



**INSTITUTE OF
OBSTETRICIANS &
GYNAECOLOGISTS**

**ROYAL COLLEGE OF
PHYSICIANS OF IRELAND**

INTERIM CLINICAL GUIDANCE

**Risk to Life or Health of a
Pregnant Woman in
relation to Termination of
Pregnancy**

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Guideline Development Group Membership

The first draft of this guidance document was written by Professor Fionnuala McAuliffe, Professor John Higgins, and Dr Vicky O'Dwyer. Feedback was received from a number of Obstetricians with expertise in maternal medicine and from physicians who care for women with medical disorders in pregnancy, including psychiatry, cardiology, hepatology, rheumatology, renal medicine, haematology, anaesthesiology. The second draft took account of these comments. The next draft was circulated to all 19 maternity units and to all members of IOG for comment. Further feedback was received and the guideline was discussed at three open meetings to which all members of the Institute were invited. A further draft was sent to all members of the Institute for further comment a second time. Thus the wider community has received this document for comment on two occasions. This final version therefore reflects feedback from the wider obstetric community.

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Additional Input

- Legal Review
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Introduction

- A termination of pregnancy may be carried out where 2 medical practitioners, having examined the pregnant woman, are of the reasonable opinion formed in good faith that there is a risk to the life, or of serious harm to the health, of the pregnant woman, the fetus has not reached viability, and it is appropriate to carry out the termination of pregnancy in order to avert the risk.
- A termination of pregnancy may be carried out by one medical practitioner where, having examined the pregnant woman, he or she is of the reasonable opinion formed in good faith that there is an immediate risk to the life, or of serious harm to the health and it is immediately necessary to carry out the termination of pregnancy in order to avert that risk.
- For women where there is risk to life or serious risk to health in early pregnancy, termination of pregnancy may be carried out under section 12 of the Health (Regulation of Termination of Pregnancy) Act 2018. This states that a medical practitioner has examined a women and is of the reasonable opinion formed in good faith that pregnancy has not exceeded 12+0 weeks gestation. The termination of pregnancy can be carried out not less than 3 days after certification has taken place and when the pregnancy has not exceeded 12+0 weeks gestation. Consideration should be given to the woman's medical and medication status in all cases.

Recommendations

- Women with medical disorders, including mental health disorders, should have prioritised access to antenatal care, access to ultrasound for pregnancy dating and have access to clinicians with expertise in the management of medical disorders in pregnancy.
- Women with mental health disorders should have access to perinatal mental health expertise.
- Obstetric units should develop pathways of referral to facilitate evaluation of women with medical disorders.
- Where termination of pregnancy is being considered, an Obstetrician and an appropriate medical practitioner should be involved in the clinical assessment. An appropriate medical practitioner is one who is on the specialist register of the Medical Council of Ireland. This may be an Obstetrician, a Psychiatrist, who preferably has expertise in perinatal mental health, or a Physician with expertise in the medical or surgical disorder that is relevant to the risk to maternal health and life.
- It is recommended that Obstetric Multidisciplinary Team (MDT) discussions take place for individual cases, which would form an important component of the assessment of the risk to the life of, or of serious harm to the health of, the pregnant woman. The MDT would also advise on a care plan for termination of pregnancy and on appropriate immediate, ongoing and postpartum medical care.
- MDT meetings could include Obstetricians, Psychiatrists, relevant Physicians and Surgeons depending on the circumstances of the particular case.

- Consideration should be given to the medical condition and current medication of each woman, when deciding on the most appropriate method of termination of pregnancy including anaesthesia, prescribing analgesia and antibiotics.
- Consideration should be given to the medical condition of each woman and current medication, when deciding on the location where the termination of pregnancy is to be performed (i.e. community care with medical team input, stand-alone maternity hospitals and general hospitals with access to intensive care).
- Where the termination of pregnancy is indicated for mental health reasons there should be access to perinatal mental health resources, which may include inpatient psychiatric care.
- Information regarding termination of pregnancy, including methods of termination of pregnancy, complications and potential risks should be discussed with the woman. This discussion should include the risk of continuing with the pregnancy and the risk of termination of pregnancy taking account of her medical disorder. Consent for termination of pregnancy should include discussion of the above risks.
- It is recommended that neonatologists are involved in decision making where pregnancies are at the threshold of viability.
- Plans for termination of pregnancy should be clearly documented and communicated with the relevant clinical staff who may be involved in the woman's care.
- If a woman does not meet criteria for termination of pregnancy, or decides to proceed with the pregnancy, she should continue to have access to medical care and MDT input, as appropriate to her medical condition.
- If a woman is having a termination of pregnancy at 7 weeks gestation or greater a blood group and Rhesus D testing should be performed to identify Rhesus D negative women. Anti-D immunoglobulin should be offered to prevent Rhesus D sensitisation during future pregnancies.
- Bereavement support should be available.
- All women should be offered appropriate contraceptive advice after termination of pregnancy. Consideration should be given to their medical condition, current medications and plans for future pregnancy.
- All women should be offered appropriate follow up for medical problems that have preceded or presented for the first time in pregnancy, particularly if these conditions have lifelong health implications.
- Appropriate training and support should be available to staff involved in the care of women requiring termination of pregnancy.
- Medical practitioners with a conscientious objection to carrying out or participating in carrying out a termination of pregnancy are obliged to refer the pregnant woman to enable her to avail of termination of pregnancy services.

- In an emergency situation necessary treatment must be provided irrespective of any conscientious objection the medical practitioner may have.
- When a medical practitioner does not certify a termination of pregnancy due to risk to life or serious risk to health, a pregnant woman can make an application for review of the decision to the HSE. The woman should be informed in writing that an application to appeal the decision can be made to the HSE.
- It is suggested that the review committee for matters relating to maternal health and life be constituted of at least three members and should include:
 - A nominee of the chair from each Obstetric MDT
 - Practitioners with experience of the medical issue relevant to the case
- It is the responsibility of the HSE review committee to organise a termination of pregnancy following their review and approval of such termination of pregnancy.
- Where the review committee does not certify a termination of pregnancy the woman should be referred back to her Obstetrician for ongoing maternity and medical care.

1.0 Introduction

The Health (Regulation of Termination of Pregnancy) Act 2018 was finalised by the Dáil on 05/12/18, by the Seanad on 13/12/18, and was signed into law on 21/12/2018. At the request of the Department of Health, the Institute of Obstetricians and Gynaecologists was asked to develop clinical guidance for the termination of pregnancy.

