National Women & Infants Health Programme

National Clinical Practice Guideline

Stillbirth – Prevention, Investigation, Management and Care

INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

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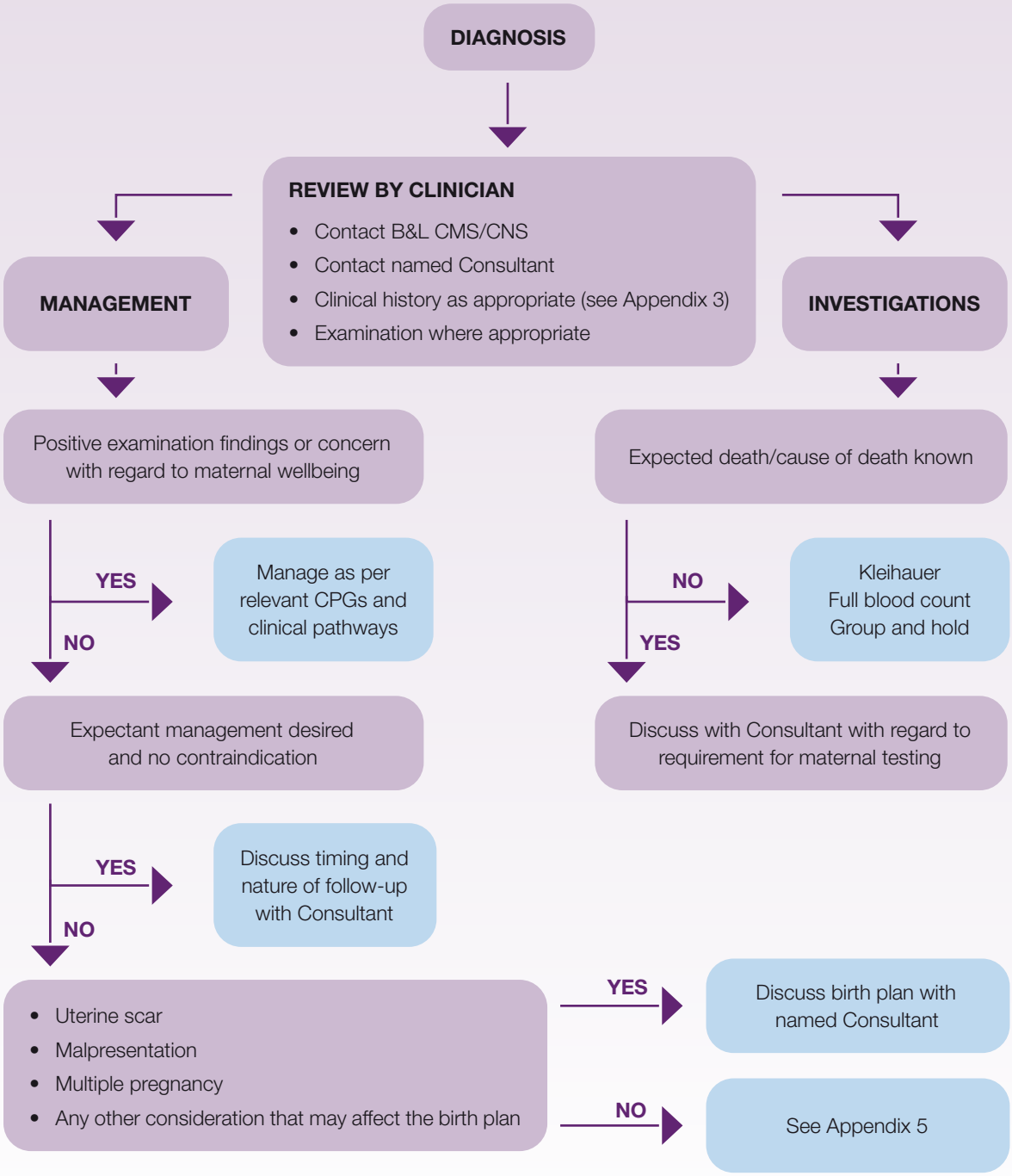
Algorithms

Algorithm 1: Algorithm for initial management following diagnosis of IUFD



Algorithm 2: Algorithm for fetal investigations following stillbirth

Prior to birth

Consider amniocentesis if felt to be contributory to diagnostics (e.g., if electing for expectant management etc.)

↓

BIRTH

↓

At the time of birth

- Harvest and store placental sample for cytogenetic analysis [1cm3 section (approximately) from a normal appearing segment of umbilical cord (away from the cord insertion site)]
- Harvest and store cord sample for cytogenetic analysis [1cm3 section from the centre of the fetal surface of the placental disc (away from the cord insertion site and any large fetal vessels)]
- Send placenta for histopathological examination

↓

Inform the Coroner

- Parents to be informed of the role of the Coroner and the intention to discuss the death of their baby with the Coroner
- Senior clinician to contact the Coroner
- All relevant details of the case to be provided

↓

Coroner's post mortem examination (PME) mandated?

YES

- Pamphlet/written information to be provided
- Consultant/senior registrar to discuss with parents
- Organ retention to be discussed, and wishes documented
- Liaise with local/regional Perinatal Pathology Services

Coroners protocol/paperwork should be followed

NO

Consented PME to be discussed/offered*

- Liaise with local/regional Perinatal Pathology Services
- Pamphlet/written information to be provided
- Consultant/senior registrar to take consent
- Organ retention to be discussed and parental consent documented
- Skeletal survey to be ordered

* If parents do not consent to a full PME then a limited PME should be discussed. Options should be clarified with the Pathologist in advance in order to inform consent.

Key Recommendations

Number	Recommendation	Grade
SECTION 1 RISK FACTORS		
Preconceptional and antenatal risk factors		
1	Healthcare professionals that are involved in the delivery of care to pregnant women should be familiar with the preconceptional and antenatal risk factors that may increase the risk of stillbirth. These risk factors are diverse and can be broadly classified as maternal, fetal or related to pregnancy-specific conditions.	*Best practice*
2	It is important for healthcare professionals to recognise that a risk factor may not exist in isolation and that an individual woman's risk for an adverse pregnancy outcome, specifically stillbirth, may depend on the complex interplay of several variables.	*Best practice*
3	While some risk factors for stillbirth may be present from the onset of pregnancy, some may emerge as the pregnancy progresses. Healthcare professionals should be vigilant of this in their interactions with pregnant women, regardless of the setting.	*Best practice*
4	While the terms modifiable and non-modifiable have traditionally been used when describing risk factors, it should be noted that these terms have limitations and they do not acknowledge the complexity of the risk factor, the environment, resourcing and human behaviour. As such, all risk factors should be considered as potentially modifiable when it comes to devising risk-reduction strategies, both at a local and national level.	*Best practice*
5	Risk factors should be identified and clearly communicated to the woman in a sensitive manner, using language that is clear and devoid of ambiguity.	*Best practice*
6	While measures to reduce socio-economic disparities are mainly focused at a public health and policy level, it is important for the clinician, and the maternity hospital/unit, to be aware of the potential barriers to accessing care for some women.	*Best practice*
7	A woman-centred approach to care is encouraged: women should be involved in the decision-making process to support a positive pregnancy experience and promote engagement with antenatal care.	*Best practice*
8	In the presence of one or more risk factors for stillbirth, a plan of care for the pregnancy should be clearly documented. This may evolve as the pregnancy progresses and should be reviewed by a consultant Obstetrician.	*Best practice*
9	When a risk factor for stillbirth is identified, healthcare practitioners should refer to the local and national clinical practice guidelines that pertain to that risk factor to optimise management.	*Best practice*

Number	Recommendation	Grade
The delivery of antenatal care		
10	It is recommended that a booking visit should be offered to pregnant women in the first trimester.	*1C*
11	Women should be screened at the booking visit for risk factors that may alter their recommended pathway of care in order to create a pregnancy plan that is tailored to their needs.	*Best practice*
12	All women should be offered a dating ultrasound scan and a detailed anatomy ultrasound that includes screening for placental localisation.	*Best practice*
13	Women should have access to, when indicated, ultrasonographic tests of fetal wellbeing including fetal biometry, biophysical profiling and Doppler ultrasound studies.	*Best practice*
14	It is recommended that service providers strive to ensure that the minimum schedule of care (eight points of contact), as delineated by the World Health Organisation, is achieved for all pregnant women. Potential barriers to accessing care should be explored and addressed.	*1C*
15	Women should be at the heart of decision-making processes, and services should strive for maternal autonomy in care. Good communication and well-designed antenatal education programmes can empower women to engage with healthcare professionals and improve pregnancy outcomes.	*Best practice*
16	Antenatal care should be delivered with the support of the multidisciplinary team.	*Best practice*
17	It is good practice to advise pregnant women to monitor for changes in patterns of fetal movement. If a woman is concerned about the quality or quantity of fetal movement, she should be advised to contact her local maternity service.	*1C*
18	Individual services and hospital groups should have clear pathways of care for the management of reduced fetal movement and staff should be educated in the implementation of these pathways.	*Best practice*
19	Maternity hospitals/units should strive to ensure that infrastructural and educational systems are in place to support the delivery of intrapartum care with the goal of reducing preventable term stillbirth.	*1C*
20	Women triaged to the specialised care pathway should have consultant-led care. This includes pregnancies complicated by a previous stillbirth.	*2C*
21	Should an individual unit be unable to meet the care requirements of a pregnancy, care should be transferred to a maternity hospital/unit with the appropriate expertise.	*Best practice*
22	In the normal-risk setting, fetal growth should be monitored by serial assessment of symphysio-fundal height (SFH). A growth estimate with ultrasound scanning in the third trimester should not be offered in the absence of a clinical indication.	*1C*
23	In the presence of risk factors for fetal growth restriction, or where SFH measurement in unreliable, serial growth measurement should be offered. Fetal growth should not be monitored at intervals of less than 2 weeks.	*1C*

Number	Recommendation	Grade
SECTION 2: DIAGNOSIS		
24	Real-time ultrasound is the gold standard method for the diagnosis of intrauterine fetal death (IUFD).	*Best practice*
25	Real-time ultrasound should be readily available in maternity hospitals/units.	*1C*
26	The use of clinical assessment or fetal heart auscultation with Pinard stethoscope or handheld Doppler is not sufficient to diagnose IUFD.	*Best practice*
27	Cardiotocography should not be used to diagnose IUFD.	*Best practice*
28	A second opinion should be sought to confirm the diagnosis of IUFD. At least one of the healthcare professionals performing the ultrasound should be a practitioner or sonographer with sufficient expertise in the use of ultrasound.	*Best practice*
29	A dedicated room should be available in the admission unit/ultrasound department for the purpose of disclosing bad news.	*1C*
30	If a woman is unaccompanied, an offer should be made to contact her partner or a close relative/friend.	*Best practice*
31	Healthcare providers should ensure, where appropriate, that a pregnant woman is not alone when leaving the hospital after a diagnosis of IUFD. Transport arrangements should be made if required. Women should also be provided with a named contact when leaving the hospital in order to facilitate effective communication.	*Best practice*
32	Healthcare providers should use appropriate language using terms that are easily understandable by the woman/parents.	*Best practice*
33	Healthcare providers should advocate for maternal choice and autonomy; parents should feel included in the decision-making process.	*Best practice*
34	Written information should be provided and should ideally be available in several languages.	*Best practice*
SECTION 3: INVESTIGATIONS		
Maternal investigations		
35	If diagnosed with an IUFD, all women should be assessed by a clinician at the time of diagnosis. This is important, not only to assess risk, but to document important features that may contribute to determining the cause of the stillbirth.	*Best practice*
36	A Kleihauer-Betke test, full blood count and group and antibody screen should be performed at the time of diagnosis. As postnatal testing can result in false positives and any delay in testing can lead to false negatives, testing for FMH should be performed prior to delivery and at the time of diagnosis of intrauterine death.	*1C*

Number	Recommendation	Grade
37	Prior to discharge, women should be tested for the following: • Acquired thrombophilias [lupus anticoagulant (LA), anticardiolipin (aCL) and anti-b2-glycoprotein 1] • Haemoglobin A1c (HbA1c) • Serum bile acids (SBA) • Serology for cytomegalovirus (CMV), toxoplasma, parvovirus B19 (PV B19) and rubella (unless immune)	*1C*
38	The following maternal tests should be performed if clinically indicated: rubella IgM/IgG, syphilis testing, coagulation studies, C-reactive protein, renal function, uric acid, liver function, thyroid function, inherited thrombophilia testing (including factor V Leiden testing), auto/alloimmune antibodies, toxicology screen, microbiological studies and parental karyotypes.	*1C*
Fetal Investigations		
39	Post mortem examination (PME) should be offered in all cases of stillbirth.	*1B*
40	All cases of stillbirth should be discussed with the local Coroner before the issue of a consented PME is raised with the woman/parents.	*Best practice*
41	Informed consent for a PME should be obtained by a senior clinician.	*Best practice*
42	All aspects of the consent process should be in line with national and local policy. The most up-to-date national guidance on PME and consent should be consulted.	*Best practice*
43	Women/parents should be given clear, honest and accurate information including the potential contribution that PME may have in providing a diagnosis or managing subsequent pregnancies.	*1C*
44	The consent-taker should be prepared to answer women's/parents' questions and written information should always be provided.	*1C*
45	For a consented PME, it should be made clear to women/parents that they are under no obligation to provide consent if they do not wish to do so.	*Best practice*
46	When a consented PME is declined – whether for personal, religious or cultural beliefs – this decision should be respected. Cultural stereotyping and culture-based assumptions should be avoided as diversity exists in all cultural groups.	*Best practice*
47	Consent forms should have a section on organ retention. This should include options regarding consent to organ retention and options surrounding organ disposition once the necessary examinations have been completed.	*Best practice*
48	Consent is not required for a Coronial PME; in the event that a post mortem examination is directed by the Coroner, written information relating to the Coronial PME process and parental rights should be provided.	*Best practice*

Number	Recommendation	Grade
49	Cytogenetic testing should be performed in all cases of stillbirth. Microarray analysis is the preferred method of testing, if available.	*1B*
50	Care needs to be taken when performing placental biopsy for cytogenetic analysis; the fetal vessels and umbilical cord insertion site should be avoided/ preserved for further pathological examination.	*Best practice*
51	A complete PME is recommended to optimise the information obtained from the examination.	*1B*
52	While a limited PME may be of value, it is important that women/parents understand that this may restrict the information obtained, and result in higher rates of unexplained stillbirth. If women/parents wish to proceed with a limited PME, the case should be discussed with the Pathologist involved in order to facilitate informed consent.	*Best practice*
53	It is recommended that a Perinatal Pathologist perform the PME and compile the final report. However, the PME may be delegated, where appropriate, to a designated medical scientist who has been deemed competent in the execution of such examinations, and who works under the supervision of the Perinatal Pathologist.	*Best practice*
54	Pathological examination of the placenta should be performed in all cases of stillbirth.	*1B*
SECTION 4: MANAGEMENT		
Planning labour and birth		
55	Expectant management can be offered to women if, following review by an Obstetrician, there is no contra-indication such as ruptured membranes, antepartum haemorrhage or evidence of maternal compromise.	*2C*
56	If a woman opts for expectant management, routine testing for coagulopathy at regular intervals is not indicated in the absence of risk factors such as suspected abruption, sepsis or prolonged fetal retention. The risk for coagulopathy should be determined on a case-by-case basis; in the first instance at diagnosis, and then again at each encounter.	*2C*
57	If a woman wishes to initiate the process of delivery as soon as possible, services should be resourced to facilitate birth within a reasonable timeframe. Ideally the process should be initiated within 24 hours from diagnosis.	*2C*
58	If no contraindication exists to vaginal birth, this is the preferred mode of delivery in the event of an intrauterine fetal death.	*2C*
59	The recommended medication regimen, for a uterus with no scar, is mifepristone 200mg followed by a course of misoprostol after an interval of 36 to 48 hours. National medication protocols should be followed.	*2B*
60	Misoprostol should be titrated to gestational age due to the increased sensitivity of the gravid uterus to prostaglandins with advancing gestational age.	*2C*
61	Intravaginal, buccal and sublingual misoprostol may be more effective than oral misoprostol.	*2C*

Number	Recommendation	Grade
62	For a woman with one uterine scar, the mode of delivery should be reviewed by the consultant overseeing the woman's care with consideration of maternal wishes.	*Best practice*
63	Induction regimens to be considered for women with one uterine scar include prostaglandins such as misoprostol at lower doses, mifepristone monotherapy, mechanical methods of cervical priming and the use of oxytocin. National medication protocols should be followed.	*2B*
64	Decisions on mode of delivery in women with two previous lower segment caesarean sections should be consultant-led.	*Best practice*
65	Women with a history of more than two caesarean scars, or atypical uterine scars, should be advised that the risk of uterine rupture likely outweighs the potential benefit of vaginal birth.	*2C*
Intrapartum care		
66	Women who have experienced an intrauterine death should be provided with a birthing space that acknowledges the emotional and practical needs of the woman/parents in addition to the medical needs of the woman.	*Best practice*
67	Women should be provided with the same options for analgesia that are offered to women with uncomplicated pregnancies.	*Best practice*
68	There is no strong evidence to recommend the use of one parenteral opioid over another.	*1C*
69	If there is a clinical concern for sepsis or coagulopathy, an FBC and coagulation profile should be obtained prior to proceeding with neuraxial anaesthesia.	*Best practice*
70	Intrapartum antibiotic prophylaxis (IAP) should not be routinely employed in cases of intrauterine fetal death.	*Best practice*
71	In women with a uterine scar, the birth attendant must rely on maternal evaluation in order to make an assessment of scar integrity. Care must be taken not to miss subtle maternal signs in the absence of fetal monitoring.	*Best practice*
72	All intrapartum interventions for a woman who has experienced an IUFD should be approached with sensitivity, whether instigated by the primary birth attendant or the covering Obstetrician.	*Best practice*
73	In cases where a difficult birth is anticipated, for example where there is a fetal malposition or a malpresentation such as breech, an appropriately skilled Obstetrician should be available to assist with the delivery.	*Best practice*
74	Women/parents should be appropriately counselled, both antenatally and during the birthing process, on the changes that take place within the baby after death, and how these may alter the physical appearance of their baby after birth.	
75	Women/parents should be supported in the decision-making process when it comes to labour and interactions with their stillborn baby after birth. Birthing conditions should facilitate open communication and informed consent.	*1C*

Number	Recommendation	Grade
Postnatal care		
76	A risk assessment for venous thromboembolism should be carried out according to national and local clinical guidelines.	*Best practice*
77	Psychological stressors may impact on the perception of pain. Care should be taken to ensure adequate analgesia for the woman, both acutely and at discharge.	*1C*
78	A standard approach to wound care should be taken as per national clinical guidelines.	*Best practice*
79	An individualised care plan should be made for each woman depending on personal, medical and peripartum risk factors.	*Best practice*
80	The need for postnatal anti-D prophylaxis should be determined after birth and should be in keeping with local and national guidance.	*Best practice*
81	Healthcare staff allocated to caring for and liaising with the bereaved woman/ parents should be kept to the minimum number required. Continuity of care, where possible, should be facilitated.	*Best practice*
82	All healthcare professionals (HCPs) that have been involved in the woman's antenatal care, or who are routinely involved in postnatal care [including the woman's General Practitioner, (GP)] should be informed of the stillbirth.	*Best practice*
83	All scheduled antenatal visits and appointments should be cancelled before the woman is discharged home.	*Best practice*
84	Physiologic lactogenesis, and what to expect, should be discussed with the bereaved woman. This discussion should include options for artificial suppression. Written information should be provided.	*Best practice*
85	Women should be advised that non-pharmacologic options for artificial lactation suppression are available, but that the efficacy of these options versus placebo (no treatment) has not been demonstrated.	*1B*
86	Cabergoline is recommended as a first line treatment for the pharmacologic suppression of lactation.	*1A*
87	Appropriate follow-up should be arranged for bereaved parents after discharge with their named Obstetrician. The nature and timing of this follow-up may depend on the woman, the clinical context and the degree of the investigations performed. Women and parents should, however, be seen within three months following the birth of a stillborn infant, to discuss the available results and address any queries or concerns.	*Best practice*
Comprehensive bereavement care		
88	Staff should be familiar with the Irish National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death (The Standards).	*Best practice*
89	Providing quality bereavement care is an integral part of every maternity service. It is vital that such bereavement support is integrated within the hospital's clinical care pathways for women/parents.	*Best practice*

Number	Recommendation	Grade
90	All maternity services should have a dedicated clinical Midwife or Nurse specialist who is experienced in the field of bereavement and loss.	*Best practice*
91	Women/parents should be provided with the opportunity to meet with a member of the bereavement team; ideally the first encounter should take place at the time of diagnosis.	*Best practice*
92	Women/parents should be provided with the opportunity to meet with a pastoral care team or chaplain/spiritual leader of their choosing.	*Best practice*
93	Women/parents should be provided with the opportunity to see or hold their baby after birth. Mementos of their baby and pregnancy experience should be offered.	*1C*
94	Women/parents should be supported in making decisions regarding funeral arrangements, including burial and cremation.	*Best practice*
95	Women/parents should be offered the appropriate psychological supports antenatally, intrapartum and postnatally with no puerperal time limit on support. Written information should be provided to women/parents on the supports available, at both a community and hospital-based level. Support may come in the form of professional counselling services, support groups and online sites or forums.	*1C*
96	Clear pathways of care should be available in all maternity units in order to optimise the parental experience. The Standards should be consulted when implementing such pathways.	*Best practice*
97	Maternity hospitals/units should regularly audit their service with reference to The National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death.	*Best practice*
98	All healthcare professionals who care for bereaved women/parents should have access to regular and appropriately designed training in bereavement care.	*Best practice*
99	A formal policy on staff support should be devised and implemented in all maternity hospitals/units.	*Best practice*
100	A range of support options should be available to staff including individual debriefing, peer group support and professional counselling.	*Best practice*
101	Tailored debriefing sessions should be made available following serious adverse events, such as intrapartum stillbirth, for all staff involved – regardless of whether the involvement is direct or indirect.	*2C*
102	Consideration should be given to the introduction of Schwartz rounds or Balint group sessions as part of the regular schedule within individual maternity units.	*2C*
103	Information regarding self-care and the available support services within a unit should be provided to staff at induction training and at regular intervals throughout the working year.	*Best practice*

Number	Recommendation	Grade
Special circumstances		
104	Every effort should be made to support women/parents in the decision-making process when diagnosed with a fetal anomaly that may be fatal or life-limiting. Comprehensive bereavement support is essential regardless of the chosen pathway of care.	*1C*
105	If a woman elects to proceed with a termination for fatal fetal anomaly and, should the pregnancy exceed 21+6 weeks, options surrounding feticide and intrapartum care should be discussed, with shared decision-making based on pregnancy-related factors and the circumstance of the termination. Intrapartum electronic fetal heart rate monitoring should not form part of the routine care plan for termination of pregnancy.	*Best practice*
106	All stillborn infants delivered at ≥ 24+0 weeks or weighing ≥ 500g need to be registered in accordance with the Stillbirths Registration Act, 1994, regardless of whether the birth occurred in the context of a termination of pregnancy.	*Best practice*
107	Decisions regarding post mortem examination after termination of pregnancy for fetal anomaly should be discussed and documented in the woman's healthcare record.	*Best practice*
108	In the event of selective intrauterine fetal death, a multiple pregnancy should be managed by an Obstetrician with appropriate expertise in the management of complicated twin and multiple pregnancies.	*Best practice*
109	Woman/parents should be counselled on the risk to the remaining fetus(es) in the event of selective intrauterine fetal death.	*Best practice*
110	While the process of grief in a multiple pregnancy may be complicated by mixed emotions, the grief reaction needs to be recognised, and women/parents should be afforded the appropriate supports in the antenatal, intrapartum and postnatal period.	*1C*
111	If delivery at the threshold of viability (23 weeks) is anticipated, every effort should be made to provide counselling to the expectant woman/parents in advance of the delivery by a specialist in neonatology.	*Best practice*
112	In the event of birth at the threshold of viability, women/parents should receive the appropriate psychological support before, during and after birth.	*1C*
113	Every effort should be made to ensure that accurate calculations of both birth weight and gestational age at the time of birth are used when documenting a stillbirth.	*Best practice*
114	Healthcare providers must ensure that both the physical and psychological needs of the woman are met in the context of an intrapartum stillbirth, particularly as the birth may be complicated by an obstetric emergency that may also compromise the wellbeing of the woman.	*Best practice*
115	Detailed documentation is important for all intrapartum deaths so that factors contributing to the death can be delineated and explored.	*Best practice*

Number	Recommendation	Grade
116	Care following an intrapartum death should be consultant-led with appropriate arrangements made for follow-up post discharge.	*Best practice*
117	Staff involved in the care of a woman who has experienced an intrapartum death should be debriefed and provided with the appropriate supports.	*2C*
118	All cases of intrapartum death should undergo a formal review process, including timely referral to the local Serious Incident Management Team (SIMT).	*Best practice*
SECTION 5: CLASSIFICATION, AUDIT AND REVIEW		
Classification and audit		
119	In the event of a stillbirth, two forms must be completed: • The Birth Notification Form • The Perinatal Death Notification Form	*Best practice*
120	In the event of a termination of pregnancy, a Birth Notification Form (BNF/01) must be completed if the gestation or birth weight exceed or are equal to 24+0 or 500g.	*Best practice*
121	The National Perinatal Epidemiology Centre (NPEC) classification system (2007) is the current system for classifying stillbirth in Ireland. All stillbirths should be reported to NPEC using their standardised notification form. It is important that accurate information is used when recording information on the details of a stillbirth.	*Best practice*
122	Perinatal audit is crucial to maintaining and improving standards. While NPEC collates data for audit at a national level, individual maternity units, and hospital groups, should have structures in place for performing perinatal audit.	*1C*
Legal requirements		
123	Registration of a stillborn infant in a civil registration centre is not mandatory. This can be organised by the woman/parents, if they wish to do so, once a certificate with the cause of death has been issued.	*Best practice*
124	Women/parents should be informed that the Coroner's role is to inquire into the cause of reportable deaths; the Coroner does not consider civil or criminal liability – they simply establish the "who, when, where and how" of the death.	*Best practice*
125	Women/parents should be informed that, in the event of a stillbirth, the Coroner will usually consult with a family member before directing an inquest.	*Best practice*
126	Women/parents should be informed that the Coroner will notify the district registrar once they have concluded the inquiry and have established a cause of death. This will permit the parents to register the stillbirth should they so wish.	*Best practice*
Multidisciplinary care and case review		
127	All bereaved women/parents should have access to multidisciplinary bereavement care. While the majority of services will be available within the treating hospital/unit, access to the extended multidisciplinary team should be available within the hospital group.	*Best practice*

Number	Recommendation	Grade
128	The multidisciplinary team (MDT) should, ideally, comprise the following: • Consultant Obstetrician • Neonatologist • Perinatal Pathologist • Anaesthetist • Midwifery and nursing staff • Palliative and bereavement care specialist • Perinatal mental health specialist • Bereavement and loss CMS/CNS • Chaplaincy/pastoral care team • Social work team • Support staff, including administrative staff, medical scientists, laboratory technicians and mortuary staff	*Best practice*
129	Good communication is important in order to optimise the parental experience. Effective communication should take place at both a bedside level and an interdisciplinary level within the MDT.	*1C*
130	Multidisciplinary care should be individualised with parental autonomy at the forefront.	*Best practice*
131	Every service should have access to a regular perinatal mortality multidisciplinary meeting (PM MDM). This may be arranged locally, at a hospital level, or on a larger scale within a hospital group.	*Best practice*
132	Staff should be facilitated in their attendance of the PM MDM in order to optimise the potential for education, learning and peer discussion.	*Best practice*
133	The PM MDM should discuss individual cases within a reasonable timeframe in order to provide information to bereaved women/parents, and to explore learning points to be had from review of the case, at both a local and regional level.	*Best practice*
SECTION 6: FOLLOW UP		
Postnatal review		
134	Follow-up should be arranged with women/parents who have experienced a stillbirth within an appropriate timeframe.	*Best practice*
135	The preferences of women/parents should be considered when organising follow-up.	*Best practice*
136	The timing of follow-up may depend on the circumstances surrounding the stillbirth and the nature of the investigations such as PME. Should some results be delayed, women/parents should still be seen within 3 months of birth to discuss any provisional results and to explore the circumstances leading up to and surrounding the birth.	*Best practice*

Number	Recommendation	Grade
137	The report from a Coronial-directed post mortem examination may take a variable and unpredictable amount of time and it is important that women/parents are made aware of this.	*Best practice*
Pregnancy after stillbirth		
138	Pregnancies after a stillbirth are at increased risk of a subsequent stillbirth; however, women/parents can be reassured the risk does not appear to be affected by the interpregnancy interval.	*2C*
139	Clinical recommendations for interpregnancy interval should consider the woman's health status, age, fertility, desired family size and child spacing, past obstetric history including mode of delivery and psychosocial readiness to conceive.	*Best practice*
140	Following a stillbirth, discussions surrounding future conception should form part of bereavement care pathways.	*Best practice*
141	Women who have experienced a previous stillbirth should be triaged to the specialised care pathway in their subsequent pregnancy and should be managed by an Obstetrician with sufficient experience to manage the pregnancy.	*2C*
142	Women should be booked early in their next pregnancy in order to create an appropriate care plan for the pregnancy and birth.	*Best practice*
143	Fetal growth should be monitored in subsequent pregnancies, if indicated, based on a review of the factors contributory to the previous stillbirth.	*Best practice*
144	The timing of birth needs to be considered on an individual basis, in consultation with the woman, her treating consultant, and the multidisciplinary team.	*Best practice*
145	Maternity services should be resourced to deliver an appropriate level of psychological support to bereaved women/parents in subsequent pregnancies. All women/parents should have access to a specialised bereavement team. This team should comprise a specialised clinical Midwife or Nurse specialist, a chaplain or spiritual guide, a social worker and a member of the perinatal mental health team if required.	*Best practice*

Chapter 1: **Initiation**

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

1.1 Purpose

The purpose of this Guideline is to provide a comprehensive evidence-based framework for the investigation and management of late intrauterine death and stillbirth in the Republic of Ireland. This Guideline also provides a review of some of the risk factors for stillbirth and, as such, constitutes an important resource for healthcare practitioners that work in the field of women's health and obstetrics.

This Guideline is designed to be used, in conjunction with other national guidelines (see Section 1.3) as a frame of reference for the organisation of antenatal services in Ireland and expands on some of the legal processes that relate to the management of stillbirth, including involvement of the Coroner's office.

The delivery of high-quality bereavement care is also highlighted in this Guideline with recommendations made in relation to pastoral care. This extends to ensuring the wellbeing of staff that work within the health service and who are charged with the care of bereaved women and families. By advocating for a holistic approach to the provision of services, this guideline aims to optimise the support provided to bereaved parents and the staff that care for them.

1.2 Scope

Target Users

The Guideline is designed to be a resource for all clinicians working in women's healthcare. This includes Doctors, Midwives, Nurses and healthcare professionals working within the setting of maternity services (including Perinatal Pathology services and pastoral care providers) as well as General Practitioners and community-based healthcare staff.

This Guideline is also useful for healthcare management and hospital groups as they implement systems and infrastructure that work to optimise both service provision and staff support.

Target Population

This Guideline is intended for women, parents, couples and families who have experienced stillbirth.

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

1.3 Objective

The objective of this Guideline is to provide evidence-based recommendations for the care of women who have experienced stillbirth. The aim is to provide a holistic approach, addressing every aspect of the bereaved woman's care at all stages of her journey from the time of diagnosis through birth, the postnatal period and extending to care in future pregnancies.

This Guideline is designed to be used in conjunction with the following Irish guidelines and documents:

- *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death (2016 & 2022)*[23].
- *Pathway for Care of Women Experiencing Stillbirth*[4].
- *Interim Clinical Guidance on the Pathway for Management of Fatal Fetal Anomalies and/or Life-Limiting Conditions Diagnosed During Pregnancy*[5].
- *National Maternity Strategy 2016-2026*[6].
- *National Standards for Safer Better Maternity Services*[7].
- *National Clinical Guidelines for Post Mortem Examination Services*[8].
- *National Clinical Practice Guideline: Prevention and Management of Primary Postpartum Haemorrhage*[9].
- *National Clinical Practice Guideline: The Fetal Anatomy Ultrasound*[10].

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2 Health Service Executive. National standards for bereavement care following pregnancy loss and perinatal death. HSE: Ireland; 2016.

3 Health Service Executive. National standards for bereavement care following pregnancy loss and perinatal death. HSE: Ireland; 2022. https://www.hse.ie/eng/services/list/3/maternity/bereavement-care/

4 National implementation group for the HSE standards for bereavement care following pregnancy loss and perinatal death. Pathway for care of women experiencing stillbirth. HSE: Ireland; 2019. https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/bereavement-care/pathway-for-stillbirth.pdf

5 Institute of Obstetricians and Gynaecologists. Interim Clinical Guidance – Pathway for Management of Fatal Fetal Anomalies and/or Life-Limiting Conditions diagnosed during Pregnancy: Termination of Pregnancy (Interim Clinical Guidance). Dublin: RCPI; 2020. https://rcpi-live-cdn.s3.amazonaws.com/wp-content/uploads/2019/01/IOG-TOPFA-PATHWAY-FINAL-180119.pdf

6 National Clinical Effectiveness Committee. National Maternity Strategy 2016-2026 (Creating a better future together). An Roinn Sláinte/Department of Health: Dublin; 2016. https://www.gov.ie/en/publication/0ac5a8-national-maternity-strategy-creating-a-better-future-together-2016-2/

7 Health Information and Quality Authority. National Standards for Safer Better Maternity Services [Internet]. 2016. https://www.hiqa.ie/sites/default/files/2017-02/national-standards-maternity-services.pdf

8 Health Service Executive. National Clinical Guidelines for Post Mortem Examination Services. HSE: Ireland; In press, 2023.

9 Byrne B, Spring A, Barrett N, Power J, McKernan J, Brophy D, Houston C, Faryal R, McMahon E, Manning C, Murphy P, Ni Ainle F. National Clinical Practice Guideline: Prevention and Management of Primary Postpartum Haemorrhage. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists. December 2022.

10 Fleming A, Corbett G, McParland P. National Clinical Practice Guideline: The Fetal Anatomy Ultrasound. National Women and Infants Health Programme and The Institute of Obstetricians and Gynaecologists; 2023.

1.4 Guideline development process

The Guideline developers agreed to undertake this work under the direction of the Guideline Programme Team (GPT). An Expert Advisory Group (EAG) was commissioned by the GPT. Their role was to critically review the Guideline prior to submission to the National Women and Infants Health Programme (NWIHP) for final approval.

See Appendix 1 for EAG membership and Appendix 2 for Guideline Programme Process.

The Guideline Development Group (GDG) comprised the following clinicians and healthcare professionals:

Team member	Background
Dr Aisling McDonnell	SpR Obstetrics and Gynaecology, CUMH
Dr Mairead Butler	Consultant Obstetrician and Gynaecologist, UHW
Dr Jessica White	Consultant Perinatal Pathologist, CUMH
Tamara Escañuela Sánchez	PhD Candidate, UCC
Sarah Cullen	Clinical Midwife Specialist in Bereavement and Loss, NMH
Riona Cotter	Assistant Director of Midwifery, CUMH
Dr Margaret Murphy	Lecturer in Midwifery at the School of Nursing and Midwifery, UCC
Professor Keelin O' Donoghue	Consultant Obstetrician and Gynaecologist and Maternal-Fetal Medicine Sub-Specialist, CUMH

The Guideline Development Group (GDG) met early in the development process in order to delineate the clinical questions to be addressed by this Guideline and to create a development plan including process of research, task allocation, agreed working timelines and a schedule for feedback and review.

While the ADAPTE[11] process was consulted in the review of international guidelines, this Guideline has been structured based on the recommendations of the GDG, and independent literature reviews were performed in order to provide recommendations based on the most up-to-date evidence available.

1.5 Stakeholder involvement

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

The GDG would like to thank the members of the National Bereavement Oversight Group for contributing their time and expertise to the peer-review process.

11 The ADAPTE Collaboration. The ADAPTE Process: Resource Toolkit for Guideline Adaptation. Version 2.0 [Internet]. 2009.

The Oversight Group (2021-22) comprised the following stakeholders:

Prof Keelin O'Donoghue	Consultant Obstetrician, Fetal Medicine Specialist and Chair
Ms Rióna Cotter	Programme Manager, Bereavement Standards
Ms Mary Jo Biggs	General Manager, NWIHP
Ms Anne Brady	Clinical Midwife Specialist, Bereavement and Loss
Ms Irene Brennan	Clinical Midwife Specialist, Bereavement and Loss
Ms Louise Brookes	NILMDTS
Ms Siobhan Canny	Group Director of Midwifery
Ms Brid Carroll	Irish Childhood Bereavement Network
Ms Mairie Cregan	Chair, Féileacáin
Ms Niamh Connolly	Irish Neonatal Health Alliance
Ms Barbara Coughlan	Midwifery Education
Dr Mary Devins	Consultant in Paediatric Palliative Care
Ms Ann Doherty	Maternity Social Worker
Dr Anne Doolan	Consultant Neonatologist
Ms Angela Dunne	Director of Midwifery, NWIHP
Dr Brendan Fitzgerald	Consultant Perinatal Pathologist
Ms Patricia Grehan	SOFT Ireland
Dr Änne Helps	Consultant Obstetrician and Gynaecologist
Marita Hennessy PhD	Post-doctoral Researcher
Ms Heather Hughes	Prenatal diagnosis Midwife
Mr Tyrone Horne	Nurse Co-ordinator for children with life-limiting conditions
Dr Mendinaro Imcha	Consultant Obstetrician and Gynaecologist
Ms Christina Kilpatrick	Neonatal Palliative Care Nurse
Dr Fiona Mc Elligott	Consultant in Paediatric Palliative Care
Mr Kilian Mc Grane	National Programme Director, NWIHP
Ms Aoife Kirwan	Chair, A Little Lifetime Foundation

Dr Deirdre Müller Neff	Consultant Perinatal Psychiatrist
Rev Dr Daniel Nuzum	Healthcare Chaplain
Ms Jennifer Ui Dhubhgain	Miscarriage Association of Ireland
Dr Stacey Power Walsh	Paediatric Palliative Care Nurse/Nurse Lecturer
Ms Margaret Quigley	Director of Midwifery, ONMSD
Dr Amanda Roberts	Bereavement Development Officer, Irish Hospice Foundation
Ms Rachel Rice	Parent Advocate
Ms Jennifer Ryan	Leanbh Mo Chroí
Dr Fionnuala Sheehan	First Light
Ms Anna Maria Verling	Clinical Midwife Specialist, Bereavement and Loss
Ms Vicky Wall	Every Life Counts
Ms Siobhan Whelan	Vasa Praevia Ireland

The GDG are grateful to Ms Mairie Cregan (Chair Féileacáin, Parent Advocate) for her detailed review of the Guideline and related documents.

1.6 Disclosure of interests

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

All interests should be declared if, in the view of a reasonable person, they are relevant, or could be perceived to be relevant, to the work of the clinical practice Guideline in question[12]. Declaring an interest does not mean there is a conflict of interest.

