INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

INTERIM CLINICAL GUIDANCE

Termination of pregnancy under 12 weeks

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Additional Input

- Legal Review
- National Women's Council of Ireland

Please refer to IOG/ICGP Interim Clinical Guidance and Guidelines document on Termination of Pregnancy for further information on methodology.

Summary of Clinical Guidance

Recommendation 1
Increasing the accessibility to medical termination of pregnancy services in the community leads to women having their termination at an earlier gestation. Since earlier termination is safest for women, this service should be made widely available.

Recommendation 2
A 24/7 telephone helpline, staffed by clinical staff is an important component of a comprehensive, island–wide service. The helpline should provide initial counselling, signposting to providers and symptom advice for women before, during and after termination of pregnancy.

Recommendation 3
The Act states that "12 weeks of pregnancy" shall be construed in accordance with the medical principle that pregnancy is generally dated from the first day of a woman's last menstrual period.
In clinical practice data regarding the woman's last menstrual period is combined with an ultrasound assessment of crown rump length to determine the gestational age. A Crown Rump Length of 63mm is defined as the upper limit for termination of pregnancy at 12 weeks + 0 days gestation.

Recommendation 4
Individuals who perform obstetric scans routinely should have specialised training that is appropriate to the practice of diagnostic ultrasound for pregnant women.

Recommendation 5
If a woman is sure of her dates and has no risk factors for or symptoms of ectopic pregnancy, an ultrasound is not mandatory prior to termination of pregnancy at gestations less than 9 weeks.

Recommendation 6
Where there are clinical concerns, based on history or examination findings, an ultrasound should be arranged prior to medical termination of pregnancy at gestations of less than 9 weeks.

Recommendation 7
In order to ensure access and to aid with counselling regarding risks and benefits of different termination of pregnancy care pathways, an ultrasound scan should be arranged prior to termination of pregnancy between 9- and 12-weeks' gestation.

Recommendation 8
Women should be asked about their wishes to see the ultrasound screen or not.

Recommendation 9
If a patient seeking a termination of pregnancy is less than 7 weeks' gestation (<49 days post LMP), the risk of Rhesus D sensitisation is negligible, therefore blood group and Rhesus D testing is not indicated.

Recommendation 10
If a patient is seeking a termination of pregnancy is 7 weeks' gestation or greater (≥49 days post LMP), a blood group and Rhesus D testing is advised, in order to identify those who are Rhesus D negative, and take steps to prevent Rhesus D sensitisation during future pregnancies.

Recommendation 11
Women should be counselled on the limitations of data estimating the risk of Rhesus D sensitisation associated with medical termination of pregnancy at 7- 9 weeks' gestation. Following full counselling on the potential risks and the limitations of the existing data, it is ultimately each woman's choice whether to receive Anti-D at this gestation.

Recommendation 12
For Rhesus D negative women who have a medical or surgical termination of pregnancy between 9- and 12-weeks' gestation, a dose of at least 250IU of anti-D immunoglobulin should be administered to prevent Rhesus D sensitisation.

Recommendation 13
Determination of the risk of Rhesus D sensitisation following a termination of pregnancy should be deemed a high research priority and high-quality, adequately-powered studies should be resourced.

Recommendation 14
The decision to evacuate the uterus following incomplete termination of pregnancy should be based on clinical signs and symptoms and not on ultrasound appearance.

Recommendation 15
Ultrasound examination should not be used routinely to screen women for incomplete abortion after medical or surgical termination of pregnancy.

Recommendation 16
As part of the medical consultation prior to termination of pregnancy, an assessment of the woman's risk of venous thromboembolism (VTE) should be considered. Women with significant risk factors for VTE may require anticoagulant treatment until the termination is performed and up to six weeks afterwards.

Recommendation 17
Routine screening for genital infections is not indicated for women prior to termination of pregnancy except where the woman has symptoms or signs of genital infection or is known to be a contact of chlamydia or gonorrhoea.

Recommendation 18
Prior to termination of pregnancy, screening for chlamydia and gonorrhoea can be offered to women at greater risk (e.g. women younger than 25 or those with a new partner in the previous 12 months).

Recommendation 19
Routine antibiotic prophylaxis is not recommended prior to first trimester medical termination of pregnancy except where the woman has symptoms or signs of genital infection or is known to be a contact of chlamydia or gonorrhoea.

Recommendation 20
Routine antibiotics are recommended prior to or at the time of surgical termination of pregnancy.

Recommendation 21

Women presenting with infectious complications of termination of pregnancy should be managed in line with the HSE antibiotic prescribing guidelines.

