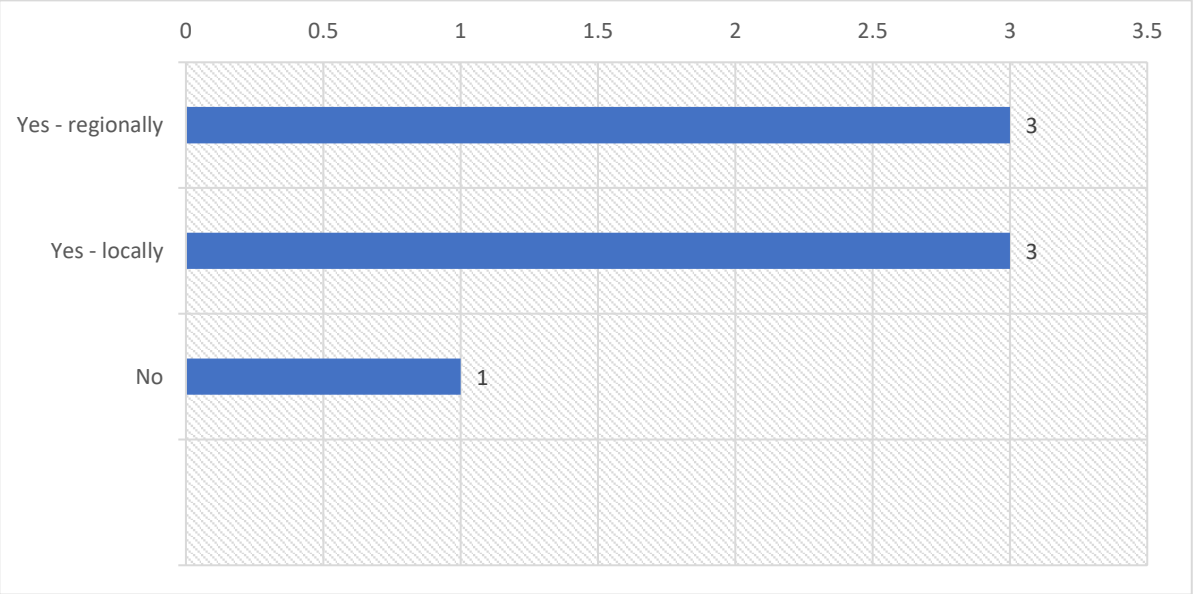

Figure 1.20

Q.Does your unit have structured and stable access to a perinatal pathology service? (N=17)

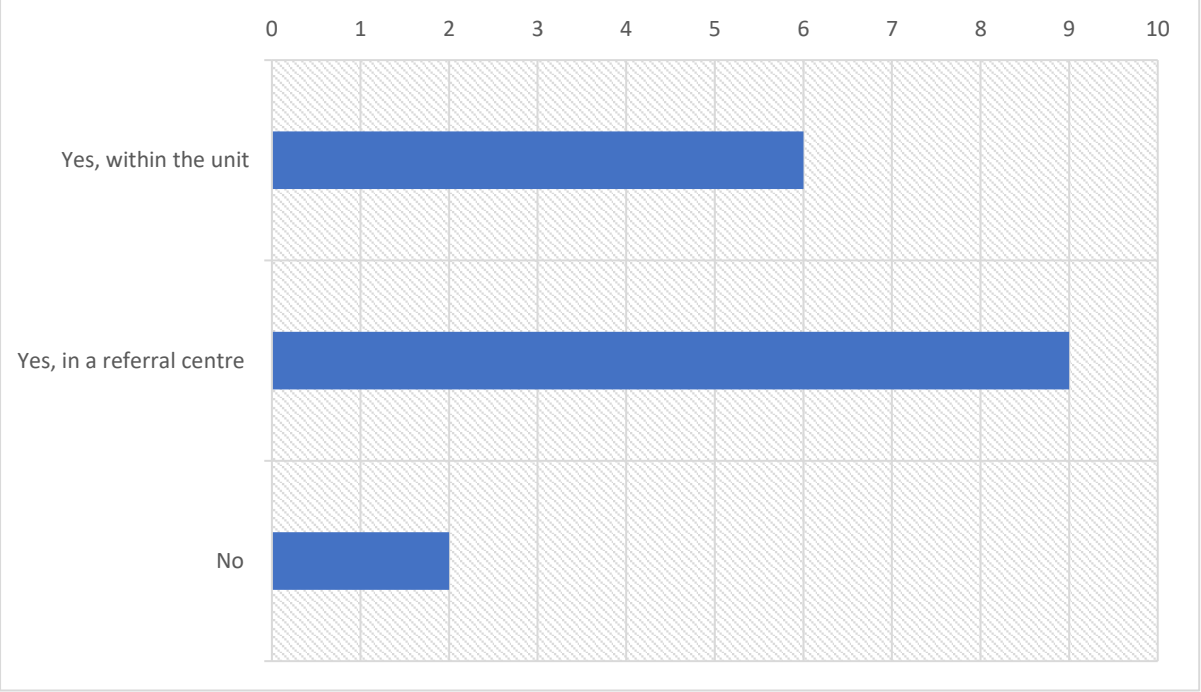

Figure 1.21

3d. Post-Mortem Examination and Investigations

Full post-mortem examination (PME) should be considered to confirm antenatally diagnosed fetal anomaly, the chance of recurrence and to inform future pregnancies. Perinatal Pathologists who completed the questionnaire were asked if there are restrictions on gestation at which post-mortem examinations are performed after TOPFA. 3/7 or 43% of those who responded said 'Yes', the remaining 4/7 or 57%

answered 'No' to this question. When asked if post-mortem genetic testing takes place in their site/hospital, 5/7 or 71% said 'Yes – Routinely', while 2/7 or 29% advised that post-mortem genetic testing is only undertaken in specific circumstances. Microarray is the most common form of genetic testing undertaken as part or routine post-mortem 7/7. Karyotype is available in 3/7 locations and in some instances sites may offer additional testing e.g. full exome sequencing or targeted genetic testing, in consultation with Clinical Genetics.

The antenatal period is a time where senior staff members may sensitively bring up the option of post-mortem investigations and examination with women/parents however, when asked at what point the role of the PME is usually discussed 9/17 respondents said 'On diagnosis', 6/17 also selected 'Birth/delivery' with 7/17 selecting 'Antenatal counselling appointment.

4. Clinical Genetics:

4a. Access to clinical genetics & genetic counselling

Only **1** fetal medicine unit reported that they had in place structured, protected access to clinical genetics and genetic counselling services. Arrangements across the remaining units were recorded as ad-hoc or did not exist.

Q. Is there a clinical genetics and genetic counselling service available to your Fetal Medicine Centre? (N=6)

Column1	Yes – Structure Sessional Commitment	Yes – On Request (ad hoc) arrangement	No
Clinical Genetics Services	1 (17%)	3 (50%)	2 (33%)
Genetic Counselling Services	1 (17%)	3 (50%)	2 (33%)

Table 1.3

4b. Genetic testing (Type & volume)

Prenatal testing for fetal abnormalities and genetic conditions is a complex and sensitive area. A report produced by the Nuffield Council on Bioethics in 2017, highlighted concerns regarding the marketing of NIPT by private providers of the test in the UK, namely: misleading use of statistics (sensitivity vs specificity); poor information about tested for conditions and a lack of follow-up support.[25]

In Ireland, unlike the UK, there is no national screening programme for aneuploidy. Non-invasive prenatal screening is not routinely provided in HSE maternity hospitals/units however, is undertaken in certain circumstances where deemed

[25] https://www.nuffieldbioethics.org/publications/non-invasive-prenatal-testing

clinically appropriate. The service evaluation sought to obtain clarity on the variety and volume of prenatal genetic tests undertaken and procedures for obtaining informed consent.

Q. Which of the following genetic tests are provided in your Fetal Medicine Centre? (N=6)

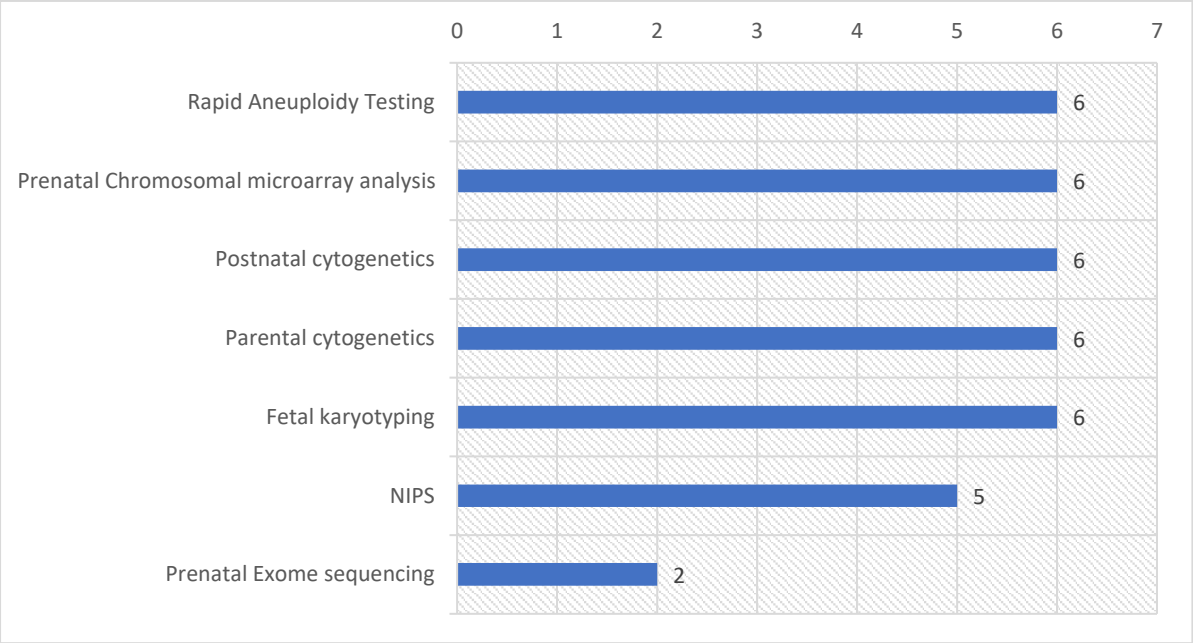

Figure 1.22

The evaluation queried whether women/parents are required to pay for any recommended genetic testing. Below is an illustration of the responses confirming that in some instances, charges for the women/parents are applied.

Q. Does the patient pay for any/all of these tests (N=17)

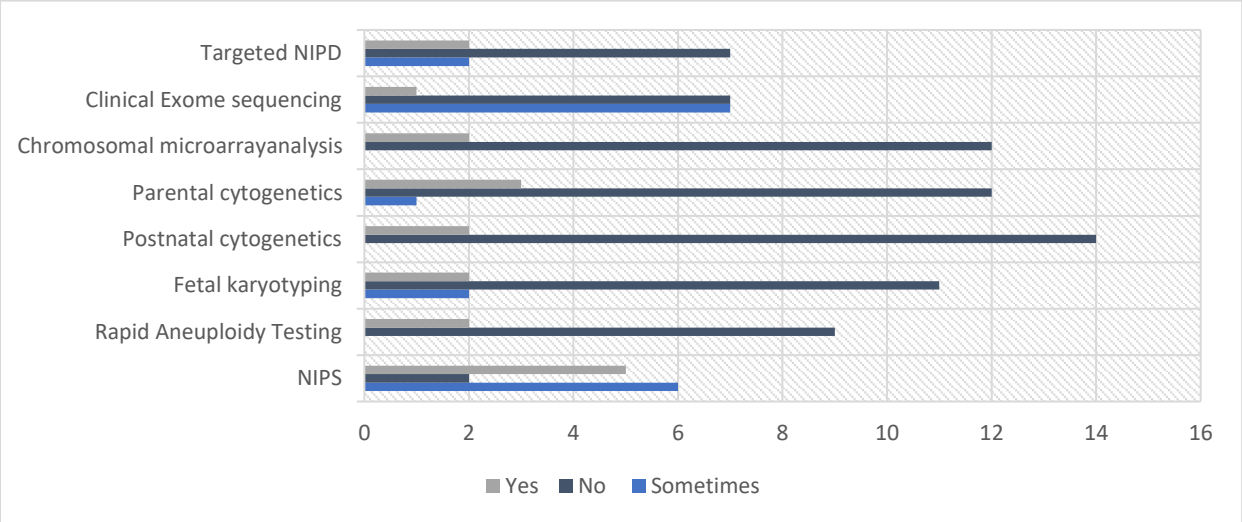

Figure 1.23

4c. Informed Consent for genetic testing

Genetic counselling and informed consent is recommended prior to all genetic testing. All 6 Fetal Medicine Centres were asked whether standardised consent forms for genetic testing were in place. 1 centre advised that they used a standard HSE consent form, 4 advised that they had a local consent form in use. The need for increased, targeted resources in order to deliver services was highlighted in open comments provided.

Analysis of open-ended questions – Secondary Care

Q. In the context of this Review of the operation of Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018, if you have any further comments or observations, please note them here.

Thirty-four people, across all five surveys, responded to this question.

All responses were analysed collectively. The majority of responses related to multi-disciplinary team-working and the need for staff – with ongoing training, education and support – to deliver services.

Many spoke about the **multi-disciplinary team approach** within their service (making decisions and providing care more generally), often highlighting that the FMS led the service with input from other specialities. Some highlighted that **greater involvement of different specialtie**s was needed.

> *"We need to look at the construct of teams caring for fetal med patients- over reliance on midwives for multi faceted roles- we need to include accredited counsellors, phycologists also need genetic counsellors/geneticists, The landscape of fetal medicine has changed completely and we need appropriately qualified staff to care for these women/families across their full episodes of care."*

A few mentioned however, that it could be difficult to get MDT input into decisions regarding TOP, due to service size, poor attendance at MDT meetings or disruptions due to COVID-19 restrictions. A few mentioned getting MDT input via other hospitals/services.

> *"Consideration should be given to having a national steering committee that could advise if there is uncertainty about a particular case and to report back if TOP has been performed in similar situations in Ireland. Bigger centres with many colleagues can discuss difficult cases in an MDT setting but this is often not available in smaller centres. These smaller centres need to be supported when faced with such cases. A national steering committee may assist in this regard."*

A few mentioned that Paediatrics/Neonatology were not involved or directly involved in the delivery of TOP services, sometimes playing an advisory or oversight role.

"We have a good relationship with our fetal medicine consultant colleagues. We have ongoing discussions around fetocide. As a group we feel that ongoing pregnancy with palliative care is different to TOPFA and that we should not be involved in providing care for a fetus that is born after TOP. We do support our colleagues with advice re medications etc if a baby is born alive after TOP, however we do feel that fetocide should be part of the package of care offered for later (>22 weeks) TOP."

"In our unit neonatologists participate in the weekly fetal medicine MDT where cases for consideration of TOP are discussed along with general fetal medicine cases, the neonatologists are there in an advisory and supervisory capacity regarding discussion of possible TOP cases but do not participate in the decision making regarding proceeding with a TOP, that is the role of the 2 obstetricians making the decision to proceed with a TOP, I view the role of the neonatologist as to advise re prognosis and provide some over sight that the legislation is being applied appropriately and not inappropriately, at present the neonatologists have not been involved in the palliative care process of any case, the need has not arisen."

The **need for staff – with ongoing training, education and support – to deliver services** was mentioned by many participants. Provision of a service, and sometimes a full service, often depended on the availability and/or appointment of certain members of staff to run and/or lead it.

"If we can appoint the 6th consultant in 2023, a full service will commence. There are also 2 impending retirements and there are two SpRs in training in the [region] have worked in [hospital] previously and have declared an interest in returning as permanent consultants and who may also be interested in the provision of a local TOP service."

"The provision of this service is under review presently. It is envisaged that a Consultant Obstetrician for the TOP service will be appointed."

The need to provide education and training along with support of staff, on an ongoing basis, was also highlighted.

"Education has been provided regionally and nationally for the introduction of the TOP service but when a full service is introduced in this unit, further MDT education will be required."

"Further training required for all midwives public health nurses GPs and NCHDs in relation to the TOP act."

"additional supports needed for midwifery /nursing staff in the form of regular debriefing."

The constraints of the current legislation was mentioned by some participants, including the three day waiting period, ambiguity around the terminology and what was covered by the legislation or not (and resultantly some women still having to travel for a termination), and bureaucracy.

"The definition of fatal fetal anomaly is unclear in the Irish context. For instance, duodenal atresia is likely to result in death within 28 days if surgery is not performed but most clinicians would not offer TOP for such an anomaly. Congenital Diaphragmatic Hernia (CDH) is considered a major fetal anomaly and most but not all cases will die within 28 days. However, as some babies can do well, many clinicians in Ireland are slow to offer TOP in this situation. In the UK, CDH is one of the conditions that can be terminated on request. There needs to be some guidelines over what cases are considered "fatal". While it will never be possible to produce an all-encompassing list, certainly some attempt should be made to make this area clearer. Also, what should we do about severe myelomeningocoele - this is a very significant condition but not one that generally results in death within 28 days as our nursing care is so excellent. Again, it is a condition that can be terminated in other jurisdictions…… If 2 clinicians, in good faith, decide that a fetal anomaly is fatal, then it should not be possible to bring a legal case against those clinicians saying that the condition may not have been lethal. It is never possible to give 100% guarantees that a case is fatal within 28 days. Also, does a TOP after viability automatically means feticide? Is it ethical to deliver a liveborn baby when a TOP for a fatal fetal anomaly has been decided upon? If that is what the public want, then what services/funding have been provided to hospitals to provide such care to these infants. Any what would happen if that baby, who was meant to have a fatal fetal abnormality survived? "

"Many Consultant Neonatologist are deeply uncomfortable with the concept that a TOPFA could result in the delivery of a liveborn baby that has reached viability."

"50% of TOPFA cases that come through our unit travel overseas for TOP, the most common diagnosis in that group being Down Syndrome."

"The majority of people in Ireland are not aware quite how restrictive the conditions are to meet for a termination here. When cases are being reviewed for termination two questions are very often confused. These are 1) likely to die within 28 days ? and 2) is it a terrible life altering diagnosis? . The first is all we are required to answer, whilst the latter is the one people often seek an answer to. Many times we have sat in rooms where we know the answer to the first question is No and the second question is Yes - this causes an unimaginable stress to families and moral injury to clinicians wanting to help, but not being lawfully able to. The current model is not working for families or clinicians in the opinion of this department."

Some comments related to the lack of resources, or need for resources to deliver services. This is tied into the above theme regarding staff and also the next theme regarding access to genetic testing and geneticists/genetic counsellors. This also links to a few comments relating to variation in service provision. For a few, services remained unfunded, the introduction was delayed, or certain aspects of service provision (e.g. fetal anatomy scans) had only recently commenced. A few also mentioned working in partnership with other service providers to deliver an extended service.

"In the context of this review I have been an observer to the lack of coordination within the fetal medicine service in our unit. Feedback to and from the service is left to individuals, leading to no standardised approach to feedback and support offered to fellow clinicians and parents. I would support a role for ANP/ fetal medicine Coordinator within our unit if funding were available."

"No national screening programme for 1st trimester - nearly every other country in Europe offers AN [antenatal screening] screening as part of antenatal care and has done for the past 30 years- u get screening if you pay for it in Ireland (IE NIPTS and nuchal scans at private clinics)

"Not all units in Ireland offer anomaly scans and that needs reviewing again its a service that has been running for decades in the rest of Europe."

"With regards to this unit significant increase in numbers attending for TOPFA due to increased fetal medicine resources. There have been delays with commencing TOP for FFA due to limited availability of a suitable room to commence the process . Although we have access to one specialised bereavement room for antenatal care and post natal care these may already be occupied. The alternative is 3 single patient rooms on antenatal ward or to block book rooms with 2-3 beds."

"Depending on gestation, TOPFA is carried out here. Over 28 weeks TOPFA is carried out in tertiary unit."

A few mentioned the *"critical need for more clinical geneticists"* and *"more consistent access to prenatal genetics to improve counselling and diagnosis".*

The lack of a national screening programme was also highlighted as problematic: *"No national screening programme for 1st trimester - nearly every other country in europe offers AN screening as part of antenatal care and has done for the past 30 years- u get screening if you pay for it in Ireland (IE NIPTS and nuchal scans at private clinics)."*

Appropriate information and support for parents was mentioned by a few participants.

"Very individualized care required, what is effective for one couple may not satisfy another couple's needs."

"Time for more public information on the services of fetal med."

Postmortem processes were the subject of few comments – with some variation in opinion in whether they should be conducted as standard following TOP or not.

"The decision for TOP is clinical and the consent for any PM should remain with the obstetrician. It is not practical for a pathologist to directly involved in the consent for a PM. We hold educational sessions every 6 months to ensure that all understand how the examination is performed."

"Post-mortems after TOP for FFA need to be seen as part of the audit process for clinical care and pre TOP diagnostics."

"In our Institution, a post mortem service is offered in these cases on a case by case basis. We require that the requesting clinician discuss the case with us prior to

performing the post mortem to ensure what additional information is expected to be gained by performing a post mortem. I personally do not think that postmortems are justified in all cases."

Finally, two participants who provided further comments stated that they currently had **no exposure** to TOPFA to date.

Section 1c Service Evaluation – Service User Perspective

Scope

This strand of the Section 11 Review investigated women and partners' experiences of care where there was a prenatal diagnosis of fetal anomaly and where a termination of pregnancy for fetal anomaly (TOPFA) was being considered.

The Review Group would once again like to thank and acknowledge the contributions of all service users who participated in this Review. The insights and contributions provided will assist healthcare professionals and policy makers in providing optimal, person-centered care in what is an exceptionally difficult time for women and their partners.

Survey design and distribution

A service evaluation questionnaire (refer to Appendix C) was designed in consultation with parent representatives on the Review Group. The questionnaire contained largely open-ended questions, so as to elicit qualitative data examining women's experience of the TOPFA service/pathway.

As referenced earlier, Leanbh Mo Chroí (LMC) facilitated the distribution of the questionnaire to its membership and provided support to those who found it challenging to re-experience what was in many instances a very distressing time. LMC provided contact details of three peer supporters at the beginning of the survey should women find completing the survey caused distress or need additional support around completing it. Despite this a number of women cited that it would be too difficult for them to complete it and that they *'couldn't get into the head space needed'* to complete it.

The survey invite was issued via the LMC WhatsApp group with the explanation of what it was for, what the results were to be used for and that anonymised parts may be used for the report. It was also placed on the LMC website and social media channels, Facebook and Instagram. The survey format was a basic Google forms survey and the results were imported into an excel spreadsheet.

Data analysis

Responses to open-ended questions were imported into NVivo (via Excel) and analysed using content analysis.

Results

Forty- three people completed the patient experience survey. Five participants indicated that their terminations were carried out before the legislation came into force, so these were excluded from the analysis for this report. One stated that they had already completed the survey but wanted to leave an additional comment, so this was counted within the existing response. Thirty-seven responses were therefore eligible for inclusion in the analysis.

Responses to each question were analysed using conventional content analysis, in which coding categories were derived directly from the data[26]. This was done predominantly in line with a more quantitative than qualitative approach, as – in many cases – it focused on counting responses rather than interpreting the data per se. The reason for doing so was because the survey questions were open-ended but many should have been asked as closed questions (e.g. yes or no), with the opportunity to provide further details in a text box. While many results are presented as counts, care should be taken in interpreting them, as participants provided unpromoted responses, i.e. participants were not provided with standard (i.e. the same) response options.

How much time passed between the time a concern was noted about your pregnancy, e.g. your 12 week or anomaly scan and seeing the fetal medicine consultant or team?

All 37 participants responded to this question. Responses were varied (see Table 1.4), and are categorised as follows (with illustrative quotes where more detailed responses provided):

- Less than 24 hours (n=10, 27%)

"At the 12 week scan at 11 week 5 days."

"12 week dating scan."

"We got the bad news at my anomaly scan i was 22 weeks, the midwife scanning asked us would it be ok to see a doctor so we knew something was wrong and we had to come back in later that day we're we met the doctor and fetal med midwife."

"Same day as consultant just happened to be in room next door but took 2 days for CVS test."

- Next day / one day (n=9, 24%)

"24 hours- told to return the next day to see fetal medicine."

"22 week scan anomaly found met with fetal medicine team the next day or two days after."

"The following evening."

"One day after Harmony Test results communicated to me via telephone."

- 2-6 days (n=9, 24%)

"Scheduled for 6 day later. I was not offered a 12 week scan, just an appointment. I then had a 20 week scan (at 21weeks pregnant)."

[26] Hsieh H-F, Shannon SE. Three Approaches to Qualitative Content Analysis. *Qualitative Health Research*. 2005;15(9):1277-1288. doi:10.1177/1049732305276687

"At my 12 week scan, my consultant spotted abnormalities on the scan. Immediately bloods were taken and 6 days later I was given a T18 diagnosis."

"Anomaly scan was Friday, back with fetal med team following Tuesday after noting some anomalies in baby's brain."

- 1-2 weeks (n=9, 24%)

"No consultant was aware about 10/14 days prior to making us aware of amniocentesis results. Microarray on amnio showed a significant deletion on chromosome 2. 98 genes were missing."

"1 week . I was a private patient who did the Harmony test which came back positive for T18."

- >2 weeks (n=2, 5%)

Table 1.4 Time passed between the time a concern was noted about the pregnancy, e.g. 12 week or anomaly scan and seeing the fetal medicine consultant or team

Timeframe	Details
< 24 hours (n=10, 27%)	• 1 hour (n=1) • 2 hours (n=1) • 12 hours (n=1) • A few hours (n=1) • At scan (n=2) • <24 hours (n=2) • Same day (n=2)
Next day / one day (n=9, 24%)	• 24 hours (n=2) • Next day (n=1) • One day (n=6)
2-6 days (n=7, 19%)	• Day or two (n=1) • 2 days (n=1) • 3 days (n=1) • 4 days (n=2) • 6 days (n=2)
1-2 weeks (n=9, 24%)	• 1 week (n=5) • 1-2 weeks (n=1) • 10 days (n=2) • 10-14 days (n=1)
>2 weeks (n=2, 5%)	• 2.5 weeks (n=1) • 7 weeks (n=1)

Timing from scan to diagnosis - meeting with MFM

All 37 participants responded to this question. Responses were varied (see Table 1.5); 17 people (46%) stated that the timing from scan to diagnosis was either on the same day or within one day.

Table 1.5. Timing from scan to diagnosis – meeting with MFM

Timeframe	Details
< 24 hours (n=6, 16%)	• Same day (n=6)
Next day / one day (n=11, 30%)	• One day (n=11)
2-6 days (n=4, 11%)	• 2 days (n=1) • 3 days (n=1) • 4 days (n=2)
1-2 weeks (n=14, 38%)	• 1 week (n=9) • 1-2 weeks (n=4) • 10 days (n=1)
>2 weeks (n=2, 5%)	• 7 weeks (n=1) • 12 weeks (n=1)

Did you meet with 1 or 2 fetal medical specialists, or more?

Thirty six participants responded to this question. Of these, a slight majority said that they met with one fetal medicine specialist (n=19, 53%), with some noting further details:

"we met with one doctor and 2 student doctors where present when they scanned me and done a Amniocentesis test - the midwife was also present."

"Fetal Medicine midwife and doctor."

"5 (1 obstetrician, 2 specialist midwives, 2 genetic consultants)."

"One consultant and one midwife who was my main contact."

"1 consultant and her team."

"No I meet the obstetrician and was referred to see the genetic consultant in [hospital name]."

"One consultant and one Doctor."

"My consultant is the only doctor I met with."

"1 initially but also a neurologist towards the end of diagnosis."

Fifteen participants (42%) said that they met with two fetal medicine specialists; again, some provided further details/context:

"Initially one but we saw a second consultant also at some points of our process."

"2(due to holidays)."

"1 fetal med specialist and 1 professor to perform amniocentesis."

"Meet with 1 specialists until a second opinion was needed."

"1 initially then another professor attended with that fm specialist and finally a very experienced sonographer to assist making the final diagnosis with the two fm specialists at 15 weeks."

One stated that they met with [several] heart specialists (3%), and another stated that they did not meet with any fetal medicine specialist (3%).

What information if any, were you given at your 1st diagnosis about your baby's condition and other testing options?

Thirty-six participants responded to this question. The majority seemed to have been given information about their baby's condition and/or diagnosis, and some mentioned prognosis (n=28, 78%). Slightly less reported receiving information about further investigations (n=22, 61%).

"we were told she had serve spina bifida and also had a lemon shaped head and problems with her brain, so they offered us the amniocentesis test to see if she had any other problems."

"I was told that the diagnosis was fatal however I was recommended to have a CVS to confirm the Harmony tests findings."

"CVS testing to confirm suspected diagnosis. Told he was presenting with severe chromosomal characteristics."

"Yes, suspected diagnosis (it was either trisomy 18 or 13) and testing options."

"That there was cists around baby's head and chest.

So, I was offered the CVS test."

"Baby had anencephaly- this was clear from the scans."

"I was told she had markers for Edwards syndrome and was given an amniocentesis."