It is important that interests are openly declared so they can be appropriately managed. Conflicts of interest can bias recommendations and ultimately be harmful to patients and the health system. Disclosures of interests and appropriate management of conflicts of interest, when identified, are therefore essential to producing high-quality, credible health guidelines[13].

12 National Institute for Health and Care Excellence. Policy on declaring and managing interests for NICE advisory committees [Internet]. NICE; 2019. Available from: https://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/declaration-of-interests-policy.pdf

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

The Guidelines International Network (GIN), a global network of guideline developers that aims to promote best practices in the development of high-quality guidelines, developed a set of 9 principles to provide guidance on how financial and non-financial conflicts of interest should be both disclosed and managed. It is recommended that Guideline developers follow the GIN principles[14].

For this national clinical practice Guideline, all guideline developers are asked to complete a conflict of interest declaration form. The response to declared interests will be managed by the guideline programme team, in accordance with GIN principles. Conflicts of interest may be reported in the published Guideline and declarations of interest can be made available.

1.7 Disclaimer

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

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

Clinical material offered in this guideline does not replace or remove clinical judgment or the professional care and duty necessary for each specific woman.

Clinical care carried out in accordance with this Guideline should be provided within the context of locally available resources and expertise.

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

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

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

1.8 Use of language

Within this guidance we use the terms 'woman' and 'women's health'. However, it is important to acknowledge that people who do not identify as cis-gender women are excluded from this descriptor, including people who identify as transgender, gender diverse and gender non-binary[15]. We also appreciate that there are risks to desexing language when describing female reproduction[16 17]. Services and delivery of care must be appropriate, inclusive and sensitive to the needs of people whose gender identity does not align with the sex they were assigned at birth. This includes training and education regarding diverse pathways to pregnancy and the use of practices which affirm the sexual and gender identities of all people using Obstetrics and Gynaecology services.

Language use is important to effectively communicate options, recommendations, and respectfully accept a woman's fully informed decision[18]. With this in mind, the use of birth is preferable to the term delivery, and is used, where possible, throughout the guidelines. It is acknowledged, however, that in some circumstances (e.g., in the case of a medically indicated intervention or surgery) or where semantics dictate, using the term delivery may be considered appropriate and this term may be used instead.

Reference is made throughout the text in this Guideline to women and parents. The term 'parents' can be used to refer to expectant and bereaved mothers, fathers, and partners. While women should always be facilitated to have a partner or support person with them at every encounter in the maternity hospital/unit, it is important to remember that not everyone will have a partner. Therefore, in this Guideline we have used the terms women and parents. These terms should be taken to represent the woman herself, the biological parents, or the woman and her partner where applicable.

15 Moseson H, Zazanis N, Goldberg E, Fix L, Durden M, Stoeffler A, *et al*. The Imperative for Transgender and Gender Nonbinary Inclusion: Beyond Women's Health. Obstet Gynecol. 2020 May;135(5):1059-68. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7170432/

16 Brotto LA, Galea LAM. Gender inclusivity in women's health research. BJOG Int J Obstet Gynaecol. 2022 Nov;129(12):1950-2. https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.17231

17 Gribble KD, Bewley S, Bartick MC, *et al*. Effective Communication About Pregnancy, Birth, Lactation, Breastfeeding and Newborn Care: The Importance of Sexed Language. *Frontiers in Global Women's Health*. 2022;3. Accessed June 9, 2022. https://www.frontiersin.org/article/10.3389/fgwh.2022.818856

18 https://blogs.bmj.com/bmj/2018/02/08/humanising-birth-does-the-language-we-use-matter/

Chapter 2:
Clinical Practice Guideline

Terminology

The terminology used in this Guideline is in keeping with the legal definition of stillbirth that has been outlined by the *Stillbirths Registration Act, 1994*[1] and the *National Standards for Bereavement Care following Pregnancy loss and Perinatal Death*[2].

IUFD	Intrauterine fetal death: In the context of this Guideline intrauterine fetal death is taken to mean late intrauterine fetal death at a gestation of ≥24^{+0} or at a fetal weight of ≥500g.
Stillbirth	An infant delivered at a gestation of ≥24^{+0} or weighing ≥500g and showing no signs of life. By the above definition for intrauterine fetal death it is synonymous with stillbirth as stillbirth implies that the fetus died in utero prior to birth. Once the birth has taken place, however, the term stillbirth is used.
sIUFD	Selective intrauterine fetal death; the death of one or more fetuses within a multiple pregnancy with at least one or more living fetuses remaining at the time of death.

Background

Stillbirth is a devastating event for a woman or parent. In Ireland the rate of stillbirth in 2019 was 4.06/1000[3] equating to just less than 1 in 250 total births (all births ≥24^{+0} or weighing ≥500g). In order to identify contributing factors for stillbirth in Ireland, and in an effort to consolidate records and countrywide trends, the National Perinatal Epidemiology Centre (NPEC) created a centralised system for the collection and analysis of national data on stillbirth and perinatal death. Since the publication of the first report in 2009, NPEC has provided valuable information on the rate, nature and aetiology of stillbirth in the Republic of Ireland.

In Ireland, the trend in the rate of stillbirth has decreased overall since 2008 (4.7/1000 to 4.06/1000)[4], however, there remains a degree of temporal fluctuation within these figures and the rate appears to have plateaued over the past few years[3]. While 31% of stillbirths in 2018 and 2019 were associated with a major congenital anomaly, 69% were not[3], suggesting scope for the identification and potential mitigation of other factors, both maternal and fetal, that contribute to the low, yet unwavering, rate of intrauterine fetal death.

In the UK, national trends in perinatal mortality are reported by MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK); a collaboration appointed by the Healthcare Quality Improvement Partnership. Their most recent annual report (published in October 2022), demonstrated a steady, albeit marginal, decrease in the annual rate of stillbirth at all gestations with the overall rate for 2020 resting at 3.33/1000[5]. Just over one in four stillbirths occur in term pregnancies (37^{+0} to 41^{+6}); this is consistent with Irish data produced by NPEC[3] and has remained relatively consistent over the last five years.

The rate of intrapartum stillbirth has been declining in Ireland, representing approximately 5% of all stillbirths in 2019[3]. A similar trend has been observed in the UK[5] and this may be, in part, due to the development of programmes and support structures such as *Each Baby Counts*[6] and *Saving Babies' Lives*[7,8]. *Each Baby Counts* is a national quality improvement strategy established in 2015 with the aim of analysing term intrapartum stillbirth as one of a number of adverse perinatal outcomes[6]. *Saving Babies' Lives* (first published in 2016 and more recently updated in 2019) is an evidence-based care bundle that has been speculated to have been effective in tackling stillbirth and seeks to further reduce preventable fetal death through supporting systems and staff in optimising their delivery of care[7,8].

These efforts have also been observed internationally. Over the last ten years, there has been a global effort to tackle the problem of preventable stillbirth, as evidenced by notable series such as those published by the Lancet[9,10] and the British Journal of Obstetrics and Gynaecology[11]. These series brought the issue of stillbirth to the forefront and highlighted a need for investment in high-quality maternity care with strategic risk assessment and appropriate allocation of resources. The focus was universal with recommendations relevant to both high and low-to-middle-income settings, including improvements in data collection, standardisation and audit.

These series, along with national reports and quality improvement strategies have also highlighted the relevance of appropriate psychological supports for bereaved women and the need for greater access to specialised bereavement services. In Ireland, following the death of Savita Halappanavar in 2012, several recommendations were made relating to the delivery of care in the Irish maternity setting, and they included the provision of adequate bereavement support[12]. The HSE Maternity Clinical Complaints Review (2017) also confirmed a common sentiment among women that there was generally a 'lack of bereavement support' within the Irish system[13]. These events instigated the development of a working group that lead to the publication and implementation of the Irish *National Standards for Bereavement Care following Pregnancy loss and Perinatal Death* in 2016[14]. These standards were later updated in 2022[2] and seek to optimise the delivery of consistent quality bereavement care at a national level.

While maternity services and policy makers strive to end preventable stillbirth, it remains a relatively common complication of pregnancy. When a woman receives this diagnosis, it is essential that management is both evidence-based and standardised in order to ensure best practice and delivery of care at a local, regional and national level.

This care extends to pregnancy following stillbirth where the identification and management of preconceptional and antenatal risk factors is important for minimising the risk to subsequent pregnancies. Unfortunately, there are gaps in knowledge with regard to risk-reduction strategies and care pathways, particularly surrounding antenatal surveillance and the management of fetal growth restriction and reduced fetal movements [15-17]. The lack of international consensus with regard to the definition of stillbirth and classification systems creates difficulties with comparing data, identifying deficits in care and ultimately selecting potential areas for improvement[18,19]. While bodies such as the International Stillbirth Alliance work to tackle these deficiencies, ongoing research and collaboration, on a global scale, are needed to provide women with the evidence-based care that will achieve the best outcome in pregnancy.

This guidance acknowledges the challenges within the literature and seeks to clarify some of the evidence pertaining to stillbirth from preconceptional risk factors to management and aftercare. In order to achieve this, and for practicality, the following chapter has been divided into seven sections: 'risk factors', 'diagnosis', 'investigations', 'management', 'classification, audit and review', 'follow-up' and 'looking to the future'; where the deficits in our knowledge base and areas of ongoing research are explored.

Section 1: Risk Factors

PRECONCEPTIONAL AND ANTENATAL RISK FACTORS

Introduction

There are a multitude of factors that can increase the risk of intrauterine death and stillbirth. Some of these are present from the onset of the pregnancy and can be readily identified at the booking visit. Others emerge as the pregnancy evolves. It is important to recognise that a risk factor may not exist in isolation and an individual woman's risk for an adverse outcome may depend on the complex interplay of several variables.

The following text gives a brief overview of the most common of these variables and has been divided, for practical reasons, into maternal, fetal and pregnancy-associated risk factors for stillbirth (*Table 1*). It is important to acknowledge, however, that overlap exists, and these categories are not independent of one another, but are intrinsically related. It is equally important to acknowledge that the terms modifiable and non-modifiable are basic terms that do not recognise the complexity of the risk factor, the environment, or human behaviour; as such, maternal risk factors may demonstrate qualities consistent with both descriptors. When creating a care plan for a pregnancy, the healthcare provider should consider the potential impact of each risk factor in context, and balance this with the risks of intervention and the wishes of the woman.

The purpose of this section is to raise awareness of the more common risk factors for stillbirth. It is beyond the scope of this guideline to provide advice on the individual management of each risk factor and, where applicable, the corresponding national and international guidelines have been referenced.

Table 1: Risk factors for stillbirth

Maternal	Fetal	Pregnancy related
Non-modifiable • Maternal age • Parity • Ethnicity • Socioeconomic background • Obstetric history • Medical history • Assisted reproduction	• Gestational age • Fetal growth restriction • Multiple gestation • Male sex • Congenital anomalies	• Gestational diabetes • Pre-eclampsia • Intrahepatic cholestasis of pregnancy
Modifiable • Antenatal care • BMI • Smoking • Substance use • Sleeping position		

Clinical Question 2.1: **What are the non-modifiable maternal risk factors that need to be considered?**

Evidence Statement

The following guidance is derived primarily from national reports and registries in addition to data from large retrospective cohorts, case-controls and meta-analyses. As intrauterine death and stillbirth are uncommon, individual studies are often underpowered to evaluate this outcome. Furthermore, assessing the influence of any one risk factor can be difficult even when results are adjusted for multiple confounders. Despite these issues, there is reasonable evidence to support the validity of the risk factors discussed in this guideline. Of greater importance still, is how we use this evidence to guide management and develop strategies aimed at reducing the rate of intrauterine death and stillbirth.

Maternal age

According to MBRRACE-UK (2019), the overall risk of stillbirth in pregnancy for a woman aged ≥40 is 4.45/1000 (1/225) births[20]. This rate has been steadily improving since 2016 but remains 41% higher than for women aged 30-34. This rate includes both stillbirth due to chromosomal/congenital anomalies and stillbirth in women with underlying comorbidities; two confounders that are linked with advancing maternal age.

Advanced maternal age (AMA, ≥35 years) does, however, appear to be an independent risk factor for stillbirth[21,22]. A retrospective analysis of 5.5 million births in the United States reported a relative risk (RR) in term (period spanning 37 to 41 weeks) healthy pregnancies of 1.32 (95%CI 1.22-1.43) for women aged 35-39 years and 1.88 (95%CI 1.64-2.16) for women aged ≥40 years when compared with women aged <35 years[22]. At 41 weeks the risk was two to threefold higher for women aged ≥40 compared to women aged <35. The hazard for women aged 25-34 years at 41 weeks was noted to be comparable to the hazard for women aged ≥40 years at 39 weeks[22].

Interestingly, while this age-related trend was similar in both nulliparous and multiparous subgroups, the absolute risk was two to threefold lower in the multiparous population (parity not specified); the risk of stillbirth quoted for multiparous women ≥40 was similar to nulliparous women ≤35[22].

The risk associated with advanced maternal age appears to be independent of maternal co-morbidities (pre-existing and pregnancy related)[21-23], and the presence of congenital anomalies[22], and may be associated with age-related changes in the uterus and local vasculature.

The risk of stillbirth follows a bimodal distribution with peaks at the extremes of reproductive age; younger maternal age also appears to be a risk factor for stillbirth. The overall risk of stillbirth for a woman aged <20 in the UK in 2019 was 4.20/1000 (1/238) total births; 33% higher than for the reference group (women aged 30-34)[20]. Data referenced by the American College of Obstetricians and Gynaecologists support this, suggesting almost a threefold increase in the risk of stillbirth for women aged <15 and a 32% and 22% increase respectively for those ages 15-17 and 18-19[24]. Of note, a recent review of 20 randomised controlled trials (RCTs) suggested a slightly reduced risk of stillbirth for those aged <20 but an overall increase in the risk of perinatal and neonatal mortality[25].

Parity

The rate of stillbirth is higher in nulliparous women[22,26,27]. A Swedish population based retrospective study of >900,000 births reported double the crude rate of still birth at ≥39 weeks in nulliparous versus multiparous women; this was most pronounced at 42 weeks with the rate in nulliparas (1.45/1000) almost three times that seen in multiparas (0.53/1000)[27].

It has been suggested that the rate of stillbirth follows a U-shaped distribution with an upward trend in higher order multiparas, particularly for the grand multipara[28]. A 2013 analysis of over 92,000 births suggested a higher risk of stillbirth with a parity of three and above, however, it is not clear whether the results were adjusted for confounders such as maternal age[26]. Overall, while the risk of stillbirth may be elevated at higher order parity, the exact point at which parity itself becomes an independent risk factor remains uncertain.

Ethnicity

The disparity in the rates of stillbirth among infants of different ethnic backgrounds is well documented[20,22,24,26,29]. The most recent MBRRACE-UK report[20] on perinatal mortality noted over double the risk of stillbirth for babies of black ethnicity compared to white ethnicity (RR 2.25); the rate of stillbirth for babies of Asian ethnicity was 57% higher. While the rate of stillbirth in all groups has improved steadily since 2017 this disparity has persisted. The reason for this is likely multifactorial and may include socioeconomic challenges, inequalities in access to healthcare and genetic predisposition to pregnancy and non-pregnancy related medical conditions[20,22,24].

Data from Irish registries, while too small to derive statistically significant results for stillbirth, support a trend towards a racial disparity in the rate of perinatal death (stillbirth plus early neonatal death)[3]. The National Institute for Health and Care Excellence (NICE) suggests that healthcare providers be aware of the above when creating a care-plan for antenatal input, labour and delivery but does not make specific recommendations in this regard[30].

Socioeconomic status

Social deprivation and its sequelae are associated with an elevated risk of stillbirth[20,31]. Socioeconomic status (SES) is a complex construct determined by the interplay of variables such as occupation, income and education and their influence on physical, psychological and financial wellbeing. In the UK, while the rate of stillbirth is falling across all socio-economic deprivation quintiles, this improvement has not been observed in equal measures for all groups; from 2015 to 2019 there was a 22% reduction in the rate of stillbirth for women living in the least deprived areas and an 8% reduction for women living in the most deprived areas[20]. In 2019 the rate of stillbirth was double for those in the most deprived quintile (4.67/1000) when compared with the rate for the least deprived quintile (2.33/1000)[20].

While one could argue that SES is a modifiable variable in the medium to long term, it is unlikely to change from booking to delivery, and so, for the purposes of this guideline has been considered as a non-modifiable risk factor.

Previous obstetric history

According to the most recent NPEC report, 2.9% of women who experienced a perinatal loss in 2019 had suffered a previous stillbirth, 7.4% had experienced a previous preterm birth or mid-trimester loss and 4.9% had a previous diagnosis of recurrent miscarriage[3].

Previous history of stillbirth is a known risk factor for subsequent stillbirth, with a quoted recurrence risk ranging from two to tenfold the background rate[32]. There exists variation in the literature due to inherent heterogeneity in study design, different population bases and significant differences in the definitions of stillbirth. A large systematic review and meta-analysis of data from high-income countries in 2015 calculated that the risk of stillbirth in a subsequent pregnancy was 2.5% for women with a history of stillbirth compared to 0.4% for those with a history of live birth (pooled odds ratio, OR 4.83 [95%CI 3.77 to 6.18])[32]. A recent Dutch study suggested that this risk may vary depending on the gestational age of the previous stillbirth; women who experience a stillbirth at <28-32 weeks may be at higher risk of recurrence[33].

The risk of stillbirth has also been shown to be increased in second pregnancies where the first pregnancy was complicated by preterm birth, small-for-gestational-age (SGA) or pre-eclampsia (PET), particularly when SGA and PET co-existed within the same pregnancy[34].

It can be difficult to counsel women on the risk of recurrence when the cause of the stillbirth is unknown. A large proportion of stillbirths remain unexplained (9.5% – 31.5% in high-income countries[3,20,35,36]) and the risk of recurrence in this cohort is less clear[32].

Medical history

Multiple preconceptional and pregnancy related conditions have been associated with an elevated risk of stillbirth including diabetes, overweight and obesity, and chronic hypertension[37,38]. Some of the co-morbidities commonly associated with stillbirth are explored below. This list is not exhaustive. It must also be noted that, while the presence of a diagnosed condition is non-modifiable by definition, disease activity can be altered by treatment; thus, chronic conditions can also be considered modifiable.

Diabetes

The number of pregnancies complicated by pregestational Diabetes Mellitus (DM) is increasing[37,39]. A British study of pregnant women spanning 17 years, from 1995 to 2012, reported a significant rise in the prevalence of both Type 1 DM (D162% to 4.09/1000) and Type 2 DM (D354% to 10.62/1000)[39] in pregnancy. Given the upward trend in the rate of maternal overweight and obesity[40,41], the rate of diabetes in pregnancy has likely increased further still over the last 10 years.

The association of pre-existing Diabetes Mellitus with stillbirth is well-documented[37,38,42,43]. Women with Type 1 DM and women with Type 2 DM have an unadjusted 4-fold and 5-fold increased risk respectively of stillbirth, compared to women without these conditions[37]. A recent Scottish study of over 5,000 women with pregestational DM reported a stillbirth rate of 16.1/1000 for women with Type 1 DM and a rate of 22.9/1000 for women with Type 2 DM[38]. In Type 1 DM the risk peaked in the 38th week (7/1000; note only 11% continued beyond this point) and in Type 2 DM the risk peaked in the 39th week (9.3/1000)[38].

Thyroid disorders

Thyroid dysfunction is the second most common endocrinopathy in pregnancy after diabetes; overt hypothyroidism occurs in approximately 0.3-0.5% of pregnancies, subclinical hypothyroidism in 2-3% of pregnancies and thyroid autoantibodies are found in about 5-15% of women of childbearing age[44]. Thyroid dysfunction has been associated to varying degrees in the literature with an increased risk of stillbirth and perinatal mortality[45,46] and women who have experienced a stillbirth appear to have slightly higher rates of biochemical derangement[46].

Hypertension

There is an elevated rate of stillbirth in women with an existing diagnosis of chronic hypertension. A recent systematic review and meta-analysis of 16 studies examining the impact of chronic hypertension and anti-hypertensive treatment on adverse perinatal outcomes reported an elevated risk of stillbirth (adjusted odds ratio, aOR 2.32 [95%CI 2.22-2.42]), small-for-gestational-age (SGA, aOR 1.96 [95%CI 1.61-2.40]), low birth weight (aOR 3.05 [95%CI 2.24-4.15]) and pre-eclampsia (aOR 5.43 [95%CI 3.85-7.65]). These risks were independent of maternal race/ethnicity[47].

Interestingly, there was no significant difference in outcomes between women who were treated with antihypertensives and those who were untreated[47] except for the prevalence of SGA where the OR was higher for those on treatment (aOR 1.86 [95%CI 1.38-2.50])[47]. The use of antihypertensive treatment, however, is often an indicator of disease severity and so these variables are intrinsically linked and difficult to evaluate independently.

Thrombophilia

Thrombophilia is defined as a defect in the coagulation or fibrinolytic system that creates a pro-thrombotic state within the affected individual and predisposes to thrombotic events (venous or arterial); they can be classed as acquired or inherited[48].

Acquired thrombophilia

Antiphospholipid syndrome (APS) is an acquired thrombophilia with strict diagnostic criteria that has been associated with recurrent miscarriage, placental pathology, fetal growth restriction (FGR) and stillbirth[49,50]. The diagnosis is made based on the presence of both clinical features and laboratory confirmed antiphospholipid antibodies (APAs).

The presence of APAs in the background population is not insignificant, with a quoted prevalence of 1-5%[51] rendering screening in asymptomatic individuals inadvisable. The prevalence of the syndrome itself is much rarer with a prevalence of approximately 0.05%[52].

While there is good evidence linking APS to fetal loss the attributable risk is difficult to quantify due to the uncommon nature of the condition in pregnancy, the rarity of stillbirth as an outcome and the resultant plethora of underpowered studies[50]. The rate of adverse outcomes including fetal demise and neonatal death, does, however, appear to be higher in women with APS and history of thrombosis, and in those who are triple positive for APAs at onset[53].

Inherited thrombophilia

Inherited thrombophilias are a heterogenous group of genetic mutations that affect components of the coagulation pathway. The more common of these include Factor V Leiden, Prothrombin gene mutation, Protein C or S deficiency and Antithrombin III (AT III) deficiency[48], however, there are numerous mutations and the list continues to expand[54]. While there may be an association between certain inherited thrombophilias and adverse pregnancy outcomes, including stillbirth, the exact nature and magnitude of these associations remain unclear[54,55].

The evidence is somewhat stronger for Factor V Leiden (FVL) with regard to unexplained stillbirth and placental pathology[56,57]. One Finnish study of 44 unexplained stillbirths proffered a 4-fold increase (95%CI 1.2-11.6) in the prevalence of FVL heterozygosity and a 10-fold (95% CI 2.1-55.3) increase when unexplained stillbirth was associated with placental lesions[56], however, large prospective studies are lacking and the relevance of heterozygosity in the pathophysiology of stillbirth continues to be disputed in the literature[57]. Furthermore, while the link between FVL homozygosity may be of greater importance, FVL homozygosity is uncommon and almost all studies are underpowered to proffer clinical significance.

Auto-immune disease

The presence of various autoimmune antibodies have been associated with, or observed with a higher frequency in women diagnosed with pregnancy loss and stillbirth[58]. However the strength of evidence is poor[58]. Systemic lupus erythematosus is associated with a higher risk of stillbirth[59], particularly in the presence of hypertension, APS and lupus nephritis[59,60].

Assisted Reproduction

Pregnancies conceived through IVF/ICSI are associated with an increased risk of stillbirth[61,62]. A recent meta-analysis proffered a 36% increase in the risk of stillbirth when pregnancies conceived through IVF/ICSI were compared to spontaneous conception (OR 1.36 [95%CI 1.10-1.67])[61]. This risk persists despite adjustment for maternal age, smoking, parity, fetal sex, preterm birth, BMI, GDM, PET, and Intrahepatic cholestasis of pregnancy[62].

It is unclear whether this increased risk is due to the multistep process inherent to some fertility treatments (IVF/ICSI) or the underlying subfertility itself; while comparisons involving IUI as an isolated variable often fail to reach statistical significance, a higher risk of stillbirth has also been suggested in this cohort[62]. One study suggested a similar risk of stillbirth when IVF/ICSI was compared to OI/IUI[61]. This hints at the potential existence of an underlying, pathophysiological process associated with subfertility itself that may be an independent contributor to the risk of stillbirth[61].

Clinical Practice

Women should be screened at their booking visit for non-modifiable maternal risk factors for stillbirth. This includes clear documentation of age, parity, socio-economic and cultural background, previous obstetric history including antenatal course, birth and outcomes, medical history, and the use of assisted reproductive technology.

Women at the extremes of reproductive age (<20 and ≥40) should have their pregnancy plan reviewed by their consultant Obstetrician at the booking visit. This includes the schedule of antenatal care and a plan for birth.

Parity, in isolation, may or may not affect the delivery of antenatal care. However, this feature should be noted in the woman's healthcare record and should be taken into account when creating a care plan for pregnancy, birth and the postnatal period.

If a woman is identified as having a medical condition (whether this was known preconceptionally or newly diagnosed because of investigations in the pregnancy), the booking Midwife or Obstetrician should establish, and consider, the potential implications that the condition may have for the pregnancy and how the pregnancy, in turn, may influence the condition. The level of control must be established, and any relevant specialist care documented. If necessary, the relevant specialist should be contacted for advice on management of the condition in pregnancy. If the condition is considered significant enough to warrant a high-risk referral, or joint obstetric care, then this should be arranged, and management should be consultant-led with reference to the relevant clinical practice guidelines (CPGs) and care pathways.

Women who have availed of assisted reproductive techniques need to have their risk of stillbirth determined at the booking visit and a plan of care decided depending on this risk.

Socio-economic and domestic barriers to care should be documented. While measures to reduce socio-economic disparities are mainly focused at a public health and policy level, it is important for the clinician, and the unit, to be aware of the potential barriers to accessing care in women of lower SES in order to optimise individual care plans. Women considered to be susceptible to these such barriers should have access to multidisciplinary input including access to social work and perinatal mental health services.

At all times a woman-centred approach should be adopted. Risks should be communicated in a clear manner, that avoids ambiguity, and decisions surrounding care should seek to involve the woman as much as possible.

Clinical Question 2.2: **What are the modifiable maternal risk factors that need to be considered?**

Evidence Statement

The following evidence has been subdivided based on the individual risk factor. The quality and nature of the supporting evidence is in keeping with that for non-modifiable risk factors.

Access to antenatal care

Access to antenatal care is the cornerstone of preventing perinatal morbidity and mortality[63,64]. A case-control study of 155 stillbirths and 310 controls from New Zealand suggested that accessing <50% of the recommended antenatal schedule was associated with a two to threefold increase in the risk of late stillbirth (adjusted odds ratio, aOR 2.68 [95% CI 1.04-6.90])[65].

In their most recent report on the subject, the World Health Organisation recommended a minimum of eight antenatal contacts in order to reduce perinatal mortality and improve women's experience of care[63]. The report quoted moderate-certainty evidence that a reduced schedule of four antenatal interactions (the previous standard) compared to a schedule of at least eight antenatal interactions may increase the rate of perinatal mortality by 15%[63]. While access to care has primarily been a challenge in low-to-middle-income countries, socio-economic factors continue to pose challenges to accessing appropriate care in high-income countries as well[66].

Body mass index

The proportion of pregnant women living with overweight or obesity is growing. A large retrospective observational study of 68,000 maternities from the Coombe Women and Infants University Hospital (CWIUH) revealed that, in 2017, only 49.9% of Irish bookers had a BMI within the normal range (BMI 18.5-24.9Kg/m^2) and, while 1.7% were considered underweight (BMI <18.5Kg/m^2), 29.5% were considered overweight (BMI 25-29.9Kg/m^2) and 18.9% were in the obese range (BMI ≥30Kg/m^2)[67]. This is consistent with figures from across the UK[40,41] where approximately 1 in 4 woman at booking now have a BMI ≥30Kg/m^2.

Several large meta-analyses have established raised maternal BMI as an independent risk factor for stillbirth[68-70]. The most recent of these reviews quoted a relative risk ranging from 1.2 (95%CI 1.14-1.26) for a BMI of 25 to 2.19 (95%CI 2.03-2.36) for a BMI of 40[69]. For every 5 unit increase in BMI there was a corresponding incremental increase of 24% in the risk of stillbirth (RR 1.24 [95%CI 1.18-1.30]). This risk appeared to be independent of confounders including, but not limited to maternal age, parity and smoking[69]. The divergence in relative risk and the impact of increasing BMI may also be more pronounced at later gestations[27].

The pathophysiological processes behind maternal adiposity presenting as an independent contributor to the risk of stillbirth has not been fully elucidated and is likely mulifactorial[69]. A case-control study in 2015 that looked at maternal preconceptional BMI and cause-specific stillbirth reported that obese (30≤BMI<35) and severely obese (≥30) women were at twice the risk of experiencing a stillbirth associated with fetal anomaly, of having placental disease and of developing a maternal medical condition (primarily hypertensive disorders)[71]. Combined preconceptional maternal overweight and obesity has been flagged as the top ranking modifiable risk factor for stillbirth in high-income countries[70].

For the purposes of stratification, BMI has been discussed here as a potentially modifiable risk factor. However, it is important to note that obesity, in its own right, is recognised both nationally and internationally as an important non-communicable disease with a need for targeted intervention strategies[72]. While weight is, strictly speaking, modifiable, the focus should be on the modification of preconceptional maternal weight; the maternal weight category at booking is unlikely to change during the pregnancy.

On this note, in 2009 The Institute of Medicine developed recommendations for optimal maternal weight-gain in pregnancy stratified by BMI[73]. This guidance expressed potential harm, not only with regard to excessive weight gain in pregnancy, but with regard to suboptimal weight gain and weight loss during pregnancy[73]. It is therefore, important that women are provided with appropriate information surrounding healthy eating and lifestyle habits at their booking visit and that communication remains free of judgement as any perceived stigmatisation during a clinical encounter may lead to barriers in care[74].

Smoking

It has been well documented that smoking is a risk factor for stillbirth[75,76]. A systematic review and meta-analysis in 2015 calculated a 47% increase in the odds of stillbirth in women who smoked during pregnancy[76]. A subgroup analysis demonstrated a 9% increase in the odds of stillbirth for pregnant women who smoked 1-9 cigarettes per day and a 52% increase for those who smoked ≥10 cigarettes per day[76].

Passive smoking is also harmful; a cross sectional study of 81,000 women concluded that the risk of stillbirth in women exposed to second hand smoke was similar to the risk in active smokers[77].

There has been conflicting evidence on whether timing of exposure to smoking has an influence of the risk of adverse outcomes and stillbirth[78,79]. A retrospective cohort study that included 116 cases of stillbirth reported on a protective effect of smoking cessation at <16 weeks with a resultant risk of stillbirth that was similar to non-smokers[78]. A retrospective case-control study that featured data from 105 stillbirth cases reported no such difference, suggesting that the first trimester was particularly susceptible to the effects of tobacco[79].

Substance use

Substance use, in the context of pregnancy, can include the consumption of alcohol, the use of illicit substances or the use of pharmaceutical medications.

Alcohol

There are few well designed studies examining the relationship between alcohol and stillbirth in the literature[80,81]. A systematic review in 2007 failed to establish a definite link between low-moderate alcohol use and adverse fetal outcomes, but noted that the majority of the contributing studies demonstrated a sizeable degree of recall bias[82]. A more recent retrospective cohort study of over 650,000 pregnancies and over 3,500 stillbirths reported an adjusted hazard ratio (HR) of 1.4 (95%CI 1.2-1.7) for stillbirth in women who consumed any volume of alcohol during pregnancy[80]. This association was stronger for 'early' stillbirth (<28 weeks)[80]. Interestingly, the highest risk was observed for those women who 'did not specify' the volume of alcohol consumed, followed by those who reported ≥5 'drinks'/week[80].

Illicit drug use

Illicit drug use has been associated with adverse pregnancy outcomes[83]. A population-based case-control study conducted by the Stillbirth Collaborative Research Network reported a twofold increase in the odds ratio (OR) for stillbirth in infants whose cord blood tested positive for an illicit substance[83]. The most common substance detected was THCA (OR 2.34 [95%CI 1.13-4.81]) however this association was likely confounded by concomitant tobacco use[83]. A trend towards positive correlation was also noted in cases that tested positive for hydrocodone and morphine[83]. Cocaine use, in particular, has been associated with placental abruption and subsequently stillbirth[84].

Medication

The antenatal use of pharmaceutical medication is common[85-87]; just over 80% of pregnant women use at least one medication (either prescribed or over the counter) in the course of their pregnancy[85,86]. Among the most commonly used medications in pregnancy are: antibiotics, analgaesics (including paracetamol), anti-emetics, anti-histamines, inhaled anti-asthmatic medication, laxatives, antacids and topical creams/ointments[86,87]. Well-structured studies and trials are lacking in the pregnant population and so there is a paucity of evidence surrounding the prevalence of adverse fetal outcomes in humans for the majority of these medications. A recent review focusing on modifiable risk factors associated with stillbirth concluded that the use of antiemetics was not associated with an increase in the risk of stillbirth and that the evidence was conflicting or insufficient with regard to the use of paracetamol, aspirin, antihistamines and selective serotonin reuptake inhibitors[81].

Sleeping position

There is evidence that sleeping in the supine position is an independent risk factor for late intrauterine fetal death[88-91]. This may be related to altered maternal haemodynamics and uterine artery blood flow in the third trimester[92-94]. A meta-analysis in 2019 of five case-control studies, encompassing 851 cases of stillbirth and 2257 controls, confirmed that the supine going-to-sleep position was independently associated with stillbirth ≥28/40 (adjusted odds ratio [aOR] 2.63, 95% CI 1.72-4.04, $p < 0.0001$) when compared to left lateral[95]. Going to sleep on the right side was comparable to the left i.e., was equally safe (aOR 1.04, 95% CI 0.83-1.31, $p = 0.75$)[95]. Furthermore, it was demonstrated that the effect of a supine going-to-sleep position may be exacerbated by the presence of pre-existing fetal compromise such as small-for-gestational-age status[95].

Case-control studies from New Zealand (NZ), Australia (AU) and the UK (UK) proffer that the population attributable risk of stillbirth for the supine going-to-sleep position may range from 3.7% (UK) to 10% (NZ/AU)[88,90,91]. This would suggest that 1 in 10 to 25 cases of late intrauterine death could potentially be prevented by avoiding this position from 28 weeks[90,91]. Accordingly, several public health campaigns have been launched internationally with the aim of raising awareness of the importance of going-to-sleep position such as the Cure Kids '*Sleep on Side; Stillbirth Prevention Campaign'* in New Zealand (https://www.sleeponside.org.nz) and Tommy's '*Sleep on Side*' pregnancy campaign in the UK (available at https://www.tommys.org/sleep). These campaigns support going to sleep on the side from 28 weeks onward. A review by NICE in 2021 supports the recommendation that women should go to sleep on their side (right or left) and avoid going to sleep on their back after 28 weeks of pregnancy[96].

Clinical Practice

Accessing quality antenatal care is vital to the prevention of perinatal morbidity and mortality. At the booking visit:

- Women should be advised of the importance of engaging with antenatal care and scheduled appointments
- Potential barriers to accessing care should be identified
- Potential solutions to addressing these barriers should be discussed
- The extended MDT should be engaged (where appropriate) e.g. social work etc.
- The above should be reassessed at each point of contact as modifications may need to be made to the plan of care.

At the booking visit maternal height and weight should be recorded and BMI calculated. In a sensitive manner, the presence of maternal underweight, or overweight and obesity should be discussed with the woman, including:

- The potential implications of underweight, overweight and obesity on pregnancy
- Healthy eating and exercise practices in pregnancy
- The need for screening for gestational diabetes
- The role of dietary supplementation
- The role of the extended MDT (where appropriate) e.g., dietetics.

Individual care plans for women with a BMI ≥30 may vary depending on the degree of obesity and the presence of compounding risk factors. Women with a BMI of ≥40 should be seen in a high-risk setting and care should be consultant-led. Further advice with regard to care can be accessed by consulting both the national CPGs on obesity and pregnancy[97,98] and the more recently developed *Model of Care for the Management of Overweight and Obesity*[99] for Ireland.

At the booking visit, maternal smoking status should be determined and documented including an estimate of daily use. With regard to ongoing care:

- Pregnant women should be advised on the potential impact that smoking may have on their pregnancy with reference to both fetal and maternal sequelae
- Pregnant women should be counselled that, while preconceptional smoking cessation is ideal, cessation at any stage in the pregnancy (particularly in the first trimester) may still be beneficial in reducing the risk of stillbirth
- Given the potential longstanding benefits, cessation should be encouraged throughout pregnancy and the puerperium
- A referral to smoking cessation should be offered at each clinical encounter as needed
- Any updates to maternal smoking status should be documented in the healthcare record
- Positive reinforcement and feedback among healthcare practitioners is encouraged.

The use of illicit substances and alcohol intake should be documented at the booking visit, including any previous diagnoses (formal or informal) of substance addiction. The extended MDT should be engaged as appropriate (e.g. social work, perinatal mental health etc.) and a referral to high-risk antenatal services may be warranted.

All medication (both over the counter and prescription) in use both preconceptionally and at the time of the booking visit should be clearly documented, including dosing regimens. Women should be advised on:

- The potential impact that a medication may have on the pregnancy
- The potential impact that pregnancy may have on the ability of a medication to function effectively
- The implications of continuing or discontinuing a medication; quality of life should also be factored in here
- The need for specialist input, where applicable

Women should be advised to avoid the supine going-to-sleep position at ≥28/40 as it has been associated with an increased likelihood of stillbirth when compared to left-lateral. Women should also be advised that there is no evidence to support one side over another; right-lateral appears to be equally as safe as left-lateral.

The identification of modifiable risk factors early in the pregnancy is important due to the potential for modification of these risk factors as the name suggests. Interventions such as education, behavioural changes and multidisciplinary input may have a significant impact on the antenatal course and clinical

outcomes. Communication is vital when interacting with women at each clinical contact; the use of clear and appropriate language is important. The aim should be to educate and engage women while avoiding terminology and actions that may lead to feelings of isolation or stigmatisation.

Clinical Question 2.3: **What are the fetal risk factors that need to be considered?**

Evidence Statement

There is high degree of evidence to support the following fetal risk factors in the pathophysiology of stillbirth. As for the previously presented guidance, supporting data is derived primarily from large retrospective cohorts and meta-analyses with minor but important contributions from prospective studies and RCTs. As for all risk factors, they do not exist in isolation and must be evaluated within the context of the pregnancy as a whole.

Gestational age

The risk of stillbirth varies with gestation with a nadir in the late second and early third trimester[22]. In a review of >90,000 births, Gardosi *et al*. noted that 52% of stillbirths occurred at >34 weeks[26] and multiple studies have focused on term stillbirths and the risks associated with postdates gestation[29,100-103]. A recent systematic review of over 15 million pregnancies and 18,000 stillbirths confirmed an upward trend in the rate of stillbirth from 37 weeks to 43 weeks[29]. This relationship is not linear with an increase in the relative risk on a week-by-week basis. A 64% increase was noted in the rate of stillbirth between the 40th and 41st week, and the weekly risk doubled thereafter[29].

