INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

# INTERIM CLINICAL GUIDANCE

## PATHWAY FOR MANAGEMENT OF FATAL FETAL ANOMALIES AND/OR LIFE-LIMITING CONDITIONS DIAGNOSED DURING PREGNANCY:

## TERMINATION OF PREGNANCY

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## 1. KEY RECOMMENDATIONS

- All women must have equal access to standardised ultrasound services, to accurately date the pregnancy, to assess the fetus for ultrasound diagnosable anomalies as part of a planned prenatal fetal diagnostic service, and for other indications if deemed necessary during the antenatal period.

- The widely accepted minimal schedule for antenatal ultrasound comprises of two examinations; a dating ultrasound in the late first trimester, followed by a fetal anomaly scan, usually performed between 20-22 weeks' gestation.

- The fetal anomaly scan is best performed between $20^{+0}$ to $22^{+6}$ weeks gestation as this time point allows the best visualisation of fetal anatomical structures. This ultrasound requires a high skill level and needs to be performed by an individual with specialised training for the practice of diagnostic ultrasonography in pregnant women.

- Fetal anomaly ultrasound should follow a strict format and should meet the minimum requirements set by the major international obstetric ultrasound professional bodies.

- 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.

- Where termination of pregnancy is being considered, a fetal medicine specialist should be involved in the antenatal diagnosis, counselling, and subsequent care of the pregnancy.

- Input from Neonatology/Paediatrics specialists may be necessary to ascertain and/or agree on prognosis, and other specialist colleagues (e.g. surgery, cardiology, neurology, radiology and genetics) should be consulted as necessary.

- All fetal medicine units should have timely access to clinical genetics specialists who may advise further on the type of testing necessary depending on the ultrasound presentation/family history and previous history.

- All fetal medicine units should have timely access to fetal MR Paediatric Radiology specialists when clinically appropriate for confirmation of diagnosis or when additional information is warranted.

- A perinatal/paediatric Cardiologist using fetal specialist echocardiography should assess cardiac anomalies or cases where specific abnormalities are associated with cardiac anomalies.

- Cases should be 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 termination of pregnancy being discussed with the Parents. Complex cardiac cases should additionally be discussed in a specialised cardiology cardiothoracic surgical multidisciplinary team meeting.

- The option of continuing the pregnancy with planned perinatal palliative care for the baby or terminating the pregnancy (in accordance with the Health (Regulation of Termination of Pregnancy) Act, 2018) should be discussed with the Parents; these discussions are usually held with the fetal medicine team and associated healthcare professionals from the multi-disciplinary team (MDT). The fetal medicine specialist and Neonatologist/Paediatrician may meet the Parents together for a consultation.

- Women should have access to accurate and objective information and, if required, counselling and support. There should be local arrangements in place for providing value-neutral information to women about termination of pregnancy.

- Information around termination of pregnancy should be provided in simple, clear and concise English with avoidance of medical terminology.

- If either the Parents or the healthcare professionals are still uncertain about the diagnosis or prognosis, a second opinion, either internal or external, should be sought. The case should be discussed at an MDT meeting. This should be facilitated in a timely fashion, ideally within 24-72 hours.

- Fetal medicine multidisciplinary team (MDT) discussions should form an important component of the assessment of fetal anomalies, their prognosis and outcomes.

- Where termination of pregnancy is being considered, a fetal medicine specialist involved with the diagnosis and care should be one of the signatories on the certification documents.

- As with Parents who continue pregnancies after antenatal diagnosis of fatal fetal anomalies/life-limiting conditions a perinatal palliative care *approach* is appropriate for those who opt for termination of pregnancy.

- An explicit care plan should be developed in conjunction with the Parents, especially for termination of pregnancy at later gestations.

- Maternal health and wellbeing during pregnancy, birth and the postnatal period remain components of maternity care, including when there is a planned termination of pregnancy for fatal fetal anomalies /life-limiting conditions.

- Fetal medicine assessment should continue alongside antenatal care, for as long as the pregnancy continues. However, care should be provided in a place away from busy maternity clinics and areas of routine clinical activity.

- Bereavement support should be provided all along the care pathway and continue through the baby's death and beyond. Parents who opt for termination of pregnancy need to be supported and given access to resources to help them through their grief.

- Appropriate consent should be obtained prior to termination of pregnancy, which clearly outlines the risks, benefits, side effects and complications of treatments or procedures.

- Women should be informed that termination of pregnancy is generally a safe procedure for which complications and mortality are rare at all gestations.

- Feticide can be performed before medical termination takes place after 21 weeks and 6 days of gestation to ensure that there is no risk of a live birth. Parents must receive sympathetic and supportive counselling before and particularly after the feticide procedure.

- Feticide should only be performed in tertiary referral centres where there are fetal medicine specialists with the appropriate level of training.

- Plans around induction, labour and delivery need to be clearly documented and communicated to the hospital staff who will be involved in the woman's care. It should be agreed who will be present at the delivery.

- The Parents should be counselled prior to birth about scenarios where the baby may be born alive, most relevant at later gestations and where feticide has not been performed. The care plan should therefore allow for a scenario where perinatal palliative care is provided.

- It is important that women receive normal postnatal care and emotional support from the midwives looking after her in delivery suite and on postnatal wards. Ideally, one midwife should be allocated to care for the Parents and the fetus/baby. Parents should be allocated a room on their own after delivery. Consideration is to be given to using the hospital bereavement symbol, if the Parents wish.

- Clinical assessment, laboratory investigations and a full post-mortem examination should be considered to confirm the antenatally diagnosed fetal anomaly, the chance of recurrence and possible means of avoiding further pregnancy complications.

- The Parents should be given verbal or written information about cremation and burial options for fetal remains, with a clear explanation of what each entails and given the opportunity to discuss them. Personal, religious or cultural needs relating to this should be met wherever possible.

- All women (and partners) should be offered a review appointment (or support visit as appropriate) in the weeks following termination of pregnancy and delivery, to assess the woman's physical and emotional wellbeing.

- The Parents must also have a formal follow-up postnatal appointment with the fetal medicine team and/or their local Obstetrician, to assess wellbeing and review results of any post-mortem investigations

- Appropriate training and support should be available for staff to enable confidence to care for the pregnant woman during delivery, the fetus/baby at birth and to deliver the supportive care plan.

- Medical practitioners with a conscientious objection to carrying out or participating in carrying out a termination of pregnancy, are obliged to make the necessary arrangements for the transfer of care of the pregnant woman, to enable her to avail of a termination of

pregnancy. In an emergency, the pregnant woman's care must be made a priority and the necessary treatment must be provided, irrespective of any conscientious objection the medical practitioner may have.

- Issues and challenges for staff arising from caring for women who have termination of pregnancy for FFA/LLC should form part of team discussions and should be addressed in hospital reviews of bereavement care.

- In all cases of termination of pregnancy a form of certification must be completed as specified by the Health (Regulation of Termination of Pregnancy) Act 2018. This is the responsibility of two medical practitioners, and includes the Obstetrician who carries out the termination of pregnancy.

- The review committee for matters relating to Section 11 certification (condition likely to lead to death of fetus) should be constituted by fetal medicine specialists, as well as in Neonatology/ Paediatrics.

- Termination of pregnancy service providers must conduct regular audit of the care they provide. The recommendations within this guideline can serve as criteria for audit.

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## 3. BACKGROUND

Around 2-3% of pregnancies are complicated by congenital anomalies, of which around 15% are life-limiting or potentially life-limiting. In the United Kingdom, MBRRACE-UK report the perinatal mortality rate as 5.92 per 1,000 births (2016); while in Ireland, the Irish National Perinatal Epidemiology Centre reported a perinatal mortality rate of 5.8 per 1,000 births for 2016 (NPEC, 2018). The leading cause of early neonatal death in Ireland is reported as congenital malformations (68/124; 54.8%) with chromosomal disorders the most common type of major anomaly reported (NPEC, 2018). Major congenital anomaly was the primary cause of death in over one in four (n=78, 31.2%) of the 250 Stillbirths that occurred in Ireland in 2016 (NPEC, 2018).

Advances in antenatal diagnosis of fetal anomalies, obstetric and neonatal care have increased the need for decision-making about end-of-life care for the fetus and neonate. These decisions also include the option of termination of pregnancy. This presents both Parents and Clinicians with new and difficult challenges. A perinatal palliative care *approach* is appropriate for Parents who continue their pregnancy after antenatal diagnosis of fatal fetal anomalies (FFA) / life-limiting conditions (LLC) as well as for those who opt for termination of pregnancy.

## 4. AIMS

The purpose of developing a pathway of care is:

- To enable clinical staff to deliver consistent, high quality ongoing care for families electing to continue or terminate pregnancy with a fetus with a life-limiting condition/fatal fetal anomaly or potential life limiting condition
- To ensure uniform standards of care wherever families are cared for in Ireland.

This pathway deals with:

- Termination of pregnancy where there are prenatally diagnosed fatal fetal anomalies or life-limiting conditions in singleton or multiple pregnancies

This pathway does not refer to:

- Unplanned imminent birth of a preterm pre-viable fetus.
- Newborn with a postnatally diagnosed life-limiting condition.

## 5. STATUTORY GROUNDS FOR TERMINATION OF PREGNANCY

The Health (Regulation of Termination of Pregnancy) Act 2018 was passed by the Dáil on 05/12/18, by the Seanad on 13/12/18 and was then signed into law the on 20th December 2018.

The Institute of Obstetricians and Gynaecologists was asked by the Department of Health to develop clinical guidance for the termination of pregnancy. On the 9th October 2018, at the request of the Chair of the Institute of Obstetricians and Gynaecologists, a fetal medicine working group was convened to work on this document.

The purpose of this pathway of care is to provide clinical guidance for healthcare providers regarding Section 11 of the Act, which deals with termination of pregnancy where there is a condition likely to lead to death of the fetus.

According to the Health (Regulation of Termination of Pregnancy) Act, 2018, in Section 11 '*Condition likely to lead to death of foetus':-*

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.*
2. *Of the 2 medical practitioners referred to in subsection (1)—*
   *(a) one shall be an obstetrician, and*
   *(b) the other shall be a medical practitioner of a relevant specialty.*
3. *A termination of pregnancy shall not be carried out under this section unless each of the medical practitioners referred to in subsection (1) has certified his or her opinion as to the matters referred to in that subsection.*
4. *The termination of pregnancy to which the certification referred to in subsection (3) relates shall be carried out*
   *i. by the obstetrician referred to in subsection (2)(a), or*
   *ii. where the medical practitioner referred to in subsection (2)(b) is also an obstetrician, by that obstetrician or the obstetrician referred to in subsection (2) (a).*

Both medical practitioners must certify his/her own opinions. The termination of pregnancy is to be carried out by an Obstetrician who certified the termination.

In the Act "termination of pregnancy", in relation to a pregnant woman, is defined as a "*medical procedure which is intended to end the life of a foetus*".

In general, it can be said that a medical practitioner acts in good faith where s/he:

- Acts in accordance with any National Clinical Guidance provided and with the Irish Medical Council Guide to Professional Conduct and Ethics
- Acts honestly and the decision taken does not reflect personal bias or external influence
- Acts to the best of his/her abilities

## 6. ANTENATAL DIAGNOSIS OF FATAL FETAL ANOMALIES / LIFE-LIMITING CONDITIONS

Structural anomalies are usually suspected or diagnosed at routine ultrasound screening in the first or second trimester of pregnancy. They can also be seen at routine scans carried out as part of general antenatal care at any stage including late pregnancy. It is important to note that ultrasound scans will not identify all structural anomalies

The Obstetrician or the Midwife/Sonographer performing a routine booking/dating or anomaly ultrasound scan may be faced with the initial breaking of bad news to the pregnant woman and partner. A second opinion may be sought in such circumstances. Those performing the initial scan should respond to Parents' questions with whatever information is available at that time.