"We were told that there was extra fluid present on the baby's neck. They were unsure why. We were told that a CVS was necessary to rule in/out chromosomal abnormalities."

"That there was a huge heart anomaly and the baby would likely not survive gestation."

"That baby had a lot of fluid around brain heart and lungs and CVS would need to be done. I thought everything would be fine as I had not been told exactly what

was going on. I had to sit through clinic right after diagnosis for bloods for another hr."

"They just confirmed by another scan that there was an issue with fluid on the baby's brain and that it could possibly point to Down Syndrome/Pataus or Edward's Syndrome. I had fluid taken from the fetal sack or whatever and it was sent away for testing."

"General information such as fluid on the brain, short limbs, bell shaped chest but no real information. Referred to FMS with same and a further possible diagnosis of TD but I was left to Google this condition in the carpark of [the hospital]"

"Information was vague but prognosis was poor (PPROM and hematoma at 15 weeks). Baby could not develop further if waters didn't start rising again. We were offered an amniocentesis by the first fetal medicine specialist but didn't go ahead with it based on more senior second fetal medicine specialists view."

"Diagnosis was confirmed after amnio test and out results were given over the phone 4 days later. No further testing was offered and we were more or less left researching all options by ourselves. We were advised of basic support options for either decision (whether continuing pregnancy or not)."

"Offered a CVS after a discussion on skeletal dysplasias."

"I was given the probability of the diagnosis from the Harmony test then what my options would be dependent on an ultrasound scan. This would determine how accurate the subsequent tests would be and also when these could be done to confirm diagnosis."

"My baby was diagnosed with anencephaly based on 12 week scan pictures. Fetal medicine consultant performed another scan. No further testing was discussed as evident on scan. I had several more scans in days following diagnosis."

"Too much fluid around the neck. Testing chromosomes was done."

"Down Syndrome- we had the amniocentesis test completed after the Harmony results showed high probability."

"Bilateral cleft and clenched hands, no other info or testing options."

"I was told that we could do chorionic villus sampling at 13 weeks. My initial anomaly was identified at a scan at 11 weeks (at this point I had had two previous miscarriages and was nervous so requested additional scans with my obstetrician) it was she who identified an abdominal wall defect which subsequently caused a host of issues with spine, bladder, anus, colon and genital malformations in addition to entire abdominal organs being outside the body in a giant exomphalos. She referred me to the fetal medicine team in the hospital on the Friday morning and I was seen by them on Monday morning."

"We received a brief report from the laboratory in England who found the deletion in the amniocentesis. Obstetric consultant wasn't able to add much re how significant the deletion would be."

"Our baby had clear markers for Trisomy 13 and also had CDH, prognosis was very serious and fatal. I was offered an amniocentesis and it was done there and then."

"Lots of detail and information on the condition."

"I was given clear information about the condition."

"Enlarged Nuchal fold- no other testing options."

"I was told there were multiple abnormalities particularly the brain and how it wasn't developing properly. I was told I needed an amniocentesis for further diagnosis depending on whether I wished to continue on with the pregnancy or not."

Some mentioned that they were given information about their options (n=5, 14%).

"We were given a detailed explanation and discussion about options."

"Diagnosis was confirmed after amnio test and out results were given over the phone 4 days later. No further testing was offered and we were more or less left researching all options by ourselves. We were advised of basic support options for either decision (whether continuing pregnancy or not)."

"High risk results from Harmony test. We were brought in the next day for a cvs. The consultant explained the procedure and diagnosis waiting time. We were told it wasn't possible to get a termination in Ireland and if termination was an option that we could make an appointment and cancel if we changed our minds as it could take weeks to get an appointment."

"Information on termination."

"I was given clear information about the condition and 4 options to choose from in relation to the next steps."

Some referred to the quality of the information received – with some stating that they received little information or didn't feel fully informed (n=8, 22%):

"Little information, at my scan I was told "well I'd be more concerned if your baby was missing a limb or something" at this appointment the corpus callosum was not seen. It was a sonographer who said the above."

"Nothing only wait for bloods."

"That baby had a lot of fluid around brain heart and lungs and CVS would need to be done. I thought everything would be fine as I had not been told exactly what was going on. I had to sit through clinic right after diagnosis for bloods for another hr."

"General information such as fluid on the brain, short limbs, bell shaped chest but no real information. Referred to FMS with same and a further possible diagnosis of TD but I was left to Google this condition [in the hospital carpark].

"Information was vague but prognosis was poor."

"Diagnosis was confirmed after amnio test and out results were given over the phone 4 days later. No further testing was offered and we were more or less left researching all options by ourselves. We were advised of basic support options for either decision (whether continuing pregnancy or not)."

"Bilateral cleft and clenched hands, no other info or testing options."

"We received a brief report from the laboratory in England who found the deletion in the amniocentesis. Obstetric consultant wasn't able to add much re how significant the deletion would be."

While others stated that they received lots or sufficient information (n=6, 17%).

"Lots I feel and all we needed."

"We were given a detailed explanation and discussion about options."

"Everything....we had a CVS.....we were told we made need an amniocentesis should it be warrented."

"Lots of detail and information on the condition."

"I was given clear information about the condition and 4 options to choose from in relation to the next steps."

"All information as far I was aware."

One participant didn't really provide information about information given at their 1st diagnosis about their baby's condition and other testing options:

"At my 20 week scan concerns were raised and I was brought back in the next morning for further scans and again the next day for a MRI."

What contact information or details were you given for someone in the hospital?

Thirty six participants responded to this question. One person interpreted the question differently and was excluded from the analysis, leaving 35 responses.

Eleven participants (n=11/35, 31%) stated that they were not given any contact information or details.

Twenty-four (n=24/35, 69%) provided information about contact information or details they received. Of these, the majority of people stated one category of contact, e.g. consultant/specialist or specialist midwife/bereavement midwife, but six mentioned more than one category of contact:

"The contact details for the nurses and the consultants secretary"

"Fetal medicine, midwife , support groups , group who could support us to travel for termination- ARC"

"The details for the fetal assessment midwives and also the genetics team, all of whom were prompt at replying."

"My consultants, at the time of deciding we need to terminate we were given details of the bereavement midwife who visited us throughout the hospital stay."

"CVS info sheet were prenatal diagnostic team information on it. We were referred to the medical social worker."

"Councillor (Counsellor) and midwife contact numbers."

The different categories of contact person mentioned by the 24 participants who stated they were given contact information/details for someone in the hospital were as follows:

- Fetal medicine midwife / Bereavement midwife / Clinical midwife specialist (n=16, 67%)

"was given the number and emails for the fetal medicine midwife's in case we had any questions."

"Bereavement midwife's number and nurse specialists contact details."

"The contact details for the nurses and the consultants secretary."

"Fetal medicine, midwife , support groups , group who could support us to travel for termination- ARC."

"business card for the midwife and information leaflet."

"The details for the fetal assessment midwives and also the genetics team, all of whom were prompt at replying."

"My consultants, at the time of deciding we need to terminate we were given details of the bereavement midwife who visited us throughout the hospital stay."

"Given a number and email address for the Clinical Midwife Specialists."

"I was given the Fetal Medicine Midwife email and phone number. They took over scheduling and all referrals when I looked for additional support."

"we were given the bereavement care midwives contact information through our consultant."

""None for [the hospital] at all but fetal medicine midwives details, email and phone number for [the other hospital]."

- Consultant (n=8, 33%)

"My consultant gave me her mobile number and met with us to discuss options etc."

"The contact details for the nurses and the consultants secretary."

"My consultants, at the time of deciding we need to terminate we were given details of the bereavement midwife who visited us throughout the hospital stay."

"We were in direct contact with fetal med specialist in hospital."

"Just my doctors."

"I was given the email address for one of the heart specialist but I was told to contact the doctor in my local hospital to get updates instead."

- Contact details provided, but details not specified (n=2, 8%)

"Email and phone number."

"A card with numbers and emails."

- Genetics team (n=1, 4%)

"The details for the fetal assessment midwives and also the genetics team, all of whom were prompt at replying."

- Medical social worker (n=1, 4%)

"CVS info sheet were prenatal diagnostic team information on it. We were referred to the medical socal [Social] worker."

Did you meet a midwife co-coordinator/ or lead or a named midwife at the fetal medicine unit?

All 37 participants responded to this question – they stated: yes (n=22, 59%), no (n=14, 38%) and one (3%) did not state or imply yes or no, stating *"We were offered to meet with someone in the fetal medicine unit but only after we had already made our decision."*

Of the 22 who answered yes, they did meet a midwife co-coordinator/ or lead or a named midwife at the fetal medicine unit, five added further details mainly in relation to the timing of contacts:

"Yes at my follow up appointment."

"Yes, very poor contact due to holidays."

"Two midwives run the unit and we met both on different occasions."

"Yes, it was the same lady who was present at ultrasound, amnio and who gave us the diagnosis results. We also met several times with her to talk. And also met with her again when we suffered a further pregnancy loss a few months later."

"Yes, she became my contact person for the time I was seen by the team."

Of those who replied no (n=14), five added that they just met the doctor/consultant and one noted that *"On day one we were told that they were trying to establish a fetal medicine unit but it wasn't streamlined yet. The midwife ultrasonographer looked after us on our first day (booking scan) but we never saw her again."*

"Met with a fetal medicine consultant and a sonographer."

What written information were you given, if any, on the final diagnosis; specifically about ending the pregnancy, choices, timelines, methods, location etc.?

Thirty-six participants provided a response to this question. Responses were varied.

Seventeen stated none (47%). Of these, five provided further information, with two noting that they were given written information on certain things/at a certain point.

"None. I was told no consultant in this country will touch you, your amnio will take too long to come back maybe up to 8 wks and then it will be too late and I was referred to a social worker who gave me business cards for [Region] sexual health clinic who would assist me in how to get an abortion in the UK. I was also refused my full Obstetrics report by the FMS and told to access this through data protection."

"No written information provided. All information was verbal."

"We were given no written information. Information was given to us verbally."

"All information was verbal but very clear and we were given a written report on the final diagnosis."

"We were given a report from the heart experts with their diagnosis. I didn't get any written information until I had already started the termination process. I never received any written information about the final diagnosis."

One (3%) alluded to only being given verbal information: "*they spoke to us about a procedure they might be able to do in belgium but after a few days i wasn't able to get if if i wish because my baby had such a bad condition."*

Ten participants (28%) said that they were given a copy of results/a test or scan report.

"No written information just a copy of the CVS and Amino . I was verbally given the information. Different wording was used by different people I met with ,termination,compassionate induction,I was told I fell under the new legislation so could end the pregnancy in [the hospital] where I was attending . There was confusion on the timeline as my consultant was eager for a decision before 20 weeks and the brevement [bereavement] midwife said I could decide at any stage of the pregnancy."

"I was given copy of MRI results, no other written information, the consultant that was over my case drew me a picture of the brain concerns which was helpful."

"I was given the CVS test report and scans. "Nothing about ending the pregnancy as I couldn't terminate it in Ireland."

"Written information after CVS test but no information on choices methods etc. I was however told about options from my own GP but she knew me extremely well."

"Well we had to go back up to get the results. We got a report back to say that it was Down Syndrome and they weren't sure how severe it was or if there were any complications, etc. We were also told that because it was Down's Syndrome and that I was at the 17 week mark that the only option was to travel for a termination to the uk and given some numbers to call etc."

"A fully detailed cover letter alongside 3 medical reports on tests that had been carried out."

"Given; copies of scans and information leaflets. No guidance or info on termination until we cancelled our next appointment as we had already made the decision within that time."

"All information was verbal but very clear and we were given a written report on the final diagnosis."

"We were given a report from the heart experts with their diagnosis. I didn't get any written information until I had already started the termination process. I never received any written information about the final diagnosis."

"I was given the MRI report and ultrasound findings but nothing written about choices for ending the pregnancy or any timelines."

Four (11%) mentioned that they received information booklets:

"I can't remember. But we were definitely given a booklet on compassionate induction."

"Given; copies of scans and information leaflets. No guidance or info on termination until we cancelled our next appointment as we had already made the decision within that time."

"I was given a printed list of websites to contact. I was also given an NHS document on the diagnosis (Trisomy 18). There was mention of the Bereavement Midwives and the chaplaincy service which may have been on the print out. Once I asked about what a medical termination involved I was also given the HSE booklet on this."

"An abortion leaflet and a lot of information about the process ahead."

Three (8%) stated that they weren't provided with enough written information.

"Written information after CVS test but no information on choices methods etc. I was however told about options from my own GP but she knew me extremely well."

"Given; copies of scans and information leaflets. No guidance or info on termination until we cancelled our next appointment as we had already made the decision within that time."

"Just CVS inform. No written information about options, time lines, methods or locations. No final results of the cvs given in writing."

Two (6%) stated that they were given lots of written information.

"we were given all information on what to do next should we need to TFMR in the UK."

Two (6%) stated that they couldn't remember if they received written information about certain things:

"can't remember. But we were definitely given a booklet on compassionate induction."

"Information on anencephaly. I can't remember if I received written information regarding ending the pregnancy."

Another two (6%) stated that they were given written information about their baby's condition or diagnosis:

"Information on anencephaly. I can't remember if I received written information regarding ending the pregnancy."

"Just CVS inform. No written information about options, time lines, methods or locations. No final results of the CVS given in writing."

One (3%) each mentioned that they *"asked for a copy of the results received from the genetic testing*."; received *"Typed notes from the cardiologist regarding the final diagnosis"; consultant's drawing ("I was given copy of MRI results, no other written information, the consultant that was over my case drew me a picture of the brain concerns which was helpful."); contact details for UK hospitals ("Just a page with phone numbers for clinics and hospitals in the UK.").*

Another (3%) mentioned that they were given details of support groups:

"I was given a printed list of websites to contact eg LMC, Feilecain etc."

For one response it was not stated or unclear if any written information was provided:

"I meet with the genetic consultant in [the hospital] she did give us alot of detail as to how significant the deletion would be on our baby she advised that the information she had was for a smaller deletion on chromosome 2 but she advised our baby would probably be more severe as the deletion was larger ie sever intellectual disability, uncontrollable seizures etc. She did not speak to us re our options just flippantly said that England would be able to look after us if we decided not to go ahead with the pregnancy. Crisis pregnancy were the only people who gave us some guidance as to our options in regard to keeping baby or having a termination."

Did you have access to a Geneticist? Was this mentioned to you as a possibility?

Thirty-six participants responded to this question. One person stated that they were "not sure what above is", leaving 35 eligible responses for analysis..

Twenty-one people said no (21/35, 60%), eight said yes (23%), five did not state (14%) and one said not applicable (3%).

Of the 21 people who stated **no**, there were varying responses:

Seven just stated *'no'*

Six stated no, never mentioned – three of whom added additional comments:

"No never mentioned . Just told it was unlucky that baby had T18."

"This was never mentioned and we didn't have access to one. I would not have thought of that."

"No at this time I did not have access to a geneticist and it was never mentioned as a possibility or a necessity."

- Six stated that there was no need, due to results received:

"Even before the CVS test, it was confirmed as trisomy 18. The CVS test confirmed it so there was no need for a geneticist. Later both my husband's and my bloods were tested for trisomies."

"No. The CVS came back as not genetic issue so it wasn't considered in my case".

"No. I asked about this and was told the diagnosis was due to insufficient folic acid rather than genetics. I eventually went to a geneticist privately."

"No but we were contacted afterwards by [the hospital] to say that it was a once off type scenario that there was nothing in the genes to have caused it."

"There really wasn't one suggested. The diagnosis came from a lab in the U.K. I have a family member who is a Geneticist and she offered to put me in touch with a genetic counsellor but it was all so final and inevitable there didn't seem much point. Nothing was going to change the outcome."

- Two stated no, further testing carried out afterwards and/or not initially:

"No but genetic testing carried out afterwards."

"Not initially. When we miscarried a pregnancy several months later they pushed for testing on the pregnancy remains and were shocked to receive same diagnosis as the tfmr. Following that, We were offered to speak with geneticist but have not pursued as we underwent some blood testing and came back clear so didn't think necessary."

Of the eight who said **yes**, two stated that they were told it wasn't necessary:

"Yes but was told it wasn't necessary as had previous healthy children."

"Yes, although our consultant didn't think it necessary to refer us as our daughters diagnosis was not due to genetics thankfully."

Another participant said that they *"did have access but did not go ahead with meeting."*

Comments from the remaining five highlight individual issues relating to access including lack of knowledge of their referral, private access to a geneticist and feeling grateful to have had access.

"Yes I received a phone call from a Genetics at week 3 after concerns notes, no one told me my information was passed to them or that they would contact me."

"Yes. I was referred to one."

"Yes, privately."

"Yes we had access."

"Yes we did thankfully have access to geneticist."

The five participants who **did not state** a firm response had various reason for doing so, including:

- Further testing (2)

"We had bloods and an amniocentesis done which gave us further results and clarity."

"They did genetic testing after baby was delivered."

- Met afterwards (2)

"Meet with the genetic consultant after as there was none working in the hospital when we received the diagnosis."

"Further down the line this was arranged for me and I got free testing and an answer approx 9 months later."

- Wait and see (1):

"We were offered to have an amniocentesis first and to wait and see what the results were of that."

One participant inferred that it was **not applicable** as they *"didn't want to discuss it at the time as we knew our decision."*

Was the process for agreeing a termination of pregnancy explained to you? Did you know that cases like these are discussed at a Multi Disciplinary Team meeting?

Thirty-seven participants responded to this question; the following responses were provided:

- No (n=19; 51%)
- Yes (n=15, 41%)
- Not applicable (n=3; 8%).

Of the 19 who stated **'no'**, 12 provided further comments. The majority related to: not knowing cases like this are discussed at a MDT; not having received this information as they had to travel.

"No didn't know it was discussed . I did a lot of goggling myself to try figure it out . I thought at one stage i would be given feticide to end the pregnancy."

"No, none was discussed with me, I was told at every appointment that a termination would not be covered in Ireland. I was nearly 23 weeks at my anatomy scan so at time of real concerns I was 26+ weeks. I was 28 weeks by the time of MRI results, I still didnt have genetic information back or a diagnosis when I decided to have a termination. I decided this with the support of a pediatrician who met me in the maternity hospital arranged by the maternity consultant."

"It was just left to us to decide where or not to continue the pregnancy as the Dr. said. No."

"No. All we were told was 'don't worry, at least we can do it here'."

"No as we could only travel to UK with our diagnosis."

"No, as our only option was to get a termination privately in a different country. I don't remember mention of that."

"No I was told after that my case would be discussed at a MDT by my obstetrician. Having obtained my information through data protection this never occurred and it was never discussed."

"No. My last appointment was a Thursday and the MD team meeting was the next Wednesday. As I would be 22 weeks by that Wednesday we felt we could not wait as time was not on our side. From what we could find online / what clinics were telling us."

"No, I was told my options for a termination in Ireland depended on results of amniosynthesis [amniocentesis] and if it was one of the 3 trisomys, I was told if it wasn't it would be a referral to liverpool and my options for a termination would be dependent on the opinion of another specialist over there agreeing with the findings."

"No our consultant stated that our case would not be excepted by the ethics board in the hospital."

"No this process was not discussed with me and this actually caused allot of stress for us. We were told by the heart experts that all options would be supported for us. We were told by our local doctor in [the hospital] that the termination process

probably won't be supported and in fact, she tried her best to guilt us into making a different decision which was extremely stressful in an a already stressful situation. This was definitely the most difficult part of the process and having clear information would have helped. I don't think our local doctor even knew the process but I got very different information from her than the heart experts."

Fifteen participants responded ***'yes'*** to this question, one of whom provided further information. Some mentioned how this information was discussed, but did not apply to them in the end due to other circumstances (travel, urgency), others mentioned how they received clear explanations, or how the process for agreeing a termination of pregnancy was discussed but not the MDT discussion of such cases.

"They explained what requirements needed to be met in ireland for a termination but we didn't meet them."

"Yes, it was very thoroughly explained."

"We were told that we will be discussed but never got back to me as we were in process of finding our own route in UK."

"Yes this was discussed. However we needed to terminate before this meeting due to rising infection (maternal health)."

"Yes our midwife specialists explained the process to us. We knew there would be a Multi Displinary team meeting and that our baby's case would be discussed and would also need to be assessed by a second specialist."

"Yes. I asked for my case to be presented at the MDT when I felt strong enough to do so. It was presented by my midwife. It actually gave me some confidence in the process and it felt like if there was any issues it could be brought up and be discussed and perhaps brought back to me if it had been likely (it wasn't). "Once the decision was made I made an appointment and that was the toughest week psychologically. On the day I was scheduled to receive mifepristone a second consultant came into to view my scan (and previous ones) and gave me his condolences after confirming the diagnosis, looking at the genetic test results etc."

"I am not from Ireland so the options were explained to me but it was distressing to have to travel to the UK on top of having a life changing diagnosis."

"Yes the process was explained to us....we were not made aware of Multi Disciplinary Team meetings."

"Yes, all was discussed and very clear."

"Yes I was aware that my case was discussed at a MDT because I had to wait for this for the final decision to be made whether I could be offered a termination or not."

"Discussed with me -yes. I did not know know about the team meeting."

Of the three who stated '**not applicable'**, one noted*: "I'm not sure I understand. We were told if we decided to end the pregnancy that we were not a patient of the hospital until we returned and that obviously our options were limited (non existent really) in Ireland due to the length of our pregnancy."*

Were you given information about feticide and your choices about this?

Thirty six participants responded to this question. Participants gave the following responses:

- No (n=17, 47%).
- One noted: *"No information given, I asked the pediatrician for advice, he explained the process a little. I was given no information from the hospital in the UK and absolutely no one explained anything to me."*
- Yes (n=13, 36%). While participants stated yes, however, there was a low level of information and/or variation in where information was provided, with some stating that this information wasn't clearly explained until they were within UK-based services.

"Yes in passing but no written information."

"Mt local consultant obstetrician was the only one who mentioned termination and asked if that was a consideration of our as it would need to be discussed at multi D meeting if so."

"From the clinic in the UK I got this information."

"The hospital I attending for TFMR did mention feticide - and that they do not do this here. Which I did not have a problem with as it was almost certain my baby would not survive the birth."

"It was always clear to us that it is our decision."

"I can't really remember, I don't believe this was explained in detail to me until I was in the clinic in UK."

"I wasn't aware of this until I contacted the bereavement midwife in the hospital myself and she mentioned feticide."

"It was mentioned as a choice from the heart experts but no detail information was provided."

"I was given a little information about feticide here but more from the UK team."

- Not sure (n=1, 3%)
- Not applicable (n=3, 8%)
- Not stated*: "was told I could contact bpas in the U.K. who could arrange a TFMR for me if I chose to do so or possibly a hospital"* (n=1, 3%)
- *"I'm not sure what this question means"* (n=1, 3%)

If you were refused the option of terminating your pregnancy was this decision given to you in writing and were you informed how to have this decision reviewed

Thirty-three participants responded to the question. Responses were classified as follows:

Eighteen participants said ***'no'*** to this question (55%). Of these, 11 expanded on their responses, and these primarily related to the option not being available to them as it didn't meet the criteria for a fatal fetal diagnosis under the legislation. A few specifically mentioned that they had no idea that an appeal was possible.

"I was simply told this option was no available in Ireland. But as said above I decided before a formal diagnosis, formal diagnosis was given two weeks after termination. I was informed of diagnosis and that my daughter would have been extremely ill and not lived long, possibly a few months."

"No, told if your baby had CDH and genetic abnormality we would look after you but not CCAM and genetic abnormality."

"No as our diagnosis didn't fit the fatal diagnosis."

"No as in our case it wasn't an option anyway except privately."

"I was never refused per se but given the impression by the FMS that there was no help here for me. In my position of distress and grief at the time I had no reason to question this as I trusted him as a medical professional. I now realise that this was a refusal due to the restrictive legislation and also his personal ideology. I was never given this in writing."

"We had a verbal discussion, being aware of Irish legislation that was sufficiant for me as I understand it is final and law."

"No. We weren't technically refused as we knew it was never an option in any healthcare setting in Ireland."

"No I wasnt told I was being refused or what would happen if I was refused, I wasnt given any definite information other than my only guarantee of a termination was one of the 3 trisomys being diagnosed on amnio (trisomy 13 thought to be likely) and I had to wait another week for results of that."

"Not at all. The team of consultants told my husband and I that in their minds the issues with my baby were so catastrophic (cloacal extrophy) that they absolutely would have considered a termination the best course for the baby's sake but that there was nothing they could do as their hands were tied by the legislation but that they hated seeing us having to travel because the issues with the baby were too many but they could not say with certainty that he would die within the 28 day timeframe. I did not know there was a right of appeal (until reading this form)."

"No I was given nothing in writing and no I was not given information on how to appeal the decision."

"No I did not received the decision in writing and had no idea that an appeals process existed."

Thirteen responses were classified as '**not applicable'** (n=13, 39%), with five participants providing further details, mainly relating to either not being refused; one mentioned contacting the UK immediately and bypassing the Irish system.

"We were not refused as we knew Irish law only allows to 12 weeks, it was not an option for us. We had to travelled to the UK."

"I was not refused."

"When we were told by the local doctor that the termination probably won't be supported, we contacted a hospital in the UK, sent them the diagnoses report and the next day we got approved for a termination. This process was allot less stressful that way."

"We ended up getting approval in ireland but the decision took a few weeks and was extremely stressful."

Two participants responses (6%) were classified as '**not stated'**, i.e unclear from responses:

"could not terminate in Ireland as baby was diagnosed with Down Syndrome after CVS test but I was told it was the Cystic Hygroma they were more worried about as the baby more than likely wouldn't live past 25 weeks."

"they refused to perform in Ireland and said we would have to travel to the UK."

If you were refused a termination of pregnancy what information were you given about travelling outside of Ireland for this?

Thirty-two participants provided a response to this question. Of these, 10 said that it was not applicable (31%). Of the remaining 22 participants whose responses were eligible for analysis, three stated that they were not given any information (3/22, 14%).

Seventeen participants (77%) stated that they were provided with some form of information, the format, and extent varied however. Some noted that they were just given the name of a service(s) – some noting verbally or written, or an information sheet with contact details/a card – and that they had to follow-up after that:

"Business cards for a sexual health clinic."

"the bereavement team gave us the contact information along with support charities, we had to do the logistics after that."

"Details to contact Liverpool Women's Hospital."

"We were given phone numbers to call to arrange a termination if we so wished, and some general information about being able to take our baby home and how you could do that."

"Verbal information ...name of clinic."

"I wasn't given any bar the obstetrician writing down the name of a clinic in England on a piece of paper. We were given information by the crisis pregnancy clinic."

"Just phone numbers for UK."

"We weren't refused it wasn't an option - we were provided with our UK options."

"The process and options for the UK were explained and we were given very helpful information and print outs of information."

"I was given a social workers information. On contact she informed me that I only had one option which was to go to London. She gave me no option within the European Union. London was the most horrific experience of my life. I would not wish my experience on anyone. I phoned the social worker on my return and explained my experience and could not believe she gave it to me as my only option, she told me no one has ever gave her feedback in their medical treatment abroad. You would not believe the ill treatment. Nor the disregard."

"An A4 sheet with phone details for Liverpool Women's hospital."

"we were told there were hospitals over in the uk we could attended so we went home and done the research our self and rang a few hospitals to see what way they deal with it."

"Told to ring BPAS."

"Verbal recommendation of BPAS."

"That I could contact bpas [BPAS] and arrange a termination. In my case I contacted bpas in liverpool and Birmingham Womens and children' hospital and the multidisciplinary committee agreed that I could have a labour and delivery there (as I wanted a post mortem to see if this issue was something which may affect future pregnancies and a post mortem cannot be carried out following a surgical termination)."

"Basic info about BPAS- we had to source all other info ourselves."

"Vaguely."

Two (2/22, 9%) participants did not explicitly state what information, if any, they were given:

"arranged travel myself due to the uncertainty and lack of information on what would happen or my options if one of the 3 trisomys was not diagnosed. I was running out of time for a guaranteed termination in the UK (23 +6 when I travelled as my anomaly scan was almost 22 weeks, and my appointment with specialist one week later, and results of my amnio one week after this). I didn't want to wait any longer not knowing what would happen and waiting on another specialist to review my case (also it was suggested I might have to travel to liverpool to be reviewed) which would have meant a greater delay and baby being older when i got a

termination which i did not want. I felt travelling was the best option but it was horrific."

"I was told that my case would be reviewed by a board of ethics in Liverpool and if they decided that they could accept me then I could travel for a termination."

Where do you find information about travelling for a termination or from whom if not given it in the hospital?

Thirty participants responded to this question, of which six said that it was not applicable. Two further participants noted staff within the hospital (the fetal medicine midwife, social worker) and a further six described the hospital, and thus were re-assigned as not applicable, leaving 16 participants with responses eligible for inclusion in the analysis. It is worth noting that a few of those excluded from the analysis mentioned other sources of information such as other parents, ARC (UK), and information found online.

"The fetal medicine midwife said if required she would provide info."

"Social worker that worked in the hospital."

"Hospital and ARC provided as info support."