While relative risk is important, absolute risk is useful for determining clinical significance and guiding management. The number needed to treat (i.e. number of pregnancies needed to induce/deliver) to prevent one stillbirth was calculated in the above meta-analysis for the following intervals: 37^{+0-6}, 9058 deliveries; 38^{+0-6}, 6242 deliveries; 39^{+0-6}, 2367 deliveries; 40^{+0-6}, 1449 deliveries; 41^{+0-6}, 604 deliveries; 42^{+0-6}, 315 deliveries[29]. These are crude rates without adjustment for confounders. When a subgroup analysis was performed for what were described as 'low-risk pregnancies' a similar trend in relative risk was noted but the absolute risks were lower[29].

A recent Cochrane review concluded that a policy of labour induction at or beyond term is associated with fewer perinatal deaths, and suggested a gestational window of 41-42 weeks for intervention[103]. There is mounting evidence, however, that induction at 41 weeks leads to a reduction in adverse fetal and neonatal outcomes without increasing adverse maternal outcomes[30,102]. Accordingly, a 2021 update to NICE guidance on induction of labour advised that a discussion be had with women on the risks and benefits of induction at 41 weeks versus continuation of the pregnancy beyond this point[30].

It is worth noting the recent publication of an RCT in the US (ARRIVE trial) that looked at outcomes following routine induction at 39 weeks in 'low-risk' nulliparous women (N = 3062) versus expectant management (N = 3044)[104]. 'Low-risk' was defined as the '*absence of any condition considered to be a maternal or fetal indication for delivery before 40 weeks and 5 days'*. This trial concluded that there was no difference in the primary outcome between the two groups (composite perinatal death or severe neonatal complications); however, the study was not powered to examine the rate of stillbirth as an independent outcome[104]. With regard to secondary outcomes, the trial proffered a relative risk of 0.84 (95%CI 0.76-0.93) for delivery by caesarean section and 0.64 (95%CI 0.56-0.74) for the occurrence of hypertensive disorders of pregnancy[104] among women who underwent routine induction at 39 weeks (39^{+0}-39^{+4}) when compared to those that were managed expectantly[104]. Of note, this study employed intention-to-treat analysis which meant that women who spontaneously laboured prior to induction in the induction group were included in the final results[104].

While there is strong evidence that induction, when compared to spontaneous onset of labour, increases the rate of caesarean section and maternal intervention in 'normal-risk' pregnancies at varying gestations from 37 to 41 weeks, the majority of studies are retrospective and are, therefore, less useful in guiding informed decision-making at a point in time during a pregnancy. As the ARRIVE trial was a prospective RCT it is somewhat more pragmatic for advising women on potential outcomes and may be used to guide the shared decision-making process. However, cost-benefit analyses are advisable in order to guide local policy and management.

Fetal growth restriction

An estimated fetal weight (EFW) or abdominal circumference of less than the 10th centile is generally accepted as the definition of small-for-gestational-age[105]. While having a small-for-gestational-age (SGA) fetus increases the risk of stillbirth by a factor of at least four[26,70,106], there is an acknowledgement that this risk differs for fetuses that are physiologically small and those that are small due to fetal growth restriction. However, it can be difficult to distinguish between these subtypes antenatally and studies often use these terms interchangeably.

The overall risk of stillbirth in an SGA/FGR fetus is approximately 1%[26,107]. The PORTO study attempted to further clarify this risk and reported a 6% rate of adverse perinatal outcomes in fetuses with an EFW <3rd centile compared with a 2% rate at an EFW of between the 3rd and 10th centile[108]. The study was underpowered to specifically report on stillbirth as an independent outcome. NPEC data from 2019 revealed that, while 48.6% of stillbirths had a birth weight of <10th centile, two thirds of these weighed <3rd[3].

Antenatal detection of the SGA/FGR in a fetus is important and has been shown to affect outcomes[26]. A cohort study of over 92,000 pregnancies reported a stillbirth rate of 9.7 per 1000 (~1%) pregnancies complicated by FGR (EFW <10th)[26]. This rate doubled when FGR was not detected antenatally but diagnosed at birth[26]. The protective effect assigned to antenatal detection is likely due to altered management and intervention post diagnosis. However, there is scope for further improvement; a recent French case control study reported that >40% intrauterine deaths continue to occur despite an antenatal diagnosis of FGR. This suggests that ongoing development of post diagnostic risk reduction strategies is warranted[109].

Multiple gestation

Twin pregnancies have a higher risk of stillbirth than singleton pregnancies and the risk increases depending on chorionicity and the number of fetuses[110-112].

A retrospective cohort study comprising 46,000 singletons, 460 monochorionic (MCDA) twins and 1100 dichorionic (DCDA) twins revealed that DCDA twins each had up to a 3-fold increase in the rate of stillbirth when compared to singletons[110]. MCDA twins had a 13-fold and 5-fold increase when compared to singletons and DCDA twins respectively[110]. This increased risk observed with MCDA twins is primarily attributable to the occurrence of twin-to-twin transfusion syndrome (TTTS) and is highest at less than 28 weeks[110,113].

A systematic review and meta-analysis examining the breakdown of perinatal mortality and the relative risks associated with delivery versus expectant management suggested that these risks reached an equilibrium at 37^{+0-6} in DCDA pregnancies and 36^{+0-6} in MCDA pregnancies[114]. In other words, the rate of stillbirth beyond these gestations began to surpass the rate of neonatal mortality, favouring delivery within these gestational windows[114].

The risk of intrauterine death and perinatal mortality is highest for MCMA twins, particularly after 32 weeks[111,115]. While the rate of stillbirth is elevated in triplets[112] and higher order multiples, the exact risk can vary depending on the distribution of chorionicity. Both MCMA and triplet pregnancies are rare; the incidence of MCMA twins is 1/10,000 pregnancies[115].

Male sex

Male sex is a risk factor for stillbirth; a meta-analysis of over 30 million births proffered a 10% increase in the risk of stillbirth for male fetuses when compared with female fetuses[116]. The reason for this remains unclear.

Congenital anomalies

In the most recent NPEC report, major congenital anomaly was the most common cause of stillbirth in Ireland in 2018 and 2019, accounting for almost one third of fetal death[3]. The majority of these (54%) were associated with an underlying chromosomal disorder[3].

The proportion of stillbirths ascribed to the presence of a congenital anomaly (CA) can differ between countries for a variety of reasons including variations in regional legislation surrounding termination of pregnancy (TOP). For instance, the proportion of stillbirth attributable to congenital anomaly is stable at just under 10% in the UK[20], while in Ireland this figure sits at just over 30%[3].

It is important to note that the provision of TOP in cases of suspected fetal anomaly skews the available data on the natural history of these anomalies and their potential contribution to rates of stillbirth. As such, the probability of stillbirth according to an antenatal diagnosis of CA can vary greatly in the literature. A recent large European retrospective cohort study of over 80,000 cases of fetal anomaly attempted to estimate the probability of stillbirth (as one of several outcomes), in pregnancies complicated by chromosomal abnormalities, isolated CA and other syndromes[117]. Data spanned a 14-year period from 1998 to 2011, prior to the introduction of regulated TOP in Ireland. Subgroup analysis by country revealed that the overall rate of stillbirth for anomalous pregnancies in Ireland was between 2.9% and 6.6% with regional variation. The overall rate of stillbirth in anomalous pregnancies, when all 11 studied countries were included, was 2.68% (1/37)[117].

Prognosis and probability of stillbirth varies greatly depending on the nature of the anomaly and underlying condition. When subgroup analysis by condition was performed for the above study the most common chromosomal abnormality was trisomy 21 with a stillbirth rate of 5%. Trisomy 18 and 13, while less common, had stillbirth rates of 37% and 22% respectively. With regard to isolated anomalies, while cardiac anomalies were the most commonly encountered, neural tube defects demonstrated the highest rate of stillbirth; in fetuses with anencephaly the rate of antenatal/intrapartum demise was 51%[117].

In Ireland, a fatal fetal anomaly or life-limiting condition is defined as a diagnosis that is highly likely to death in utero or within 28 days of delivery[118]. This definition includes trisomy 18, 13 and anencephaly among other congenital and acquired anomalies/conditions. This list is relevant for women/parents wishing to explore the option of termination of pregnancy for fetal anomaly (TOPFA); further details on this service can be accessed by consulting the relevant CPG[118].

Clinical Practice

Fetal risk factors for stillbirth may be present from pregnancy onset or may emerge as the pregnancy evolves. Healthcare professionals must be aware of these risk factors in order to appropriately manage the pregnancy.

Advancing gestational age is inherent to every pregnancy. For uncomplicated pregnancies in a normal-risk setting, it is not unreasonable for the pregnancy to continue beyond the assigned due date. In such circumstances the current evidence supports offering induction by 41 weeks (40^{+7}) in order to minimise the risk of adverse fetal outcomes. Pregnant women should be counselled on the pros and cons of intervention at individual gestations to facilitate best management and informed choice. For further guidance the most up-to-date national CPG on the induction of labour should be consulted.

In the presence of other independent risk factors for stillbirth, the optimal gestational window for birth will depend on the number and nature of these risk factors. Decision-making with regard to timing of birth outside of a normal-risk setting should be consultant-led.

With regard to optimising management for pregnancies complicated by fetal growth restriction and multiple pregnancies, the relevant national CPGs should be consulted[119,120].

While male sex is a risk factor for stillbirth, there is no evidence to support altering management based on this risk factor alone.

If a fetal anomaly is suspected at any point in the pregnancy, the pregnancy should be managed as per national guidance[121]. This will usually involve referral to a fetal medicine specialist. The woman should be counselled on the relative risk of IUFD depending on the nature of the anomaly and/or suspected fetal condition.

Antenatal screening tests (e.g., non-invasive prenatal screening, [NIPS]) and diagnostic tests such as CVS and amniocentesis can guide management and should be offered when considered appropriate and contributory to care. These tests should be performed within a unit with the relevant expertise.

Termination of pregnancy in the event of fatal fetal abnormality is beyond the scope of this guideline but evidence and guidance surrounding this service can be accessed through the recently developed national CPGs[118,122].

Clinical Question 2.4: **What pregnancy related risk factors need to be considered?**

Evidence Statement

The following evidence is derived from the most up-to-date literature on gestational diabetes, pre-eclampsia and intrahepatic cholestasis of pregnancy. For a more detailed exploration of the supporting data, the relevant national and international CPGs should be consulted[123-125]. These conditions were selected for discussion due to their prevalence and well documented association with adverse fetal outcomes including stillbirth. There are a multitude of pregnancy-related conditions that may influence fetal development and contribute to the risk of intrauterine death, and an in-depth review of all such contributors is beyond the scope of this guideline.

Gestational Diabetes

The prevalence of gestational diabetes (GDM) in Ireland and the UK is rising and the reason for this is multifactorial[126]. The National Institute for Health and Care Excellence quotes an antenatal prevalence of approx. 4.5%, however the diagnostic threshold associated with this figure is not in common use in Ireland[127].

Exact rates, as well as data on outcomes, vary by region and hospital group due to variations in demographics and diagnostic standards, and this can lead to difficulties when it comes to counselling the pregnant woman. A recent case control study, however, suggested that women who were ‘at risk’ of GDM but not screened were at a 44% higher risk of stillbirth[128]. Furthermore, women who were ‘diagnosed’ but not ‘treated’ for GDM experienced four times the rate of stillbirth. The relative risk approached that of the non-diabetic population when women were both adequately screened and appropriately managed[128].

Pre-eclampsia

Pre-eclamptic toxaemia (PET) of pregnancy, as it was historically known, falls under the spectrum of hypertensive disorders of pregnancy[129]. While traditionally defined as the presence of new onset hypertension and proteinuria in the second half of pregnancy, it is now understood to represent a heterogenous collection of several clinical entities including hypertension, proteinuria, maternal multisystem dysfunction (renal, hepatic, neurologic or haematologic) in addition to placental dysfunction as evidenced by fetal growth restriction or abnormal uteroplacental blood flow[130]. The incidence in pregnancy of PET in Europe and North America is approximately 1.4% to 4%[131].

Stillbirth is a recognised complication of PET. A population based cohort from Norway reported an increase in the risk of intrauterine death in women with preeclampsia (RR, 1.45 [95%CI 1.2-1.76])[132]. The risk was significantly higher at earlier gestations; the RR was calculated to be 86 (95%CI 46-142) in pregnancies complicated by PET at 26 weeks, 7.3 (95%CI 3.3-11) at 34 weeks and 3.0 (95%CI 1.7-4.1) at 38 weeks[132].

While biomarkers such as placental growth factor (PlGF) have been adopted by NICE as part of care pathways for early-onset pre-eclampsia[133], their role in the prediction of stillbirth remains unclear. A retrospective unblinded cohort of 979 'high-risk' pregnancies suggested an odds ratio of 15.9 (95%CI 7.6-33.3) for stillbirth in women who had a PlGF result at the time of first testing of <100 pg/ml[134]. However, how this translates into clinical practice and models of care remains uncertain.

Due to the morbidity and mortality associated with PET, screening for the condition is integral to antenatal care and is the basis for blood pressure measurement and urinalysis at every routine clinical encounter.

Intrahepatic cholestasis of pregnancy

Intrahepatic cholestasis of pregnancy (ICP) is a pregnancy related condition with a predilection for the second and third trimester that is characterised by elevated levels of serum bile acids, abnormal liver function tests and symptomatic pruritus[135]. The overall incidence in the UK is determined to be 6.6/1000 pregnances[136].

One of the main concerns related to a diagnosis of ICP is the potential for adverse fetal outcome and the risk of stillbirth. While elevated rates of stillbirth have been reported among women diagnosed with this condition antenatally, there has been difficulty in quantifying this risk in the literature[135]. This is particularly true for later gestations as there is a propensity to deliver women with ICP early to circumvent the risk of fetal death[135]. A meta-analysis of 23 studies published in 2019 proffered an overall OR for stillbirth of 1.46 (95% CI 0·73-2·89), that did not meet statistical significance, for pregnancies complicated by ICP[137]. However, when cases were stratified by serum bile acid (SBA) level, the rate of stillbirth was found to be significantly increased for those with levels of ≥100mM (HR 30·50 [95%CI 8·83-105·30])[137]. While a similar trend of lesser magnitude was noted for an SBA of ≥40mM, particularly after 38 weeks, the hazard ratio was not significant (HR 2·35 [95%CI 0·52-10·50])[137].

While there are limitations within the research, the current data would suggest that the risk of stillbirth is elevated in pregnancies complicated by ICP and that there is a dose-response effect with regard to serum bile acid level. Accordingly, international guidance on the management of ICP has seen recent updates that reflect this[125].

Infection

Antenatal infection is a risk factor for stillbirth. This risk factor is explored in greater detail under Clinical Question 2.11 as part of the maternal investigations.

Clinical Practice

Healthcare practitioners should be familiar with the conditions, unique to pregnancy, that increase the risk of stillbirth.

In Ireland GDM is screened for based on the presence or absence of both preconceptional and gestational risk factors. These risk factors are available from the national CPG for the diagnosis and management of pre-gestational and gestational diabetes[123]. It should be noted, however, that a new model of care is currently under development for application in the Irish setting that will supersede elements of the existing guidance. The diagnosis of GDM is important as the evidence would suggest that the excess risk of stillbirth attributable to GDM can be almost entirely mitigated by timely recognition and appropriate management.

Pregnant women should be assessed for risk factors for PET at their booking visit and the schedule of care for the pregnancy should be tailored accordingly. Evaluating for hypertension and proteinuria at each antenatal visit is fundamental to screening for PET. If a diagnosis of PET is made, care should be consultant-led and management should be determined based on both the maternal and fetal status in conjunction with the relevant national guidelines[124,138].

The fetal risk is higher when a diagnosis of PET is made at less than 34 weeks with increasing fetal morbidity and mortality at earlier gestational ages. Healthcare providers should be particularly cautious of early-onset PET and should make appropriate provisions for fetal monitoring as part of the care plan.

There is no routine screening for ICP in Ireland. Diagnostic tests are performed based on the presence of absence of symptoms such as pruritus or signs such as biochemical hepatic derangement. Guidelines are continuing to evolve with regard to intrahepatic cholestasis of pregnancy. The outcome of stillbirth, while rare, is elevated in pregnancies complicated by ICP when compared to the background population. The current evidence suggests that Obstetricians should be guided by serum bile acid levels and clinical status. There is no evidence to support one schedule of fetal monitoring over another and there is no evidence that an increased frequency of fetal monitoring improves outcomes. Recent developments within the literature have led to a revision in international guidelines[135] and the most up-to-date peer-agreed guidance should be consulted when it comes to managing women with ICP.

Recommendations

1. **Healthcare professionals that are involved in the delivery of care to pregnant women should be familiar with the preconceptional and antenatal risk factors that may increase the risk of stillbirth. These risk factors are diverse and can be broadly classified as maternal, fetal or related to pregnancy-specific conditions.**
2. **It is important for healthcare professionals to recognise that a risk factor may not exist in isolation and that an individual woman's risk for an adverse outcome, specifically stillbirth, may depend on the complex interplay of several variables.**
3. **While some risk factors for stillbirth may be present from the onset of pregnancy, some may emerge as the pregnancy progresses. Healthcare professionals should be vigilant of this in their interactions with pregnant women, regardless of the setting.**

4. While the terms modifiable and non-modifiable have traditionally been used when describing risk factors, it should be noted that these terms have limitations and they do not acknowledge the complexity of the risk factor, the environment, resourcing and human behaviour. As such, all risk factors should be considered as potentially modifiable when it comes to devising risk-reduction strategies, both at a local and national level.
5. Risk factors should be identified and clearly communicated to the woman in a sensitive manner, using language that is clear and devoid of ambiguity.
6. While measures to reduce socio-economic disparities are mainly focused at a public health and policy level, it is important for the clinician, and the maternity hospital/unit, to be aware of the potential barriers to accessing care in some women.
7. A woman-centred approach to care is encouraged: women should be involved in the decision-making process in order to support a positive pregnancy experience and promote engagement with antenatal care.
8. In the presence of one or more risk factors for stillbirth, a plan of care for the pregnancy should be clearly documented. This may evolve as the pregnancy progresses and should be reviewed by a consultant Obstetrician.
9. When a risk factor for stillbirth is identified, healthcare practitioners should refer to the local and national clinical practice guidelines that pertain to that risk factor in order to optimise management.

THE DELIVERY OF ANTENATAL CARE

Introduction

According to the most recent MBRRACE[20] and NPEC[3] reports the rate of stillbirth in the UK and Ireland continued to display a downward trend over the 6 year period spanning 2013 to 2019; in the UK this meant a decrease from 4.2/1000 in 2013 to 3.35/1000 in 2019 while in Ireland the uncorrected stillbirth rate saw a marginal drop from 4.3/1000 to 4.06/1000. Due to significant differences in termination of pregnancy legislation between the UK and Ireland, particularly prior to 2019, death due to non-modifiable pre-existing conditions, such as congenital anomalies played, and continues to play, a larger role in the rate of intrauterine death in Ireland[3,20].

As the risk of stillbirth in anomalous pregnancies is difficult to modify and the majority of stillbirth occurs in the non-anomalous infant, interventions aimed at reducing the rate of stillbirth in the UK and Ireland have largely focused on mitigating environmental risk factors that shape the development of the feto-maternal unit and the health of the fetus. Special attention has also been given to improving on antenatal detection rates of women and foetuses at higher risk of stillbirth as well as the standard of intrapartum care.

Strategies such as *Saving Babies' Lives*[7,8] and *Each Baby Counts*[6] have highlighted the following as instrumental in reducing the risk of intrauterine death and stillbirth: accessing antenatal care, identifying antenatal risk factors, triaging to appropriate pathways of surveillance, the timely detection of fetal growth restriction, educating women and the provision of high-quality intrapartum care. This text provides a brief exploration of these factors with a focus on the available evidence and reference to national and international best practice.

Clinical Question 2.5: **What are the principles and standards of antenatal care in Ireland?**

Evidence Statement

There is strong evidence that receiving an appropriate level of antenatal care positively affects outcomes in pregnancy, reduces the risk of stillbirth and improves the pregnancy experience. The provision of quality antenatal care is recognised as an essential tool in the prevention of both maternal and fetal morbidity and mortality[63].

In 2016, the World Health Organisation updated its global recommendations for the delivery of maternity care, promoting a model of at least eight points of contact over the course of a pregnancy[63]. The WHO quoted moderate quality evidence that the previous standard of four interactions may increase the perinatal mortality rate (PMR) by 15%[63] and secondary analyses have suggested that the excess risk to the fetus is highest at 32 to 36 weeks[139]. Accordingly, the following schedule of care was offered for consideration: first contact in the first trimester (up to 12 weeks) with seven subsequent interactions at 20, 26, 30, 34, 36, 38 and 40 weeks[63].

Through its reports and publications, the World Health Organisation has consistently supported a holistic approach to antenatal care and promotes the concept of a 'positive pregnancy experience'[63]. This experience has been defined as "maintaining physical and sociocultural normality, maintaining a healthy pregnancy for mother and baby (including preventing or treating risks, illness and death), having an effective transition to positive labour and birth, and achieving positive motherhood (including maternal self-esteem, competence and autonomy)"[63].

Irish standards for maternity care echo this philosophy[140]. In 2016, as part of the *National Maternity Strategy*[141], the Health Information and Quality Authority (HIQA) released the *National Standards for Safer Better Maternity Services*[140]. This document details the target standards for the provision of antenatal care in Ireland and highlights the importance of woman-centred models, maternal autonomy and a multidisciplinary approach to the delivery of care. There are 44 standards that comprise a total of 422 criteria or recommendations contained within this document. While an in-depth review of these recommendations is beyond the scope of this Guideline, some of the most pertinent points that specifically relate to the provision of antenatal services are summarised within the guidance on clinical practice.

Antenatal education is vital to the delivery of effective antenatal care. It is important that women actively participate in care and are aware of symptoms that may indicate a deviation from normal. The ability to monitor and report fetal movement as a sign of fetal wellbeing has been explored at length within the literature. While the AFFIRM tial[16] failed to establish a reduction in the rate of stillbirth with the implementation of a package designed to both increase antenatal awareness of reduced fetal movement (RFM) and provide tailored pathways for management, a large prospective Norwegian cohort study reported a 30% reduction in the rate of stillbirth with such interventions[17]. There is a lack of international consensus regarding the optimal advice when it comes to the perception of fetal movement and the recognition of RFM. Strong evidence to support effective intervention strategies is also lacking.

With regard to the antenatal model of care and choice of primary provider, this depends on the level of risk. A recent Cochrane review of RCTs examining outcomes from midwife-led continuity models in 'low-risk' women suggested that, among other outcomes such as improved spontaneous vaginal birth rates and reduced use of neuraxial anaesthesia, the composite rate of fetal loss (at all gestations) plus

neonatal death was lower in women who received midwife-led care (RR 0.84, 95%CI 0.71 to 0.99)[142]. While the reasons for this are likely multifactorial, the authors conclude that further research would be beneficial in delineating the mechanisms of this proffered protective effect. As outlined in the Department of Health's *National Maternity Strategy*[141] the choice of midwifery-led models of care should be available to all women who are considered to be 'normal'-risk.

Intrapartum IUFD is uncommon when compared to antenatal pre-labour IUFD; in Ireland this category accounted for 5.7% of all stillbirths for the years 2018 and 2019[3]. On evaluation of the circumstances surrounding stillbirth, neonatal mortality and severe morbidity that occur as a direct result of intrapartum incidents at term, Each Baby Counts has consistently reported that, in up to three quarters of cases, different care may have made a difference to outcome[6]. Among the contributing factors to adverse outcomes in labour, the three most common themes were; risk recognition and management, education and training deficits and individual human factors including lack of situational awareness, lack of leadership, stress and fatigue[6].

Clinical Practice

The following guidance on clinical practice provides a brief summary of some of the basic standards of care, that have particular relevance to the prevention of stillbirth. They are in keeping with the *National Standards for Safer Better Maternity Services*[140], *National Clinical Guideline No. 23: Stratification of Clinical Risk in Pregnancy*[143] and *National Clinical Practice Guideline: The Fetal Anatomy Ultrasound*[121].

- An antenatal booking visit should be provided to all women. A booking visit is defined as the first scheduled antenatal visit within the maternity service and should be offered by the end of the first trimester. This is one of the most important interactions in the course of the pregnancy as it provides the woman with the opportunity to have her medical, obstetric, social and psychosocial needs reviewed and appropriately addressed. This allows the pregnancy to be triaged to the appropriate pathway of care and should be jointly performed by an experienced Midwife and Obstetrician.
- While care plans should always be tailored to an individual pregnancy, HIQA describes a model comprising three basic pathways, stratified by risk, that services should be familiar with:

  Supported care pathway: This pathway is intended for women that are considered to be at 'normal-risk'. Women triaged to this pathway may avail of midwifery led care, with the option of a community-based service.

  Assisted care pathway: This pathway is intended for woman considered to be at 'medium risk' who need a greater degree of oversight and for woman at 'normal-risk' who choose an obstetric-led service. Care should be delivered by Obstetricians and Midwives as part of the greater MDT within the setting of the maternity unit/hospital.

  Specialised care pathway: This pathway is for women who are considered to be at 'high risk'. These pregnancies require a more intensive level of care and may need input from specialised clinicians on one occasion or throughout their pregnancy.

  As a pregnancy evolves, a woman may be escalated or de-escalated to a different pathway of care. Services should demonstrate the ability to identify risk factors as they emerge, and re-triage based on clinical need. Women should be informed about their individual risks in the context of pregnancy. They should be given an opportunity to input into decisions following risk assessment and allocation to an individual pathway of care.

- Maternity services should be equipped to provide the following ultrasound service to all pregnant women;

  Dating ultrasound scan: The purpose of this scan, performed in the first trimester, is to ascertain viability, clarify gestational age, determine the number of fetuses and chorionicity, and can, in some instances, identify early fetal abnormalities.

  Detailed anatomy scan: The role of this scan, typically performed between 20 and 22 weeks, is to detect structural abnormalities within the fetus and differentiate the 'likely normal' from the 'likely abnormal'. If a fetal anomaly is suspected at this scan, further counselling and management should be in line with national guidance on fetal anatomy screening in pregnancy[121].

  Placental localisation: Placental localisation should be performed in the second and third trimester and is typically reported at the anatomy scan.

  Cord insertion: Placental cord insertion should be documented at the fetal anatomy ultrasound. Pregnancies that demonstrate marginal or velamentous cord insertion may have an association with fetal growth restriction and a growth scan is recommended at 32 weeks for these women[121].

  Screening for vasa praevia: If there are risk factors for vasa praevia (e.g., velamentous cord insertion, placenta dysmorphology, succenturiate or bi-lobed placenta, low-lying placenta, multiple pregnancy, IVF pregnancy) then this should be screened for at the anatomy scan using transabdominal or transvaginal colour doppler. Any suspected case of vasa praevia should be referred to a fetal medicine specialist[121].

  Fetal wellbeing assessment: Tests of fetal wellbeing, when indicated, are integral to evaluating the health of a fetus. These include biometry to assess fetal growth, determination of the biophysical profile score (an assessment of fetal movement, fetal breathing movement, fetal tone and amniotic fluid volume) and Doppler studies. Identifying the 'at-risk' fetus is the first step in instigating potential risk reduction strategies.
- Women should be at the heart of decision-making processes, and services should strive for maternal autonomy in care. Good communication and well-designed antenatal education programmes can empower women to engage with healthcare professionals and improve outcomes.
- Care should be delivered with the support of the greater multidisciplinary team. The multidisciplinary team includes Obstetricians, Midwives, General Practitioners, relevant medical and surgical specialists as well as allied healthcare professionals.

This guidance acknowledges that, while a standard of care must be met nationally, individual schedules will vary depending on the woman and the individual unit. While basic antenatal care in Ireland usually involves 10-12 clinical encounters in the normal-risk setting, the healthcare provider should be cognisant of the challenges that some women may face with accessing routine care. All units should strive to ensure that the minimum contact, as delineated by the World Health Organisation[63], is achieved in order to optimise maternal and fetal outcomes.

Women who are considered to be normal-risk and who are triaged to the *supported pathway of care* should be advised that the current evidence supports a midwifery-led model of care with regard to optimising maternal and fetal outcomes. Local resourcing should be in place to facilitate the delivery of this model of care.

With regard to labour and birth, targeted interventions at both an infrastructural and individual level may help to reduce the rate of preventable term stillbirth related to intrapartum events. Units should ensure that birth attendants and relevant healthcare professionals are sufficiently educated, trained and supported in the delivery of intrapartum care; this includes ensuring that labour wards are appropriately resourced to facilitate the safe delivery of care. Open and effective communication is vital and formal staff

training in this regard is encouraged. For further information relating specifically to care of the fetus in labour the *National Clinical Guideline for Intrapartum Fetal Heart Rate Monitoring* should be consulted[144].

While there is a paucity of supporting evidence, it is good practice to advise pregnant women to monitor for changes in the pattern of fetal movement throughout the pregnancy. If a woman is concerned about the quality or quantity of fetal movement, she should be advised to contact her local maternity service. Individual services and hospital groups should have clear pathways of care for the management of reduced fetal movement in keeping with national and regional guidelines and staff should be educated in the execution of these pathways.

Recommendations

10. It is recommended that a booking visit should be offered to pregnant women in the first trimester.
11. Women should be screened at the booking visit for risk factors that may alter their recommended pathway of care in order to create a pregnancy plan that is tailored to their needs.
12. All women should be offered a dating ultrasound scan and a detailed anatomy ultrasound that includes screening for placental localisation.
13. Women should have access to, when indicated, ultrasonographic tests of fetal wellbeing including fetal biometry, biophysical profiling and Doppler ultrasound studies.
14. It is recommended that service providers strive to ensure that the minimum schedule of care (eight points of contact), as delineated by the World Health Organisation, is achieved for all pregnant women. Potential barriers to accessing care should be explored and addressed.
15. Women should be at the heart of decision-making processes, and services should strive for maternal autonomy in care. Good communication and well-designed antenatal education programmes can empower women to engage with healthcare professionals and improve pregnancy outcomes.
16. Antenatal care should be delivered with the support of the multidisciplinary team.
17. It is good practice to advise pregnant women to monitor for changes in patterns of fetal movement. If a woman is concerned about the quality or quantity of fetal movement, she should be advised to contact her local maternity service.
18. Individual services and hospital groups should have clear pathways of care for the management of reduced fetal movement and staff should be educated in the implementation of these pathways.
19. Maternity hospitals/units should strive to ensure that infrastructural and educational systems are in place to support the delivery of intrapartum care with the ultimate goal of reducing preventable term stillbirth.

Clinical Question 2.6: **How should a pregnancy that is considered to be 'high-risk' be managed?**

Evidence Statement

A pregnancy may be considered to be at high risk if there are one or more attributes that excessively increase the risk of either maternal or fetal morbidity and mortality. The degree of risk, and the nature of the management needed to mitigate this risk, will depend on the contributing factors themselves.

The *National Standards for Safer Better Maternity Services*[140] stipulate that maternity services should have access to multidisciplinary team clinics that provide contact with a variety of specialised medicine including, but not limited to, anaesthetics, endocrinology, nephrology, cardiology, psychiatry and neurology. Where combined clinics are not feasible or where these specialities are not available on site, the maternity unit should use their respective networking platforms to ensure that access to the appropriate care is obtained[140]. This may involve liaising with an external or affiliated tertiary unit.

In the case of a previous intrauterine death or stillbirth, there is some evidence that specialised delivery of care in subsequent pregnancies improves outcomes[145], although this may depend on the nature of the previous stillbirth. Advocates for specialised antenatal clinics for those women who have experienced a previous stillbirth, also referred to as 'Rainbow Clinics', proffer that attending such a clinic not only improves outcomes but can decrease parental anxiety and is cost-effective[146]. While there is a paucity of evidence in this regard, a prospective observational study is currently underway to evaluate the impact of Rainbow Clinics on pregnancy outcomes and on the maternal experience[146].

Clinical Practice

Women should be encouraged to play an active role in decision-making when it comes to directing their antenatal and intrapartum care.

Maternity services should have clear care plans when it comes to managing 'high-risk' pregnancies or pregnancies that have been triaged to the *specialised care pathway*. As previously mentioned, the risk status of a pregnancy may evolve during the antenatal period, and it is important to assess the pregnancy at every clinical encounter for a deviation from 'normal'.

The infrastructure within an individual maternity unit will determine how the high-risk service for that unit is delivered. Larger units with a larger client base may have dedicated high-risk clinics that may demonstrate subspecialisation depending on the nature of the contributing risk factors. Smaller units may incorporate the delivery of high-risk care into routine antenatal clinics. Provided that the pathway of care is consultant-led, and the needs of the pregnancy are met, both models are acceptable.

Care should be multidisciplinary in nature with consultation of the relevant medical or surgical specialists if needed. Where combined clinics are not feasible or where these specialities are not available on site, the maternity unit should use their respective networking platforms to ensure that access to the appropriate care is obtained

Should an individual unit be unable to meet the care requirements of a pregnancy, care should be transferred to a maternity service with the appropriate expertise.

For advice with regard to the treatment and management of specific maternal, fetal and pregnancy-related conditions, the individual national CPGs should be consulted.

In the case of a previous stillbirth, this guidance supports the referral of a subsequent pregnancy to a specialised pathway of care. The antenatal care plan should be determined by a senior clinician with sufficient knowledge in the management of pregnancies complicated by previous stillbirth.

Recommendations

20. **Women triaged to the specialised care pathway should have consultant-led care. This includes pregnancies complicated by a previous stillbirth.**
21. **Should an individual unit be unable to meet the care requirements of a pregnancy, care should be transferred to a maternity hospital/unit with the appropriate expertise.**

Clinical Question 2.7: **What is the role of routine ultrasonographic assessment of fetal growth?**

Evidence Statement

While the link between fetal growth restriction (FGR) and stillbirth is well established, exploring the effect of policies targeting FGR and detection rates can be difficult due to the rarity of stillbirth as an outcome. There is a reasonable body of research exploring the role of routine ultrasound to assess fetal growth in normal-risk pregnancies, however, in the high-risk setting, recommendations are largely based on international best practice and expert opinion.

Fetal growth restriction is a recognised risk factor for stillbirth[26,70,106] and, in recent years, has been specifically targeted by national care plans in the UK aimed at reducing perinatal mortality. As the risk of stillbirth is highest when FGR goes undetected[26], these care plans focus on improving rates of antenatal detection as a first step. Monitoring for fetal growth restriction in pregnancy can be broadly divided into two categories: surveillance in the normal-risk population and surveillance in pregnancies deemed to be at higher risk of FGR and stillbirth.

Normal-risk setting

The standard of care for the normal-risk pregnancy is to monitor fetal growth by plotting serial measurements of symphysio-fundal height (SFH) on a centile chart[96]. This model of surveillance has been supported by NICE[96] and both versions of the *Saving Babies' Lives* care bundle published by the National Health Service[7,8] in the UK. Healthcare providers should be competent in measuring, plotting and appropriately interpreting SFH measurements, allowing them to appropriately refer for ultrasound when indicated[8].

The role of routine ultrasound in uncomplicated, normal-risk pregnancies, has been examined by several randomised trials over the last 30 years[147]. A recent systematic review and meta-analysis of these RCTs concluded that, while routine ultrasonographic assessment increased the rate of detection of SGA/FGR, it did not affect perinatal mortality or composite fetal and neonatal outcomes[147]. However, it must be noted that many of these studies did not individually investigate perinatal mortality as an independent outcome and all were underpowered to specifically look at stillbirth[147]. It must also be noted that a large proportion of low/normal-risk pregnancies receive a clinically indicated ultrasound at some point in the third trimester in the absence of routine scanning[148].

The National Institute for Health and Care Excellence (NICE) does not recommend routine ultrasonographic assessment in the third trimester for the low/normal-risk pregnancy, but recommends access to this service if clinically indicated[96,149]. Based on the available research, this guideline supports NICE recommendation, while acknowledging the limitations in the evidence, and the scope for adequately powered studies going forward.

Higher risk of FGR

Serial growth monitoring with ultrasound imaging is common practice in pregnancies deemed to be at particularly high risk of SGA/FGR. The Royal College of Obstetricians and Gynaecologists (RCOG) has offered an algorithm for triaging pregnancies to serial growth measurement based on the nature of the risk factors identified at the booking visit and those that emerge as the pregnancy evolves105. The algorithm varies depending on whether the risk factor is considered to be major or minor. As part of the most recent Saving Babies Lives care bundle, the RCOG algorithm was referenced and further modified8. Both models advocate for the use of uterine artery Doppler as a screening tool, scan intervals of 3-4 weeks in the moderate risk setting with shorter intervals if indicated, and involvement of fetal medicine in severe or atypical cases.

In their most recent guidance the Institute of Obstetricians and Gynaecologists (IOG) recommends ultrasound surveillance at 2 to 4 week intervals from 26 weeks onwards in the presence of significant risk factors for FGR119. However, it should be noted that an updated version of the Irish national Guideline on the detection and management of fetal growth restriction is in development and is due to be published in 2023.

The risk factors for FGR that have been highlighted by the RCOG and Saving Babies Lives care bundle as warranting additional ultrasonographic assessment have significant overlap with the risk factors for stillbirth discussed in this Guideline and those proposed by the IOG. Further details on how these risk factors are incorporated into proposed algorithms and how they influence pathways of care can be accessed in the source documents[8,105,119].

Clinical Practice

Monitoring for fetal growth is a standard element of routine antenatal care and an estimate of absolute and relative growth should be made at each clinical encounter.

In a normal-risk setting, growth should be estimated using symphysio-fundal height (SFH). Staff that are involved in the delivery of antenatal care should be adequately trained in both the measurement and the plotting of symphysio-fundal height. If there is a concern with regard to a reduction in growth trajectory – as evidenced by diminishing centiles – or should the absolute measurement plot below the 10th centile, then the woman should be referred for ultrasound assessment. At present, routine growth monitoring with ultrasound is not recommended in the normal-risk setting.

If there exists a barrier to the accurate measurement of SFH, such as central adiposity or the presence of uterine fibroids, it is not unreasonable to offer an ultrasonographic assessment of fetal growth at 28 and 36 weeks. This can be determined and modified on a case-by-case basis.

If significant risk factors for FGR exist, surveillance of fetal growth with ultrasound is advised. A schedule of biometry at 28, 32 and 36 weeks is not unreasonable. The frequency of monitoring may depend on the nature of the risk factors and the findings on ultrasound.

For further guidance on screening for fetal growth restriction we advise consulting the national CPG on the diagnosis and management of fetal growth restriction[119] which is due to be revised in 2023.

Recommendations

22. **In the normal-risk setting, fetal growth should be monitored by serial assessment of symphysio-fundal height (SFH). A growth estimate with ultrasound scanning in the third trimester should not be offered in the absence of a clinical indication.**
23. **In the presence of risk factors for fetal growth restriction, or where SFH measurement in unreliable, serial growth measurement should be offered. Fetal growth should not be monitored at intervals of less than 2 weeks.**

Section 2: Diagnosis

Introduction

The diagnosis of an intrauterine fetal death is a significant event for any parent and can be devastating for those involved. It is, therefore, important that the diagnosis is not only accurate, but is confirmed and delivered in a sensitive manner that acknowledges the magnitude of the event.