Recommendation 22
Women diagnosed with a chlamydia or gonorrhoea should be offered full Sexually Transmitted Infection screening, including serology for HIV, Hepatitis B, syphilis and Hepatitis C (where indicated).

Recommendation 23
Women diagnosed with chlamydia or gonorrhoea should be managed in line with the HSE antibiotic prescribing guidelines.

Recommendation 24
Many women have decided to have a termination of pregnancy before seeking care, and this decision should be respected. A woman should not be compelled to attend mandatory counselling.

Recommendation 25
It is important that women have access to a trained professional 24/7 to answer clinical queries during home medical termination of pregnancy.

Recommendation 26
Counselling should be available promptly and provided by appropriately trained individuals to all pregnant women who request this service, prior to, during and post termination of pregnancy.

Recommendation 27
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.

Recommendation 28
After surgical or medical termination of pregnancy, all women should be offered contraceptive information and, if desired, the contraceptive method of their choice or referral for this service.

Recommendation 29
It is important for health care professionals to recognise that some women prefer to discuss contraceptive options after the termination is completed.

Recommendation 30
Doctors with a conscientious objection to carrying out or participating in carrying out a termination of pregnancy, are obliged to make the necessary arrangements for the transfer of care of the pregnant woman, to enable her to avail of a termination of pregnancy.

Recommendation 31
A termination may be carried out by a medical practitioner where, having examined the pregnant woman, the medical practitioner 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, of the pregnant woman and it is immediately necessary to carry out the termination of pregnancy in order to avert that risk. In an emergency, the patients' care must be made a priority and the necessary treatment must be provided. This remains the position irrespective of any conscientious objection of the medical practitioner.

1.0 Introduction

1.1 Background and Statutory Context

This 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. On the 5th November 2018, a multidisciplinary early pregnancy working group, led by the Institute of Obstetricians and Gynaecologists, was convened to collate the evidence presented in this guidance document.

The purpose of this guidance document is to provide clinical guidance for health care providers, regarding section 12 and section 10 of the Act, which deals with termination of pregnancy prior to 12 weeks (12 weeks +0 days) gestation. Section 9 and section 11 are dealt with in separate guidance documents.

Section 12 of the Health (Regulation of Termination of Pregnancy) Act 2018 states that:

> **Early pregnancy**
> **12.** (1) 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 the pregnancy concerned has not exceeded 12 weeks of pregnancy.
>
> (2) A termination of pregnancy shall not be carried out under this section unless the medical practitioner referred to in *subsection (1)* has certified his or her opinion as to the matter referred to in that subsection.
>
> (3) The termination of pregnancy shall not be carried out by a medical practitioner unless a period of not less than 3 days has elapsed from—
> (a) the date of certification under *subsection (2)* by that medical practitioner, or
> (b) where a certification was previously made in respect of the pregnancy by another medical practitioner for the purposes of *subsection (2)*, the date of that previous certification.
>
> (4) A termination of pregnancy to which the certification referred to in *subsection (2)* relates shall be carried out as soon as may be after the period referred to in *subsection (3)(a)* or *(b)*, as the case may be, has elapsed but before the pregnancy has exceeded 12 weeks of pregnancy.
>
> (5) For the purposes of this section, "12 weeks of pregnancy" shall be construed in accordance with the medical principle that pregnancy is generally dated from the first day of a woman's last menstrual period.

Under the Health (Regulation of Termination of Pregnancy) Act 2018, a termination of pregnancy may be carried out if a medical doctor has certified that, the pregnancy has not exceeded 12 weeks, and a period of not less than three days have elapsed from the date of certification.

1.2 Certification

The Institute of Obstetricians and Gynaecologists requested clarity from the Department of Health regarding the 3-day certification period and received a response from the Chief Medical Officer (CMO), see Appendix 1. In practice, if certification occurs on Monday the procedure may commence on Thursday, and so forth.

It is of utmost importance that doctors comply with the certification process as legally required by the Act. At the time of finalising this guidance document, no information was available from the Department of Health regarding how the certification process would occur.

