



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

Summary



Dr Colm Henry - Chief Clinical Officer (CCO) HSE – Commissioner of the Section 11 Review.

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. 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. 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 so as 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. The need to undertake this Review has been further underpinned and highlighted by recent experiences. 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. 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.



**Professor Dame Lesley Regan – Chair
of the Section 11 Review Group**

The Review Group was independently Chaired by Professor Dame Lesley Regan.

The 25th of May 2018 was a monumental day for reproductive rights and women’s health empowerment. The Republic of Ireland voted by a two-thirds 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.

***“When we get it right
for women,
everybody in society
benefits.”***

Prof. Dame Lesley Regan

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 due to fetal anomaly, as well as 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 /point-in-time 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 a fetal anomaly, Leambh 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.

Background and Context

This Review engaged with clinical experts and service users to identify what is required to enhance the provision of termination of pregnancy services under Section 11, specific to the clinical circumstances of the fetus and parent(s), with provision of compassionate care and emotional supports for families being central. This Review and assessment was comprised of two distinct work-streams:

- 1.) A comprehensive service evaluation across primary and secondary and a separate evaluation of the lived experience of the service;
- 2.) An extensive review of the relevant literature around screening and diagnosis of fetal anomaly as well as care pathways around termination of pregnancy for fetal anomaly (TOPFA).

The Review and work-streams thereunder, has provided an evidence-informed overview of current services, identifying and describing gaps and/or deficiencies in the service from both a service provider and service user perspective, and has enabled the Review Group to prepare a roadmap and deliver clear recommendations to the Oversight Group, in order to improve the safety and management of services provided under the Act.

In order to achieve its purpose, the Group undertook a review of pathways of care available to women seeking to access termination of pregnancy services under Section 11, mindful and giving due cognizance and consideration to the entry points of women and their families on these pathways of care vis-à-vis their gestational stage and any specific and unique elements of care that may be required by women on this basis.

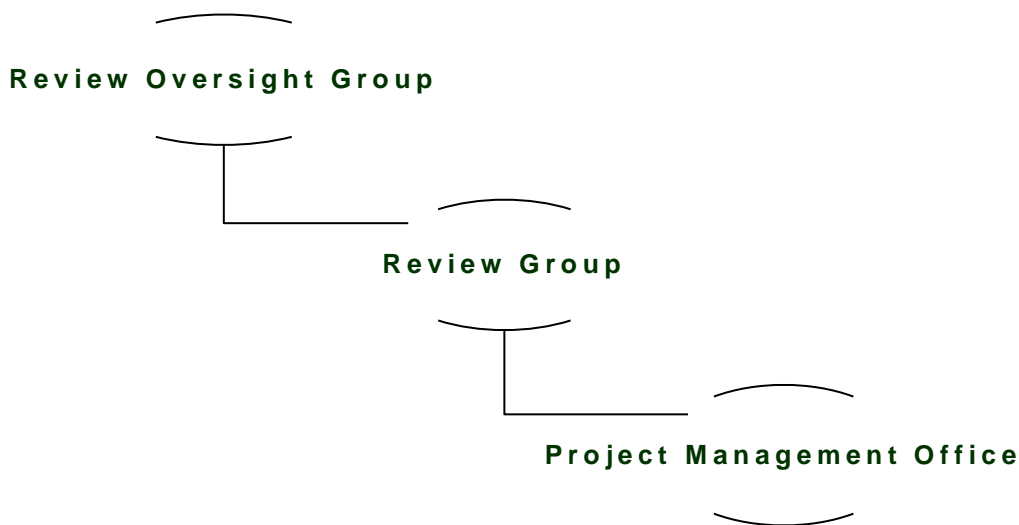
The Review assessed and evaluated pathways of care guided by the following parameters:

- Ensuring access for women seeking terminations under Section 11 independent of their means
- Ensuring availability of compassionate care and comprehensive family supports following a diagnosis;
- Enabling ready and timely access to relevant testing (screening & diagnostic) for service users;
- Enabling ready availability of comprehensive information for service users and their families to enable and support informed decision making;
- Ensuring availability of required clinical multidisciplinary expertise both for service providers and service users;

- Any other area(s) of care that may be identified by the Group as pertinent and relevant to their work programme as provided under Section 11 of the Health (Regulation of Termination of Pregnancy) Act 2018.

In undertaking this Review, the Group worked collaboratively with key stakeholders involved in the delivery and management of termination of pregnancy under Section 11 of the Act and engaged with service users so that their experience of the service was central to informing the ensuing recommendations.