Clinical Question 2.8: **How is intrauterine death diagnosed?**

Evidence Statement

The use of ultrasound in the investigation of intrauterine fetal death was first documented in the mid 1960s[150] and has not been superseded by any other form of bedside testing. Early case series demonstrated its superiority over clinical assessment and auscultation alone[151] and, while these methods have a role in the initial investigation for reduced fetal movement and suspected IUFD, they should not be used to confirm the diagnosis[151,152].

As a rule, the diagnosis of intrauterine fetal demise is made by demonstrating the unequivocal absence of fetal cardiac activity. While additional ultrasonographic signs of intrauterine demise have been well described, these features are not consistent and should not be used in isolation. Secondary features of IUFD include overlapping of the fetal skull bones, hydrops, distorted anatomy due to fetal maceration and intra-fetal gas formation[150,153-155]. The presence of the above, in addition to maternal factors such as raised BMI, can render clear visualisation of the fetal mediastinum and heart difficult – in these cases, review by an experienced sonographer is necessary.

It is important to note that spurious (false) fetal movement has been documented post IUFD and may reflect both passive intrauterine movement and non-uterine visceral sensations[156].

Clinical Practice

Ultrasound is the gold standard modality for the diagnosis of intrauterine fetal death. Auscultation or cardiotocography should not be used to diagnosis fetal death and should not be used as reassurance of viability when the index of suspicion for IUFD is high. Maternal arterial pulsations can be erroneously captured by these devices and misinterpreted as being fetal in origin – particularly when performed in the presence of a maternal tachycardia.

Once a diagnosis of IUFD is made and communicated, a second opinion should be sought to confirm the diagnosis. Ideally, this should be a practitioner or technician with sufficient expertise in the use of ultrasound. Where circumstance allows, at least one of the healthcare professionals providing the diagnosis should be an appropriately – qualified sonographer or a consultant Obstetrician. Appropriate expertise is particularly important when factors exist that may affect the quality of the image such as maternal adiposity, uterine anatomy, fetal position or oligohydramnios.

If there is any doubt with regard to the diagnosis, then a repeat ultrasound scan should be performed.

Women should be advised that the perception of ongoing fetal movement after a diagnosis of IUFD is not uncommon. If these movements are a cause for maternal concern, then a repeat ultrasound should be performed.

Recommendations

24. **Real-time ultrasound is the gold standard method for the diagnosis of intrauterine fetal death (IUFD).**
25. **Real-time ultrasound should be readily available in maternity hospitals/units.**
26. **The use of clinical assessment or fetal heart auscultation with Pinard stethoscope or handheld Doppler is not sufficient to diagnose IUFD.**
27. **Cardiotocography should not be used to diagnose IUFD.**
28. **A second opinion should be sought to confirm the diagnosis of IUFD. At least one of the healthcare professionals performing the ultrasound should be a practitioner or sonographer with sufficient expertise in the use of ultrasound.**

Clinical Question 2.9: **What is best practice for breaking bad news?**

Evidence Statement

The following guidance is derived primarily from qualitative research studies and opinion-based articles. Current guidelines and standards relating to bereavement care and breaking bad news, both national and international, were also consulted[14,157].

The diagnosis of an intrauterine fetal death is a devastating event that can have a profoundly negative psychological impact on both the bereaved parents and the healthcare provider[158-163]. Breaking bad news to a parent who has experienced an intrauterine or peripartum death is not easy. Furthermore, the diagnosis is often made in the acute setting, with little time for reflection or advanced preparation[164].

The concept of breaking bad news as an ascertainable skill that can be taught and developed has been extensively explored in the literature, particularly in the fields of oncology and palliative medicine. Several tools have been offered to aid clinicians when interacting with patients in these settings[165-168] and the same principles of care can be applied when approaching a bereaved parent[169]. These common principles include adequate preparation, building a rapport and demonstrating empathy, appropriate communication (including listening) and advocating for patient choice and autonomy.

While adequate preparation is important with regard to breaking bad news this is not always possible in the context of intrauterine fetal death. Making the diagnosis and delivering the news are not distinct events; the diagnosis is conveyed in real-time where the ultrasound scan is performed. It is vital, nonetheless, that every effort is made to respect the privacy of the woman/parents and that the diagnosis is conveyed in an appropriate setting, regardless of the circumstances of her presentation[169,170].

If a woman is unaccompanied, an offer should be made to contact her partner or a close relative/friend so that she feels supported when receiving the bad news[14,169,170]. While it is not always possible to achieve this at the exact moment of diagnosis, windows of opportunity often exist prior to performing the ultrasound scan in cases where an IUFD is strongly suspected. Healthcare providers should also ensure that appropriate transport arrangements are available for the woman and should offer support if appropriate[14,169,170].

Appropriate communication when breaking bad news is vital. Language should be clear and devoid of ambiguity; euphemisms should be avoided[169,171]. Studies have suggested that parents find delays in communication or diagnosis distressing, and great value is placed on relaying accurate information in a timely manner[158,170,172]. Tone, wording and body language are also important in communicating effectively and conveying empathy. These can impact greatly on a parent's experience at the time of the event and their ability to process information[158,169]. This can, in turn, influence the grieving process as a whole.

Receiving a diagnosis of intrauterine fetal death can be both devastating and overwhelming for those involved. While parents should be provided with the appropriate medical advice and guidance, parental wishes should be respected at all times. Women should feel included in the decision-making process and should feel empowered in her ability to choose[169]. Assumptions should not be made as bereaved parents can display a wide variety of reactions and desires when it comes to their ongoing care and the grieving process[173]. Parents should be given the opportunity to ask questions at any point and re-visit elements of the conversation if desired.

The British Medical Ultrasound Society (BMUS) has published a useful guideline to aid sonographers and clinicians in the delivery of unexpected news at the time of sonographic diagnosis[174]. This was the product of a concerted effort to create a structured framework for addressing both the practical and emotional aspects of breaking bad news. The goal of this guideline was to standardise the delivery of care and, in doing so, improve the experience for both the healthcare professional and the bereaved parents.

Clinical Practice

If there is a high index of suspicion for intrauterine death, an ultrasound should be performed by a sonographer or clinician with sufficient experience in the use of ultrasound. This should take place in an environment that respects the privacy of the parent(s). A dedicated room should be available in the emergency department, admission unit or ultrasound department for the purpose of disclosing bad news[14].

If a woman is unaccompanied, an offer should be made to contact her partner or someone that may be in a position to provide support. This offer should be made in advance of imaging if the index of suspicion for adverse findings, such as IUFD, is high.

Healthcare providers should practice effective communication when breaking bad news. Effective communication includes the following principles:

- Healthcare professionals should communicate with empathy and use wording that is sensitive to the nature of the encounter.
- Language should be clear and devoid of ambiguity. Euphemisms should be avoided.
- While it is important to allow time to ensure that an accurate diagnosis is made, it is important that bad news is delivered in a timely manner. Any unnecessary delays should be avoided to minimise parental distress.
- If the parents have questions that are beyond the expertise of the healthcare professional that has delivered the diagnosis, a clinician with sufficient expertise should be consulted.
- Written information should be provided as a reference point to complement and support the information relayed at the time of diagnosis. This can include patient information leaflets (PILs), practical information and points of contact for the bereaved parents.
- If a language barrier exists, an appropriate means of translation should be used. Ideally written information should be provided in a variety of languages.
- Healthcare professionals should be aware that acute grief as a process is unique to the individual woman/parents. Assumptions should not be made with regard to parental wishes or the direction of care. The parent(s) should be at the heart of the decision-making process and autonomy in care should be encouraged.

Maternity services should provide formal training for staff in the care of a woman who has experienced pregnancy loss or perinatal death.

For further guidance on the delivery of bad news the *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death* in Ireland and the BMUS Guideline on the communication of unexpected news via ultrasound should be consulted[14].

Recommendations

29. **A dedicated room should be available in the admission unit/ultrasound department for the purpose of disclosing bad news.**
30. **If a woman is unaccompanied, an offer should be made to contact her partner or a close relative/friend.**
31. **Healthcare providers should ensure, where appropriate, that a pregnant woman is not alone when leaving the hospital after a diagnosis of IUFD. Transport arrangements should be made if required. Women should also be provided with a named contact when leaving the hospital in order to facilitate effective and seamless communication.**
32. **Healthcare providers should use appropriate language using terms that are easily understandable by the woman/parents.**
33. **Healthcare providers should advocate for maternal choice and autonomy; parents should feel included in the decision-making process.**
34. **Written information should be provided and should ideally be available in several languages.**

Section 3: Investigations

MATERNAL INVESTIGATIONS

Introduction

Maternal investigations performed in the context of an intrauterine death or stillbirth can be categorised as those performed as part of the acute management of the circumstances surrounding the fetal death and those performed to elucidate the cause of the fetal death. While these two categories are not mutually exclusive there is a distinction. With regard to the latter there remains, internationally, a lack of certainty as to how a fetal death should be investigated and the attributable impact of individual tests. Differences in classification systems for the causes of stillbirth can also make the relative importance of diagnostic tests difficult to compare.

Within the most recent guidelines on intrauterine death and stillbirth, however, a shift in emphasis can be seen toward fetal investigations including placental histopathological assessment, post mortem examination (PME) and genetic analysis, and away from extensive maternal testing[175-177]. A retrospective review of 512 stillbirths published by the Stillbirth Collaborative Research Network (SCRN) in 2017 reported on the usefulness of the following investigations in determining the cause of fetal death, offered as a percentage; placental pathology 64% (95% CI 57.9-72.0), post mortem examination 42.4% (95% CI 36.9-48.4), genetic testing 11.9% (95% CI 9.1-15.3), APA testing 11.1% (95% CI 8.4-14.4), testing for feto-maternal haemorrhage 6.4% (95% CI 4.4-9.1), glucose level 1.6% (95% CI 0.7-3.1), parvovirus screening 0.4% (95% CI 0.0-1.4), and syphilis screening 0.2% (95% CI 0.0-1.1)[178]. These figures are largely in keeping with a previous Dutch cohort study of 1025 fetal deaths from 2012[179].

Accordingly, in 2020 the American College of Obstetricians and Gynecologists (ACOG) in conjunction with the Society for Maternal-Fetal Medicine (SMFM), the Society of Obstetricians and Gynaecologists of Canada (SOGC) and the Perinatal Society of Australia and New Zealand (PSANZ) issued updated clinical guidelines surrounding intrauterine death and stillbirth that advocated for a more targeted approach to maternal testing based on the clinical history and context of the fetal death[175-177]. While these updates have largely been guided by available evidence and cost-benefit analyses, ease of application of a guideline must also be considered in addition to subtle regional differences that exist in the structure and delivery of antenatal care.

The following guidance reflects current international trends while acknowledging the influence of local resourcing and clinical practice. While there remains a level of uncertainty within the literature as to the optimal degree of maternal investigation that should be performed, several recent systematic reviews and retrospective studies have aided in creating a more evidence-based approach to testing.

It is worth noting here that the purpose of performing an investigation is to obtain information that may influence care or contribute to determining a cause of death. Where a fetal death is expected, or where the cause of death is known at the time of fetal demise (for example a previously diagnosed fatal fetal anomaly), the following recommendations may not apply. However, where uncertainty exists, the following guidance should be consulted. As always, recommendations may be tailored to the clinical context and the opinion of the treating clinician.

This section should be used in conjunction with Appendices 3-6.

Clinical Question 2.10: **What is involved in the initial workup for a woman diagnosed with an intrauterine death?**

Evidence Statement

The initial work-up and treatment for a woman diagnosed with an intrauterine fetal death will depend on the clinical context and the circumstances surrounding the diagnosis. While the cause of the fetal death will ultimately need to be investigated, the immediate concern is for the wellbeing of the woman. While a significant proportion of IUFD presents in a well woman on a background of reduced fetal movement or known fetal pathology, the diagnosis may also be made in the setting of maternal haemorrhage, sepsis, trauma or in the course of labour. In 2019, 9.1% of stillbirths in Ireland were associated with antepartum or intrapartum haemorrhage and 6.6% were associated with infection[3].

A thorough history and clinical examination, where indicated, is the cornerstone of determining the appropriate pathway of care for the bereaved woman and deciding on the appropriate investigations with regard to ascertaining the cause of fetal death. However, it is important that bereaved parents are informed of the limitations in diagnostic testing. While the percentage of unexplained stillbirth varies due to regional disparities and the classification systems in use, numbers for high-income countries (HIC) remain high with 9.5% to 31.5% of intrauterine deaths ultimately classed as unexplained[3,20,35,36].

Clinical Practice

Women who present as acutely unwell at the time of diagnosis should be triaged, managed and resuscitated as per local and national guidelines on the management of pre-eclampsia, haemorrhage, sepsis, and the critically ill mother[124,180-184]. A peripartum diagnosis of intrauterine death warrants clinical assessment for some of these maternal complications.

If an antenatal diagnosis of IUFD is given to a woman that appears clinically well, a review by a clinician should be organised regardless of who provided the initial diagnosis. A clinical history should be taken, and examination (when indicated) performed in order to determine the presence or absence of features that may pose an immediate risk to the woman's health. This assessment will also help to determine aetiological factors that may have contributed to the intrauterine death. Appendix 3 details the clinical history that should be explored, either during the initial encounter if relevant to the delivery of care, or in the course of management and follow-up.

Recommendations

35. **If diagnosed with an IUFD, all women should be assessed by a clinician at the time of diagnosis. This is important, not only to assess risk, but to document important features that may contribute to determining the cause of the stillbirth.**

Clinical Question 2.11: **What maternal investigations are indicated in the event of intrauterine death and stillbirth?**

Evidence Statement

The following text gives an overview of the evidence surrounding maternal investigations that should be performed in the event of an unexpected intrauterine death. These recommendations were formulated following a review of both international guidance and current evidence, and have been adapted for clinical practice in Ireland.

Kleihauer-Betke test

A large cross-sectional study of 828 stillbirths in 2015 concluded that feto-maternal haemorrhage (FMH) played a role in 4.1% of cases[185]. Three quarters (74%) of FMH occurred in term fetuses; females were twice as likely to be affected than males and the rate of FMH in multiple pregnancies was six times that of singletons[185].

As postnatal testing can result in false positives and any delay in testing can lead to false negatives, testing for FMH should be performed prior to birth and at the time of diagnosis of intrauterine death.

Group and antibody screen

While the presence of anti-red cell antibodies as a cause of fetal death is uncommon in countries with established screening and prophylaxis programmes, childbirth is regarded as a sensitising event and may alter the accuracy of this investigation if performed based on clinical indicators in retrospect at a later date. We therefore advise performing a group and antibody screen along with the Kleihauer test at the time of diagnosis. Having a valid group and hold sample in the hospital laboratory is also worthwhile should maternal complications, such as haemorrhage or surgical intervention, be anticipated.

Full blood count

A full blood count (FBC) is often performed in the event of IUFD or stillbirth, not to determine the cause of the fetal death, but to assess the maternal status. It is unlikely that an unanticipated result will be had in an uncomplicated pregnancy for a woman who has engaged with antenatal care prior to the diagnosis. An FBC should be performed in the absence of a recently documented FBC. An FBC should also be performed if there is clinical evidence of antepartum haemorrhage, pre-eclampsia, maternal sepsis, in the presence of known or suspected haematological disorders or if surgical intervention is anticipated.

Thrombophilia testing

Acquired

Antiphospholipid syndrome (APS) has been associated with recurrent miscarriage, placental pathology, FGR and stillbirth[49,50] (see Clinical Question 2.1; *Acquired thrombophilia*). The ACOG, the PSANZ and the RCOG do not recommend routine screening for APS in the event of an intrauterine death but suggest triaging women to testing based on clinical risk factors and the context of the fetal death[152,176,177].

The PSANZ recommends APS screening if one of the following criteria are present: 1) a family history of thrombosis; 2) a personal history of thrombosis; 3) evidence of fetal growth restriction; 4) evidence of placental abruption or 5) evidence of placental infarction[177]. The RCOG recommendations are similar[152] and the ACOG further contributes testing in the event of unexplained and intrapartum stillbirth[176].

According to the most recent NPEC report 48.6% of non-anomalous stillbirths in 2018 and 2019 weighed less than the 10th centile; 31.5% weighed less than the 3rd[3]. This would suggest that approximately half of stillbirths in Ireland would meet the criteria for testing for APS based on the FGR criterion alone. With regard to unexplained stillbirth, 9.5% of stillbirths in Ireland were unexplained in 2019 and 20.7% in 2018[3]. As this is a diagnosis of exclusion, performing maternal investigations based on the results of fetal investigations may mean waiting a variable amount of time depending on local resourcing and procedure, during which some women may conceive again with an increased risk of recurrent stillbirth.

Regarding treatment, there is evidence that treatment with LMWH plus or minus aspirin may improve live birth rates in women with APS[186]. There is also evidence that the greatest benefit from the use of LMWH may be seen in those women with APS who have a history of thrombosis, or who are positive for all three APAs[187].

The British Society for Haematology (BSH) recommends that screening for APS be considered if there is a history of recurrent or late pregnancy loss[188]. This Guideline recommends the routine screening for APS in the event of stillbirth. The three antibodies that are tested for are lupus anticoagulant (LA), anticardiolipin (aCL) and anti-b2-glycoprotein 1. The revised Sapporo criteria stipulate that, to meet the laboratory criteria for APS, women must test positive for at least one of these antibodies on two occasions at least 12 weeks apart[189].

Inherited

With regard to inherited thrombophilia, there is insufficient evidence to perform routine screening for inherited thrombophilia in the context of stillbirth as evidence to support a causative link is lacking for the majority of mutations/phenotypes[54,55,57]. While some studies proffer an increased risk of late pregnancy loss and adverse pregnancy outcomes in women with inherited thrombophilia, controversy over causality and therapeutic options continue to exist[190]. The evidence does appear to be somewhat more robust for the Factor V Leiden (FVL) mutation and there is weak evidence supporting the role of this mutation in the pathophysiology of stillbirth[56,57], particularly in unexplained stillbirth[56] (see Clinical Question 2.1; *Inherited thrombophilia*).

Regarding treatment, there is a lack of data that specifically looks at the therapeutic effect of medication use on the rate of livebirths in women who have experienced a previous stillbirth and who are diagnosed with an inherited thrombophilia. While several meta-analyses examining the use of low-molecular-weight heparin (LMWH) in women with a history of pregnancy loss and inherited thrombophilia have concluded that LMWH does not improve outcomes, it is important to note that most of the participants within these analyses did not have a history of stillbirth, but rather a history of first (majority) or second trimester loss[191-193]. While this Guideline acknowledges the lack of evidence to support the use of LMWH in the context of inherited thrombophilia, caution must be used in interpreting data from studies that are either not designed to or are underpowered to assess the use of LMWH in women with a history of both inherited thrombophilia and stillbirth. While further research would be beneficial, designing adequately powered studies may be limited by the rarity of stillbirth as an outcome.

Given the lack of supporting evidence for treatment benefit, the British Society of Haematology do not recommend the routine testing of inherited thrombophilia as part of the maternal investigations for women with a history of recurrent miscarriage or adverse pregnancy outcomes; however, it should be noted that stillbirth is not specifically mentioned as an adverse outcome[188]. This is consistent with the most up-to-date guidance from the ACOG with regard to investigations following stillbirth[176]. While the PSANZ discourage routine testing for inherited thrombophilia following stillbirth, they suggest that testing for the Prothrombin G20210A and Factor V Leiden mutations may be carried out if indicated and in accordance with individual jurisdictional guidance[177].

This Guideline therefore recommends against routine testing for inherited thrombophilia. However, testing should be considered on a case-by-case basis and additional risk factors should be considered such as a personal or family history of VTE.

HbA1c

Both pregestational and gestational diabetes have been associated with an elevated risk of stillbirth[37,38,42,43,128]. The risk is highest with Type 1 DM (16.1/1000) and Type 2 DM (22.9/1000)[38]. While the prevalence of these two conditions is increasing significantly the absolute rates remain low (4.09/1000 maternities for Type 1 DM and 10.62/1000 maternities for Type 2 DM). Gestational diabetes, however, is common with prevalence rates that fluctuate based on regional demographics and thresholds for diagnosis.

In a multicentre prospective study from the Netherlands 7.9% of 907 cases of stillbirth had a HbA1c of >42 mmol/mol at the time of fetal demise[179]. For 61.8% of women this represented a new diagnosis, although risk factors for diabetes such as obesity and fetal macrosomia were noted to be more prevalent in this group. While a positive result does not indicate causality it is an important diagnosis to make, as alterations to care in a subsequent pregnancy may mitigate the risk and potentially improve future pregnancy outcomes.

The ACOG currently recommends selective testing for HbA1c in cases of stillbirth where there is evidence of macrosomia[176]. The PSANZ echoes this but also suggests testing in cases of SGA and FGR[177]. The reasoning for this is that the pre-test probability is low in the normally grown fetus. However antenatal care in the US, Australia and New Zealand includes universal screening for GDM[194,195] while Ireland, the UK and the Netherlands offer a targeted screening programme based on the presence of pre-determined risk factors[123,127,196]; thus the potential for undetected GDM in this setting is higher.

Accordingly, this Guideline recommends the routine testing of HbA1c in all cases of intrauterine death and stillbirth.

Bile acids

The available evidence would suggest that the risk of stillbirth is elevated in women with a history of intrahepatic cholestasis of pregnancy (ICP)[137]. The PSANZ and the SOGC[175,177] recommend testing for serum bile acids if there is a history of pruritus at the time of fetal death as the risk of ICP in the absence of this symptom is low. The RCOG recommends routine screening[152].

It is important to note, however, that the degree of pruritus in ICP does not correlate well with disease severity or the risk of adverse outcomes and cases of asymptomatic ICP have also been documented[197]. The concept of asymptomatic hypercholanaemia of pregnancy (AHP) is also emerging as a clinical entity in the literature but there remains debate as to where this condition lies on the pathway from physiology to pathology within the spectrum of ICP[198,199].

As such, this Guideline continues to recommend routine testing for serum bile acid level subsequent to a diagnosis of intrauterine death.

Infection

The following list is not exhaustive but includes some of the more common infections associated with intrauterine death.

Cytomegalovirus

Cytomegalovirus (CMV), also known as Human Herpesvirus 5, is a virus that is endemic to most communities; approximately 50% of pregnant women that book will be IgG seropositive by the age of 20 and approximately 70% by the age of 40[200]. The risk of seroconversion in pregnancy may demonstrate regional variation, but has been quoted to be around 1/133[200].

Infection in the first trimester has been associated with an elevated rate of fetal loss[200]. Fetal CMV has also been linked with a variety of negative fetal outcomes including neurocognitive deficits[201], however, while the vertical transmission rate increases as the pregnancy progresses, the rate of fetal insult, if the fetus is infected, decreases[201]. With regard to late intrauterine death and stillbirth, an Australian study of 130 unexplained singleton stillbirths in 2011 demonstrated evidence of CMV DNA in the tissues of 15% at post mortem examination[202]. However, the significance of this is unclear; while there was a trend in this study towards an association between the presence of CMV and villitis it did not reach statistical significance[202]. Of additional interest is that placental thrombotic vasculopathy was observed at twice the frequency in the placentas of fetuses that tested positive for CMV[202] when compared to those that did not test positive[202].

Toxoplasmosis

Toxoplasma gondii is a parasitic protozoan that is found worldwide. Exposure in pregnancy is thought to typically result from contact with infected feline faeces or the consumption of undercooked meat or unpasteurised dairy[203].

Toxoplasmosis infection in pregnancy has been linked with miscarriage and fetal morbidity including chorioretinal lesions, intracranial calcifications and hydrocephaly[204]. As with CMV, while vertical transmission rates increase with advancing gestation, the rate of fetal insult and negative sequelae decreases[204]. In countries where the risk of exposure to *T. gondii* is low, fetal toxoplasmosis as a contributor to stillbirth is considered to be rare.[203].

Parvovirus B19

Parvovirus B19 is a common infection often acquired in childhood. Also known as erythema infectiosum (EI), fifth disease and slapped cheek syndrome, rates of immunity to parvovirus B19 in women of reproductive age are consistently quoted at approximately 50-70%, although regional variation exists[205-207]. In the absence of symptoms or suspected exposure the risk of seroconversion during pregnancy is <1%[207]. A German study of almost 16,000 pregnancies revealed the following rates of PVB19 IgM seroconversion depending on presentation: arthropathy and rash (48%); arthropathy alone (12%); non-specific rash (4.7%) and contact with a suspected case of EI (4.0%)[207].

If acquired during pregnancy the rate of vertical transmission is thought to be 30-33%[208,209]. While the majority of women who contract parvovirus B19 during pregnancy will have a normal outcome[208], fetal infection has been associated with anaemia, hydrops and fetal death with the risk of a negative outcome quoted at 5-10%[208,210]. The risk of congestive cardiac failure (CCF) and severe hydrops is higher when fetal infection occurs in the second trimester[208,210], primarily at less than 20 weeks[211].

While parvovirus B19 has been classically associated with fetal death subsequent to CCF, viral DNA has been recovered from fetal tissues in late IUFD without evidence of hydrops potentially suggesting an alternate mechanism when infection occurs in the third trimester[212].

Syphilis

Syphilis is a bacterial infection caused by the spirochaete *Treponema pallidum* and has been associated with adverse pregnancy outcomes including congenital abnormalities, preterm birth, low birth weight, fetal loss and stillbirth[213,214]; in 2016 syphilis was responsible for 143,000 cases of fetal death and stillbirth wordwide[215]. Due to the global burden of congenital syphilis, and the availability of effective treatments, the WHO recommends screening all pregnant women at their first antenatal visit[216]. If syphilis has been tested for antenatally it does not need to be repeated after an intrauterine death unless specifically indicated based on pregnancy specific risk factors or clinical findings.

Rubella

Rubella is an RNA virus that is associated with a constellation of anatomical and functional fetal/neonatal anomalies, known as congenital rubella syndrome, in addition to fetal death and stillbirth[217]. This risk to the fetus is highest when acquired at less at less than 20 weeks with a peak in the first trimester[217]. Accordingly, screening for the presence of IgG to Rubella is recommended for all women at the first antenatal visit. In 2009 the rate of seropositivity in Irish bookers was 93.6%[218] and this is largely down to the existence of childhood and maternity vaccination programmes. In countries with established vaccination programmes rubella is an uncommon cause of stillbirth[179]. Testing for rubella should not be performed if seropositive at booking.

COVID-19

Intrauterine death attributable to SARS-CoV-2 infection is primarily due to acute placental insufficiency as a result of direct infection of the placenta with the virus leading to severe placentitis[219]. Linehan *et al*. described a triad of pathological findings that constitute SARS-CoV-2 placentitis namely chronic histiocytic intervillositis, massive perivillous fibrin deposition and villous trophoblast necrosis[220]. This histological pattern was confirmed in a series of 6 cases of stillbirth associated with Covid-19 from Ireland in 2021[221] and is consistent with international findings[222].

A review of the literature in 2022 noted that all documented cases of intrauterine death associated with SARS-CoV-2 placentitis were observed in unvaccinated women[219]. The author suggested that vaccination against the virus may limit the degree of inflammation in the placenta by reducing the severity or duration of maternal viraemia[219]. Overall the risk of fetal death from Covid-19 infection is, based on current data, in the region of 1% and this risk appears to be mitigated by maternal vaccination[223].

Clinical Practice

If a fetal death is unexpected, it will require investigation in order to ascertain the cause of death. If the cause of death is known, further testing may not be necessary.

At the time of diagnosis of intrauterine fetal death all women should have a Kleihauer-Betke test performed along with a group and antibody screen.

Prior to discharge – either at the time of diagnosis or, more likely, post-delivery – all women should have a blood sample drawn and sent for antiphospholipid antibodies, HbA1c, bile acids, antibodies to CMV, toxoplasma, parvovirus B19 and Rubella (unless previous immunity has been demonstrated).

Ideally testing for antiphospholipid syndrome should be avoided during pregnancy as the results may be less reliable[188]. To meet the laboratory criteria for APS, women must test positive for at least one antiphospholipid antibody, on two occasions, at least 12 weeks apart.

For women diagnosed with stillbirth, screening for hereditary thrombophilia should not be undertaken, unless it is 1) in the context of research and/or 2) in women with additional risk factors and only after consultation with local haematology service. Risk factors include women who have a significant history of VTE (personal or first degree relative), or who experience an adverse pregnancy outcome related to thrombosis.

If a decision is made to test for FVL then this should be achieved, in the first instance, by testing for activated protein C resistance (APCr). This method of testing has good sensitivity and reasonable specificity; 90% of APC resistance is due to the presence of FVL[48]. However, any circumstance that artificially prolongs the activated partial thromboplastin time (APTT) may lead to a false positive result[48]. Therefore, a positive result should prompt genetic testing for the FVL mutation. Genetic testing will also differentiate heterozygotes from homozygotes. It must be noted, however, that formal consent should

be sought prior to genetic testing, with adequate explanation of the ramifications of such testing for the individual and their family. It is also important to clarify local laboratory policy regarding written consent for the APCr test as this will often engender a reflex genetic test and a completed consent may be required in advance.

Regarding infective serology, some guidelines recommend storing a maternal serum sample at the time of diagnosis of IUFD and testing the serological status based on the results of fetal investigations as the probability of a contributory positive result in the context of normal fetal and placental findings is low. However, this is not currently practical in an Irish setting and so this Guideline recommends routine virologic testing as delineated above. Consideration should also be given to viral profiling in the fetal tissue such as testing for CMV DNA.

Recommendations

36. **A Kleihauer-Betke test, full blood count and group and antibody screen should be performed at the time of diagnosis. As postnatal testing can result in false positives and any delay in testing can lead to false negatives, testing for FMH should be performed prior to birth, at the time of diagnosis of intrauterine death.**
37. **Prior to discharge, women should be tested for the following:**
    - **Acquired thrombophilia [lupus anticoagulant (LA), anticardiolipin (aCL) and anti-b2-glycoprotein 1]**
    - **Haemoglobin A1c (HbA1c)**
    - **Serum bile acids (SBA)**
    - **Serology for cytomegalovirus (CMV), toxoplasma and parvovirus B19 (PV B19) and rubella (unless immune)**

Clinical Question 2.12: **What additional case specific investigations may be indicated in the management of intrauterine death and stillbirth?**

Evidence Statement

There is limited evidence to support the use of routine haematological and biochemical tests in the work-up for stillbirth. Guidance in this regard is largely based on best practice and expert opinion.

Thyroid dysfunction has been associated to varying degrees in the literature with an increased risk of stillbirth and perinatal mortality[45,46] and women who have experienced a stillbirth appear to have slightly higher rates of biochemical derangement[46]. However, there remains uncertainty as to the benefit of screening euthyroid women when it comes to identifying the cause of the stillbirth or preventing future adverse outcomes[46].

There is limited evidence to support the role of inherited thrombophilia in the pathophysiology of stillbirth[54,55,57]. The pre-test probability of a positive diagnosis is higher in the context of a positive family history of VTE and a positive diagnosis in this setting may be important for the individual outside of pregnancy.

The presence of anti-Ro/SSA antibodies in the pregnant population is rare with a prevalence of 5-6/10,000 maternities[224]. The risk of intrauterine death in a pregnancy with positive anti-SSA is around 1% although the attributable excess risk is primarily confined to fetuses affected by cardiac conduction deficits (atrioventricular node [AVN] block)[224]. As such, testing for these antibodies is only indicated if there is evidence of hydrops, endomyocardial fibro-elastosis or AVN calcification at post mortem examination[225,226]. It is also reasonable to test for these antibodies in the presence of known maternal autoimmune disease such as systemic lupus erythematosus, Sjögren's syndrome etc., although the serostatus of these women is often known preconceptionally.

Alloimmune anti-platelet antibodies are uncommon and are usually diagnosed in retrospective due to the presence of neonatal alloimmune thrombocytopenia (NAIT) in an infant. Intrauterine death due to fetal AIT is rare in the general population[227], however, the diagnostic yield from maternal testing is greater in the presence of confirmed intracranial fetal haemorrhage at post mortem examination. FNAIT has a high rate of recurrence in subsequent pregnancies and effective antenatal treatments exist[227]. Therefore, testing in the presence of clinical suspicion is indicated.

Illicit drug use has been associated with a wide variety of maternal and fetal complications including IUFD and stillbirth[83] and so should be screened for if the index of suspicion is high.

There is a limited role for the routine employment of standard microbiological studies in the work-up for IUFD and stillbirth as the diagnostic yield and 'usefulness' of these tests is low[179] in the absence of a clinical suspicion of infection.

There is no role for parental karyotyping if cytogenetic analysis of the fetal tissue is normal.

Clinical Practice

Coagulation studies

Coagulation studies i.e., PT, INR, aPTT and fibrinogen should be performed if clinically indicated such as in the event of maternal haemorrhage or sepsis. If a woman is following expectant management, the need for such testing can be determined at each clinical encounter.

C-reactive protein

A CRP should be performed in the event of an intrauterine death or stillbirth if there is a clinical suspicion of infection or maternal sepsis.

Renal function

A renal profile should be performed if clinically indicated. Indications for a renal profile include suspected pre-eclampsia, a history of renal disease and to assess for pre-renal failure in the context of obstetric haemorrhage and sepsis.

Uric acid levels

A urate level should be included with the maternal investigations when there is a suspicion of pre-eclampsia.

Liver function

Liver function should be performed if clinically indicated. Indications for testing liver function include symptomatic intrahepatic cholestasis, suspected pre-eclampsia and evidence of maternal haemorrhage or sepsis.

Thyroid function

Thyroid function tests should be sent if thyroid disease is suspected based on clinical history or examination. It is also reasonable to test in the setting of a known thyroid disorder if no recent testing has been documented.

Inherited thrombophilia

This Guideline recommends against routine testing for inherited thrombophilia. However, testing should be considered on a case-by-case basis and additional risk factors should be considered such as a personal or family history of VTE, with testing only after consultation with local haematology services.

Anti-Ro and anti-La antibodies

These antibodies should be tested for if there is evidence of hydrops, endomyocardial fibro-elastosis or AV node calcification at post mortem examination[225,226]. It is also reasonable to test for these antibodies in the presence of known maternal autoimmune disease such as systemic lupus erythematosus, Sjögren's syndrome, systemic sclerosis etc. although the serostatus of these women is often known preconceptionally.

Maternal alloimmune anti-platelet antibodies

Alloimmune anti-platelet antibodies should be tested for if there is evidence of fetal intracranial haemorrhage at post mortem examination.

Toxicology

A maternal toxicology screen should be performed if the clinical history or examination is suggestive of illicit drug use.

Microbiology

Maternal microbiological studies in the form of urine culture, genital swabs, viral swabs and blood cultures should be performed if there is a clinical suspicion of maternal or intrauterine infection.

Parental karyotypes

Parental karyotyping should be performed if a balanced translocation is identified or suspected within the fetus. It should also be performed if the clinical history is strongly suggestive of a possible underlying fetal aneuploidy and the fetal cell culture or microarray is unsuccessful.

Please see Appendix 4 for a summary of maternal investigations.

Recommendations

38. **The following maternal tests should be performed if clinically indicated: rubella IgM/IgG, syphilis testing, coagulation studies, C-reactive protein, renal function, uric acid, liver function, thyroid function, inherited thrombophilia testing (including factor V Leiden testing), auto/alloimmune antibodies, toxicology screen, microbiological studies and parental karyotypes.**

FETAL INVESTIGATIONS

Introduction

The mainstay of fetal investigations following an intrauterine death or stillbirth includes fetal autopsy (which will be referred to in this Guideline as post mortem examination or PME) and placental histopathology. External imaging of the stillborn infant also plays an important role, particularly when access to the aforementioned investigations is limited due to parental choice or tissue quality.

As previously discussed there has been a shift in focus away from extensive maternal testing and toward fetal testing when it comes to investigating the cause of a stillbirth[175-177], with placental histopathology and fetal post mortem examination proffered as the most useful tests when it comes to determining the cause of death[178,179].

Clinical Question 2.13: **What is the consent process for fetal investigations after a diagnosis of intrauterine death or stillbirth?**

Evidence Statement

The evidence that supports the following guidance is largely derived from published national standards, legal documents and charitable guidance. This guidance also makes reference to the recently published *National Clinical Guidelines for Post Mortem Examination Services*[228]. The GDG has also included good practice points based on their expert opinion.

The introduction of the *Coroners (Amendment) Act 2019* means that all stillbirths are now reportable to a Coroner[229]. The Coroner is an independent public official (a barrister, solicitor or medical practitioner[230]) who is legally responsible for investigating sudden, violent or unexplained deaths. The role of the Coroner is to determine the facts of the case and the cause of the death; this is often described as the 'who, when, where and how'. If there is any uncertainty with regard to these facts the Coroner may direct an inquest. It is important to note that a Coroner's inquest is non-adversarial in nature; strictly speaking there are no competing parties, and no liability is assigned. The aim is simply to determine the facts of the case and the burden of proof is civil. Potential verdicts given at inquest for stillbirth include accidental death, medical misadventure, natural causes and open verdict.

Prior to 2019 the legislative framework that governed the Office of the Coroner was contained within the *Coroners Act, 1962*[230]. An amendment to this act was introduced in 2019 with the aim of modernising the coronial system. Within this new legal framework, the powers of the Coroner were augmented, the range of reportable deaths expanded and rules surrounding the reporting and investigation of death were further clarified.

Whether or not a PME is mandated in the case of a stillbirth is, largely speaking, at the discretion of the Coroner and is based on the details of the case. How the *Coroners (Amendment) Act 2019* relates to clinical practice and the consent process is explored in greater detail within this guidance.

It is vitally important that parents receive accurate and sensitive information when it comes to discussing PME[231]. This is particularly true for parents that are involved with the coronial process in the case of mandated PME and inquest. A recent review of the recommendations from Irish inquiries surrounding pregnancy loss revealed that information provided was often lacking in sufficient detail and parents often felt unsupported in their navigation of the coronial system leading to feelings of anger and upset[231]. While consent is not necessary for the coronial process to be initiated, certain elements of this process are governed by choice, and it is important that parental autonomy is maintained where possible.

Obtaining informed consent from bereaved parents for PME can involve relaying information that may be difficult for the parents to understand or process. Explaining the obligations associated with a Coroner's mandated PME can also come with challenges. To assist clinicians with this task, the stillbirth and neonatal death charity (SANDS), based in the UK, has developed a guide for consent takers[232]. The *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death* in Ireland echo the core principles delineated within this guide including the provision of contemporaneous and locally accurate information surrounding the post mortem process and obtaining valid consent[14].

A recent qualitative study exploring the decision-making process for parents with regard to PME revealed that, while there are a multitude of influencing factors, the emotional response to the loss can have a profound impact on the direction of care and fetal investigation[233]. Communication, information and appropriate bereavement care is key to ensuring that the parents are supported in the decision-making process and the provision of informed consent.

Clinical Practice

The first action with regard to organising fetal investigations after a stillbirth is for the case to be discussed by a senior clinician (usually the consultant involved) with the local Coroner. Parents should be informed that a discussion will take place with the Coroner and that he or she may direct a PME. Parents should not be asked to give consent at this stage. Clarity as to whether the Coroner intends to direct a PME should be achieved before discussing this investigation with the parents. Documentation of any discussions with a Coroner should be recorded in the medical record.

Coronial post mortem examination

Where a Coroner directs that PME should be carried out consent is not required. Therefore, it is not appropriate for parents to be asked for their consent in this setting as it may cause confusion and unnecessary upset.