This guidance document has been developed to assist health professionals in providing care to pregnant women where their life or health is at risk. **While the context for the document preparation is the Health (Regulation of Termination of Pregnancy) Act 2018, this is a good practice guidance document rather than a summary of the regulation. It is important that all practicing clinicians familiarise themselves with the law. The document particularly draws on Part 2, Sections 9 & 10 of the 2018 Act.**

Risk to life or health

9. (1) *A termination of pregnancy may be carried out in accordance with this section where 2 medical practitioners, having examined the pregnant woman, are of the reasonable opinion formed in good faith that—*

- (a) there is a risk to the life, or of serious harm to the health, of the pregnant woman,*
- (b) the foetus has not reached viability, and*
- (c) it is appropriate to carry out the termination of pregnancy in order to avert the risk referred to in paragraph (a).*

(2) *Of the 2 medical practitioners referred to in subsection (1)—*

- (a) one shall be an obstetrician, and*
- (b) the other shall be an appropriate medical practitioner.*

(3) *A termination of pregnancy shall not be carried out under this section unless each of the medical practitioners referred to in subsection (1) has certified his or her opinion as to the matters referred to in that subsection.*

(4) *The termination of pregnancy to which the certification referred to in subsection (3) relates shall be carried out—*

- (a) by the obstetrician referred to in subsection (2)(a), or*
 - (b) where the medical practitioner referred to in subsection (2)(b) is also an obstetrician, by that obstetrician or the obstetrician referred to in subsection (2)*
- (a).*

Risk to life or health in emergency

10. (1) *Notwithstanding the generality of section 9, or any determination made or pending pursuant to section 16 of an application under section 13(2), a termination of pregnancy may be carried out in accordance with this section by a medical practitioner where, having examined the pregnant woman, he or she is of the reasonable opinion formed in good faith that—*

- (a) there is an immediate risk to the life, or of serious harm to the health, of the pregnant woman, and*

(b) it is immediately necessary to carry out the termination of pregnancy in order to avert that risk.

(2) Where a medical practitioner proposes to carry out a termination of pregnancy under this section, he or she shall certify his or her opinion as to the matters referred to in subsection (1)—

*(a) before carrying out the termination of pregnancy concerned, or
(b) where it is not practicable to do so before carrying out the termination of pregnancy, as soon as may be but, in any event, not later than 3 days after the carrying out of the termination of pregnancy concerned.*

1.1 Background

Due to advances in medicine, women who have complex medical conditions are becoming pregnant. For some women, the risk to life and serious risk to their health due to their background medical condition may be exacerbated by pregnancy. For some women complications that occur during pregnancy can cause a risk to life or serious risk to health (such as chorioamnionitis). It has been highlighted in recent maternal mortality reports, including MMBRACE-UK that cardiac disease and suicide remain leading causes of maternal death, and this document refers to risk to life and serious risk to health including both physical and mental health.

1.2 Aims

The purpose of this guidance document is:

- To provide guidance to the Obstetrician in the assessment, certification and management of women where there is a risk to life or serious risk to health due to physical or mental health issues in pregnancy, prior to viability of the fetus.
- To ensure optimum care of such women requiring termination of pregnancy.
- To recommend a pathway of care incorporating standards of practice which are consistent with national recommendations.

This guidance document does not deal with:

- Management of cases where the fetus has reached viability.
- Provide an exhaustive list of possible scenarios of risk to life or serious risk to health in pregnancy.

2.0 Pathway of Care

Women with medical disorders, including mental health disorders, should have prioritised access to antenatal care, access to ultrasound for pregnancy dating and have access to clinicians with expertise in the management of medical disorders in pregnancy.

Women with mental health disorders should have access to perinatal mental health expertise including inpatient psychiatric care, where appropriate. Obstetric units should develop pathways of referral to facilitate evaluation of women with medical disorders

Termination of pregnancy may be an indicated treatment when the life of a mother is at risk, or there is a risk of serious harm to the mother's health, as set out in the Health (Regulation of Termination of Pregnancy) Act 2018, sections 9 and 10. Therefore, the provisions of the Medical Council's Guide to Professional Conduct and Ethics for Registered Medical Practitioners of the Medical Council will apply from the time a woman, or someone acting on her behalf with her consent, makes initial contact with the healthcare services through to referral, assessment, certification, review, treatment and post-treatment, as appropriate. Of note, at the time of writing this guidance document, the Irish Medical Council are in the process of updating their Guide to Professional Conduct and Ethics for Registered Medical Practitioners to take into account the Health (Regulation of Termination of Pregnancy) Act 2018. Further detail on this is awaited.

For women where there is risk to life or serious risk to health in early pregnancy, termination of pregnancy may be carried out under section 12 of the Health (Regulation of Termination of Pregnancy) Act 2018. This states that a medical practitioner has examined a woman and is of the reasonable opinion formed in good faith that pregnancy has not exceeded 12+0 weeks gestation. The termination of pregnancy can be carried out not less than 3 days after certification has taken place, and when the pregnancy has not exceeded 12+0 weeks gestation. Consideration should be given to a woman's medical condition and medication in all care pathways.

If a health professional is of the opinion that the life of a mother is at risk or there is a risk of serious harm to the mother's health because of pregnancy, then certification should follow section 9 & 10 of the Act 2018. We recommend that multi-disciplinary teams work together coming to a joint assessment and care plan in these cases.

If a health professional is of the opinion that the life of a mother is at risk or there is a risk of serious harm to the mother's health because of pregnancy and he/she does not feel qualified to treat her, he/she would be expected to make urgent referral to or seek advice from an appropriate medical practitioner, with expertise in maternal medicine, for further assessment. We recommend that multi-disciplinary teams work together coming to a joint assessment and care plan. Plans for termination of pregnancy should be clearly documented and communicated with the relevant clinical staff who may be involved in the woman's care.

Where a woman attends an Obstetrician and requests a termination of pregnancy on the grounds of a risk of suicide or a serious risk to her mental health if the pregnancy continues, she should be assessed. If the Obstetrician is of the opinion that there may be sufficient mental health grounds that require further assessment, advice should be sought from a Psychiatrist, preferably one with expertise in perinatal mental health. If a pregnant woman has a severe mental disorder she should be referred for a mental health assessment in the usual way. In an emergency, local pathways for accessing emergency mental health care should be utilised. A mental health emergency may affect decision making capacity. The overall health and wellbeing of the woman should be prioritised rather than performing an immediate emergency termination of pregnancy.

If the woman has been referred to the Obstetrician by a consultant Psychiatrist she must also be assessed by that Obstetrician. A MDT meeting may be indicated.

2.1 Role of Obstetrician/Gynaecologist

The role of the Obstetrician/Gynaecologist is central to the process of assessment, certification and treatment. The Obstetrician/Gynaecologist may also have a role in the referral pathway. If the risk arises from physical or mental ill-health, referral will be to the appropriate medical specialist or Psychiatrist.

Referral to a maternal medicine specialist should be considered for management of pregnancies with complex medical disorders. A maternal medicine specialist is an Obstetrician who is actively practicing in the area of maternal medicine. The maternal medicine specialist has undergone specific further training either through a maternal-fetal medicine fellowship or maternal medicine fellowship, or has clinical expertise in maternal medicine. The maternal medicine specialist works as part of multidisciplinary team to care for women with medical disorders in pregnancy.