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.

There are different pathways around antenatal diagnosis/initial care:

- 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 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 termination of pregnancy being discussed with the Parents, as well as any implications for maternal health where the pregnancy is on-going.

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

## Referral to fetal medicine services

### *What is a fetal medicine specialist?*

A fetal medicine specialist is a medical practitioner who is actively practicing in the area of fetal medicine. The fetal medicine specialist has undergone specific further training either through an approved Maternal-Fetal Medicine (MFM) fellowship or a higher qualification in diagnostic ultrasound, or has a long term expertise in ultrasound/fetal medicine and trained at a time before these fellowships/qualifications were available.

### *Fetal medicine consultation*

A fetal medicine specialist should confirm the antenatal diagnosis of a structural anomaly and a suspected fatal fetal anomaly / life-limiting condition (FFA/LLC).

This will usually involve performing diagnostic ultrasound on an appropriate, functioning, up to date ultrasound machine. Further invasive investigations including amniocentesis, chorionic villus sampling, fetal blood sampling to establish the fetal genetic profile, in addition to maternal bloods and fetal MRI to confirm the diagnosis or to add further information may be necessary.

All fetal medicine units should have timely access to clinical genetics specialists who may advise further on the type of testing necessary, depending on the ultrasound presentation/family history and previous history.

All fetal medicine units should have timely access to fetal MR Paediatric radiology specialists when clinically appropriate, for confirmation of diagnosis, or when additional information is warranted.

A perinatal cardiologist using fetal specialist echocardiography should assess cardiac anomalies or cases where specific abnormalities are associated with cardiac anomalies. This should be carried out in the relevant tertiary centre, ideally within a short time frame.

Appropriate investigations may need to be agreed by a multidisciplinary team (MDT). This is not essential in fetal conditions for which there are simple definitive diagnostic tests and an agreed prognosis, e.g. anencephaly.

These investigations should be followed by a multidisciplinary team discussion to agree the diagnosis and prognosis and to consider any implications for maternal health and antenatal care. The diagnosis and prognosis is then explained and discussed with the Parents.

*Principles of management*

The option of continuing the pregnancy with planned perinatal palliative care for the baby or terminating the pregnancy should be discussed with the Parents. These discussions are usually held with the fetal medicine team and associated professionals. It can be helpful to involve Neonatologists / Paediatricians at this point.

There is a significant challenge in decision-making for Parents; this is related to the degree of certainty of the antenatal diagnosis, expected prognosis, and the certainty of death before or shortly after birth, as well as the meaning of the diagnosis for the Parents.

For some, terminating a pregnancy is the correct decision for them and their family, but it is rarely what we understand as a 'choice'. It is often traumatic. Others may benefit from an alternative approach and continue their pregnancy. A perinatal palliative care *approach* can provide support to families who make either of these decisions and hospital guidelines must be structured in a way to allow this.

### Types of antenatal diagnosis

Fatal fetal anomalies/life-limiting conditions (FFA/LLC) have an almost certain diagnosis and prognosis, including a very high chance of death in utero or by 28 days of life (the neonatal period) despite medical treatment.

Potential life-limiting conditions include diagnoses where there is a significant chance of death in utero or in the newborn period and are often associated with substantial burden of care for the family.

Definitive diagnosis may follow early or mid-trimester ultrasound. However, prognosis may not always be clear at the time of diagnosis and may be influenced by a variety of factors including fetal growth restriction, fetal hydrops or multiple pregnancy. The prognosis may become clearer as the pregnancy progresses.

Neonatology input may be necessary to ascertain and/or agree on prognosis, and specialist colleagues (e.g. surgery, cardiology, neurology, radiology, and genetics) should be consulted as necessary. If there are differing opinions within the team, then additional formal multi-disciplinary team meetings may be necessary.

It is important to note that lists of fetal diagnoses or conditions are neither definitive nor static over time. Any list of eligible diagnoses may become outdated in a number of years. Similarly, combinations of fetal anomalies which by themselves may not be fatal, in combination with other anomalies could lead to a prognosis that is extremely poor and therefore the following lists should not be considered to be exhaustive or complete.

Fatal fetal anomalies /life-limiting conditions include diagnoses that are highly likely to lead to death in utero or in the newborn period (28 days of life), although for some of these diagnoses, survival beyond 28 days has been reported. For these conditions, the diagnosis and prognosis are unequivocal. Estimates of prevalence range from 1 in 1000 (anencephaly) to 1 in 10,000 (Triploidy; Trisomy 13; Renal agenesis).

FFA/ LLC *may include but are not limited to:*

- Bilateral renal agenesis
- Severe skeletal dysplasia
- Anencephaly/acrania
- Thanatophoric dysplasia
- Trisomy 13 or Trisomy 18
- Triploidy
- Hydranencephaly
- Severe osteogenesis imperfecta
- Multicystic/dysplastic kidneys with early onset anhydramnios
- Infantile polycystic kidney disease with early onset anhydramnios
- Congenital severe hydrocephalus with absent or minimal brain growth
- Non-immune hydrops with major cardiac defect
- Inoperable conjoined twins
- Craniorachischisis / Exencephaly/ Iniencephaly

Potentially fatal fetal anomalies/ life-limiting conditions (PFFA/PLLC) include diagnoses where there is a significant chance of death in utero or in the newborn period. Prognosis may not always be clear at the time of diagnosis, and it may not be clear until after birth whether or not active intervention is indicated.

PFFA/PLLC *may include but are not limited to*:

- Severe multicystic dysplastic kidneys and oligohydramnios
- Holoprosencephaly
- Severe hydrocephalus
- Hydrops fetalis
- Life limiting complex cardiac defects as agreed by the paediatric cardiology MDT

## 7. PREGNANCY OPTIONS AFTER DIAGNOSIS OF FFA/LLC

Following diagnosis of FFA/LLC, Parents should be counselled about all available pregnancy options.

Parents should be counselled by the fetal medicine specialist regarding their options:

- To terminate the pregnancy, in accordance with the Health (Regulation of Termination of Pregnancy) Act, 2018.
- To continue the pregnancy with a perinatal palliative care plan,
- Or (in some cases where the prognosis is uncertain or may change) continuation of pregnancy with a perinatal palliative care and a post-natal care plan.

Initial counselling is usually delivered by the fetal medicine Consultant/Obstetrician with fetal medicine training with input from a specialist Midwife/ Midwife sonographer. It is recommended that additional counselling be provided from a Neonatologist/Paediatrician. In some cases, it would be helpful if the fetal medicine specialist and Neonatologist/Paediatrician met the Parents together for a consultation.

In cases of serious and possibly fatal fetal anomaly, and where termination is to be offered, Parents should *always* receive counselling from a fetal medicine specialist.

If either the Parents or healthcare professionals are still uncertain about the diagnosis or prognosis, a second opinion, either internal or external, should be sought. The case should be discussed at an MDT meeting if this can be convened in a timely manner. The involved department should arrange this, although some Parents may want to choose another tertiary centre, and this should also be facilitated in a timely fashion, ideally within 24-72 hours.

Congenital cardiac defects are highly variable in complexity and prognosis. In fetal life cardiac lesions may evolve in severity during gestation. Complex cardiac cases will be discussed in a specialized cardiology cardiothoracic surgical multidisciplinary team in a closed conference setting. The recommendations from this multidisciplinary team will be communicated formally to the fetal maternal medicine team, who will then proceed with therapeutic options as recommended.

Healthcare professionals should be aware of their personal beliefs and consider the possible influence they may have on women's experiences, especially when caregivers and women's choices diverge.

Ideally, to develop expertise all staff should be mentored by senior colleagues before taking the lead in this sensitive area. It is particularly important to discuss openly Parents' priorities, hopes and fears, in order to facilitate shared decision-making that is respectful of Parents' values, and to tailor support to their needs.

Respect for the values and decisions of Parents is central to providing compassionate supportive care in pregnancies complicated by FFA/LLC.

*Refer to the Pathway for Management of Fetal Anomalies/ Life-limiting Conditions diagnosed during Pregnancy. National Implementation Group, HSE Standards for Bereavement Care following Pregnancy Loss or Perinatal Death, January 2019*

### Multi-disciplinary team meetings in Fetal Medicine

It is good practice to ensure that fetal medicine multidisciplinary team (MDT) discussions should form an important component of the assessment of fetal anomalies, their prognosis and outcomes.

A summary of the outcome of these clinical meetings should be documented in the clinical notes. These discussions would include management plans for the delivery of the care.

The key features of the fetal medicine MDT meeting should include:

- It is a formally-constituted committee of the hospital – this is likely to be at hospital group level where the fetal medicine expertise is concentrated
- Requires administrative support to ensure a record of MDT attendees is kept and that the cases discussed are recorded
- Clinical representation might be required from the smaller hospitals within each group, depending on where the case under discussion was referred from
- Attendance and participation at MDTs would usually be open to all relevant Consultants in the hospital group
- Membership should include a range of medical and allied specialties

*Suggested members of the multidisciplinary team may include:*

Consultant Obstetrician / Fetal Medicine Specialist
Consultant Neonatologist / Consultant
Paediatrician Paediatric Palliative Care Consultant
Paediatric Radiologist
Consultant Clinical Geneticist / Genetics Counsellor
Hospital Bereavement Clinical Midwife/ Nurse Specialist
Dedicated Prenatal Diagnosis / Fetal Medicine Midwife
Prenatal Diagnosis Co-Ordinator/Clinical Midwife Specialist (CMS)
Midwife Sonographer
Delivery Suite Senior Midwife
Maternity Social Worker
Neo-natal Unit Senior Midwife/ Nurse
Chaplaincy / Spiritual care

## 8. CARE AROUND TERMINATION OF PREGNANCY FOR FFA/LLC

Where a prenatal diagnosis of a FFA/LLC is made during pregnancy, management options include terminating the pregnancy.

Healthcare professionals should know what the law allows and be clear about the circumstances in Ireland for which termination of pregnancy for fatal fetal anomalies is legal in 2019 and beyond (Health, Regulation of Termination of Pregnancy, Act 2018).

The National Women and Infants Health Programme is responsible for ensuring that an accessible service is available for Irish women in all geographic regions of Ireland; this is outlined by the HSE's Model of Care for Termination of Pregnancy Services Document (2018).

Women should have access to accurate and objective information and, if required, counselling and support. There should be local arrangements in place for providing value-neutral information to women about termination of pregnancy. Healthcare professionals need to be aware that these decisions may be revisited over time by the Parents, and as clinical information about prognosis may change during the pregnancy.

For some Parents, termination of pregnancy in Ireland may still not be an option, and this may be for complex reasons including legislative restrictions in Ireland for non-fatal but major fetal anomalies, the need to travel to another country for treatment, financial or social considerations, as well as to access specific medical procedures. During this time, and before termination of pregnancy, *these* Parents should be assisted with preparing for the birth and death of their baby. Opportunities for memory-making can be discussed and planned, as well as the logistics around making arrangements for the baby when the Parents are back in Ireland.