Although consent is not required parents will still require information about the PME procedure itself[232]. Written information should always be provided[232] and should pertain, not only to the process of PME, but to timelines for results, legal protocols and parental rights relating to the Coroner's court and inquest.

Of particular note is the need to discuss and document parental wishes for the final disposition of any organs that may be retained as part of the PME. These wishes should be clearly documented on a Coronial PME organ retention form.

Consented post mortem examination

If a Coroner does not direct a PME then consent is required for a PME to take place. All aspects of the consent process should be in line with national[228,234], and local policies and guidance. The following highlights some of the more salient points in relation to stillbirth.

Primary responsibility for seeking and obtaining consent should rest with the consultant who is responsible for care of the deceased[228]. A consultant may delegate the task to another clinician but they should ensure that this person has the appropriate training and understanding to undertake this function[228]. In practical terms this means that the consent should be taken by a senior clinician i.e. a senior registrar or consultant. An improvement in PME rates has been demonstrated when senior staff are involved in counselling[235].

Taking consent for a PME is a unique situation for a clinician as it requires taking consent for a procedure that they will not carry out themselves. It is important to be well prepared so that parents' questions can be answered, their wishes recorded accurately and unambiguous instructions can be given to the Pathologist[232].

Parents should be given clear, comprehensive and accurate information[228]. The *National Clinical Guidelines for Post Mortem Examination Services*[228] should be consulted for further information on the consent process in the context of PME. The Stillbirth and Neonatal Death Charity (SANDS) have also published guidance that, while not designed specifically for use in Ireland, can aid clinicians in their interactions with bereaved parents[232]. Again written information should always be provided[14,228]. Importantly, it should be explained to parents that they are under no obligation to provide consent if they do not wish to do so[228].

When a consented PME is declined – whether for personal, religious or cultural beliefs – this decision should be respected. When discussing post mortem examinations cultural stereotyping and culture-based assumptions should be avoided as diversity can exist in all cultural groups[2].

It is important to ensure that, when consent is sought, it is valid. Currently, in Ireland, only parents who are guardians can give consent on behalf of their children and, where parents are unmarried, only the mother is the automatic legal guardian of their child[228]. It is advisable that both parents (if present) are involved in discussions around PME and that both are given the opportunity to sign the consent form. However, confusion around validity of consent can be avoided by always ensuring that the mother has signed the consent form.

Consent forms should have a section on organ retention[228]. This should include options regarding consent to organ retention and options surrounding organ disposition once the necessary examinations have been completed. Parental wishes with regard to organ retention should be clearly documented on the consent form.

For further information on obtaining informed consent (including the capacity to consent) the *National Clinical Guidelines for Post Mortem Examination Services*[228] and the *National Consent Policy* should be consulted[234].

Recommendations

39. **Post mortem examination (PME) should be offered in all cases of stillbirth.**
40. **All cases of stillbirth should be discussed with the local Coroner before the issue of a consented PME is raised with the woman/parents.**
41. **Informed consent for a PME should be obtained by a senior clinician.**
42. **All aspects of the consent process should be in line with national and local policy. The most up-to-date national guidance on PME and consent should be consulted.**
43. **Women/parents should be given clear, honest and accurate information, including the potential contribution that PME may have in providing a diagnosis or managing subsequent pregnancies.**
44. **The consent-taker should be prepared to answer women's/parents' questions and written information should always be provided.**
45. **For a consented PME, it should be made clear to women/parents that they are under no obligation to provide consent if they do not wish to do so.**
46. **When a consented PME is declined – whether for personal, religious or cultural beliefs – this decision should be respected. Cultural stereotyping and culture-based assumptions should be avoided as diversity can exist in all cultural groups.**

47. **Consent forms should have a section on organ retention. This should include options regarding consent to organ retention and options surrounding organ disposition once the necessary examinations have been completed.**
48. **Consent is not required for a Coronial PME; in the event that a post mortem examination is directed by the Coroner, written information relating to the Coronial PME process and parental rights should be provided.**

Clinical Question 2.14: **What is the role of fetal cytogenetic analysis in the investigation of intrauterine death and stillbirth?**

Evidence Statement

Cytogenetic testing is important as a large proportion of stillborn babies will have a chromosomal anomaly[3,179]. While international data quotes a rate of 6-13%[179], Irish figures have historically been higher due to limitations in access to termination of pregnancy prior to 2019. Accordingly almost one third of stillbirth in 2018 and 2019 was attributed to chromosomal or genetic anomalies[3]. Some anomalies are potentially recurrent and early identification can facilitate parental testing and referral for genetic counselling if appropriate.

Ideally, more than one cytogenetic technique should be available to maximise the chance of contributory results. Access to chromosomal microarray analysis, in particular, is recommended as this has been demonstrated to increase the yield of informative results and to increase test success rate when compared with conventional karyotyping[236,237]. It also has the advantage of not requiring viable cells and, therefore, can be useful in cases of macerated stillbirth[177]. Several fetal tissue types (e.g. skin, muscle, liver) can be used for microarray testing although common and easily accessible sites include the umbilical cord and placental tissue[238].

Placental biopsy is often a convenient method of sampling for cytogenetic testing as it can be performed close to the time of birth, and can be performed even in cases where a full PME does not take place. It should be borne in mind that, in cases of confined placental mosaicism, the results from the placental sampling may not reflect the true fetal chromosomal complement[239].

If conventional karyotyping is the only available method further consideration should be given to the type of tissue submitted for testing as skin is associated with a higher rate of culture failure[237]. Samples from multiple tissues can be used to increase the chance of culture. Of note amniocentesis, performed at the time of diagnosis, has the highest yield for successful culture[237] with a failure rate of <10%[240]. This technique may also provide an uncontaminated sample for microbiological assessment if fetal infection is suspected.

If appropriate, particularly in cases of multiple congenital anomalies, consideration can be given to saving frozen tissue samples as a future DNA source[238].

Clinical Practice

Cytogenetic analysis should be offered to all parents who experience an intrauterine death or stillbirth. Local guidelines and laboratory service agreements will determine the laboratory involved, precise techniques used, the sample requirements and the reporting turnaround times. Users should make

themselves aware of the above protocols and agreements to avoid sample rejection and failure and in order to appropriately counsel women and parents.

It is important to note, however, that there is no national genetics laboratory within the Republic of Ireland and, as such, all genetic tests are processed by external laboratories – in Ireland this testing has traditionally been performed in the United Kingdom. This has significant implications for both cost and turnaround. It is therefore vital that there are clear guidelines that detail the indications for genetic testing and the exact nature of the tests to be performed. Request forms and documentation should be clear and easy to use.

While amniocentesis provides the greatest diagnostic yield for conventional karyotype, its usefulness, in the setting of stillbirth, has been superseded by the widespread availability of microarray techniques which are easily obtained from cord and placental samples. Routine amniocentesis for genetic testing is, therefore, no longer recommended. However, if invasive sampling of the amniotic fluid is felt to be appropriate to the clinical situation or potentially contributory, it may be discussed with parents prior to birth.

Care needs to be taken in performing placental biopsy in order to reduce the risk of maternal contamination but also to preserve the fetal vessels and umbilical cord insertion site for further pathological examination. It is recommended that two samples are taken; a 1cm^3 section (approximately) from a normal appearing segment of umbilical cord (away from the cord insertion site) and a 1cm^3 section from the centre of the fetal surface of the placental disc (away from the cord insertion site and any large fetal vessels).

Recommendations

49. **Cytogenetic testing should be performed in all cases of stillbirth. Microarray analysis is the preferred method of testing, if available.**
50. **Care needs to be taken when performing placental biopsy for cytogenetic analysis; the fetal vessels and umbilical cord insertion site should be avoided/preserved for further pathological examination.**

Clinical Question 2.15: **What is the role of post mortem examination (including imaging) in the investigation of intrauterine death and stillbirth?**

Evidence Statement

Placental examination and post mortem examination are the most useful investigations when it comes to determining the aetiology of a stillbirth[178,179]. PME alone provides information that changes or significantly adds to the clinical information in approximately 50% of cases[238].

PME is carried out with the intention of identifying a cause of death. However, even in cases where a definitive cause of death is not identified, PME can provide valuable information. It may identify factors that contributed to the death or exclude conditions which may have implications for future pregnancies. It may provide reassurance to parents or answer other questions that they may have about their baby. PME also provides important information for the audit of clinical care.

In cases where consent is not given for a full PME, a more limited examination can be offered and may be of value[241]. While a complete PME is the recommended investigation, parents may wish to limit the examination for a number of reasons; these may be personal, religious, cultural or they may wish for only a certain clinical question to be answered. In these cases, the PME may be limited in several ways:

- The internal examination may be limited to exclude the examination of certain body cavities or organs.
- The examination may be limited to external examination only. In this case only a detailed external examination of the baby to include external measurements and photography will take place. No internal examination will be performed.

Placental examination has been determined by at least two large cohort studies (retrospective and prospective) to be most helpful test when it comes to classifying the cause of stillbirth[178,179] In the absence of a Coronial or consented PME the parents should be informed that the placenta will be sent for pathological examination.

Alternative imaging methods such as micro-computed tomography (micro-CT) and magnetic resonance imaging (MRI) may provide useful information in this setting, particularly if paired with targeted biopsies. However, imaging-based PME should never be undertaken without an expert external examination of the body having first been performed by an appropriately trained and experienced individual[238]. Furthermore, imaging techniques are poor at detecting certain pathologies which may have contributed to the stillbirth[238]. Practically speaking, these imaging modalities, and the expertise required to interpret them along with targeted biopsies are currently not widely available[238]. It is, therefore, unlikely that they will supersede traditional PME techniques in the short term.

Placental analysis and PME are extremely important when it comes to determining the cause of stillbirth and providing an answer to parents. Two large cohort studies determined that the 'usefulness' or 'value' of these two tests in the evaluation of the cause of stillbirth was 64.6% – 95.7% for placental pathology and 42.4% – 72.6% for PME. The classification of the death will depend on the system in use, which explains jurisdictional variation. The NPEC classification system has consistently reported rates of 10 to 20% for unexplained stillbirth over the last few years; in their most recent report (2019) the quoted rate was 9.5% meaning that in over 90% of cases that year a cause was assigned[3]. This is on a par with international classification systems such as CODAC and Tulip[19].

Clinical Practice

The value of PME after stillbirth is well documented and parents should be offered a complete examination. If consent is not obtained for a complete PME, a limited examination may still be of value.

It is recommended that a Specialist Perinatal Pathologist perform the PME.

A complete PME should consist of[238]:

- Whole body x-ray
- Routine external body measurements
- Detailed external examination
- Detailed examination of internal organs including the central nervous system
- Histological analysis of internal organs
- Detailed macroscopic and histological examination of the placenta, membranes and umbilical cord
- Photography to document any identifiable anomalies.

If a limited internal examination is being considered it is recommended that the consenting clinician discusses this with the Pathologist beforehand. For practical reasons it may not be possible to limit the examination to the extent that parents expect, and the specifics of this need to be understood by both the Pathologist and the consenting parent before the examination takes place. It is important that both clinicians and parents are aware that limitation of the PME will place limits on the information that the PME can provide and may result in the cause of the stillbirth remaining only partially explained or unexplained[228].

Further samples (e.g. for microbiology or metabolic tests) may be taken if the circumstances dictate this.

Placental examination is strongly recommended regardless of whether or not a PME of the infant is performed. Parents should be informed when placental tissue is sent for histopathological examination.

The Pathologist should be provided with comprehensive clinical details prior to performing the post mortem examination[177,238]. This may dictate the need for specialist techniques or testing. It also provides the Pathologist with the information necessary to interpret their findings when compiling their final PME report.

It must be recognised that there is a shortage of dedicated Perinatal Pathologists in Ireland for placental and post mortem examination. While it is recommended that a Specialist Perinatal Pathologist perform the PME and compile the final report, the PME, or elements of the PME, may be delegated, where appropriate, to a designated medical scientist who has been deemed competent in the execution of such examinations. Any work performed by qualified medical scientists should be carried out under the supervision of the Perinatal Pathologist who is responsible for the final report.

Recommendations

51. **A complete PME is recommended in order to optimise the information obtained from the examination.**
52. **While a limited PME may be of value, it is important that women/parents understand that this may restrict the information obtained, and result in higher rates of unexplained stillbirth. If women/parents wish to proceed with a limited PME, the case should be discussed with the Pathologist involved in order to facilitate informed consent.**
53. **It is recommended that a Perinatal Pathologist perform the PME and compile the final report. However, the PME may be delegated, where appropriate, to a designated medical scientist who has been deemed competent in the execution of such examinations, and who works under the supervision of the Perinatal Pathologist.**
54. **Pathological examination of the placenta should be performed in all cases of stillbirth.**

Section 4: Management

PLANNING LABOUR AND BIRTH

Introduction

The concept of giving birth to a stillborn infant can be a source of great distress for the bereaved parent. While the emotional aspect of such an event needs to be acknowledged and managed appropriately, there are also several medical and practical elements that need to be considered when planning birth following the diagnosis of an intrauterine fetal death.

Clinical Question 2.16: **What is the best evidence for determining timing and mode of delivery?**

Evidence Statement

The following guidance is based primarily on retrospective descriptive analyses and case control studies, in addition to internationally agreed best practice and expert opinion. Due to reduced rates of expectant management for women with a diagnosis of intrauterine death, a large proportion of evidence relating to outcomes with regard to expectant management is somewhat dated. However, the data remains valid and contributes to our understanding of the natural physiologic timeline in these cases and allows us to offer a more rounded opinion when advising women who have experienced an IUFD on their management choices.

Early studies into outcomes post IUFD would suggest that between 75 and 90% of women will labour spontaneously within two weeks of diagnosis[242-244]. Beyond 3-4 weeks, however, the rate of SOL decreases and spontaneous delivery becomes less predictable with a 6% rate of fetal retention at 5 weeks[244] post diagnosis.

One of the primary maternal health concerns linked with IUFD is that of disseminated intravascular coagulation (DIC), i.e., a consumptive coagulopathy. Fibrinogen has been used frequently in the literature as a marker for evolving DIC and, while a drop in maternal levels can occur at any point, rates of hypofibrinogenaemia have been shown to vary depending on the length of fetal retention and the presence of co-existing pathology[244-247].

Prolonged fetal retention (>5 weeks) has been associated with a 33-35% rate of biochemical coagulopathy[244,245]. While early studies suggested that the risk of DIC within 4-5 weeks of diagnosis was negligible, subsequent reviews report an overall rate of 7-10% in this group[245,246]. Part of the reason for this may be the presence of significant pathology at the time of diagnosis; in a study of 183 cases of IUFD > 24 weeks gestation, the rate of significant coagulopathy was 50% in the context of placental abruption and 83% when abruption co-existed with pregnancy induced hypertension (83%)[247]. When studies controlled for major placental abruption and significant co-morbidity the rate of coagulopathy was low at 2-3%[244,247].

While clinicians may wish to expedite delivery in order to minimise the risk of DIC and emotional distress in parents, some women may wish to defer the birth for personal or practical reasons. If the fetal membranes are intact and there is no clinical suspicion of sepsis, placental abruption or evolving pre-eclampsia, it is not unreasonable to offer expectant management if the woman so desires.

When birth planning for bereaved parents it is also important to minimise psychological trauma as much as possible. A large Swedish retrospective case control study (N = 380/379) proffered a fivefold increase in the rate of anxiety in those women who experienced a delay in the initiation of the delivery process of >25 hours (OR 4.8)[248]. However, the use of the term 'delay' would suggest that for this group of women (N=65), the expectation may have been that of immediate delivery with any delay perceived as unintended and beyond their control. A retrospective Chinese study (N=193) comparing immediate induction of labour to expectant management post IUFD reported no significant difference in rates of postnatal depression or referral to psychiatric services between the two groups[249]. One of the key points to note here was that women in the expectant arm chose this course of management and could opt for induction at any point in the process.

The take home message is that the diagnosis of IUFD is an inherently traumatic event and how a pregnant woman perceives and wishes to direct her care may depend on factors including personal and cultural preferences. Healthcare providers should remain open to modifying treatment plans depending on the clinical context and parental wishes. Should a woman opt to avoid any delays, supports should be in place to allow initiation of the birth process within 24 hours of the diagnosis.

Regarding mode of delivery, vaginal birth offers the potential advantages of quicker recovery times, the minimisation of surgical risk and avoidance of complications in future pregnancies associated with the presence of a uterine scar. A case series of 96 women with a diagnosis of IUFD >24 weeks gestation reported a successful vaginal birth rate of 87.5% and 95.8% at 24 and 48 hours respectively post administration of misoprostol[250]. While induction of labour is the preferable method, a caesarean section may be indicated due to clinical factors or occasionally due to maternal request.

Clinical Practice

Women should be counselled on what to expect following a diagnosis of IUFD. Expectant management should only be offered to women if, following review by a senior Obstetrician, there exists no contra-indication such as ruptured membranes, antepartum haemorrhage or evidence of maternal compromise or illness.

Should a woman opt for expectant management, she should be:

- educated in symptoms of labour and pregnancy-related complications and written information should be provided on who to contact and where to present should she have any concerns.
- advised that prolonged fetal retention can alter the appearance of her infant at birth and that post mortem investigations may not be possible or as contributory due to tissue degradation.

In the absence of risk factors such as abruption, sepsis and prolonged fetal retention, the risk of DIC for women that pursue expectant management is low. While routine twice weekly monitoring for coagulopathy is suggested by some international guidance[152], there is no strong evidence to support this management strategy, and regular testing in the absence of clinical concern or altered risk profile is not recommended.

Should a woman wish to initiate the process of giving birth as soon as possible, having received a diagnosis of IUFD, maternity services should be resourced to facilitate this. Regardless of mode of delivery, services should be able to initiate the process of giving birth within 24 hours of diagnosis.

If no contraindication exists to vaginal birth, this is the preferred mode of delivery in the event of an IUFD. Mode of delivery may be influenced by several factors; maternal factors such as illness, comorbidity and preference; pregnancy-related factors such as the nature of the intrauterine death, the presence of a uterine scar or placental localisation; fetal factors such as presentation, potentially obstructive anomalies and number of fetuses.

Where a relative or absolute contraindication exists to vaginal birth, or if the pregnant woman does not wish to proceed with vaginal birth, all discussions and decision-making should be consultant-led, and a caesarean section may need to be considered. The risks and benefits of each option for birth should be discussed in full, with consideration for parental wishes and clinical risk at all times.

Women should be counselled on expected timeframes for birth of the baby when labour is induced. It is not unusual that the labour process is protracted, especially in nulliparous women. The preparation for birth is usually instigated as an outpatient via the administration of mifepristone with admission 36 to 48 hours later to commence the active induction process in the form of prostaglandin administration. Response times can vary and women should be fully informed of this to allow them to prepare psychologically for their inpatient stay and the birth of their baby.

Recommendations

55. **Expectant management can be offered to women if, following review by an Obstetrician, there is no contra-indication such as ruptured membranes, antepartum haemorrhage or evidence of maternal compromise.**
56. **If a woman opts for expectant management, routine testing for coagulopathy at regular intervals is not indicated in the absence of risk factors such as suspected abruption, sepsis or prolonged fetal retention. The risk for coagulopathy should be determined on a case-by-case basis; in the first instance at diagnosis, and then again at each service encounter.**
57. **If a woman wishes to initiate the process of delivery as soon as possible, services should be resourced to facilitate birth within a reasonable timeframe. Ideally the process should be initiated within 24 hours from diagnosis.**
58. **If no contraindication exists to vaginal birth, this is the preferred mode of delivery in the event of an intrauterine fetal death.**

Clinical Question 2.17: **What medications can be used to induce and manage labour?**

Evidence Statement

There is a large body of evidence studying the use of induction agents in both live pregnancies and IUFD. The following guidance is based primarily on retrospective reviews, randomised trials and systematic reviews.

International protocols for induction of labour post IUFD vary. Regimens may include the use of the following medications: the hormonal peptide oxytocin, the steroidal antiprogestogen mifepristone, PGE1 analogues (gemeprost and misoprostol) and the PGE2 analogue dinoprostone. While mechanical methods may also be used to induce labour, there is less evidence for their specific use in the context of IUFD.

Misoprostol, as an induction agent, has the advantages of efficacy, reduced cost and ease of storage[250-253]. Compared to gemeprost and dinoprostone, misoprostol can be stored at room temperature. Two randomised trials that compared the efficacy of low-dose intravaginal misoprostol (PGE1, 25-50mcg)

and intravaginal dinoprostone (PGE2, 2-3mg) for induction of labour in term pregnancies with live fetuses suggested a comparable success rate at 24 hours and comparable induction to delivery intervals[254,255]. There appeared to be no difference in maternal outcomes or complications. Similar results were seen in a prospective randomised trial comparing low-dose intravaginal misoprostol with a 10mg slow release dinoprostone insert[256].

Misoprostol appears to be more effective than oxytocin for the peripartum management of IUFD with intact membranes[251,257]. In a randomised trial (N=120) comparing oxytocin with misoprostol induction in IUFD >18 weeks, efficacy, as measured by complete evacuation of the uterus at 48 hours, was 96.7% in the oxytocin arm and 100% in the misoprostol arm. There was a shorter interval from initiation to delivery with the use of misoprostol, however this effect appeared less marked in the third trimester. Misoprostol has the added benefit of being administrable at ward level without the need for titration or a giving set.

In a study of 96 women with an IUFD >24 weeks gestation examining the efficacy of mifepristone and misoprostol combination therapy, 87.5% women achieved a vaginal birth at 24 hours post administration of PGE1 with a median PGE1 to delivery interval of 8.5 hours. This compared favourably with alternative monotherapy induction regimens at the time[250]. Interestingly, while an interval of 36-48 hours between the administration of mifepristone and misoprostol was recommended in the above study, 76% women did not find this acceptable and ultimately received their first dose of misoprostol within 24 hours of the antiprogestogen. A recent systematic review of dosing intervals in mid-trimester termination of pregnancy has suggested that a flexible approach to dosing intervals, particularly shorter intervals, may reduce absolute time to delivery interval and may be beneficial from a psychological point of view[258]. Therefore, while a 36-48-hour interval is recommended to maximise efficacy, this interval can be tailored to the circumstances of the case.

In 2019, on behalf of the National Women and Infants Health Programme, a review of the literature was performed and nationally recommended regimens for the use of mifepristone and misoprostol in the management of intrauterine death were devised. These protocols are gestation dependent with suggested regimens in the presence of a uterine scar[259].

Intravaginal, sublingual and buccal misoprostol may be more effective than oral misoprostol[260,261]. While an increase in gastrointestinal side effects may be observed with the oral route[261,262], it is less invasive than the intravaginal route and may, therefore, be more acceptable to the woman[263]. The most updated guidance from the International Federation of Gynecology and Obstetrics (FIGO) on the use of misoprostol suggests avoiding the vaginal route in the presence of bleeding or significant infection[264].

Mechanical methods are also effective for inducing labour, however, the majority of the evidence is derived from studies of induction in live pregnancies, where fetal indications for delivery exist [265,266]. A recent individual participant data meta-analysis of 12 RCTs (11 of which excluded women with a uterine scar) reported that the use of balloon catheters had a similar rate of vaginal birth and caesarean section when compared to vaginal prostaglandins[265]. There was also no difference in composite maternal outcomes including postpartum haemorrhage and infection[265]. A Cochrane review of mechanical methods of induction suggested that the risk of infection with balloon catheters was comparable to that of locally-applied prostaglandin[267], however, no comparisons for this outcome have been made in the context of intrauterine death.

Clinical Practice

This guidance recommends combination treatment in the form of mifepristone followed by misoprostol at a 36-48-hour interval as the first line protocol for induction of labour in the context of IUFD.

The recommended dose of mifepristone is 200mg orally, however, doses of up to 600mg can be used if the there is a poor response to the first round of medical management. While a 36-48-hour interval is recommended to maximise efficacy, discretion can be used on a case-by-case basis depending on the individual woman's needs.

Misoprostol dosing should be titrated to gestational age[268] due to the increased sensitivity of the gravid uterus to prostaglandins as pregnancy progresses, and the potential risk of uterine hypertonus and rupture. A suggested protocol with dosing regimens for the management of IUFD based on the NWIHP guidance can be accessed in Appendix 5[259], and should be readily available in all maternity units.

In Ireland misoprostol has primarily been used in maternity services off-label in a 200mcg tablet form (Cytotec®). Dose titration has traditionally required tablet splitting or dilution with administration in aliquots. This has the potential to lead to inaccurate dosing and inefficient use of medication. In 2020 a 25mcg tablet (Angusta®) was licensed for use in term inductions >37/40, however, use in IUFD <37/40 remains off-label.

Mechanical methods of induction may be offered and appear to have a similar efficacy to prostaglandin use with a similar maternal outcome profile. However, it must be noted that there is a paucity of evidence comparing outcomes for these methods in the context of intrauterine death.

Recommendations

59. **The recommended medication regimen, for a uterus with no scar, is mifepristone 200mg followed by a course of misoprostol after an interval of 36 to 48 hours. National medication protocols should be followed.**
60. **Misoprostol should be titrated to gestational age due to the increased sensitivity of the gravid uterus to prostaglandins with advancing gestational age.**
61. **Intravaginal, buccal and sublingual misoprostol may be more effective than oral misoprostol.**

Clinical Question 2.18: **What modifications need to be made when managing women with a uterine scar?**

Evidence Statement

There is a paucity of data relating to the management of women with an intrauterine death and a uterine scar. The following guidance is, therefore, largely extrapolated from data on vaginal birth and induction of labour in women with a live fetus and a history of caesarean section. While there is a notable lack of randomised trials in this group, there is reasonable supporting evidence in the form of systematic reviews and meta-analyses.

While the presence of a uterine scar no longer poses a risk for the fetus in utero, there remains the risk of uterine scar rupture and its sequelae for pregnant women. For this reason, decisions regarding mode and method of delivery for women with a uterine scar should be made by a senior clinician, ideally the woman's treating consultant.

The majority of studies detailing the use of prostaglandins for induction of labour in both live pregnancies and IUFD often exclude women with a uterine scar; well-designed studies and RCTs are, therefore, lacking. The RCOG recommend careful consideration prior to the use of prostaglandins in this group and quote an elevated risk of uterine rupture of 0.87%[269]. A large retrospective Norwegian study of 11,954 women[270] who attempted VBAC reported a 1.6% risk of uterine rupture when prostaglandins were used alone (OR 2.72 [1.6-4.7], 95% CI vs. SOL) however standard doses of 3mg dinoprostone (PGE2) appear to have been used in these women. A more up-to date meta-analysis (2021) of the pooled results of 69 studies that looked at PGE2 use in women with a previous uterine scar proffered a risk of uterine rupture of 0.5% (95% CI 2-9/1000, I^2 47.7%, 122/9000) which is comparable to the risk with spontaneous onset[271]. Subset analyses of formulations, dosing regimens, routes of administration and combination with oxytocin were not possible.

A systematic review in 2009 quoted a rate of 0.28% (1 in 357) for uterine rupture in mid-trimester pregnancies with a previous uterine scar treated with misoprostol (GA range 13-28 weeks)[272]. The most recent FIGO guidance on the use of misoprostol for IUFD in women with a previous uterine scar supports its use for medical management from 13 to 26 weeks. In cases of IUFD beyond 26 weeks FIGO acknowledges the lack of evidence and advises referral to local guidelines.

Monotherapy with mifepristone can be used as an alternative to misoprostol. It is less effective than other forms of induction, however, a recent retrospective case control suggested a 74% rate of vaginal birth in term VBAC inductions with mifepristone with a 33% rate of oxytocin use[273]. A double blind RCT comparing mifepristone to placebo in IUFD reported a success rate of 63% at 72 hours versus 18% in the expectant group[274]. Two doses of 600mg of mifepristone, 24 hours apart, is licensed in Ireland for the induction of labour (Mifegyne® 200mg and 600mg tablets). A review of the induction method is suggested in the absence of labour onset at 72 hours.

Appendix 5 sets out a suggested dosing regimen for mifepristone and misoprostol in women without a uterine scar based on the national guidance issued by NWIHP[259]. This guidance recommends that dosing should be individualised in the setting of a uterine scar. While some international institutions recommend mifepristone monotherapy in women with a previous caesarean section, others recommend half-dosing of misoprostol or extended dosing intervals[118].

Mechanical methods of induction may be used as an alternative to chemical cervical ripening agents. A small prospective study of 37 term women with a live pregnancy, one previous caesarean section and a Bishop score <4, who underwent mechanical induction with an Atad® balloon device, reported an overall vaginal birth rate of 65% (24/37)[275]. A recent review of the evidence places the success rate of balloon catheters for induction in women with an unripe cervix and one previous caesarean section at >50%[276]. The rate of uterine rupture appears to be comparable to that of spontaneous onset for women with a previous uterine scar (0.58%, OR 1.04 [0.4-2.6])[270]. There are no reliable large-scale studies that explore mechanical methods of induction for IUFD where the risk of surgical intervention for fetal distress is not a factor.

There are no large studies that explore the medical management of intrauterine fetal death in women with a history of two previous caesarean sections. A recent systematic review exploring outcomes for labour in women with live fetuses and two uterine scars (VBAC-2) reported a pooled rupture rate of 1.36% (0-5.4%, 74/5421)[277]. Subgroup analyses comparing the risk of uterine rupture in women with one (VBAC-1) and two (VBAC-2) previous caesarean sections returned with rates of 0.72% and 1.59% respectively, giving an OR of 0.42 for women with one previous uterine scar. Maternal morbidity (hysterectomy, transfusion, febrile illness) was comparable for VBAC and elective repeat caesarean in women with two previous sections[277]. There is limited data on induction for VBAC following two caesarean sections. In the case of IUFD, a decision should be made by a senior clinician in conjunction with the woman and with consideration for the clinical context.

Women with a history of more than two caesarean scars or atypical uterine scars should be advised that the maternal risk is unknown[152]. International best practice, however, would dictate that the risk of labour and uterine rupture outweighs the potential benefit of vaginal birth for this group of women.

Clinical Practice

For woman with one uterine scar, the mode of delivery should be determined by the consultant overseeing the woman's care. As with decisions for women without a uterine scar, several factors must be taken into consideration, and the woman should be at the heart of the decision-making process.

Prostaglandins are the preferred method of pharmaceutical induction in women with a previous uterine scar. Misoprostol is the drug of choice and dosing should be individualised to the woman and the clinical context. Alternative methods to misoprostol include mifepristone monotherapy. Oxytocin may be used at variable points in the induction process, however a decision to administer oxytocin should be consultant-led.

The risk of uterine rupture may be reduced with the use of mechanical methods of induction. However, this must be balanced with the rate of oxytocin use. Overall, mechanical methods appear to be safe and acceptable to women and may be used as an alternative to misoprostol. As previously mentioned, it must be borne in mind that there is a lack of evidence detailing the use of mechanical methods in the context of IUFD.

There is limited data on induction for VBAC following two caesarean sections. In the case of IUFD, a decision should be made by a senior clinician, with consideration of the clinical context and maternal wishes.

There is also limited data on induction of labour for women with a history of more than two caesarean scars or atypical uterine scars. In such circumstances, women should be advised of this fact and that the risk of uterine rupture likely outweighs the potential benefit of vaginal birth. In the context of one previous caesarean with an atypical scar, previous notes should be consulted where possible, as this may influence decision-making.

Recommendations

62. **For a woman with one uterine scar, the mode of delivery should be reviewed by the consultant overseeing the woman's care with consideration of maternal wishes.**
63. **Induction regimens to be considered for women with one uterine scar include prostaglandins such as misoprostol at lower doses, mifepristone monotherapy, mechanical methods of cervical priming and the use of oxytocin. National medication protocols should be followed.**
64. **Decisions on mode of delivery in women with two previous lower segment caesarean sections should be consultant-led.**
65. **Women with a history of more than two caesarean scars, or atypical uterine scars, should be advised that the risk of uterine rupture likely outweighs the potential benefit of vaginal birth.**

INTRAPARTUM CARE

Introduction

The birth of a stillborn baby may be overwhelming for both the mother and those charged with her care. The following section provides guidance on the care of a woman at the time of birth. While there is a special focus on vaginal birth, the same principles of care may be applied in the setting of caesarean section.

Clinical Question 2.19: **What additional considerations are there when caring for a woman in labour who has been diagnosed with an intrauterine death?**

Evidence Statement

The evidence for the following is largely based on expert opinion, national guidelines and international best practice. Where applicable, case reports and systematic reviews have contributed to the guidance.

The *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death* in Ireland aim to standardise the delivery of care, at a local and national level, for parents who have experienced an intrauterine death[14]. The principles delineated within these standards are applicable at all stages of a woman's journey, including her delivery. As the birth is both physically and emotionally demanding at the best of times, the diagnosis of an intrauterine death can exacerbate the stress of labour and even a medically uncomplicated labour can become a traumatic event[278].

A pathway for staff that care for bereaved women has been developed by the working group for the *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death* in Ireland[279]. This is a useful tool and should be used, where possible, in order to optimise the parental experience and minimise the trauma inherent to delivering a stillborn infant.

Appropriate analgesic cover is extremely important. There is evidence that women who have been diagnosed with an intrauterine death have greater analgesic demands in labour[278]. Options for analgesia include oral and parenteral preparations in addition to neuraxial anaesthesia. The Royal College of Obstetricians and Gynaecologists[152] recommends the use of diamorphine over pethidine due to its proposed greater analgesic effects. However, a recent Cochrane review of 61 studies involving more than 8000 women concluded that there was insufficient evidence to recommend one opioid over another[280].

Intrapartum prophylaxis in cases of suspected or known GBS colonisation is primarily used to reduce the risk of early onset GBS disease in the neonate[281,282]. While GBS can be associated with maternal morbidity[283,284], prophylaxis for this reason alone is not currently recommended. It must be recognised, however, that regardless of the aetiology of an IUFD, the non-viable fetus can act as a nidus for infection and can perpetuate and exacerbate systemic sepsis in the woman[285]. In one study of 96 women undergoing induction of labour for IUFD, the rate of sepsis was 3.1%[250].

With regard to labour, while some would advocate for a more hands-off approach with a longer passive stage, there is no evidence to support one form of management over another. The most recent NPEC report revealed that, while 8.9% of stillbirths in Ireland have a birth weight ≥90th centile, 97.8% have an absolute weight <4000g[3].

Destructive procedures such as cleidotomy, craniotomy, cranioclasis and decapitation are not routinely practiced in modern day obstetrics and are often not within the skillset of the attending Obstetrician.

However, in experienced hands, and in the right clinical context, such procedures could potentially be used as a last resort with the consent of the woman, to reduce both the short and long term maternal morbidity associated with caesarean section in advanced labour[286].

Clinical Practice

Basic principles

On arrival to the labour ward, the parents should be introduced to the midwifery and medical team. At this point the care plan should be rediscussed with the parents and an experienced Midwife should be assigned to look after the women in labour.

Staff should try to ensure a quiet environment for the parents. Ideally the maternity unit should have a dedicated labour ward room where women with an uncomplicated IUFD can give birth. This birthing space should acknowledge the emotional and practical needs of the parents, without compromising safety.

Analgesia

Women should be offered the same choices for intra-partum analgesia when labour takes place in the context of an intrauterine death. This includes the use of oral and parenteral analgesia and the use of neuraxial anaesthetic techniques. With regard to the use of parenteral opioids in labour, local guidelines on the standard management of labour should be consulted; there is no evidence for the use of one parenteral opioid over another. Women with an IUFD are also at increased risk of coagulopathy and DIC[244-247]. If there is a clinical concern for infection or coagulopathy, an FBC and coagulation profile should be obtained prior to proceeding with regional anaesthesia.

Intrapartum care

Intrapartum antibiotic prophylaxis (IAP) should not be routinely employed in cases of IUFD. Staff must be vigilant for signs of evolving sepsis and suspected infection should be investigated and treated as for any woman in labour. This includes the use of broad-spectrum intravenous antibiotics when indicated in accordance with local microbiology protocols.

Women with a previous uterine scar should be closely monitored for uterine rupture. In the absence of fetal heart rate abnormalities, the attending Midwife/Doctor must rely on maternal symptoms of uterine rupture including atypical pain, vaginal bleeding, haematuria as well as systemic signs such as tachycardia, haemodynamic instability and maternal collapse. The decision to commence oxytocin in a woman with a uterine scar, whether for induction or augmentation, should be made by a senior Obstetrician.

The maternal indications for caesarean section in labour are the same as those for a woman who has a live fetus. These include dystocia, maternal illness or compromise, cephalopelvic disproportion and persistent fetal malposition.

Additional considerations

The birth of a stillborn baby is an inherently difficult process for a woman or parent. All healthcare professionals interacting with bereaved parents should be mindful of the circumstances and act with empathy. The aim is to guide the woman/parents through what is both a physically and emotionally demanding event, while upholding the basic principles of standard obstetric care. If an assisted vaginal birth is required, the Obstetrician should handle this with sensitivity. Appropriate analgesia, in keeping with maternal wishes, should be offered.

Apart from the absence of fetal heart rate monitoring, intrapartum management is similar to that for women with a live fetus. In cases where a difficult birth is anticipated, for example where there is a fetal malposition or a malpresentation such as breech, an appropriately skilled Obstetrician should be available to assist with the birth.

At birth, the woman/parents should be provided the opportunity, if desired, to:

- see their baby
- cut the cord
- have the baby delivered into the woman's arms
- spend time alone with their baby
- get to know their baby
- experience skin to skin contact
- take photographs.

The wishes of the woman/parents should be clarified prior to the birth. Parents should be informed that they may change their mind at any point and that this is OK.

Women/parents are often ill-prepared for the appearance of their baby. This is particularly true when a significant amount of time has elapsed between the death of the baby and the birth. Post mortem changes such as skin slippage, bruising and other features of maceration may be present which can be a source of significant distress for the woman/parents, even with advance counselling. In order to optimally prepare parents for what to expect following the birth of their baby, the potential effects of fetal maceration should be discussed; both antenatally (by a member of the bereavement care team or the treating Obstetrician), and again during the birthing process by the attending Midwife.

The woman/parents may need to be guided in carrying out tasks for their baby. The attending Midwife or Obstetrician should handle the stillborn infant as they would a live infant. Affording the newly stillborn baby the same respect and care as would be given to a live baby is essential.

Recommendations

66. **Women who have experienced an intrauterine death should be provided with a birthing space that acknowledges the emotional and practical needs of the woman/parents in addition to the medical needs of the woman.**
67. **Women should be provided with the same options for analgesia that are offered to women with uncomplicated pregnancies.**
68. **There is no strong evidence to recommend the use of one parenteral opioid over another.**
69. **If there is a clinical concern for sepsis or coagulopathy, an FBC and coagulation profile should be obtained prior to proceeding with neuraxial anaesthesia.**
70. **Intrapartum antibiotic prophylaxis (IAP) should not be routinely employed in cases of intrauterine fetal death.**
71. **In women with a uterine scar, the birth attendant must rely on maternal evaluation in order to make an assessment of scar integrity. Care must be taken not to miss subtle maternal signs in the absence of fetal monitoring.**

72. All intrapartum interventions for a woman who has experienced an IUFD should be approached with sensitivity, whether instigated by the primary birth attendant or the covering Obstetrician.
73. In cases where a difficult birth is anticipated, for example where there is a fetal malposition or a malpresentation such as breech, an appropriately skilled Obstetrician should be available to assist with the delivery.
74. Women/parents should be appropriately counselled, both antenatally and during the birthing process, on the changes that take place within the baby after death, and how these may alter the physical appearance of their baby after birth.
75. Women/parents should be supported in the decision-making process when it comes to labour and interactions with their stillborn baby after birth. Birthing conditions should facilitate open communication and informed consent.