2.2 Role of relevant specialities

It is recommended that formal involvement of relevant specialties will be applicable in cases where the life or health of the pregnant woman is at risk. Relevant specialities will include (but are not limited to), anaesthesiology, cardiology, oncology, psychiatry, haematology, respiratory medicine, neurology, nephrology, gastroenterology, hepatology, microbiology, etc., depending on the woman's condition.

A Psychiatrist will be involved in the care of women whose life or health is at serious risk based on mental health. This would ideally be a perinatal psychiatrist.

It is recommended that Neonatologists are involved in decision making where pregnancies are at the threshold of viability.

3.0 Clinical assessment process

According to the 2018 Act, section 9. (1):

9. (1) A termination of pregnancy may be carried out in accordance with this section where 2 medical practitioners, having examined the pregnant woman, are of the reasonable opinion formed in good faith that—

(a) there is a risk to the life, or of serious harm to the health, of the pregnant woman,

(b) the foetus has not reached viability, and

(c) it is appropriate to carry out the termination of pregnancy in order to avert the

risk referred to in paragraph (a).

(2) Of the 2 medical practitioners referred to in subsection (1)—

a) one shall be an obstetrician, and (b) the other shall be an appropriate medical practitioner.

An appropriate medical practitioner is one who is on the specialist register of the Medical Council of Ireland, who may be an Obstetrician, a Psychiatrist (who preferably has expertise in perinatal mental health), or a Physician with expertise in the medical or surgical disorder that is relevant to the risk to maternal health and life.

While the legislation requires only two medical practitioners for certification under the legislation, this guidance document recommends discussion at an Obstetric Multidisciplinary Team meeting as a good practice point. We recommend that **Obstetric Multidisciplinary Team (MDT)** discussions take place for individual cases, which would form an important component of the assessment of the risk to the life of, or of serious harm to the health of, the pregnant woman. MDT meetings could be convened to include Obstetricians, Midwives and relevant Physicians, Psychiatrists, Surgeons and General Practice, depending on the circumstances of the particular case. A summary of the outcome of these clinical meetings should be documented in the clinical notes. These discussions would include a management plan for the delivery of the care.

The key features of the Obstetric MDT could include:

1. It is a formally constituted committee
2. It requires administrative support to ensure a record of MDT attendees and cases discussed is maintained
3. Has a key role in providing obstetric care in a range of pregnancies, not just for discussion for cases considering termination of pregnancy
4. Hospital groups may avail of the option of using a single Obstetric MDT across their maternity network
5. If a decision is required prior to the usual meeting of the regular MDT, good practice would suggest that documented consultation take place with a number of appropriate medical practitioners which could include both Obstetricians and Physicians as required by the clinical scenario
6. Attendance and participation at MDTs would be open to all relevant consultants in the service
7. Membership should include a range of medical and surgical specialities
8. Psycho-social issues and the woman's preference in terms of care options should form an important component of the MDT assessment
9. Decisions of MDT are usually made by a majority consensus of those experts present. Two medical practitioners are required for certification as stated under the law

There are situations where the risk to the health or life of the mother is obvious and waiting for discussion at an MDT may involve undue delay. In such situations, if agreed by two qualified people, a round table discussion may not be necessary.

In an emergency situation, consultation with MDT is not required (Section 10) and only one practitioner is required by law for certification.

3.1 Risk to life or serious harm to the health in emergency

Under section 10 of the Act:

(1) Notwithstanding the generality of section 9, or any determination made or pending pursuant to section 16 of an application under section 13(2), a termination of pregnancy may be carried out in accordance with this section by a medical practitioner where, having examined the pregnant woman, he or she is of the reasonable opinion formed in good faith that—

(a) there is an immediate risk to the life, or of serious harm to the health, of the pregnant woman, and

(b) it is immediately necessary to carry out the termination of pregnancy in order to avert that risk.

(2) Where a medical practitioner proposes to carry out a termination of pregnancy under this section, he or she shall certify his or her opinion as to the matters referred to in subsection (1)—

(a) before carrying out the termination of pregnancy concerned, or

(b) where it is not practicable to do so before carrying out the termination of

pregnancy, as soon as may be but, in any event, not later than 3 days after the

carrying out of the termination of pregnancy concerned.

3.2 Assessing severity of risk to maternal health

Each woman will need a detailed individual assessment of risk, which could include the woman's own assessment of her situation. In assessing the severity of risk to maternal physical or mental health, practitioners may find it useful to refer to published literature, such as the National Perinatal Epidemiological Centre's Severe Maternal Morbidity Report and MMBRACE-UK Saving Lives, Improving Mothers' Care report.

Although maternal death in Ireland is a rare event, the majority of deaths in the most recent Confidential Enquiry into Maternal Deaths were due to indirect causes (70%). Indirect causes are pre-existing conditions that are exacerbated by pregnancy. Cardiac disease and maternal suicide were the leading causes of maternal death in Ireland in this triennium. The majority of deaths occurred in the setting of an Intensive Care Unit. It is a national recommendation that women with pre-existing medical and mental health conditions should undergo risk assessment at their first antenatal visit and should be afforded high priority by colleagues in other medical disciplines, when referred for assessment. Improvements in communication between clinicians in the event of serious maternal illnesses is also recommended.

Risk to the life, or serious risk to the health of the mother may arise in a number of scenarios. Such risk may occur due to a pre-existing condition, such as chronic renal disease or cardiac disease; may become apparent for the first time in the first or second trimester of pregnancy (cancer or cardiomyopathy); or may be as a result of a sudden deterioration during the first half of pregnancy (chorioamnionitis or severe early onset pre-eclampsia). These cases pose a unique challenge for the clinician with regard to estimation of risk and where a decision is to perform a termination of pregnancy, the timing, mode and place of the procedure in order to best deliver optimal care for the woman. Post termination of pregnancy management and follow up is also central to the care of the woman. This may include bereavement counselling, future pregnancy planning, contraceptive advice and perinatal mental health, or medical follow up, as appropriate to each case. It is not within the scope of this guideline to present all the possible scenarios.

The evaluation of the risk of suicide or serious harm from mental health poses challenges for the Obstetrician in evaluation of risk, decision regarding certification of termination of pregnancy and ongoing management. Guidance is required for direction in the management of acute and urgent mental health problems. It is recommended that perinatal mental health expertise is sought in all cases. Chronic serious mental health disorders include bipolar disorder and schizophrenia which may develop, recur or deteriorate in the perinatal period. Severe depressive illness is the most serious form of

depression where symptoms are severe and persistent and significantly impair a woman's ability to function normally. In line with the HSE's Specialist Perinatal Mental Health Services Model of Care for Ireland Obstetricians need ready access to perinatal mental health experts for acute mental health crises.