"we got information from the hospital."

"the hospital provided options."

"Was given in the hospital and was also provided with access to a hospital counsellor in the 5 weeks from diagnosis to travel for TFMR. She also mentioned bpas [BPAS] as the option."

"Midwife in hospital and other parents who had travelled before us."

"The hospital gave me some information about Liverpool and I found other information online."

Of the 16 participants with eligible responses, some stated more than one source, so numbers below are slightly higher and percentages do not add up to 100. The vast majority (n=10, 63%) stated that they did their own research – the majority online, with some making phone calls.

"I was given no information on termination in the UK or no information for any support groups. I got information from google. I spent HOURS on hold trying to get appointment in any part of the uk. As it was so last minute the only option for me was to go to a clinic in one part of london on day one for the first procedure and then travel across London on the tube in agony and so so upset in order to go to a different clinic in a different part of London the next day. This was the only appointments I could get and I tried all the organisations. It was the worst journey of my entire life and I was very sick at the time."

"The Internet and online forums."

"Online, Google, my GP also sent me a number of a support group in Ireland that support women going over to the UK from Ireland for terminations. I also rang a clinic in the UK for information."

"We were provided phone numbers but absolutely everything else was researched and arranged by us."

"The internet. Over a UK long weekend. We spent Friday - Tuesday calling countless clinics and hospitals hoping for an appointment."

"Google."

"Internet- BPAS website."

Other information sources included: TMFR (n=3, 19%); ARC (n=2, 13%); BPAS Abortion Support (n=2, 13%); Leanbh Mo Chroí (n=1, 6%); ASN, Abortion Support Network (n=1, 6%); Crisis Pregnancy Clinic (n=1, 6%); GP (n=1, 6%); Sexual Health Clinic (n=1, 6%).

Were you given information about useful support groups or organisations, who shared this with you and at what stage were you given this information?

Thirty-five people responded to this question. Of these, 13 (37%) said no. Some expanded on their responses to reflect the lack of information given (with one noting the impact of this), or how they sourced information for themselves.

"No. No single person I seen in the hospital even informed me of the mental health team available to me. This team phoned me as I was packing to travel the day before my termination, and I later found out it was my brother that co tactes [contacted] the hospital worried about me and asked for someone to call. My choices may have been very different if I had of seen anyone. I was in a fog or thinking I was doing best for my child. All the team asked was if I was going to hurt myself, they then gave me a text with a contact name and number, as I said it was too later for my [me] and my baby, I was packing and completely lost emotionally."

"No. We received no information whatsoever."

"I discovered these through Google. ARC in the UK was the most helpful. There are booklets & brochures online which informed me about what to expect when going in to have our baby. I could not find anything similar for Ireland."

"No, found though friends and online."

"No never. I was given a business card and shown the door."

"Not about termination, more for baby loss support groups."

"No I wasn't given any of this information I sourced out same myself after we had a termination."

The remainder (n=22, 63%) said yes and/or noted the specific support group/organisation(s) mentioned (Table 1.6). Twelve did not specify the support group/organisation, but 10 did; these included: LMC (n=4), Féileacáin (n=2), LMC and A Little Lifetime (n=1), TFMR (n=2), and a therapist [N/A as such] (n=1).

Ten people mentioned who shared information about useful support groups with them: Fetal medicine midwife/Bereavement midwife/Midwife (n=8), medical social worker in hospital (n=1), and counsellor in the hospital (n=1).

Nine mentioned when this information was shared with them: straight away/while still pregnant/at or soon after diagnosis (n=6), or after the termination (n=3).

Table 1.6. Information about useful support groups or organisations, who shared by and at what stage

Support groups / organisation(s)	Informed by who	When
Not specified (n=12)	Not specified (and verbally only)	Not specified
	Fetal medicine midwife	Initial appointment and then again when had CVS results
	Bereavement midwife	Straight after diagnosis
	Bereavement midwife	While still pregnant
	Not specified	Pretty early in the diagnosis with day or so
	Fetal assessment midwives	Not specified
	Fetal medicine midwife	At first appointment
	Not specified	Not specified
	Not specified	Not specified
	Not specified	Straight away
	Fetal medicine midwife	Not specified
	Medical social worker in hospital	Two weeks after termination
LMC (n=4)	Midwife	Not specified
	Not specified	Not specified
	Not specified	After we came back home
	Counsellor in the hospital	Not specified
Féileacáin (n=2)	Not specified	Not specified
	Not specified	After the termination
LMC and A Little Lifetime (n=1)	Not specified	Not specified
TFMR (n=2)	Not specified	Not specified
	Not specified	Not specified
Therapist [N/A as such] (n=1)	Midwife	Not specified

Some of the comments provided more insight into participants' experiences – including the need for the right kind of support for individual circumstances, at the right time:

"Yes. LMC but I can't remember where I got this information as those weeks and months are a blur."

"I spoke with [woman's name] after we came back home and it was at that stage that she gave me the names of some groups including LMC."

"Counsellor in the hospital gave me the information details for leanbh mo chroi thank god I really needed someone's support at the time. I felt truly shunned by the Irish health system and so dirty for having to travel for this reason. Even still people don't know I had to travel for TFMR (in sept 2020)."

"We were given the information of LMC and also A Little Lifetime for counselling support. Everything else we sourced online myself in terms of Facebook groups, Instagram accounts etc."

"TFMR. Found the group on the internet."

"Given details of TMFR."

"Our midwife gave us the email address of a therapist who specialises in bereavement. She also brought us back afterwards to speak with us and check in."

"I was told about Feilican charity but I didn't feel like I belonged with them as I was ending the pregnancy by choice. I wish that I had been given LMC information also at this crucial point."

"We were told about feileacain but only after the termination. We didn't get any counselling or charity support before the decision."

Did you meet with a counsellor? Was this through your hospital or private? Do you think access to counselling is important for people in this situation?

All 37 participants responded to this question, with the majority (n=29, 78%) saying that they did meet with a counsellor, while the remainder did not.

Of the eight who said that they did not meet a counsellor, some of their comments provide further insights into their reasons for not doing so – such as cancelling an appointment after scan showed "severe issues", or lack of time before termination. Many highlighted the need for this form of support, and in a timely manner:

"No. Actually I had an appointment with a pregnancy Councillor as I had seen her in my previous pregnancy but that appointment was cancelled after the ultrasound showed severe issues."

"Appointment with pregnancy counsellor cancelled after signs of trisomy seen on scan."

"There was no time I had 9 days before my option of termination was no longer available to me. So I had no time but clinic in UK got me to talk to one over what the phone."

"No I never met anyone, how can anyone help me now, it's too late."

"No, I felt like we had no support apart from my parents support."

"No. And yes I think its important. All women when given a diagnosis should be given the bereavement midwife immediately even if this is just a phone service for support. If they have to travel or have had a TFMR here this support should also be here as well as access to the mental health midwife. And then a councilor or a session with the peri natal psychiatrist."

"No, I have not yet met with a counsellor, the hospital social worker did come to see me and has left an open door for me, it has been 8 weeks since we had to say goodbye to our daughter so we are still finding our feet after such a traumatic ordeal, but I do think it is a service I will avail of in the future and I think it is so important that all women in these horrendous circumstances have access to counselling in these situations."

Of the 29 people who said that they met with a counsellor, only nine of these (31%) specified that this was through the hospital, including three who said that they met with the bereavement midwife. The remainder stated that they sought counselling privately (n=10, 34%), or did not specify whether public or private (n=10, 34%).

"i got in touch with a counsellor through the foundation a little life time, the midwife came me his name. yes it is very important because it can be hard to talk about how you feel with close family and friends."

"I went for private counselling. I was not offered any through the hospital . Its so important to be given information about what help is available as you never know how fragile someone is."

"Yes months after and only after we sought it. It was very helpful."

"Yes, after the delivery. The counsellor is provided through [the hospital] and specialized in TFMR."

"Yes. Private. Yes."

"A few weeks afterwards I contacted the bereavement team to ask about counselling. They gave me the name of a counsellor who I visited privately. The counsellor then became employed by the hospital and she saw me through the hospital for counselling (ag no cost)."

"I sought private counselling after my TFMR. I This was the hardest thing & most devastating thing I have gone through. Counselling gave me an opportunity to talk& express my emotions & know that it was normal to feel how I did after what I had gone through. At no point during our process from diagnosis to delivery did the bereavement midwife in our maternity hospital contact us. I felt that this was a

huge gap in care. She should have been involved from the minute we received our diagnosis."

"I met with the bereavement midwife. I think a counsellor is so important to have available to parents."

"Private and so so important."

"No, I wasn't ready for at least 2 years later. I arranged this privately myself."

"Yes. It was private. Yes, it is a fundamentally traumatic experience and access to counselling following such an experience is essential."

"Bereavement midwife through the hospital and yes very important."

"Yes I still attend counselling over one year later. We were given our counsellor's phone number, but I was also given same contact by a friend who lost a baby previously. Access to counselling and peer support is absolutely vital and one of the only things that got me through was knowing that I wasn't alone in having to make this horrific decision and go through this awful and traumatic process."

"Yes, through my GP. I found it somewhat helpful. However looking back, a year post termination, I think it was too early for us. The fog and shock has only really lifted recently. I don't even really remember the sessions we had."

"Yes I believe it is important. I'm only now reaching out to support groups. I found our midwife and team really supportive but perhaps more direct lines to support groups could be provided as I find that now I'm trying to look up the groups, get in contact with them..etc."

"Psychological support wasn't as strongly suggested as I expected and I asked for this as this was probably the aspect I needed most. Even just from a decision making perspective I thought it would be essential yet if I hadn't have asked I would not have had psychological support before my daughter was born. It was also the one thing I could understand the place of in the whole process (for me): the rest seemed so final and desperately sad. The therapist wasn't available post diagnosis/pre birth so I was sent to the hospital psychiatrist. It was helpful to a point but I think we both knew I shouldn't have been there so I only went back once. I requested to see the Fetal medicine therapist a few months after my daughter's birth when she was available and that was infinitely better. She has helped me so much in my recovery and I would continue to see her if I could. She mentioned that the team think women only need a few therapy sessions but in reality she sees women for up to a year. I feel it's such a difficult area that you need a therapist that really understands that. I've even considered looking outside of Ireland as I approach my daughters anniversary and my connection to the hospital ends. There are counsellors that specialise in this area privately overseas and I feel they might handle it better even if it's via Zoom. I have a family member who has worked as a psychotherapist for over ten years and she has never had a client with a similar scenario to mine. That confirms to me that people in similar situations need someone who can understand just how complicated the whole process is in terms of grief and loss, guilt and all the other emotions. There is also now a stigma

around grief and TMFR which isolates people further. Appropriate psychological support would help recovery from what is probably the worst thing than has happened in one's life to date and maybe ever."

"I met with bereavement midwife."

"I met with a private counsellor. Counselling is VERY MUCH NEEDED."

"we met with the counsellor after the termination and about 6-8 weeks post TFMR, it was provided through the hospital."

"Yes. Medical Social Worker found the organisation and sent me the details. Counselling is extremely important."

"Met bereavement midwife at a later stage."

"Yes through the hospital. After my TFMR I went for private counselling. It's absolutely vital but the crux of all of this is being forced to travel - no family, friends nothing. I had a massive haemorrhage 9 days later because I had retailed placenta and needed 3 units of blood transfused because I lost 1.5litres within a space of 2 minutes. If this had have happened me on the flight back from birmingham I would have almost certainly died from blood loss as I had to be rushed to theatre. Helpful and all as the hospital was in birmingham once the baby was delivered they didn't really consider me to be their patient and would not scan me for retained products before I left their care. Similarly once I had gone to the U.K. for a TFMR I wasn't really considered a patient here in the hospital in my home town either and when I was feeling dreadful and still experiencing contraction type pains after 9 days I went to the maternity here myself and begged to be scanned. I was scanned and kept in with a view to having a d+c the following morning but I had a haemorrhage during the night instead and it became an emergency situation. Mentally if this had have happened anywhere but in the hospital I don't think I would have coped as it was so frightening and traumatic."

"Yes, name was given by midwife in hospital. Yes, I feel counselling is so important for people in this situation."

"I attended counselling through the crisis pregnancy clinic I wouldn't be here without the assistance I received from the counsellor. It is a vital service after such a traumatic event."

"I contacted a counsellor privately but I do feel counsellors who specialise in the area of fatal fetal diagnosis and loss ought to be available."

"We were only told about this service following the termination. The counsellor was surprised that the local doctor did not put us in contact with her while we were making our decision. I think counselling support is vital in these situations."

"Brief phone call so far- organised by MSW. I feel someone needs to be available to talk to."

"I was given access to a counsellor about 2 months after the termination when I rang the hospital and they advised that they now had one available to me. She wasn't working at the hospital at the time of my termination."

"Yes - sexual health clinic outside hospital."

Did you have a choice about the location of your termination or delivery? For example could you choose between your original hospital/unit or another hospital

NB: Caution should be exercised when interpreting 'choice' in the responses to this question, and how people interpreted the level of choice they had, e.g. no choice but to go to UK, but had choice of service in UK.

All 37 participants provided a response to this question. Of these, only two said **yes** (5%); they did not provide any further details.

Twenty-five participants said **no** (68%). Fifteen of these just said no, and did not provide further details. Ten participants gave various reasons for saying no, including having to travel to UK, lack of appointment availability, gestational age at the time of termination, COVID-19 restrictions:

"No my local hospital "doesn't have the resources" so I was referred to the larger regional hospital where I was scanned and out the door after 15 minutes told no help in this country and secured a last minute appointment at the 3rd hospital on the way to the airport to the UK. All done in desperation so there was never a choice."

"No. As I mentioned it took us days to secure a definite appointment. Clinics such a Marie Stopes only had stand by appointments which meant I was 5th in line for 4 people to not show up for their terminations. Which didn't feel hopeful. On the Tuesday a hospital in London called us back with an appointment on the Thursday. I did not have a choice to deliver."

"I was told I had absolutely no option only London and I e hospital. I believed this information."

"No- had to travel to UK, away from all our supports, which increased the trauma of the difficult situation of making that decision on a much wanted pregnancy."

"we did not have a choice as the only one who had availability and could do my late term was narrowed down for us."

"No I was not given a choice I had to have a surgical termination I would have preferred to have had a medical termination but it wasn't an option at the time due to covid."

"Not really I was limited as during CoVid lock down and I wanted a surgical termination so I could only go to an abortion clinic and limited in my choice due to my gestation as not all clinics would treat me."

Within these responses, two mentioned that they did not have a choice, but were happy or wouldn't have chosen anywhere other than their hospital.

"wasn't given a choice but I wouldn't have chosen anywhere different to my original hospital."

"No choice was given but I was happy to stay in [the hospital]."

Another mentioned that they were *"in hospital for two weeks prior to termination" so had no choice.*

Ten participants **didn't directly respond 'yes' or 'no'** (27%). Of these, five stated that they had a choice of UK hospital only:

"The only choice i had was which hospital i could pick in the uk."

"We were presented with various UK based options."

"As we had to travel for care, we had both hospital or clinic setting to choose from."

"It was a choice of either Birmingham Womens and children's or a bpas clinic."

"I had the choice of going to London or Liverpool so within the UK I had a choice but obviously not the choice to have the termination here in Ireland."

Four participants stated that they had the termination in the same hospital they attended or local hospital:

"I was always in [the hospital]."

"Thankfully it was done in the primary hospital I attended."

"Our termination was carried out in our Maternity hospital so we had no need or want to go elsewhere thankfully and this was such a blessing."

"I just went to my local maternity hospital."

A further participant stated that they had to take what they could get due to COVID:

"CoVID peak, take what you can get. Got to Birmingham which were fabulous."

Were you asked for feedback about your experience in any formal way from the unit you attended?

Thirty-six participants responded to this question. The majority (n=30, 83%) stated no. Of these, four made further comments relating to feedback which they did give (n=3), or support they received (n=1):

"No. When the bereavement midwife contacted me about 2 weeks post TFMR I gave verbal feedback about the lack of supports and poor communication that we had experienced. I was told that if I wanted to put it in writing it would have more impact. I did not want to be seen to be complaining about the hugely compassionate, diligent & overworked staff we had met during the process. It was the lack of communication, knowledge & psychological support we felt let down by."

"No but I gave it!!!"

"No not formally but I did feel comfortable discussing any issues that I had with the [the hospital] and did do so on my return visit after my termination. I also returned to [the other hospital (referring)] to share my feedback with them as I felt they dealt with the whole situation very badly on a number of areas/staff but I was just told to send an email in, I didn't feel that it was taken very seriously."

"No but they offered help and support if I need it."

Six participants (17%) stated that they were asked for feedback about their experience in a formal way. One noted: *"A follow-up meeting was arranged for us with our fetal medicine consultant and midwife 4 weeks after our daughters birth. This was so important for us to ask any questions we had and for closer and peace of mind."*

It is completely optional to respond to this question. Which maternity unit or units did you attend?

Thirty-six participants responded to this question. One stated that it was not applicable (3%) and another stated that they would prefer not to say (3%).

"Prefer not so say in case there would be any ramifications for the hospital. I believe they did all they could for me but the legislation stopped them from actually helping me. I have nightmares still about the entire situation. It has been hugely difficult on my mental health. Thank you for reading this. I hope eventually our consultants will be able to make the right decisions for their patients with their patients. My consultants absolutely agreed that I should be helped here in Ireland. But as they said themselves their 'hands were tied' and off I went to book my flight."

Of the remainder some mentioned more than one hospital, so responses do not add up to 100%. Of note, four mentioned a hospital in the UK, solely (n=2) or in conjunction with an Irish hospital (n=2).

- Cork University Maternity Hospital (n=4/36, 11%)
- Galway University Hospital (n=1, 3%)
- Mayo General Hospital/Castlebar (n=2, 6%)
- National Maternity Hospital, Holles Street (n=10, 28%)
- Our Lady of Lourdes Hospital, Drogheda (n=1, 3%)
- Portiuncula University Hospital (n=1, 3%)
- Rotunda Hospital (n=5, 14%)
- St Luke's General Hospital, Kilkenny (n=1, 3%)
- The Coombe Hospital (n=4, 11%)
- UK hospital stated (n=4, 11%)
- University Hospital Kerry (n=1, 3%)

- University Hospital Waterford (n=1, 3%)
- University Maternity Hospital Limerick (n=7, 19%)
- Wexford General Hospital (n=1, 3%)

Of these, nine noted other comments within their responses, some positive and some negative aspects of their care (e.g. whether treated with dignity and respect or not, presence or absence of supportive/compassionate care), or further context to their care.

Section 2.0

Literature Review

Section 2: Literature Review

Overview

The Group established to undertake the Review to Improve the Safety and Management of the Provision of Termination Services as Provided under Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018 (The National Review Group) determined that, in order to report gaps and/or deficiencies in the services provided under the Act and to frame the findings from the service evaluation (Section 1), a review of the relevant literature around screening and diagnosis of fetal anomaly as well as termination of pregnancy for fetal anomaly (TOPFA) was needed.

A review of the literature was undertaken in late 2022, and updated in early 2023, using relevant keywords. Due to the timeframe and scope, it was not possible to perform a full scoping review or systematic review for each of the topics explored. Searches were restricted to published systematic and scoping reviews, national audits and cohort data, randomised control trials, published national clinical guidance and professional committee opinions and statements. The findings of this review also refer to and use the guidelines of other associations and professional bodies. These include: International Society of Ultrasound in Obstetrics and Gynaecology (ISUOG); American Institute of Ultrasound in Medicine (AIUM); The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG); Society of Obstetricians and Gynaecologists of Canada (SOGC); National Institute for Health and Care (NICE); NHS Fetal Anomaly Screening Programme (FASP); Royal College of Obstetricians and Gynaecologists (RCOG); British Medical Ultrasound Society (BMUS) Guidelines and the International Federation of Gynaecology and Obstetrics (FIGO).

This part of the National Review Group's report is divided into the following sections: Screening for fetal anomaly (incorporating screening for aneuploidy, dating scans/ first trimester anatomy and fetal anatomy ultrasound), Fetal medicine and TOPFA (incorporating fetal medicine services/centres, care pathways around TOPFA and Neonatology), Clinical Genetics, Investigation and follow-up (incorporating Perinatal Pathology and Bereavement Care) and Professional development.

Screening for fetal anomaly

Congenital anomalies are defined as abnormalities of body structure or function that are present at birth and are of prenatal origin.(1) Approximately 2% of pregnancies are diagnosed with a congenital anomaly each year. A proportion of these anomalies will be lethal or fatal, and congenital anomalies remain the leading cause of fetal death and infant mortality.(2–4) In Ireland, the National Perinatal Epidemiology Centre reported a perinatal mortality rate of 6.25 deaths per 1,000 live births in 2020, with 32.9% of stillbirths and 58.1% of early neonatal deaths classified as due to congenital anomaly.(5) There is currently no clear consensus on defining what is a major congenital anomaly. The Centres for Disease Control and Prevention (CDC) defines major congenital anomalies as structural changes that have significant medical, social or cosmetic consequences for the affected individual, and typically require medical intervention.(1)

Screening for aneuploidy

Prenatal testing for chromosomal abnormalities accurately assesses the woman's risk of carrying a fetus with a chromosomal abnormality. The incidence of fetal chromosomal abnormalities increases as a woman ages but can affect women at any age and is not related to race or ethnicity. Testing for chromosomal abnormalities should be an informed choice based on clinical scenarios, healthcare resources, beliefs, and goals. After review and discussion, every woman has the right to pursue or decline prenatal genetic screening and diagnostic testing. Pre-test and post-test counselling is essential. A wide range of screening tests is available, with varying performance levels. (6) (7)

National screening programmes exist in many countries with different combinations of maternal serum biochemical markers with or without nuchal translucency [NT] measurement. Combined first-trimester and second-trimester screening with either integrated, sequential, or contingent screening involving serum analytes, NT, or both measurements provided a higher detection rate for trisomy 21, 18, and 13 than one-step serum analyte screening. Depending on the test selected, there is variable timing of when results are available. (8,9)

The American College of Obstetrics and Gynaecology (ACOG) recommends that prenatal genetic screening (serum screening with or without NT ultrasound, or cell-free DNA screening) and diagnostic testing (CVS or amniocentesis) options should be discussed and offered to all pregnant women regardless of age or risk for chromosomal abnormality. (9)

Cell-free fetal DNA (cffDNA) released into the maternal circulation is of placental origin, and the proportion in the mother's plasma ranges from 3 to 30% when measured between 10 and 30 weeks of gestation.(10) The amount of cffDNA in maternal blood increases with gestational age and for aneuploidy testing, at the current depth of sequencing, many protocols allow detection only when the fetal DNA percentage is at least 4–5%.(11) Non-invasive molecular approaches with an acceptable detection rate and specificity include sequencing, PCR, single nucleotide polymorphisms (SNPs), or microarray.(11) The many commercially available aneuploidy tests (NIPT is predominantly used to screen for T21, T13 and T18) are generally stated to be for pregnant women from 10 weeks of gestation; a dating scan to establish gestational age before the sample is drawn is required.(12)

NIPT is now available in over 60 countries and has been described as one of the fastest spreading genetic technologies globally.(10) Recently maternal plasma cffDNA, widely referred to as non-invasive prenatal testing (NIPT), was incorporated into national screening programmes as a first-tier or second-tier test in several European countries, including France, Switzerland, Italy, Denmark, Norway, Sweden and Finland. (13–17) However, the clinical implementation of NIPT differs widely between countries, where it may be provided by commercial organisations, medical professional associations and private insurers or embedded in public health.(10) Common issues have emerged with the spread of NIPT – its use as a first or second tier screening test, cost as a barrier to equitable access, the complexity of decision-making about public funding, and a shortage of resources that promote informed choice.(10)

Belgium and the Netherlands were among the few countries worldwide to offer NIPT as a first-tier screening test to all pregnant women as part of a national prenatal screening

programme. A nationwide implementation study was launched in the Netherlands on NIPT as a first-tier test offered to all pregnant women. The TRIDENT-2 study, licensed by the Dutch Ministry of Health, confirmed that genome-wide NIPT is a reliable and robust screening test for detecting fetal aneuploidy.(13,18) Women who chose first-tier NIPT were satisfied with the choice between genome-wide NIPT and targeted NIPT, and most women wanted this broader future screening offer.(19) Follow-up studies in the Netherlands have shown high rates of informed decision-making and perceived freedom to choose regarding fetal aneuploidy screening among the pregnant population, addressing prior concerns about making screening routine and differing societal perspectives on Down syndrome.(20) However, studies from Belgium showed lower levels of informed choice and different views about trisomy, reminding researchers that differences in women's decision-making regarding NIPT and the conditions screened are likely to influenced by counselling aspects and country-specific societal and cultural contexts.(21)

In England, the National Health Services (NHS) now recommends that following a primary higher chance combined screening result (defined as a risk greater than 1 in 150), NIPT should be offered as a second or contingent screening test. (22) This was first recommended in 2015 and eventually implemented in 2021. Evidence for this came from several sources, and included a cost-consequence analysis, and an independent public engagement exercise by the Nuffield Council on Bioethics.(10,23) Offering the new cffDNA test to pregnant women who test positive using the current combined test is proposed to reduce the number of invasive tests, and therefore to reduce the number of miscarriages of unaffected fetuses caused by invasive testing. NIPT is thus offered as an optional second screening test and this rollout is still being evaluated. When this technique is used as a screening test it is still recommended that results that indicate an increased possibility of an anomaly are confirmed with more invasive tests (ie CVS or amniocentesis).(24,25) Early reports from England also show that that NIPT contingent screening is highly acceptable to women with a resulting reduction in invasive procedures performed.(26)

NIPT was shown in a recent metanalyses to have higher sensitivity and specificity for T21, T18, and T13 compared to the traditional combined first and second-trimester screening tests. With test performance reported as greater than 99% detection rate for fetal trisomy 21, 98% detection rate for fetal trisomy 18, and 99% detection rate for fetal trisomy 13 with a combined false-positive rate of 0.13%. (27) The evidence in favour of the extended use of NIPT to screen for conditions other than these trisomies (including genome-wide NIPT) remains a topic of debate with no national or international organisation supporting clinical implementation for these indications.(28)

Before NIPT screening, a first-trimester ultrasound should be performed, as some findings can change management. These findings include an earlier than expected gestational age, confirmation of viability, number of fetuses, presence of a vanishing twin or empty gestational sac, or presence of a fetal anomaly.(29,30)

The International Society for Prenatal Diagnosis (ISPD) and the American College of Medical Genetics and Genomics (ACMG) advise that NIPT could be the first-tier screening test for the general population. NIPT implementation has reduced many unnecessary diagnostic procedures and concomitant fetal loss for those with a high risk of T21.(31,32) In the NHS,

the use of NIPT allows increased ease of testing, improved access and reduced costs. (24,25) Based on their experience of national implementation, the Netherlands health services have argued that offering NIPT as a first-tier test has several advantages over contingent NIPT: no time window for testing, higher sensitivity with fewer false negatives, and more women get a definitive result after a single test.(33)

The NIPS Evidence-Based Guideline Work Group relied on the results from the recent American College of Medical Genetics and Genomics (ACMG) systematic review to form the evidentiary basis of their recent guideline on NIPS screening in a general risk population. As evidence demonstrated improved accuracy of NIPS compared with traditional screening methods for trisomies 21, 18, and 13 in singleton and twin gestations, the ACMG strongly recommended NIPS over traditional screening methods for all pregnant women with singleton and twin gestations for fetal trisomies 21, 18, and 13 and recommended NIPS be offered to all women to screen for fetal sex chromosome aneuploidy.(34)

Although NIPT is considered superior to conventional screening, it is important to note that professional societies still recommend performing NT ultrasound (30). ISUOG recommends in women with a negative NIPT test result, that NT thickness should still be measured and reported as a raw value and centile. The management of increased NT with a normal NIPT test result is currently based on local guidelines.(35)

Dating scans / first trimester anatomy

Routine obstetric ultrasound is an integral part of antenatal care.(36) (37) 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. The Society and College of Radiographers (ScOR) and the British Medicine Ultrasound Society (BMUS) 2019 guidelines for professional practice 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.(38,39)

Dating scans are recommended by the UK NICE Guidelines (37) and multiple international professional bodies throughout high-income countries.(40) These scans should ideally be performed after 10 and before 14 weeks gestation.(40) The importance of dating scans includes the confirmation of viability, the accurate determination of gestational age, the identification of multiple pregnancy and fetal/maternal structural anomalies. These factors are fundamental to determining a woman’s pathway of care and stratifying her risk category for pregnancy.