### Guiding principles of care

- To provide timely support tailored to the needs of families
- To provide multidisciplinary support for Parents' choices and values
- To facilitate Parents' choice in location of delivery where possible
- To provide specialist input and advice to support hospitals to facilitate local provision of care to families delivering in their local maternity hospital
- To provide training and support for staff in tertiary and regional units
    - to instil confidence to care for the pregnant woman in the antenatal period,
    - to care for the fetus/ baby at birth,
    - to assist in transitioning to neonatal palliative care after birth

While women and families with an antenatal FFA/LLC diagnosis opting for termination of pregnancy may not be referred to all members of the multi-disciplinary perinatal palliative care team, their care can still have a perinatal palliative *approach*.

Fetal medicine Consultants/ Obstetricians and Neonatologists/ Paediatricians should be involved together in care planning around termination of pregnancy for fetal anomaly (TOPFA); the Bereavement CMS/CNS or Fetal Medicine Midwife may act as liaison antenatally.

Bereavement support should be provided all along the care pathway and continue through the baby's death and beyond.

*Refer to the Pathway for Management of Fetal Anomalies/ Life-limiting Conditions diagnosed during Pregnancy. National Implementation Group, HSE Standards for Bereavement Care following Pregnancy Loss or Perinatal Death, January 2019*

## Place of birth

For babies with confirmed FFA/LLC, the aim, where possible, if appropriate, and if requested by Parents, is to facilitate delivery in their local maternity hospital, in which the Parents had originally booked their care, to be near families and for ongoing psychological and practical support. As the Act (Health, Regulation of Termination of Pregnancy, Act 2018) makes clear, the termination of pregnancy must be carried out by an Obstetrician who certified the termination. Therefore if delivery is to be in the local maternity hospital, one of the Obstetricians in the local hospital must be a co-signatory on the certification process.

Delivery in the tertiary centre may be appropriate (as would be the case for any pregnancy), where there are anticipated specialist obstetric or neonatal care needs that cannot be provided locally. Where this is planned, the local maternity hospital team should remain updated about care planning, as some patients may present locally in emergency situations.

The tertiary centre team is responsible for communicating the care plans to the referring hospital, referring Consultant and General Practitioner (GP). These decisions around planned place of birth (most likely in the tertiary centre) should be made well in advance by the multidisciplinary team and communicated appropriately to all.

## Care planning

An effective care plan ensures care is delivered according to the wishes of the Parents maintaining their autonomy and assisting in decisions around care for the mother and baby.

For Parents who have received a definitive diagnosis of FFA/LLC the focus should be on supporting Parents to build a relationship antenatally with their baby and on individualised memory-making, preparing them for the birth and death of their baby. Family-centered care, including psychological, spiritual and social support should be available throughout, as the Parents needs may change over time.

For Parents where the exact diagnosis is uncertain but the diagnosis is determined to be a FFA/LLC, the antenatal period is also a time where their Obstetrician may sensitively bring up the option of post-mortem investigations and examination.

Planning management around birth is important to ensure that the care reflects the wishes of Parents and the best interests of the baby, especially at later gestations of pregnancy. Formal care plans should be communicated to all involved in the pregnancy. In particular, communication between tertiary and local centres needs to be clear and timely.

While there are many conditions where there is reasonable certainty of death during fetal and early neonatal life, there are babies who survive longer than expected during supportive and end-of-life care. This is why, at later gestations, feticide needs to be available and may be considered as part of the termination of pregnancy procedure.

It is vital that all care planning is continuously reviewed in the best interests of the pregnant woman and the baby. There should be parallel planning for transition periods into and out of active, supportive and end-of- life care. The care plan may need to be altered to allow for changes in the place of care, the condition of the woman or the baby, and the Parents' views and wishes.

### Training and support of staff and multidisciplinary teams

Successful implementation of a care pathway for TOPFA requires appropriate training and support for healthcare professionals, to enable confidence to care for the pregnant woman during delivery, the fetus/baby at birth and to deliver the supportive care plan.

The representative bodies are responsible for providing training to their members, in keeping with international best practice. Training should be coordinated between training bodies so there is a joined up approach and understanding of the roles of the individual groups.

For TOPFA deliveries where the baby is anticipated to die soon after birth, consideration should be given to supporting and debriefing (formally and informally) staff caring for the Parents; these needs should be assessed in each circumstance. It is recommended that there are trained healthcare professionals in each tertiary centre to assist with supporting other staff members. This is the responsibility of local hospital management.

Issues and challenges for staff arising from caring for women who have a termination of pregnancy for FFA/LLC should form part of team discussions and should be addressed in hospital reviews of bereavement care.

## 9. OVERVIEW OF DELIVERY OF CARE

Maternal health and wellbeing during pregnancy, birth and the postnatal period remain components of maternity care, including when there is a planned termination of pregnancy for FFA/LLC. Joint consultation with Obstetrics/Neonatology Consultants or Paediatrics/Palliative care specialists, along with Midwife specialists potentially serves to ensure efficient review within the shortest time, reducing unnecessary overlap in counselling, and improving communication between teams.

### Antenatal care

It is important to reach (in as much as possible) an accurate antenatal diagnosis in the pregnancy to ensure that consistent clinical care and management are provided to the Parents. This may take time. The diagnosis may only be reached after further investigations and/or further ultrasound scans and/or observation of the evolving natural history of a condition.

In most cases, during this time the pregnant woman would continue to receive antenatal care even for a short time with individualised support from the multidisciplinary team. Fetal medicine assessment should continue alongside antenatal care, for as long as the pregnancy continues. However, the care should be provided in a place away from busy maternity clinics and areas of routine clinical activity. The staff whom the Parents meet at the antenatal / fetal medicine clinic should also be informed of the situation beforehand. This will help with continuity of care and avoid unintentionally saying things that could cause additional distress.

Parents who opt for termination of pregnancy need to be supported and given access to resources to help them through their grief. There is a focus on supporting Parents to build bonds with their baby in this (brief) antenatal period, as well as on memory-making and antenatal counselling /anticipatory grief counselling.

If the fetal diagnosis increases the risk to maternal health (e.g. fetal hydrops or polyhydramnios), additional appropriate and timely antenatal care should be arranged and decision making around termination of pregnancy may need to be expedited. Care can be revised and agreed by the Multi-Disciplinary Team and the Parents as circumstances change.

An explicit care plan should be developed in conjunction with the Parents, especially for termination of pregnancy at later gestations. This should include the use and discussion around feticide, the use of fetal monitoring (which is not recommended if there is certainty around the diagnosis of FFA/LLC), the action to be taken in the event of abnormal fetal monitoring, conduct of the delivery, and how the baby will be handled and cared for at and after the birth. An anaesthetic review may also be organised to discuss analgesia at the time of delivery. The pregnant woman's medical chart must be updated throughout the pregnancy. The antenatal diagnosis and care plan must be clearly documented in the notes.

### Termination of pregnancy procedures

Women should be informed that termination of pregnancy is generally a safe procedure for which complications and mortality are rare at all gestations. However, the risk is dependent on the stage of pregnancy at which the termination of pregnancy is performed in addition to the procedure used. Communicating the risk of complications associated with TOPFA in an understandable way is essential to informed decision making whilst emphasizing the overall safety of the procedure. Information should be given about how and where the termination will be performed. Written information leaflets should be provided to include information about complications, risks and psychological sequelae.

Termination of pregnancy can be performed surgically before 14 weeks of pregnancy, when uterine evacuation can usually be achieved by vacuum aspiration with an appropriate-sized instrument after cervical preparation with misoprostol. After this gestational age, fetal size precludes complete aspiration and dilatation and evacuation (D&E) becomes necessary. The Royal College of Obstetricians & Gynaecologists (RCOG, UK) only recommends D&E when undertaken by specialist practitioners with access to the necessary instruments and who have a sufficiently large caseload to maintain their skill. It is unlikely that surgical termination of pregnancy after 12 weeks will be widely available nor that D&E after 14 weeks will be offered in Ireland in 2019, but this may change over time.

When undertaking a termination of pregnancy, the intention is that the fetus should not survive and that the process of termination of pregnancy 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 abnormality for which termination was performed or because of concomitant extreme prematurity.

In later stage termination of pregnancy there is the possibility that the fetus could be delivered showing signs of life. This can be traumatic for the woman undergoing the termination and challenging for the healthcare professionals providing treatment and care. Appropriate local policies should be in place to deal with later gestation medical terminations of pregnancy and should be clear about the role of the healthcare professional, in the event of the neonate showing signs of life. Feticide can be performed before medical termination takes place after 21 weeks and 6 days of gestation to ensure that there is no possibility of a live birth.

### Feticide

Feticide refers to induced fetal demise performed as part of termination of pregnancy procedure. Feticide should only be performed in tertiary referral centres where there are fetal medicine specialists with the appropriate level of training. In Ireland, it is likely that feticide will only be performed by a few fetal medicine specialists in a small number of tertiary centres.

Feticide is most commonly performed before medical termination for FFA/LLC after 21 weeks and 6 days of gestation to ensure that there is no chance of a live birth. Inducing fetal death before medical termination of pregnancy may have beneficial emotional, ethical and legal consequences. In terminations where the fetal anomalies are not compatible with life, abortion without feticide may be preferred. However, in cases where the fetal anomaly is not immediately lethal and TOPFA is being undertaken after 21 weeks and 6 days of gestation, failure to perform feticide could result in a live birth and survival, an outcome that contradicts the intention of the termination.

Parents should be offered sympathetic and supportive counselling before and particularly after the procedure. Some may still not opt for feticide, preferring to spend time with the baby whilst alive.

Feticide should be performed by an appropriately trained practitioner under aseptic conditions and continuous ultrasound guidance. To perform feticide, intra-cardiac potassium chloride (KCl) injection is most commonly administered and is the recommended method to ensure fetal asystole. Alternatively, and less commonly, fetal demise may be induced by intra-amniotic or intrathoracic injection of digoxin or by umbilical venous or intra-cardiac injection of 1% lidocaine. Neither of these procedures, however, consistently induces fetal demise.

After aspiration of fetal blood to confirm correct placement of the needle, 2–3 ml strong (15%) KCl is injected into a fetal cardiac ventricle. A repeat injection may be required if asystole has not occurred after 30–60 seconds. Asystole should be documented for at least 2 minutes and a scan repeated after 30–60 minutes to ensure fetal demise.

It is recommended (RCOG, UK; BMFMS, UK) 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.

Selective feticide can be employed in circumstances where one fetus in a multiple pregnancy has a FFA/LLC. This can be undertaken at various gestational ages. The type of procedure is determined by chorionicity. When fetuses have separate placentas intra-cardiac potassium chloride injection is most commonly performed. In shared chorionicity, selective feticide of the affected twin should be performed by a vascular occlusion procedure such as radiofrequency ablation, bipolar cord coagulation, laser cord coagulation or cord ligation. The optimal surgical approach remains undetermined and is dependent upon gestational age and available expertise. Women may need to be referred to an international centre for these procedures.

The Institute of Obstetricians and Gynaecologists requested clarity from the Department of Health regarding feticide and received a response from the Chief Medical Officer (Appendix 1).

### Medical protocols of induction

The protocols described here represent best practice from a review of international guidelines and published literature (Appendix 2). Misoprostol is administered buccally or vaginally. The buccal route is recommended, and the vaginal route should be avoided if there is vaginal bleeding or signs of infection. Misoprostol doses should be decreased in later pregnancy as sensitivity to prostaglandins increases with gestation. As the risk of uterine rupture increases with the presence of a uterine scar, individual assessment is important and medical practitioners should seek expert advice on dosing where required.

