Joint Committee on the Eighth Amendment of the Constitution

Wednesday October 11, 2017 – Session B:

Professor Fergal Malone

Master / CEO, Rotunda Hospital Dublin

Chairman, Department of Obstetrics and Gynaecology, Royal College of Surgeons in Ireland School of Medicine

INTRODUCTION:

I am the Master of the Rotunda Hospital Dublin, and Chairman of the RCSI Department of Obstetrics and Gynaecology. I am a Fellow both of the American College of Obstetricians and Gynecologists and of the Royal College of Obstetricians and Gynaecologists. I am a practicing consultant obstetrician as well as a subspecialist in the area of maternal-fetal medicine, and I am currently certified by the American Board of Obstetrics and Gynecology in this subspecialty. I have worked at the level of a consultant in Ireland for the last 13 years since 2005 and before that in New York and Boston for eight years. I am a co-author of "*Fetology – Diagnosis and Management of the Fetal Patient*", which is the internationally acknowledged reference textbook on prenatal diagnosis and treatment of fetal abnormalities.

In addition to my administrative responsibilities at the Rotunda and at RCSI, my particular area of expertise is in the field of prenatal diagnosis and treatment. The Rotunda is the largest provider of prenatal screening and diagnostic services in the state, and as such, we see patients referred from all other maternity hospitals in this country, and from Northern Ireland, for our services. I may therefore be in a position to assist the Committee in providing factual context regarding the prenatal diagnosis of fetal abnormalities and the options for management that currently exist for mothers who are unfortunate enough to be diagnosed with such problems. I may also be able to assist the Committee in analysing the options suggested by the Citizens Assembly in terms of the practical implementation of a potential change in the legal status surrounding termination of pregnancy in Ireland.

I wish to clarify at the outset however that I am not here as an advocate for either a so-called pro-choice or pro-life agenda. As a practicing specialist in this area it is absolutely crucial that our patients trust their doctors to be completely objective in their professional advice and are not perceived in any way to have a political agenda. If I publicly take either a pro-choice or a pro-life stance, it is possible that some patients may no longer trust the professional advice that we provide when they are in a vulnerable position having just received information regarding a serious fetal abnormality. For this reason, I have always been cautious to keep my own personal views out of the public realm and instead am here today to answer whatever questions the Committee may have of a factual nature on the area of fetal abnormalities and their management options.

SCOPE OF THE ISSUE:

It is generally accepted in obstetrics that approximately 2%-3% of all fetuses have a significant congenital abnormality. However, more recently with the advent of more advanced genetic technologies, it is clear that at least a further 1% of all fetuses have additional genetic abnormalities. Some genetic abnormalities, such as Trisomy 21 (Down syndrome), Trisomy 18 (Edwards syndrome) and Trisomy 13 (Patau syndrome), are strongly associated with advancing maternal age. Given that one third of our pregnant patients are now over 35 years of age, this is becoming an increasing challenge for us in contemporary obstetric practice. Additionally, Ireland has long been known to have one of Europe's highest incidences of neural tube defects, such as anencephaly and spina bifida, which occur at a rate of one in every 1,000 births. Congenital heart defects occur in eight in every 1,000 births, or almost 1% of all births, some of which are extremely complex requiring multiple surgeries without certainty of successful repair. Therefore, prenatal diagnosis of fetal abnormalities, and the management of such pregnancies, is a major public health issue in Ireland.

PRENATAL SCREENING:

Screening for fetal abnormalities is quite limited in Ireland compared with most other developed countries. The internationally accepted minimum standard is that all pregnant women should have a fetal anomaly scan at 20-24 weeks' gestation, which will successfully detect the majority of significant structural malformations when performed in an optimal setting. Unfortunately, many Irish maternity hospitals do not have the resources to provide such ultrasound scanning. In 2016, the Rotunda Hospital provided over 10,000 such second trimester fetal anomaly scans.