Ongoing technological advancements have allowed assessment of fetal anatomy in detail in the first trimester.(40) It is important that those undertaking first trimester ultrasound assessment have a checklist of structures that are usually visualised at this time, and are aware of major structural conditions that should be diagnosed or excluded in the first trimester. The conditions most likely to be detected in the first trimester are anencephaly, alobar holoprosencephaly, abdominal wall defects (exomphalos and gastroschisis),

univentricular heart; megacystis and body stalk anomalies, while major conditions involving the majority of cardiac, diaphragmatic, skeletal conditions will likely not be diagnosed with certainty until the second trimester anatomy ultrasound examination.(41) (42) (43)

ISUOG Practice Guidelines on the performance of the first-trimester fetal ultrasound scan, published in 2013, recommend a first trimester scan to confirm viability, establish gestational age accurately, determine the number of fetuses, and, in the presence of a multiple pregnancy, assess chorionicity and amnionicity.(40) The scan also offers an opportunity to detect gross fetal abnormalities and, in health systems that provide first-trimester aneuploidy screening, measure the nuchal translucency thickness (NT). ISUOG guidelines recommend trans-abdominal (TAS) for completion of the first trimester scan.(40) However, it is important to note that transvaginal (TVS) high-frequency probes can increase the detection of anomalies in the entire population, especially in women with a high BMI.(44) (45)

This anatomical assessment scan should optimally be performed between 11 to 13+6 weeks of gestation. Structural anomalies account for the largest proportion of all congenital defects, so it is not surprising that (46) first-trimester ultrasound to detect morphology is becoming the main goal of the previous dating ultrasound examination.(43) An early scan performed at 12–13 weeks' gestation by a competent sonographer can detect about half of the prenatally detectable structural anomalies and 100% of those expected to be seen at this stage. (47) (48)

In a systemic review of all publications on detection rates in first trimester ultrasound, rates of first-trimester fetal anomalies ranged from 32% in low-risk groups to more than 60% in high-risk groups, demonstrating that first-trimester ultrasound has the potential to identify a large proportion of fetuses affected with structural anomalies.(43) The use of a standardised anatomical protocol was also shown to improve the sensitivity of first-trimester ultrasound screening for all anomalies and major anomalies in populations of varying risk.(43) A recent study describing using standardised scans in first-trimester screening for fetal structural anomalies in an unselected cohort of pregnant women. The detection rate of fetal anomalies during the first trimester reached 43.1%. For some malformations, a detection rate of >90% was achieved.(49) Of note, a review of dating ultrasound in an Irish tertiary unit (published in 2022), showed that fetal anomalies were detected in 0.4% of dating scans, (50) significantly less than the largest published systematic review where 1% of first trimester scans detected anomalies, (43) which suggests room for improvement in first trimester ultrasound.

A recent meta-analysis also reported that first-trimester (11-14 weeks) ultrasound examination of the fetal heart allows identification of over half of fetuses affected by major cardiac pathology. These authors concluded that future first-trimester screening programmes should follow structured anatomical assessment protocols to improve detection rates of fetal cardiac pathology.(51)

One advantage of first-trimester scans is that pregnant women prefer to be informed in the first trimester about any anomaly in their fetuses.(52) Additionally, it may decrease the diagnostic time for structural malformations and provides sufficient time for prenatal genetic testing and appropriate specialist consultation. Reports after the introduction of national NIPT in the Netherlands showed that large numbers of fetal anomalies remained undetected until the second trimester in the absence of formal first trimester ultrasound.(53)

An early comprehensive fetal anatomic ultrasound examination at 13–16 weeks' gestation may also 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. A recent study of pregnant women with increased BMI ≥ 35 kg/m2 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.(54,55) A paradigm of first-trimester prenatal care has been proposed by ACOG with a dating ultrasound scan at 7 to 8 weeks followed by NIPT at 10 to 11 weeks; anatomic scanning is then performed at 12 to 13 weeks, optimizing visualisation of fetal defects.(56)

The SOGC's 2019 first trimester ultrasound guideline recommends that basic fetal anatomy should be reviewed whenever obstetric ultrasound is done at 11−14 weeks, while women at increased risk of fetal structural and genetic anomalies can be offered enhanced screening, if performed by ultrasound providers with appropriate imaging expertise.(57) Their subsequent committee opinion document in 2021 recommended that all women should be offered an ultrasound scan at 11−14 weeks gestation, and advised that as approximately 40% to 66% of fetal anomalies can be identified during this examination, routine prenatal sonography at 11−14 weeks gestation provides important information that guides pregnancy management.(58)

Fetal anatomy ultrasound

Examination of fetal wellbeing throughout the pregnancy is an integral part of maternity care throughout the world. In the late seventies, routine fetal ultrasound examination became established. Early randomised controlled trials (RCTs) demonstrated that the management of various pregnancy conditions, 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.(59) (60)

The World Health Organization (WHO) recommends one ultrasound examination before 24 weeks' gestation as part of routine antenatal care.(61) There is considerable variance between countries and international bodies from a one ultrasound examination to a two to three stage approach and with varying detail suggested at each assessment.

On the recommendation of the UK National Screening Committee, in 2010 the National Health Service Fetal Anomaly Screening Programme (FASP) introduced a national protocol for an 18+0–20+6 week gestation fetal anomaly ultrasound scan to screen for the presence of 11 conditions for which the growing (but limited at that time) data suggested a detection rate of at least 50%.(62) This made England the first country worldwide to introduce such a standardised approach to ultrasound screening in pregnancy.(63)

Objectives of the anatomy ultrasound scan

The aim of the fetal anatomy ultrasound examination is to diagnose fetal abnormalities allowing 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.(64) (65) 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 pregnancy and a probable reduction of maternal anxiety.(66,67) (60)

The benefits from timely prenatal diagnosis of fetal anomalies and subsequent management include :-(64,68)

- Allowing timely diagnosis to facilitate multidisciplinary discussion and anticipatory management at delivery
- Allowing delivery in a setting with optimal resources – tertiary centre, neonatal intensive care, access to adjacent paediatric surgical or cardiothoracic services
- Detecting anomalies which require immediate/early intervention following delivery or which may benefit, in a small number of cases, from intrauterine treatment
- Reduction in perinatal morbidity and mortality due to timely diagnosis and optimal care provision after delivery
- Informed decision making with regard to termination of pregnancy, within legislative frameworks

There are additional benefits of routine anatomy ultrasound examination outside of its diagnostic role in antenatal care including: (66,69,70)

- Bonding between mother and fetus
- Health-improvement motivation
- Engaging partners in the antenatal care experience

Information and informed consent

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.(71) They recommend that clear guidance, grounded in principles of person-centred care, is provided to support sonographers in facilitating a discussion about the examination prior to the ultrasound.(71) This is supported by the National Health Service (NHS) Fetal Anomaly Screening Programme (FASP), in the UK, which aims to ensure equal access to uniform and quality assured screening across England.(62) 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.

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.(72) 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.(41)

Gestation of the anatomy ultrasound

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 consensus on what is the optimal time.(72) Ideally the ultrasound examination should be completed in a single visit if possible and 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. Therefore, it is ideally performed in the 20–22-week window as 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.(60)

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 access fetal anatomy.(73) The ISUOG Clinical Standards Committee recommends performance of the mid-trimester ultrasound examination between 18 and 24 weeks.(72) 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.(62) RANZCOG recommends ultrasound assessment for fetal structures between 19-22 weeks to optimise detection rates(41) while the Society of Obstetricians and Gynaecologists of Canada (SOGC) advocate for a slightly earlier gestational age of 18-20 weeks.(74)

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 advances in ultrasound technology and that 30 to 70% of congenital anomalies can be diagnosed prior to 14 weeks.(60) However later ultrasound examinations provide improved anatomical detail and greater sensitivity for anomaly detection.(75) First trimester anatomy results may only be achievable and reproducible by highly skilled operators in specialised centres.(40) Frequently, structural abnormalities diagnosed prior to 14 weeks will require a second trimester ultrasound examination to confirm findings.

Detection rates of anomalies

The use of a standardised anatomical protocol improves the sensitivity of the anatomy ultrasound examination.(60) Standards for the basic examination have been adapted worldwide, although requirements regarding images and views vary considerably from 7 (FASP, UK(76)) to 24 views (Canada(74)). The NHS fetal anomaly screening programme (FASP) quotes overall detection rates for ultrasound screening are 83% for anomalies incompatible with life, 50% for serious anomalies where survival is possible and 16% for those requiring immediate care after birth. (62) (76)

Many studies have examined detection rates for fetal abnormalities at the time of second trimester ultrasound examinations and there is a wide variation in reported rates.(60) A 2008 NICE systematic review of 17 studies reported an overall sensitivity of 24% for detection of fetal anomalies prior to 24 weeks. However, this ranged between 13.5% and 87.5%. Of note at that stage, there was no difference in detection rates at different gestational ages.(37)

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.(77)

The NHS fetal anomaly screening programme (FASP) has recently published results of a retrospective audit of 12 694 diagnoses across a 3-year national cohort. National guidance includes expected condition-specific detection rates for 14 conditions, ranging from 50 to 98%, based on an updated review of 20 years of published literature. Detection rates of the anatomy scan met FASP expected detection rates for anencephaly and congenital diaphragmatic hernia, and exceeded them for bilateral renal agenesis, cleft lip ± palate, lethal skeletal dysplasia, spina bifida, and all cardiac anomalies. Detection rates did not meet FASP expected detection rates for Edwards syndrome, exomphalos, gastroschisis and Patau syndrome, but the majority (78.9%) of detections of these four conditions occurred before the anatomy scan.(63)

Communicating about an abnormal anatomy scan

Fetal ultrasound scans are performed by a variety of healthcare 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.(39) (71) (78) 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.(79) (73)

Women do not attend an antenatal appointment with a neutral mindset.(80) (81) Parents expect that everything will be fine with their baby and are often unprepared for scan results when an anomaly is detected, thus compounding shock.(82) The delivery of "bad news" holds the potential for severe perinatal stress and to shatter expectations of a routine pregnancy.(83–85)

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.(83) 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 them 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.(83)

These findings support an Irish study that highlighted that women said rapid access for a Fetal Medicine opinion, (preferably within 24 hours of the initial ultrasound examination), was desirable.(82) 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. In the UK, the FASP standard is to see a fetal medicine consultant/specialist within 5 working days.(76)

Sonographers /clinicians undertaking fetal anatomy ultrasound should 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)(78) and also the Australian guidelines on parent centered communication in obstetrics.(86) (60) Both guidelines provide a pragmatic framework for ultrasound practices, professional bodies and educational institutions when delivering news of unexpected or adverse outcomes. In addition, they aim to support sonographers and educators by outlining specific phrases and parent-centred communication strategies they can apply, as research indicates this level of specificity is important to expectant parents.(86) Specific recommendations from the ASCKS framework included that: honest and clear communication should be prioritised, even with uncertain findings; technical terms should be used, but these should be written down together with their lay interpretations; and at the initial news disclosure, communication should focus on information provision.(87)

Fetal medicine and TOPFA

Fetal medicine

The discipline of maternal-fetal medicine includes preconception care, specialised prenatal and intrapartum care, obstetric and medical complications of pregnancy, diagnosis and management of fetal anomalies, fetal complications, and fetal testing.(88) Fetal medicine as a subspecialty implies caring for pregnancies at high risk for fetal complications. This includes diagnosis, counselling and management of pregnancies complicated by fetal anomalies, disorders of fetal growth, and pregnancies affected by fetal infection or maternal antibodies. It also includes the screening and management of pregnancies at risk for fetal disorders due to a background history, such as prior pregnancy complications, or known or suspected genetic predispositions.(88)

Several professional organisations provide documents that define the various roles that the maternal-fetal medicine (MFM) subspecialist can fulfil within different health care systems

through consultation, management, and transfer of care, as well as education, research, and leadership.(88,89)

Fetal medicine centres are limited in number and generally act as tertiary level referral centres for a defined population base. Specialising a limited number of centres allows for a sufficiently concentrated throughput of complex cases to maintain the expertise of the fetal medicine team. As an example, there are less than 20 centres providing specialised fetal medicine services in England.(90) The North American Fetal Therapy Network (NAFT-Net) network includes 47 member centres.(91,92) The most complex branch of fetal medicine involves fetal therapy; typically, due to the rarity of cases, these services are provided by an even smaller number of centres in high-income countries. (91–93)

Fetal medicine centre infrastructure and staffing: the multidisciplinary team.

A fetal medicine service involves prenatal screening and diagnosis, fetal therapy and counselling and support for parents. Pre and post pregnancy counselling for future risk and pregnancy planning is also a core service. The provision of the service requires appropriate resourcing with highly trained and skilled fetal medicine staff, a defined partnership with a multidisciplinary team, and relationships or interdependencies with several other specialised services.

The centre should be staffed by subspecialist consultants. These are consultants in Obstetrics and Gynaecology who have completed subspecialty training in maternal and fetal medicine.(88) Accredited training programmes are provided by several international bodies, and they each detail their curricula, training requirements and assessments. Each programme consists of a minimum of 2 years additional training in maternal and fetal medicine. These include the Royal College of Obstetricians and Gynaecologists (RCOG) in the UK(89), the European Board and College of Obstetricians and Gynaecologists (EBCOG) (94), the Society for Maternal and Fetal Medicine (SMFM) in the U.S. (95,96), and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG).(97)

It is logical that there should be a minimum of two full-time consultants working as subspecialists in any Fetal Medicine Centre to ensure no break in service or delay in acceptance of referrals occurs. Indeed this is listed as a requirement by the RCOG for training accreditation.(89) A number of complex cases will often be reviewed by more than one fetal medicine consultant as well as the wider multidisciplinary team (MDT).

The fetal medicine service also requires specialised and dedicated midwifery support. These specialised fetal medicine midwives work in partnership with the fetal medicine consultants to co-ordinate care for women/parents, and often will have additional qualifications in obstetric ultrasound. Specialised fetal medicine midwives are a key part of the multidisciplinary team involved in the patient pathway. They are often the direct contact provided to women with complex pregnancies where the fetus has a confirmed or suspected disorder. They are involved in pre and post assessment counselling, assist at fetal procedures, and are key co-ordinators of the pathway, particularly where liaison with bereavement and loss services or termination of pregnancy for fetal anomaly options are appropriate.

Fetal Medicine Centres must have a dedicated prenatal multidisciplinary team with regular MDT meetings and ready access to prenatal multidisciplinary counselling. Each Fetal Medicine team works closely with obstetric and genetic services, as well as neonatal and paediatric services.(88,91) The multidisciplinary team should meet on a regular basis to discuss the current caseload of the Fetal Medicine Centre, and to allow for clear communication and co-ordination of high-risk cases.

There should be a robust relationship with the referring base, including the obstetric team, midwives, sonographers, general practitioners, and public health teams to ensure effective two-way communications and continuity of care. The fetal medicine team will focus on determining and managing the risk to the fetus; ongoing obstetric care and support for delivery planning is often provided for by the general obstetric team who need to be kept regularly informed of the clinical scenario.

Neonatal services should be involved, ideally from an early stage to allow for planning of immediate Neonatal care, which may often involve co-ordination with general and specialised paediatric services. In several cases antenatal consultations for parents with both Neonatology and specialised Paediatric services are of benefit, both for information and counselling, and for optimal co-ordination of post-delivery care.

Clinical geneticists are an increasingly integral part of the fetal medicine MDT. They provide pre and post pregnancy counselling in cases of confirmed or suspected hereditary genetic disorders and develop future pregnancy testing pathways. Clinical Geneticists have training and expertise in the recognition and diagnosis of rare fetal malformations, and work closely with fetal medicine specialists to make a diagnosis when these are identified. They are also involved in the pathway for management of fetal anomalies and perinatal palliative care.

In addition to the fetal medicine MDT above, a Fetal Medicine Centre requires defined links to other specialised and allied health services. These whole system relationships and interdependencies include but are not limited to:

- Medical genetics laboratory services: Perinatal genetics services will require a robust and reliable laboratory for testing from pre-pregnancy carrier screening to antenatal screening, and diagnostic testing for aneuploidy, single gene disorders, and whole exome sequencing.
- Paediatric Cardiology: A Fetal Medicine Centre requires a regular paediatric cardiology service owing to the frequency and complexity of congenital heart disease. This service should have established links and pathways to the paediatric MDT including paediatric cardiothoracic surgeons, and critical and paediatric intensive care specialised nurses and doctors.
- Paediatric Surgery: The fetal medicine MDT should facilitate and develop robust referral pathways for women who require onward referral for other services, such as paediatric surgery (including neurosurgery), paediatric endocrinology and paediatric urology/nephrology services.
- Haematology: Input from specialised haematology expertise is required for the management of fetuses at risk of complications related to maternal red cell or platelet antibodies.

- Microbiology: Input from specialised microbiology expertise is required for the management of fetuses at risk of complications related to certain maternal infections.
- Perinatal pathology: Pathologists with specific subspecialty training in fetal and perinatal pathology work closely with the fetal medicine and clinical genetics team in the investigation and diagnosis of complex fetal anomalies and play an important role in determination of future risk.
- The Fetal Medicine service works closely with several other professionals who form part of the wider MDT; these include Medical Social workers, Bereavement and Loss teams, Palliative care specialists, and Perinatal Mental Health teams.

Fetal Medicine Centre referral pathways

The objective of a Fetal Medicine service is to provide a safe and effective pathway for women and babies either with, or at risk of, a fetal anomaly or condition. All associated assessments, including structured fetal ultrasound, genetic assessment and counselling, and all forms of invasive prenatal diagnosis testing (chorionic villus sampling, amniocentesis, and fetal blood sampling) should be available in a timely manner. Increasingly the ability to improve the outcome of some fetal disorders because of advances in prenatal diagnosis and fetal therapy has developed. The more specialised of these fetal therapies will only be available in a smaller number of centres due to the relative rarity of cases and need for a critical workload to maintain skill. Increasingly these centres are referred to as Fetal Therapy Centres.(91–93)

General Fetal Medicine services include:(89,94,95,97)

- Assessment of the fetus with a suspected anomaly:

Such referrals arise following a routine ultrasound which suspects a fetal anomaly. In most of these cases the finding will be unexpected and be a source of great distress to parents. Timely review of such cases in the Fetal Medicine Centre is appropriate, and international guidance sets out expected interval standards of 1-3 days for major anomalies. (72,76) Assessment allows for specialised ultrasound and detailed counselling, to include an explanation of the findings and diagnosis/ differential diagnosis. Further testing should be discussed and offered at this visit as appropriate, including cffDNA (12,35), invasive prenatal testing with amniocentesis or chorionic villus sampling (98), parental screening or further imaging such as fetal MRI.

- Assessment of the fetus at risk:

Risk of fetal anomaly may arise due to a prior history in an affected pregnancy or family member or a known genetic hereditary disease. Referral sources as a result may be from primary care, obstetric care, medical genetics, or paediatric sources. In many cases the woman will have been previously linked with the fetal medicine team and it deemed appropriate to contact directly and self – refer in future pregnancy. Timing of review of these referrals will often depend in the nature of the risk and the appropriate timing of any testing which has been deemed appropriate in pre and post pregnancy counselling.

- Prenatal Screening and Diagnosis:

Prenatal screening for chromosomal abnormalities assesses the woman's risk of carrying a fetus with a chromosomal abnormality and are discussed earlier. Confirmation or otherwise of a "high-risk" result warrants referral to a Fetal Medicine Centre for consultation and invasive testing, generally with chorionic villous sampling (CVS) or amniocentesis.(31) Pre and post-test counselling is an integral part of this pathway and will often involve perinatal genetics input. CVS testing carried out to obtain placental villi for analysis, is usually performed between 11+0 and 13+6 weeks' gestation. Amniocentesis, to obtain amniotic fluid for analysis, is generally performed after 15+0 weeks' gestation. Pre-test counselling should include informed consent, outlining the procedure related miscarriage risk. Women/parents should also be aware that the results of a CVS can be affected by confined placental mosaicism in 1-2% of cases. It is strongly recommended that if there are no structural abnormalities on scan, and the qfPCR results following a CVS suggest aneuploidy, that a full karyotype is awaited before pregnancy decisions in relation to termination of pregnancy are made.(31,98,99)

- Assessment of the Small Fetus:

Criteria for a fetal growth restriction diagnosis include an estimated fetal weight (EFW) <10th percentile for gestational age on ultrasound based on accurate dating. Consideration for referral for a fetal medicine opinion is based on local and national guidance and includes the following situations: additional findings to small fetal size, such as amniotic fluid abnormalities soft markers or structural anomalies, very early and/or severe fetal growth restriction, and where delivery <32 weeks is anticipated due to Doppler abnormalities, and/or where there is uncertainty regarding the optimal surveillance and timing of delivery.(100)

- Management of fetuses at risk due to maternal antibodies

Cases of known or newly diagnosed maternal red cell or platelet antibodies confers a risk of fetal anaemia or thrombocytopenia. In the most severe of such cases fetal therapy such as intrauterine transfusion may be necessary. Criteria for referral and timing of review in these cases depends on the underlying antibody type and quantitation, as well the prior history. Involvement of haematology expertise and well as close liaison with local laboratory and blood transfusion services is required in many of these cases.

- Assessment and management of complicated twin, triplet and higher order multiple pregnancies. The following scenarios require prompt referral to a Fetal Medicine Centre:
  - All invasive diagnostic tests in twins or higher order multiple pregnancies
  - Surveillance and management of triplet and higher order multiple pregnancies
  - Dichorionic twins with discordant fetal growth or suspected fetal anomaly
  - All monochorionic twins from 14-16 weeks' gestation
  - Monochorionic twins where there has been single fetal death.

Specialised fetal medicine services include those which may be offered in a smaller number of Fetal Medicine Centres, or Fetal Therapy centres.(92,93)

These include:

- Intrauterine transfusion for fetal anaemia
- Intravenous immunoglobulin therapy and/or transfusion therapy for fetal thrombocytopaenia (Fetal alloimmune thrombocytopaenia)

- Fetoscopic laser ablation for twin-to-twin transfusion syndrome in monochorionic twins/triplets(101–103)
- Fetal shunt procedures (thoraco-amniotic shunts, vesico-amniotic shunt, cyst drainage)
- Intrauterine myelomeningocele repair for fetal spina bifida(104)
- Fetoscopic tracheal occlusion (FETO) and FETO reversal(105)
- Invasive procedures in relating to termination of pregnancy including multifetal pregnancy reduction, feticide, radiofrequency ablation and cord occlusion.
- Other fetal therapies, e.g. laser therapy for fetal tumours, balloon valvuloplasty.

To perform any fetal intervention, provide all the associated care needs, address any potential risks and assess outcomes, a fetal therapy centre requires a dedicated operational infrastructure, which encourages and facilitates the close collaboration of healthcare professionals from maternal, fetal, nursing, anaesthetic, and paediatric specialties. This is clearly set out in detail in some recent publications, which (91) include proposed fetal therapy levels for centres according to case complexity and resource settings.

Fetal Medicine Centre training and continuous professional development

The management of fetal disorders is increasingly complex and requires the input and oversight of training bodies and individuals with specialised training in maternal and fetal physiology, as well as genetics, embryology, fetal and maternal screening and diagnoses.(91)

The European Board and College of Obstetricians and Gynaecologists endorses that Maternal-Fetal medicine should be recognised as a subspecialty in Europe. (106)The purpose of the MFM subspecialty curriculum is to produce doctors with the generic professional and subspecialty-specific capabilities needed to advise and treat people presenting with the full range of maternal and fetal medical conditions in tertiary referral centres. MFM subspecialists should have the skills to organise and supervise services at a local and regional level, contribute to academic maternal and fetal medicine, lead on the translation of new research findings into clinical practice, be providers of support and guidance to non-subspecialist colleagues, and be active in teaching and quality management.(89)

No training body exists in Ireland at present for oversight and delivery of an MFM subspecialty training programme. MFM consultants in current clinical practice in Ireland have completed their training through recognised international programmes (in the US, UK or Australia). Fetal Medicine Centres in Ireland offering MFM training at present (2 or 3 posts) do so through the RCOG in London.(89) In every country, the estimated number of training posts should reflect the national need for subspecialists in the area, the complexity of the case load available for training as well as the facilities and finances available for training. As such the number of posts in Ireland will always be limited, and programmes are likely to continue to incorporate training in another international Fetal Medicine Centre.(106)

MFM subspecialty training programmes have clearly defined entry criteria, curricula, and assessments.(89,94) (95,97) Assessments apply not only to the trainee, but also to the Fetal Medicine Centre itself. For the centre this demands a clear record of caseload and continuous professional development.

These training programmes are clearly detailed; a summary overview is provided below.

Entry criteria involve either a recognised specialist qualification in Obstetrics and Gynaecology, and/or a minimum number of years (>5) spent in an approved training programme in the specialty. The duration of subspecialty training should include a minimum of two years; additional approved research time of at least 12 months is generally in addition to this. This research requirement may be exempted in cases of completion of approved research, such as a higher degree, specific to MFM, in advance of commencement of training.

Training should be structured to cover all aspects of the curriculum, with clearly defined targets and completion of a validated logbook of experience.
The curriculum should include the clinical and research aspects of:

- Basic Science relevant to the specialty
- Ultrasound and other imaging modalities
- Genetics
- Neonatology
- Maternal and fetal surveillance in complex pregnancies
- Counselling

The RCOG lists requirements in terms of caseload to retain accreditation as an MFM training centre.(89) Fetal medicine requirements include a minimum of six Fetal Medicine sessions per week and a minimum of 3 Fetal Medicine consultants accepting referrals with ≥2 sessions per week. The centre must have ≥150 referrals for major fetal anomaly per annum coming from at least 2 other referral units.

In terms of fetal invasive procedures, a minimum of 100 CVS procedures per annum with a minimum of 30 more complex fetal procedures (e.g. multifetal reduction, feticide, shunt insertions, fetal transfusions, laser ablation) is required. Previous trainees in the post should have completed a minimum of 30 CVS and 50 amniocentesis procedures. They also require that the centre must have an annual delivery rate of >5000 per annum.(89) Similarly Fetal Medicine Centres accredited for MFM training undergo regular assessment to ensure that both caseload and supervision continue to fulfil training requirements to maintain accreditation.(89)

EBCOG recommend that in all European countries approval of training and trainers should be the responsibility or regional authority which has the power to withdraw recognition, if necessary. They recommend that approval of a training centre should be based on annual statistics, internal audit, and organised teaching sessions. They specify the availability of the multidisciplinary team as outlined above, specifically to include clinical genetics, neonatal intensive care, adult intensive care and perinatal pathology.(106)

Similarly, the RCOG specifies that the centre must have multidisciplinary MFM meetings with evidence of regular MFM consultant attendance. There must be evidence of ready access to prenatal multidisciplinary counselling and robust audit/MDT meetings. They also recommend that there is ready access within a <50-mile radius to all the following regional services:

Paediatric surgery, Fetal echocardiography/paediatric cardiology, Fetal MRI, all cytogenetics, molecular genetics and clinical genetics sessions.(89)

Not all Fetal Medicine Centres will have the required throughout of the most complex cases to allow for accreditation for MFM training. However, all Fetal Medicine Centres require a clear governance pathway to ensure appropriate continuous professional development goals are set and achieved.(91) (91) These should include clear indications and referral pathways to larger accredited Fetal Medicine or fetal therapy centres as required. As an evolving specialty a commitment to encouraging all in the Fetal Medicine MDT to attend and collaborate in local and international meetings in advances in the specialty should be encouraged.