1.3 Definition of 12 weeks

Further clarification was also sought from the Department of Health regarding the "12-week rule". The letter of response from the CMO is attached in Appendix 2. This specifies that, as per the legislation:

> **12.** (1) 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 the pregnancy concerned has not exceeded 12 weeks of pregnancy.
>
> *"Twelve weeks plus 1 day exceeds 12 weeks. Therefore, 12 weeks is 12 weeks + 0 days"*

1.4 Failed Terminations after 12 weeks

Further clarification was also sought from the Department of Health on the situation where a medical termination of pregnancy is attempted but an ongoing pregnancy is subsequently discovered after 12 weeks + 0 days. The response indicated that a termination procedure that begins before 12 weeks can be lawfully completed, however a repeat course of treatment cannot be instigated. Once a pregnancy has exceeded 12 weeks and 0 days, no further intervention is legally permitted unless the maternal or fetal grounds set out in the Act are fulfilled (See Appendix 3). The legal implication of breaching the legislation is outlined below (full text from legislation available in Appendix 4):

> **23.** (1) It shall be an offence for a person, by any means whatsoever, to intentionally end the life of a foetus otherwise than in accordance with the provisions of this Act.
>
> (5) A person who is guilty of an offence under this section shall be liable on conviction on indictment to a fine or imprisonment for a term not exceeding 14 years, or both.

1.5 Accessibility

It is universally recognised that abortion is safest when performed at the earliest gestation possible. Services should be able to meet the local demand for abortion so that women can have their abortion at the earliest possible gestation and as close to home as possible (RCOG 2015). To minimise delay, service arrangements should be such that the abortion can be provided as soon as possible, and a system should be in place to ensure that the required certification documentation is completed accurately and in a timely manner (RCOG 2015). Services for women with an unplanned pregnancy should be freely accessible in an equitable manner across all areas of Ireland. Women should have access to confidential advice, free of judgement and pressure. They should receive detailed, non-directive information on all options available to them. They should be enabled to explore their thoughts and feelings around the pregnancy, and consider the personal implications of different outcomes and decisions. Women should be empowered to trust their own judgement (Department for Health and Ageing (DHA), Government of South Australia 2014).

TOP up to 9 weeks gestation

Increasing the accessibility of medical termination of pregnancy (MTOP) services in the community leads to women having their termination at an earlier gestation (Fiala *et al*. 2012). In European countries, over 90% of women choose medical TOP when available. Medical TOP is currently the most

frequent method of termination of pregnancy in Scandinavian countries (>90%), Portugal (65%), Spain (63%) and Switzerland (62%). The introduction of medical TOP in Sweden led to the percentage of terminations occurring under 9 weeks increasing from 40% in 1991 to 80% in 2011 (Fiala *et al*. 2012). This trend has been reflected in many other countries where TOP is easily accessible in the community. Early medical TOP is preferable for many reasons: local to the woman; avoidance of surgery/anaesthesia; reduction of pain; perceived safety; efficacy, privacy; a "more natural" approach and the ability to accommodate other commitments (eg. work, home life) (WHO 2014).

TOP care 9-12 weeks' gestation

Termination of pregnancy between 9 and 12 weeks gestation usually takes place in secondary care. Initially, women will be admitted to secondary care for medical or surgical termination of pregnancy. The National Women and Infants Health Programme is responsible for ensuring that an accessible service is available for Irish women in all geographic regions of Ireland; this is outlined in the HSE Model of Care Document (2018).

Since this is a new service which some doctors will opt-in to provide, the first point of contact will be a 24/7 helpline which will provide:

- Non-directive crisis pregnancy counselling
- Signposting to community-based providers (who have opted to share their details publicly)
- Advice regarding pain and bleeding during home MTOP
- Follow up counselling
- **Contact details for 24/7 helpline: website - *myoptions.ie*; phone - *1800 828 010***

Recommendation

Increasing the accessibility to medical termination of pregnancy services in the community leads to women having their termination at an earlier gestation. Since earlier termination is safest for women, this service should be made widely available.

Recommendation

A 24/7 telephone helpline, staffed by clinical staff is an important component of a comprehensive, island–wide service. The helpline should provide initial counselling, signposting to providers and symptom advice for women before, during and after termination of pregnancy.

2.0 Ultrasound dating

As per the legislation:

> (5) For the purposes of this section, "12 weeks of pregnancy" shall be construed in accordance with the medical principle that pregnancy is generally dated from the first day of a woman's last menstrual period.

In clinical practice, the data from a woman's menstrual history is combined with an ultrasound assessment of the crown-rump length (CRL) to assess gestational age. While it is important to take into consideration the information provided by the woman (menstrual data, first day of last menstrual period (LMP) etc.) regarding her gestation, an ultrasound measured CRL is considered the gold standard.