4.0 Certification and Notification

In all cases of termination of pregnancy, a form of certification must be completed as specified by the Health (Regulation of Termination of Pregnancy) Act 2018. This certification must confirm the basis for termination of pregnancy as specified by the terms of the Act and provide confirmation of whether the termination of pregnancy to which the certification relates was the subject of a review. This is the responsibility of two medical practitioners, and includes the Obstetrician who carries out the termination of pregnancy. Certification forms are made available by the Department of Health and should be circulated by the HSE to all hospitals. A copy of the certification form is to be retained in the patient's medical file and at least one of those who notify and those who certify need to overlap as per the legislation.

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

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

A certification shall—

- (a) be made in the prescribed form and manner, and*
- (b) contain the prescribed information which shall include—*
 - (i) confirmation of whether the termination of pregnancy to which the certification relates was the subject of a review, and*
 - (ii) in the case of a section 9 certification, section 10 certification or section 11 certification, the clinical grounds for carrying out the termination of pregnancy to which the certification relates*

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

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

Where a termination of pregnancy is carried out in accordance with Sections 9 & 10, the medical practitioner who carried out the termination of pregnancy must also complete the notification forms, as specified by the Health (Regulation of Termination of Pregnancy) Act 2018, and forward these to the Minister for Health at the Department of Health no later than 28 days after the termination of pregnancy has been carried out.

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

Where a termination of pregnancy is carried out in accordance with section 9, 10, 11 or 12, the medical practitioner who carried out the termination of pregnancy shall—

- (a) keep, or cause to be kept, a record, in the prescribed form and manner, of—
 - (i) the carrying out of the termination of pregnancy, and
 - (ii) the information specified in subsection (2), and
- (b) not later than 28 days after the termination of pregnancy has been carried out, forward, or cause to be forwarded, a copy of that record, or such part of that record as may be prescribed, to the Minister in such manner as may be prescribed.

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

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

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

4.1 Non-Certification

Application for review of medical opinion

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

- (a) does not give an opinion, or
 - (b) gives an opinion but not such as would be required for the purposes of a section 9 certification or section 11 certification, as the case may be,
- (in this Part referred to as a “relevant decision”) he or she shall inform the pregnant woman in writing that an application may be made in accordance with subsection (2) to review the relevant decision.

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

Specialists should keep GPs/referring doctors informed of any clinical decision as per usual medical practice.

5.0 Medical Procedure

5.1 Location

Consider the medical condition and current medication of each woman when deciding on the location where the termination of pregnancy is to be performed (i.e. community care with medical team input, stand-alone maternity hospitals and general hospitals with access to intensive care). Where the termination of pregnancy is indicated for mental health reasons, there should be access to perinatal mental health resources, which may include inpatient psychiatric care.

The termination of pregnancy procedure should be carried out in an institution with access to resources and staff with the relevant expertise for optimal care of the woman's particular medical, surgical or obstetric condition. For women attending standalone maternity hospitals who have serious comorbidities or who are critically ill, consideration should be given to transferring women to a general hospital setting to perform the procedure. In this circumstance the Obstetrician caring for the woman will co-ordinate the appropriate location and identify the responsible doctor who will perform the procedure in accordance with the Act.

5.2 Methods of Termination of Pregnancy

Consider the medical condition and current medication of each woman when deciding on the most appropriate method of termination of pregnancy including anaesthesia, prescribing analgesia and antibiotics.

In addition, consider the medical condition of each patient and possible contraindication to medical management with Mifepristone, Misoprostol, analgesia and antibiotic use, and if so an alternative may be required.

Due to certain medical conditions, or in accordance with women's choice, surgical termination may be preferred to medical termination. Consultation with anaesthesiology is advised prior to surgical procedure in women with medical conditions that cause a risk to life or serious risk to health.

Consider the woman's medical condition when choosing the appropriate surgical termination of pregnancy procedure.

Details of medical and surgical methods of termination of pregnancy are found in the Appendix (section 15). This includes the medications for termination of pregnancy, surgical procedures, analgesia, complications and follow-up advice. These protocols may be updated regularly and the clinician is advised to refer to the most up to date protocols.

5.3 Viability

An important consideration in relation to the carrying out of the medical procedure is the issue of viability. We recommend that viability, where appropriate, be discussed as part of multidisciplinary team including Obstetricians and Neonatologists.

6.0 Review

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

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

(a) does not give an opinion, or

(b) gives an opinion but not such as would be required for the purposes of a section 9 certification or section 11 certification, as the case may be, he or she shall inform the pregnant woman in writing that an application may be made in accordance with subsection (2) to review the relevant decision.

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

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

Section 14 (2)

The membership of the review panel shall consist of—

(a) medical practitioners who are registered in the Specialist Division of the register, and

(b) medical practitioners of relevant specialties

The HSE will establish and convene a review committee (Section 15; Health (Regulation of Termination of Pregnancy) Act, 2018) with the necessary expertise to conduct the review. This must happen 'as soon as may be' but not later than 3 days from the date on which the HSE receives an application under section 13 (2). This is detailed in section 16 of the Act.

Section 15 (2)

A review committee shall consist of-

(a) an obstetrician, and

(b) in the case of—

(i) a review of a relevant decision which relates to the circumstances referred to in section 9(1), an appropriate medical practitioner,

Where the review panel agrees that termination of pregnancy is appropriate, the review panel liaises with the HSE to make appropriate clinical arrangements.

Where the review committee does not certify a termination of pregnancy the woman should be referred back to her medical practitioner for ongoing maternity and medical care.

Section 16 Review of relevant decision

(1) The review committee shall complete its review of a relevant decision as soon as may be but, in any event, not later than 7 days from the date on which the review committee was established and convened under section 15(1).

(2) Where the review committee, having examined the pregnant woman, has completed its review of the relevant decision and is of the reasonable opinion formed in good faith that—

(a) (i) there is a risk to the life, or of serious harm to the health, of the pregnant woman,

(ii) the foetus has not reached viability, and

(iii) it is appropriate to carry out a termination of pregnancy in order to avert the risk referred to in subparagraph (i), or

(b) there is present a condition affecting the foetus that is likely to lead to the death of the foetus either before, or within 28 days of, birth, the committee shall jointly certify their opinion as to the matters referred to in paragraph (a) or (b), as the case may be, and, as soon as may be, give notice in writing of its determination to the pregnant woman (or, if the application under section 13(2) concerned was made by another person on behalf of the woman, to that other person and the pregnant woman) and the Executive.

(3) Where the review committee makes a certification referred to in subsection (2), it shall make such arrangements as may be necessary for the carrying out of the termination of pregnancy to which that certification relates in accordance with section 9 or 11, as the case may be.

(4) Where the review committee has completed its review of the relevant decision and is not of the opinion referred to in subsection (2)(a) or (b), it shall, as soon as may be, give notice in writing of its determination to the pregnant woman (or, if the application under section 13(2) concerned was made by another person on behalf of the woman, to that other person and the pregnant woman) and the Executive.