#### *Under 24 week's gestation*

The recommended protocol is;-

- Mifepristone 200mg taken orally
- Followed at an interval of not less than 24 hours and not more than 48 hours
- By Misoprostol 400microgram taken buccally or administered vaginally, 3-hourly to a maximum of 5 doses

If this protocol fails to complete the medical termination;-

- The protocol can be restarted after a minimum of 12 hours rest and preferably 24 hours
- Mifepristone 200mg orally can then be repeated
- Followed at a minimum interval of 12 hours
- By Misoprostol 400microgram (buccally or vaginally) 3-hourly to a maximum of 5 doses

In the setting of a previous uterine scar:-

- Mifepristone 200mg is taken orally
- Followed at an interval of not less than 24 hours and not more than 48 hours
- By a reduced dose of Misoprostol 200microgram (buccally or vaginally) 4-hourly to a maximum of 5 doses. Note - Misoprostol intervals are increased to 4-hourly
- The protocol can be repeated after 24 hours, with 6-hourly intervals

### *At $24^{+0}$ - $26^{+6}$ weeks' gestation*

The recommended protocol is;-

- Mifepristone 200mg taken orally
- Followed at an interval of not less than 24 hours and not more than 48 hours
- By Misoprostol 200microgram taken buccally or administered vaginally
- At 4-6 hourly intervals to a maximum of 5 doses

If this protocol fails to complete the medical termination;-

- The protocol can be restarted after 24 hours

### *At $27^{+0}$ - $28^{+0}$ weeks' gestation*

The recommended protocol is;-

- Mifepristone 200mg taken orally
- Followed at an interval of not less than 24 hours and not more than 48 hours
- By Misoprostol 100microgram (buccally or vaginally)
- At 4-6 hourly intervals to a maximum of 5 doses

If this protocol fails to complete the medical termination;-

- The protocol can be restarted after 24 hours

### *At over 28 weeks' gestation*

The recommended protocol is;-

- Mifepristone 200mg taken orally
- Followed at an interval of not less than 24 hours and not more than 48 hours
- By Misoprostol 25-50microgram (buccally or vaginally)
- At 4- 6 hourly intervals to a maximum of 5 doses

If this protocol fails to complete the medical termination;-

- The protocol can be restarted after 24 hours

### *In the setting of a previous uterine scar at gestations over 24 weeks' gestation*

- Management should be individualised
- Consideration should be given to using a higher dose of Mifepristone (e.g. 600mg) or repeated doses (200mg)
- Misoprostol doses are 25-50microgram (buccally or vaginally)
- Misoprostol intervals are increased to 6-hourly

### *Misoprostol administration*

Misoprostol is available in 100, 200 and 400 microgram strengths. Some strengths may have to be imported as unlicensed medicines. Where a dose reduction is required due to the presence of a uterine scar, advice should be sought from a Clinical Pharmacist on the formulations available in the local institution.

Although halving of tablets is feasible, further division of tablets may result in inaccurate doses (https://www.ncbi.nlm.nih.gov/pubmed/12237637 ). Low doses may be administered orally by dissolving a 200 microgram tablet in 200ml of water to prepare a 1 microgram/ml solution (http://www.misoprostol.org/dilute-200-mcg-misoprostol-200ml-water). Alternatively, 25 microgram tablets have become available internationally recently.
(https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.14657 )

### Intrapartum care

Plans for induction, labour and delivery need to be clearly documented and communicated to the hospital staff who will be involved in the woman's care.

There needs to be a focus on the emotional support given to the woman during induction, labour and delivery. The Parents' personal wishes around the care of their baby, including comfort care, bonding, cultural & religious preferences, need to be facilitated. It should be agreed who should be present at the delivery.

If a decision of non-intervention has been definitively made prior to delivery, it is appropriate that the woman be managed by her healthcare team (Midwife and Obstetrician) during labour and delivery. The Paediatric/Neonatal team may still need to be available for support and reassurance, depending on the gestation at termination of pregnancy and the medical procedures that have been used. The suitability of the care plan should be confirmed after delivery by a senior Paediatrician or Neonatologist.

The Parents should be counselled prior to birth about scenarios where the baby may be born alive, relevant at later gestations. Healthcare teams may also need to be supported in these situations.

The baby should remain with the Parents for as long as they wish. The baby should be weighed, measured and examined for signs of congenital anomalies when appropriate and at a time when the Parents are comfortable with this. All of this should be clearly documented.

In the event of baby's death, staff should explain to Parents the physical changes that are likely to occur as their baby dies and should discuss with them whether they want to see and hold their baby while dying / or after death. It is important to make it clear to the Parents that they can change their minds at any time.

Depending on the gestation at termination of pregnancy, Parents may or may not wish to handle their baby immediately after birth, and some may opt not to see the fetus/baby at all.

Liaison with the Bereavement support team and the Parents is important to ensure that they receive appropriate support and bereavement care when the infant dies.

The different scenarios that may arise during labour / after birth / delivery should be discussed with the Parents. This is especially relevant where feticide was not performed at later gestations of pregnancy.

These scenarios include:

- Intrapartum death (death during labour resulting in Stillbirth)
- Neonatal death on the delivery suite (minutes or hours)
- Leaving the delivery suite / admission to wards for ongoing palliative care (days)
- Admission to the neonatal unit for care / investigation
- Discharge from the neonatal unit to be with the Parents for end of life
- Transition to palliative care in the neonatal unit and/or home /or location chosen by Parents

Parents should be aware that while there is a high probability of death prior to delivery or in the early neonatal period, there will be babies who survive longer than expected during end of life care. The care plan should therefore allow for a scenario where perinatal palliative care is provided. Fetal medicine specialists / Obstetricians and Neonatologists / Paediatricians should be involved in care planning in cases where there is a probability of survival in the early neonatal period.

### Immediate postpartum care

It is important that women receive normal postnatal care and emotional support from the midwives looking after her in delivery suite and on postnatal wards. Ideally, one midwife should be allocated to care for the Parents and the fetus/baby. Parents should be allocated a room on their own after delivery. In discussion with the Parents, consideration should be given to display on hospital records and room doors, the hospital symbol that is used for pregnancy loss and perinatal death.

After delivery care for the woman should follow local care pathways established for miscarriage, vaginal birth or caesarean birth (depending on the gestation of the termination of pregnancy). This includes attention to the option of lactation suppression after second trimester fetal demise/stillbirth neonatal death. Women should be assessed for thromboprophylaxis as per local protocols and established guidelines, but termination of pregnancy is not a risk factor on its own. Parents/family bonding and holding the baby, providing comfort care and the making of mementoes should be facilitated (and encouraged), and in accordance with Parents' wishes.

In the case of fetal demise / neonatal death:

- Local care pathways for same should be followed.
- Bereavement support should be provided by members of the MDT caring for the Parents in conjunction with the bereavement CMS/CNS.
- A senior member of staff (Obstetrics/ Neonatology/ Paediatrics) should sensitively discuss consent to post-mortem investigations and examination to help clarify the diagnosis and management of subsequent pregnancies.

For those babies that are born with signs of life, a tentative palliative care plan will be in place, and will be overseen by the neonatology team.

It is important for the Woman's GP and Public Health Nurse to be informed as soon as possible of the outcome of the pregnancy, once the Parents give permission for this.

## Investigations

Clinical assessment, laboratory investigations and a full post-mortem (PM) examination should be considered to confirm the antenatally diagnosed fetal anomaly, the chance of recurrence and possible means of avoiding further pregnancy complications.

For those babies that are stillborn, an external examination can be performed after delivery by a neonatologist / paediatrician or by a perinatal pathologist. Prior discussions about post-mortem examination and appropriate cytogenetic testing will have taken place, and these options will again be discussed with the Parents after the termination of pregnancy. If a full PM is declined, in certain circumstances a limited PM, including an imaging PM (MRI or CT), may also be an option. The PM examination will be organised via the hospital group system in a timely fashion to assist with funeral / burial arrangements. Further input may be required from clinical genetics specialists after the PM is reported on.

Confirmatory testing with PM / cytogenetics/ imaging / clinical genetics referral may help to consolidate the diagnosis and will inform discussions on recurrence risk for future pregnancies. Further testing may be performed as per Neonatology assessment and recommendations.

## Burial/cremation/disposal of fetal remains

Cremation and burial should be available options for the disposal of pregnancy remains. Sensitive incineration, separate from clinical waste, may be used at early gestations where the woman makes this choice or does not want to be involved in the decision, and where hospital management considers this the most appropriate method of disposal.

The Parents should be given verbal or written information about these options with a clear explanation of what each option entails and given the opportunity to discuss them. They should be supported and cared for in a manner appropriate to the specifics of their case to ensure that they can make the decision that is right for them. At later gestations, Parents should be given specific information regarding hospital burial and be facilitated to make choices. Some Parents will make their own burial arrangements at a family plot or choose cremation.

If Parents are considering a hospital burial they need to be made aware that shared plots are used, and should be given information on the relevant cemetery. If Parents decide on hospital burial, or cremation, the services of the hospital's Undertakers are offered. Written consent for hospital burial is completed and placed in the chart, while a copy is also given to the Parents. Local guidelines apply regarding this process.

If more time is required to make a decision regarding burial / cremation options, information should be provided regarding who to contact and the timescale for this. Personal, religious or cultural needs relating to this should be met wherever possible. Consideration should also be given to the fact that some Parents may not wish to know about the disposal of the pregnancy remains or be involved in these decisions, and are free to decline the offer of information about the possible options.

Each institution should document the provision and receipt of relevant information pertaining to the disposal of remains and in cases where information has been declined, this should also be recorded in the medical record. Some Parents may wish to find out at a later date as to arrangements around disposal of remains, therefore local policies and procedures need to acknowledge and make provision for this fact.

Hospitals' policies around pregnancy remains should ensure that remains are treated with respect and that women are aware that there are different options available to them. The needs of the Parents are of paramount importance in the development of a policy around disposal of fetal remains, and all local paperwork should reflect the sensitive nature of these cases and be written in a clear concise language format making it suitable for those who choose to access it.

All staff that may be asked, or expected, to provide information about disposal of pregnancy remains should be aware of the hospital policy and prepared to discuss it. They should be sensitive to the values and beliefs of a wide range of cultures and religions, and should have detailed knowledge of, and understand the practical aspects of, each form of disposal. Staff involved should be able to properly communicate this information to the woman. Each institution is responsible for training or accessing training for relevant staff caring for these women and where needed have access to counselling services should they require support themselves.

Some Parents may wish to make their own arrangements for the disposal of their pregnancy remains. It is appropriate in these cases for the hospital to offer advice and assistance and support in these cases. In these cases the remains should be stored in an appropriate container in a safe place and made available for collection by the Parents or their representatives. The decision, and the date of collection, should be recorded in the medical notes and Parents should be given written confirmation that they are entitled to take the remains and make their own arrangements.

Where the woman has not made a decision about the pregnancy remains within a locally specified period of time since the termination, the hospital responsible for the woman's care should make arrangements for disposal in line with this guidance. The Parents should be made aware of the time period when first given information about disposal options. The hospital must retain information in relation to when, how and where the remains were disposed of and ensure that full information is available to be provided at a later date if requested.

Records kept by hospitals or external agencies (e.g. cemetery, crematorium) around disposal of fetal remains after termination of pregnancy need to be mindful of the need to protect the privacy of the pregnant woman and the confidentiality of the medical details involved.