POSTNATAL CARE

Introduction

Childbirth is both an emotionally and physically demanding event in the life of a woman. In the event of stillbirth, the experience is compounded by the grief associated with losing a child. The emotional distress that is inherent to the grieving process needs to be acknowledged and treated in addition to providing appropriate medical care. This principle applies to the antenatal period, to care in labour, and carries through to the puerperium.

Clinical Question 2.20: **What are the standard principles for postnatal care?**

Evidence Statement

There is no high-quality research in the literature that looks specifically at postnatal care in women who experience an IUFD. The same basics principles of postnatal care apply when caring for a bereaved woman with some additional considerations in the context of IUFD and stillbirth. Tailored postnatal care is dictated by the individual's clinical risk based on antenatal, intrapartum and postnatal risk factors.

There is some evidence that experiencing a stillbirth may increase the postpartum risk of venous thromboembolism (VTE)[287]. A large retrospective cohort study in the UK suggested that stillbirth may be an independent risk factor for VTE with an adjusted incidence of 4-6/100,000 person-years in the puerperal period[287]. However, the rate of IUFD in this study was low and not all confounders could be adjusted for. The authors of this study advocate that stillbirth be included as a major risk factor when calculating a woman's postpartum risk of VTE[287] while the RCOG have simply recommended that stillbirth be used as a criterion in the screening process and have listed this outcome as a minor risk factor (score = 1)[288].

Women who experience stillbirth are exposed to the same sources of physical pain associated with childbirth as women with a liveborn infant. The nature and type of analgesia will depend on the individual and the mode of delivery. Qualitative research has suggested that women who deliver a stillborn infant have greater analgesic requirements in labour[278] and this may follow through to the postnatal period.

Clinical Practice

Venous thromboembolism

It is important to conduct a thorough risk assessment for all bereaved women in accordance with national[289] and local guidelines for thromboprophylaxis. Consideration should be given to the inclusion of stillbirth as a risk factor when screening for the risk of VTE in the postpartum period. An up-to-date postnatal weight should be obtained in order to prescribe the appropriate weight-based dose of low-molecular-weight heparin.

Analgesia

Special attention should be given to identifying and treating sources of physical pain for the bereaved woman. If the level of pain voiced by the women deviates from what is to be expected, or if a postnatal complication is suspected, then a review by an Obstetrician should be arranged.

Women should be counselled on the symptoms of uterine involution, also referred to as 'afterpains'. These pains may be unexpected and simple counselling in this regard may avoid unnecessary concern and anxiety. Appropriate analgesia should be provided as required.

Wound care

Wound care involves the management of both abdominal and perineal trauma as a consequence of childbirth. Routine postnatal care should be followed in this regard with reference to national[290] and local guidelines in wound management.

Anti-D prophylaxis

If a woman is RhD antigen negative, then she may require postnatal anti-D prophylaxis. This usually depends on the result from a neonatal or cord blood sample after delivery. As this is often not possible in the case of a stillbirth, anti-D immunoglobulin should be administered as standard, providing the woman has not been sensitised.

Some hospitals provide a service whereby a maternal sample is sent in early pregnancy to detect the presence of cell-free fetal DNA and provide a prediction of the RhD antigen status of the fetus. While this test has both good positive and negative predictive values, the decision for postnatal administration of anti-D will often be based on the neonatal or cord sample due to the small risk of false negative results. In the event of a stillbirth, where the antenatal fetal prediction was RhD negative and where postnatal testing is not possible, a discussion should be had with the woman on the risks and benefits of empiric prophylaxis.

For more information on anti-D prophylaxis the national CPG on the use of anti-D immunoglobulin for the prevention of RhD haemolytic disease of the newborn should be consulted[291].

As previously stated, individualised postnatal care plans are formulated based on women's antenatal, intrapartum and postnatal risk factors. This will include a determination of frequency of observations as well as monitoring for both obstetric and medical complications.

All cases of stillbirth should be discussed at a perinatal mortality multidisciplinary meeting. This should ideally take place once the results of all the investigations have returned and prior to meeting the parent(s) postnatally. However, the GDGs appreciates that detailed discussion of the particulars of a case, and the timing of this discussion, may be limited by several factors including coronial jurisdiction and governance. Please see Section 5 for more information on the role of the PM MDM following stillbirth.

Recommendations

76. A risk assessment for venous thromboembolism should be carried out according to national and local guidelines.
77. Psychological stressors may impact on the perception of pain. Care should be taken to ensure adequate analgesia for the woman, both acutely and at discharge.
78. A standard approach to wound care should be taken as per national guidelines.
79. An individualised care plan should be made for each woman depending on personal, medical and peripartum risk factors.
80. The need for postnatal anti-D prophylaxis should be determined after birth and should be in keeping with local and national guidance.

Clinical Question 2.21: **What special postnatal considerations are there in the context of intrauterine death and stillbirth?**

Evidence Statement

The Irish standards and pathways on bereavement care have guided the practical considerations presented in this Guideline with regard to the care of women who have recently delivered a stillborn infant[14,279]. There is also an abundance of qualitative research into the maternal perceptions of care before, during and after delivery that provides valuable information on the maternal experience[158,164,292-295].

In addition to emotional and supportive aspects of care, there are also practical, medical aspects that need to be considered including the management of lactation. To understand the role of lactation suppression it is useful to understand the physiology. The formation of breast milk or lactogenesis is a normal physiologic process that begins mid-pregnancy and continues after delivery. In the first stage of lactogenesis, small volumes of a proteinaceous form of milk called colostrum are secreted[296]. The composition and volume of breastmilk evolves rapidly from day two to four postnatal (second stage of lactogenesis), and by day five breastmilk is produced with potential daily expressed volumes in excess of 500ml[296]. This leads to rapid engorgement of the breasts that is traditionally relieved by breastfeeding or manual expression.

This physiologic change can be a source of distress and anxiety for bereaved women[297]. Problems encountered include breast engorgement and discomfort in addition to the unwanted and unpredictable leaking of breastmilk[297,298]. For these women, lactation suppression constitutes an important element of care.

There are non-pharmacological and pharmacological methods of artificial lactation suppression. Non-pharmacologic methods are numerous with a varying degree of efficacy. A 1998 review of the literature reported at least a moderate degree of milk leakage, breast engorgement and pain in up to 48%, 52% and 68% percent of women, respectively, who used non-pharmacologic methods such as brassieres or binders, ice packs and analgesics to treat the symptoms of milk retention[298]. A Cochrane review from 2012 concluded that there was no evidence to indicate that non-pharmacologic approaches were more effective than no treatment[299] mainly due to a lack of comparative research.

Many pharmacologic agents have been used to date in an attempt to suppress lactation[299]. Dopamine agonists are the mainstay of treatment via their inhibition of prolactin secretion. The Cochrane database recognised the efficacy of pharmacologic treatment in the suppression of lactation while acknowledging weaknesses in the evidence due to limitations in study design; a lack of specific comparison of side effect profiles was also flagged[299].

Bromocriptine has a larger body of research and has been shown to be effective in the suppression of lactation[299]. Cabergoline is an alternative to bromocriptine that is available as a once-off dose and appears to be non-inferior in terms of efficacy[299]. A double blinded RCT comparing pharmaceutical lactation suppression in 272 women reported that cabergoline was non-inferior when compared to bromocriptine in terms of efficacy and resulted in less rebound breast activity, adverse events and was reportedly simpler to administer[300].

Bromocriptine and cabergoline are contra-indicated in the presence of hepatic insufficiency, pre-eclampsia or hypertensive disorders of pregnancy and should not be co-administered to women on anti-psychotic medications for psychiatric disorders[301]. Extreme caution should be taken in women with cardiovascular problems and a history of puerperal psychosis[301].

Oestrogen based compounds have been shown to be effective in suppressing lactation[299], however their use in the puerperium is generally discouraged due to a reported increase in the risk of venous thromboembolism based on weak evidence[152,302,303].

It must also be acknowledged that grief is a complex process that is unique to the individual. While some women seek to suppress lactation, this may not be the case for every woman. It has been recognised in the literature that some women may wish to prolong lactogenesis or opt for physiologic suppression for personal reasons[304].

Written information and advice detailing options for lactational support or suppression should be made available to bereaved women at the time of, or shortly after diagnosis to facilitate informed decision-making. A lack of information and support in this regard has been highlighted by several qualitative studies as a concern for women who have experienced stillbirth[164,297,304], and represents a window for continued improvement.

Clinical Practice

Practical considerations

One Midwife should be allocated, where possible, to care for the parents and the baby in order to facilitate continuity of care and to minimise the potential for parental distress from unnecessary or repetitive interactions.

Parents should be allocated a room on their own after the birth. There should be open access for designated partners (or other support person) to visit and facilities should permit the partner/support person to remain with the woman at night.

The *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death*[2] recommend the use of a symbol that is easily recognised by hospital staff and the public, and that indicates the presence of ongoing end-of-life care or a recent bereavement. The symbol selected for use in each hospital should be agreed locally by staff and management, and may be displayed on the woman's healthcare records or outside her room. Parental consent for use of the symbol is necessary[2].

Parents should be advised with regard to rooming with the baby; this includes the use of a cuddle-cot (or cold-cot) at the bedside and the need for the baby to be placed, on occasion, in a designated quiet room.

All relevant healthcare professionals (HCPs) should be informed of the occurrence of an intrauterine death or stillbirth. Relevant HCPs include but are not limited to:

- The woman's general practitioner
- The Public Health Nurse
- The local bereavement team/Midwife
- The hospital chaplain
- Social work
- Other healthcare providers or specialists that have been involved in the woman's care

All existing antenatal appointments should be cancelled. There should be an agreed system in place, in each unit, that outlines how these tasks are delegated in order to minimise human error. Ideally the GP should be contacted by telephone, if possible, as a letter or email may not be received in an appropriate timeframe. This should be done on the day of delivery if during working hours, or the next morning if the delivery occurs outside of working hours. In the event of the latter, the task must be handed over to a member of the oncoming team that is charged with the care of the woman.

Suppression of lactation

A discussion should be had with the bereaved woman with regard to physiologic lactogenesis and what to expect. This discussion should include options for artificial suppression. Assumptions should not be made, and clinicians should allow the woman time to decide on the best pathway of care for her. Written information should be provided.

Women should be advised that non-pharmacologic options for artificial lactation suppression are available, however, the efficacy of these options versus placebo (no treatment) has not been demonstrated. Should the woman wish to proceed with pharmaceutical suppression, she should be advised that this option is most effective when instigated within the first 24 hours postnatally.

Cabergoline is recommended as the first-line treatment for the pharmacologic suppression of lactation. Care should be taken to assess for the presence of any absolute or relative contraindications to this treatment prior to initiation. Cabergoline is licensed in Ireland for the suppression of lactation under the tradename Dostinex® (Pfizer Healthcare Limited)[301]. The dose is 1mg PO to be taken within 24 hours of delivery. In the event of established lactation a dosing regimen of 0.25mg PO BD for 2 days has been recommended[301].

Bromocriptine is also licensed in Ireland (Parlodel®, Mylan IRE Healthcare Limited) for the suppression of lactation. The dose is 2.5mg PO to increase after 2-3 days to 2.5mg PO BD for 14 days[301].

The use of hormonal suppression with oestrogen is not recommended. If an absolute contraindication exists to dopamine agonists and pharmaceutical suppression is greatly desired by the woman, then oestrogen-containing compounds could be considered. However, this decision must be consultant-led, a full VTE assessment must be performed, and the woman needs to be informed of the risks and potential outcomes of postnatal venous thromboembolism.

As previously stated, women should be provided with written information on what to expect whether they chose physiologic or medical routes of suppression. Ideally this should be available in several languages.

Follow-up

Women who experience stillbirth should be referred to the bereavement service as an inpatient and appropriate follow-up should be arranged on discharge. Relevant contact details should be provided – this includes information on who to contact in the event of a complication or concern, as well as written information on community-based support and advocacy groups.

The nature and timing of clinician follow-up after discharge may depend on the woman, the clinical context and the degree of investigations performed. This follow-up appointment should be with the woman's named Obstetrician who was charged with her care at the time of diagnosis of intrauterine death. The GDG acknowledges that the results from some investigations may take some to return, particularly in the event of Coronial PME or inquest. Women/parents should, however, be seen within three months of the birth of a stillborn infant, to discuss the available results and address any queries or concerns.

Recommendations

81. Healthcare staff allocated to caring for and liaising with the bereaved woman/parents should be kept to the minimum number required. Continuity of care, where possible, should be facilitated.
82. All healthcare professionals (HCPs) that have been involved in the woman's antenatal care, or who are routinely involved in postnatal care [including the woman's general practitioner, (GP)] should be informed of the stillbirth.
83. All scheduled antenatal visits and appointments should be cancelled before the woman is discharged home.
84. Physiologic lactogenesis, and what to expect, should be discussed with the bereaved woman. This discussion should include options for artificial suppression. Written information should be provided.
85. Women should be advised that non-pharmacologic options for artificial lactation suppression are available, but that the efficacy of these options versus placebo (no treatment) has not been demonstrated.
86. Cabergoline is recommended as a first line treatment for the pharmacologic suppression of lactation.
87. Appropriate follow-up should be arranged for bereaved parents after discharge with their named Obstetrician. The nature and timing of this follow-up may depend on the woman, the clinical context and the degree of the investigations performed. Women and parents should, however, be seen within three months following the birth of a stillborn infant, to discuss the available results and address any queries or concerns.

COMPREHENSIVE BEREAVEMENT CARE

Introduction

Supportive bereavement care needs central to the mission of the hospital and is provided in accordance with the religious, secular, ethnic, social and cultural values of parents who have experienced an intrauterine death or stillbirth[14]. Clinicians and healthcare professionals that care for bereaved parents should be familiar with the *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death*[2] and should use this document to guide their approach to parental interaction and the delivery of care.

Clinical Question 2.22: **What are the national standards for bereavement care in Ireland?**

Evidence Statement

The purpose of the *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death* is to improve the quality of care delivered to parents who experience pregnancy loss or perinatal death and act as a guide for all members of the MDT who care for bereaved parents[2]. This document is an important resource for parents, healthcare professionals and hospital management.

The Standards promote multidisciplinary staff involvement in preparing and delivering a comprehensive range of bereavement care services that address the immediate and long-term needs of parents who are bereaved while under the care of a maternity service. The Standards guide and direct bereavement care staff on how to lead, develop and improve the hospital response to parents who experience a stillbirth. They serve to assist staff in developing care pathways that will facilitate the hospital's response to the grief experienced by parents and their families.

The document comprises four themes: "Bereavement Care", "The Hospital", "The Baby and Parents" and "The Staff". The standards address all aspects of bereavement care following any kind of pregnancy loss or perinatal death. They also address the needs of staff in relation to training and support[14].

Clinical Practice

A Clinical Midwife/Nurse Specialist (CMS/CNS) in bereavement should be available in all maternity services to co-ordinate the care for women who experience a stillbirth. The CNS/CMS should liaise with the multidisciplinary team in order to provide holistic care for parents. They should also liaise with allied healthcare and professional services including chaplaincy, the social work counselling team and the hospital undertakers.

The loss of a baby during pregnancy or after birth is a devastating experience for parents and can also have an impact on the staff caring for them. The *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death* should be consulted by staff as they provide a comprehensive framework to aid with the delivery of care to bereaved parents. It is important that the needs of bereaved families are met, both in the short and the long-term following the death of a baby.

Recommendations

88. Staff should be familiar with the Irish *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death (The Standards)*.
89. Providing quality bereavement care is an integral part of every maternity service. It is vital that such bereavement support is integrated within the hospital's clinical care pathways for women/parents.
90. All maternity services should have a dedicated clinical Midwife or Nurse specialist who is experienced in the field of bereavement and loss.

Clinical Question 2.23: **What special considerations must be made in the context of antenatal, intrapartum and postnatal care?**

Evidence Statement

The following clinical practice points have largely been developed from consultation of the *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death* in Ireland.

Whether parents benefit from seeing and holding their baby has been researched in the literature with mixed opinions and advice. One study reported higher levels of depression for women who saw their stillborn infant[305]. However, subsequent articles suggested caution in the interpretation of this data and recommended against changing clinical practice based on these results[306]. Rådestad *et al*. found that parents who had a stillborn baby after 37 weeks did benefit from holding their infant, but suggested that the evidence for babies born before 37 weeks was less clear[307]

Regardless of a perceived benefit, the RCOG Guideline on the management of stillbirth cautions medical professionals against persuading parents to view or hold their stillborn infant[152]. This being said, a number of studies have reported that parents feel some degree of persuasion may be appropriate and ultimately beneficial[292,295]. An Australian study from 2015 found that the majority of parents did choose to hold their stillborn infant but also reported little observed regret among parents, regardless of the decision to hold the baby or not[308]. Most authors agree seeing and holding the baby should be a matter of choice for the parents and one which should be discussed openly and in a supportive manner. Parents are often not well prepared for the appearance of their baby[293], and preparatory support from staff in advance of seeing their baby is advised[14].

Regardless of whether parents choose to see their baby, the evidence would suggest that they value mementos of the baby, including good quality photographs, handprints, footprints and locks of hair[295,309-311]. However, the grief response is an individual and unique process and, as parental wishes in this regard may differ, they should always be consulted.

Parents benefit from support and guidance from staff when it comes to making funeral arrangements – this may include decision-making with regard to burial and cremation[309]. It is important that parents receive both verbal and written information with regard to the available services and that they receive support from the bereavement team in relation to navigating these services[14,306]. Parents may also value the opportunity to have their baby blessed[309] and an offer should be made to meet with a chaplain or chosen spiritual leader[14].

Parents require psychological support from the time of diagnosis of intrauterine death, throughout their hospital admission and following discharge[14,306]. Parents who experience a stillbirth are at risk of developing prolonged psychological problems and this appears to be much more likely if professional support is not given[152]. Parents should receive written information about the grief and support services that are available to them both within the maternity service and in the community [14,152,306]. Advice surrounding counselling services should be provide to all women/parents who experience a stillbirth[152].

Clinical Practice

Antenatal consultation

Parents should be provided with the opportunity to meet with a member of the bereavement team at the time of diagnosis of intrauterine death. This encounter provides the bereavement team and the parents with the opportunity to familiarise themselves with one another and create a rapport. This allows parents to ask important questions that may have been missed during the medical encounter and re-explore aspects of the care plan.

Written leaflets or cards should be provided detailing the contact information of the bereavement team and practical information on where to present in the event of a scheduled admission or an emergency.

Multidisciplinary engagement

An offer should be made to parents to meet with members of the bereavement team (Clinical Midwife Specialist in bereavement, chaplain, medical social worker and a member of the perinatal mental health team where applicable) during the antenatal and postnatal period. The role of each discipline needs to be explained to parents and they should decide what is most appropriate for them.

Spiritual care

Parents should be provided with the opportunity to have their baby blessed if desired and should they wish to meet with a chaplain or their chosen spiritual leader, this should be arranged.

Seeing or holding the baby

Following birth, parents should be provided with the option to see and hold their baby. This should be discussed prior to birth as well as after, in order to provide parents with the opportunity to decide what is best for them. Parents who decide not to see their baby may change their mind and this choice should be facilitated. Staff should not persuade parents in one direction but should fully inform parents, supporting them in the decision that they make.

Should a parent choose to see their baby, they should be prepared by the staff involved in their care that the appearance of the baby may have been altered after death.

Memory-making

Parents should be offered mementos of their baby and of the pregnancy experience. Maternity services should have access to tools for creating memories such as ‘memory boxes’. Such boxes contain items that facilitate memory-making, bonding and care of the stillborn infant. If possible, parents should be offered the services of a professional photographer.

Memory-making may include services such as creating clay imprints of the infants hands and/or feet. Often this service is provided by a dedicated bereavement and loss CMS/CNS. However, maternity units should aim to ensure, where possible, that women have access to such services when the bereavement and loss CMS/CNS is unavailable, such as during leave or in the event of a bank holiday weekend. This may mean providing the relevant training to staff midwives/nurses that routinely care for women who experience pregnancy loss.

Funeral arrangements

Parents should be counselled on the options for funeral/service arrangements and should be provided with written information in this regard. This includes options around burial and cremation. This should be facilitated by the bereavement and loss service.

Psychological support

Parents should be provided with the appropriate psychological support both antenatally, during the puerperium and thereafter. The type of support that an individual parent needs may vary and will be influenced by the nature of their grieving process and personal choice. Written information should be provided to parents on the supports available, at both a community and hospital-based level. Support may come in the form of professional counselling services, support groups and online sites or forums.

Recommendations

91. **Women/parents should be provided with the opportunity to meet with a member of the bereavement team; ideally the first encounter should take place at the time of diagnosis.**
92. **Women/parents should be provided with the opportunity to meet with a pastoral care team or chaplain/spiritual leader of their choosing.**
93. **Women/parents should be provided with the opportunity to see or hold their baby after birth. Mementos of their baby and pregnancy experience should be offered.**
94. **Women/parents should be supported in making decisions regarding funeral arrangements, including burial and cremation.**
95. **Women/parents should be offered the appropriate psychological supports antenatally, intrapartum and postnatally with no puerperal time limit on support. Written information should be provided to parents on the supports available, at both a community and hospital-based level. Support may come in the form of professional counselling services, support groups and online sites or forums.**

Clinical Question 2.24: **How can support for bereaved parents/ families be optimised?**

Evidence Statement

The national guidelines and pathways that have been developed for bereavement care are essential to the delivery of holistic, woman-centred care across Ireland. The goal of these guidelines is to ensure that the level of care provided adheres to best practice and professional codes of conduct[14].

Healthcare professionals have highlighted the need for further education in the area of perinatal bereavement support[312,313]. Sensitive, empathetic communication with bereaved parents is of vital importance[294,295,309,314] and staff training and education should reflect this[14,309].

In order to address this need for education, maternity units in Ireland have started to provide formal training in bereavement care. Of particular note, a workshop was developed in the South/South West Healthcare Group in Ireland (TEARDROP; Teaching, Excellent, pArent, peRinatal, Deaths-related, inteRactions, tO, Professionals) with the aim of educating staff on the standards of bereavement care

and developing skills in the areas of patient interaction and communication[315]. The working group for this project recently published an evaluation of the programme concluding that the workshop was well received with high levels of participant satisfaction and an interest in annual/national rollout[315].

Such workshops also provide an opportunity to ask staff for feedback on perceived deficits within pathways of care or local resourcing which can inform the restructuring of services and ultimately the optimisation of the parental experience.

Clinical Practice

Local guidelines and pathways of care should be in place every maternity group that reflect the *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death* in Ireland and the national pathways for women who have experienced a stillbirth. This will ensure that the care provided by an individual service meets the minimum requirements expected of that service.

All maternity services should have protocols in place to audit the delivery of bereavement care. This allows services to ascertain the efficacy of their pathways and interventions and determine areas for improvement. Parents should be involved in the audit process and feedback in the form of individual interviews and surveys can be invaluable.

Structured training and education workshops should be provided to all healthcare professionals that are involved in the care of bereaved women. Staff should be allocated time within their schedule to attend such workshops. Whether this training is mandatory or voluntary should be determined at a local level and may depend on the role of the staff member and the nature of their work.

Recommendations

96. **Clear pathways of care should be available in all maternity units in order to optimise the parental experience. *The Standards* should be consulted when implementing such pathways.**
97. **Maternity hospitals/units should regularly audit their service with reference to the *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death.***
98. **All healthcare professionals who care for bereaved women/parents should have access to regular and appropriately designed training in bereavement care.**

Clinical Question 2.25: **How can we support staff that care for bereaved families?**

Evidence Statement

Caring for bereaved parents can have an emotional impact on the staff working in a maternity unit[313] and significant problems in relation to burnout among healthcare professionals have been highlighted in Irish studies[316,317]. In order to provide compassionate care to parents while also avoiding fatigue and burnout among staff, staff need to be provided with the appropriate supports. It is important that maternity units strive to create a supportive environment that enables employees to be proactive in protecting and enhancing their own health and wellbeing[318].

Healthcare organisations that implement the appropriate structures for staff wellbeing and support see a greater level of positive outcomes including:

- improved clinical care
- enhanced service user experience
- improved staff wellbeing
- lower absenteeism rates
- improved staff retention[319-321].

It is, therefore, vital that healthcare organisations consider initiatives to improve the resources available to staff at all levels. The *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death* lay out quite clearly what is expected of maternity units with regard to staff training and support.

Efforts should be made to improve access to debriefing sessions following adverse events[322]. Formal and informal debriefing sessions following perinatal death are important and should be available[14]. Schwartz rounds have been shown to create a stronger sense of teamwork and unity which, in turn, has been felt to lead to a reduction in burnout among hospital staff[323]. Within some maternity units[324]. Schwartz rounds have been shown to be beneficial and may be worth considering as a routine element of hospital-based practice[325].

Optimising staff support can be challenging for a healthcare system. A consensus on the ideal method for supporting healthcare professionals in both daily practice and subsequent to an adverse outcome has yet to be reached; a multifaceted approach is likely to give the best result as the needs of the individual are varied and staff members may interact with support services on different levels depending on these needs. In accordance with the *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death* and in order to help healthcare employers optimise their provision of staff support, a document was developed for maternity services that is designed to be used along with HSE and local HR policies. This document is available at http://pregnancyand.wpengine.com/staff-support/.

Clinical Practice

Maternity units should ensure that staff are provided with access to appropriate support services including day-to-day support, access to professional counselling and formal debriefing sessions in the event of an adverse outcome. Local resourcing may dictate the exact nature of the supports provided but a minimum standard as delineated by the *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death* must be met. A formal policy on staff support services should be devised and available in each maternity unit.

Adequate funding should be made available to ensure that staff support systems are appropriately resourced. Schedules should permit healthcare staff to access these services when required and consideration should be had for the introduction of regular debriefing and discussion sessions such as Schwartz rounds or Balint group sessions.

Supporting staff also includes training for senior clinicians and management and maternity services should ensure that these training requirements are met.

For more information on cultivating a positive work environment and supporting healthcare staff the *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death*[14] should be consulted.

Recommendations

99. A formal policy on staff support should be devised and implemented in all maternity hospitals/units.
100. A range of support options should be available to staff including individual debriefing, peer group support and professional counselling.
101. Tailored debriefing sessions should be made available following serious adverse events, such as intrapartum stillbirth, for all staff involved – regardless of whether the involvement is direct or indirect.
102. Consideration should be given to the introduction of Schwartz rounds or Balint group sessions as part of the regular schedule within individual maternity units.
103. Information regarding self-care and the available support services within a unit should be provided to staff at induction training and at regular intervals throughout the working year.

SPECIAL CIRCUMSTANCES

Introduction

The following guidance gives a brief insight into special circumstances that exist within the context of intrauterine death and stillbirth. Further information regarding these circumstances and associated conditions can be obtained through accessing the corresponding clinical guidelines, both local and national.

Clinical Question 2.26: **What is the appropriate care for a woman that undergoes a termination for fatal fetal anomaly?**

Evidence Statement

The national clinical guidance for the care of women diagnosed with a fatal fetal anomaly (*Pathway for Management of Fatal Fetal Anomalies and/or Life-Limiting Conditions diagnosed during Pregnancy: Termination of Pregnancy*)[118] was consulted to advise on the following clinical practice. The decision to terminate a pregnancy due a diagnosis of fatal fetal abnormality is not an easy decision to make, and the choice is a personal one. The *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death*[14] recognise the grief reaction that is inherent to such diagnoses[326] regardless of the chosen pathway of care and advocate for a holistic approach, with the provision of appropriate psychological support for these women.

While the circumstances surrounding the death of a baby for a woman who elects to have a termination for fatal fetal anomaly differ from those surrounding the unexpected death of reportedly healthy baby, the grief response is similar[326,327]. This should be reflected in local policy and pathways of care in order to minimise distress for, and optimally support the woman from diagnosis through delivery and the puerperium.

Clinical Practice

Every effort should be made to support parents in the decision-making process. Comprehensive bereavement support, as set out elsewhere in this guideline, should be provided regardless of the chosen pathway of care.

When a woman proceeds with a medical termination for fatal fetal anomaly, a care plan for labour and delivery should be discussed in advance, particularly for women at later gestations and all decisions and discussions pertaining to care should be clearly documented in the healthcare record.

Prior to initiation of the delivery process a conversation should take place surrounding the option of antenatal feticide (if the pregnancy is >21^{+6} weeks gestation). Should a woman wish to proceed without feticide, a discussion should be had with the woman on what to expect with regard to fetal monitoring; intrapartum electronic fetal heart rate monitoring should not form part of the routine care plan for termination of pregnancy. The woman should be counselled on the possibility of an intrauterine fetal death during the first or second stage. Listening in for the presence of fetal heart activity once during the second stage may be helpful in further preparing the woman for what to expect following birth. This should be offered to the woman; however, she may wish to decline, and her decision should be respected.

Management of labour includes monitoring for complications associated with labour and birth and modifying treatment accordingly. The recommendations for analgesia in labour are the same as for women with uncomplicated pregnancies.

Women should receive the appropriate psychological support, depending on their needs, both antenatally and in the postnatal period.

As per the *Stillbirths Registration Act, 1994*[1], all stillbirths greater than 24 weeks gestation or 500g in weight must be registered. This also applies to termination of pregnancy. However, the parents may delegate this task to a relative or medical body.

While a termination for fatal fetal anomaly, by definition, should not require a mandated Coroner's post mortem examination, whether or not these births are to be reported to the Coroner at all will depend on the local jurisdiction and the local Coroner's direction. Maternity units should, therefore, be familiar with the policies of the local Coroner's office. Parent's may elect to proceed with a consented PME depending on the nature of the fetal anomaly, and this should be discussed both antenatally and following the birth.

Recommendations

104. Every effort should be made to support women/parents in the decision-making process when diagnosed with a fetal anomaly that may be fatal or life-limiting. Comprehensive bereavement support is essential regardless of the chosen pathway of care.

105. If a woman elects to proceed with a termination for fatal fetal anomaly and, should the pregnancy exceed 21+6 weeks, options surrounding feticide and intrapartum care should be discussed, with shared decision-making based on pregnancy-related factors and the circumstance of the termination. Intrapartum electronic fetal heart rate monitoring should not form part of the routine care plan for termination of pregnancy.

106. All stillborn infants delivered at ≥ 24+0 weeks or weighing ≥ 500g need to be registered in accordance with the Stillbirths Registration Act, 1994, regardless of whether the birth occurred in the context of a termination of pregnancy.

107. Decisions with regard to post mortem examination after termination of pregnancy for fetal anomaly should be discussed and documented in the woman's healthcare record.

Clinical Question 2.27: **What is the appropriate care for a woman that experiences an intrauterine death or stillbirth in the context of a multiple pregnancy?**

Evidence Statement

Multiple pregnancies have a greater rate of IUFD and stillbirth than singleton pregnancies[110-112]. Furthermore, the death of one twin or triplet (selective or sIUFD) increases the risk of death in the remaining fetus or fetuses[112]. The reasons for this are varied and a thorough exploration of the complications of multiple pregnancy is beyond the scope of this Guideline. The magnitude and nature of these risks, however, depend on the chorionicity and the gestation of the pregnancy at the time of fetal demise[112].

In MCDA pregnancies, the most common pathology associated with sIUFD is twin-to-twin transfusion syndrome (TTTS)[328]. In MCDA pregnancies that have been complicated by sIUFD, the rate of co-twin fetal demise has been quoted as 41% and the risk may be higher still should sIUFD occur prior to 28 weeks[329]. Should the co-twin survive, the rate of abnormal cerebral findings on MRI with potential neurological sequelae has been calculated to be between 20 and 40%[329]. The risk for DCDA pregnancies in the event of sIUFD, while lower than for MCDA pregnancies, remains significant with a 23% rate of co-twin demise[329].

The above figures are based on the findings from the most up-to-date meta-analysis on the prognosis of co-twins following sIUFD[329]. A small, but more recent, prospective study based on data from MCDA pregnancies in the UK would suggest that the rate of co-twin demise following sIUFD at >14 weeks, is actually nearer to 14%[328]. While the data are not directly comparable, this may reflect advances in antenatal care and the management of complicated twin pregnancies.

Selective IUFD has also been associated with an elevated rate of preterm birth (both spontaneous and iatrogenic), neurodevelopmental comorbidity and neonatal death[328,329]. Recent data from the UK suggests inconsistency, however, when it comes to both antenatal and postnatal screening for the presence of CNS pathology in the surviving twin and structured guidance in this area is lacking[328].

It is important to remember that the death of a baby is a devastating event regardless of whether the death is that of a singleton fetus or one or more fetuses within a multiple pregnancy[330,331]. A qualitative study among Irish parents who received an antenatal diagnosis of a selective fatal fetal anomaly in twin pregnancies highlighted that parents were wholly unprepared for such a diagnosis and the support requirements of parents who received such a diagnosis differed substantially from those carrying a singleton pregnancy[330]. Emotional conflict was a recurrent theme when interviewing parents who experienced the selective death of one twin; while a parent might be in the process of grieving for one twin, this process was complicated by their feelings toward, and focus on the healthy twin, potentiating a state of emotional turmoil[330,332].

These findings are in keeping with several international studies on perinatal bereavement and loss in multiple pregnancy[331-333] and consolidate the concept that the psychological needs of these parents are complex. Acknowledgement of twinship and the continued identification of the surviving infant as one of a set of twins after the death of their sibling is vitally important to parents[332]. Studies have repeatedly shown that, while parents may find consolation in the birth of a healthy baby, this does not diminish their grief for the lost sibling[330,331].

Clinical Practice

Multiple pregnancies should be triaged to the *specialised care pathway* at booking and should be managed by a consultant with the appropriate expertise in the management of such pregnancies. The level of risk ascribed to a multiple pregnancy and the level of experience required to manage this risk will depend on the number of fetuses and the chorionicity.

In the event of selective IUFD, it is important that parents are counselled sufficiently on the risks to the living fetus(es) and appropriate specialist input should be provided. Ongoing management will depend on several factors including the nature of the sIUFD, the number of fetuses, the chorionicity, the gestation at the point of demise as well as other maternal, fetal and pregnancy-related factors.

A holistic approach must be taken when managing antenatal or intrapartum stillbirth within a multiple pregnancy. It is important that healthcare professionals acknowledge the complexity of the grief reaction when multiple pregnancies are selectively complicated, and recognise the sense of loss that accompanies adverse outcomes such as selective stillbirth. The psychological needs of bereaved parents should never be minimised, regardless of whether there is a good outcome for the remaining fetus or fetuses, and an appropriate level of support should be provided.

Recommendations

108. In the event of selective intrauterine fetal death, a multiple pregnancy should be referred to an Obstetrician with appropriate expertise in the management of complicated twin and multiple pregnancies.

109. Women/parents should be counselled on the risk to the remaining fetus(es) in the event of selective intrauterine fetal death.

110. While the process of grief in a multiple pregnancy may be complicated by mixed emotions, the grief reaction needs to be recognised, and women/parents should be afforded the appropriate supports in the antenatal, intrapartum and postnatal period.

Clinical Question 2.28: **What is the appropriate care for a woman who experiences a stillbirth at the threshold of viability?**

Evidence Statement

In Ireland stillbirth is defined by the *Stillbirths Registration Act, 1994* as a child born weighing 500 grams or more or having a gestational age of 24 weeks or more who shows no signs of life[1]. Stillbirth definitions worldwide are derived from determined thresholds of viability[334], which are naturally dependent on regional resourcing and access to advanced neonatal care. Therefore, in an attempt to standardise data collection the World Health Organisation recommends that countries include all infants weighing ≥500g in their national statistics for stillbirth. However, for international comparison a threshold of 1000g and/or 28 weeks is recommended[335].

With advances in neonatal care, the threshold of viability has been reducing steadily over the last 25 years[334] and current Irish neonatal guidance advocates for establishing the threshold of viability for the initiation of resuscitative measures at 23^{+0} [336]. From 2015 to 2017, the survival-to-discharge rate in the Republic of Ireland for infants born at 23 weeks was 30-34% and for 24 weeks ranged from

51-65%[337]. A recent review of the data spanning the last ten to fifteen years quoted a varied range of survival in HMI countries at 23 weeks (25-65%) with >50% survival at 24 weeks for almost 70% of the countries studied[334]. While survival at 23 weeks in Ireland is improving, mortality and morbidity remain high, with two thirds of infants either stillborn or dying in the neonatal period and surviving infants faced with significant rates of both short and long-term morbidity[336]. Delivery at a site that is co-located with neonatal intensive care services afford the greatest chance of a positive outcome[336].

It is worth noting that some countries have set the threshold of intervention at 22 weeks. In the previously mentioned review Japan, Sweden, and Norway had the highest survival rates for liveborn infants at 22 weeks (37%, 30% and 18% respectively) while Ireland, France, Spain, and Switzerland reported no survival at 22 weeks[334]. In their most recent guidance on the management of extreme premature birth, the British Association of Perinatal Medicine have advised that resuscitation may be provided to an infant born at ≥22^{+0}, after careful consideration of the clinical context[338].

While the UK continues to define stillbirth based on gestational age (24^{+0}), most jurisdictions use a combination of both gestation and weight based criteria and worldwide cut-offs demonstrate remarkable variation with ranges spanning 12 to 28 weeks gestation and 350-1000g[334]. This lack of international consensus, can, quite understandably, lead to problems when it comes to the design and interpretation of comparative studies. There are also real-world psychological implications for bereaved parents and practical consequences to consider such as parental rights and access to maternity leave[334]. For these reasons and, based on current trends in survival rates for very low birth weight infants, support has been voiced for altering the legal definition of stillbirth in Ireland to include infants born ≥22 weeks and/or 400g[334], a standard that can be more readily aligned with international views such as those of the EURO-Peristat project[339].

Clinical Practice

Where birth at such an early gestation is anticipated, it is important that, where possible, the parents are seen and counselled by the neonatology team in advance of the birth so that an appropriate plan can be put in place should the infant be born alive.

If the woman is not being cared for in a facility with access to neonatal intensive care services, arrangements should be made, where possible and practical, to transfer the woman in advance of the birth. Delivery at a site that is co-located with a NICU allows for appropriate antenatal counselling and an appropriate level of expertise for the neonate.

Regardless of the location of birth, perinatal mortality rates including stillbirth, remain high. It is important that parents receive the appropriate counselling and psychological support before, during and after the birth.

As preterm birth (both spontaneous and iatrogenic) can be associated with maternal or pregnancy-related morbidity such as haemorrhage, sepsis, pre-eclampsia etc, it is important that an assessment of the physical needs of the woman is made, and appropriate treatment instigated if indicated.

When a stillbirth occurs, it is important that accurate dates and measurements are used as, in Ireland, definitions surrounding stillbirth will determine whether the death is notifiable to the Coroner's office and may influence parental supports such as the provision of maternity leave.