Care pathways around TOPFA

Referral to fetal medicine services

The suspicion of a fetal anomaly may be suggested by a family history or may be detected by chance when a routine scan is performed for another reason, for example, because of concerns about fetal growth or clinical suspicion of polyhydramnios. However most fetal anomalies are detected as a result of screening for aneuploidy and / or routine ultrasound screening for major structural anomalies. (63,77,107)

Where there are findings on ultrasound suggesting a fetal anomaly, the woman should be referred as soon as possible to a person or centre with expertise in fetal medicine, where there is knowledge about the prognosis of the anomaly and the options available. Units without a fetal medicine specialist should refer women to the nearest unit with fetal medicine expertise, although some women may first want to discuss the findings further with their local obstetrician.(76,84,108)

Prompt referral to a fetal medicine specialist ideally within 24 to 72 hours is the standard of care where a major fetal anomaly is suspected, followed by provision of written information, resources, and support. While awaiting referral the parents should be given direct contact details of a support person in the referring hospital.(72,76) The NHS FASP programme includes as standards: the number of women referred locally and seen in ≤ 3 working days of the screening scan (within the same hospital) and the number of women referred externally to a tertiary centre and seen in ≤ 5 working days of the screening scan.(76)

The shock of any prenatal diagnosis of fetal anomaly makes it hard for women/parents to take in the information that they need to assimilate to make potentially life-changing decisions. It is essential, therefore, when a diagnosis is made, to have well-planned and well-coordinated care pathways in place in all units, as well as a clearly defined care pathway to ensure that appropriate information and support are available.(82,84,87)

Care pathways around TOPFA

Optimal care for women after a diagnosis of fetal anomaly relies on a multidisciplinary approach. All involved in the process should be clear on their role and make sure that the women and her partner are carefully guided along a planned care pathway by fully briefed and supportive staff. This is particularly important when care is divided between local and tertiary units and clear lines of communication must always be in place. This communication must include primary care as it is essential that the woman's general practitioner is informed of the anomaly diagnosis and that/if the pregnancy is not continuing so that support can be offered to the woman.(108,109)

Effective support after diagnosis of a major, possibly fatal, fetal anomaly, should ideally involve continuity of care with healthcare professionals trained in pregnancy loss and sensitive communication. Parents should be given adequate information, both oral and written, and directed to online resources and also to counselling, if appropriate, then or later.(110) Care should involve the multidisciplinary team, beginning in the antenatal period from the first suggestion of a fetal anomaly and continuing into the postnatal period, where appropriate and as required. (111) All staff involved in the care of a woman or couple facing a possible termination of pregnancy must adopt a nondirective, non-judgemental and supportive approach. The use of appropriate literature and the availability of help from non-directive external agencies can be helpful.(108,109,112)

Decision-making

From the literature it is clear that differences in attitudes and counselling among fetal medicine specialists and teams may relate to divergent personal values, professional interests, clinical experiences, interpretation of the "facts" of the clinical situation, approaches to dealing with medical uncertainty, and different experiences with evolving tools for prenatal diagnosis and therapy.(113) Prenatal decisions and outcomes may sometimes reflect provider attitudes, and it is important that this is evaluated over time. (113)

Research has examined the decision-making experiences around TOPFA of fetal medicine professionals working within various legal frameworks. When asked, UK fetal medicine specialists reported that working with a list of conditions for which post-24-week termination was legal, would be an overwhelming disadvantage as individual diagnoses need individual decisions.(114) In the absence of a definitive list, they felt that other specialists (such as paediatricians, cardiologists) were more likely to have input to decision-making, which was seen as helpful to both parents and staff working in fetal medicine units. Guidance was instead seen as welcome, but there was acknowledgement of the need for professionals to show similar decision making to their peers. Practice regarding which anomalies met the legal criteria appeared to be governed largely by consensus between colleagues within their own and other units and in discussion with other specialists.(114)

The role of physicians as gatekeepers has been explored in detail in SMFM's recent Special Statement: A critical examination of abortion terminology as it relates to access and quality

of care.(115) This states that 'although the role of medical professionals as legal and institutional gatekeepers to abortion access is largely undesired and unsought, caregivers, in particular MFM subspecialists, often find themselves as the formal or informal gatekeepers to abortion care.' The SMFM state that 'qualified healthcare providers should be free to discuss a wide range of prognoses when they exist and to support patients in making individualised decisions that reflect their own risk tolerance and circumstances.'(115)

> "Legal, institutional, and insurance policies are often written in concrete terms that demand diagnostic or prognostic certainty at odds with medicine, which is appropriately accustomed to probabilities and uncertainty. Such restrictions fail to account for the range of prognoses that accompany many fetal diagnoses and maternal medical conditions, and the complexities of mental health, psychosocial circumstances, and disparities in access to care. This range of prognoses can only be fully contextualised within the unique life circumstances of the individual patient by that person themselves, in consultation with trusted family, community, and caregivers. Enshrining physicians as gatekeepers within the law infantilizes patients and reduces their autonomy."(115)

Research from Ireland contextualises this further. Fetal medicine specialists in 2020 feared getting a fetal diagnosis incorrect because of media scrutiny and criminal liability associated with the TOPFA legislation. Challenges with the ambiguous and 'restrictive' legislation were identified that 'ostracised' severe fetal anomalies. Teamwork was essential to facilitate opportunities for learning and peer support; however, conflict with colleagues was experienced regarding the diagnosis of fatal fetal anomalies, the provision of feticide and palliative care to infants born alive following TOPFA.(116)

Feticide

The RCOG recommends feticide for termination of pregnancy over 21 weeks and 6 days of gestation, except in the case of lethal fetal anomaly, and says that feticide should always be performed by an appropriately trained practitioner using aseptic conditions and with continuous ultrasound. The guidance clarifies that feticide should be routinely offered after 21 weeks and 6 days, other than when the fetal anomaly is not compatible with life, when abortion without feticide may be preferred. (108,117)

The feticide method recommended by the RCOG is intracardiac potassium chloride (KCl) injection into a cardiac ventricle (108,118,119) although alternative approaches and techniques are noted by other professional bodies. Intracardiac KCl is mostly regarded as a means of causing rapid death which does not require analgesia. (108) This method requires more skill than other methods e.g. intra-amniotic injection of digoxin and while the latter may be slightly less effective in inducing fetal demise, its use is said to be an option for services that lack personnel with sufficient skill in administering intracardiac injections. The RCOG recommends that Clinicians performing feticide by methods other than those recommended must be aware of the possible failure of the technique.(108)

A recent review of feticide before TOP in England and Wales from 2012-2020 showed that intracardiac potassium chloride was the method used in 67% of the 9310 procedures recorded (0.5% of all abortions) and that most took place at 23 weeks' gestation. (British Maternal and Fetal Medicine Society; unpublished data, 2022).

A review of methods and indications for late pregnancy termination and feticide in European countries presented at the RCOG World Congress in 2021 reported that feticide was performed in 13 countries (Austria, Czech Republic, Denmark, Estonia, France, Greece, Latvia, the Netherlands, Portugal, Slovenia, Switzerland, Turkey and the United Kingdom). Like the UK, most TOP procedures after 22 weeks in France are associated with feticide, although umbilical cord injection of xylocaine is the more common method from a 2019 national survey (120). Indications for feticide included pregnancy termination after 21+6 weeks of gestation, psychosocial reasons, and women's request. The most used method for feticide was transabdominal intracardiac administration of potassium chloride. In the 2019 French survey, 15 of 39 centres reported that feticide was not performed in all TOPFA cases, because of a fetal anomaly associated with a high probability of rapid neonatal death (13 centres), pregnant woman's refusal (11 centres), and technical impossibility of performing feticide (one centre).(120)

In a 2010 EUROCAT report on TOPFA after 24 weeks, twelve countries reported cases: no gestational limit for severe anomalies (Austria, Belgium, England and Wales, France, Germany); no limit if lethal (Netherlands, Norway, Portugal, Switzerland, Denmark); upper limit [Italy (24 weeks/fetal viability), Ukraine (28 weeks)]. The rate of TOPFA with a gestation of 24 weeks or more varied considerably between countries, from less than 0.1 per 1000 births in the Netherlands, Denmark and Norway, to 2.65 per 1000 in France, with all countries other than France having rates under 0.6 per 1000.(121)

In a UK-based qualitative study with parents and healthcare professionals, feticide was perceived as a legitimate, well-established procedure by both healthcare professionals and parents who had been counselled for feticide. This legitimacy seemed partly due to careful management of consent and decision making. Parents had mixed views; feticide was perceived as both a necessary intervention to bring suffering to an end and as an excessive ordeal for the dying baby to experience. Feticide and termination of pregnancy (TOP) for fetal anomaly were not seen as exclusively medical events, and the impact of social factors was acknowledged. For both parents and health professionals, the medicolegal framing of TOP for fetal anomaly was important in how feticide was framed as legitimate.(122)

In much of the literature, fetal medicine specialists report conducting feticide as difficult but necessary. Providing feticides is deemed as potentially stigmatising. Optimal conditions include involvement in the process from the initial decision-making and team support, and training and guidance are needed to ensure both staff wellbeing and quality of TOP care.(122,123) There is also evidence that many fetal medicine specialists fail to discuss the possibility of live birth after TOP, which is problematic especially in countries where feticide is not commonly practised.(118)

It has been recommended by specialist societies that all units performing feticide develop their own local written guidance with documented procedures - noting, for example, the time

at which the needle is inserted, the drugs employed, and dose administered, and the times when a needle is withdrawn, and asystole confirmed and reconfirmed. (British Maternal and Fetal Medicine Society, letter to membership, 2020). (108) When feticide is discussed, it is very important that the woman is told what the procedure involves, where it will be performed and what she may feel during and after the procedure. This should be sensitively explained using appropriate terminology. The woman also needs to know when and where her labour will be induced after the feticide procedure.(108,124) Some parents have been reported to be relieved knowing that their fetus will not suffer during induced labour or be born alive, although in other accounts parents described the procedure as particularly distressing.(122,123,125)

Overall, it is important that women seeking a termination for fetal anomaly receive accurate, realistic and accessible information about the termination methods available to them, what each procedure involves, what to expect before and after procedures and the potential risks and complications of each procedure. This information should include the relevant information about the expected length of each procedure, and how long a woman will need to stay in hospital.(124)

Medical care

Regardless of the nature of the fetal anomaly diagnosed, it is necessary to ensure that the woman's needs as an expectant mother are not overlooked. Antenatal care should be arranged so that the woman does not have to wait with others where pregnancies are straightforward. She should also be offered one-to-one antenatal sessions tailored to her specific needs. Wherever the termination is to take place, the woman should be given a private room with facilities for her partner to stay.(111,124)

Pre-termination discussions will include how and where the procedure will be managed, the options regarding pain relief and whether the woman might want to see the baby and have mementos. The prospect of labouring will be difficult for many and discussions about the procedure will require sensitive handling by experienced staff. The woman will also need information about the postnatal period, including physical implications for her and the possibility of a post mortem examination being performed.(126) (127) She will need to be made aware of information from a post mortem examination that may be relevant for a subsequent pregnancy. These discussions are likely to be distressing for the woman and her partner so they should be handled by a suitably skilled and trained member of staff.(128)

Well-organised follow-up care is essential after a termination for fetal anomaly. The post-termination follow-up appointment needs careful management, as many women find it difficult to return to the hospital. At the follow-up appointment with the obstetrician the autopsy findings will be discussed, and the risk of recurrence clarified. It may be necessary to obtain genetic advice. Ideally, an appointment to discuss post mortem results needs to be arranged as soon as possible and any unavoidable delays should be explained to women and their partners and the stress this causes acknowledged. (108,111,124,129,130)

Reports and guidelines acknowledge that many women will be very anxious about this appointment because of the implications it may have for subsequent pregnancies. The drawing up of a provisional plan for prenatal diagnosis in a subsequent pregnancy should be envisaged. Subsequent pregnancy also requires sensitive management, with a care plan agreed as early in the pregnancy as possible.(111,124,131)

Neonatology

Prenatal counselling – Neonatology and Fetal Medicine

The input of many members of the MDT may be required to address the needs of parents when a potential fatal fetal anomaly or life limiting condition is diagnosed. It is important that parents are provided with detailed and robust information in an open and non-directive way.(82,108,112). This should be provided by multidisciplinary teams (MDTs) that may include Fetal Medicine Specialists, Neonatologists, Specialist Midwives, Counsellors, Bereavement Team, with input from other medical specialists as required.

Any list of potentially fatal anomalies is long and cannot be complete. The outcome for some conditions (e.g. anencephaly, trisomy 18, Potter's sequence) is more predictable than others. For conditions with very predictable outcomes, counselling by an extensive MDT is not necessary and consultation with the Fetal Medicine Specialist and team is sufficient. However, counselling by a Neonatologist should be available to all parents; and there may be benefit in arranging joint consultations for parents with Fetal Medicine Specialists, Neonatologists and other specialists as required.

Studies show that neonatal and obstetric specialists who provide prenatal counselling to women in the setting of congenital fetal conditions report contrasting perceptions of their professional obligations toward pregnant women and fetuses and further, that their divergent ethical sensitivities regarding pregnancy termination, pregnant women and fetuses, may influence clinical care.(113,132) Counselling following prenatal diagnosis should be non-directive, but research shows variability in advice and opinions offered.(113,133) It is recognised as important that clinical roles, attitudes and personal convictions do not mean that providers' rather than patients' preferences determine access to services such as pregnancy termination or prenatal neonatal/paediatric specialist consultation.(132)

Fetal-neonatal MDT meeting

Morbidity and mortality (M&M) meetings are regarded as the cornerstone of hospital governance process, although there is little high quality evidence in the medical literature that they are effective in improving patient outcomes, even with the best standardised approaches.(134) The aim of most types of MDT meetings is to improve patient safety, improve quality of care, and act as a learning resource. (135,136)

Within healthcare, teams have become an integral feature of care provision with the aim of valuing the skills and knowledge of each discipline within the MDT, to achieve holistic patient-centered care.(137) Care decisions should therefore be based on staff experience and knowledge rather than established role hierarchies, but it is acknowledged in the literature that traditional norms of organisations mean that some voices within MDTs are more valued and have more influence than others. Gaining an understanding of MDT power dynamics is recommended to support delivery of collaborative and safe care.(137)

A dedicated MDT Meeting is a component of providing care that meets the individual needs of the parents after diagnosis of a fetal anomaly. It is usually the responsibility of the Lead Obstetrician/ Fetal Medicine specialist to coordinate the multidisciplinary approach in pregnancies complicated by fetal anomaly.(88) The Neonatologist may help to refine the prognosis and/or seek the opinion of other specialists. If parents request to terminate the pregnancy, this should be considered, and respected, in a non-judgemental way. It is reasonable for the relevant subspecialist to sign relevant certification confirming the parents decision. In cases where parents do not wish to terminate the pregnancy, the Neonatologist can advise regarding planning and provision of postnatal care.(138)

Perinatal palliative care

Perinatal palliative care (PPC) is defined as the planning and provision of supportive care during life and end-of-life care for a fetus or newborn infant.(138,139) It is relevant, and can be considered, when there is an antenatal or postnatal diagnosis of a condition which is not compatible with long term survival. It is an intrinsic component of the care to be provided to a couple who opt to continue with their pregnancy when such a diagnosis is made antenatally and parts of this approach (138) can be considered for parents who opt for TOP, if they wish.(111,140,141) PPC should be planned multidisciplinary input involving the Fetal Medicine specialists, Neonatologists, Midwives, bereavement team and palliative care specialists, as required. Palliative care that is initiated in the antenatal period allows the family to prepare and feel supported for the birth and eventual death of an infant with a major fetal anomaly.(111,141) Non-resuscitation, or limitations to resuscitation, should be discussed and with the neonatal team and updated as required.(139,140,142,143)

Care for the fetus born showing signs of life

When undertaking a termination of pregnancy, the intention is that the fetus should not survive and that the process of abortion should achieve this. Death may occur before delivery, either by the procedure undertaken by an obstetrician (feticide) or as a consequence of a compromised fetus being unable to tolerate induced labour. Death may also occur after birth either because of the severity of the anomaly for which termination was performed or because of extreme prematurity (or both).(108)

In any country, like the Republic of Ireland, where there is no statutory upper limit of gestation for termination of pregnancy for fetal anomaly, it is inevitable that a fetus may be born who shows signs of life unless there is rigid adherence to performing feticide prior to the procedure or providing care using a surgical option, namely dilatation and evacuation (D&E). Live birth becomes increasingly common after 22 weeks of gestation and, when a decision has been reached to terminate the pregnancy for a fetal anomaly after 21+6 weeks, clinical guidance says that feticide should be routinely offered. Feticide is available in Ireland, and it is recommended that it should be used for terminations over 21+6 weeks gestation, similar to international guidelines.(108,117,144) The RCOG Guideline states that the only exception to this is when the fetal anomaly itself is so severe as to make early neonatal death inevitable

irrespective of the gestation at delivery.(108) More information on feticide is set out in an earlier section of the report.

Notwithstanding all of that, feticide is not mandatory and can only be performed with the agreement of the couple. Where the fetal anomaly is not compatible with survival, termination of pregnancy without prior feticide may also be preferred by some women. In such cases, the delivery management should be discussed and planned with the parents and all healthcare professionals involved with a written care plan agreed before the termination takes place.(108) It is inevitable that there will be instances when a fetus is born showing signs of life, albeit with major fetal anomaly, and at a preterm period of gestation. A fetus born alive with anomalies incompatible with life should be managed to maintain comfort and dignity during terminal care.(108) It is important that compassionate comfort care is provided to such an infant on the uses of medication, specific symptoms, and their management. (78,92). There is a duty of care for both mother and baby. The baby is deserving of the highest level of compassionate and professional care including perinatal palliative care. Additionally, the approach to this care requires sensitivity and compassion for parents and families.(111,143)

The Nuffield Council on Bioethics recognised that a minority of pregnant women do not wish to have feticide, whatever the diagnosis. In their 2006 report entitled; “Critical care decisions in fetal and neonatal medicine :ethical issues”, they recommended that there should be greater uniformity of practice and interpretation of the law, which does not require all possible measures to be taken to prolong the life of a baby born alive if it is not in his or her best interests.(145) When a baby is delivered later in pregnancy suffering from severe disabilities, or when a baby is born alive after a lawful termination of pregnancy, the legal obligation is to provide appropriate care. Such care does not necessarily include admission to a neonatal intensive care unit. The Council opined that there is no legal obligation to preserve the life of a newborn with such serious abnormalities as this may be against his or her best interest. Doctors should therefore feel able to respect the woman’s wish if she chooses to decline feticide and not be obliged to press her to reconsider. What is essential in these circumstances however, is that there should be thorough discussions with the woman/parents and a care plan agreed.(145)

Clinical Genetics

Clinical genetics in prenatal care and fetal medicine

Genetics Speciality - Clinical Genetics

Clinical Genetics is the medical specialty which provides a diagnostic service and genetic counselling for individuals or families with, or at risk of, conditions which may have a genetic basis.(146) Genetic conditions can affect any body system and any age group and can arise antenatally. The aim of Genetic Services is to help those affected by, or at risk of, a genetic condition to live and reproduce as normally as possible.

Genetic conditions include:

- Chromosomal abnormalities, which cause birth defects, intellectual/developmental disability and/or reproductive problems.
- Single gene conditions such as cystic fibrosis, muscular dystrophy, Huntington's disease, sickle cell disease, ciliopathies, and rasopathies.
- Familial cancer and cancer-predisposition syndromes such as inherited breast or colorectal cancer and neurofibromatosis.
- Birth defects with a genetic component such as structural brain abnormalities, congenital diaphragmatic hernia, neural tube defects and cleft lip and palate.

Clinical Genetics is a medical speciality recognised since 1997 by the Medical Council of Ireland. There is a recognised higher specialist training programme for clinical genetics in Ireland since 2012, run by the Institute of Medicine in the RCPI (https://www.rcpi.ie/Learn-and-Develop/Training-Programmes/Higher-Specialist-Training/Internal-Medicine-Higher-Specialist-Training/Specialties-and-Mandatory-Courses). Clinical geneticists have an essential role to play in the provision of a high-quality fetal medicine service, at all stages of a pregnancy. A clinical geneticist must complete 4 years of training and is trained across numerous specialised fields including oncology, fetal medicine, paediatrics, neurology, and nephrology.(147)

Genetics Speciality - Genetic Counsellors

Genetic counsellors are allied health professionals who have specialist education, training and knowledge in human genetics, genomics counselling and health communication skills. They provide information to individuals and families about genetic conditions that are inherited or the potential risk of developing a particular condition. Genetic counsellors are trained to provide emotional and practical support to help people adjust to living with, or being at risk for, a genetic condition.(148) Genetic counsellors work in a range of settings including hospitals, medical specialist clinics, obstetric practices and research institutions. They work as part of a team, usually with medical specialists such as clinical geneticists, oncologists, obstetricians and cardiologists.(148) There are genetic conditions in practically every medical specialty for which genetic counselling may be sought.

Helpfully, the scope of professional roles for genetic counsellors and clinical geneticists for the UK have recently been outlined by the UK Association of Genetic Nurse Counsellors and the Clinical Genetics Society.(149) It is clear that both disciplines have essential roles to play in fetal medicine. Broadly speaking, the clinical geneticist leads on diagnostics and therapeutics and the genetic counsellor leads on psychosocial issues and care of the extended family.

Clinical Genetics involvement in fetal medicine

- Pre-conception genetic assessment

When Clinical Genetics services see families with genetic conditions, a significant role is to provide families with accurate information on the likelihood of a future pregnancy for a family member being affected by the genetic condition in the family. In addition, the options for dealing with the risk of recurrence are discussed, which can include options such as proceeding with a pregnancy as usual, prenatal genetic testing, preimplantation genetic testing, non-invasive genetic testing for single gene disorders, gamete donation, adoption, or not having a family. Not all such options are available, depending on the clinical circumstances, and depending on the specificity of genetic testing in the particular family. The pre-conception discussion also covers what non-genetic surveillance, such as ultrasound or fetal MRI, may be available for family members at increased risk of a pregnancy affected by a genetic disorder.

When discussing invasive or non-invasive prenatal genetic testing in an established pregnancy, the consequences of getting an adverse result from such testing are discussed. That will include what options would be available if a couple choose to continue with a pregnancy, as well as the supports available to a couple if they choose not to continue with a pregnancy.

Predictive genetic testing (performed due to a known recurrence risk due to family history) in a pregnancy should only take place after pre-test genetic counselling and testing should be co-ordinated through clinical genetic services. While genetic counsellors play a key role in delivery of pre-test counselling and setting up testing in pregnancy, they work with a consultant clinical geneticist who provides the clinical governance.(149)

- First Trimester non-invasive prenatal genetic testing

The technology has developed over the last 20 years to allow analysis of cell free fetal DNA in maternal blood during the first trimester by massively parallel DNA sequencing.(12) Such developments have significantly altered the management of many clinical conditions, such as Rhesus disease, and determination of fetal gender for pregnant women who carry X-linked disorders which may only affect males. The technology has also led to the introducing of non-invasive first-trimester screening for fetal trisomy in maternal blood.

A further and newer application is the use of massively parallel DNA sequencing of fetal DNA in maternal blood is to use it to determine whether or not a pregnancy is affected by a known

single gene condition already present in the family, known as non-invasive prenatal diagnosis (NIPD). Such testing is now available for such conditions as cystic fibrosis and spinal muscular atrophy, where parental genotypes are already known. The use of the relative haplotype dosage model for NIPD can also allow testing to be extended to families with other genetic conditions. However, NIPD testing may not be suitable for all single gene conditions and requires significant clinical and laboratory work-up beforehand. Bespoke NIPD can be delivered using paternal exclusion. This is clinically useful for paternally inherited autosomal dominant conditions and in autosomal recessive conditions where the parents have different variants.

- Non-invasive prenatal trisomy screening

At present there is no publicly funded prenatal screening programme for trisomy or other chromosome conditions in Ireland. Non- invasive prenatal screening is widely available with significant uptake recorded in the annual reports of some of the maternity hospitals. Women who receive a high-risk result are referred to fetal medicine departments. Delivery of care after high-risk results for trisomy 13, 18 and 21 is through fetal medicine. High risk results for microdeletions should be cared for through a clinical geneticist.(13) Decisions regarding termination of pregnancy should be made as part of an MDT, which includes a consultant clinical geneticist with access to the laboratory scientists.

- Second trimester Invasive prenatal genetic testing for known genetic conditions

For some families, a specific genetic diagnosis has already been made prior to a pregnancy, and there is a significant recurrent risk, and a known pathogenic single gene or chromosomal variant. However, NIPD may not be technically possible for those families. Those families may then choose to have targeted invasive prenatal diagnosis by chorionic villus sampling at 11 weeks or amniocentesis at 15 weeks. The sample taken is then tested for the pathogenic variant known to be present in the family. The clinical genetic service will see a couple in this situation early in pregnancy prior to any such invasive procedure, counsel them and liaise closely with the diagnostic laboratory and the fetal medicine service to ensure a smooth process in planning the genetic testing, co-ordinating prenatal testing, and the provision of genetic test results.

If a couple then receive an adverse result, and the diagnosis is that of a fatal genetic fetal anomaly (for example trisomy 13) the genetic service will liaise closely with the fetal medicine service to update them of the results. If the couple request a TOP, the consultant clinical geneticist will provide input into the MDT discussion. The clinical genetics service will provide copies of genetic reports along with a report outlining the clinical implications of the result. The clinical genetic service will also liaise with the family during and after the TOP, particularly if the couple wish to discuss plans for future pregnancies.

- Second and third trimester diagnosis of fetal anomaly

In many instances, the first encounter a couple has with a diagnosis of a fetal malformation is at either the 11-13 week scan or the anatomy scan, and there is no prior history of a genetic condition or fetal malformation for either parent. Determining the cause of either a single fetal malformation or multiple fetal malformations requires considerable training and

expertise for the clinicians involved, and previously the diagnostic yield was low, with 40-60% remaining undiagnosed. This was the situation prior to the introduction of rapid trio exome sequencing into clinical care. The diagnostic yield of monogenic conditions in some scenarios ranges from 6-80%.(150) Optimisation of diagnostic yield depends on pre-test selection of cases and as such, in the National Health Service in the UK, trio exome sequencing can only be ordered by a clinical geneticist.(151,152)

Clinical Geneticists have training and expertise in the recognition and diagnosis of rare fetal malformations and are able to support fetal medicine specialists when such malformations are identified. This can occur by clinical geneticists attending regular fetal medicine case discussion MDT meetings, advising fetal medicine specialists on the specific genetic tests that may be indicated, and meeting in a timely manner couples who have had a diagnosis of fetal malformation. Increasingly, there is a requirement for deep and reverse phenotyping with the advent of advanced genetic testing including prenatal exome sequencing. It is widely understood that the prenatal phenotype of monogenic disorder is different to the postnatal phenotype making interpretation of genomic data challenging without deep phenotyping with joint fetal medicine and clinical genetics clinics.

As outlined in the recently published UK document regarding the role of a clinical geneticist and genetic counsellor, the interpretation of genetics and genomic results and application of same is the responsibility of the clinical geneticist.(149) In the setting of an abnormal result, outside the standard trisomies 13, 18 and 21, a consultant clinical geneticist is required to determine the genotype/phenotype correlation. This is critically important in the setting of Array CGH and exome sequencing results.(153,154)

Clinical geneticists and genetic counsellors meet with couples who have had a specific genetic cause of the fetal malformation identified prenatally, to discuss the implications, prognosis and options for management, as well as recurrence in future pregnancies. Clinical geneticists also work closely with fetal medicine specialists to develop specific clinical pathways for couples where a fetal malformation has been identified. Clinical geneticists are also integral to fetal medicine MDTs where couples with a pregnancy with anomalies, including fatal fetal anomalies are discussed. Clinical geneticists have expertise in and experience of rare genetic conditions, such as rare neurologic or metabolic diseases conditions, and so can also contribute to MDT decisions about such rare cases.

- Recommendations on diagnostic genetic testing

1. Chromosome microarray

The introduction of chromosome microarray as a first line prenatal genetic test for the investigation of fetal malformation or nuchal translucency became standard in many countries around 2015, with a significantly higher diagnostic rate than conventional G Banded karyotyping, of 8.4%.(155) Standards were set for the uniformity of coverage of chromosome regions, and for CMA probe density, and a move towards a consensus clinical classification of Copy Number Variants (CNVs), was proposed, following the American College of Medical Genetics.(156) The UK model proposed a panel of laboratory and clinical geneticists to provide advice on the interpretation of rare non-recurrent CNV findings, to aid clinical management.(156) The SMFM in its 2016 statement on the use of chromosomal microarray

for prenatal diagnosis recommended that "pre and post-test counselling should be performed by appropriately qualified and trained genetic counsellors, geneticists or other providers with expertise in the complexities of interpreting chromosomal microarray results".(157)

2. Prenatal gene panel testing

The widespread availability of massively parallel sequencing (Next Generation Sequencing or NGS) has allowed rapid analysis of multiple genes in one process. Analysis of a specific set of genes for specific clinical indications (gene panel testing) is now widely available. The use of fetal gene panel testing in specific clinical settings has been studied widely. For some situations, such as fetal gene panel testing in the prenatal diagnosis of skeletal dysplasia, gene panel testing has been shown to be effective.(158) Non-invasive prenatal single gene testing for specific skeletal dysplasias, such as FGFR3 specific variant testing in thanatophoric dysplasia and achondroplasia, has also been shown to be effective.(159)

In other clinical settings, such as non-immune fetal hydrops, prenatal trio exome testing has been proposed to have an advantage over gene panel testing, as demonstrated in the UK multicentre FIND study,(160) and a similar study from California.(161) The limiting factor for gene panels is the length of time to get a result as well as the lack of data regarding the clinical utility in the prenatal setting. As such, in clinical practice, gene panels are rarely used in the setting of a pregnancy anymore.

3. Fetal Exome sequencing

The clinical use of trio exome sequencing (parents DNA and fetal DNA) has been reported in several large studies. The multicentre 2019 PAGE study in the UK of trio prenatal exome sequencing had an overall diagnostic rate of 8.5% in pregnancies with structural malformations, higher in pregnancies with multiple malformations.(154) A similar study from New York showed a 10% diagnostic rate.(162) A 2022 systematic review and meta-analysis gave a 31% additional diagnostic rate with the use of prenatal exome sequencing.(163) Prenatal trio exome sequencing is now offered through clinical genetics with fetal medicine specialists through joint clinics centres worldwide.

The American College of Medical Genetics 2020 document on the use of exome sequencing in prenatal diagnosis has made a series of recommendations.(164) Trio exome sequencing should be considered in a fetus with ultrasound anomalies and a normal chromosome microarray and karyotype. Pre-test and post-test counselling is ideally provided by a genetics professional, and options in relation to reporting of secondary findings should be discussed.