### Care following termination of pregnancy

Parents need integrated and ongoing support through the end of the pregnancy, delivery and into the postnatal period, as well as bereavement care. Parents must be offered bereavement support by the bereavement team, preferably in their local maternity hospital (e.g. the Bereavement CMS/CNS, or the CMS in Prenatal Diagnosis), although this will obviously depend on where the woman delivers.

The bereavement team (a named healthcare professional) should also follow up with the Parents and offer them bereavement support.

All women (and partners) should be offered a review appointment (or support visit as appropriate) in the weeks following termination of pregnancy and delivery, to assess the woman's physical and emotional wellbeing.

The Parents must also have a formal follow-up postnatal appointment with the fetal medicine team and/or their local Obstetrician, to assess wellbeing and review results of any post-mortem investigations, as well as review management of the recent pregnancy. This post-pregnancy visit should also discuss potential planning for future pregnancies (if appropriate) and relevant preconception care or future early prenatal screening. This is generally arranged in the hospital where the baby is born, although may also involve the local Obstetrician, where the baby is born in a tertiary hospital.

## 10. REGISTRATION

The Birth Notification Form (Form BNF/01) is usually completed with the Parent(s) by hospital staff (in the case of hospital births) to guarantee that correct and accurate information is recorded. This form outlines the information to be recorded in the Register of Births. The form is forwarded to the Registrar's office letting the Registrar know that a birth has occurred. The registration of the birth is carried out based on information provided by a qualified informant who is required to attend at the office of the Registrar to sign the Register of Births. The mother and father of the child are the main qualified informants and, where possible, must attend personally for the registration of the birth.

The current legislation on registration of live births before the age of viability confirms that: if an infant is born with signs of life, regardless of birthweight or gestational age at delivery, the birth is registered as a live birth and if the subsequent death of the infant occurs during the perinatal period, the death should then also be registered as a neonatal death.

Where a baby is stillborn or dies in the neonatal period, following a termination of pregnancy for fatal fetal anomaly, the cause of death should be stated as that directly leading to the death, and also the antecedent causes or conditions which gave rise to this. It is important to note that the reported disease or condition directly leading to death does not mean the mode of dying; it means the disease which caused death.

### Stillbirth

Babies born dead after the 24th week of pregnancy are defined in law as a Stillbirth and must be registered as such, regardless of whether a termination of pregnancy has been performed.

In line with the Stillbirths Registration Act (1994), all stillbirths occurring in Ireland since 1 January 1995 must be registered, if the baby weighs at least 500 grammes or has a gestational age of at least 24 weeks. The Parents are responsible in law for registering the birth but can delegate the task to a healthcare professional.

In cases of stillbirth the medical practitioner who attends the delivery or examines the baby provides the required medical certificate to the mother or the father of the stillborn child; this is usually done after the results of any post-mortem examination are known.

### Neonatal Death

Babies born with signs of life who die in the neonatal period must be registered. The responsible Neonatologist / Paediatrician or Obstetrician as appropriate completes the Death Notification form (part 1). This is usually done after the results of any post-mortem examination are known.

## 11. CERTIFICATION AND NOTIFICATION

In all cases of termination of pregnancy, a form of certification must be completed as specified by the Health (Regulation of Termination of Pregnancy) Act 2018. This certification must confirm the basis for termination of pregnancy as specified by the terms of the Act and provide confirmation of whether the termination of pregnancy to which the certification relates was the subject of a review. This is the responsibility of two medical practitioners, and includes the Obstetrician who carries out the termination of pregnancy. Certification forms are made available by the Department of Health and should be circulated by the HSE to all hospitals.

http://www.irishstatutebook.ie/eli/isbc/2018_31.html#associatedsecondary

Section 19 of the Health (Regulation of Termination of Pregnancy) Act 2018 states that:

> *A certification shall—*
> *(a) be made in the prescribed form and manner, and*
> *(b) contain the prescribed information which shall include—*
> *(i) confirmation of whether the termination of pregnancy to which the certification relates was the subject of a review, and*
> *(ii) in the case of a… section 11… certification, the clinical grounds for carrying out the termination of pregnancy to which the certification relates*

The following information is specified for the purposes of certification under the Act:

- the Medical Council registration numbers attached to the registration of the medical practitioners who made the certification concerned and
- that of the medical practitioner who carried out the termination of pregnancy,
- the address of the woman involved
- the date of birth of the pregnant woman
- the estimated weeks of pregnancy and
- the clinical grounds for carrying out the termination of pregnancy

Where a termination of pregnancy is carried out in accordance with Section 11, the medical practitioner who carried out the termination of pregnancy must also complete the notification forms, as specified by the Health (Regulation of Termination of Pregnancy) Act 2018, and forward these to the Minister for Health at the Department of Health no later than 28 days after the termination of pregnancy has been carried out.

Section 20 of the Health (Regulation of Termination of Pregnancy) Act 2018 states that:

> *Where a termination of pregnancy is carried out in accordance with section 9, 10, 11 or 12, the medical practitioner who carried out the termination of pregnancy shall—*
> *(a) keep, or cause to be kept, a record, in the prescribed form and manner, of—*
> *(i) the carrying out of the termination of pregnancy, and*
> *(ii) the information specified in subsection (2), and*
> *(b) not later than 28 days after the termination of pregnancy has been carried out, forward, or cause to be forwarded, a copy of that record, or such part of that record as may be prescribed, to the Minister in such manner as may be prescribed.*

The following information is specified for the purposes of notification under the Act:

- the Medical Council registration numbers attached to the registration of the medical practitioners who carried out the termination of pregnancy
- the Medical Council registration numbers attached to the registration of the medical practitioners who made the certification concerned
- the county or place of residence of the woman involved and
- the date on which the termination of pregnancy was carried out

For the purposes of Section 20 of the Act, a copy of the notification form shall be (a) marked "STRICTLY PRIVATE AND CONFIDENTIAL", and (b) forwarded to the Minister at Bioethics 2 Unit, Department of Health, Block 1, Miesian Plaza, 50—58 Lower Baggot Street, Dublin, D02XW14.

## 12. CONSENT

All women should have the opportunity to discuss the different pregnancy options available to them. Appropriate consent should be obtained prior to termination of pregnancy, which clearly outlines the risks, benefits, side effects and complications of treatments or procedures. If written consent cannot be obtained a contemporaneous note of the woman's consent should be taken.

Nothing in the Health (Termination of Pregnancy) Act 2018 operates to remove or amend any existing rule of law in relation to consent.

### Informed consent

Consent is the giving of permission or agreement for an intervention, receipt or use of a service or participation in research following a process of communication about the proposed intervention. Consent must be obtained before starting treatment or investigation, or providing personal or social care for a service user or involving a service user in teaching and research. This requirement is consistent with fundamental ethical principles, with good practice in communication and decision-making and with national health and social care policy. The need for consent is also recognised in Irish and international law.

No other person such as a family member, friend or carer and no organisation can give or refuse consent to a health or social care service on behalf of an adult service user who lacks capacity to consent unless they have specific legal authority to do so. Health and social care professionals

have a responsibility to keep themselves informed of professional standards relevant to obtaining consent in their practice. The general principles of consent are set out in the HSE's National Consent Policy (2017).

For consent to be valid, the woman must:

- Have received sufficient information in a comprehensible manner about the nature, purpose, benefits and risks of an intervention/service or research project.;
- Not be acting under duress;
- And have the capacity to make the particular decision.

Discussions with pregnant women should as much as possible be tailored according to:

- Their needs, wishes and priorities
- Their level of knowledge about, and understanding of, their condition, prognosis and the treatment options
- Their ability to understand the information provided/language used

Information around termination of pregnancy should be provided in simple, clear and concise English with avoidance of medical terminology. Pregnancy options should be discussed in a place and at a time when the woman is best able to understand and retain the information. Sensitive issues should be discussed in an appropriate location to ensure that the woman's privacy is protected to the greatest degree possible in the circumstances. It is essential to provide adequate time and support.

For a person under the age of 18 years, the statutory reporting requirements of Children First: National Guidance and Withholding of Information Act, should be followed. Additional guidance is also available in the HSE National Consent Policy (HSE 2017) and the Guide to Professional Conduct and Ethics for Registered Medical Practitioners (IMC 2016).

## 13. CONSCIENTIOUS OBJECTION

According to the Act (Section 22 (1); Health (Regulation of Termination of Pregnancy) Act, 2018), no Medical Practitioner, Nurse or Midwife will be obliged to carry out, or to participate in carrying out, a termination of pregnancy to which he or she has a conscientious objection.

> *Subject to subsections (2) and (3), nothing in this Act shall be construed as obliging any medical practitioner, nurse or midwife to carry out, or to participate in carrying out, a termination of pregnancy in accordance with section 9, 11 or 12 to which he or she has a conscientious objection.*

This is qualified by Section 22(2) which states that a person who has a conscientious objection shall, as soon as possible, make such arrangements for the transfer of care of the pregnant woman concerned as necessary to enable the woman to avail of the termination of pregnancy.

*A person who has a conscientious objection referred to in subsection (1) shall, as soon as may be, make such arrangements for the transfer of care of the pregnant woman concerned as may be necessary to enable the woman to avail of the termination of pregnancy concerned.*

Therefore, in emergency situations, a medical practitioner must provide treatment to the pregnant woman, irrespective of any conscientious objection that the medical practitioner, may have. This is stated clearly in the relevant section of the HSE's (2018) Model of Care document and also in the HSE Guidelines for medical practitioners, nurses, and midwives in HSE hospitals and agencies funded under Section 38 of the Health Act 2004 regarding conscientious objection (2018).

### HSE Guidelines

The HSE Guidelines regarding conscientious objection were issued on 28 December 2018. They state that Section 22 of the Act applies to medical practitioners, nurses and midwives.

The HSE guideline says that "*the right of medical practitioners, nurses or midwives to decline to carry out (or to decline to participate in carrying out) a termination of pregnancy is not unlimited, even if they have a conscientious objection*". Specifically, a medical practitioner, nurse or midwife cannot decline to carry out (or to participate in carrying out), a termination of pregnancy where a medical practitioner believes:- (a) there is an immediate risk to the life, or serious harm to the health, of the pregnant woman; and (b) it is immediately necessary to carry out a termination of pregnancy in order to avert that risk.

The HSE guideline states that "*if a medical practitioner, nurse or midwife has a conscientious objection to carrying out, or participating in carrying out a termination of pregnancy under Section 11 (titled "Condition likely to lead to death of foetus") of the Act, they are obliged under the Act to make arrangements for the transfer of care of the pregnant woman to enable her to avail of the termination of pregnancy concerned. The Act says that the medical practitioner, nurse or midwife must do this 'as soon as may be'."*

The HSE requires that medical practitioners, nurses and midwives inform an appropriate manager as soon as practicable if they have a conscientious objection as referred to in Section 22 of the Act. This is necessary in order to allow the HSE hospital or Section 38 agency to take appropriate steps to ensure that there is sufficient staff available to provide the termination of pregnancy services provided for in the Act (HSE Guidelines, 2018)

### Irish Medical Council

The 8th Edition of the Irish Medical Council's Guide to Professional Conduct and Ethics (2016) states that Doctors "have a duty to provide care, support and follow up for women who have had an Abortion"(Section 48.5).

The Medical Council deleted paragraphs 48.1 to 48.4 (Section 48) of the 2016 Ethical Guide in December 2018, thus removing any conflict between the Ethical Guide and the Legislation.