Recommendations

111. If delivery at the threshold of viability (23 weeks) is anticipated, every effort should be made to provide counselling to the expectant woman/parents in advance of the delivery by a specialist in neonatology.
112. In the event of birth at the threshold of viability, women/parents should receive the appropriate psychological support before, during and after birth.
113. Every effort should be made to ensure that accurate calculations of both birth weight and gestational age at the time of birth are used when documenting a stillbirth.

Clinical Question 2.29: **What special considerations are there in the care of a woman who experiences an intrapartum death?**

Evidence Statement

An intrapartum death (IPD) is often an unexpected and devastating event both for the parents and the healthcare providers[340]. An intrapartum death, by the nature of it, occurs at a time of intense physical and emotional stress for the woman and may occur in the setting of an obstetric emergency such as antepartum haemorrhage, suspected intrapartum fetal distress, infection, malpresentation or shoulder dystocia[340] – circumstances that can lead to asphyxia, trauma or sepsis in the infant. The mode of delivery may be vaginal (both spontaneous and assisted) or caesarean in nature. Regardless of the mode of delivery, obstetric emergencies come with an inherent risk to the woman and significant physical trauma may accompany the psychological trauma associated with the birth of a stillborn infant.

The WHO stipulates that, where women receive good care during childbirth, intrapartum stillbirth should represent <10% of stillbirth due to unexpected severe complications[335]. 5.7% of stillbirths (N=26) that occurred in the Republic of Ireland in 2018 and 2019 were classified as intrapartum[3]. Major congenital anomaly, which can lead to expected stillbirth in certain cases, was determined to be the cause for 54% of these and the second most common cause of death was intrauterine infection associated with chorioamnionitis (11.5%)[3].

It has been suggested that intrapartum deaths, in non-anomalous babies, can be largely circumvented by the provision of high quality intrapartum care[341]. Strategies, such as *Each Baby Counts* in the UK, have consistently reported that, in up to 75% cases, different care may have made a difference to outcome[6]. This highlights the importance of timely process review and root cause analysis in the event of an intrapartum death in order to learn from mistakes that may have been made or missed opportunities in care. As previous referenced, the three most commonly reported themes when identifying deficits in care were; risk recognition and management, education and training deficits and individual human factors including lack of situational awareness, lack of leadership, stress and fatigue[6] and strategies on both an individual and systems level are necessary in order to minimise the rate of intrapartum fetal death.

Intrapartum fetal death can have a profoundly negative psychological impact on the Obstetrician involved in the care of the woman or the birth of the infant[322]. A recent Irish qualitative study exploring the reactions of healthcare professionals to intrapartum death revealed that a large proportion of healthcare professionals in obstetrics (80%) had involvement with at least one IPD in the course of their professional career[322]. 82% reported having received no training in dealing with IPD and only 11% reported that they were offered support in the form of a debriefing session[322].

Clinical Practice

Detailed documentation is important for all intrapartum deaths so that factors contributing to the fetal death can be delineated and explored. This is important on a personal, procedural and infrastructural level. Care following an intrapartum death should be consultant-led with appropriate arrangements made for follow-up post discharge.

As intrapartum death may be associated with maternal complications of labour and birth, it is vitally important that a full assessment of the woman is made in the acute setting. The medical and psychological needs of the woman must be met, both immediately following birth, and during the postnatal period.

Staff involved in the care of women who have experienced an intrapartum death will also need to be debriefed and provided with the appropriate support depending on the nature and context of the fetal death, and their level of involvement.

Maternity units should ensure that all staff involved in the provision of intrapartum care have received the appropriate training, and that resources within the unit are sufficient to meet the demands of that care.

Occasionally, an intrapartum death is anticipated as a potential outcome, for example in the context of an antenatal diagnosis of a fatal fetal anomaly. Often parents will have been counselled to expect such an outcome and will have been afforded the appropriate psychological support antenatally. This support must continue throughout the process of labour and into the postnatal period. While fetal monitoring does not normally feature as part of the intrapartum care plan for these women, the maternal risks associated with labour are still present and the woman must be monitored and treated in keeping with best practice for the management of labour.

As with all cases of stillbirth, the Coroner must be notified. An intrapartum death should also be reported to the Serious Incident Management Team (SIMT) within the maternity unit who will review the particulars of the incident and determine whether any immediate or long-term action needs to be taken in response to the incident. Further details on the internal and external processes for the review of perinatal death, including IPD, are discussed elsewhere in this Guideline.

Recommendations

114. Healthcare providers must ensure that both the physical and psychological needs of the woman are met in the context of an intrapartum death or stillbirth, particularly as the delivery may be complicated by an obstetric emergency that may also compromise the wellbeing of the woman.

115. Detailed documentation is important for all intrapartum deaths so that factors contributing to the death can be delineated and explored.

116. Care following an intrapartum death should be consultant-led with appropriate arrangements made for follow-up post discharge.

117. Staff involved in the care of a woman who has experienced an intrapartum death should be debriefed and provided with the appropriate supports.

118. All cases of intrapartum death should undergo a formal review process, including timely referral to the local Serious Incident Management Team (SIMT).

Section 5: Classification, Audit and Review

CLASSIFICATION AND AUDIT

Introduction

The accurate classification of intrauterine death and stillbirth is vitally important, not only as a diagnostic aid but also as a tool to inform practice and resource provision. No classification system is perfect, and standards are constantly evolving. However, international inconsistency persists which can lead to difficulty with comparing standards and outcomes on a local, regional and global level.

Clinical Question 2.30: **What is the process for recording data on intrauterine death and stillbirth in Ireland?**

Evidence Statement

The following text is a brief, practical summary of the formal pathways that exist in Ireland for the registration and recording of intrauterine death and stillbirth. This information is up to date as of the date of issue of this Guideline. Additional information pertaining to these processes can be accessed by consulting the relevant government documents as referenced.

In Ireland, data is collected and recorded via the use of two notification forms, namely the Birth Notification Form and the Perinatal Death Notification Form.

Birth Notification Form

This form contains demographic data and details about antenatal care and birth. In the case of stillbirth, the sections on perinatal death and cause of death are completed. The National Perinatal Reporting System (NPRS) instruction manual[342] states that the cause of death on this form refers to the 'pathological condition, which, in the opinion of the Doctor in charge, made the greatest contribution to the death of the foetus or infant', rather than the underlying cause of death as is the practice generally. It is accepted that all investigations may not be available at the time that this form is completed.

Perinatal Death Notification Form

The Perinatal Death Notification Form is completed by a perinatal mortality data coordinator. It is a comprehensive, multi-page document used for the purpose of perinatal audit. This contrasts with the Birth Notification Form, which focuses on population and demographic data collection for national statistical analysis. Each maternity unit has a designated perinatal mortality data coordinator.

Information collected is dependent on the quality of the data recorded in the maternal and/or neonatal notes. Data sources include medical, midwifery and neonatology clinical records, as well as the results of investigations (including cytogenetics, placental histopathology and PME reports). A standardised notification datasheet is completed and submitted (either electronically or via paper format) to NPEC. The data is compiled and analysed each year as part of the annual national perinatal audit.

All data is validated directly with the individual maternity units. NPEC also undertakes extensive reconciliation of its perinatal mortality dataset with the NPRS from the Healthcare Pricing Office (HPO) to ensure completeness and accuracy of information. This consolidation with the NPRS is in response to recommendations by the Chief Medical Officer (CMO) and ensures that both agencies' datasets represent the most accurate record of perinatal mortality annually[343].

Additional specific considerations in the context of stillbirth include the following:

Data protection

Within each hospital access to the online NPEC database is restricted to the appointed hospital perinatal mortality data coordinators and clinical leads. The secure database is password-protected and is only accessible after installation of a security certificate unique to the perinatal mortality data coordinator's computer. Individual usernames and passwords are issued directly by NPEC. Within NPEC, all perinatal mortality data is maintained on a high-security server with access limited to the relevant NPEC personnel only[343].

Medical Certificate

A medical certificate should be completed by the medical practitioner who attends the birth or examines the baby. However, this is often not practical as the cause of death may not be evident at the time of birth. In most circumstances, the medical certificate is completed after the results of any post mortem and placental examinations are known, if performed. Should a Coronial PME be directed, or an inquest held, a medical certificate of stillbirth can only be issued once the Coroner has released the cause of death. The certificate is then provided to the mother or the father of the stillborn child.

Termination of pregnancy

Under section 11 of the *Health (Regulation of Termination of Pregnancy) Act 2018* a termination of pregnancy may be carried out if there is a condition affecting the fetus that is likely to lead to death of the fetus either before or within 28 days of birth[118,344]. If an infant is stillborn at $\geq 24^{+0}$, or if the infant weighs ≥500g, a Birth Notification Form is required to record the birth on the Register of Births. The cause of death should be stated as that directly leading to the death, in addition to the causes or conditions which gave rise to this. It does not mean the mode of dying; it means the disease which caused the death[118]. A Medical Certificate is also required and should be provided to the parents by the medical practitioner (often an Obstetrician) who attended the birth or examined the baby after birth.

Clinical Practice

Birth Notification Form

A Birth Notification Form is completed for every baby born in Ireland as part of the National Perinatal Reporting System (NPRS). It is usually completed by a dedicated member of staff tasked with the registration of births. In the case of a home birth the health care professional who attended the birth will complete the form with the parents.

There are four parts to the Birth Notification Form:

1. White Copy (to be given to the Registrar of Births)
2. Yellow copy (to be given to the Director of Public Health and Medicine)
3. Green Copy (to be given to the National Perinatal Reporting System (NPRS), Healthcare Pricing Office (HPO)
4. Pink Copy (for the hospital's own records).

The first copy (white copy) is sent to the Registrar of Births as soon as possible, with the second and third copies sent no later than eight days post-birth.

Perinatal Death Notification Form

Every maternity unit should have a perinatal mortality data coordinator. It is the responsibility of the perinatal mortality data coordinator to complete the Perinatal Death Notification Form and submit it to NPEC. In the case of stillbirth, data sources include the woman's antenatal healthcare record and the results of any investigations that may have been sent.

It is important that data submitted is correct in order to facilitate accurate local, regional and national statistics. It is vitally important that notes entered into the healthcare record at the time of the stillbirth are factual and easy to interpret.

A medical certificate of stillbirth will need to be issued to the parents; however, it may not be possible to issue this certificate at the time of birth. The reason for this should be explained to parents and should form part of their bereavement and loss care plan.

Data protection is extremely important and all data pertaining to perinatal death should be password protected and appropriately stored.

In the case of a termination of pregnancy a BNF01 form will need to be filled out if the infant is ≥500g or ≥24^{+0} weeks gestation.

Recommendations

119. In the event of a stillbirth, two forms must be completed
- **The Birth Notification Form**
- **The Perinatal Death Notification Form**

120. In the event of a termination of pregnancy, a Birth Notification Form (BNF/01) must be completed if the gestation or birth weight exceed or are equal to 24+0 or 500g.

Clinical Question 2.31: **What is the current system for classifying intrauterine death and stillbirth in Ireland?**

Evidence Statement

The following text directly references the current classification system in use in Ireland while also providing a review of international systems for comparative purposes from the published literature.

The NPEC Classification System (2007) is the current system for classifying intrauterine death and stillbirth in Ireland[3]. Details are entered into Section 11 and 12 of the NPEC notification form. This form assigns a main cause of death as well as noting associated factors. This form, along with the associated reference manual for completion can be accessed at https://www.ucc.ie/en/npec/npec-clinical-audits/perinatalmortality/perinatalmortalityreportsandforms/.

The NPEC classification system relies on detailed maternal and fetal data collected using specific categories. The principal cause of death is assigned with reference to this comprehensive history, as well as the investigations including post mortem examination and placental pathology (if performed). The NPEC notification dataset was based on the validated Centre for Maternal and Child Enquiries (CMACE) Perinatal Death Notification Form and was implemented nationally in 2011.

Accurate classification forms the cornerstone of prevention. It allows for useful lessons to be learned and informs clinical practice, public health policy and research in addition to providing accurate information to the parents.

Many different systems are used worldwide[19]. There is a lack of standardisation between, and even within countries; the International Stillbirth Alliance Collaborative for Improving Classification of Perinatal Deaths reported 81 documented classification systems for perinatal deaths[19]. Historically, systems such as the Wigglesworth[345] and Aberdeen[346] classification systems have been widely used, however, these are often considered sub-optimal given the large proportion of stillbirths which are attributed to non-specific or unexplained causes[19,347]. The lack of information gained limits the lessons that could be learned, inhibits the identification of public health interventions and may impact on the counselling of bereaved parents[348]. Similarly, the ICD-10 for perinatal mortality (ICD-PM) recommended by the World Health Organisation, has limitations as it uses rules based only on death certificate data[19]. To better elucidate risk factors associated with perinatal death, audit tools would, ideally, capture information on antecedent maternal, infant, and clinical conditions.

Over ten years ago, the RCOG Green-top Guideline on stillbirth cited investigating the optimal system for classification of stillbirth as a key priority[152]. More recently, the ACOG/SMFM consensus statement on the management of stillbirth acknowledged the importance of classification systems, but did not recommend one specific system over another[176].

In an attempt to standardise the reporting of stillbirth on a global scale, a system of classification is currently under development through the International Stillbirth Alliance (ISA) and is modelled on some of the top performing international systems in active use. This classification system, once available, will hopefully tackle of the obstacles that have been encountered in the past, and improve both the consistency and accuracy of classifying and documenting the cause of fetal death.

Clinical Practice

The National Perinatal Epidemiology Centre's classification system (2007) for stillbirth is the current system for classifying intrauterine death and stillbirth in Ireland. All stillbirths should be reported to NPEC using their standardised notification form.

Recommendations

121. The National Perinatal Epidemiology Centre (NPEC) classification system (2007) is the current system for classifying stillbirth in Ireland. All stillbirths should be reported to NPEC using their standardised notification form. It is important that accurate information is used when recording information on the details of a stillbirth.

Clinical Question 2.32: **What is the role of audit in maintaining and improving national data and standards in intrauterine death and stillbirth?**

Evidence Statement

The following text is based on the opinion of the Guideline Development Group and is in keeping with international and national expert consensus.

Perinatal audit is crucial in maintaining and improving standards[349]. The core function is to improve the care of women and babies through the provision of key epidemiological data and the monitoring of adverse perinatal outcomes. By identifying deficiencies or suboptimal care, audit can lead to recommendations that ultimately improve the quality of the service provided. More broadly, it informs public and economic policy-makers, the research agenda, and facilitates international comparison and bench-marking[349].

The Lancet and BJOG stillbirth series in 2016[9-11] highlighted the importance of perinatal audit and advocated strongly for its use. Internationally there has been evidence of a reduction in perinatal mortality in countries through the use of perinatal audit and reivew[349]; in New Zealand, stillbirth rates at term have declined over the seven years since a system of national perinatal audit was introduced[177]. By comparison, in Ireland the overall rate of perinatal mortality has remained relatively flat for the last decade[3]. Nonetheless, perinatal audit has had a positive impact in progressing clinical services in Ireland, both locally and nationally. Examples of this include the development of perinatal pathology services, the provision of bereavement midwives across all units and improved nationwide access to ultrasound[325]. The datasets provided by the process of national audit are vital for economic evaluation and to encourage further investment and improvement within the health service.

While discussing perinatal audit, it is also important to mention the role of local perinatal mortality review. This process involves a multidisciplinary team of local clinicians and allied healthcare professionals in addition to (ideally) an external reviewer to provide an element of external objectivity. The focus within these reviews is to constructively learn from mistakes while shifting from a culture of blame. A specific feature of the review process is that it should include communication with, and involvement of, the bereaved parents. In the UK a standardised perinatal mortality review tool has been designed to assist units in completing a structured, standardised and thorough review of individual cases of perinatal mortality. This review process is different to the national perinatal system of confidential enquiry (MBRRACE-UK). However, it is important that both are used as they fulfil different functions and roles in the investigation of perinatal death.

Clinical Practice

Data from all cases of stillbirth should be communicated to NPEC using the perinatal death notification form to allow for national audit of current trends in the rates and aetiology of stillbirth.

Local review of individual cases of stillbirth in the form of local or regional perinatal mortality review sessions should be available on a regular basis in each maternity service. Such meetings should form part of the structured weekly or monthly schedule with protected time allocated for staff to attend.

It is important that an ethos of psychological safety is promoted at these meetings, with room for open discussion, input and feedback. A culture of blame should be avoided as this will not be conducive to staff engagement or positive change.

Based on recommendations from perinatal mortality multidisciplinary meetings and SIMT review, local audit of practice should take place with a view to improving on the delivery of care and prevention of adverse outcomes. The process of individual case review is explored elsewhere in this Guideline.

Recommendations

122. Perinatal audit is crucial to maintaining and improving standards. While NPEC collates data for audit at a national level, individual maternity units, and hospital groups, should have structures in place for performing perinatal audit.

LEGAL REQUIREMENTS

Introduction

With regard to stillbirth in Ireland there are clearly defined definitions and legal protocols. It is important that all healthcare professionals that are charged with the care of bereaved parents understand, and are familiar with, these definitions and protocols in order to avoid any unnecessary delays, or errors, that may impact on the parental experience or the delivery of care.

Clinical Question 2.33: **What is the process of registration of stillbirth in Ireland?**

Evidence Statement

In Ireland there are several key pieces of legislation that pertain to the registration, investigation and certification of intrauterine fetal death and stillbirth: the *Civil Registration Act 2004*[350], the *Stillbirths Registration Act, 1994*[1] and the *Coroners (Amendment) Act 2019*[229]. The following text gives a brief summary of the most relevant features of these legal documents to assist healthcare professionals in their dealings with bereaved parents. For more detailed information on the content of these legal documents, the source texts should be consulted.

All stillbirths occurring in Ireland since 1 January 1995 should be registered within 12 months of the birth. It is not mandatory for the parents themselves to register the stillbirth. While a Birth Notification Form must be completed for all stillborn infants of greater than ≥24 weeks or weighing ≥500 grams[1] to inform NPRS data, parents are not obliged to attend a civil registration office to formally register the stillbirth. However, if a stillbirth is not registered within 12 months, the hospital, Midwife or medical practitioner who attended the birth may be asked to register it.

Registration requires providing the particulars laid out within the schedule of the Stillbirths Act[1] along with a medical certificate to the Registrar. The parent(s) must sign the register in the presence of the Registrar at their local Civil Registration Office; this is voluntary and there is no fee. As per the *Stillbirth Registration Act 1994*, the 'medical practitioner who attends a stillbirth or examines the child shall provide the required medical certificate to the mother or the father of the stillborn child'. In the event of a consented PME, the certificate is only issued once the results of the PME are available. In the event of a Coronial PME or inquest, the stillbirth may only be registered once the cause of death has been released by the Coroner's office, and a certificate issued.

The Birth Notification Form (BNF/01) is a statutory form sent to inform the Registrar of Births of all births, including stillbirth. This is different to formal registration by the parents. The white copy of this form is sent within 24 hours of birth. There is an option to mark all submitted documentation as sensitive if a stillbirth has occurred; the Civil Registration System automatically generates an information and reminder letter for birth registration to the parents on the 10th and 35th day postnatally, and flagging a case as sensitive prevents these letters being sent.

The General Registration Office sends information regarding registered stillbirths via an encrypted file to the Central Statistics Office (CSO) to compile an annual national infant mortality dataset. All stillbirths registered on or after 1, January 2007 are classified according to The World Health Organisation's International Classification of Diseases, Version 10 (ICD-10)[351]. The statistics generated by the CSO are often less than those noted by the NPRS as not all parents choose to register their stillborn babies. The NPRS figures are based on the returned Birth Notification Forms.

If a stillbirth occurred prior to 1 January 1995, specific evidence must be produced at the point of registration. Such written evidence may include an authoritative statement from a hospital, a nursing centre or a Midwife stating the date and place of birth, the weight and/or the gestational age of the stillborn child. The Registrar may accept, subject to the approval from the Superintendent Registrar, other forms of evidence[352]

Clinical Practice

Relevant healthcare professionals should be familiar with the legal requirements with regard to registration and notification following a stillbirth as delineated in the evidence statement. Each maternity unit should have a dedicated member of staff whose role it is to navigate the process of birth registration and liaise with the parents. With regard to counselling parents in the context of stillbirth, this role may be shared by the bereavement team involved in the woman's care.

Recommendations

123. Registration of a stillborn infant in a civil registration centre is not mandatory. This can be organised by the woman/parents, if they wish to do so, once a certificate with the cause of death has been issued.

Clinical Question 2.34: **What is the role of the Coroner in the investigation of stillbirth in Ireland?**

Evidence Statement

The Coroner is an independent public official (a barrister, solicitor or medical practitioner[230]) whose role it is to inquire into the cause of reportable deaths. In simple terms, they seek to establish the "who, when, where and how" of an unexplained death. The *Coroners (Amendment) Act 2019*[229] expanded on the powers of the Coroner including the range of reportable deaths. Whether the cause is known or unknown, all cases of stillbirth must be reported to the district Coroner, who may then determine the course of the investigate process based on the clinical details of the case.

The Coroner is an independent inquirer whose aim is to determine the cause of death, thus facilitating the issuance of a stillbirth (death) certificate. They do not consider civil or criminal liability; they simply establish the facts. In some cases, they may need to direct a post mortem examination, and if unable

to ascertain the cause of death based on this alone, an inquest may be held. If a PME is directed by the Coroner, parental consent is not legally required. In the case of a stillbirth, the Coroner will usually consult with a family member, before directing an inquest.

Under the *Coroners (Amendment) Act, 2019*, the Coroner will provide a copy of the PME report (on request) to a family member of the deceased[229].

Under the Civil Registration Act 2004 (Section 28, subsection 7) the Coroner will notify the district registrar once they have concluded the inquiry and established a cause of death. This allows the parents to register the stillbirth[350].

Clinical Practice

All cases of stillbirth must be reported to the Coroner by a consultant Obstetrician involved in the woman's care or a senior registrar with sufficient experience and knowledge of the case. Based on the clinical details provided, the Coroner will then determine the level and nature of inquiry required.

Recommendations

124. **Women/parents should be informed that the Coroner's role is to inquire into the cause of reportable deaths; the Coroner does not consider civil or criminal liability – they simply establish the "who, when, where and how" of the death.**
125. **Women/parents should be informed that, in the event of a stillbirth, the Coroner will usually consult with a family member before directing an inquest.**
126. **Women/parents should be informed that the Coroner will notify the district registrar once they have concluded the inquiry and have established a cause of death. This will permit the parents to register the stillbirth should they so wish.**

MULTIDISCIPLINARY CARE AND CASE REVIEW

Introduction

The needs of bereaved parents are complex and must be evaluated on both a physical and emotional level. It is of vital importance that a multidisciplinary approach is taken in order to optimise the delivery of care and address these needs.

Clinical Question 2.35: **How do we provide appropriate multidisciplinary care to parents who experience a stillbirth?**

Evidence Statement

The following guidance is based primarily on international best practice and expert opinion and is in keeping with the current standards in bereavement care and the management of stillbirth[14].

Multidisciplinary care is necessary for parents who experience a stillbirth. Each member of the team should work together to provide individualised care that is tailored to each parent's specific needs[353]. Within the maternity setting the multidisciplinary team (MDT) may include Sonographers, Fetal Medicine Consultants, Obstetricians, Neonatologists, Perinatal Pathologists, Anaesthetists, Midwives, Nurses,

Palliative and Bereavement Care Specialists, Perinatal Mental Health Specialist, Allied Bereavement Care Staff including Chaplains, Medical Social Workers and Clinical Midwife Specialists in addition to administrative, laboratory and mortuary staff[14]. The degree to which each element of the MDT contributes to care and the women's experience will depend on her specific needs. To provide effective multidisciplinary bereavement care following a stillbirth it is necessary that all members of the multidisciplinary team have the time, training and support to provide the necessary care[169].

Having structured, multidisciplinary evidence-based pathways for dealing with bereaved parents is essential to optimise and streamline the delivery of care[14]. Communication is important, both internally within the MDT and between the MDT and the parents[14,169]. It is important that care is devoid of ambiguity and that the MDT communicates a common message in order to avoid confusion which can lead to parental distress and mistrust.

Clinical Practice

Every maternity unit should be able to provide multidisciplinary care that is appropriate to the woman's needs. Specifically, every maternity unit should have a functioning multidisciplinary bereavement team.

Members of the MDT should consult each other's notes within the healthcare record and ensure that a clear and common message is being communicated to parents. Healthcare providers should ensure that bereaved parents receive sensitive, appropriate and accessible information about what has happened when their baby has died, and what to expect going forward. Parents should understand the role of each member of the MDT in their care pathway.

The multidisciplinary team must ensure that the bereavement care provided is suitable for the needs and choices of the bereaved parents and their families. The MDT should advocate for personal autonomy and should allow the parents to take an active role in the decision-making process.

Recommendations

127. All bereaved women/parents should have access to multidisciplinary bereavement care. While the majority of services will be available within the treating hospital/unit, access to the extended multidisciplinary team should be available within the hospital group.
128. The multidisciplinary team (MDT) should, ideally, comprise the following:
    - Consultant Obstetrician
    - Neonatologist
    - Perinatal Pathologist
    - Anaesthetist
    - Midwifery and Nursing staff
    - Palliative and bereavement care specialist
    - Perinatal mental health specialist
    - Bereavement and loss CMS/CNS
    - Chaplaincy/pastoral care team
    - Social work team
    - Support staff, including administrative staff, medical scientists, laboratory technicians and mortuary staff
129. Good communication is important in order to optimise the parental experience. Effective communication should take place at both a bedside level and an interdisciplinary level within the MDT.
130. Multidisciplinary care should be individualised with parental autonomy at the forefront.

Clinical Question 2.36: **What is the process for review of individual cases of intrauterine death and stillbirth at the hospital level and what is the role of the perinatal mortality meeting?**

Evidence Statement

Process for the review of individual cases

It is essential that the review process following intrauterine death and stillbirth includes the members of the multidisciplinary team. This team comprises the many professionals that provide care for women, babies and their families. Failure to examine perinatal deaths restricts the ability to learn from experience and identify improvements in care that may mitigate the risk of future events[349]. There are different types of review that must be considered following a stillbirth;

Review by the hospital's Serious Incident Management Team

The role of the Serious Incident Management Team (SIMT) is to oversee the review and management of all serious incidents that occur within the hospital or service[354]. The HSE published a Framework for Incident Management in 2020 that gives clear guidance as to the steps and personnel involved in investigating serious incidents reported to the SIMT. All category 1 incidents must be referred to the SIMT[354].

Coronial investigation and inquest

All stillbirths must be reported to the Coroner who may decide whether or not to direct a Coronial post mortem examination based on the particulars of the case. The Coroner may also decide to hold a coronial inquest to establish the facts surrounding the intrauterine death or stillbirth[229]

National Perinatal Epidemiology Centre annual audit

NPEC carries out an annual national clinical audit of perinatal mortality. The purpose of this audit is to review all perinatal deaths, to identify quality improvement initiatives and make recommendations for the improvement of care for women and babies in Ireland[3].

Perinatal mortality multidisciplinary meeting (PM MDM)

This review meeting is organised on a local or regional level by individual hospitals and hospital groups[14]. Ideally all of the staff who were involved in the woman's care should attend the meeting[349]. This includes the treating Obstetrician(s), the Perinatal Pathologist who conducted the post mortem or placental examination, and any relevant healthcare professionals involved in the woman's care.

The aim of this meeting is to:

- Update the multidisciplinary team on the cause of the stillbirth
- Obtain the opinion of the MDT centred on peer-based discussion
- Discuss any alterations that could have been made to the woman's care or that may have affected outcome
- Plan care in the event of future pregnancies
- Provide an opportunity to educate the MDT on stillbirth, contributing factors and preventative measures.

It is essential that all staff that are, or may be, involved in the care of bereaved parents have the opportunity to attend perinatal mortality MDMs. A recent qualitative study examining the barriers that prevent clinical staff from engaging with the perinatal mortality meeting identified three main obstacles to participation including staffing levels and workload, meeting logistics and lack of communication[355]. Participation in multidisciplinary discussion is important to quality improvement as it promotes personal development, improved system performance and better maternal outcomes and maternity services should strive to ensure that staff have protected time to engage with this process.

Discussion should be well-managed and foster and environment of open discussion and psychological safety; the goal is not to criticise practice or assign blame but to identify areas for improvement and promote positive changes to the delivery of care[349].

It is important that the perinatal multidisciplinary meeting is conducted in a timely manner[14] in order to update the greater MDT and provide information to the parent(s) who may be anticipating the results and who may be looking to conceive again.

Clinical Practice

All cases of stillbirth should be referred to the Serious Incident Management Team within the maternity hospital/unit.

All maternity services should provide a regular perinatal mortality multidisciplinary team meeting for review of individual cases at a local level. This may be provided at the level of the maternity unit/hospital, or the wider hospital group and all cases of stillbirth should ultimately be discussed and reviewed. Each service should ensure that staff who wish to take part or should take part in the meeting are facilitated in their attendance. This may involve auditing identifiable barriers to engagement within an individual unit.

Systems should be in place for communication of the results of the PM MDM to the parents in an appropriate and timely manner. Ideally, results from the MDM should be relayed to the parents by the consultant who was charged with their care at the time of the perinatal death.

Recommendations

131. Every service should have access to a regular perinatal mortality multidisciplinary meeting. This may be arranged locally at a hospital level or on a larger scale within a hospital group.

132. Staff should be facilitated in their attendance of the PM MDM in order to optimise the potential for education, learning and peer discussion.

133. The PM MDM should discuss individual cases within a reasonable timeframe in order to provide information to bereaved women/parents, and to explore learning points to be had from review of the case, at both a local and regional level.

Section 6: Follow Up

POSTNATAL REVIEW

Introduction

The following section will describe the current literature relating to follow-up after stillbirth, future conception and pregnancy and make recommendations for care. Pregnancy following stillbirth can be a challenging time for women/parents. The grief of stillbirth changes women's/parents' perception of their imagined family and can influence decision-making and future family planning. The faith that pregnancy will have a positive outcome may be challenged and the knowledge that future pregnancies may carry a higher risk of a similar outcome can be a cause of concern and anxiety. As such the pregnancy will need to be managed by a service with access to the appropriate expertise and multidisciplinary care.

Clinical Question 2.37: **When should bereaved parents be seen in the postnatal period?**

Evidence Statement

The following guidance is based on reviews of primarily qualitative evidence and is largely derived from pre-existing standards on bereavement care and management of stillbirth[14].

It is important that the wishes of the parents are taken into account when arranging follow-up[152]. Ideally the results of all investigations should be available prior to this appointment[152]. The timing of follow up is debated in the literature and there is no evidence to indicate one practice over another[152]. A recent literature review assessing the evidence for hospital-based interventions following miscarriage has suggested that early follow-up, one to six weeks following the event, may mitigate the subsequent development of more serious psychological sequelae for the grieving parents[356].

In the event of a post mortem examination, the Irish standards for bereavement care suggest three months as an appropriate first follow-up in order to allow time for the results of the PME to have returned[14]. Results from a Coronial PME, particularly if the case is assigned to inquest, can take a variable and often greater amount of time to return and parents should be made aware of this[14].

Clinical Practice

A follow-up appointment with the treating consultant Obstetrician should be arranged for the bereaved parents following an intrauterine death or stillbirth. Ideally this should be the consultant charged with the care of the woman at the time of the stillbirth. In units where there is a dedicated pregnancy and perinatal loss service, this role may be taken on by the consultant that oversees this service.

Follow-up should be arranged in a timely manner to minimise anxiety and provide information to parents. A balance must be struck; while it would be ideal to conduct a review with parents when the results of all of the relevant investigations have returned, an interim visit may need to be arranged for a provisional discussion of the circumstances surrounding the stillbirth and a review of the available results. This is particularly relevant for cases that have been directed to Coronial inquest.

The *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death* recommend follow-up at 3 months, however, as stated above, intervals should be individualised based on the clinical context and the needs of the parents. The wishes of the woman/parents should be considered at all times.

Recommendations

134. Follow-up should be arranged with women/parents who have experienced a stillbirth within an appropriate timeframe.
135. The preferences of women/parents should be considered when organising follow-up.
136. The timing of follow-up may depend on the circumstances surrounding the stillbirth and the nature of the investigations such as PME. Should some results be delayed, women/parents should still be seen within at least 3 months of birth to discuss any provisional results and to explore the circumstances leading up to and surrounding birth.
137. The report from a Coronial-directed post mortem may take a variable and unpredictable amount of time and it is important that women/parents are made aware of this.

PREGNANCY AFTER STILLBIRTH

Introduction

The following text explores the current literature surrounding conception and pregnancy following a diagnosis of stillbirth. The evidence is primarily qualitative in nature, and the quality of the evidence is low to moderate. When counselling a woman/parent, it is important to consider the circumstances surrounding the loss as well as individual-level factors and parental wishes.

Clinical Question 2.38: **What are the implications for future conception and pregnancy planning?**

Evidence Statement

The World Health Organisation (WHO) recommends that women wait at least two years after a livebirth and at least six months after a miscarriage or induced abortion before conceiving again, while acknowledging that these recommendations were based on observational studies which may now be obsolete[357]. Several studies have reported conflicting results with some suggesting that both short interpregnancy intervals (IPI, <6 months) and long interpregnancy intervals (IPI, 18-24 months) have been associated with adverse pregnancy outcomes[358-360].

For long IPIs the evidence is somewhat stronger. A large international longitudinal cohort study of 5,521,211 births in Australia (1980-2016), Finland (1987-2017), Norway (1980-2016) and the United States (California, 1991-2012) found consistently elevated odds of adverse pregnancy outcomes (preterm birth and small-for-gestational-age) following long IPIs, with relative risk starting to rise at 24 months and peaking at >120 months[359]. It was not possible, however, to adjust for all confounders and variables such as advancing maternal age are intrinsically linked to increasing interpregnancy interval[359]. The effect of IPI on the rate of stillbirth was not specifically studied as an outcome.

With regard to short IPIs, a smaller retrospective cohort study of 14,452 births in women who had experienced a stillbirth in the previous pregnancy found that conception within 6 and 12 months of delivery was common, revealing that 63% of women conceived within 12 months of delivery[361]. Furthermore, they did not appear to be at increased risk of adverse outcomes, including stillbirth, in the subsequent pregnancy[361].

It is also worth noting that these studies did not control for mode of delivery. While large studies looking at interpregnancy interval after caesarean section are lacking, a retrospective cohort of 1768 maternities with one previous caesarean delivery quoted that the risk of uterine rupture in labour for interpregnancy intervals of 18, 18-23 and ≥24 months was 1.3%, 1.9% and 4.8% respectively[362].

Discussions regarding future pregnancy may begin before leaving the hospital following the delivery of a stillborn infant[363]. However, deciding on if, or when, to proceed with another pregnancy is a both a complex and very personal decision for parents. A small qualitative study based on interviews with eight couples who conceived subsequent to stillbirth shed light on some of the challenges that may be faced when embarking on this journey[364]. In heterosexual couples, gender emerged as a notable variable with women seen to be ready to proceed with another pregnancy sooner than their male counterparts; men wished to wait longer and this was suggested to be due to an ongoing desire to parent the deceased infant[364].

Parents whose babies died as a result of a fatal fetal anomaly, often wished to discuss the results of investigations such as post mortem examination and genetic testing prior to proceeding with another pregnancy, while parents whose babies died unexpectedly (unrelated to known fetal anomaly) were more likely to report earlier conception[364]. Psychological challenges associated with the process of conception were similar to those reported in studies on couples with a history of recurrent miscarriage and subfertility such as maternal feelings of inadequacy or of providing a suboptimal environment, and male pressure to perform sexually[364].

Dyer *et al*. in their 2019 systematic review of 15 qualitative studies found that healthcare professionals have a significant role to play with regard to supporting women and couples in deciding on, and planning for, subsequent pregnancy after stillbirth. However, they acknowledged that further research is needed in this area to address the specific individual and couple supports required [365].

Clinical Practice

Women should be advised that, while there is some evidence that a short pregnancy interval (<6 months) may be associated with an increased risk of spontaneous preterm birth, there is no evidence to suggest an association with other adverse pregnancy outcomes.

Clinical recommendations for interpregnancy interval should consider the woman's health status, age, fertility, desired family size and child spacing, past obstetric history including mode of delivery and psychosocial readiness to conceive.

Women should be advised that planning for a subsequent pregnancy can be emotionally challenging, and they should be encouraged to make the decision that is right for them. The appropriate level of multidisciplinary bereavement support should be provided, and this support should be tailored to the woman's/parents' needs.

Where there also exists a history of subfertility, referral to or liaison with the appropriate specialists in subfertility may be indicated.

Recommendations

138. Pregnancies after a stillbirth are at increased risk of a subsequent stillbirth; however, women/parents can be reassured the risk does not appear to be affected by the interpregnancy interval.
139. Clinical recommendations for interpregnancy interval should consider the woman's health status, age, fertility, desired family size and child spacing, past obstetric history including mode of delivery and psychosocial readiness to conceive.
140. Following a stillbirth, discussions surrounding future conception should form part of bereavement care pathways.

Clinical Question 2.39: **What considerations need to be had in the management of pregnancy following stillbirth?**

Evidence Statement

There is a lack of strong evidence to guide management of pregnancies following stillbirth and there is subsequently a wide variation in clinical practice. The following guidance explores some of the existing evidence and attempts to provide a platform for the standardisation of care.

Currently there is a dearth of quality research to inform care in pregnancy after stillbirth, despite the wealth of research that demonstrates the challenges faced by women, parents and families during subsequent pregnancies[366]. A recent web based survey of 79 global stakeholders identified four interventions to focus on for subsequent pregnancies: (1) medical therapies for placental dysfunction (e.g., antiplatelet agents); (2) additional antenatal fetal surveillance (e.g., ultrasound scans); (3) early planned birth from 37 weeks; and (4) different forms of psychosocial support for parents and families[367].

One of the biggest risk factors for stillbirth is a history of previous stillbirth, a recurrence risk of two to tenfold the background rate[32]. Pregnancy after stillbirth is associated with increased risk of additional adverse outcomes including preterm birth, low birth weight, and placental abruption[368]. Due to this fact, intervention in pregnancy subsequent to stillbirth is higher; a recent Irish cohort study of 145 cases reported that pregnancy after stillbirth was associated with increased surveillance and intervention[369]. The women in this study had higher rates of caesarean birth, induction of labour, and preterm birth when compared to the general multiparous population[1]. The cause and classification of the index stillbirth may determine the risk of stillbirth recurrence in conjunction with other maternal, pregnancy-related and fetal risk factors such as lower socioeconomic status, advanced maternal age, smoking, BMI, hypertension, pre-eclampsia and fetal growth restriction to name a few[70,370,371]

Pharmacological treatments deemed to be safe in pregnancy may be given to optimise placental function including low-dose aspirin[372].

Serial ultrasounds are recommended to screen for the presence of small-for-gestational-age fetuses and fetal growth restriction[373]. Additional investigations, including uterine artery Doppler, may be beneficial in screening this population.

Timing of birth is a challenging issue for parents and clinicians. Parents may be eager to conclude the pregnancy while the infant is alive and will be anxiously awaiting the birth of a live baby[374]. Studies have demonstrated the tendency of Obstetricians to deliver women early (often aiming for 37 weeks) due to a multitude of factors including the unknown risk to the fetus of continuing with the pregnancy and aversion of parental anguish, however, strong evidence to support this strategy is lacking[369,375].