The UK NHS provides trio Exome Sequencing as a publicly funded service since October 2020. This test is only available if ordered by a clinical geneticist and is run in parallel to QF-PCR and array CGH in most circumstances. Early referral to a consultant clinical geneticist to consider prenatal exome sequencing is advised to optimise testing and deliver a timely result.(153)

The ISPD issued a statement in 2022 on the use of fetal exome and fetal whole genome testing in prenatal diagnosis.(165) The statement is similar to the ACMG document, giving indications for testing, recommending that pre-test and post-test counselling be carried out by a provider

with in-depth knowledge of the benefits and risks of the test, typically a genetic health provider. The ISPD statement is more nuanced about secondary findings, acknowledging that there is no universal consensus. The ISPD statement does not make any recommendation on whether whole exome or whole genome testing is preferable.(165)

4. Fetal whole genome sequencing

The additional benefit (166) of carrying out whole genome sequencing, as opposed to exome sequencing, in a prenatal setting, has not yet been reported. Data from whole genome trio analysis compared to exome sequencing in ill neonates gives a diagnostic rate of 41% for whole genome sequencing, compared to 36% for exome sequencing.
The Canadian College of Medical Genetics has produced a statement in 2021 on the clinical application of fetal genome wide sequencing (GWS) during pregnancy (167), which covers both exome sequencing and whole genome sequencing. Similar to other recent statements, the CCMG recommended the use of GWS in the investigation of multiple fetal anomalies. The CCMG recommended that GWS be order by, or in collaboration with, a clinical geneticist, and that genetic counselling is crucial. In contrast to other statements, the CCMG recommended that reporting should be limited to pathogenic or likely pathogenic variants that are likely to be associated with the identified fetal anomalies. The CCMG also recommended that reporting of secondary findings should not by default be performed in the prenatal context.

<u>Involvement in Multidisciplinary Care</u>

Clinical Geneticists and Genetic Counsellors need to work closely with fetal medicine staff in providing integrated care to couples who have a diagnosis of fetal anomaly or are a risk of a genetic disorder affected a pregnancy. Roles and responsibilities need to be agreed, and agreed care pathways are essential, so that couples in a difficult situation are supported as much as possible on their journey. Regular involvement of clinical genetics in fetal medicine MDTs in each fetal medicine unit is extremely important. Decisions regarding termination of pregnancy should be made with the involvement of a consultant clinical geneticist, where appropriate in the event of a diagnosis of FFA or new condition diagnosed in pregnancy. A genetic counsellor should not be responsible for these decisions.

An MDT meeting may often take place with fetal medicine, pathology, and other specialities after TOPFA, prior to agreeing on diagnosis or diagnoses. Such MDTs can also be used to determine who should subsequently meet the family, and when, as well as what information needs to be conveyed by a fetal medicine specialist, and what needs to be conveyed by the clinical geneticist.

Clinical Genetics staff can provide expertise in advising on appropriate investigations that may or may not be needed after TOPFA, not only genetic testing, but also biochemistry and radiology if necessary. If an autopsy takes place, clinical geneticists can also work closely with perinatal pathologists in the interpretation of often complex autopsy findings. A timely and sensitive meeting with the couple is essential to discuss the final diagnosis, recurrence risks and reproductive options if subsequent pregnancies are being considered. Further follow up with a genetic counsellor can also be very important, to aid couples to come to terms with the information they have received.

Investigations and follow up

Perinatal pathology

Perinatal pathologists are important members of the multidisciplinary team involved in the investigation of pregnancy complications including fetal anomalies. In large fetal medicine units with perinatal pathology services, it is not unusual for pathologists to participate in fetal medicine multidisciplinary meetings, both to contribute to discussions and to learn about advancements in fetal medicine and antenatal diagnostics.

In cases of termination of pregnancy for fetal anomaly the 2001 Report of the Joint Working Party of the RCOG and the Royal College of Pathology (RCPath) outline that "pathological confirmation after termination for structural anomalies is strongly recommended in order to confirm the diagnosis, to look for additional anomalies that may influence the recurrence risk and for audit". (168)

In keeping with this the RCPath Guidelines on Autopsy practice covering termination of pregnancy for congenital anomaly specify that resulting autopsy summaries should specify "concordance or discordance of findings with the clinical history and prenatal testing, likely/possible unifying diagnosis and recommendation for genetic referral or further tests if appropriate".(169)

Where termination of pregnancy is based on anomalies identified at ultrasound one study showed that post mortems performed by specialist pathologist "changed the estimated risk of recurrence in 27% of cases and in 8% this was to a higher (one in four) risk" (3) . In another study of termination for fetal anomaly, without a known cytogenetic abnormality, fetal autopsy found "additional abnormalities in 54.4% of cases and genetic counselling was "modified in 20.6% of cases".(170)

Post mortem is still of value in the era of more sophisticated genetic investigation. The Standards and Guidelines for the Interpretation of Sequence Variants: A Joint Consensus Recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology, states that "clinical laboratories are encouraged to form collaborations with clinicians to provide clinical information to better understand how genotype influences clinical phenotype".(171) It is reasonable to argue that post mortem examinations in cases of fetal anomaly contribute to these important phenotypic descriptions.

Molecular autopsy using exome sequencing has increased genetic diagnostic yield in cases of fetal anomaly. In molecular-based studies it is not always clear how much the autopsy specifically contributed to the phenotypic description informing the molecular investigation but one study specifically addressing this issue stated that there is support for "the routine use of molecular autopsy using trio exome sequencing and full autopsy" in the investigation structural fetal anomaly.(172)

A recent study on genomic reported a high diagnostic yield to provide more evidence that genomic autopsy in the investigation of pregnancy loss, pregnancy terminations and perinatal death is advantageous over currently performed diagnostic tests. The authors concluded that the addition of a genomic approach (and thus collaboration between clinical genetics and perinatal pathology) to the first line of investigation in the clinical standard-of-care for fetal and neonatal loss will provide more families with answers, leading to reproductive confidence (for de novo variants) or enabling options to prevent recurrence (for inherited variants).(173)

Bereavement care

Bereavement describes the anticipation of death and subsequent adjustment to living without a loved one. Dealing with the loss of a baby or pregnancy can be a difficult and devastating time for parents and families, and they may need a range of immediate and longer term supports to help them with their bereavement. The provision of bereavement care is based on the needs of the parents and not on the type of pregnancy loss. (111,124,128,130,131,174–177) There are frameworks and standards which seek to guide the MDT in providing high-quality holistic care to the baby and their family from diagnosis through to birth, death, and bereavement.(111,124,143)

Following a prenatal diagnosis of a fetal anomaly, some parents may choose to terminate their pregnancy. This decision is likely to have been a difficult one for all concerned. Parents are faced with challenging and complex ethical decisions that are often fused with strong emotion with the anticipated death of their baby.(143) A perinatal palliative care approach, if acceptable to parents, can provide support, whether they choose to continue with their pregnancy or choose termination.(140,141,143,177)

However, the range of attachment to the baby evident in literature(178,179) highlights the need for a sensitive approach to the parents' specific coping style after termination of pregnancy. A recent Irish study adds to the body of evidence that the approach to facilitating baby's personhood must be at a level that is individualised and comfortable with the parents.(180) It is worth noting that previous work indicates attachment is influenced by gestation at the time of the termination of pregnancy rather than the decision to terminate alone.(181)

Perinatal palliative care is a concept which involves providing integrated holistic ongoing support from the initial diagnosis of a fatal fetal anomaly in pregnancy to post-natal care, which honours the baby and the families' choices.(139,141,143) Therefore, if appropriate, a perinatal palliative care approach should be encouraged but at a level which is appropriate and sensitive to parents' individual experiences and how they frame their loss. An important recommendation that arises from the recent Irish study (180) and prior research is "that the individual nature of parents' responses is recognised in care, and choices are given that neither bias parents or make presumptions that would limit parental choices". (130,141)

In addition, during this time, anticipatory bereavement care should be initiated to assist parents in preparing for the birth and death of their baby. Anticipatory bereavement care for parents who have received an FFA diagnosis involves supporting them to build a relationship

antenatally with their baby, individualised memory making, and preparing them for the birth and death of their baby. Good anticipatory bereavement care plays an important role in lessening the intensity of the post-death bereavement as well as providing valuable opportunities for bonding and memory making. When discussing with parents that they might want to create memories of their baby, staff should remember that parental choice is paramount. (111,124)

In summary, all treatment planned and provided for a baby with a diagnosis of a fatal fetal anomaly should keep the care needs of the parents and baby as the primary focus. This approach ensures that the delivery of care is well planned and compassionately provided to all babies and their families regardless of the circumstances of pregnancy or birth, while respecting the personal and professional rights of healthcare staff.(143)

Parent experience – what matters

When looking at the parent experience of TOPFA, narratives in the literature encompass several themes such as the difficult nature of decision-making in the context of late TOP, the perceived pressure of time, fragmented healthcare support during prenatal diagnosis, and the lack of standardised bereavement care.(177,182) The overarching themes from much of the literature is 'falling through the gap' where care received did not meet the needs of the woman or her partner.(125,182)

The diagnosis of a major, possibly fatal, fetal anomaly can result in an intense grief reaction for parents which can be exacerbated by inadequate care and support. (82,130) Healthcare professionals' communication should sensitively and compassionately recognise this intense grief, as lack of recognition of their loss and trauma is distressing to parents.(180) (177,183) A variety of responses to the diagnosis of a fetal anomaly as well as coping strategies have been identified, demonstrating a spectrum of parental health care needs. These needs often extend beyond routine care.(184)

Parents need clear and comprehensive information on anomalies, prognosis and future care plans. Many studies on perinatal loss have identified the importance of the parents' relationship with caregivers.(110,185) Privacy, empathy and information quality are all ranked highly as preferences.(185) Encounters with caregivers have the potential to make parents feel comfortable, safe, and supported after the diagnosis of a fetal anomaly. Conversely, negative encounters can increase stress, with a lack of communication and support leading to parents feeling isolated.(174–176,184,186) Studies show that parents at times are dissatisfied with communication and an already distressing experience can be further exacerbated by inappropriate interactions.(82,180,187)8-12

A recent literature review aimed to (a) synthesise findings from the international literature on the healthcare experiences and needs of parents who undergo a termination of pregnancy following an antenatal diagnosis of a fetal anomaly, (b) carry out a thematic analysis of the evidence, and (c) provide comprehensive narrative synthesis, focusing on the views, experiences, feelings, opinions and needs of both parents.(125)

Findings from this review (which included 30 international studies) suggested that a trusting relationship with healthcare professionals who provide compassionate care positively impacts on parents' experience of TOPFA. The review also identified key components that may optimise healthcare practice and enhance quality of care, as well as implications for policy, providing opportunity to improve healthcare provision, organisation and delivery. This work is explored in more detail here, as its findings are relevant in the Irish context and support the detail in the service evaluation work presented earlier in this report.(125)

Most studies addressed parents' need for information and the impact it had on their experience. While most parents acquired information themselves from a range of sources, clear and unbiased information provided by healthcare professionals was greatly valued. When parents were given relevant and timely information, particularly about the diagnosed anomaly and healthcare procedures, it had a positive impact by reducing their fears and worries and helping them understand their choices. Parents who felt ill-informed at any stage in the process felt less well-prepared physically and psychologically about what to expect and, for some, their experience was more traumatic.

Healthcare providers' capacity to provide compassionate and empathetic care was potentially the most influential element in how parents perceived their experience, positively and negatively. Parents valued being cared for by experienced members of staff and found it reassuring. The importance of non-judgmental staff was highlighted as a recurring theme linked to stigma.

Well organised care, which is timely, efficient, and properly resourced was identified as a major contributor in parent satisfaction. Delays in appointments for further diagnostic tests and slow turnaround times for results were experienced as frustrating and increased parents' anxiety. Co-ordination and continuity of care were also highlighted as important elements of effective care.

Aftercare was identified by some parents as a gap in the services available to them within the healthcare system, and for many was not routinely provided. For those who were signposted to or who accessed aftercare, they found it to be helpful and beneficial. Parents expressed the view that the aftercare for those who had undergone TOPFA should be bespoke as it was not the same as other perinatal losses and support groups for other infant losses were mostly considered to be unhelpful or inappropriate.

Finally, there is evidence from the studies reviewed that parents' experiences of TOPFA were impacted negatively by wider contextual factors including legislation, local procedures, professional practices and societal attitudes about termination of pregnancy.(125)

Professional development

Clinical guidelines

Evidence-based clinical guidelines are recommendations to assist practitioners and patients to make decisions about appropriate healthcare for specific clinical circumstances.(188) Guidelines should integrate best research evidence in conjunction with clinical expertise, values of those using the services, and cost.(189,190) Clinical guidelines are an important source of information for healthcare workers. Published international guidelines are a valid source of information, although it is important for physicians to be aware of the limitations of guidelines.(191–193)

Guidelines are part of an evidence-based practice toolkit which, transformed into practice recommendations, have the potential to improve both the process of care and patient outcome. Guidelines are also a common point of reference for prospective and retrospective audits of clinicians' or hospitals' practices: the tests, treatments, and treatment goals recommended in guidelines provide ready review criteria for rating compliance with best care practices. Guidelines and care pathways around prenatal ultrasound, prenatal screening and diagnosis developed by professional societies and groups are common across high income countries; these documents also offer information resources and educational opportunities.

Examples of relevant international professional bodies include;

- SMFM https://www.smfm.org/publications
- RCOG https://www.rcog.org.uk/guidance
- ACOG https://www.acog.org/clinical/clinical-guidance/clinical-practice-guideline
- ISPD https://www.ispdhome.org/
- ISUOG https://www.isuog.org/clinical-resources.html
- BAPM https://www.bapm.org/pages/191-resources

Audit

One of the best ways to improve medical practice is the use of audit and feedback. Audit and feedback are typically represented as a cycle-reviewing clinical practice, setting the standards for care, monitoring practice against these standards, findings analysis, assessing options and implementation of new practices and finally returning to the starting point of reviewing the newly instituted clinical practice. (194)

A review published in 2006 found that in the field of obstetric care, a multifaceted strategy based on audit and feedback and facilitated by a local opinion leader is advised to effectively change behaviours. Moreover, the review findings support the assumption that interventions in which health professionals actively participate in an ongoing review and modification of the work process enhance performance and optimise maternal and perinatal outcomes. (195)

Regular audit, peer review and quality assurance procedures in ultrasound are recognised to improve and sustain good practice.(39,196,197) A recent study shown that large-scale clinical

audit, coupled with implementation of targeted changes and feedback to sonographers, can lead to improvements in image quality on the mid-trimester anomaly scan.(198)
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 continuous professional development (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.

The Irish Medical Council's Guide to Professional Conduct and Ethics for Registered Medical Practitioners (2019) says that competent doctors review and reflect on their activity levels and outcomes so they can identify and fix any problem areas within their practice and engage with quality improvement initiatives to help improve health services and care for all patients

Ultrasound unit audit is encouraged in a timely manner. The BMUS recommended audit tool has been developed from various peer review tools available. This tool has been tested by a group of ultrasound experts who form the BMUS Professional Standards Group.(39)

Weekly/monthly perinatal (e.g. mortality) multidisciplinary meetings are important learning opportunities for healthcare professionals. Those MDT meetings should discuss ongoing cases as well as perinatal mortality cases to improve diagnosis and care.(135,199)

Reflective practice also provides the foundation for good care. Developing insight into professional practice is important to improve standards of care. Reflective practice includes formal reviews through audit and outcome data. It also includes informal reflection on how personal values may affect communication with patients, colleagues, or others, and ultimately the care provided.

Accreditation, ongoing quality review, and publication of outcomes have become a standard in many industries. Scrutiny with regard to safe and responsible care is said to be even more important as the number of centres providing prenatal diagnosis and fetal intervention has increased, with proliferation of genetic testing.(93) There is ongoing debate about the need for Fetal Medicine Centres to audit and report their practice and benchmark against clinical standards. International societies have committed to quality improvement and practitioners are encouraged to report results and contribute to various registries to help improve safety and outcomes.(93)

Education and training

Lifelong learning is necessary for the development of healthcare workers and for patients safety. National and international guidelines are continuously published and should be implemented in daily clinical practice.

In 2019 the Interprofessional (continuing professional development) CPD and Lifelong Learning Working Group (UK) published principles for CPD and lifelong learning in health and social care.(200)

These 5 principles set out that CPD should:

- be each person's responsibility and be made possible and supported by the employer.
- benefit service users.
- improve the quality-of-service delivery.
- be balanced and relevant to each person's area of practice or employment.
- be recorded and show the effect on each person's area of practice.

The benefits of CPD were also reported:

- Encourages a positive learning culture
- Improves skills, knowledge, and ways of thinking and working
- Makes you feel valued, motivated and confident
- Develops your career and helps you to move between sectors and roles
- Makes you feel able to drive change and innovation
- Means you remain fit to practice and meet regulatory body standards (including codes of conduct)
- Keeps you up to date with changing technology and service demands
- Improves experience and outcomes
- Makes you feel safe and confident in the services provided
- Increases satisfaction with services
- Contributes to up-to-date and evidence-based services
- Influences service development
- Improves the quality-of-service delivery
- Supports recruitment, keeping staff, and creating a flexible workforce
- Adds to the mix of skills and productivity of staff
- Improves performance

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 continuous professional development (CPD). This is achieved through participation in audits, internal and external training events and self-learning and study days. Departmental teaching sessions and participation in online course and webinars should be encouraged. Professional development review (PDR) should be encouraged for each health professional performing ultrasound screening.(39,196–198,200)

The Irish Medical Council's Guide to Professional Conduct and Ethics for Registered Medical Practitioners (2019) says that competence is required in all aspects of professional practice. Competent doctors base their practice on evidence, as far as it is available and keep up to date with developments in their field of practice and with clinical guidelines on best practice. The guide also notes that a commitment to lifelong learning is essential to providing up-to-date and effective care. Doctors should make sure they are up to date with developments in their area of practice by participating regularly in CPD and in other formal and informal education, training and development.

Specific issues and requirements relating to education and training in the specialty of maternal-fetal medicine, for practitioners and centres, are explored in previous sections of this report.(88,89,94,106)

Authors

Lead author	Professor Keelin O'Donoghue
Contributions from	Professor Andrew Green Dr Samantha Doyle Professor John Morrison Dr Jennifer Walsh Dr Brendan Fitzgerald
Reviewed by	Dr Aoife Mullally Ms Fiona Hanrahan Members of the National Review Group

References

1. CDC. Birth defects surveillance kit [Internet]. US; Available from: https://www.cdc.gov/ncbddd/birthdefects/surveillancemanual/chapters/chapter-1/chapter1-4.html
2. Santoro M, Coi A, Pierini A, Rankin J, Glinianaia SV, Tan J, et al. Temporal and geographical variations in survival of children born with congenital anomalies in Europe: A multi-registry cohort study. Paediatr Perinat Epidemiol. 2022 Nov;36(6):792–803.
3. Tucker FD, Morris JK, JRC Management Committee, Neville A, Garne E, Kinsner-Ovaskainen A, et al. EUROCAT: an update on its functions and activities. J Community Genet. 2018 Oct;9(4):407–10.
4. Morris JK, Springett AL, Greenlees R, Loane M, Addor MC, Arriola L, et al. Trends in congenital anomalies in Europe from 1980 to 2012. PloS One. 2018;13(4):e0194986.
5. Perinatal Mortality National Clinical Audit in Ireland Annual Report 2020.
6. Committee Opinion No. 693: Counseling About Genetic Testing and Communication of Genetic Test Results. Obstet Gynecol. 2017 Apr;129(4):e96–101.
7. Alldred SK, Takwoingi Y, Guo B, Pennant M, Deeks JJ, Neilson JP, et al. First trimester ultrasound tests alone or in combination with first trimester serum tests for Down's syndrome screening. Cochrane Pregnancy and Childbirth Group, editor. Cochrane Database Syst Rev [Internet]. 2017 Mar 15 [cited 2023 Jan 8];2017(3). Available from: http://doi.wiley.com/10.1002/14651858.CD012600
8. Audibert F, De Bie I, Johnson JA, Okun N, Wilson RD, Armour C, et al. No. 348-Joint SOGC-CCMG Guideline: Update on Prenatal Screening for Fetal Aneuploidy, Fetal Anomalies, and Adverse Pregnancy Outcomes. J Obstet Gynaecol Can JOGC J Obstet Gynecol Can JOGC. 2017 Sep;39(9):805–17.
9. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Obstetrics, Committee on Genetics, Society for Maternal-Fetal Medicine. Screening for Fetal Chromosomal Abnormalities: ACOG Practice Bulletin, Number 226. Obstet Gynecol. 2020 Oct;136(4):e48–69.
10. Ravitsky V, Roy MC, Haidar H, Henneman L, Marshall J, Newson AJ, et al. The Emergence and Global Spread of Noninvasive Prenatal Testing. Annu Rev Genomics Hum Genet. 2021 Aug 31;22:309–38.
11. Rather RA, Saha SC. Reappraisal of evolving methods in non-invasive prenatal screening: Discovery, biology and clinical utility. Heliyon. 2023 Mar;9(3):e13923.
12. RCOG London. Non-invasive Prenatal Testing for Chromosomal Abnormality using Maternal Plasma DNA [Internet]. 2014 Mar. Available from: https://www.rcog.org.uk/guidance/browse-all-guidance/scientific-impact-papers/non-invasive-prenatal-testing-for-chromosomal-abnormality-using-maternal-plasma-dna-scientific-impact-paper-no-15/
13. van der Meij KRM, Sistermans EA, Macville MVE, Stevens SJC, Bax CJ, Bekker MN, et al. TRIDENT-2: National Implementation of Genome-wide Non-invasive Prenatal Testing as a First-Tier Screening Test in the Netherlands. Am J Hum Genet. 2019 Dec 5;105(6):1091–101.
14. Bayón JC, Orruño E, Portillo MI, Asua J. The consequences of implementing non-invasive prenatal testing with cell-free foetal DNA for the detection of Down syndrome in the Spanish National Health Service: a cost-effectiveness analysis. Cost Eff Resour Alloc CE. 2019;17:6.

15. van der Meij KRM, de Groot-van Mooren M, Carbo EWS, Pieters MJ, Rodenburg W, Sistermans EA, et al. Uptake of fetal aneuploidy screening after the introduction of the non-invasive prenatal test: A national population-based register study. Acta Obstet Gynecol Scand. 2021 Jul;100(7):1265–72.
16. Perrot A, Horn R. The ethical landscape(s) of non-invasive prenatal testing in England, France and Germany: findings from a comparative literature review. Eur J Hum Genet EJHG. 2022 Jun;30(6):676–81.
17. Gadsbøll K, Petersen OB, Gatinois V, Strange H, Jacobsson B, Wapner R, et al. Current use of noninvasive prenatal testing in Europe, Australia and the USA: A graphical presentation. Acta Obstet Gynecol Scand. 2020 Jun;99(6):722–30.
18. van der Meij KRM, Henneman L, Sistermans EA. Non-invasive prenatal testing for everybody or contingent screening? Prenat Diagn. 2023 Jan 8;pd.6296.
19. van der Meij KRM, van de Pol QYF, Bekker MN, Martin L, Gitsels-van der Wal J, van Vliet-Lachotzki EH, et al. Experiences of pregnant women with genome-wide non-invasive prenatal testing in a national screening program. Eur J Hum Genet EJHG. 2022 Dec 9;
20. Krm van der M, A N, L M, Jt G van der W, Mn B, Eh van VL, et al. Routinization of prenatal screening with the non-invasive prenatal test: pregnant women's perspectives. Eur J Hum Genet EJHG [Internet]. 2022 Jun [cited 2023 Feb 22];30(6). Available from: https://pubmed.ncbi.nlm.nih.gov/34385671/
21. Lannoo L, van der Meij KRM, Bekker MN, De Catte L, Deckers S, Devriendt K, et al. A cross-country comparison of pregnant women's decision-making and perspectives when opting for non-invasive prenatal testing in the Netherlands and Belgium. Prenat Diagn. 2023 Feb 17;pd.6329.
22. PHE Screening. NIPT rolls out to all areas of England as part of the existing NHS screening pathway for Down's syndrome, Edwards' syndrome and Patau's syndrome [Internet]. 2021 Jul. Available from: https://phescreening.blog.gov.uk/2021/07/01/nipt-rolls-out-to-all-areas-of-england-as-part-of-the-existing-nhs-screening-pathway-for-downs-syndrome-edwards-syndrome-and-pataus-syndrome/
23. Non-invasive prenatal testing: ethical issues. London: Nuffield Council on Bioethics; 2017.
24. Royal College of Physicians, Royal College of Pathologists and British Society for Genetic, Medicine. Ethical issues in prenatal genetic diagnosis. Guidance for clinical practice. Report of the Joint Committee on Genomics in Medicine. London: RCP, RCPath and BSGM; 2022.
25. Horn R, Parker M. Opening Pandora's box?: ethical issues in prenatal whole genome and exome sequencing: Ethical issues in prenatal whole genome and exome sequencing. Prenat Diagn. 2018 Jan;38(1):20–5.
26. Bowden B, de Souza S, Puchades A, Williams K, Morgan S, Anderson S, et al. Implementation of non-invasive prenatal testing within a national UK antenatal screening programme: Impact on women's choices. Prenat Diagn. 2022 May;42(5):549–56.
27. Geppert J, Stinton C, Johnson S, Clarke A, Grammatopoulos D, Taylor-Phillips S. Antenatal screening for fetal trisomies using microarray-based cell-free DNA testing: A systematic review and meta-analysis. Prenat Diagn. 2020 Mar;40(4):454–62.
28. Christiaens L, Chitty LS, Langlois S. Current controversies in prenatal diagnosis: Expanded NIPT that includes conditions other than trisomies 13, 18, and 21 should be offered. Prenat Diagn. 2021;41(10):1316–23.

29. Mohamed M, McCormick CA, Foo A, Meaney S, O' Donoghue K. Dating Ultrasounds are Fundamental to Modern Obstetric Care. Ir Med J. 2022 Apr 29;115(4):582.
30. Brown I, Fernando S, Menezes M, da Silva Costa F, Ramkrishna J, Meagher S, et al. The importance of ultrasound preceding cell-free DNA screening for fetal chromosomal abnormalities. Prenat Diagn. 2020 Oct;40(11):1439–46.
31. Benn P, Borrell A, Chiu RWK, Cuckle H, Dugoff L, Faas B, et al. Position statement from the Chromosome Abnormality Screening Committee on behalf of the Board of the International Society for Prenatal Diagnosis. Prenat Diagn. 2015 Aug;35(8):725–34.
32. Gregg AR, Skotko BG, Benkendorf JL, Monaghan KG, Bajaj K, Best RG, et al. Noninvasive prenatal screening for fetal aneuploidy, 2016 update: a position statement of the American College of Medical Genetics and Genomics. Genet Med Off J Am Coll Med Genet. 2016 Oct;18(10):1056–65.
33. van der Meij KRM, Henneman L, Sistermans EA. Non-invasive prenatal testing for everybody or contingent screening? Prenat Diagn. 2022 Dec 27;
34. Dungan JS, Klugman S, Darilek S, Malinowski J, Akkari YMN, Monaghan KG, et al. Noninvasive prenatal screening (NIPS) for fetal chromosome abnormalities in a general-risk population: An evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG). Genet Med. 2022 Dec;100336.
35. Salomon LJ, Alfirevic Z, Audibert F, Kagan KO, Paladini D, Yeo G, et al. ISUOG updated consensus statement on the impact of cfDNA aneuploidy testing on screening policies and prenatal ultrasound practice. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2017 Jun;49(6):815–6.
36. Committee on Practice Bulletins—Obstetrics and the American Institute of Ultrasound in Medicine. Practice Bulletin No. 175: Ultrasound in Pregnancy. Obstet Gynecol. 2016 Dec;128(6):e241–56.
37. Antenatal care for uncomplicated pregnancies [Internet]. London: National Institute for Health and Care Excellence (NICE); 2019 [cited 2023 Jan 17]. (National Institute for Health and Care Excellence: Guidelines). Available from: http://www.ncbi.nlm.nih.gov/books/NBK552849/
38. Bioeffects and Safety Committee, Salvesen K, Lees C, Abramowicz J, Brezinka C, Ter Haar G, et al. ISUOG-WFUMB statement on the non-medical use of ultrasound, 2011. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2011 Nov;38(5):608.
39. Society of Radiographers and British Medical Ultrasound Society. BMUS Guidelines for Professional Ultrasound Practice [Internet]. 2021. Available from: https://www.bmus.org/static/uploads/resources/2021_SoR_and_BMUS_guidelines_v1.0_.pdf
40. ISUOG Practice Guidelines (updated): performance of 11-14-week ultrasound scan. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2023 Jan;61(1):127–43.
41. Andrew McLennan and Sue Walker. Prenatal assessment of fetal structural conditions. HGSA/RANZCOG Joint Committee on Prenatal Diagnosis and Screening; 2018.
42. Yagel S. Re: Effectiveness of 12-13-week scan for early diagnosis of fetal congenital anomalies in the cell-free DNA era. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2018 Oct;52(4):550.
43. Karim JN, Roberts NW, Salomon LJ, Papageorghiou AT. Systematic review of first-trimester ultrasound screening for detection of fetal structural anomalies and factors that affect screening performance. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2017 Oct;50(4):429–41.