Screening for genetic chromosomal abnormalities has changed significantly in the last five years. We now have the potential to detect 95% - 99% of fetal chromosomal abnormalities, such as Trisomy 21 or Trisomy 18, as early as 9 – 10 weeks' of pregnancy by means of a simple blood test from the pregnant woman. The advantage of these screening tests is that they give risk assessment and reassurance without any chance of triggering a pregnancy loss. Such cell free fetal DNA testing is now available in Ireland, but only as an opt-in test for those who can afford to pay for it. In 2016, the Rotunda Hospital provided over 1,500 first trimester fetal screening tests.

PRENATAL DIAGNOSIS:

Following a high risk prenatal screening test, such as a cell free fetal DNA test, it is still necessary to perform an invasive diagnostic test, such as chorionic villus sampling (CVS) or amniocentesis, in order to confirm or exclude a true genetic abnormality. Such invasive testing, coupled with the latest micro-array genetic testing, is available in Ireland and is primarily used when structural fetal abnormalities are noted on a fetal anomaly scan or when first trimester fetal screening suggests a high risk of a problem. The main disadvantage of CVS or amniocentesis is the small risk that such procedures might trigger a miscarriage, which is 1% for CVS and less than one in 1,000 (0.1%) for amniocentesis. In 2016, the Rotunda Hospital performed over 160 such invasive prenatal diagnostic tests.

PATIENT CHOICES WHEN FATAL FETAL ABNORMALITY IS DIAGNOSED:

Currently at the Rotunda, when a patient is given a prenatal diagnosis of a so-called "fatal fetal abnormality", non-directive counselling is provided. This means that all options for management are discussed in a non-judgmental manner. Initially, the specific diagnosis is explained together with what exactly is meant by the term "fatal" or "lethal". This includes quoting statistics on the chances of survival to birth and thereafter. Only two options for management exist:

a) Continuation of pregnancy

One option for pregnancy management is to continue with the pregnancy and to provide perinatal hospice care. This care journey generally involves regular meetings with a specialist fetal medicine midwife, an obstetrician, a neonatologist, a social worker and bereavement counsellors. Appropriate family support is provided. When the mother presents to the hospital in labour, generally fetal heart rate monitoring is not provided and intensive neonatal resuscitation is also not provided. Instead, the parents generally hold their baby until such time as the baby passes away. Appropriate postnatal supports are provided, including the use of a "cuddle cot" such that the family can spend as much time as possible with their baby. Memory boxes with appropriate mementoes are created. The mother and her partner are provided with as much subsequent outpatient support as is necessary, together with onward referral to a range of potential external support organisations.

This care journey is very well organised at the Rotunda and works in a tremendously supportive manner for families in terribly tragic situations. The main challenge for us with this management plan is the lack of sufficient resources to be able to provide appropriate time, personnel and attention for the patients who select this approach.

b) Termination of pregnancy

The alternative option for pregnancy management in this situation is to not continue with the pregnancy, which means undergoing pregnancy termination. This involves having a pregnancy termination procedure outside of the jurisdiction, most often in Liverpool or in London. Patients who select this course of action, after non-directive counselling, are supported to the extent that is permissible by our legislation. The Rotunda Hospital has a close working relationship with a number of professional medical centres in the United Kingdom, and our patients are provided with their contact details, together with all relevant medical records. We do not make direct referrals for pregnancy termination nor do we advocate for one management option over another. Parents must make their own appointments and make their own travel arrangements.

If less than 12 – 14 weeks' gestation, patients can chose between a surgical termination of pregnancy, which involves suction evacuation of the uterus, or a medical termination of pregnancy, which involves administering medications to make the uterus contract and expel the contents of the uterus. A surgical termination of pregnancy is generally completed as a day case procedure, such that the patient can return home to Ireland immediately. A medical termination of pregnancy can take 24 – 72 hours, and therefore often warrants the patient spending more time abroad. After 14 weeks' gestation, many centres in the UK will only provide a medical termination of pregnancy procedure. This is because of a limit in the number of obstetricians

who have the technical skills and experience to perform a later surgical termination procedure. There are a small number of centres in the UK who will provide a later surgical termination procedure up to 24 week's gestation. This is in contrast to the US, where the majority of later pregnancy terminations are performed surgically, which is in keeping with the current recommendations of the American College of Obstetricians and Gynecologists.