Crown rump length assessment is used to date pregnancies in the first trimester. CRL measurements can be carried out by transabdominal or transvaginal ultrasound. As per the International Society of Ultrasound in Obstetrics & Gynaecology (ISUOG) Practice Guidelines 2013, "A midline sagittal section

of the whole embryo or fetus should be obtained, ideally with the embryo or fetus oriented horizontally on the screen. An image should be magnified sufficiently to fill most of the width of the ultrasound screen, so that the measurement line between crown and rump is at about 90◦ to the ultrasound beam. Electronic linear callipers should be used to measure the fetus in a neutral position (i.e. neither flexed nor hyperextended). The end points of crown and rump should be defined clearly. Care must be taken to avoid inclusion of structures such as the yolk sac" (Salomon *et al*. 2013).

ISUOG guidelines also recommend that individuals who perform obstetric scans routinely should have specialised training that is appropriate to the practice of diagnostic ultrasound for pregnant women (Salomon *et al*. 2013).

A measurement of 54mm is the 50th centile for the crown rump length at 12weeks + 0 days gestation (Loughna *et al.* 2009). There are multiple factors which contribute to the range of variation (ROV) at any given gestation. These include biological variation in fetal size, variation in maturity and therefore variation in fetal length as a result of individual differences in the timing of ovulation and fertilization (Drumm, Clinch & MacKenzie 1976, Pedersen 1982, Daya 1993, Lasser *et al*. 1993). Ultrasound measured CRL is also affected by intra- and inter-observer variability involved in the measurement technique (Robinson & Fleming 1975, Wisser, Dirschedl & Krone 1994).

Hence the crown-rump length at 12weeks + 0 days can range from a mean (50th centile) measurement of 54mm to the 95th centile measurement of 63mm (Robinson 1993). See Appendix 5 Table 1 for more detail.

Recommendation

The Act states that "12 weeks of pregnancy" shall be construed in accordance with the medical principle that pregnancy is generally dated from the first day of a woman's last menstrual period.
In clinical practice data regarding the woman's last menstrual period is combined with an ultrasound assessment of crown rump length to determine the gestational age. A Crown Rump Length of 63mm is defined as the upper limit for termination of pregnancy at 12 weeks + 0 days gestation.

Recommendation

Individuals who perform obstetric scans routinely should have specialised training that is appropriate to the practice of diagnostic ultrasound for pregnant women.

2.1 The role of pre-abortion ultrasound

French (CNGOF), British (RCOG), Canadian (SOGC) and American (ACOG) national guidelines on abortion care suggest that while ultrasound should be readily available, it is not mandatory prior to early medical termination of pregnancy (RCOG 2011, ACOG 2014, Costescu *et al*. 2016 & Vayssière *et al.* 2018). If the certifying doctor has concerns that history or examination findings may suggest an ectopic pregnancy or a gestational age of more than 9 weeks, an ultrasound should be performed. Ultrasound providers should have sufficient crisis pregnancy counselling training to ensure that they are in a position to provide non-judgemental care.

2.2 Ectopic pregnancy

The risk of failure to diagnose an ectopic pregnancy in the setting of early medical TOP is low. In a large study of 233,805 women who underwent early medical TOP, Cleland et al. found that the rate of diagnosis of ectopic pregnancy post early medical TOP was 7 per 100,000 (Cleland *et al*. 2013). If there is clinical concern regarding a suspected ectopic pregnancy, an ultrasound should be immediately arranged.

Signs and symptoms of ectopic pregnancy include:

- Abdominal pain (especially unilateral iliac fossa pain)
- Vaginal bleeding
- Shoulder tip pain
- Collapse
- Smaller than expected uterus given Last Menstrual Period (LMP)
- Cervical motion tenderness
- Presence of an adnexal mass on pelvic examination

Risk factors for ectopic pregnancy include:

- Conception via Assisted Reproductive Technology (ART)
- Previous tubal surgery or ligation
- Intrauterine device in situ
- History of Pelvic Inflammatory Disease (PID)
- History of ectopic pregnancy

2.3 Uncertain dates

Exact gestational age (GA) is not a crucial factor in assessing whether medical TOP is appropriate, especially at lower gestational ages, and methods other than ultrasound can be used to determine this. An American study found that 98.4% of pregnancies were correctly assessed by LMP and a physical examination as being less than 9 weeks, and thus eligible for medical TOP in the community (Bracken *et al*. 2011). Studies have found that clinician-determined GAs are accurate, and more importantly, that GA is very rarely underestimated (Schonberg *et al*. 2014). Studies have also shown patient-provided LMP and/or bimanual exams are reliable sources of GA estimates (Fielding, Schaff & Nam 2002, Kaneshiro *et al.* 2011, Raymond & Bracken 2015).

If an ultrasound is performed, women should be asked about their wishes to see the ultrasound screen or not. If the woman chooses not to view the screen, her wishes must be respected (Kulier & Kapp 2011, RCOG 2011).