44. Paladini D. Sonography in obese and overweight pregnant women: clinical, medicolegal and technical issues. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2009 Jun;33(6):720–9.
45. Stothard KJ, Tennant PWG, Bell R, Rankin J. Maternal overweight and obesity and the risk of congenital anomalies: a systematic review and meta-analysis. JAMA. 2009 Feb 11;301(6):636–50.
46. Hui L, Pynaker C, Bonacquisto L, Lindquist A, Poulton A, Kluckow E, et al. Reexamining the optimal nuchal translucency cutoff for diagnostic testing in the cell-free DNA and microarray era: results from the Victorian Perinatal Record Linkage study. Am J Obstet Gynecol. 2021 Nov;225(5):527.e1-527.e12.
47. Kenkhuis MJA, Bakker M, Bardi F, Fontanella F, Bakker MK, Fleurke-Rozema JH, et al. Effectiveness of 12-13-week scan for early diagnosis of fetal congenital anomalies in the cell-free DNA era. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2018 Apr;51(4):463–9.
48. Syngelaki A, Hammami A, Bower S, Zidere V, Akolekar R, Nicolaides KH. Diagnosis of fetal non-chromosomal abnormalities on routine ultrasound examination at 11-13 weeks' gestation. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2019 Oct;54(4):468–76.
49. Liao Y, Wen H, Ouyang S, Yuan Y, Bi J, Guan Y, et al. Routine first-trimester ultrasound screening using a standardized anatomical protocol. Am J Obstet Gynecol. 2021 Apr;224(4):396.e1-396.e15.
50. Mohamed M, McCormick CA, Foo A, Meaney S, Donoghue KO. Dating Ultrasounds are Fundamental to Modern Obstetric Care.
51. Karim JN, Bradburn E, Roberts N, Papageorghiou AT, ACCEPTS study. First-trimester ultrasound detection of fetal heart anomalies: systematic review and meta-analysis. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2022 Jan;59(1):11–25.
52. Maiz N, Burgos J, Barbazán MJ, Recio V, Martínez-Astorquiza T. Maternal attitude towards first trimester screening for fetal abnormalities. Prenat Diagn. 2016 May;36(5):449–55.
53. Bardi F, Beekhuis AM, Bakker MK, Elvan-Taşpınar A, Bilardo CM. Timing of diagnosis of fetal structural abnormalities after the introduction of universal cell-free DNA in the absence of first-trimester anatomical screening. Prenat Diagn. 2022 Sep;42(10):1242–52.
54. Toscano M, Grace D, Pressman EK, Thornburg LL. Does transvaginal ultrasound at 13-15 weeks improve anatomic survey completion rates in obese gravidas? J Matern-Fetal Neonatal Med Off J Eur Assoc Perinat Med Fed Asia Ocean Perinat Soc Int Soc Perinat Obstet. 2021 Mar;34(5):803–9.
55. Gupta S, Timor-Tritsch IE, Oh C, Chervenak J, Monteagudo A. Early second-trimester sonography to improve the fetal anatomic survey in obese patients. J Ultrasound Med Off J Am Inst Ultrasound Med. 2014 Sep;33(9):1579–83.
56. Li YL, Li DZ. Is there a role for nuchal translucency in the detection of rare chromosomal abnormalities in the era of noninvasive prenatal testing? Am J Obstet Gynecol. 2021 Oct;225(4):463–4.
57. Van den Hof MC, Smithies M, Nevo O, Oullet A. No. 375-Clinical Practice Guideline on the Use of First Trimester Ultrasound. J Obstet Gynaecol Can. 2019 Mar;41(3):388–95.
58. Simula N, Brown R, Butt K, Morency AM, Demers S, Grigoriu A, et al. Committee Opinion No. 418: The Complete 11–14 Week Prenatal Sonographic Examination. J Obstet Gynaecol Can. 2021 Aug;43(8):1013–21.

59. Crane JP, LeFevre ML, Winborn RC, Evans JK, Ewigman BG, Bain RP, et al. A randomized trial of prenatal ultrasonographic screening: impact on the detection, management, and outcome of anomalous fetuses. The RADIUS Study Group. Am J Obstet Gynecol. 1994 Aug;171(2):392–9.
60. Fleming A, Corbett G, McParland P. National Clinical Practice Guideline – The Fetal Anatomy Ultrasound. 2023 Jan;
61. WHO antenatal care recommendations for a positive pregnancy experience: Maternal and fetal assessment update: imaging ultrasound before 24 weeks of pregnancy [Internet]. Geneva: World Health Organization; 2022 [cited 2023 Jan 18]. (WHO Guidelines Approved by the Guidelines Review Committee). Available from: http://www.ncbi.nlm.nih.gov/books/NBK579604/
62. NHS Fetal Anomaly Screening Programme (FASP). Fetal anomaly screening programme handbook [Internet]. NHS England; 2022. Available from: https://www.gov.uk/government/publications/fetal-anomaly-screening-programme-handbook
63. Aldridge N, Pandya P, Rankin J, Miller N, Broughan J, Permalloo N, et al. Detection rates of a national fetal anomaly screening programme: A national cohort study. BJOG Int J Obstet Gynaecol. 2023 Jan;130(1):51–8.
64. Boyd PA, Rounding C, Chamberlain P, Wellesley D, Kurinczuk JJ. The evolution of prenatal screening and diagnosis and its impact on an unselected population over an 18-year period. BJOG Int J Obstet Gynaecol. 2012 Aug;119(9):1131–40.
65. Braz P, Machado A, Matias Dias C. The impact of prenatal diagnosis on congenital anomaly outcomes: Data from 1997 to 2016. Eur J Med Genet. 2018 Sep;61(9):508–12.
66. Moncrieff G, Finlayson K, Cordey S, McCrimmon R, Harris C, Barreix M, et al. First and second trimester ultrasound in pregnancy: A systematic review and metasynthesis of the views and experiences of pregnant women, partners, and health workers. PloS One. 2021;16(12):e0261096.
67. Kaelin Agten A, Xia J, Servante JA, Thornton JG, Jones NW. Routine ultrasound for fetal assessment before 24 weeks' gestation. Cochrane Pregnancy and Childbirth Group, editor. Cochrane Database Syst Rev [Internet]. 2021 Aug 26 [cited 2022 Mar 7];2021(8). Available from: http://doi.wiley.com/10.1002/14651858.CD014698
68. Grytten J, Skau I, Sørensen R, Eskild A. Does the Use of Diagnostic Technology Reduce Fetal Mortality? Health Serv Res. 2018 Dec;53(6):4437–59.
69. Lapaire O; Alder J; Peukert R; Holzgreve W; Tercanli S. Two- versus three-dimensional ultrasound in the second and third trimester of pregnancy: impact on recognition and maternal-fetal bonding. A prospective pilot study. Arch Gynecol Obstet. 2007 Nov;276(5):475–9.
70. Ji EK, Pretorius DH, Newton R, Uyan K, Hull AD, Hollenbach K, et al. Effects of ultrasound on maternal-fetal bonding: a comparison of two- and three-dimensional imaging. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2005 May;25(5):473–7.
71. Clinical radiology UK workforce census 2017 report. Clin Radiol. 2017;
72. Salomon LJ, Alfirevic Z, Berghella V, Bilardo CM, Chalouhi GE, Da Silva Costa F, et al. ISUOG Practice Guidelines (updated): performance of the routine mid-trimester fetal ultrasound scan. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2022 Jun;59(6):840–56.
73. Reddy UM, Abuhamad AZ, Levine D, Saade GR, Fetal Imaging Workshop Invited Participants. Fetal imaging: Executive summary of a Joint Eunice Kennedy Shriver National

Institute of Child Health and Human Development, Society for Maternal-Fetal Medicine, American Institute of Ultrasound in Medicine, American College of Obstetricians and Gynecologists, American College of Radiology, Society for Pediatric Radiology, and Society of Radiologists in Ultrasound Fetal Imaging Workshop. Am J Obstet Gynecol. 2014 May;210(5):387–97.
74. Cargill Y, Morin L. No. 223-Content of a Complete Routine Second Trimester Obstetrical Ultrasound Examination and Report. J Obstet Gynaecol Can JOGC J Obstet Gynecol Can JOGC. 2017 Aug;39(8):e144–9.
75. Schwärzler P, Senat MV, Holden D, Bernard JP, Masroor T, Ville Y. Feasibility of the second-trimester fetal ultrasound examination in an unselected population at 18, 20 or 22 weeks of pregnancy: a randomized trial. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 1999 Aug;14(2):92–7.
76. NHS Fetal Anomaly Screening Programme (FASP). Guidance: Fetal anomaly screening standards valid for data collected from 1 April 2022 [Internet]. 2022. Available from: https://www.gov.uk/government/publications/fetal-anomaly-screening-programme-standards/fetal-anomaly-screening-standards-valid-for-data-collected-from-1-april-2022#fasp-s08-referral-timeliness-to-intervention-20-week-screening-scan
77. Rydberg C, Tunón K. Detection of fetal abnormalities by second-trimester ultrasound screening in a non-selected population. Acta Obstet Gynecol Scand. 2017 Feb;96(2):176–82.
78. Alt S, Arezina J, Arnold J, Bailey S, Beety H, Bender-Atik R, et al. Improving News Delivery in Ultrasound (INDira) Contributors.
79. AIUM-ACR-ACOG-SMFM-SRU Practice Parameter for the Performance of Standard Diagnostic Obstetric Ultrasound Examinations. J Ultrasound Med Off J Am Inst Ultrasound Med. 2018 Nov;37(11):E13–24.
80. Smith RP, Titmarsh S, Overton TG. Improving patients' knowledge of the fetal anomaly scan: Anomaly scan knowledge. Ultrasound Obstet Gynecol. 2004 Dec;24(7):740–4.
81. Lalor JG, Devane D. Information, knowledge and expectations of the routine ultrasound scan. Midwifery. 2007 Mar;23(1):13–22.
82. Lalor JG, Devane D, Begley CM. Unexpected Diagnosis of Fetal Abnormality: Women's Encounters with Caregivers. Birth. 2007 Mar;34(1):80–8.
83. Johnson J, Dunning A, Sattar R, Arezina J, Karkowsky EC, Thomas S, et al. Delivering unexpected news via obstetric ultrasound: A systematic review and meta-ethnographic synthesis of expectant parent and staff experiences. Sonography. 2020 Jun;7(2):61–77.
84. Eurenius K, Axelsson O, Gällstedt-Fransson I, Sjöden PO. Perception of information, expectations and experiences among women and their partners attending a second-trimester routine ultrasound scan. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 1997 Feb;9(2):86–90.
85. Lalor J, Begley CM, Galavan E. Recasting Hope: a process of adaptation following fetal anomaly diagnosis. Soc Sci Med 1982. 2009 Feb;68(3):462–72.
86. Australasian Society for Ultrasound in Medicine. Parent-centred communication in obstetric ultrasound. 2022 Mar.
87. Johnson J, Arezina J, Tomlin L, Alt S, Arnold J, Bailey S, et al. UK consensus guidelines for the delivery of unexpected news in obstetric ultrasound: The ASCKS framework. Ultrasound. 2020 Nov;28(4):235–45.
88. Sciscione A, Berghella V, Blackwell S, Boggess K, Helfgott A, Iriye B, et al. Society for Maternal-Fetal Medicine (SMFM) Special Report: the maternal-fetal medicine subspecialists' role within a health care system. Am J Obstet Gynecol. 2014 Dec;211(6):607–16.

89. Royal College of Obstetricians and Gynaecologists. Subspecialty Training Maternal & Fetal Medicine Definitive Document 2019. London, UK; 2019 Oct.
90. NHS England. Fetal Medicine Service Specifications. Report No.: E12a.
91. Baschat AA, Blackwell SB, Chatterjee D, Cummings JJ, Emery SP, Hirose S, et al. Care Levels for Fetal Therapy Centers. Obstet Gynecol. 2022 Jun;139(6):1027–42.
92. Moon-Grady AJ, Baschat A, Cass D, Choolani M, Copel JA, Crombleholme TM, et al. Fetal Treatment 2017: The Evolution of Fetal Therapy Centers - A Joint Opinion from the International Fetal Medicine and Surgical Society (IFMSS) and the North American Fetal Therapy Network (NAFTNet). Fetal Diagn Ther. 2017;42(4):241–8.
93. Moldenhauer JS, Johnson A, Van Mieghem T. International Society for Prenatal Diagnosis 2022 DEBATE: There should be formal accreditation and ongoing quality assurance/review for units offering fetal therapy that includes public reporting of outcomes. Prenat Diagn. 2022 Dec 21;pd.6286.
94. European Association of Perinatal Medicine. Subspecialist Training Programme in Maternal-Fetal Medicine. 2022 Nov.
95. Accreditation Council for Graduate Medical Education (ACGME). ACGME Program Requirements for Graduate Medical Education in Maternal-Fetal Medicine. 2022 Feb.
96. Stone J, Abu-Rustum RS, Bromley B, Fuchs KM, Anton T, Cooper T, et al. Curriculum and competency assessment program for training maternal-fetal medicine fellows in the performance of the detailed obstetric ultrasound examination. Am J Obstet Gynecol. 2023 Feb;228(2):B2–9.
97. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Certification in Maternal and Fetal Medicine. 2023.
98. Navaratnam K, Alfirevic Z, the Royal College of Obstetricians and Gynaecologists. Amniocentesis and chorionic villus sampling: Green-top Guideline No. 8. BJOG Int J Obstet Gynaecol [Internet]. 2022 Jan [cited 2022 Dec 21];129(1). Available from: https://onlinelibrary.wiley.com/doi/10.1111/1471-0528.16821
99. Monaghan KG, Leach NT, Pekarek D, Prasad P, Rose NC, ACMG Professional Practice and Guidelines Committee. The use of fetal exome sequencing in prenatal diagnosis: a points to consider document of the American College of Medical Genetics and Genomics (ACMG). Genet Med Off J Am Coll Med Genet. 2020 Apr;22(4):675–80.
100. Lees CC, Stampalija T, Baschat A, da Silva Costa F, Ferrazzi E, Figueras F, et al. ISUOG Practice Guidelines: diagnosis and management of small-for-gestational-age fetus and fetal growth restriction. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2020 Aug;56(2):298–312.
101. Akkermans J, Peeters SHP, Klumper FJ, Lopriore E, Middeldorp JM, Oepkes D. Twenty-Five Years of Fetoscopic Laser Coagulation in Twin-Twin Transfusion Syndrome: A Systematic Review. Fetal Diagn Ther. 2015;38(4):241–53.
102. Bamberg C, Hecher K. Twin-to-twin transfusion syndrome: Controversies in the diagnosis and management. Best Pract Res Clin Obstet Gynaecol. 2022 Nov;84:143–54.
103. Kontopoulos E, Chmait RH, Quintero RA. Twin-to-Twin Transfusion Syndrome: Definition, Staging, and Ultrasound Assessment. Twin Res Hum Genet Off J Int Soc Twin Stud. 2016 Jun;19(3):175–83.
104. Sacco A, Ushakov F, Thompson D, Peebles D, Pandya P, De Coppi P, et al. Fetal surgery for open spina bifida. Obstet Gynaecol J Contin Prof Dev R Coll Obstet Gynaecol. 2019 Oct;21(4):271–82.

105. Danzer E, Rintoul NE, van Meurs KP, Deprest J. Prenatal management of congenital diaphragmatic hernia. Semin Fetal Neonatal Med. 2022 Dec;27(6):101406.
106. European Board and College of Obstetricians and Gynaecologists Subspecialist Training Programme in Maternofetal and Perinatal Medicine. Report of the Postgraduate Training and Assessment Working Party.
107. Wood S, Owen J, Jenkins S, Harper L. The Utility of Repeat Midtrimester Anatomy Ultrasound for Anomaly Detection. Am J Perinatol. 2018 Dec;35(14):1346–51.
108. RCOG London. Termination of Pregnancy for Fetal Abnormality. 2010 May; Available from: https://www.rcog.org.uk/media/21lfvl0e/terminationpregnancyreport18may2010.pdf
109. Ralston SJ, Leuthner SR, American College of Obstetricians and Gynecologists, Committee on Ethics, American Academy of Pediatrics, Committee on Bioethics. Maternal-Fetal Intervention and Fetal Care Centers. Pediatrics. 2011 Aug 1;128(2):e473–8.
110. Hunt LM, de Voogd KB, Castañeda H. The routine and the traumatic in prenatal genetic diagnosis: does clinical information inform patient decision-making? Patient Educ Couns. 2005 Mar;56(3):302–12.
111. National Women and Infants Health Programme, HSE. National Standards for Bereavement Care Following Pregnancy Loss and Perinatal Death [Internet]. 2022. Report No.: 2. Available from: https://www.hse.ie/eng/services/list/3/maternity/bereavement-care/
112. Wilkinson D, Thiele P, Watkins A, De Crespigny L. Fatally flawed? A review and ethical analysis of lethal congenital malformations: Lethal malformations. BJOG Int J Obstet Gynaecol. 2012 Oct;119(11):1302–8.
113. Brown SD, Ecker JL, Ward JRM, Halpern EF, Sayeed SA, Buchmiller TL, et al. Prenatally diagnosed fetal conditions in the age of fetal care: does who counsels matter? Am J Obstet Gynecol. 2012 May;206(5):409.e1-409.e11.
114. Statham H, Solomou W, Green J. Late termination of pregnancy: law, policy and decision making in four English fetal medicine units: BJOG Int J Obstet Gynaecol. 2006 Dec;113(12):1402–11.
115. Heuser CC, Sagaser KG, Christensen EA, Johnson CT, Lappen JR, Horvath S. Society for Maternal-Fetal Medicine Special Statement: A critical examination of abortion terminology as it relates to access and quality of care. Am J Obstet Gynecol. 2022 Dec;S0002937822025807.
116. Power S, Meaney S, O'Donoghue K. Fetal medicine specialist experiences of providing a new service of termination of pregnancy for fatal fetal anomaly: a qualitative study. BJOG Int J Obstet Gynaecol. 2021 Mar;128(4):676–84.
117. RCOG London. The Care of Women Requesting Induced Abortion: Evidence-based Clinical Guideline Number 7 [Internet]. 2011. Available from: https://www.rcog.org.uk/media/nwcjrf0o/abortion-guideline_web_1.pdf
118. Habiba M, Da Frè M, Taylor D, Arnaud C, Bleker O, Lingman G, et al. Late termination of pregnancy: a comparison of obstetricians' experience in eight European countries: Obstetricians' experience of late termination of pregnancy. BJOG Int J Obstet Gynaecol. 2009 Sep;116(10):1340–9.
119. Pasquini L, Pontello V, Kumar S. Intracardiac injection of potassium chloride as method for feticide: experience from a single UK tertiary centre. BJOG Int J Obstet Gynaecol. 2008 Mar;115(4):528–31.

120. Maurice P, Letourneau A, Benachi A, Jouannic JM. Feticide in second- and third-trimester termination of pregnancy for fetal anomalies: Results of a national survey. Prenat Diagn. 2019 Dec;39(13):1269–72.
121. Garne E, Khoshnood B, Loane M, Boyd P, Dolk H, The EUROCAT Working Group. Termination of pregnancy for fetal anomaly after 23 weeks of gestation: a European register-based study: Termination of pregnancy for fetal anomaly after 23 weeks of gestation. BJOG Int J Obstet Gynaecol. 2010 May;117(6):660–6.
122. Graham RH, Mason K, Rankin J, Robson SC. The role of feticide in the context of late termination of pregnancy: a qualitative study of health professionals' and parents' views. Prenat Diagn. 2009 Sep;29(9):875–81.
123. Fay V, Thomas S, Slade P. Maternal-fetal medicine specialists' experiences of conducting feticide as part of termination of pregnancy: a qualitative study. Prenat Diagn. 2016 Jan;36(1):92–9.
124. SANDS UK. National Bereavement Care Pathway: Termination of Pregnancy due to Fetal Anomaly (TOPFA) Full Guidance Document [Internet]. 2022 Jul. Available from: https://nbcpathway.org.uk/
125. Heaney S, Tomlinson M, Aventin Á. Termination of pregnancy for fetal anomaly: a systematic review of the healthcare experiences and needs of parents. BMC Pregnancy Childbirth. 2022 May 26;22(1):441.
126. Stewart B, Kane SC, Unterscheider J. Medical termination of pregnancy for fetal anomaly at or beyond 20 weeks' gestation—What are the maternal risks? Prenat Diagn. 2022 Nov;42(12):1562–70.
127. Guidelines on autopsy practice: Fetal autopsy. The Royal College of Pathologists. June 2017.
128. Meaney S, Gallagher S, Lutomski JE, O'Donoghue K. Parental decision making around perinatal autopsy: a qualitative investigation. Health Expect. 2015 Dec;18(6):3160–71.
129. Helps Ä, O'Donoghue K, O'Connell O, Leitao S. Bereaved parents involvement in maternity hospital perinatal death review processes: 'Nobody even thought to ask us anything'. Health Expect Int J Public Particip Health Care Health Policy. 2022 Nov 6;
130. Statham H, Solomou W, Chitty L. Prenatal diagnosis of fetal abnormality: psychological effects on women in low-risk pregnancies. Baillieres Best Pract Res Clin Obstet Gynaecol. 2000 Aug;14(4):731–47.
131. Meaney S, Everard CM, Gallagher S, O'Donoghue K. Parents' concerns about future pregnancy after stillbirth: a qualitative study. Health Expect. 2017 Aug;20(4):555–62.
132. Brown SD, Donelan K, Martins Y, Sayeed SA, Mitchell C, Buchmiller TL, et al. Does professional orientation predict ethical sensitivities? Attitudes of paediatric and obstetric specialists toward fetuses, pregnant women and pregnancy termination. J Med Ethics. 2014 Feb;40(2):117–22.
133. Wilkinson D. Fatal fetal paternalism. J Med Ethics. 2012 Jul;38(7):396–7.
134. Fraser J. The morbidity and mortality meeting: time for a different approach? Arch Dis Child. 2016 Jan;101(1):4–8.
135. Burke B, Boyd S, McNamara K, O'Donoghue K. Barriers to attendance at a tertiary hospital's perinatal mortality meeting. Ir J Med Sci. 2022 Sep 2;1–6.
136. George J. Medical morbidity and mortality conferences: past, present and future. Postgrad Med J. 2017 Mar;93(1097):148–52.

137. Rogers L, Hughes Spence S, Aivalli P, De Brún A, McAuliffe E. A systematic review critically appraising quantitative survey measures assessing power dynamics among multidisciplinary teams in acute care settings. J Interprof Care. 2023 Jan 28;1–16.
138. Hain R, Rapoport A, Meiring M, Goldman A, editors. Oxford textbook of palliative care for children 3e. 3rd ed. New York: Oxford University Press; 2021. (Oxford textbooks).
139. British Association of Perinatal Medicine (BAPM). Palliative Care (Supportive and End of Life Care) A Framework for Clinical Practice in Perinatal Medicine. 2010 Aug.
140. Barbeyrac C, Roth P, Noël C, Anselem O, Gaudin A, Roumegoux C, et al. The role of perinatal palliative care following prenatal diagnosis of major, incurable fetal anomalies: a multicentre prospective cohort study. BJOG Int J Obstet Gynaecol. 2022 Apr;129(5):752–9.
141. Breeze ACG, Lees CC, Kumar A, Missfelder-Lobos HH, Murdoch EM. Palliative care for prenatally diagnosed lethal fetal abnormality. Arch Dis Child Fetal Neonatal Ed. 2007 Jan;92(1):F56-58.
142. Balaguer A, Martín-Ancel A, Ortigoza-Escobar D, Escribano J, Argemi J. The model of palliative care in the perinatal setting: a review of the literature. BMC Pediatr. 2012 Dec;12(1):25.
143. Hain R, Rapoport A, Meiring M, Goldman A, editors. Oxford textbook of palliative care for children 3e. 3rd ed. New York: Oxford University Press; 2021. (Oxford textbooks).
144. Wellington, Ministry of Health, New Zealand. New Zealand Aotearoa Abortion Clinical Guideline. 2021;
145. Nuffield Council on Bioethics. Critical care decisions in fetal and neonatal medicine: ethical issues. 2006.
146. UK Clinical Genetics Society [Internet]. 2022 Nov. Available from: https://www.clingensoc.org/
147. Commission Regulation (EU) No 213/2011 of 3 March 2011 amending Annexes II and V to Directive 2005/36/EC of the European Parliament and of the Council on the recognition of professional qualifications Text with EEA relevance. Document 32011R0213. [Internet]. 2011. Available from: https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32011R0213
148. Middleton A, Marks P, Bruce A, Protheroe-Davies LK, King C, Claber O, et al. The role of genetic counsellors in genomic healthcare in the United Kingdom: a statement by the Association of Genetic Nurses and Counsellors. Eur J Hum Genet EJHG. 2017 Mar 22;25(6):659–61.
149. Middleton A, Taverner N, Houghton C, Smithson S, Balasubramanian M, Elmslie F. Scope of professional roles for genetic counsellors and clinical geneticists in the United Kingdom : Position on behalf of the Association of Genetic Nurses and Counsellors and the Clinical Genetics Society. Eur J Hum Genet EJHG. 2023 Jan;31(1):9–12.
150. F M, H AS, S D, S H, Dj M, S A, et al. Evolving fetal phenotypes and clinical impact of progressive prenatal exome sequencing pathways: cohort study. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol [Internet]. 2022 Jun [cited 2023 Jan 18];59(6). Available from: https://pubmed.ncbi.nlm.nih.gov/34940998/
151. Han J, Yang YD, He Y, Liu WJ, Zhen L, Pan M, et al. Rapid prenatal diagnosis of skeletal dysplasia using medical trio exome sequencing: Benefit for prenatal counseling and pregnancy management. Prenat Diagn. 2020 Apr;40(5):577–84.
152. Lei TY, Fu F, Li R, Yu QX, Du K, Zhang WW, et al. Whole-exome sequencing in the evaluation of fetal congenital anomalies of the kidney and urinary tract detected by ultrasonography. Prenat Diagn. 2020 Sep;40(10):1290–9.

153. Chandler NJ, Scotchman E, Mellis R, Ramachandran V, Roberts R, Chitty LS. Lessons learnt from prenatal exome sequencing. Prenat Diagn. 2022 Jun;42(7):831–44.
154. Lord J, McMullan DJ, Eberhardt RY, Rinck G, Hamilton SJ, Quinlan-Jones E, et al. Prenatal exome sequencing analysis in fetal structural anomalies detected by ultrasonography (PAGE): a cohort study. Lancet Lond Engl. 2019 Feb 23;393(10173):747–57.
155. Patterson J, Wellesley D, Morgan S, Cilliers D, Allen S, Gardiner CA, et al. Prenatal chromosome microarray: 'The UK experience'. A survey of reporting practices in UK genetic services (2012-2019). Prenat Diagn. 2021 May;41(6):661–7.
156. Carol Gardiner, Diana Wellesley, Mark D Kilby and Bronwyn Kerr, on behalf of the Joint Committee on Genomics in Medicine. Recommendations for the use of chromosome microarray in pregnancy. 2015 Jun.
157. Society for Maternal-Fetal Medicine (SMFM). Electronic address: pubs@smfm.org, Dugoff L, Norton ME, Kuller JA. The use of chromosomal microarray for prenatal diagnosis. Am J Obstet Gynecol. 2016 Oct;215(4):B2-9.
158. Scocchia A, Kangas-Kontio T, Irving M, Hero M, Saarinen I, Pelttari L, et al. Diagnostic utility of next-generation sequencing-based panel testing in 543 patients with suspected skeletal dysplasia. Orphanet J Rare Dis. 2021 Oct 9;16(1):412.
159. Chitty LS, Mason S, Barrett AN, McKay F, Lench N, Daley R, et al. Non-invasive prenatal diagnosis of achondroplasia and thanatophoric dysplasia: next-generation sequencing allows for a safer, more accurate, and comprehensive approach. Prenat Diagn. 2015 Jul;35(7):656–62.
160. Mone F, Eberhardt RY, Hurles ME, Mcmullan DJ, Maher ER, Lord J, et al. Fetal hydrops and the Incremental yield of Next-generation sequencing over standard prenatal Diagnostic testing (FIND) study: prospective cohort study and meta-analysis. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2021 Oct;58(4):509–18.
161. Sparks TN, Lianoglou BR, Adami RR, Pluym ID, Holliman K, Duffy J, et al. Exome Sequencing for Prenatal Diagnosis in Nonimmune Hydrops Fetalis. N Engl J Med. 2020 Oct 29;383(18):1746–56.
162. Petrovski S, Aggarwal V, Giordano JL, Stosic M, Wou K, Bier L, et al. Whole-exome sequencing in the evaluation of fetal structural anomalies: a prospective cohort study. Lancet Lond Engl. 2019 Feb 23;393(10173):758–67.
163. Mellis R, Oprych K, Scotchman E, Hill M, Chitty LS. Diagnostic yield of exome sequencing for prenatal diagnosis of fetal structural anomalies: A systematic review and meta-analysis. Prenat Diagn. 2022 May;42(6):662–85.
164. Monaghan KG, Leach NT, Pekarek D, Prasad P, Rose NC. The use of fetal exome sequencing in prenatal diagnosis: a points to consider document of the American College of Medical Genetics and Genomics (ACMG). Genet Med. 2020 Apr;22(4):675–80.
165. Van den Veyver IB, Chandler N, Wilkins-Haug LE, Wapner RJ, Chitty LS, ISPD Board of Directors. International Society for Prenatal Diagnosis Updated Position Statement on the use of genome-wide sequencing for prenatal diagnosis. Prenat Diagn. 2022 May;42(6):796–803.
166. Clark MM, Stark Z, Farnaes L, Tan TY, White SM, Dimmock D, et al. Meta-analysis of the diagnostic and clinical utility of genome and exome sequencing and chromosomal microarray in children with suspected genetic diseases. NPJ Genomic Med. 2018;3:16.
167. Lazier J, Hartley T, Brock JA, Caluseriu O, Chitayat D, Laberge AM, et al. Clinical application of fetal genome-wide sequencing during pregnancy: position statement of the Canadian College of Medical Geneticists. J Med Genet. 2022 Oct;59(10):931–7.