(5) In this section, “jointly certify”, in relation to the review committee, means that the members of the committee jointly make the certification concerned.

It is suggested that the review committee for matters relating to maternal health and life be constituted of at least three members and should include:

- A nominee of the chair from each Obstetric MDT
- Practitioners with experience of the medical issue relevant to the case

7.0 Pre- and Post- Termination of Pregnancy counselling

7.1 Pre-TOP counselling

- The MDT would advise on a care plan for termination of pregnancy and on appropriate immediate, ongoing and postpartum medical care.
- A discussion about the risk to life or serious risk to health should take place prior to termination of pregnancy. Counselling will be tailored to the individual clinical scenario. This discussion should also include an explanation of the termination of

pregnancy process, either medical or surgical, and what will be done during and after the procedure.

- This counselling would also include risk of continuing the pregnancy and risks of termination of pregnancy taking account of her medical disorder:
 - what she is likely to experience (e.g. menstrual like cramps, pain and bleeding)
 - how long the process is likely to take
 - what pain management will be made available to her
 - risks and complications associated with the termination method
 - when she will be able to resume her normal activities, including sexual intercourse
 - follow-up care

7.2 Women who decide to continue with pregnancy

If a woman does not meet criteria for termination of pregnancy, or decides to proceed with the pregnancy, she should continue to have access to medical care and MDT input, as appropriate to her medical condition.

7.3 Post TOP Counselling

All women should be offered appropriate follow up care for medical problems that have preceded or presented for the first time in pregnancy, particularly if these conditions have lifelong health implications.

Women should be given information on counselling services and how to access them, including bereavement care, where appropriate.

In the context of providing termination of pregnancy services, medical staff should be aware of factors likely to increase the risk of poorer mental health outcomes and arrange follow up to enable early detection of those women in need of additional support.

8.0 Contraception

All women should be offered appropriate contraceptive advice after termination of pregnancy, taking into account their medical condition, current medications and plans for future pregnancy.

All women with a high risk pregnancy should be offered counselling on appropriate contraception to avoid a future scenario, where a pregnancy is a risk to their life and health, taking account of the woman's wishes. Caution is suggested when changing contraceptive methods in patients with significant medical disorders. Post-partum contraception prior to discharge needs to be considered in those who have had complicated pregnancies and those of very high parity. The Faculty of Sexual and Reproductive Health (FSRH) of the Royal College of Obstetricians and Gynaecologists (RCOG) UK Medical Eligibility Criteria provides advice about what contraceptive methods can be safely used based on medical conditions a woman may have.

This position is also upheld by WHO, Royal College of Obstetricians and Gynaecologists (RCOG), Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and College National des Gynecologues et Obstetriciens Francais (CNGOF) whose guidance advise that post TOP contraception is part of TOP provision and after-care.

The WHO (2014) advise that “Before leaving the health-care facility following the surgical abortion procedure or administration of medical abortion pills, all women should receive contraceptive information and, if desired, the contraceptive method of their choice or referral for such services”. The WHO also advise “that some women prefer to discuss options after the abortion is completed.” Therefore, it is imperative that a patient centred approach is used, and personal choice is taken into consideration.

Immediate initiation of most methods of contraception can either be started on the day Mifepristone is taken or the day of surgical termination. The only exception is for Intra Uterine Devices (IUDs), where it’s advised to delay insertion until medical abortion is deemed complete. Long acting reversible contraceptives (LARCs) should be promoted as the most effective method of contraception and should be initiated immediately for both medical and surgical TOPs.

9.0 Training and Education

Appropriate training and support should be available to staff involved in the care of women requiring termination of pregnancy.

Obstetricians and other healthcare professionals involved in the care of seriously ill pregnant women require education/training regarding implementation of this guidance document. This would include education on counselling regarding risk, as well as counselling on risks and benefits of termination of pregnancy, when there is a risk to life or risk of serious harm to health.

Additional training to develop the specific skills required in surgical termination of mid trimester pregnancy may be required.

Educational sessions are required to inform doctors about the pathway outlined in this guidance document, and to ensure familiarity with the procedures, paperwork and the operations of the Review panel.

All clinical staff, including medical, midwifery, nursing and support workers should have access to evidence- based training. This is essential to ensure that they have the relevant knowledge, skills and competencies to provide medical and surgical terminations in line with clinical guidelines. Staff should have access to training on:

- Outline of legal context, model of care and location of services
- Medical termination of pregnancy
- Surgical termination of pregnancy
- Frequency and management of complications of termination of pregnancy
- Values clarification
- Post termination contraception, including permanent contraception
- Case based discussions
- Outcome measures and Clinical Audit

From a holistic perspective, training should also address the following:

- Non-directive information and support for women seeking abortion care
- Contraceptive provision

- Participation in values clarification exercises to enable providers differentiate their own personal beliefs and attitudes from the needs of women seeking termination of pregnancy
- Wellbeing / supporting the carer / vicarious trauma / emotional fatigue

As medical practitioners in the community, as well as Obstetricians in secondary and tertiary care will be responsible for the provision of termination of pregnancy care, there are many opportunities for collaborative learning.

10.0 Audit

We recommend ongoing audit of termination of pregnancy for the risk of maternal death or serious maternal morbidity to ensure appropriate implementation of this guidance document and to inform continuous quality improvement.

11.0 Consent

Nothing in the Act operates to remove or amend any existing rule of law in relation to consent.

All women should have the opportunity to discuss the different options available to them. Appropriate consent should be obtained prior to medical or surgical termination of pregnancy which clearly outlines the risks, benefits, side effects and complications of both pathways.

12.0 Conscientious Objection

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

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

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

13.0 Disposal of fetal tissue

Women who have a medical or surgical termination in secondary care should be made aware of the options that exist for fetal tissue disposal prior to the procedure. Women should be given verbal or written information about the options and given the opportunity to discuss them (HSE 2018). These pathways will be arranged by the HSE via the National Women and Infant Health Programme, in conjunction with local hospital management. Women may not wish to know about the disposal of the pregnancy remains or be involved in decisions about disposal, and may decline the offer of information about the possible options. These options include incineration, cremation and burial of pregnancy remains.

Care should be provided in a manner appropriate to the specifics of each case to ensure that a women can make the decision that is right for them. At later gestations, women should be given specific information regarding hospital burial and be facilitated to make choices. Some women will make their own burial arrangements at a family plot or choose cremation.

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

Women should be offered bereavement support by the bereavement team when desired, preferably in their local maternity hospital (e.g. the Bereavement CMS), although this will depend on where the woman delivers.