Paragraph 48.5 of the Guide, slightly edited, "You have a duty to provide care, support and follow up for women who have had a termination of pregnancy" remains in place.

The Medical Council is working through a detailed process in 2019 to update their Ethical Guidance following the enactment of the Health (Regulation of Termination of Pregnancy) Act 2018. The Ethics Working Group is reviewing the Guide to ensure that the Guidance is relevant and appropriate for doctors and for patients in light of the new legislation.

Regarding conscientious objection, the current Guide (section 49) states that:

- You may refuse to provide or to take part in the provision of lawful treatments or forms of care which conflict with your sincerely held ethical or moral values.
- If you have a conscientious objection to a treatment or form of care, you should inform patients, colleagues and your employer as early as possible.
- When discussing these issues with patients, you should be sensitive and considerate so as to minimise any distress your decision may cause. You should make sure that patients' care is not interrupted and their access to care is not impeded.
- If you hold a conscientious objection to a treatment, you must: inform the patient that they have a right to seek treatment from another Doctor; and give the patient enough information to enable them to transfer to another Doctor to get the treatment they want.
- If the patient is unable to arrange their own transfer of care, you should make these arrangements on their behalf.
- In an emergency, you must make your patient's care a priority and give necessary treatment

### Royal College of Obstetricians and Gynaecologists (RCOG), UK

RCOG guidance highlights that Doctors involved in the provision of abortion care are bound by the duties of a Doctor as laid out by the General Medical Council's Guide to Good Medical Practice, in particular making sure that their personal beliefs do not prejudice their patients' care. The RCOG advise trainees that the conscientious objection clause only covers refusal to participate in terminations.

To clarify, the rights of a professional to conscientious objection, as summarised by the British Medical Association (BMA) and presented in the RCOG guidance, are:

- Doctors may refuse to participate in terminations, but are obliged to provide necessary treatment in an emergency, when the woman's life may be in jeopardy
- Doctors with a conscientious objection may not impose their views on others, but may explain their views to a patient if invited to do so
- Refusal to participate in paperwork or administration connected with abortion procedures lies outside the terms of the conscientious objection clause
- Practitioners cannot claim exemption from giving advice or performing the preparatory steps to arrange an abortion where the request meets the legal requirements; such steps include referral to another Doctor, as appropriate
- The conscientious objection clause may be used by medical students to opt out of witnessing terminations

### Society for Maternal-Fetal Medicine (SMFM), USA

The Society for Maternal-Fetal Medicine asserts that MFM physicians have the professional responsibility to respect women's autonomy in decisions about pregnancy and to provide non-judgmental care to women, either directly or through appropriate referrals. However, the Society recognises that some physicians may have religious or moral objections to participating in certain health care services, including pregnancy termination. In the event an MFM physician has a religious or moral reason for not providing abortion or other legal reproductive health services, the physician has a professional responsibility to provide timely referrals to his or her patients who request or require such care. While SMFM recognizes that support for or opposition to pregnancy termination services is a personal matter and respects the need for its members to determine their individual positions, as an organization, SMFM supports pregnancy termination as a valuable health care service and opposes legislation and policies that limit its access to women, especially those experiencing high-risk pregnancies.

## 14. REVIEW PROCESS

If the Consultant(s) does not certify to facilitate a termination of pregnancy, this opinion must be communicated to the pregnant woman in writing, and a review process is available. This is set out in Section 13; Health (Regulation of Termination of Pregnancy) Act, 2018. In this case the pregnant woman, or a person acting on her behalf, can make an application to the HSE and seek a review of the medical opinion.

*(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, 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.*

The HSE will establish and maintain an appointed panel of medical practitioners (Section 14; Health (Regulation of Termination of Pregnancy) Act, 2018) for the purposes of the establishment of a review committee in relation to a relevant decision.

*Section 14 (2)*
*The membership of the review panel shall consist of—*
*(a) medical practitioners who are registered in the Specialist Division of the register, and*
*(b) medical practitioners of relevant specialties*

The HSE will establish and convene a review committee (Section 15; Health (Regulation of Termination of Pregnancy) Act, 2018) with the necessary expertise to conduct the review. This must happen 'as soon as may be' but not later than 3 days from the date on which the HSE receives an application under section 13 (2).

*Section 15 (2)*
*A review committee shall consist of-*
*(a) an obstetrician, and*
*(b) in the case of— (ii) a review of a relevant decision which relates to the circumstances referred to in section 11(1), a medical practitioner of a relevant specialty.*

It is recommended that the review committee for matters relating to Section 11 certification (condition likely to lead to death of fetus) be constituted by fetal medicine specialists, as well as in Neonatology/ Paediatrics; ideally these Doctors will have already agreed to be on the HSE's established review panel.

## 15. AUDIT

Termination of pregnancy service providers should conduct regular audit of the care they provide, and this should include the experience of services users. The recommendations within this guideline can serve as criteria for audit around the management of pregnancies complicated by FFA/LLC. Data collection will help to assess performance against specified standards to feedback to staff, who can implement changes to improve quality of care.

### Suggested auditable standards include:

- *Pathways of Care*
  Services should undertake audit to determine whether staff are familiar with all these pathways of care and whether they are being used appropriately and effectively.

- *Information Provision*
  Audit whether information (routes of access to TOP, pregnancy options, TOP procedures, complications, risks, adverse effects and sequelae) is being offered and if it is understood.

- *Pre-termination of pregnancy assessment*
  Audit intervals in all referral pathways, timing of fetal anomaly ultrasound scan, gestation at diagnosis, discussion at fetal medicine MDT meetings, and appropriate contact with members of the MDT

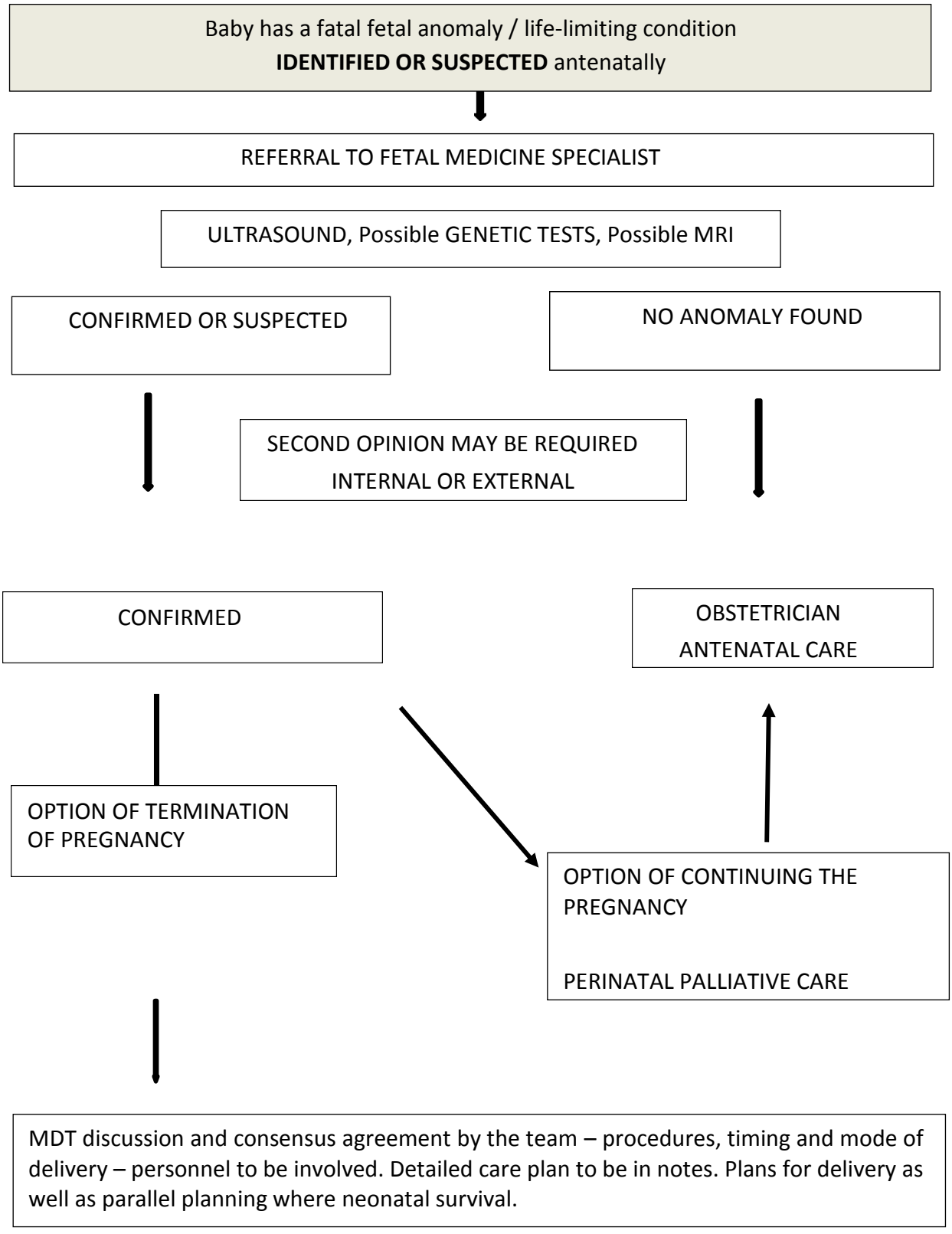
- *Termination of Pregnancy Procedures*
  Audit rate of complications, practice of feticide, induction to delivery intervals, length of stay in hospital, adherence to medication protocols, failure rates, and surgical procedures

- *Care after termination of pregnancy*
  Audit follow-up arrangements, VTE prophylaxis, hospital accommodation, appropriate contact with members of the MDT, bereavement support and contact with members of the bereavement team, contraceptive plans, communication with GP, staff training and support