Following termination of pregnancy, the patient is asked to make a decision on how she would like the fetal remains to be managed – either looked after locally by the hospital such as by cremation, or returned to the mother in Ireland so that she can make her own funeral arrangements. The patient then travels back to Ireland and our obstetric and counselling staff at the Rotunda continue to provide all required follow-up care. Courier costs to transport fetal remains back to Ireland are substantial, and instead some patients make an additional return trip to the UK to collect the remains themselves at a later stage.

This particular journey is clearly associated with significant additional challenges for patients:

- Major practical challenges associated with travelling for healthcare to an unfamiliar city with an unfamiliar healthcare system and without family or personal supports
- Significant financial cost, typically €800 to €1,500 medical costs depending on the gestational age and method of termination, plus the costs associated with travel
- Limited autopsy or genetic testing performed, as the cost of such testing must be paid for separately, such that many patients chose to forego such vital tests
- Distress associated with leaving their baby's remains in a foreign country, and possible subsequent transport of these remains home at a later date

In 2016, 55 patients from the Rotunda Hospital travelled to the UK to undergo pregnancy termination following the prenatal diagnosis of fetal abnormalities.

PATIENT CHOICES WHEN COMPLEX FETAL ABNORMALITY IS DIAGNOSED:

The prenatal diagnosis of complex fetal abnormalities, in which fetal or neonatal death is *not* expected, causes similar management challenges in Ireland as seen with fatal fetal abnormality. Following the diagnosis, complete multidisciplinary counselling is provided with multiple meetings with an obstetrician, various paediatricians, including a neonatologist (specialist in caring for newborn infants) and relevant paediatric subspecialists (such as, for example, a paediatric cardiologist or a paediatric surgeon). These cases are generally discussed at multi-disciplinary team meetings and care plans are created.

Ultimately, following such counselling, parents can choose to follow one of two management options – continuation of pregnancy followed by appropriate paediatric treatment, or termination of pregnancy. When patients chose to continue with their pregnancy, this care journey is very well developed in Ireland and coordinated obstetric-paediatric care is carried out consistent with best possible international standards. In contrast, for patients who chose to terminate their pregnancy, this care journey is poorly developed and is associated with similar challenges as seen with fatal fetal abnormalities.

CHALLENGES FOR OBSTETRICIANS IN IRELAND WITH CURRENT LEGISLATION:

The current legislative status regarding termination of pregnancy in Ireland poses significant practical challenges for obstetricians when faced with the prenatal diagnosis of fatal or complex fetal abnormalities. These include:

i. Inability to refer patients for care
ii. Inability to access timely care
iii. Lack of continuity of care
iv. Risks to mother's health when travelling
v. Unregulated access to medications for pregnancy termination
vi. Incomplete evaluation and confirmation of prenatal diagnosis
vii. Threat of imprisonment

i. Inability to refer patients for care

The Regulation of Information (Services Outside the State for Termination of Pregnancies) Act, 1995, effectively prohibits our staff from directly making an appointment for a mother with a severe fetal abnormality at a hospital outside of the jurisdiction, although it does permit the provision of copies of medical records. While our staff are very familiar with the names and contact details of professionals in reputable medical centres in the UK, we cannot contact these staff directly on behalf of a particular patient and instead need to rely on patient's themselves relaying potentially complex medical information to other medical staff. This places additional burdens on patients during a very vulnerable and emotional time.

ii. Inability to access timely care

Recently, we have been faced with a number of cases of patients with fatal or complex fetal abnormalities not being able to make an appointment with a centre in the UK for pregnancy termination because that centre has been too busy or because the patient has been at a later gestational age. This can add significantly to patient distress, but additionally, it also adds to the complexity of the pregnancy termination procedure when performed at later gestational ages. Additionally, we are unsure as to what the impact of Brexit will be on the ease of access, or potentially lack of access, for our patients to pregnancy termination in the UK.