168. Fetal and Perinatal Pathology, Report of a Joint Working Party. Royal College of Obstetricians and Gynaecologists and Royal College of Pathologists, June 2001.
169. Boyd PA, Tondi F, Hicks NR, Chamberlain PF. Autopsy after termination of pregnancy for fetal anomaly: retrospective cohort study. BMJ. 2004 Jan 17;328(7432):137.
170. Peyronnet V, Anselem O, Loeuillet L, Roux N, Tsatsaris V. Diagnostic value of fetal autopsy after early termination of pregnancy for fetal anomalies. PloS One. 2022;17(10):e0275674.
171. Richards S, Aziz N, Bale S, Bick D, Das S, Gastier-Foster J, et al. Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology. Genet Med Off J Am Coll Med Genet. 2015 May;17(5):405–24.
172. Quinlan-Jones E, Lord J, Williams D, Hamilton S, Marton T, Eberhardt RY, et al. Molecular autopsy by trio exome sequencing (ES) and postmortem examination in fetuses and neonates with prenatally identified structural anomalies. Genet Med Off J Am Coll Med Genet. 2019 May;21(5):1065–73.
173. Byrne AB, Arts P, Ha TT, Kassahn KS, Pais LS, O'Donnell-Luria A, et al. Genomic autopsy to identify underlying causes of pregnancy loss and perinatal death. Nat Med [Internet]. 2023 Jan 19 [cited 2023 Jan 21]; Available from: https://www.nature.com/articles/s41591-022-02142-1
174. Nuzum D, Meaney S, O'Donoghue K. The impact of stillbirth on bereaved parents: A qualitative study. Warland J, editor. PLOS ONE. 2018 Jan 24;13(1):e0191635.
175. O'Connell O, Meaney S, O'Donoghue K. Caring for parents at the time of stillbirth: How can we do better? Women Birth J Aust Coll Midwives. 2016 Aug;29(4):345–9.
176. Koopmans L, Wilson T, Cacciatore J, Flenady V. Support for mothers, fathers and families after perinatal death. Cochrane Database Syst Rev. 2013 Jun 19;2013(6):CD000452.
177. Hendriks MJ, Abraham A. Perinatal loss and parental loneliness: Narratives of late termination of pregnancy. Death Stud. 2022 Jul 3;46(6):1490–500.
178. Stainton MC, McNeil D, Harvey S. Maternal tasks of uncertain motherhood. Matern Child Nurs J. 1992;20(3–4):113–23.
179. Drugan A, Greb A, Johnson MP, Krivchenia EL, Uhlmann WR, Moghissi KS, et al. Determinants of parental decisions to abort for chromosome abnormalities. Prenat Diagn. 1990 Aug;10(8):483–90.
180. Jackson P, Power-Walsh S, Dennehy R, O'Donoghue K. Fatal Fetal Anomaly: Exploring Experiences of Women and their Partners. Prenat Diagn. 2023 Jan 13;
181. Yarcheski A, Mahon NE, Yarcheski TJ, Hanks MM, Cannella BL. A meta-analytic study of predictors of maternal-fetal attachment. Int J Nurs Stud. 2009 May;46(5):708–15.
182. Lotto R, Armstrong N, Smith LK. Care provision during termination of pregnancy following diagnosis of a severe congenital anomaly - A qualitative study of what is important to parents. Midwifery. 2016 Dec;43:14–20.
183. McCoyd JLM. Pregnancy interrupted: loss of a desired pregnancy after diagnosis of fetal anomaly. J Psychosom Obstet Gynaecol. 2007 Mar;28(1):37–48.
184. Lotto R, Smith LK, Armstrong N. Diagnosis of a severe congenital anomaly: A qualitative analysis of parental decision making and the implications for healthcare encounters. Health Expect Int J Public Particip Health Care Health Policy. 2018 Jun;21(3):678–84.
185. Alkazaleh F, Thomas M, Grebenyuk J, Glaude L, Savage D, Johannesen J, et al. What women want: women's preferences of caregiver behavior when prenatal sonography

findings are abnormal. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2004 Jan;23(1):56–62.
186. Lotto R, Smith LK, Armstrong N. Clinicians' perspectives of parental decision-making following diagnosis of a severe congenital anomaly: a qualitative study. BMJ Open. 2017 Jun 6;7(5):e014716.
187. Chitty LS, Barnes CA, Berry C. Continuing with pregnancy after a diagnosis of lethal abnormality: experience of five couples and recommendations for management. BMJ. 1996 Aug 24;313(7055):478–80.
188. Richardson PEH. David Sackett and the birth of Evidence Based Medicine: How to Practice and Teach EBM. BMJ. 2015 Jun 8;350:h3089.
189. National Clinical Effectiveness Committee Department of Health. National Clinical Effectiveness Committee Standards for Clinical Practice Guidance. 2015.
190. HSE National Framework for developing PPPGs [Internet]. HSE. 2021. Available from: https://www.hse.ie/eng/about/who/qid/use-of-improvement-methods/nationalframeworkdevelopingpolicies/
191. Woolf SH, Grol R, Hutchinson A, Eccles M, Grimshaw J. Clinical guidelines: potential benefits, limitations, and harms of clinical guidelines. BMJ. 1999 Feb 20;318(7182):527–30.
192. Graham ID. Evaluation and adaptation of clinical practice guidelines. Evid Based Nurs. 2005 Jul 1;8(3):68–72.
193. Pagano D, Home P, Irs A, Ledermann J, Curigliano G, Iwatani T, et al. The path for medical associations to sponsor trustworthy guidelines: is it feasible? J R Soc Med. 2022 Jul;115(7):252–6.
194. Costa ML, Cecatti JG, Milanez HM, Souza JP, Gülmezoglu M. Audit and feedback: effects on professional obstetrical practice and healthcare outcomes in a university hospital. Acta Obstet Gynecol Scand. 2009;88(7):793–800.
195. Ivers N, Jamtvedt G, Flottorp S, Young JM, Odgaard-Jensen J, French SD, et al. Audit and feedback: effects on professional practice and healthcare outcomes. Cochrane Database Syst Rev. 2012 Jun 13;(6):CD000259.
196. Mahgerefteh S, Kruskal JB, Yam CS, Blachar A, Sosna J. Peer review in diagnostic radiology: current state and a vision for the future. Radiogr Rev Publ Radiol Soc N Am Inc. 2009;29(5):1221–31.
197. The Royal College of Radiologists, the Society and College of Radiographers. Standards for the provision of an ultrasound service. 2014;30.
198. Yaqub M, Kelly B, Stobart H, Napolitano R, Noble JA, Papageorghiou AT. Quality-improvement program for ultrasound-based fetal anatomy screening using large-scale clinical audit. Ultrasound Obstet Gynecol Off J Int Soc Ultrasound Obstet Gynecol. 2019 Aug;54(2):239–45.
199. Helps A, Leitao S, Greene R, O'Donoghue K. Perinatal mortality audits and reviews: Past, present and the way forward. Eur J Obstet Gynecol Reprod Biol. 2020 Jul;250:24–30.
200. The Interprofessional CPD and Lifelong Learning, UK Working Group. Principles for continuing professional development and lifelong learning in health and social care. 2019 Jan.

Glossary of terms and abbreviations

ACMG	American College of Medical Genetics and Genomics
ACOG	The American College of Obstetrics and Gynaecology
AIUM	The American Institute of Ultrasound in Medicine
BMUS	British Medical Ultrasound Society
CDC	The Centres for Disease Control and Prevention
cffDNA	Cell-free fetal DNA
CCMG	Canadian College of Medical Genetics
CHO	Community Health Organisation
CMS	Clinical Midwife Specialist
CPD	Continuing Professional Development
CVS	Chorionic Villous Sampling
EBCOG	The European Board and College of Obstetricians and Gynaecologists
EUROCAT	European network of population-based registries for the epidemiological surveillance of congenital anomalies
FASP	National Health Service Fetal Anomaly Screening Programme
FFA	Fatal Fetal Anomaly
FIGO	The International Federation of Gynaecology and Obstetrics
HSE	Health Service Executive
ICGP	Irish College of General Practitioners
IOG	Institute of Obstetricians and Gynaecologists
ISPD	The International Society for Prenatal Diagnosis
ISUOG	International Society of Ultrasound in Obstetrics and Gynaecology
MDT	Multi-Disciplinary Team
MFM	Maternal Fetal Medicine
NAFT_Net	The North American Fetal Therapy Network
NHS	National Health Service
NICE	The National Institute for Health and Care
NIPS	Non-Invasive Prenatal Screening
NIPT	Non-Invasive Prenatal Testing
NT	Nuchal translucency
NWIHP	National Women and Infants Health Programme
PME	Post Mortem Examination
PPC	Perinatal Palliative Care
RANZCOG	Australia and New Zealand College of Obstetricians and Gynaecologists
RCOG	The Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RCPath	Royal College of Pathology

RCPI	Royal College of Physicians Ireland
RCR	The Royal College of Radiologists
RCT	Randomised controlled trial
ScOR	The Society and College of Radiographers
SMFM	The Society for Maternal and Fetal Medicine
SOGC	The Society of Obstetricians and Gynaecologists of Canada
TFMR	Termination for Medical Reasons
TOP	Termination of Pregnancy
TOPFA	Termination of Pregnancy for Fetal Anomaly
WHO	World Health Organisation

Section 3.0

Appendices

Section 11 Review Questionnaire - Primary Care

Introduction to the Review of Termination of Pregnancy (TOP) services, as provided under Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018.

Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018, provides the legislative framework for the provision of termination of pregnancy services in circumstances where there is present a condition likely to lead to the death of the fetus. Provision of this component of termination services commenced in Ireland in January 2019. It is now incumbent on the HSE to undertake a review of this relatively new and complex service, to identify and evaluate what changes and/or improvements are required in this service in accordance with the above Act so as to improve its safety and quality from both a service provider and service user perspective.

This survey provides an opportunity for key stakeholders involved in the delivery and management of terminations under Section 11 of the Act to ensure their experience of the service is central to informing any recommendations which may be made. We would like to thank you in advance for your participation in the survey.

There are 3 sections in this survey with a total of 21 questions:

Section 1: Current service provision
Section 2: Future service provision
Section 3: Demographics

Section 1: GP Role/Participation - Current service provision

At what gestation do women usually present to your practice?

How long do your appointments with newly pregnant women take on average?

How often do newly pregnant women enquire about non-invasive prenatal screening (NIPS) (e.g. Harmony or Panorama) or any other form of first trimester screening?

How often do you discuss NIPS with newly pregnant women at their booking visit?

Do you provide written information on screening tests like NIPS to patients e.g. pamphlets etc?

How strongly to you agree or disagree with the following statement:
I feel knowledgeable enough about NIPS to discuss the screening tests, its limitations and benefits with my patients.

Are NIPS available from your practice?

How often do you seen patients who have had NIPS, subsequently presenting back to your practice with results (high or low risk)?

Have you referred patients for NIPS?

How often have you referred patients for NIPS?

Where do you refer patients to for NIPS?

Do you provided counselling/support to women pre-referral for NIPS?

Do you feel patients have a clear understanding of what the test is before having it?

Do you feel that clinics performing NIPS have a planned pathway for onward care after NIPS?

How easy is access to Early Pregnancy Assessment Unit for routine referral for;
How easy is access to maternity hospitals/units for first/booking visits?

Section 2: GP Role/Participation Questions - Future state of service

If NIPS was implemented in the first trimester do you feel you would be adequately equipped to discuss this with women routinely? (this programme may be traditional screening or NIPS)

If NIPS was implemented in the first trimester would you participate?

At what level would you participate? Please select all that apply.

Section 3: Demographics

What CHO are you based in?

In your professional opinion, how would you rate the level of awareness and knowledge of Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018 amongst the GP Community

In the context of this Review of the operation of Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018, if you have any further comments or observations, please note them here.

You have now reached the end of the survey. Please select the submit button below in order to complete the survey, or use the arrow button below to review your responses prior to final submission.

Section 11 review Questionnaire- Secondary Care

Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018, provides the legislative framework for the provision of termination services in circumstances where there is present a condition likely to lead to the death of the fetus. Provision commenced in January 2019.

The HSE is now undertaking a review of this relatively new and complex service, to identify and evaluate what changes and/or improvements are required in this service in accordance with Section 11 of the above Act. Results of this survey will be used to improve safety and quality of services provided under the Act.

This survey provides an opportunity for key stakeholders to ensure their experience of the services provided under section 11 are central to informing recommendations which will be made to the HSE's Chief Clinical Officer as the commissioner of the Review.

There are a number of sections in this survey. When you commence this survey and identify your role you will automatically be directed to the appropriate section(s). The survey should take between 5 and 15 minutes to complete, depending on your role.

The National Women and Infants Health Programme (NWIHP) would like to thank you in advance for your participation in the survey.

Section 1: Please identify your role from the list below.
Your role

Section 2: Unit Specific Information - Nursing/Midwifery
To be completed by the Director of Midwifery.

Are dating scans available for all women attending your service?

What is assessed as part of a routine dating scan within your hospital/unit? (Tick all that apply)

On average, at what gestation are dating scans performed in your service?

Who performs dating scans in your unit (Tick all that apply)?

Where are your dating scans predominantly performed?(Tick one option only)

Is an annual audit/report of the dating scan service conducted? This could include recall rates, diagnoses made, etc.

Are key findings from the annual audit/report included in your hospital/sites annual report?

Is there written information provided to women regarding fetal anomalies before the dating scan ?

What type of written information is provided? (Tick all that apply)

In relation to fetal anomalies, is written information given to women following abnormal findings on a dating scan?

What type of written information is provided? (Tick all that apply)

If a fetal anomaly is found on a dating ultrasound scan, what is the referral pathway to the fetal medicine service? (Tick all that apply)

Who usually co-ordinates referrals to fetal medicine? (Tick all that apply)

How are referrals to fetal medicine usually made?

What is the average wait time to be seen by the fetal medicine service?

How much communication is received back from the Fetal Medicine Service once the woman has been seen?

Are anomaly scans available for all women attending your service?

On average, at what gestation is the anomaly scan performed in your service?

Who performs the anomaly scan in your unit? (Tick all that apply)

Where are your anomaly scans predominantly performed? (Tick one option only)

Is an annual audit/report of the anomaly scan service conducted? This could include recall rates, diagnoses made, etc.

Are key findings from the annual audit/report referenced annual audit/report included in your hospital/sites annual report?

Is written information routinely provided to women regarding fetal anomalies before the anomaly scan ?

What type of written information is provided? (Tick all that apply)

Is written information routinely given to women following abnormal findings on an anomaly scan?

What type of written information is provided? (Tick all that apply)

Are women signposted to support groups following the discovery of a fetal anomaly on an anomaly scan?

If a fetal anomaly is found on an anomaly scan, what is the referral pathway to the fetal medicine service? (Tick all that apply)

Is this referral made by paper or electronically?

What is the average wait time to be seen by the fetal medicine service? (Tick one option)

How much communication is received back from the Fetal Medicine Service once the woman has been seen?

Is there a designated, identifiable co-ordinator in your unit for managing referrals to and from the fetal medicine service?

Who usually co-ordinates the referrals to and from the fetal medicine service? (Tick all that apply)

Is there a fetal medicine lead midwife/midwife sonographer in your hospital/unit?

Is there a fetal medicine unit manager post in your hospital/unit?

What level of care does your unit routinely provide for TOPFA cases? (Tick all that apply)

With regard to TOPFA cases, who does your unit provide care for? (Tick all that apply)

Does your hospital/unit provide dedicated counselling support to women following the diagnosis of a FFA?

Which of the following counsellors / supports are available? (Tick all that apply)

Do you have a CMS in Bereavement and Loss in post as of 1st September 2022?

Does the CMS in Bereavement & Loss attend your units MDT meetings?

Is the CMS in Bereavement & Loss involved in bereavement care for TOPFA cases?

What involvement do they have? (Tick all that apply)

Are the cases that you refer to a Fetal Medicine Centre/service audited and reported on each year?

Has TOPFA been the subject of education /training for nurses/midwives in your unit?

What education and training has been provided? (Tick all that apply)

In your professional opinion, how would you rate the level of awareness and knowledge of Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018 amongst your nursing and midwifery personnel? (Tick one only)

In the context of this Review of the operation of Section 11 of the Health (Regulation of Termination of Pregnancy Act) 2018, if you have any further comments or observations, please note them here.

You have now reached the end of your section. Please select the submit button below in order to complete the survey, or use the arrow button below to review your responses prior to final submission.

Section 3: Unit Specific Information - Obstetrics and Gynaecology

To be completed by the Clinical Lead in Obstetrics and Gynaecology
Does your service have a structured contractual arrangement and protected access to a Consultant Geneticist?

Does this Consultant have a special interest in Perinatal Genomics?

Does this Consultant Geneticist consult on / review cases for TOPFA?

How many sessions are contracted for Perinatal Genomics?

Are there genomics medical laboratory scientists in your hospital/unit?

Does your site provide a structured genetic counselling service?

Does the genetic counsellor work under the governance of a Consultant Clinical Geneticist?

Is this genetic counsellor role dedicated to perinatal genomics?

Does your hospital/unit have an SOP or other contractual arrangement for perinatal genetic testing with a laboratory in Ireland?

Does your hospital/unit have an SOP or other contractual arrangement for perinatal genetic testing with a laboratory outside of Ireland?

Does the patient pay for any/all of these tests? (Tick one option per row)

Does your unit have structured and stable access to a perinatal pathology service? (Tick one option)

At what point is the role of post-mortem usually discussed with the couple where TOPFA is being considered? (Tick all that apply)

Does your unit offer a perinatal post mortem examination after TOPFA?

Does your unit arrange for DNA storage for couples?

Where is the DNA stored? (Tick one option)

Does your unit report perinatal deaths after TOPFA to the local Coroner?

Do all women undergoing surgical TOP receive a standard of care, benchmarked against the surgical pathway as set out by the HSE/RCSI/COA guidelines on the model of care for elective surgery?

Is a full range of pain relief modalities for labour, including epidural analgesia, available to all women undergoing medical TOPFA?

How would you rate the availability of Anaesthesiology support for complications of TOPFA?

How would you rate the availability of Anaesthesiology support for pre-operative / pre-labour consultations for TOPFA?

Does your unit provide any of the following for TOPFA cases? (tick all that apply)

Do you routinely provide written information to women in relation to the review process (as per Section 13 of the Health (Regulation of Termination of Pregnancy) Act 2018)?

Has TOPFA been the subject of education / training for doctors in your unit?

What education and training has been provided? (Tick all that apply)

In your professional opinion, how would you rate the level of awareness and knowledge of Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018 amongst medical staff in your hospital/unit?

In the context of this Review of the operation of Section 11 of the Health (Regulation of Termination of Pregnancy Act) 2018, if you have any further comments or observations, please note them here.

You have now reached the end of your section. Please select the submit button below in order to complete the survey, or use the arrow button below to review your responses prior to final submission.

Section 5: Neonatology/Paediatrics
To be completed by the Consultant Neonatologist or Consultant Paediatrician who is the Clinical Lead

Do Neonatology / Paediatric personnel participate in antenatal consultations for major fetal anomaly, where the plan is TOPFA?

How often do Neonatology / Paediatric personnel participate in antenatal consultations for major fetal anomaly, where the plan is TOPFA?

Do Neonatology/Paediatric personnel attend the fetal medicine MDT meetings in the designated Fetal Medicine Centre for your service?

In what capacity do Neonatology / Paediatric personnel routinely attend the fetal medicine MDT meetings? (Tick all that apply)

Are Neonatal/Paediatric consultants involved in neonatal/perinatal palliative care after birth where an infant is born alive (e.g. TOPFA with no feticide after 22 weeks)?

In your hospital/unit do Neonatal/Paediatric personnel have any involvement with pregnancies returning to the local unit for delivery/TOPFA?

In your professional opinion, how would you rate the level of awareness and knowledge of Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018 amongst Neonatology/Paediatric personnel in your hospital/unit?

In the context of this Review of the operation of Section 11 of the Health (Regulation of Termination of Pregnancy Act) 2018, if you have any further comments or observations, please note them here

You have now reached the end of your section. Please select the submit button below in order to complete the survey, or use the arrow button below to review your responses prior to final submission.

Section 6: Perinatal Pathology
To be completed by the Consultant Perinatal Pathologist

In your hospital/unit, is a post-mortem service routinely available if requested for infants born after TOPFA?

In your hospital/unit, are there restrictions on gestation at which a post-mortem is performed after TOPFA?

Is there separate paperwork for Post-Mortem / Organ retention/ Burial for TOPFA cases?

Who is routinely involved in the consent process and post-mortem discussion with the couple? (Tick all that apply)

Does post-mortem genetic testing take place in your site/hospital?

What genetic testing is undertaken as part of the routine post-mortem process or pregnancy loss investigation process? (Tick all that apply)

Are pathologists involved in the fetal medicine MDT meeting?

In what capacity are pathologists involved in the fetal medicine MDT meeting? (Tick all that apply)

Are TOPFA cases discussed at a local or regional Perinatal Pathology MDT meeting? (Tick one option)

In your professional opinion, how would you rate the level of awareness and knowledge of Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018 amongst staff in your hospital/unit?

In the context of this Review of the operation of Section 11 of the Health (Regulation of Termination of Pregnancy Act) 2018, if you have any further comments or observations, please note them here.

You have now reached the end of your section. Please select the submit button below in order to complete the survey, or use the arrow button below to review your responses prior to final submission.

Section 8: Fetal Medicine
To be completed by the Consultant Fetal Medicine Specialist (Lead)

How many fetal medicine consultants are currently in post in your Fetal Medicine Centre?

How many fetal medicine consultant lists are run per week on average in your Fetal Medicine Centre?

How many fetal medicine consultant lists are run per week in a regional affiliated unit(s)?

Is there a designated, identifiable fetal medicine co-ordinator in post in your Fetal Medicine Centre?

What is the WTE of the fetal medicine co-ordinator in post in your Fetal Medicine Centre?

Is there a fetal medicine lead midwife/midwife sonographer in your Fetal Medicine Centre?

If yes, what is the WTE of the fetal medicine lead midwife/midwife sonographer in your Fetal Medicine Centre?

Is there a fetal medicine unit manager post in your Fetal Medicine Centre?

What grade is the fetal medicine unit manager post in your Fetal Medicine Centre?

What is the WTE of the fetal medicine unit manager post in your Fetal Medicine Centre?

Is there dedicated counselling support within your Fetal Medicine Centre?

Which of the following counsellors / supports are available? (Tick all that apply)

What information is given to women re. follow up care / plans for next pregnancy following a FA diagnosis? Please provide information re. content, format and source.

How would you rate the availability of Anaesthesiology support for pre-operative / pre-labour consultations?

Do fetal medicine MDT meetings take place in your Fetal Medicine Centre?

How often are the fetal medicine MDT meetings held? (Tick one option)

How are Fetal Medicine MDT meetings held? (Tick one option)

Which specialties attend the Fetal Medicine MDT meetings? (Tick all that apply)

Is attendance at the Fetal Medicine MDT meetings routinely recorded?

Are minutes of the Fetal Medicine MDT meetings routinely recorded?

Are decisions made at the Fetal Medicine MDT meetings around / in TOPFA recorded?

Where are decisions made at the Fetal Medicine MDT around / in cases of TOPFA recorded? (Tick all that apply)

What is the role of the Fetal Medicine MDT in considering TOPFA? (tick all that apply)

What is the decision making approach of the Fetal Medicine MDT in considering TOPFA? (Tick one option)

Do you routinely provide written information to women on clinical decisions made around TOPFA? (Tick one option)

Do you ever refer TOPFA cases to another Fetal Medicine Centre for review/second opinion?

Does your Fetal Medicine Centre refer cases externally, within Ireland?

Under what circumstances/criteria does your Fetal Medicine Centre refer cases externally, within Ireland? (Tick all that apply)

Does your Fetal Medicine Centre refer cases outside of Ireland for the following indications?

Does your unit provide any of the following for TOPFA cases? (tick all that apply)

Is feticide provided in your Fetal Medicine Centre?

Which of the following best describes the gestational range at which feticide is provided in your Fetal Medicine Centre? (Tick one option)

What method of feticide is used in your Fetal Medicine Centre? (Tick all that apply)

Does your Fetal Medicine Centre refer women back to their local unit for delivery post feticide?

Does your Fetal Medicine Centre routinely audit the following?

Does your hospital/units annual report include the following? Please select the response that best describes your situation:

Does your Fetal Medicine Centre have guidelines on the following

Is your Fetal Medicine Centre recognised for sub-speciality training (accreditation)?

With whom is your Fetal Medicine Centre recognised for sub-speciality training (accreditation)?

Is there a clinical genetics service available to your Fetal Medicine Centre?

Is there a clinical genetics counselling service available to your Fetal Medicine Center?

Does your Fetal Medicine Centre provide amniocentesis?

On average, how many amniocentesis are carried out per week?

Does your Fetal Medicine Centre provide CVS?

On average, how many CVSs are carried out per week?

Which of the following genetic tests are provided in your Fetal Medicine Centre? (tick all that apply)

Is written information regarding these genetic tests given?

Does your Fetal Medicine Centre have standardised consent forms for genetic testing in pregnancy?

Approximately how many patients a year does your Fetal Medicine Centre refer for genetic testing? Please insert number of patients/cases for each type of genetic testing, even if this is 0.

In your opinion, is genetic testing capacity adequate in relation to demand?

Approximately how many patients a year would you refer for genetics services if capacity was available to meet demand? Please insert number of cases for each type of genetic testing, even if this is 0.

Does your hospital/unit have access to a clinical geneticist for the following scenarios?

Does a clinical geneticist attend your Fetal Medicine Centre's MDT meeting?

What is the Clinical Geneticists role in your Fetal Medicine Centre's MDT? (Tick all that apply)

Does the clinical geneticist complete TOP paperwork/certification under section 11 of the Act?

Does a clinical geneticist attend your Fetal Medicine Centres perinatal mortality MDT meeting?

In your professional opinion, how would you rate the level of awareness and knowledge of Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018 amongst staff in your Fetal Medicine Centre?

In the context of this Review of the operation of Section 11 of the Health (Regulation of Termination of Pregnancy Act) 2018, if you have any further comments or observations, please note them here.

You have now reached the end of your section. Please select the submit button below in order to complete the survey, or use the arrow button below to review your responses prior to final submission.

Section 11 Review Questionnaire – Patient Perspective

Patient Perspective Questionnaire

1. How much time passed between the time a concern was noted about your pregnancy, e.g. your 12 week or anomaly scan and seeing the fetal medicine consultant or team?

2. Did you meet with 1 or 2 fetal medical specialists, or more?

3. What information if any, were you given at your 1st diagnosis about your baby's condition and other testing options?

4. What contact information or details were you given for someone in the hospital?

5. Did you meet a midwife co-coordinator/ or lead or a named midwife at the fetal medicine unit?

6. What written information were you given, if any, on the final diagnosis; specifically about ending the pregnancy, choices, timelines, methods, location etc.?

7. Did you have access to a Geneticist? Was this mentioned to you as a possibility?

8. Was the process for agreeing a termination of pregnancy explained to you? Did you know that cases like these are discussed at a Multi Disciplinary Team meeting? Was this discussed with you?

9. Were you given information about feticide and your choices about this?

10. If you were refused the option of terminating your pregnancy was this decision given to you in writing and were you informed how to have this decision reviewed (i.e. appeal the decision)?

11. If you were refused a termination of pregnancy what information were you given about travelling outside of Ireland for this?

12. Where do you find information about travelling for a termination or from whom if not given it in the hospital?

13. Were you given information about useful support groups or organisations, who shared this with you and at what stage were you given this information?

14. Did you meet with a counsellor? Was this through your hospital or private? Do you think access to counselling is important for people in this situation?

15. Did you have a choice about the location of your termination or delivery? For example could you choose between your original hospital/unit or another hospital you were referred to?

16. Were you asked for feedback about your experience in any formal way from the unit you attended?

17. It is completely optional to respond to this question. Which maternity unit or units did you attend?

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