Governance of the Review



Review Oversight Group

The Commissioner of this Review, the Chief Clinical Officer of the HSE, chaired the Review Oversight Group. Membership of this Group included:

- Dr Colm Henry, Chief Clinical Officer, Health Service Executive (Chair)
- Dr Orla Healy, National Clinical Director for Quality and Patient Safety
- Mr Kilian McGrane, Director, National Women and Infants Health Programme
- Mr Liam Woods, National Director, Acute Operations
- Ms Yvonne O Neill, National Director for Community Operations

Review Group

The Chair of the Review, Prof. Dame Lesley Regan DBE, FRCOG, Secretary General of the International Federation of Gynaecology and Obstetrics (FIGO) working closely with the National Women and Infants Health Programme and Chairs of the work-streams provided updates to the Commissioner of the Review and Review Oversight Group at regular intervals.

Membership of the Review Group included:

- Prof. Dame Lesley Regan, Secretary General FIGO (**Section 11 Review Group Chair**)
- Dr Cliona Murphy, Clinical Director National Women and Infants Health Programme (**Review Group - Vice-Chair**)
- Ms Alison Lynch, Co-Chair, Leanbh Mo Chroí Bereavement Support Group (advocacy group for fatal fetal anomalies in Ireland)
- Ms Angela Dunne, National Lead Midwife, National Women and Infants Health Programme
- Prof. Andrew Greene, Consultant Clinical Geneticist
- Dr. Aoife Mullally, Clinical Lead for Termination of Pregnancy Services
- Dr. Brendan Fitzgerald, Consultant Perinatal Pathologist
- Dr Ciara McCarthy, General Practitioner, ICGP Representative – Clinical Lead for Women’s Health
- Prof. Colm O’Donnell, Consultant Neonatologist
- Ms Eileen Ronan, Director of Midwifery
- Ms Fiona Hanrahan, Chair, National Forum of Directors of Midwifery (**Work-stream Chair**)
- Ms Fiona Mulligan, Clinical Midwife Specialist in Bereavement and Loss
- Ms Jennifer Ryan, Co-Chair, Leanbh Mo Chroí Bereavement Support Group (advocacy group for fatal fetal anomalies in Ireland)
- Prof. John Morrison, Clinical Director, Maternity Network
- Prof Keelin O’Donoghue, Consultant Obstetrician and Gynaecologist, Maternal Fetal Medicine Specialist (**Work-stream Chair**)
- Ms Marie Culliton, Medical Scientist, Clinical Lead National Clinical Programme for Pathology
- Ms Mary-Jo Biggs, General Manager, National Women and Infants Health Programme
- Dr Noirin O’Herlihy, General Practitioner, ICGP Representative
- Mr Robert Kidd, Assistant National Director, Acute Operations
- Dr Rosemary Harkin, Consultant Obstetrician and Gynaecologist
- Prof Sam Coulter-Smith, Chair, Institute of Obstetricians & Gynaecologists, Ireland
- Dr Sam Doyle, Consultant Clinical Geneticist
- Dr Terry Tan, Consultant A

Approach and Methodology



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:

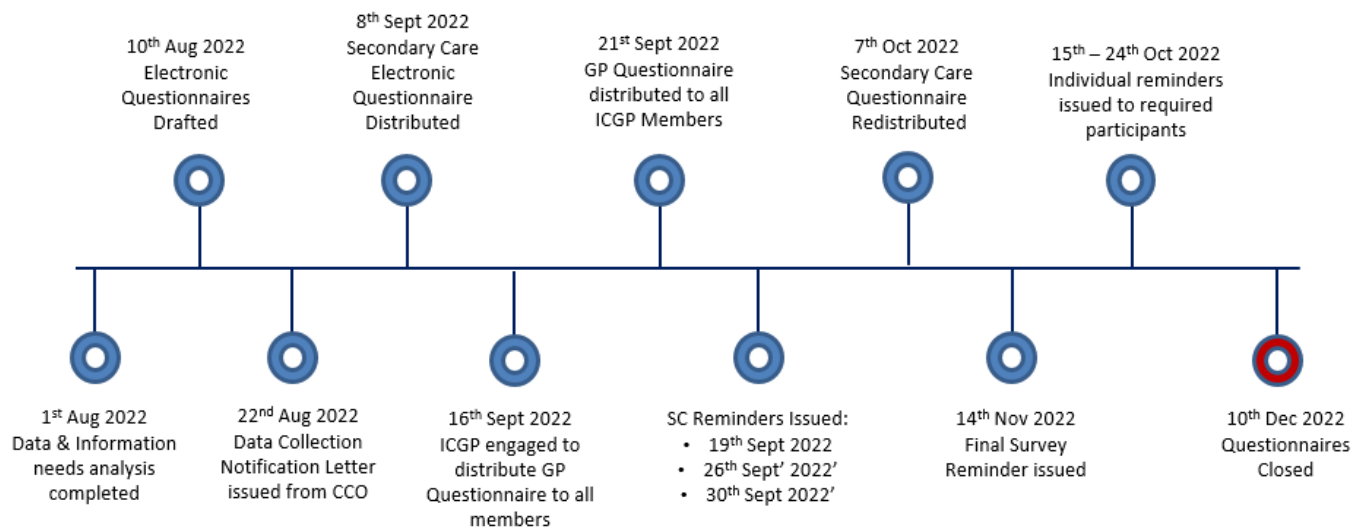
- General Practice
- Obstetrics and Gynaecology
- Fetal Medicine
- Perinatal Pathology
- Neonatology
- Midwifery