iii. Lack of continuity of care

There is a distinct lack of fairness in which patients with fatal or complex fetal abnormalities who chose to continue with their pregnancy have prompt access to highly effective, professional and continuous care within a single healthcare team, while those who chose not to continue with their pregnancy are forced to endure split care across two different jurisdictions which completely undermines the ability to provide continuity of care.

iv. Risks to mother's health when travelling

One of the main risks of splitting care for vulnerable patients between two healthcare teams across two jurisdictions is the potential risks to the mother's physical health when traveling. Post-

termination haemorrhage occurs in 0.5% to 1% of procedures, retained pregnancy tissue occurs after 1% to 8% of procedures, and infection occurs in 0.1% to 4% of procedures. We are aware of at least one mother from Ireland who died following a complication from a surgical termination of pregnancy while traveling between Ireland and a centre abroad. Given these risks, forcing patients to travel between two jurisdictions, particularly when dealing with travel between islands, will inevitably increase the risks to mothers' physical health and wellbeing. The impact on mothers' emotional health and wellbeing is difficult to quantify, but is likely to be negatively impacted further by being forced to travel to another jurisdiction for her healthcare.

v. *Unregulated access to medications for pregnancy termination*

It is likely that the current legislative setting regarding pregnancy termination is driving patients into sourcing medications to procure pregnancy termination through unregulated channels, such as from internet suppliers or street suppliers. We are concerned regarding the unregulated aspects of this practice and the risks that patients may take in procuring a medically unsupervised pregnancy termination, in particular if they do not have ready access to a doctor or medical centre to assist in the event of unexpected complications. Additionally, patients in this situation can have little or no confidence as to the pharmacological content or safety of what they have sourced.

vi. *Incomplete evaluation and confirmation of prenatal diagnosis*

We have had a number of patients who have travelled to the UK for pregnancy termination following the prenatal diagnosis of a range of complex fetal malformations, but in which the overarching diagnosis has not initially been clear. Such patients require a detailed perinatal autopsy, often supplemented by specific additional genetic testing in order to confirm a final diagnosis. When patients experience a stillbirth in Ireland in the setting of such malformations, all possible pathology tests are performed at no charge as part of the public health service, such that a final diagnosis is made, thereby enabling accurate patient counselling regarding recurrence risks. If however, such a patient travels abroad for a pregnancy termination and has to personally pay for these additional tests, potentially doubling the cost, it is possible that some parents may not be able to afford such tests and will never obtain a final accurate diagnosis. This places these patients at a considerable disadvantage for future pregnancy management as they will not know recurrence risks or options for prevention.

vii. *Threat of imprisonment*

Section 22 of the Protection of Life During Pregnancy Act 2013 specifies that a term of imprisonment of up to 14 years may be applied if a doctor is convicted for participation in a procedure to "intentionally destroy unborn human life". There is a lack of clarity currently amongst some doctors as to whether they may have a vulnerability to such a conviction if they are involved in any way with the management of a patient who has a pregnancy termination in another jurisdiction. Similarly, Section 23 of the Act specifies that a corporate body, presumably a hospital, could also be guilty of a criminal offence if a termination is performed with its "consent or connivance". There is a lack of clarity currently as to whether a hospital's assistance to its patients in seeking a pregnancy termination for fetal abnormalities in another jurisdiction might be seen as "consent or connivance".

CONSIDERATIONS FOR POTENTIAL FUTURE LEGISLATION:

Given these practical challenges facing obstetricians and maternity hospitals in Ireland, I would suggest that the Committee might consider the following issues:

- Decriminalisation of pregnancy termination in the setting of fetal abnormalities
- Enabling access to termination of pregnancy for fetal abnormalities
- Avoidance of limitations by specific fetal diagnosis
- Avoidance of limitations by specific gestational age

Decriminalisation:

Obstetricians and maternity hospitals in Ireland should be able to provide complete and appropriate healthcare services to their patients without the threat of criminal conviction. Section 22 of the Protection of Life During Pregnancy Act 2013 specifies that no prosecution would occur without the consent of the Director of Public Prosecutions, and presumably this would unlikely be given in a situation where a doctor or hospital was acting in good faith to care for a patient in a difficult circumstance. Nonetheless, when faced with the practical reality of caring for mothers with complex fetal abnormalities, it is difficult to justify retaining a threat of criminal conviction for doctors or hospitals providing appropriate and contemporary healthcare.