14.0 Glossary

ACOG	American College of Obstetricians and Gynecologists
CNGOF	Collège National Des Gynécologues et Obstétriciens Français
CO	Conscientious objection
DOH	Department of Health
D&E	Dilatation and Evacuation
ERPC	Evacuation of retained products of conception
EVA	Electric Vacuum Aspiration
FBC	Full blood count
GA	Gestational age
GP	General Practitioner
Hb	Haemoglobin
hCG	Human chorionic gonadotrophin
HSE	Health Service Executive
HTN	Hypertension
ICGP	Irish College of General Practitioners
IOG	Institute of Obstetricians and Gynaecologists
IUD	Intrauterine device
LARC	Long acting reversible contraception
MDT	Multi-disciplinary team
MTOP	Medical termination of pregnancy
MVA	Manual vacuum aspiration
NPEC	National Perinatal Epidemiology Centre
PO	Per Os (Oral administration)
PV	Per vagina
PR	Per rectum
RCOG	Royal College of Obstetricians and Gynaecologists

Rh	Rhesus
STOP	Surgical termination of pregnancy
TOP	Termination of pregnancy
VTE	Venous thromboembolism
WHO	World Health Organization

15.0 Appendix: Methods of Termination of Pregnancy

Caution: Consider the medical condition of each patient and possible contraindication to medical management with mifepristone, misoprostol, analgesia and antibiotic use, and if so an alternative may be required.

If a woman is having a termination of pregnancy at 7 weeks gestation or greater a blood group and Rhesus D testing should be performed. This will identify Rhesus D negative women, who should be offered Anti-D immunoglobulin to prevent Rhesus D sensitisation during future pregnancies.

1. Methods of Medical Termination of Pregnancy (MTO) < 9 weeks

Mifepristone will be taken in the presence of the medical provider. Pregnant women will be provided with a dedicated medication pack containing a second dose of 400 micrograms misoprostol, a prescription for analgesia and a low-sensitivity pregnancy test. This pack will also contain the written information leaflets prepared by the HSE implementation group on the termination process, including details of what to expect and when to seek help. Patients will be provided with the 24/7 helpline number and advised to phone if they have concerns (Contact details for 24/7 helpline: website - myoptions.ie; phone - 1800 828 010).

The process of medical termination of pregnancy involves:

- 200mg mifepristone orally
- 24 – 48 hours later 800 micrograms misoprostol (buccal, vaginal or sublingual administration) at home
- Administer Anti-D to Rhesus negative women if GA > 7 weeks

Analgesia

- Ibuprofen 600mg/solpadeine (paracetamol 1000mg/codeine phosphate 16mg) to be taken with first dose of misoprostol
- Paracetamol 1000mg 6 hourly if required
- If pain not controlled by above analgesics, return to care provider for review +/- additional analgesia
- **Consider the medical condition and current medication when prescribing medication.**

Common medication side effects (Hamoda et al. 2005)

- Nausea 69%
- Vomiting 49%
- Diarrhoea 42%
- Thermoregulatory effects – fever, warmth, hot flushes or chills

Complications

- Emergency ERPC for pain +/- bleeding increases from 1.4% at 43-49 days, to 2.5% at 57-63 days (Gatter, Cleland & Nucatola 2015)
- Continuing pregnancy with this regimen increases with gestation: A meta-analysis of clinical trials yielded estimates of 0.4% at 49 days or less; 0.8% at 50-56 days; 1.8% at 57-63 days and 2.9% at 64-70 days (Cleland et al., 2013)
- Infection 0.01-0.92% (Shannon et al., 2004, Gatter, Cleland & Nucatola 2015, Raymond et al. 2013, Upadhyay et al., 2015)

- Blood transfusion 0.03-0.1% (Raymond et al. 2013, Gatter, Cleland & Nucatola 2015)
- Vomiting within 45 minutes after the intake of mifepristone could lead to a decrease in mifepristone efficacy: oral intake of a further 200mg mifepristone dose is recommended in this situation.

Follow up

- **For women with a serious medical condition hospital follow up care is appropriate.**

2. Methods of Medical Termination of Pregnancy (MTO) 9-12 weeks

- 200mg mifepristone administered in an outpatient setting
- 24 – 48 hours later, admit to hospital for 800 micrograms misoprostol (buccal, vaginal or sublingual administration)
- Administer Anti-D to Rhesus negative women

Analgesia

- Ibuprofen 600mg/solpadeine (paracetamol 1000mg/codeine phosphate 16mg) to be taken with first dose of misoprostol
- Paracetamol 1000mg 6 hourly if required
- **Consider the medical condition and current medication when prescribing medication.**

Common medication side effects (Hamoda et al. 2005)

- Nausea 69%
- Vomiting 49%
- Diarrhoea 42%
- Thermoregulatory effects – fever, warmth, hot flushes or chills
- A complete list of potential adverse effects is available in the manufacturer’s summary of product characteristics.

Complications

- 3 per 100 women will experience pain and bleeding prior to commencing misoprostol
- Prolonged bleeding up to 12 days is common
- Continuing pregnancy occurs at a rate of 1.5 % - 2.9% (Ashok et al. 2002, Chen et al. 2013, Chen & Creinin 2015)
- Vomiting within 45 minutes after the intake of mifepristone could lead to a decrease in mifepristone efficacy: oral intake of a further 200mg mifepristone dose is recommended in this situation

Follow up

All patients must be advised to perform a low sensitivity urine pregnancy test at two weeks post TOP to rule out ongoing pregnancy. If this is still positive, if the woman still feels pregnant, or if the bleeding has been light, an urgent ultrasound and medical review are required. All women should be informed of the option to attend their GP or community doctor for an aftercare visit to discuss contraception plus any further counselling needs. **Hospital follow up may be more appropriate for women depending on their medical condition.**

Contraindications

Mifepristone should not be used in the following situations:

- Chronic adrenal failure
- Hypersensitivity to mifepristone or to any of the excipients
- Severe asthma uncontrolled by therapy
- Inherited porphyria
- Suspected extra-uterine pregnancy
- Contraindication to misoprostol

Misoprostol should not be used in the following situations:

- Hypersensitivity to Misoprostol or other prostaglandins, or to any of the excipients
- Suspected ectopic pregnancy

Prescribers must be familiar with the special warnings and precautions for use available in the manufacturer's summary of product characteristics.

Drug interactions with Medical TOP

On the basis of Mifepristone's metabolism by CYP3A4, it is possible that ketoconazole, itraconazole, erythromycin, and grapefruit juice may inhibit its metabolism (increasing serum levels of Mifepristone). Furthermore, rifampicin, dexamethasone, St. John's Wort and certain anticonvulsants (phenytoin, phenobarbital, carbamazepine) may induce Mifepristone metabolism (lowering serum levels of mifepristone).

Consultation with a clinical pharmacist and other relevant medical specialties should occur before a patient is prescribed Mifepristone in the following scenarios:

- Adrenal failure
- Long term corticosteroid therapy for asthmatic patients (efficacy may be decreased during the 3 to 4 days following intake of mifepristone and therapy may need to be adjusted)
- Chronic Kidney disease
- Inherited porphyria
- Coagulopathy or anticoagulant therapy
- Severe anaemia – Hb <9.5g/dl
- Severe cardiovascular disease (uncontrolled HTN, angina, valvular disease, arrhythmia, heart failure).