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

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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. ¹



Survey design and distribution

For Primary and Secondary Care a service evaluation questionnaire was designed in consultation with members of the Review Groups ‘Trimester One’ and ‘Trimester 2&3’ working groups. 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. The questionnaire was distributed electronically to all members of the Irish College of General Practitioners (ICGP; n=4000), with a resulting questionnaire completion rate of 4% (n=163). It was sent via direct mail to the Consultant Obstetrics & Gynaecology (Lead), Director of Midwifery and Consultant Neonatologist/Paediatrician (Lead) at each of 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.

A service evaluation questionnaire was designed in consultation with service user 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. Leanbh Mo Chroí 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. 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. 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.

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.

International Best Practice Review

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 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), 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).

The Literature Review was 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.

The full literature review will be published on the HSE website once the report and recommendations have been through all relevant approval protocols.

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.

Summary of Findings

Previous studies have shown that in the main, the overall experience of termination of pregnancy services in Ireland is frequently described positively by service users.² However, 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.³

Healthcare professionals also need support and appropriate training to meet the needs of women/parents. An Irish 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.⁴

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.

² Unplanned Pregnancy and Abortion Care (UnPAC) Study. July 2022

³ 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>

⁴ 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.

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 units/hospitals 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 tests for aneuploidy (e.g. NIPS) without appropriate pre and post-test counselling and without the 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's/parents' perceived experience of the service, was their interactions with healthcare professionals and the manner, level and appropriateness of communication regarding their pregnancy.

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.

Recommendations

The national recommendations set out in this 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 for fetal anomaly, prenatal diagnosis, termination of pregnancy, Investigations, follow-up and supportive care.

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.

Thanks and Acknowledgements

Professor Dame Lesley Regan	Chair of the Section 11 Review Group
Ms Alison Lynch	Service User Representative, Leanbh Mo Chroí
Prof Andrew Green	Consultant Geneticist
Ms Angela Dunne	NWIHP, National Lead Midwife
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Dr Brendan Fitzgerald	Consultant Perinatal Pathologist
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Dr Cliona Murphy	NWIHP, Clinical Director
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Ms Fiona Hanrahan*	Director of Midwifery,
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Ms MaryJo Biggs	NWIHP, General Manager
Dr Noirin O'Herlihy	General Practitioner, 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

* Chair of Work-stream 1 – Primary Care

Chair of Work-stream 2 - Secondary Care and Lead Author of the **S.11 National Review Group, Literature Review Report

Acknowledgements also to Dr Marita Hennessy, Postdoctoral Researcher within the Pregnancy Loss Research Group, INFANT Centre at University College Cork, for ensuring rigour in qualitative content analysis and thematic analysis as part of this Review.

Next Steps

- Report and recommendations presented to Commissioner of the Review and Review Oversight Group for endorsement/approval (April 2023)
- Report and recommendations shall be presented to the HSE Executive Management Team (EMT), HSE Safety and Quality Committee and the HSE Board. (May 2023)
- NWIHP to prepare costed, time-bound implementation plan (Phase 1 – Discovery/scoping phase) (June 2023)
- NWIHP prepare New Service Development (NSD) Bid for 2024 annual estimates process. (July 2023)