Recommendation

If a woman is sure of her dates and has no risk factors for or symptoms of ectopic pregnancy, an ultrasound is not mandatory prior to termination of pregnancy at gestations less than 9 weeks.

Recommendation

Where there are clinical concerns, based on history or examination findings, an ultrasound should be arranged prior to medical termination of pregnancy at gestations of less than 9 weeks.

Recommendation

In order to ensure access and to aid with counselling regarding risks and benefits of different termination of pregnancy care pathways, an ultrasound scan should be arranged prior to termination of pregnancy between 9- and 12-weeks' gestation.

Recommendation

Women should be asked about their wishes to see the ultrasound screen or not.

3.0 Consent

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

All patients 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.

4.0 Anti-D and prevention of Rhesus sensitisation

There is limited data on which to base practice (Jorgensen 1969, Jabara & Barnhart 2003). After consultation with the Irish Haematology Society, the following was suggested.

Approximately 15%, 7.5% and 3.5% of Caucasian, African and Asian women have a Rhesus D (Rh(D)) negative blood group (Fiala, Fux & Danielsson 2003, Dutch Association of Abortion Specialists 2011). These women can develop antibodies against the Rh(D) antigen ("Rhesus sensitisation") if sufficient volumes of Rh(D) positive fetal red blood cells enter their bloodstream. Rhesus sensitisation carries significant risks during future pregnancies, including fetal anaemia requiring transfusion, hydrops and death due to haemolytic disease of the fetus and newborn. Therefore, it is important to protect women who are at risk by the simple step of administering Anti-D to those who are Rh(D) negative. This greatly reduces a Rh(D) negative woman's chance of becoming sensitised if she is exposed to Rh(D) positive fetal red blood cells.

Medical or surgical termination of pregnancy is predicted to be associated with a higher risk of Rh(D) sensitisation than spontaneous miscarriage (Goldman & Eckerling 1972, Fiala, Fux & Danielsson 2003, Dutch Association of Abortion Specialists 2011). Unfortunately, the absolute associated risk, particularly during the first trimester, is poorly defined due to the lack of adequately powered, well-designed prospective studies (Fiala, Fux & Danielsson 2003). Current international guidelines in most western countries including the UK, US, Canada, Australia, New Zealand and the Netherlands (from 7 weeks' gestation) recommend administration of Anti-D to Rh(D)-negative women undergoing termination of pregnancy and in most countries, this has been the case for decades (Fiala, Fux & Danielsson 2003, Sperling *et al*. 2017, Fung & Eason 2018). Dutch guidelines do not recommend Rh(D) testing or Anti-D administration before 7 weeks' gestation (49 days of amenorrhea) due to lack of predicted expression of Rh(D) antigen on fetal red cells before this time and extremely low predicted risk of sensitisation (Dutch Association of Abortion Specialists 2011). Prior to the widespread implementation of such guidelines, studies dating back to the 1960s and 1970s with significant methodological limitations reported variable sensitisation rates of ~2-13% during termination of pregnancy in Rh(D) negative women who did not receive Anti-D (Jorgensen 1969, Queenan *et al*. 1971, Goldman & Eckerling 1972, Fiala, Fux & Danielsson 2003). Confidence intervals for these estimates were not reported and are likely to be wide. Moreover, significant changes in both laboratory methodology, induction of termination of pregnancy and general obstetric care have occurred since the publication of these reports.

Administration of Anti-D to Rh(D) negative women undergoing induced termination of pregnancy appears to be associated with apparently absent Rh(D) sensitisation and it is likely that a dose of 250 IU is sufficient for this purpose (Goldman & Eckerling 1972, Fiala, Fux & Danielsson 2003, Dutch Association of Abortion Specialists 2011). Currently, only the 1500IU dose of Anti-D immunoglobulin is available in Ireland. This working group requested that the National Women & Infant Health Programme prioritise sourcing the lower dose of Anti-D. It is also imperative that there is integration

between primary and secondary care to ensure that women can easily access Anti-D immunoglobulin in a timely manner.

Recommendation
If a patient seeking a termination of pregnancy is less than 7 weeks' gestation (<49 days post LMP), the risk of Rhesus D sensitisation is negligible, therefore blood group and Rhesus D testing is not indicated.

Recommendation
If a patient is seeking a termination of pregnancy is 7 weeks' gestation or greater (≥49 days post LMP), a blood group and Rhesus D testing is advised, in order to identify those who are Rhesus D negative, and take steps to prevent Rhesus D sensitisation during future pregnancies.