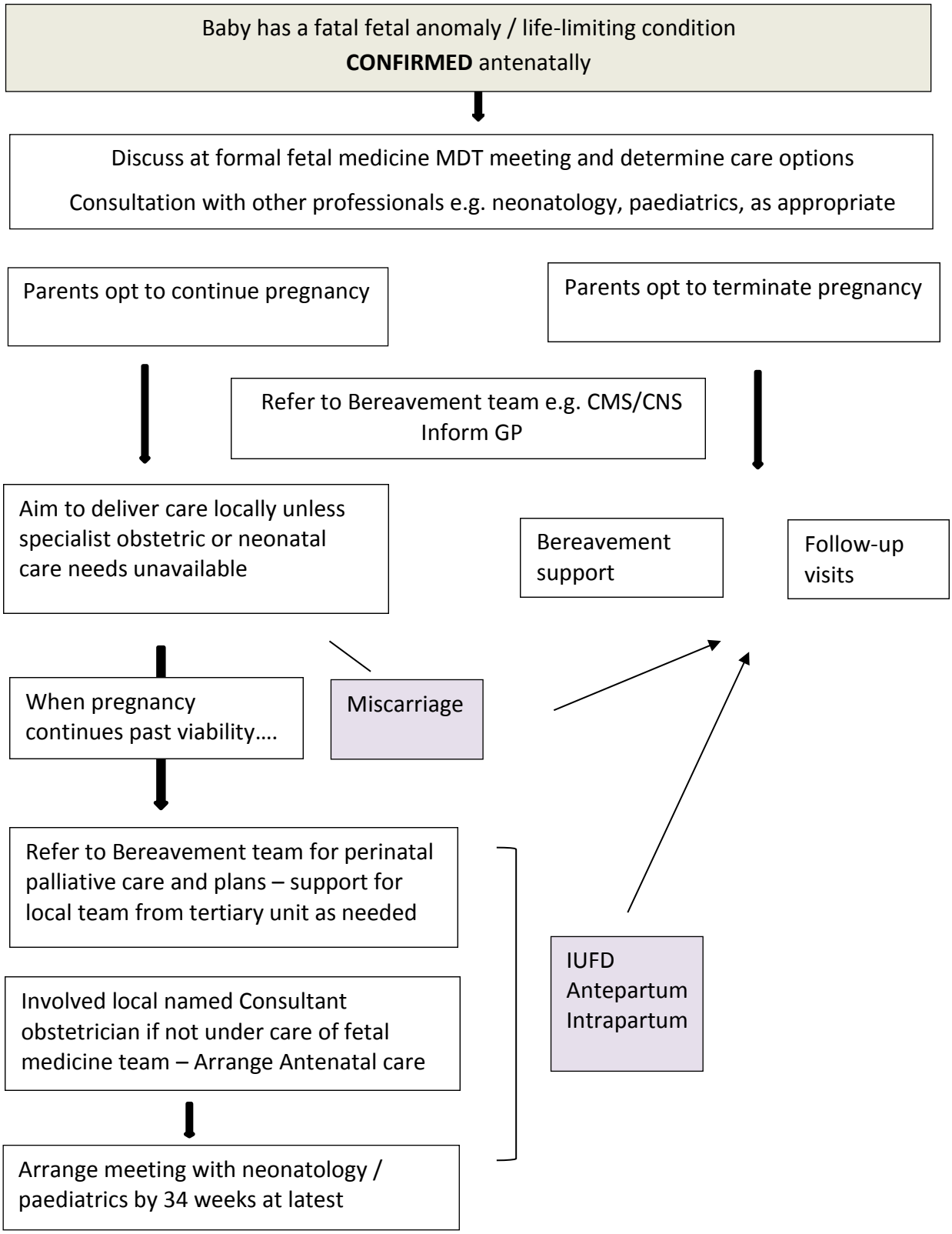
- *Investigations after termination of pregnancy*
  Audit complete investigations, post-mortem examination rates, concordance of PM investigations with prenatal diagnosis

## 16. PATHWAYS

### ANTENATAL PATHWAY AFTER ANOMALY ULTRASOUND SCAN (1)

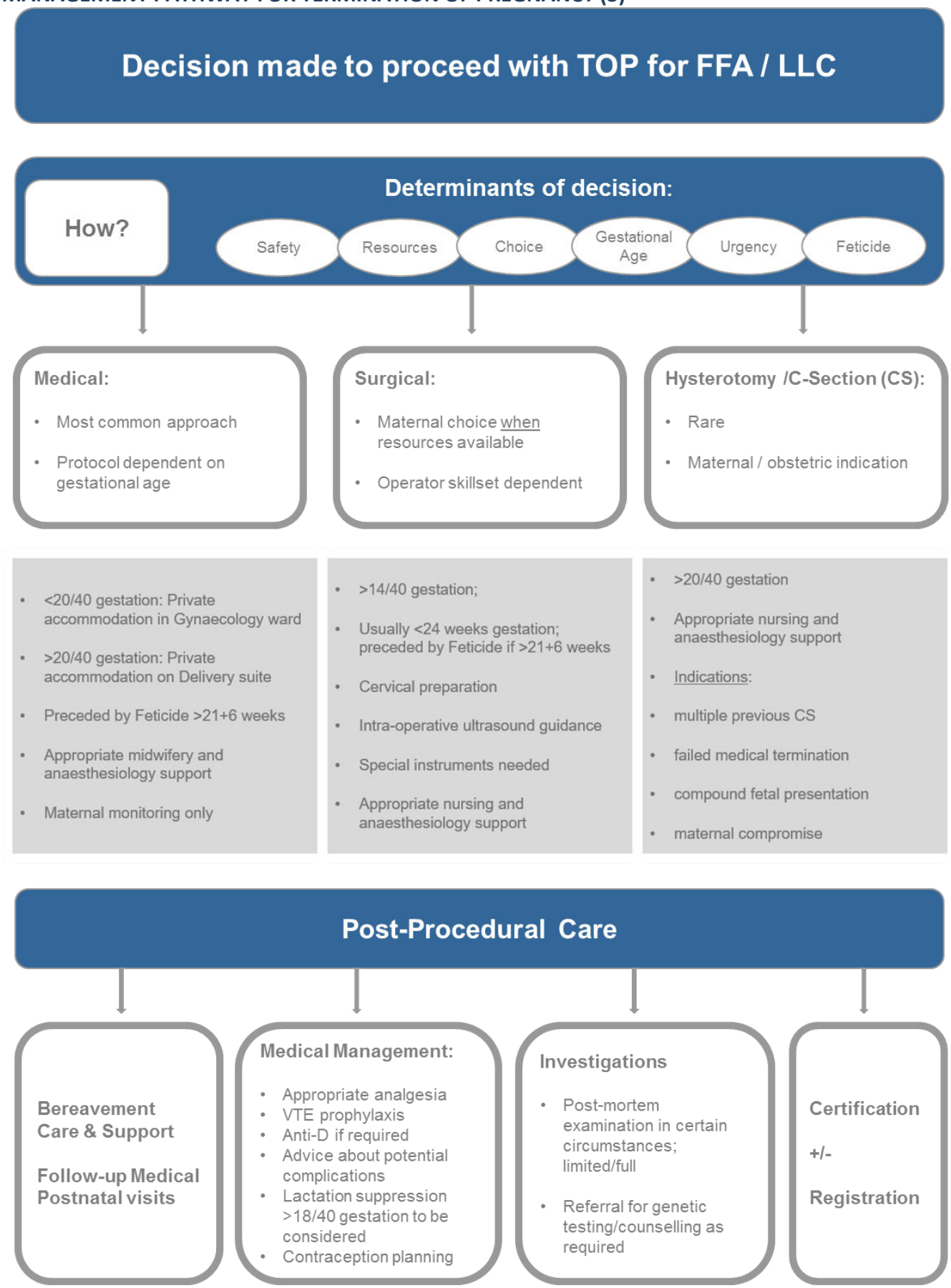


## ANTENATAL PATHWAYS AFTER PRENATAL DIAGNOSIS (2)




MDT discussion and consensus between all members of team - timing and mode of delivery – personnel to be involved – parents' birth plans. Detailed care plan to be in notes. Plans for term and preterm delivery as well as parallel planning where neonatal survival.

## MANAGEMENT PATHWAY FOR TERMINATION OF PREGNANCY (3)



## 17. CONTACTS AND SUPPORT SERVICES (Ireland)

A Little Lifetime Foundation (previously Irish Stillbirth and Neonatal Death Society)
www.alittlelifetime.ie

Every Life Counts
http://www.everylifecounts.ie/

Fèileacàin (Stillbirth and Neonatal Death Association of Ireland)
www.feileacain.ie

First Light (previously Irish Sudden Infant Death Association)
https://firstlight.ie/

Irish Hospice Foundation
https://hospicefoundation.ie/bereavement-2-2/

Irish Multiple Births Association
http://www.imba.ie/

Leanbh Mo Chroi
https://lmcsupport.ie/

Now I Lay Me Down To Sleep
https://www.nowilaymedowntosleep.org/articles/nilmdtsinireland/

SOFT Ireland
http://www.softireland.com/

Termination For Medical Reasons Ireland
http://tfmrireland.com/

## 18. GLOSSARY

| | |
|---|---|
| ACOG | American College of Obstetricians and Gynaecologists |
| BMA | British Medical Association |
| BMFMS | British Maternal and Fetal Medicine Society |
| BUCCAL | Pills are placed between the cheek and gums and swallowed after 30 minutes |
| CS | Caesarean section |
| CMS/CNS | Clinical Midwife Specialist/ Clinical Nurse Specialist |
| CNGOF | Collège National Des Gynécologues et Obstétriciens Français |
| D&E | Dilatation & Evacuation |
| EARLY NEONATAL DEATH | Death of a live-born baby within the first seven days of life |
| END OF LIFE CARE | Describes the care that is offered during the period when death is imminent, and life expectancy is limited to a short number of days, hours or less. It is care of the baby before death, during death, after death and bereavement care. |
| FETUS | The developing baby in utero after 8 weeks of pregnancy |
| FFA | Fatal Fetal Anomaly/Anomalies |
| FIGO | The International Federation of Gynecology and Obstetrics |
| GP | General Practitioner |
| GRIEF | The reaction to loss and bereavement |
| HSE | Health Service Executive |
| IMC | Irish Medical Council |
| ISUOG | International Society of Ultrasound in Obstetrics & Gynaecology |
| IUFD | Intra-uterine fetal death<br>Describes the death of a baby in the womb. |
| KCl | Potassium Chloride |

| | |
|---|---|
| LLC | Life-limiting condition |
| MBRRACE-UK | Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK |
| MDT | Multi-disciplinary team |
| MFM | Maternal and Fetal Medicine |
| MRI | Magnetic resonance imaging |
| NWIHP | National Women and Infants Health Programme |
| NEONATAL | Refers to the period after birth up until 28 days |
| NEONATAL DEATH | Death of an infant within the first 7 days of life (early) or within the first 28 days of life (late) |
| NICE | National Institute for Clinical Excellence |
| NPEC | National Perinatal Epidemiology Centre |
| PALLIATIVE CARE | Care of the patient with a life-limiting / life-threatening condition and their families- a philosophy of care. |
| PERINATAL PALLIATIVE CARE | Describes the perinatal palliative care of a baby when life expectancy is limited and death is imminent. It encompasses care of the baby from the time of diagnosis through to death, and care of the baby and Parents following death. |
| PERINATAL PERIOD | The period from 23/24 weeks gestation to 7 days following birth |
| PM | Post-mortem examination |
| PPC | Perinatal palliative care |
| RANZCOG | Royal Australian and New Zealand College of Obstetricians and Gynaecologists |
| RCOG | Royal College of Obstetricians and Gynaecologists |
| RCPI | Royal College of Physicians in Ireland |
| SMFM | Society for Maternal and Fetal Medicine |
| STILLBIRTH | A child born weighing 500 grammes or more or having a gestational age of 24 weeks or more who shows no sign of life |

| | |
|---|---|
| TOP | Termination of Pregnancy |
| TOPFA | Termination of Pregnancy for Fetal Anomaly |
| VAGINAL | Pills are placed in the vaginal fornixes (deepest portions of the vagina) and the individual is instructed to lie down for 30 minutes. |
| VTE | Venous Thromboembolism |
| WHO | World Health Organisation |

## 19. ACKNOWLEDGEMENTS

**Reviewers:**

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National Implementation Group for the HSE Bereavement Care Standards following Pregnancy Loss and Perinatal Death

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## 20. DISCLAIMER

*This guidance document has been developed at the request of the Department of Health to provide guidance in respect of the Health (Regulation of Termination of Pregnancy) Act 2018. It contains a general summary and an interim outline of guidance on the Act only and does not constitute a complete or definitive statement of the law. All clinicians have a professional responsibility to read and familiarise themselves with the legislation. This is necessary for clinicians to be clear where something is a legislative requirement, and where something is best practice, but not required as a matter of law. This guidance document does not purport to provide for all situations which may arise but set out a general guide only. It is not to be considered a substitute for the legislation and the legislation is the overriding statutory framework. Guidance documents are not a substitute for a clinician's responsibility and accountability to exercise good clinical professional judgment nor do they in any way restrict or modify a clinician's legal obligations. Legal advice should be obtained where appropriate*.