Consultation with a clinical pharmacist and other relevant medical specialties should occur before a patient is prescribed Misoprostol in the following scenarios:

- Hypersensitivity to Misoprostol or other prostaglandins, or to any of the excipients
- Women with risk factors for cardiovascular disease (e.g. age over 35 years with chronic smoking, hyperlipidemia, diabetes) or established cardiovascular disease

3. Methods of Surgical Termination of Pregnancy (STOP)

Caution: Consider the medical condition of each patient and possible contraindication to medications, and if so an alternative medication may be required.

Surgical Termination of Pregnancy (STOP) < 9 weeks

Due to certain medical conditions or in accordance with women's choice, surgical termination may be preferred to medical termination, even at earlier gestations. It is unlikely that surgical termination of pregnancy will be performed at gestations less than 7 weeks due to the possibility of missing the gestational sac during aspiration (Fiala et al. 2012).

Surgical Termination of Pregnancy (STOP) 9-12 weeks

Manual vacuum aspiration (MVA) is usually performed without general anaesthetic (e.g. under a para cervical block). Electric vacuum aspiration (EVA) is usually performed under general anaesthetic or procedural sedation. All surgical terminations must be performed by or under the supervision of a trained and experienced operator. A pelvic ultrasound is routinely recommended prior to surgical termination of pregnancy. **Consider the woman's medical condition when deciding on the appropriate surgical method of termination of pregnancy.**

Manual Vacuum Aspiration Procedure

- Pre-operative analgesics (ibuprofen 800mgs PO or diclofenac 75mgs PO/100 mg PR) 60 – 90
- minutes prior to procedure and antibiotics (doxycycline/azithromycin unless contraindicated by medical condition)
- Pre-operative cervical priming (400 micrograms misoprostol administered PV) 3-4 hours prior to procedure (World Health Organization 2014)
- Paracervical block is sometimes administered
- Entonox should be available on request
- Intravenous sedation by an anaesthesiologist can also be used as an alternative to local anaesthesia
- When local anaesthesia is being used the constant presence of a nurse or health care assistant entirely dedicated to the service user is essential
- Administer Anti-D to Rhesus negative women if GA > 7 weeks

Complications of Manual Vacuum Aspiration

- Incomplete evacuation (0.5%) - may require medication or further procedures to limit the risk of infection
- Perforation of the uterus (0.7%)
- Damage to other structures (e.g. bladder - very rare)

Contra indications to Out Patient Manual Vacuum Aspiration

- Patient declines to have procedure under sedation
- A history of difficulty in tolerating speculum examinations
- Complex medical problems, e.g. cyanotic congenital heart disease
- Bleeding disorders

MVA combines the advantages of a surgical procedure with lower cost than EVA. MVA has the advantage that the patient may eat or drink as normal prior to having the procedure performed (Milingos et al. 2009, Kumar et al. 2013). The mean and median time from arrival to discharge

with MVA in a recent study was 2.5 and 2.57 hours respectively (Pillai et al. 2015). Of note, the MVA procedure may not be suitable for women having a termination of pregnancy under section 9 & 10 of the Act.

Electric Vacuum Aspiration

Caution: Consider the medical condition of each patient and possible contraindication to medications, and if so an alternative medication may be required.

Caution: Consider the woman's medical condition when choosing the appropriate surgical procedure for termination of pregnancy.

Procedure of Electric Vacuum Aspiration

- Usually in theatre under general anaesthetic
- Obtain FBC and Group and hold
- Pre-operative Cervical Priming (400 micrograms misoprostol administered PV) 3-4 hours prior to procedure (World Health Organization 2014)
- Prescribe analgesia and antibiotics (doxycycline/azithromycin unless contraindicated by medical condition)
- Administer Anti-D to Rhesus negative women if GA > 7 weeks

Complications of Electric Vacuum Aspiration

- Repeat procedure 2%
- Uterine perforation 0.6-0.8%
- Intra-abdominal trauma 0.1%
- Ongoing pregnancy 0.23%
- Cervical damage < 1%
- Haemorrhage
- Infection
- Intrauterine adhesions

Contraindications to EVA

- For women with medical disorders liaise with anaesthetist regarding general anaesthesia for EVA.

Follow up

- Appropriate follow up should be offered by the relevant obstetrical and medical team post pregnancy
- No need for routine pregnancy test unless woman still feels pregnant
- No indication for routine post procedure ultrasound
- All women should be informed of the option to attend their GP or hospital doctor for an aftercare visit to discuss contraception plus any further counselling needs

4. Methods of Termination of Pregnancy - over 12 weeks gestation

Caution: Consider the medical condition of each patient and possible contraindication to medical management with Mifepristone, Misoprostol, analgesia and antibiotic use, and if so an alternative may be required.

Medical termination of pregnancy over 12 and under 24 weeks gestation

The recommended protocol is;

- Mifepristone 200mg taken orally
- Followed at an interval of not less than 24 hours and not more than 48 hours
- By Misoprostol 400microgram buccal, vaginal or sublingual administration, 3-hourly

If this protocol fails to complete the medical termination;

The protocol can be restarted after a minimum of 12 hours rest and preferably 24 hours

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

In the setting of a previous uterine scar:

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

In the setting of suspected chorioamnionitis/pyrexia following second trimester preterm prelabour rupture of membranes it may be more appropriate to consider oxytocin rather than mifepristone and misoprostol for termination of pregnancy. Oxytocin should be administered as per a hospital's usual protocol.

Misoprostol administration

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

Surgical termination of pregnancy

Termination of pregnancy after 14 weeks of pregnancy, when fetal size precludes complete aspiration requires dilatation and evacuation (D&E). The Royal College of Obstetricians & Gynaecologists (RCOG, UK) only recommends D&E when undertaken by specialist practitioners with access to the necessary instruments and who have a sufficiently large caseload to maintain their skill. It is unlikely that surgical termination of pregnancy after 12 weeks will be widely available nor that D&E after 14 weeks will be offered in Ireland in 2019, but this may change over time.