Recommendation
Women should be counselled on the limitations of data estimating the risk of Rhesus D sensitisation associated with medical termination of pregnancy at 7- 9 weeks' gestation. Following full counselling on the potential risks and the limitations of the existing data, it is ultimately each woman's choice whether to receive Anti-D at this gestation.

Recommendation
For Rhesus D negative women who have a medical or surgical termination of pregnancy between 9- and 12-weeks' gestation, a dose of at least 250IU of anti-D immunoglobulin should be administered to prevent Rhesus D sensitisation.

Recommendation
Determination of the risk of Rhesus D sensitisation following a termination of pregnancy should be deemed a high research priority and high-quality, adequately-powered studies should be resourced.

5.0 Methods of Termination of Pregnancy

Early medical termination of pregnancy (MTOP) is defined as medical abortion up to 9 weeks gestation. MTOP can be safely provided in General Practice or other community settings. Medical or surgical TOP after 9 weeks gestation is usually performed in secondary care due to increased risk of complications. The rate of complications after medical TOP up to 9 weeks is 2-3%. (Gatter, Cleland & Nucatola 2015). The rate of emergency evacuation of retained products of conception (ERPC) increases from 1.4% at 43-49 days, to 2.5% from 57-63 days. Continuing pregnancy rates increase from 0.3% at 43-49 days gestation, to 1.63% from 57-63 days gestation (Chen & Creinin 2015). Admission to hospital for infection or heavy bleeding requiring transfusion is low, at 1-3 in 10,000 early medical terminations.

5.1 Location and staffing of abortion services

Primary care refers to community-based care. This is delivered by a range of healthcare professionals including general practitioners and women's health specialists working in other community settings. Practice nurses and midwives have an important role to play in the care of women with induced TOP, in the provision of counselling, advice and follow up.

Secondary care refers to hospital-based care provided by consultant and trainee Obstetrician Gynaecologists, as well as midwifery and nursing staff, and allied health professionals such as social

work and counsellors. In cases where a patient requires a surgical procedure, care may be provided by Anaesthesiologist consultants and trainees.

5.2 Methods of Termination of Pregnancy

Gestational age < 9 weeks

- Early medical termination of Pregnancy in primary care where a patient receives mifepristone in the GP clinic and is given misoprostol to take at home
- Manual vacuum aspiration (MVA) in primary care (without general anaesthetic/under paracervical block)
- Manual vacuum aspiration (MVA) or electric vacuum aspiration (EVA) in secondary care

Gestational age 9-12 weeks

- Medical TOP in secondary care where a patient receives mifepristone as an outpatient and is admitted to complete the misoprostol regime in hospital
- Manual vacuum aspiration (MVA) in secondary care (without general anaesthetic/under paracervical block)
- Electric vacuum aspiration (EVA) in secondary care (usually under general anaesthetic)

5.3 Medical Termination of Pregnancy (MTOP)

This method requires an active involvement of the woman who should be informed of the following:

- The necessity to combine initial treatment of an anti-progesterone medication (mifepristone, with a prostaglandin analogue (misoprostol) to be administered 24 – 48 hours afterwards
- The need for a follow-up low sensitivity urine hCG test in order to check for complete expulsion
- The possible failure of the method, leading to a pregnancy termination by another method
- Failure rates increase in the following scenarios: with advancing gestational age; oral rather than vaginal/buccal administration of misoprostol; if repeat misoprostol dose omitted; and if interval between mifepristone and misoprostol is less than 24 hours (Raymond *et al*. 2013)
- The potential for requiring repeat doses of misoprostol
- Misoprostol is more effective if taken by vaginal or buccal route rather than oral route (Kapp *et al*. 2018).
- Gastrointestinal side effects are common (Hamoda *et al.* 2005)

Detailed descriptions of medication doses used for medical TOP can be found in Appendix 6, Table 3.

MTOP < 9 weeks

Mifepristone will be taken in the presence of the community medical provider. Patients 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 administration) at home

- 400 micrograms of misoprostol to take home (to be taken if no bleeding 4 hours after initial misoprostol dose) (RCOG 2011)
- 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 primary care provider for review +/- additional analgesia

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

- 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

All women should be informed of the option to attend their GP or community doctor for an aftercare visit to ensure appropriate follow up, discuss contraception, and any further counselling needs. All patients must be advised to perform a low sensitivity urine pregnancy test at 2 weeks post MTOP to rule out ongoing pregnancy. If this is still positive, or if the woman still feels pregnant, or the bleeding has been light, an urgent ultrasound is required.