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## 22. APPENDICES

### APPENDIX 1 – Letter from CMO re. ending the life of a fetus

**An Roinn Sláinte**
Department of Health
Office of the Chief Medical Officer

5 December 2018

Dr Cliona Murphy
Chair
Institute of Obstetricians and Gynaecologists
Royal College of Physicians of Ireland
Frederick House
19 South Frederick Street
Dublin 2

Dear Dr Murphy

Thank you for your letter of 4th December concerning the Health (Regulation of Termination of Pregnancy) Bill 2018, and the legality of the practice of ending the life of a foetus.

'Termination of pregnancy' has been defined in the Bill as meaning 'a medical procedure which is intended to end the life of the foetus'. I can confirm that under the terms of the Bill, such a medical procedure may be carried out where there is a risk to the life or of serious harm to the health of the pregnant woman, in an emergency situation where such a risk is immediate, where there is a condition present which is likely to lead to the death of the foetus either before or within 28 days of birth, and without restriction up to 12 weeks of pregnancy. A medical practitioner carrying out a medical procedure, which includes the prescribing of a drug or medicine, intended to end the life of a foetus within the provisions of the legislation will not be subject to prosecution.

Yours sincerely

Dr Tony Holohan
Chief Medical Officer

## APPENDIX 2 - Medication Protocols For Termination of Pregnancy

| | |
|---|---|
| **TOP second trimester <24 weeks** | RCOG (2,3)<br><br>Mifepristone 200mg orally followed 36-48 hours later by Misoprostol 800 microgram vaginally, followed by misoprostol 400 microgram orally or vaginally every 3 hours until expulsion, to a maximum of four further doses.<br><br>If after 24 hours, expulsion does not occur, Mifepristone can be repeated 3 hours after the last dose of misoprostol. Recommence misoprostol 12 hours after the repeat mifepristone dose. |
| | CNGOF France (4)<br><br>Mifepristone 200mg orally followed 24-48 hours later by Misoprostol 800 microgram vaginally.<br><br>Up to 5 additional Misoprostol 400 microgram doses may be administered vaginally, buccally or sublingually every 3 hours until expulsion. |
| | NVOG Netherlands (5,6)<br><br>Mifepristone 200mg orally followed 24-48 hours later by Misoprostol 800 microgram vaginally.<br><br>Up to 4 additional Misoprostol 400 microgram doses may be administered vaginally, buccally or sublingually every 3 hours until expulsion. |
| | ACOG US (7)<br><br>Mifepristone 200mg orally followed 24-48 hours later by<br><br>- Misoprostol 400 microgram buccally every 3 hours for 5 doses or<br>- Misoprostol 800 microgram vaginally followed by 400 microgram vaginally or sublingually every 3 hours for 5 doses.<br><br>If expulsion does not occur, repeat the regimen after 12 hours rest.<br><br>If Mifepristone is unavailable- Misoprostol 400 microgram administered vaginally or sublingually every 3 hours for 5 doses. |
| | FIGO 13-24 weeks (8)<br><br>Misoprostol 400 microgram vaginally/buccally/sublingually every 3 hours.<br><br>*Several studies limited dosing to 5 times; most women have complete expulsion before use of 5 doses, but other studies continued beyond 5 and achieved a higher total success rate with no safety issues* |

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| | WHO (1)<br><br>Mifepristone 200mg orally followed 1-2 days later by repeat doses of Misoprostol 400 microgram vaginally, buccally or sublingually every 3 hours. The minimum recommended interval between use of mifepristone and misoprostol is 24 hours.<br><br>*Repeat doses of misoprostol can be considered when needed to achieve success of the abortion process.*<br><br>*The use of a loading dose of misoprostol is not necessary. This guideline does not provide a maximum number of doses of misoprostol. Health-care providers should use caution and clinical judgement to decide the maximum number of doses of misoprostol in pregnant Individuals with prior uterine incision.* |
| | RANZCOG (9)<br><br>Mifepristone 200mg orally<br><br>*Refers to various Misoprostol regimens in use and suggests RCOG clinical practice guidelines (2, 3) are used.* |
| | QCG, AUS (10)<br><br>Mifepristone 200mg orally followed 36-48 hours later by Misoprostol 800 microgram vaginally or 400 microgram orally.<br><br>Followed by Misoprostol 400 microgram vaginally or sublingually every 3 hours for 4 further doses.<br><br>*If previous uterine scar:*<br><br>Misoprostol 200microgram vaginally followed by misoprostol 200ug vaginally every 4 hours for 4 further doses.<br><br>If unsuccessful at 24 hours after the initial dose, this can be followed by misoprostol 400microgram vaginally every 6 hours for 4 doses.<br><br>Finally, if unsuccessful at 48 hours after the initial dose, consideration can be given to a period of rest, a repeat misoprostol regimen, the use of Oxytocin or surgical management. |

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| **IUFD and /or MTOP >24 weeks** | WHO (1)<br><br>*For IUFD >14 weeks and <28 weeks*<br>Use 200 mg Mifepristone administered orally, followed 1–2 days later by repeat doses of 400µcg Misoprostol administered sublingually or vaginally every 4–6 hours. The minimum recommended interval between use of Mifepristone and Misoprostol is 24 hours.<br><br>*Repeat doses of misoprostol can be considered when needed to achieve success of the abortion process. Use of a loading dose of misoprostol is not necessary.*<br><br>*In this guideline we do not provide a maximum number of doses of misoprostol. Health-care providers should use caution and clinical judgement to decide the maximum number of doses of misoprostol in pregnant individuals with prior uterine incision*. |
| | RCOG UK (11)<br><br>Mifepristone 200mg orally followed by:<br>Misoprostol 100 microgram every 6 hours before 26+6 weeks<br>Misoprostol 25-50 microgram every 4 hours at 27+0 weeks or more<br><br>Mifepristone 600mg once daily for 2 days if there is a history of caesarean section.<br><br>Misoprostol can be used safely at lower doses of 25-50microgram. |
| | ACOG USA (12)<br><br>*<28 weeks*<br>Misoprostol 200-400 microgram vaginally every 4-12 hours<br>*If previous uterine scar, studies of Misoprostol 400 microgram vaginally every 6 hours are cited.*<br><br>*>28 weeks*<br>Usual obstetric protocols are advised<br>*If previous uterine scar CS – suggests management is individualised* |
| | RANZCOG (8)<br><br>Mifepristone 200mg orally<br><br>*For more detail relevant to clinical treatment regimens, clinicians are referred to the RCOG guidelines (2,3,11)* |

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| | FIGO (9)<br><br>*For pregnancy termination*<br>25-26 weeks Misoprostol 200 microgram vaginally/sublingually/buccally every 4 hours<br>27-28 weeks Misoprostol 200 microgram vaginally/sublingually/buccally every 4 hours<br>>28 weeks Misoprostol 100 microgram vaginally/sublingually/buccally every 6 hours<br><br>*For fetal death*<br>25-26 weeks Misoprostol 200 microgram vaginally/sublingually/buccally every 4-6 hours<br>27-28 weeks Misoprostol 100 microgram vaginally/sublingually/buccally every 4 hours<br>>28 weeks Misoprostol 25 microgram vaginally every 6 hours<br>or 25 microgram orally every 2 hours |
| | QCG, AUS (10, 13)<br><br>*Therapeutic termination > 24 weeks*<br>Reduce the dose of Misoprostol due to increased sensitivity of the uterus to prostaglandins. Consider individual circumstances. Seek expert advice.<br><br>*IUFD < 34 weeks*<br>Mifepristone 200mg orally followed by:<br>Misoprostol 100 -200 microgram every 3- 6 hours vaginally or sublingually<br>For a maximum of 6 doses in 24 hours<br>Misoprostol 200microgram vaginally every 6 hours if previous uterine scar<br><br>*IUFD > 34 weeks*<br>Mifepristone 200mg orally followed by:<br>Misoprostol 50-100 microgram every 3- 6 hours vaginally or sublingually<br>For a maximum of 5 doses in 24 hours<br>Misoprostol regimen can be repeated after 24 hours<br><br>*If previous uterine scar*: Misoprostol can be used safely at lower doses of 25-50microgram, sublingually or vaginally every 4 hours to a maximum dose of 300microgram in 24hours |

*MISOPROSTOL ADMINISTRATION)*

Buccal

Pills are placed between the cheek and gums and swallowed after 30 minutes.

Vaginal

Pills are placed in the vaginal fornixes (deepest portions of the vagina) and the individual is instructed to lie down for 30 minutes.

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## APPENDIX 3 – Protocol

# Protocol for Medical Termination of Pregnancy

| | Under 24 Weeks Gestation | $24^{+0}$ – $26^{+6}$ Weeks Gestation | $27^{+0}$ – $28^{+0}$ Weeks Gestation | Over 28 Weeks Gestation |
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| **Protocol for Medical Termination of Pregnancy** | Mifepristone 200mg Orally<br>≥24 hours - ≤48 hours<br>Misoprostol 400microgram Bucally or Vaginally 3-hourly (to a maximum of 5 doses) | Mifepristone 200mg Orally<br>≥24 hours - ≤48 hours<br>Misoprostol 200microgram Bucally or Vaginally 4-6 hourly (to a maximum of 5 doses) | Mifepristone 200mg Orally<br>≥24 hours - ≤48 hours<br>Misoprostol 100microgram Bucally or Vaginally 4-6 hourly (to a maximum of 5 doses) | Mifepristone 200mg Orally<br>≥24 hours - ≤48 hours<br>Misoprostol 25-50microgram Bucally or Vaginally 4-6 hourly (to a maximum of 5 doses) |
| **If Initial Medication Protocol Fails: Restart after a minimum of 12 hours rest and preferably 24 hours (≥24 hours if > 24 weeks gestation)** | Mifepristone 200mg Orally<br>≥12 hours<br>Misoprostol 400microgram Bucally or Vaginally 3-hourly (to a maximum of 5 doses) | Mifepristone 200mg Orally<br>≥12 hours<br>Misoprostol 200microgram Bucally or Vaginally 4-6 hourly (to a maximum of 5 doses) | Mifepristone 200mg Orally<br>≥12 hours<br>Misoprostol 100microgram Bucally or Vaginally 4-6 hourly (to a maximum of 5 doses) | Mifepristone 200mg Orally<br>≥12 hours<br>Misoprostol 25-50microgram Bucally or Vaginally 4-6 hourly (to a maximum of 5 doses) |
| **If Previous Uterine Scar** | Mifepristone 200mg Orally<br>≥24 hours - ≤48 hours<br>Misoprostol 200microgram Bucally or Vaginally 4-hourly (to a maximum of 5 doses)<br>*This protocol can be repeated after 24 hours with 6-hourly Misoprostol intervals | • Management should be individualised in the setting of a previous uterine scar at gestations over 24 weeks<br>• Consideration should be given to using higher doses of Mifepristone (e.g. 600mg) or repeated doses (200mg)<br>• Misoprostol 25-50microgram Bucally or Vaginally<br>• Misoprostol intervals are increased to 6-hourly | | |

**Note**: Misoprostol is available in 100, 200 and 400 microgram strengths. Some strengths may have to be imported as unlicensed medicines. Where a dose reduction is required due to the presence of a uterine scar, advice should be sought from a Clinical Pharmacist on the formulations available in the local institution.

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