Pregnancy after loss is a very stressful time for parents. Feelings of anxiety, worry, grief and increased health service utilisation all feature as part of the experience of pregnancy subsequent to stillbirth[376,377]. It has been recognised that there is a lack of research on psychosocial interventions in pregnancy after loss, and further study of this aspect of care would be useful.

Parents have reported benefits from being cared for in dedicated 'pregnancy after loss' services with continuity of carer and access to staff with expertise in bereavement care[377]. Several studies in high-income settings reported that a specialised pathway of care was greatly valued by parents in subsequent pregnancies[378,379]. In addition to continuity of carer, studies on women and parents evaluating specialised services for women who have experienced a stillbirth in the UK and Australia have reported on the value of access to additional psychosocial support structures such as dedicated Midwife specialists, useful contact information, increased access to cardiotocography and ultrasound, and dedicated clinics with antenatal classes separate to the general maternity population[1,2].

Clinical Practice

Previous stillbirth is one of the most important risk factors for subsequent stillbirth. Women/parents should be cared for within the specialist care pathway by a specialist multidisciplinary team led by an experienced clinician with, where possible, an interest in pregnancy after stillbirth.

Women should be booked early in their subsequent pregnancy in order to agree a plan of care and provide reassurance. Any additional risk factors should be identified and managed accordingly. Specific treatments for stillbirth risk reduction should be instigated early e.g. smoking cessation, medications to reduce placental complications (low dose aspirin), and guidance on safe sleeping practice. Dietary advice should be in keeping with national guidance on nutrition in pregnancy[380].

Additional antenatal fetal surveillance (e.g., serial ultrasound scans) should be scheduled at appropriate intervals. This may change throughout the pregnancy depending on the fetal status and other maternal/fetal risk factors.

The timing of birth needs to be considered on an individual basis, in consultation with the woman, her treating consultant and the multidisciplinary team.

Maternity services (clinics, ultrasound scans, antenatal education classes etc.) should be offered separately from the general maternity population (where feasible and if desired by the woman). Maternity staff need to be aware that re-experiencing pregnancy, revisiting the maternity services, the process of birth, and the postnatal period may involve emotional triggers for bereaved women and consideration needs to be given to a parent's individual needs. All parents should have access to specialised bereavement care during their pregnancy with the level of input depending on their needs.

Recommendations

141. Women who have experienced a previous stillbirth should be triaged to the *specialised care pathway* in their subsequent pregnancy and should be managed by an Obstetrician with sufficient experience to manage the pregnancy.
142. Women should be booked early in their next pregnancy in order to create an appropriate care plan for the pregnancy and birth.
143. Fetal growth should be monitored in subsequent pregnancies, if indicated, based on a review of the factors contributory to the previous stillbirth.
144. The timing of birth needs to be considered on an individual basis, in consultation with the woman, her treating consultant, and the multidisciplinary team.
145. Maternity services should be resourced to deliver an appropriate level of psychological support to bereaved women/parents in subsequent pregnancies. All women/parents should have access to a specialised bereavement team. This team should comprise a specialised clinical Midwife or Nurse specialist, a chaplain or spiritual guide, a social worker and a member of the perinatal mental health team.

Section 7: Looking To The Future

Clinical Question 2.40: **What are the gaps in knowledge and future research priorities for stillbirth in Ireland?**

Placental investigation

Placental dysfunction is a major contributor to stillbirth and very preterm births in high-income countries[381]. Even though research into placental disease has identified placental abruption and placental insufficiency as the most frequent conditions associated with stillbirth[382], the precise role of these lesions is still unclear. Further research is, therefore, necessary to understand the underlying mechanisms of placental dysfunction as a risk factor for stillbirth, and to investigate medical therapies with the potential to treat or mitigate placental dysfunction (e.g., antiplatelet agents such as low-dose aspirin)[383].

Antenatal surveillance

Antenatal testing to detect women at increased risk of stillbirth include antenatal testing with non-stress tests (NSTs), biophysical profile (BPP), amniotic fluid measurements, fetal movement assessment and Doppler velocimetry[384]. However, there is uncertain evidence as to which types of populations would benefit from additional antenatal testing and clinical practice varies substantially[384]. More research is necessary to identify which pregnant women would benefit from additional antenatal surveillance, and to determine the cost-effectiveness of routine third-trimester ultrasound in order to develop standardised clinical guidelines and protocols[385].

Modifiable risk factors and public health campaigns

Previous literature has associated modifiable risk factors such as maternal weight status, substance use, attendance at antenatal care and sleep position with an increased risk of stillbirth. However, the general public are often not aware of these associations[386], and neither are women in the postnatal period[387,388].

The level of knowledge, and understanding, that women have about advice received during pregnancy will have an impact on their attitude toward, and capacity for, behavioural change[389,390]. Women who are less aware, or who hold misconceptions about the consequences of their behaviours will be less likely to engage with behavioural change[389,391,392].

Risk-reduction strategies should not only focus on the individual, however, but on social supports, home environment and the quality of antenatal care. Using BMI as an example, a recent meta-synthesis of the facilitators and barriers with regard to weight management during pregnancy revealed three overriding themes for women and services: 'awareness, beliefs and emotions about weight gain and weight management', 'antenatal healthcare' and 'social and environmental influence'[392]. This study highlighted several deficits in the provision of care: a lack of effective and accessible preconceptional and antenatal information surrounding the risks of maternal obesity and optimum gestation weight gain; a hesitancy among healthcare professionals to address weight-related issues with women due to concerns surrounding stigmatisation and negative effects on the healthcare relationship; and a lack of recognition of the significant influence of home environment and cultural attitudes on behavioural change and lifestyle decisions[392].

Government and healthcare policies should take a multifaceted approach when creating strategies targeted at mitigating supposedly modifiable risk factors to optimise outcomes. Antenatal education standards and healthcare training programmes should provide guidance to support healthcare professionals in promoting health with service users – this should include open communication surrounding risk factors for stillbirth and other adverse outcomes. In order to address these potentially modifiable risk factors and meet women's needs, further research is needed into models of behavioural change that can be applied in pregnancy with a view to developing evidence-based and effective interventions on a local, regional and national level.

Predicting risk after perceived reduced fetal movements

Maternal perception of decreased fetal movement has been widely studied as a potential screening test for fetal compromise[393]. However, there is conflicting evidence regarding the use of fetal movement to confirm fetal well-being, whether it is advisable to encourage women to monitor fetal movement and how women should be advised to do this; there is no consensus as to what amount of movement is considered 'normal'[15]. When a woman does present with concerns about fetal movement there is also a variation, depending on local policy and resourcing, in the investigations performed and the care received[15]. Further research, therefore, is necessary to establish the appropriate care pathways in women who present with reduced fetal movements, in order to improve identification of the potentially compromised fetus.

Development of novel test to detect risk of stillbirth

Biomarker discovery for stillbirth risk might increase clinicians ability to discriminate between pregnancies at high and low risk for stillbirth[15]. Examples of biomarkers that have previously been evaluated as potential predictors include pregnancy-related plasma protein A (PAPP-A) and placental growth factor (PlGF), with PlGF making a greater contribution to prediction performance[394]. Although biochemical tests may prove promising as screening tools when combined with ultrasound, the evidence available regarding biomarkers to determine the risk of stillbirth is limited[385] and further research in this area is necessary.

Bereavement care following stillbirth

Stillbirth is one of the most devastating pregnancy outcomes that women, parents and families can experience. Those involved require additional care from healthcare professionals immediately after their loss, but also in the longer term. Hence, it is crucial that bereavement care is integrated within maternity

medical and clinical care bundles[14]. In Ireland, the *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death* were developed in 2016[14]. This publication mandated a standardised approach to the delivery of bereavement care and triggered reform within the Irish maternity services. This reform was a collaborative effort that included local obstetric services, perinatal bereavement care teams and bereaved parents, with the aim of establishing support organisations in the field of pregnancy loss[14]. Although significant efforts have been made to ensure that the best bereavement care is offered to parents who experience a stillbirth, further research is necessary to optimise the service provided.

Pregnancy after stillbirth

Those who have experienced a stillbirth have specific needs and concerns regarding their future pregnancies, and their experience requires individualised multidimensional care[14]. Research has shown that many women who have experienced a stillbirth are highly motivated to conceive soon after their loss, with some research showing that half of bereaved women are pregnant again within six months[395]. The time between the new pregnancy and the loss is important, as higher rates of depression, stress and anxiety have been reported amongst women who conceive quickly after a perinatal loss[396]. Being aware of the circumstances and categorisation of the cause of death for a previous stillbirth is important in order to counsel couples about the risk of recurrent stillbirth[397]. However, the evidence informing each step of the medical and psychological management of a subsequent pregnancy after a stillbirth is scarce[398]. Further research is needed regarding the optimal management of pregnancies after stillbirth and a large element of this is refining our systems of investigation and classification of stillbirth.

Post mortem examination

Post mortem examination is the gold standard investigation for identifying possible causes of stillbirth and their potential implications on future pregnancies[399]. However, comprehensive investigations should involve elements of the family, maternal and current pregnancy history[175]. More research is necessary to establish which investigations are cost-effective, and the level of resourcing necessary to provide them consistently. Furthermore, previous research has demonstrated that the process of obtaining consent for a PME can be difficult for both parents and healthcare professionals. A Cochrane review from 2013 tried to identify interventions that might support parents in the decision-making process with regard to PME[400] however no conclusions could be drawn due to a lack of evidence. Hence, more research is needed in this area.

Stillbirth definition

Stillbirth definitions vary among different countries around the world. The fact that different jurisdictions may use different criteria to classify antenatal death and stillbirth can interfere with data collection, interpretation and international comparison[334]. Furthermore, the lack of standardisation can impact on women's rights when it comes to accessing care, having their baby formally registered or applying for benefits such as maternity leave[334]. There is an argument for revising the definition of stillbirth in Ireland, with reference to current practice in the EU and other high-income countries, in order to facilitate standardisation of research data and ultimately intervention strategies. However, this lack of consensus is a global problem that needs to be addressed at an international level.

Perinatal mortality reviews and audit

Perinatal mortality reviews and national audits have the potential to identify contributing factors of suboptimal care in a case of stillbirth. However, research exploring different types of perinatal mortality review internationally has shown that differences in the classification of perinatal death can hinder their efficacy[349]. Accordingly, a structured approach to the perinatal mortality review and national auditing process is needed that provides for the implementation of recommendations and includes a phase of re-assessment[349].

Healthcare professional training

Healthcare professionals should be supported in identifying and adequately managing women at higher risk of stillbirth in addition to providing information and support to women who need to engage in behavioural change to reduce their risk. In order to achieve this healthcare professionals should receive specialised training in relation to stillbirth management and aftercare[399]. In Ireland, the Pregnancy Loss Research Group has developed and evaluated the TEARDROP workshop, which was created in line with the Irish National Bereavement Care Standards with the objective of improving confidence and competence levels among healthcare professionals who care for bereaved parents[315]. However, further evaluation of this workshop, among others, is needed in order to facilitate programme expansion and national uptake within the wider maternity service.

Chapter 3: Development of Clinical Practice Guideline

3.1 Literature search strategy

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

Using the ADAPTE process, the guidelines on late intrauterine death and stillbirth from four international bodies were selected for review and critical appraisal; the Perinatal Society of Australia and New Zealand (PSANZ), the Royal College of Obstetricians and Gynaecologists (RCOG), the American College of Obstetricians and Gynecologists (ACOG) and the Society of Obstetricians and Gynaecologists of Canada (SOGC).

Beyond the review of clinical guidelines, the nature of the search strategy with regard to the available and current literature depended on the nature of the clinical question to be addressed. Databases such as Pubmed, ScienceDirect, Google Scholar and the Cochrane database were used to locate suitable source documents. For example when compiling the evidence on the medical management of IUFD terms such as “intrauterine death”, “late intrauterine death”, “medical management”, “mifepristone”, “prostaglandins”, “misoprostol”, “oxytocin”, “mechanical induction”, “balloon induction”, “methods of inuction”, “induction regimens” etc. were employed in isolation or in combination. The publishing window extended back to 1950 for certain clinical questions whereas lower limits of 2000 were set for others. Search terms also varied depending on the question being asked.

The literature review extended from December 2021 to August 2022. Published texts were then reviewed with inclusion or rejection determined by an appraisal of the evidence provided. Priority was given to evidence from randomised-controlled trials, meta-analyses and systematic reviews. Where such evidence wasn’t available, population and cohort studies were consulted. Qualitative studies contributed to guidance surrounding service user and employee support requirements and needs.

3.2 Appraisal of evidence

Following a comprehensive literature review the quality, validity and relevance of the evidence gathered were critically appraised by the guideline developers under the following headings:

- Study design
- Relevance of primary and secondary outcomes
- Consistency of results across studies
- Magnitude of benefit versus magnitude of harm
- Applicability to practice context

A number of evidence-based recommendations for the investigation and management of late intrauterine death and stillbirth were agreed upon. They have been adapted to reflect care in the Irish healthcare setting.

3.3 AGREE II process

While being developed, the Guideline was assessed using the AGREE II checklist (Appendix 6) as recommended by the Department of Health in the 'How to Develop a National Clinical Guideline Manual', 2019[401].

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

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

3.4 Literature review

The literature review search strategy is outlined in Section 3.1. A list of clinical questions was devised by the Guideline Development Group early in the creation process. These clinical questions were assigned to individual developers for literature review depending on their area of expertise.

The clinical questions were assigned as follows:

- Dr Aisling McDonnell[a] Clinical questions 1-12, 16-21, 26-29
- Dr Mairead Butler Clinical questions 30-34
- Dr Jessica White Clinical questions 13-15
- Tamara Escañuela Sánchez Clinical question 2 and 40
- Sarah Cullen Clinical questions 22-25 and 37
- Riona Cotter Clinical questions 35 and 36
- Dr Margaret Murphy Clinical questions 38 and 39
- Prof Keelin O'Donoghue[b] Clinical lead/supervisor

Once individual clinical questions were completed they were amalgamated and reviewed and edited by the lead developer[a] and clinical lead/supervisor[b].

The final document was peer-reviewed by the guideline developers and an oversight group compiled of a selection of clinical stakeholders with an interest in the field of stillbirth and bereavement and loss (*see Section 1.5*).

3.5 Grades of recommendation

GRADE offers a transparent and structured process for developing and presenting evidence summaries and for carrying out the steps involved in developing recommendations[402]. While we acknowledge that for this particular work an extensive GRADE approach is not possible, we have used the suggested language set out in the GRADE table when making recommendations[403] (Appendix 7).

3.6 Future research

An important outcome of the Guideline development process is in highlighting gaps in the evidence base. This has been addressed in section 7 of this document.

Chapter 4: Governance and Approval

4.1 Formal governance arrangements

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

4.2 Guideline development standards

This Guideline was developed by the Guideline Developer Group (GDG) within the overall template of the HSE National Framework[404] for developing Policies, Procedures, Protocols and Guidelines[404] (Appendix 8) and under supervision of the Guideline Programme Team (GPT).

A review was conducted by a group of experts, specialists and advocates (the EAG) prior to approval by the Clinical Advisory Group (CAG) of the National Women and Infants Health Programme (NWIHP) with final sign off for publication by CAG Co-Chairs, the Clinical Director of NWIHP and the Chair of the IOG. See Appendix 9 for list of CAG members.

Chapter 5:
Communication and Dissemination

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

Effective ongoing clear communication is essential in explaining why the Guideline is necessary and securing continued buy-in. It provides an opportunity to instil motivation within staff, helps overcome resistance to change and gives an opportunity for feedback[405].

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

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

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

Chapter 6: **Implementation**

6.1 Implementation plan

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

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

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

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

6.2 Education plans required to implement the Guideline

It is acknowledged that this Guideline should be complemented by ongoing education, training and assessment where required.

This Guideline's education plan could include:

- a formal launch of the Guideline locally, regionally and nationally
- the provision of formal education sessions for staff with facilitated attendance
- the incorporation of the implementation of this Guideline into existing educational programmes, including those in pregnancy loss and bereavement
- the promotion of guideline awareness through the use of both medical and patient-accessible media, including online sites such as NWIHP, RCPI and www.pregnancyandinfantloss.ie
- the promotion of local audit process in addition to specialised roles such as 'local heroes' and advocates.

6.3 Barriers and facilitators

To ensure successful implementation of guidelines, it is first necessary to look at potential barriers and facilitators. Taking these into account when developing the implementation plan should improve levels of support from relevant users[401,405].

Barriers may be categorised as internal (specific to the Guideline itself) or external (specific to the clinical environment). The Guideline Development Group has aimed to address any internal barriers during the development of this Guideline.

Potential external barriers include:

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

In the case of this Guideline, it will be necessary to examine possible barriers and consider implementation strategies to address them. For example, differences to the structure of antenatal care nationwide and across different units creates a barrier to appropriately risk assessing women early in pregnancy and providing the appropriate ultrasonographic screening at the recommended intervals. Tackling this is not only a question of resource provision but of infrastructural change to the provision of services which requires investment at both a management and individual level.

As the number of pregnancies triaged to the *specialised pathway of care* increases, providing the 'recommended' level of care to all pregnancies considered to be at higher risk of adverse outcomes, including stillbirth, will become increasingly difficult if limitations exist regarding local resourcing. Local and national audit can help to delineate the level of resourcing required at individual unit level in order to inform resourcing and staffing allocation.

6.4 Resources necessary to implement recommendations

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

Chapter 7: Audit and Evaluation

7.1 Introduction to audit

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

7.2 Auditable standards

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

The *National Standards for Bereavement Care following Pregnancy Loss and Perinatal Death* provide a clearly defined list of standards that have been carefully developed with the aim of improving and standardising the delivery of care in Irish maternity units[2,14]. These standards focus on four primary themes: bereavement care, the baby and parents, the hospital and the staff. Every recommendation made within each of these domains is amenable to local, regional and national audit and this document should be consulted as part of service improvement strategies with regard to the delivery of bereavement care in Ireland.

Additional standards to be considered in the context of the prevention, investigation and management of stillbirth include:

1. The proportion of women who attend for a booking visit within the first trimester and who are risk assessed at this visit by a Midwife and Obstetrician.
2. The proportion of women who attend for at least eight scheduled points of contact in the course of their pregnancy.
3. The proportion of women undergoing the appropriate maternal investigations after a stillbirth.
4. The proportion of stillborn infants that undergo post mortem examination.
5. The proportion of post mortem examinations that are directed by the Coroner.
6. The proportion of stillbirth cases where the discussion (and consent) with regard to post mortem examination was undertaken by an appropriately trained senior Obstetrician.
7. The proportion of stillbirth cases that have placental histopathology and cytogenetic analysis performed.
8. The proportion of maternity units/hospitals that have access to perinatal pathology services.
9. In the event of induction of labour, the time from initiation to delivery (first mifepristone to delivery) and from induction to delivery (first misoprostol to delivery).

10. In the event of induction of labour, the number of women that receive both mifepristone and misoprostol and the time interval between the two medications.
11. The proportion of women that receive both verbal (documented) and written information on the physiology of lactation and the methods of suppression.
12. The proportion of women that receive pharmaceutical lactation suppression. In the event of suppression with cabergoline, the number of women that receive the appropriate dose within 24 hours of delivery.
13. The proportion of women who experience a preterm delivery at the threshold of viability (currently 23-24 weeks, however the exact gestation may vary depending on updates to neonatal guidelines) that receive an antenatal neonatology consultation.
14. The proportion of stillbirths that are reported to and discussed at the hospital/unit SIMT.
15. The timeframe from stillbirth to the availability of the post mortem examination report for women/parents and clinicians.
16. The proportion of maternity services who have access to a regular scheduled perinatal mortality multidisciplinary meeting (PM MDM).
17. The proportion of stillbirths that undergo review at the PM MDM meeting and the interval between the stillbirth and the PM MDM discussion.
18. The proportion of women/parents who attend for a postnatal review with a consultant Obstetrician within three months of delivery.
19. The proportion of women who have experienced a previous stillbirth that are triaged to the specialised pathway of care in a subsequent pregnancy.
20. The planned gestation of elective delivery in pregnancies subsequent to a stillbirth.

Outcomes in pregnancies subsequent to a stillbirth should also be audited.

7.3 Evaluation

Evaluation is defined as a formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved[406].

Implementation of this Guideline will be audited periodically at national level with standards for this set by the NWIHP. Evaluation of the auditable standards should also be undertaken locally by senior hospital clinical management to support implementation.

Chapter 8: **Revision Plan**

8.1 Procedure for the update of the Guideline

It may be a requirement to amend, update or revise this Guideline as new evidence emerges. This Guideline will be reviewed at national level every three years, or earlier if circumstances require it, and updated accordingly[404].

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

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

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

8.2 Method for amending the Guideline

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

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

a. 3 years since the Guideline was published

b. 3 years since last review was conducted

c. Update required as a result of new evidence

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

Chapter 9: **References**

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Supporting Evidence

GRADE: http://www.gradeworkinggroup.org/

AGREE: http://www.agreetrust.org/agree-ii/

HSE: https://www.hse.ie/eng/about/who/qid/use-of-improvement-methods/nationalframeworkdevelopingpolicies/

Glossary
(for the Purpose of this Guideline)

aCL Anticardiolipin antibody

ACOG American College of Obstetricians and Gynecologists

AGREE Appraisal of Guidelines for Research and Evaluation

AMA Advanced maternal age

APS Antiphospholipid syndrome

BMI Body mass index

BMUS British medical ultrasound society

CAG Clinical Advisory Group

CMS Clinical midwife specialist

CMV Cytomegalovirus

CPG Clinical practice guideline

CS Caesarean section

DCDA Dichorionic diamniotic

DIC Disseminated intravascular coagulation

DM Diabetes mellitus

EAG Expert Advisory Group

FBC Full blood count

FGR Fetal growth restriction

FIGO International Federation of Gynaecology and Obstetrics

GDG Guideline development group

GDM Gestational diabetes mellitus

GP General Practitioner

GPT Guideline Programme Team

GRADE Grading of Recommendations, Assessments, Developments and Evaluations

HCP Healthcare professional

HIC High-income country

HIQA Health Information and Quality Authority

HSE Health Service Executive

IAP Intrapartum antibiotic prophylaxis

ICP Intrahepatic cholestasis of pregnancy

IOG Institute of Obstetricians and Gynaecologists

IUFD Intrauterine fetal death

LA Lupus anticoagulant

LMWH Low molecular weight heparin

MCDA Monochorionic diamniotic

MDT Multidisciplinary team

NCEC National Clinical Effectiveness Committee

NICE The National Institute for Health and Care Excellence

NIPS Non-invasive prenatal screening

NPEC National Perinatal Epidemiology Centre

NPRS National Perinatal Reporting System

NWIHP National Women and Infants Health Programme

PET Pre-eclampsia

PIGF Placental growth factor

PM MDM Multidisciplinary team

PME Post mortem examination

PPPG Policy, Procedures, Protocols and Guidelines

PSANZ Perinatal Society of Australia and New Zealand

RCOG Royal College of Obstetricians and Gynaecologists

RCPI Royal College of Physicians of Ireland

RCT Randomised controlled trial

SBA Serum bile acids

SES Socio-economic status

SFH Symphysio-fundal height

SGA Small for gestational age

SIMT Serious incident management team

SMFM Society for Maternal-Fetal Medicine

SOGC Society of Obstetricians and Gynaecologists of Canada

TTTS Twin-to-twin transfusion syndrome

VBAC Vaginal birth after Caesarean section

VTE Venous thromboembolism

WHO World Health Organisation

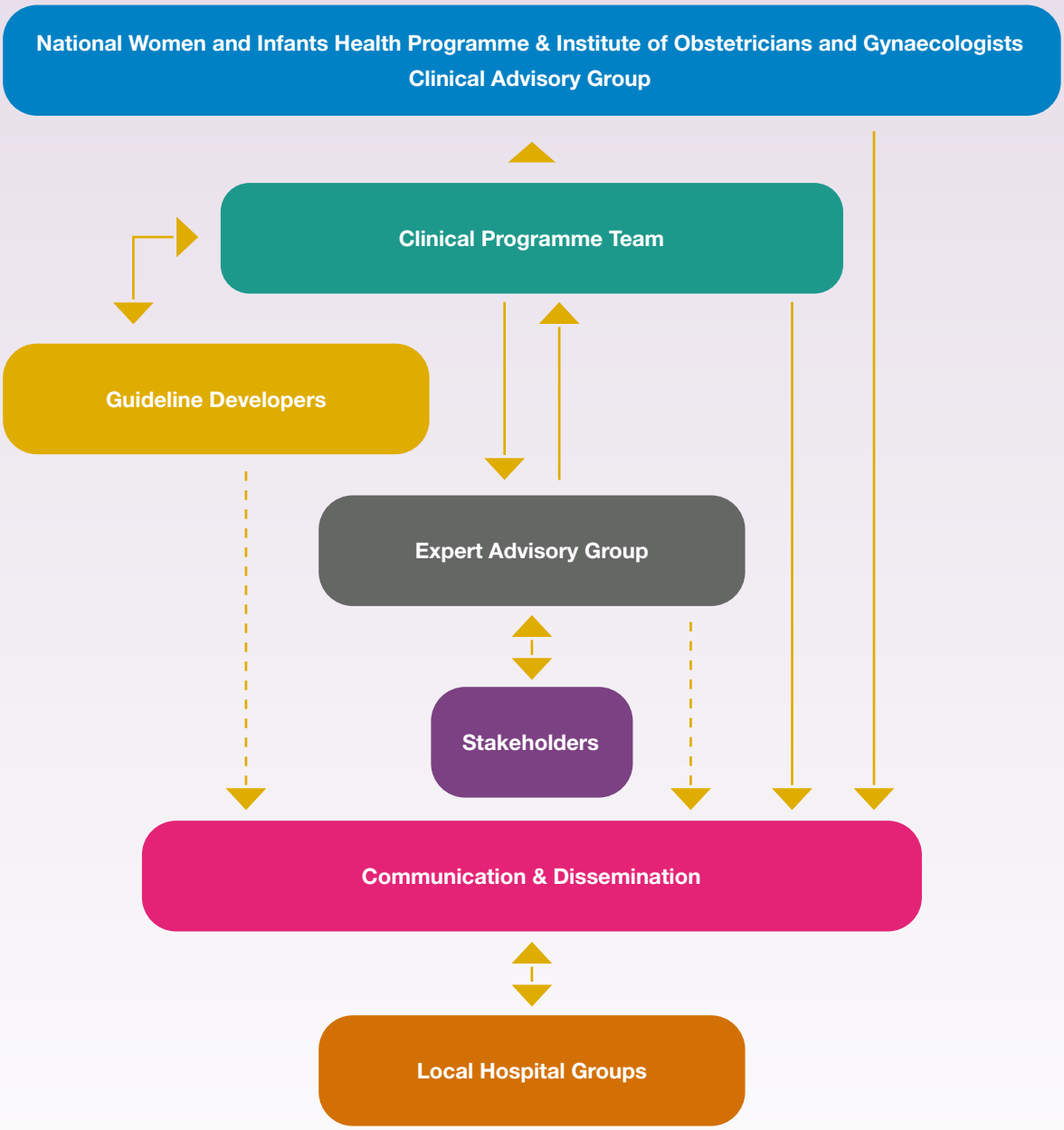
Appendix 1: **Expert Advisory Group Membership 2021-**

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

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

Appendix 2:
Guideline Programme Process

Guideline Programme Process



Appendix 3: **Elements of a clinical history in the event of an intrauterine fetal death**

General	• Maternal age • Gestational age • Ethnicity • Parity • Socio-economic background
Presentation	• Pain/contractions • Rupture of membranes • History of antepartum haemorrhage • History of trauma • Symptoms/signs infective process • Symptoms/signs of systemic illness
Maternal risk factors	• BMI • Medical history including pregestational diabetes, hypertension, renal disease, thyroid disease, epilepsy, autoimmune disease, mental health issues, any other significant medical condition
Fetal risk factors	• Multiple pregnancy • Fetal growth restriction • Fetal macrosomia • Known structural/chromosomal anomaly • Known fetal complication
Obstetric antecedents	• Previous caesarean section • Previous stillbirth • Previous recurrent miscarriage • Previous preterm birth • Previous pregnancy related complications • Previous neonatal morbidity/conditions
Current pregnancy	• Pre-eclampsia • Intrahepatic cholestasis of pregnancy • Gestational diabetes • Antenatal infection • Substance use (alcohol, tobacco, cocaine, other) • Medication use (prescribed, over the counter)
Family history	• Hereditary conditions • Relevant familial medical conditions • Consanguinity
At delivery	• Cord abnormalities (prolapse, hypercoiling, knot etc.) • Placental abnormalities (infarcts, appearance, presence of retroplacental clot etc.)

Appendix 4: **Summary of maternal investigations following stillbirth**

Recommended – all cases
At diagnosis:
☐ Kleihauer-Betke test
☐ Full blood count
☐ Group and antibody screen
Prior to discharge (at or subsequent to diagnosis):
☐ Acquired thrombophilias [lupus anticoagulant (LA), anticardiolipin (aCL) and anti-glycoprotein 1]
☐ HbA1c
☐ Serum bile acids (SBA)
☐ Serology for CMV, toxoplasma and parvovirus B19
Recommended – case specific
☐ Rubella IgM/IgG
☐ Syphilis testing
☐ Coagulation studies
☐ C-reactive protein
☐ Renal function
☐ Uric acid
☐ Liver function
☐ Thyroid function
☐ Inherited thrombophilia (including Factor V Leiden)
☐ Auto/alloimmune antibodies
☐ Toxicology screen
☐ Microbiological studies
☐ Parental karyotypes

Appendix 5: **Suggested regimens for the pharmaceutical induction of labour**

Compiled on behalf of the HSE National Women and Infants Health Programme by Prof. Keelin O'Donoghue, consultant obstetrician CUMH and clinical lead for the implementation of the National Standards for Bereavement care following pregnancy Loss and Perinatal Death, Dr. Brian Cleary, chief pharmacist, Rotunda and MNCMS medications lead, Ms. Elmarie Cottrell, senior clinical informatics pharmacist, CUMH. Medication protocol for the medical management of intrauterine fetal death. Health Service Executive (HSE): Ireland; 2019. Available at https://pregnancyandinfantloss.ie.

Protocol for Medical Management of Intrauterine Fetal Death

Type of Pregnancy Loss		Mifepristone	Misoprostol	If Previous Uterine Scar
Itrauterine Fetal Death	24+0 – 26+6 weeks gestation	Mifepristone 200mg PO → ≥ 24 hours - ≤48 hours	Misoprostol 200 microgram PV/ Bucc 4-6 hourly (to a maximum of 5 doses)	• Management should be individualised in the setting of a previous uterine scar at gestations over 24 weeks • Consideration should be given to using higher doses of Mifepristone (e.g. 600mg) or repeated doses (200mg) • Misoprostol 25-100 microgram Buccally or Vaginally • Misoprostol interval increased to 6-hourly
	27+0 – 28+0 weeks gestation	Mifepristone 200mg PO → ≥ 24 hours - ≤48 hours	Misoprostol 100 microgram PV/ Bucc 4-6 hourly (to a maximum of 5 doses)	
	Over 28 weeks gestation	Mifepristone 200mg PO → ≥ 24 hours - ≤48 hours	Misoprostol 25-50 microgram PV/ Bucc 4-6 hourly (to a maximum of 5 doses)	• Management should be individualised in the setting of a previous uterine scar at gestations over 24 weeks • Consideration should be given to using higher doses of Mifepristone (e.g. 600mg) or repeated doses (200mg) • Misoprostol 25-50 microgram Buccally or Vaginally • Misoprostol interval 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. 25 microgram tablets have become available internationally recently. 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.

Appendix 6: AGREE II Checklist[19]

AGREE Reporting Checklist 2016

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

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

19 AGREE Reporting Checklist is available on the AGREE Enterprise website, a free and open access resource to support the practice guideline field (www.agreetrust.org)

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
5. TARGET POPULATION PREFERENCES AND VIEWS *Report how the views and preferences of the target population were sought/considered and what the resulting outcomes were.*	☐ Statement of type of strategy used to capture patients'/publics' views and preferences (e.g., participation in the guideline development group, literature review of values and preferences) ☐ Methods by which preferences and views were sought (e.g., evidence from literature, surveys, focus groups) ☐ Outcomes/information gathered on patient/public information ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
6. TARGET USERS *Report the target (or intended) users of the guideline.*	☐ The intended guideline audience (e.g. specialists, family physicians, patients, clinical or institutional leaders/administrators) ☐ How the guideline may be used by its target audience (e.g., to inform clinical decisions, to inform policy, to inform standards of care)	
DOMAIN 3: RIGOUR OF DEVELOPMENT		
7. SEARCH METHODS *Report details of the strategy used to search for evidence.*	☐ Named electronic database(s) or evidence source(s) where the search was performed (e.g., MEDLINE, EMBASE, PsychINFO, CINAHL) ☐ Time periods searched (e.g., January 1, 2004 to March 31, 2008) ☐ Search terms used (e.g., text words, indexing terms, subheadings) ☐ Full search strategy included (e.g., possibly located in appendix)	
8. EVIDENCE SELECTION CRITERIA *Report the criteria used to select (i.e., include and exclude) the evidence. Provide rationale, where appropriate.*	☐ Target population (patient, public, etc.) characteristics ☐ Study design ☐ Comparisons (if relevant) ☐ Outcomes ☐ Language (if relevant) ☐ Context (if relevant)	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
9. STRENGTHS & LIMITATIONS OF THE EVIDENCE *Describe the strengths and limitations of the evidence. Consider from the perspective of the individual studies and the body of evidence aggregated across all the studies. Tools exist that can facilitate the reporting of this concept.*	☐ Study design(s) included in body of evidence ☐ Study methodology limitations (sampling, blinding, allocation concealment, analytical methods) ☐ Appropriateness/relevance of primary and secondary outcomes considered ☐ Consistency of results across studies ☐ Direction of results across studies ☐ Magnitude of benefit versus magnitude of harm ☐ Applicability to practice context	
10. FORMULATION OF RECOMMENDATIONS *Describe the methods used to formulate the recommendations and how final decisions were reached. Specify any areas of disagreement and the methods used to resolve them.*	☐ Recommendation development process (e.g., steps used in modified Delphi technique, voting procedures that were considered) ☐ Outcomes of the recommendation development process (e.g., extent to which consensus was reached using modified Delphi technique, outcome of voting procedures) ☐ How the process influenced the recommendations (e.g., results of Delphi technique influence final recommendation, alignment with recommendations and the final vote)	
11. CONSIDERATION OF BENEFITS AND HARMS *Report the health benefits, side effects, and risks that were considered when formulating the recommendations.*	☐ Supporting data and report of benefits ☐ Supporting data and report of harms/side effects/risks ☐ Reporting of the balance/trade-off between benefits and harms/side effects/risks ☐ Recommendations reflect considerations of both benefits and harms/side effects/ risks	
12. LINK BETWEEN RECOMMENDATIONS AND EVIDENCE *Describe the explicit link between the recommendations and the evidence on which they are based.*	☐ How the guideline development group linked and used the evidence to inform recommendations ☐ Link between each recommendation and key evidence (text description and/or reference list) ☐ Link between recommendations and evidence summaries and/or evidence tables in the results section of the guideline	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
13. EXTERNAL REVIEW *Report the methodology used to conduct the external review.*	☐ Purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence) ☐ Methods taken to undertake the external review (e.g., rating scale, open-ended questions) ☐ Description of the external reviewers (e.g., number, type of reviewers, affiliations) ☐ Outcomes/information gathered from the external review (e.g., summary of key findings) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations)	
14. UPDATING PROCEDURE *Describe the procedure for updating the guideline.*	☐ A statement that the guideline will be updated ☐ Explicit time interval or explicit criteria to guide decisions about when an update will occur ☐ Methodology for the updating procedure	
DOMAIN 4: CLARITY OF PRESENTATION		
15. SPECIFIC AND UNAMBIGUOUS RECOMMENDATIONS *Describe which options are appropriate in which situations and in which population groups, as informed by the body of evidence.*	☐ A statement of the recommended action ☐ Intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects) ☐ Relevant population (e.g., patients, public) ☐ Caveats or qualifying statements, if relevant (e.g., patients or conditions for whom the recommendations would not apply) ☐ If there is uncertainty about the best care option(s), the uncertainty should be stated in the guideline	
16. MANAGEMENT OPTIONS *Describe the different options for managing the condition or health issue.*	☐ Description of management options ☐ Population or clinical situation most appropriate to each option	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
17. IDENTIFIABLE KEY RECOMMENDATIONS *Present the key recommendations so that they are easy to identify.*	☐ Recommendations in a summarized box, typed in bold, underlined, or presented as flow charts or algorithms ☐ Specific recommendations grouped together in one section	
DOMAIN 5: APPLICABILITY		
18. FACILITATORS AND BARRIERS TO APPLICATION *Describe the facilitators and barriers to the guideline's application.*	☐ Types of facilitators and barriers that were considered ☐ Methods by which information regarding the facilitators and barriers to implementing recommendations were sought (e.g., feedback from key stakeholders, pilot testing of guidelines before widespread implementation) ☐ Information/description of the types of facilitators and barriers that emerged from the inquiry (e.g., practitioners have the skills to deliver the recommended care, sufficient equipment is not available to ensure all eligible members of the population receive mammography) ☐ How the information influenced the guideline development process and/or formation of the recommendations	
19. IMPLEMENTATION ADVICE/TOOLS *Provide advice and/or tools on how the recommendations can be applied in practice.*	☐ Additional materials to support the implementation of the guideline in practice. For example: • Guideline summary documents • Links to check lists, algorithms • Links to how-to manuals • Solutions linked to barrier analysis (see Item 18) • Tools to capitalize on guideline facilitators (see Item 18) • Outcome of pilot test and lessons learned	

CHECKLIST ITEM AND DESCRIPTION	REPORTING CRITERIA	Page #
20. RESOURCE IMPLICATIONS *Describe any potential resource implications of applying the recommendations.*	☐ Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs) ☐ Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.) ☐ Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course) ☐ How the information gathered was used to inform the guideline development process and/or formation of the recommendations	
21. MONITORING/ AUDITING CRITERIA *Provide monitoring and/or auditing criteria to measure the application of guideline recommendations.*	☐ Criteria to assess guideline implementation or adherence to recommendations ☐ Criteria for assessing impact of implementing the recommendations ☐ Advice on the frequency and interval of measurement ☐ Operational definitions of how the criteria should be measured	
DOMAIN 6: EDITORIAL INDEPENDENCE		
22. FUNDING BODY *Report the funding body's influence on the content of the guideline.*	☐ The name of the funding body or source of funding (or explicit statement of no funding) ☐ A statement that the funding body did not influence the content of the guideline	
23. COMPETING INTERESTS *Provide an explicit statement that all group members have declared whether they have any competing interests.*	☐ Types of competing interests considered ☐ Methods by which potential competing interests were sought ☐ A description of the competing interests ☐ How the competing interests influenced the guideline process and development of recommendations	

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

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

Appendix 7: **Grades of Recommendation**[20]

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

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

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

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

Appendix 8: **Policies, Procedures, Protocols and Guidelines checklist**

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

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

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

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

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

Appendix 9: **NWIHP/IOG CAG membership 2022**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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