16.0 Bibliography / References

Institute of Obstetricians and Gynaecologists – Interim Clinical Guidance: [Pathway For Management Of Fatal Fetal Anomalies And/Or Life-Limiting Conditions Diagnosed During Pregnancy](#). Author – Keelin O’Donoghue. January 2019

Institute of Obstetricians and Gynaecologists – Interim Clinical Guidance: [Termination of Pregnancy – under 12 weeks](#). December 2018

Severe Maternal Morbidity in Ireland Annual Report 2016
<https://www.ucc.ie/en/media/research/nationalperinatalepidemiologycentre/annualreports/SevereMaternalMorbidityinIrelandAnnualReport2016.pdf>

MBRRACE-UK Report - Saving Lives, Improving Mothers’ Care - Lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2014–16
<https://www.npeu.ox.ac.uk/downloads/files/mbrance-uk/reports/MBRRACE-UK%20Maternal%20Report%202018%20-%20Web%20Version.pdf>

Guide to Professional Conduct and Ethics for Registered Medical Practitioners. Irish Medical Council. 8th Edition, 2016
https://issuu.com/mcirl/docs/guide_to_professional_conduct_and_e?e=12642421/35694606

Health (Regulation of Termination of Pregnancy) Act, 2018
<https://data.oireachtas.ie/ie/oireachtas/act/2018/31/eng/enacted/a3118.pdf>
<http://www.irishstatutebook.ie/eli/2018/act/31/enacted/en/html?q=termination>

Health (Regulation of Termination of Pregnancy) Act 2018 (Notifications) Regulations 2018 ([S.I. No. 597 of 2018](#))

Health (Regulation of Termination of Pregnancy) Act 2018 (Certification) Regulations 2018 ([S.I. No. 596 of 2018](#))

Health (Regulation of Termination of Pregnancy) Act 2018 (Application for Review of Relevant Decision) Regulations 2018 ([S.I. No. 595 of 2018](#))

HSE Guidelines for medical practitioners, nurses, and midwives in HSE hospitals and agencies funded under Section 38 of the Health Act 2004 regarding conscientious objection under the Health (Regulation of Termination of Pregnancy) Act 2018. HSE, 2018

Protection of Life During Pregnancy Act 2013
<http://www.irishstatutebook.ie/eli/2013/act/35/section/5/enacted/en/html>

Second-trimester abortion. ACOG Practice Bulletin No. 135:
Obstet Gynecol. 2013 Jun; 121 (6):1394-406. doi: 10.1097/01.AOG.0000431056.79334.cc.

Faculty of Sexual Reproductive Health UK Medical Eligibility Criteria for Contraceptive Use (UK MEC) <https://www.fsrh.org/ukmec/>

Specialist Perinatal Mental Health Services – Model of Care for Ireland, November 2017
<https://www.hse.ie/eng/services/list/4/mental-health-services/specialist-perinatal-mental-health/specialist-perinatal-mental-health-services-model-of-care-2017.pdf>

Gatter M., Cleland K. & Nucatola D.L. (2015) Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days. *Contraception*, **91**(4), 269-273.

Chen M.J. & Creinin M.D. (2015) Mifepristone with buccal misoprostol for medical abortion: a systematic review. *Obstetrics & Gynecology*, **126**(1),12-21.

Raymond E.G., Shannon C., Weaver M.A. & Winikoff, B. (2013) First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review. *Contraception*, **87**(1), 26-37.

Kapp N., Eckersberger E., Lavelanet A. & Rodriguez M.I. (2018) Medical abortion in the late first trimester: a systematic review. *Contraception*. Retrieved from <https://www.sciencedirect.com/>, DOI: <https://doi.org/10.1016/j.contraception.2018.11.002> on 13th December 2018

Hamoda H., Ashok P.W., Flett G.M. & Templeton A. (2005) A randomised controlled trial of mifepristone in combination with misoprostol administered sublingually or vaginally for medical abortion up to 13 weeks of gestation. *British Journal of Obstetrics and Gynaecology*, **112**(8), 1102-8.

Royal College of Obstetrics and Gynaecologists (2011) *The care of women requesting induced abortion: Evidence based clinical guideline number 7*. Sussex place, London.

Cleland K., Creinin M.D., Nucatola D., Nshom M. & Trussell J. (2013) Significant adverse events and outcomes after medical abortion. *Obstetrics and Gynecology*, **121**(1), 166-171.

Shannon C., Brothers L.P., Philip N.M. & Winikoff B. (2004) Infection after medical abortion: a review of the literature. *Contraception*, **70**(3), 183-190.

Upadhyay U.D., Desai S., Zlidar V., Weitz T.A., Grossman D., Anderson P. & Taylor D. (2015) Incidence of emergency department visits and complications after abortion. *Obstet Gynecol*, **125**(1), 175-183.

Royal College of Obstetricians and Gynaecologists (2015) *Best Practice in Comprehensive Abortion Care: Best Practice Paper No.2*. Sussex Place, London.

Ashok P.W., Kidd A., Flett G.M., Fitzmaurice A., Graham W. & Templeton, A. (2002) A randomized comparison of medical abortion and surgical vacuum aspiration at 10–13 weeks' gestation. *Human reproduction*, **17**(1), 92-98.

Chen Q.J., Zhang J., Huang Z.R., Fan X.F., Wang H.Y., Hong Z.H.U., Hou S.P., Liu Y.H., Qiao Q.Q., Zhang P. & Yan, L.I.U. (2013) Mifepristone in Combination with Misoprostol for the Termination of Pregnancy at 8–16 Weeks' Gestational Age: A Multicentre Randomized Controlled Trial. *Journal of Reproduction and Contraception*, **24**(2), 101-113.

Fiala C., Cameron S., Carmo-Bombas T., Gemzell-Danielsson K., Parachini M. & Shojai R. (2012) *Early Medical Abortion: A Practical Guide for Health Professionals*. International Federation of Professional Abortion and Contraception Associates (FIAPAC).

Milingos D.S., Mathur M., Smith N.C. & Ashok P.W. (2009) Manual vacuum aspiration: a safe alternative for the surgical management of early pregnancy loss. *BJOG: An International Journal of Obstetrics & Gynaecology*, **116**(9), 1268-1271.

Kumar V., Chester J., Gupta J. & Shehmar M. (2013) Manual vacuum aspiration under local anaesthetic for early miscarriage: 2 years' experience in a university teaching hospital in UK. *Gynecological Surgery*, **10**(4), 241-246.

Pillai M., Welsh V., Sedgeman K., Gazet A.C., Staddon J. & Carter H. (2015) Introduction of a manual vacuum aspiration service: a model of service within an NHS Sexual Health Service. *J Fam Plann Reprod Health Care*, **41**(1), 7-32.

World Health Organisation (2014) *Clinical Practice Handbook for Safe Abortion*. Geneva, Switzerland.

American Psychological Association, Task Force on Mental Health and Abortion (2008) Report of the Task Force on Mental Health and Abortion. Washington, DC: Author. Retrieved from <http://www.apa.org/pi/wpo/mental-health-abortion-report.pdf>

Schreiber C.A., Sober S., Ratcliffe S., & Creinin M.D. (2011) Ovulation resumption after medical abortion with mifepristone and misoprostol. *Contraception*, **84**(3), 230-3

Okusanya B.O, Oduwole O. & Effa E.E. (2014) Immediate postabortal insertion of intrauterine devices. *Cochrane Database Systematic Reviews*, **28**(7).



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