MTOP 9-12 weeks

- 200mg mifepristone administered in an outpatient setting
- 24 – 48 hours later, admit to hospital for 800 micrograms misoprostol (buccal administration)
- 400 micrograms misoprostol should be taken 3 hourly x 4 doses by buccal route if no bleeding occurs (RCOG 2015)
- Repeated doses are more likely to be required at higher gestational age and are more effective if taken vaginally or buccally rather than orally (Kapp *et al.* 2018)

- A requirement for repeated doses is more likely at a higher gestational age
- 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

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 is 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.

5.4 Contraindications

Mifepristone:

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:

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.

5.5 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

5.6 Surgical Termination of Pregnancy (STOP)

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 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.

5.6.1 Manual Vacuum Aspiration

Procedure of Manual Vacuum Aspiration

- Pre-operative analgesics (ibuprofen 800mgs PO or diclofenac 75mgs PO/100 mg PR) 60 – 90 minutes prior to procedure

- Pre-operative cervical priming (400 micrograms misoprostol administered PV) 3-4 hours prior to procedure (World Health Organization 2014)
- Paracervical block is usually 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).

5.6.2 Electric Vacuum Aspiration

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
- 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

- In practice, contraindications to general anaesthetic are unlikely. Patients may be allergic to certain drugs but normally there are substitutions thus the contraindication to GA usually relates to severe comorbidities.

Follow up

- 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 community doctor for an aftercare visit to discuss contraception plus any further counselling needs.

5.7 The role of Ultrasound post termination of pregnancy

Since the rate of continuing pregnancy after surgical termination of pregnancy is low (2.3 per 1000), routine ultrasound follow up is not indicated after STOP (RCOG 2011). Several studies have recommended low sensitivity pregnancy tests as a satisfactory follow up post medical termination of pregnancy (Grossman & Grindlay 2011). The routine use of ultrasound post medical TOP can be misleading as ultrasound appearances are not a clinically useful predictor for the subsequent need for surgical evacuation (RCOG 2011). Ultrasound appearances and measurements of endometrial thickness correlate poorly both with symptoms suggestive of retained products of conception, and with later histological examination, thus the decision to undertake uterine evacuation should be based upon the presence of signs and symptoms only (Acharya *et al*. 2004, Cowett *et al*. 2004, Rufener *et al*. 2008, McEwing *et al*. 2009, Reeves *et al.* 2009). If an ultrasound is performed after medical TOP, its only aim should be to confirm the absence of a gestational sac (Vayssière *et al.* 2018).

Recommendation

The decision to evacuate the uterus following incomplete termination of pregnancy should be based on clinical signs and symptoms and not on ultrasound appearance.

Recommendation

Ultrasound examination should not be used routinely to screen women for incomplete abortion after medical or surgical termination of pregnancy.

5.8 Potential teratogenic effects of misoprostol

Patients must be counselled on the potential risk of teratogenesis after taking abortifacient medication, if the termination is not subsequently complete. Data in this area is limited to case reports, case control and cohort studies, some of which report self-prescribed non-validated non-clinician supervised use, with dosage ranging from 200 micrograms to 16,000 micrograms (Philip, Shannon & Winikoff 2002). Over thirty five different fetal anomalies are described, with lower limb defects being most common (82%), followed by central nervous system anomalies (55%), upper limb defects (40%) and skeletal defects (27%). Specific anomalies included equinovarus, terminal transverse limb defects, arthrogryposis, cranial nerve abnormalities and Moebius syndrome (Gonzalez *et al.* 1998, Da Silva Dal Pizzol, Knop & Mengue 2006, Vauzelle *et al.* 2013).

6.0 Venous thromboembolism (VTE) assessment

A VTE assessment should be considered for all pregnant women (HSE 2013). This should include women presenting for abortion care. The recent maternal mortality report from MBRRACE "Saving

lives, Improving Mothers' care" (Knight *et al.* 2018) reiterated the importance of assessing risk factors for thromboembolism in early pregnancy. The need for reassessment after a surgical procedure for termination, miscarriage or ectopic pregnancy was also emphasised. Whereas the overall rate of maternal death from VTE is low (1.39 per 100,000 maternities), ten out of thirty-seven deaths occurred in the first trimester (seven while still pregnant and three after pregnancy loss) from 2014-2016 in the UK and Ireland.

Women with significant risk factors for VTE should have input in their care from haematology and maternal medicine specialists in the hospital setting, and may require anticoagulant treatment until the termination is performed, and up to six weeks afterwards. Significant risk factors for VTE include previous pregnancy associated VTE, known thrombophilia, obesity or other significant medical issues. The VTE assessment checklist is included in Appendix 7, Figure 2.