Access to termination for fetal abnormalities:

Obstetricians and maternity hospitals in Ireland should be able to provide legal termination of pregnancy in the setting of fatal or complex fetal abnormalities if, following complete non-directive counselling, a patient choses to follow this course of action. This will allow both pathways of care to be equally provided to all patients when faced with the traumatic situation of a prenatal diagnosis of fatal or severe fetal abnormalities. It should also be possible to provide this care pathway in a manner that supports individual doctors or midwives right to conscientious objection. A major challenge for the Irish healthcare service will be the lack of adequate resources to perform such procedures, if legalised, within the context of under-resourcing of maternity services and lack of fit-for-purpose contemporary maternity hospital buildings.

Limitations on specific fetal diagnoses:

With any proposed legislative change, it would not be appropriate to provide a list of specific fetal diagnoses that would be considered “eligible” for pregnancy termination. Prenatal diagnosis of fetal abnormalities is constantly evolving such that new genetic diagnoses and their association with structural fetal malformations are being updated regularly. Lists of fetal diagnoses are therefore not static or stable over time, such that any list of “eligible” diagnoses today would likely be outdated in a number of years. Similarly, combinations of fetal abnormalities are commonly seen, such that while individually a particular abnormality might not be considered “lethal”, in combination with other very complex abnormalities the overall prognosis would be extremely poor or effectively

“fatal”. For these reasons, it would not be possible to generate a list of fetal diagnoses or conditions that would be “eligible” for pregnancy termination. It is recommended instead that the individuals best placed to make such a decision are the patient and her doctor, without the direct involvement of external parties or agencies.

Limitations on gestational age:

Pregnancy termination is defined as “the intentional procurement of miscarriage that results in fetal death”. In Ireland, we would not foresee a situation in which a pregnancy termination is performed at, for example, 30 or 36 weeks’ gestation. Instead, if a pregnancy at 30 or 36 weeks’ gestation needs to be ended, the procedure would be either an induction of labour or a caesarean section, and not a pregnancy termination. Appropriate care would always be provided to the newborn in all such cases. However, we do not believe that it would be appropriate to specify a precise gestational age limit in weeks beyond which a pregnancy termination would be illegal. This is because the definition of fetal viability is not precise and is likely to change periodically as obstetric and paediatric care advances. Additionally, fetal size and fetal health are independent predictors of fetal viability, separate to defining viability based only on gestational age in weeks. For example, a severely growth restricted fetus at 25 weeks’ gestation may not be viable while a normally grown fetus at 23 weeks’ gestation may survive. Similarly, a completely healthy fetus at 23 weeks’ gestation would have a higher chance of survival than a fetus at 25 weeks’ gestation with very complex cardiac or spine malformations. For these reasons, it is not practical to place rigid gestational age cut-offs into legislation that may place arbitrary restrictions on clinical practice, when other factors can also make a significant impact on the definition of fetal viability. It is recommended instead that the individuals best placed to make such a decision are the patient and her doctor, without an arbitrary legal cut-off.

I hope that these observations on the current status of prenatal diagnosis and management of fetal abnormalities are of assistance to the Committee, and also that my observations on the practical challenges and options for change may also be informative for the Committee’s future deliberations. I would also separately like to endorse the ancillary recommendations of the Citizens Assembly, which calls for equal access for all patients to early pregnancy scanning and testing, improved counselling and support services for patients, and detailed consideration of how pregnancy termination should be resourced. If constitutional, and subsequent legislative, changes are enacted that result in the availability of pregnancy termination for selected cases in Ireland, this will inevitably have an additional impact on resources for our maternity services, which are already under significant pressure. These resource implications will need to be separately addressed.