Recommendation

As part of the medical consultation prior to termination of pregnancy, an assessment of the woman's risk of venous thromboembolism (VTE) should be considered. Women with significant risk factors for VTE may require anticoagulant treatment until the termination is performed and up to six weeks afterwards.

7.0 Screening for genital infection, the role of antibiotic prophylaxis, and treatment of infectious complications of termination of pregnancy

Routine screening for genital infections is not indicated for women prior to TOP. Organisms that have been implicated in infectious complications following TOP include chlamydia, gonorrhoea and the organisms that can lead to bacterial vaginosis. Without screening or prophylactic treatment, the incidence of post TOP infection is less than 2% (White 2015). With universal prophylaxis, or treatment of women positive for Chlamydia, infection post-TOP occurred in <0.4% of cases. Surgical TOP has a slightly higher risk for infection than medical TOP. In Europe, septic TOP is rare and almost always the consequence of an unsafe procedure. Treatment for septic TOP requires prompt and accurate recognition of infection and the signs of sepsis, urgent removal of the infected products of conception, as well as the administration of fluid and broad-spectrum antibiotics (Eschenbach 2015).

7.1 Screening for genital infection

Screening for genital infection prior to TOP should be undertaken in women with symptoms and/or signs of genital infection, or where the woman is known to be a contact of chlamydia or gonorrhoea. Women at greater risk of chlamydia and gonorrhoea infection include those with age <25 years or women with a new partner in the previous twelve months. Consideration may be given to screening these women for chlamydia and gonorrhoea prior to TOP. Screening for genital infection prior to TOP is not required in women without symptoms of genital infection, or in those who are not known to be contacts of or at greater risk of infection with chlamydia or gonorrhoea.

A diagnosis of bacterial vaginosis can be made clinically, and treatment initiated without waiting for the results of a high vaginal swab. Further information on the diagnosis and management of bacterial vaginosis is available on the HSE antibiotic prescribing website, https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/conditions-and-treatments/genital/bacterial-vaginosis/bacterial-vaginosis.html

The gold standard test for diagnosis of chlamydia and gonorrhoea is a nucleic acid amplification technique (NAAT). Most available test kits will test for both organisms on the same sample. Vaginal swabs are more sensitive than endocervical swabs, regardless of whether they are provider or self-taken. The following sampling options are available to screen for chlamydia and gonorrhoea using NAATs.

- Endo-cervical swab
- Provider taken or self-taken low vaginal swab

Known contacts of chlamydia and gonorrhoea should be tested and empirically treated prior to TOP. Antibiotic choices and further information on management of these infections are available at https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/conditions-and-treatments/genital/.

Recommendation

Routine screening for genital infections is not indicated for women prior to termination of pregnancy except where the woman has symptoms or signs of genital infection or is known to be a contact of chlamydia or gonorrhoea.

Recommendation

Prior to termination of pregnancy, screening for chlamydia and gonorrhoea can be offered to women at greater risk (e.g. women younger than 25 or those with a new partner in the previous 12 months).

7.2 Infection risk for medical termination of pregnancy

The rate of serious infections following medical termination of pregnancy is rare. An overall frequency of post-TOP infection of <1%. Changing the route of administration of misoprostol from vaginal to buccal can reduce these to less than 0.1%. (Fjerstad *et al.* 2009). Use of routine antibiotics reduced this risk further to 0.06 per 1000 abortions (Fjerstad *et al.* 2009). Because of the rarity of post medical TOP infection, the WHO does not recommend the use of routine antibiotics for medical TOP (2018).

Recommendation

Routine antibiotic prophylaxis is not recommended prior to first trimester medical termination of pregnancy except where the woman has symptoms or signs of genital infection or is known to be a contact of chlamydia or gonorrhoea.

7.3 Infection risk for surgical termination of pregnancy

Even though the risk of infection is low after surgical termination, antibiotic prophylaxis at the time of the procedure significantly reduces the likelihood of infection by 58% (Sawaya *et al*. 1996, Low *et al.* 2012). Prophylaxis may be more effective and less expensive than a screen-and-treat approach for Chlamydia, gonorrhoea and bacterial vaginosis (Penney *et al.* 1998).

As per RCOG (2015) Best Practice in comprehensive Abortion Care, the following regimens are recommended for perisurgical abortion antibiotic prophylaxis:

- 200mg Doxycycline within 2 hours pre procedure, OR
- 500mg Azithromycin within 2 hours pre procedure

Recommendation

Routine antibiotics are recommended prior to or at the time of surgical termination of pregnancy.

7.4 Management of established infection post TOP

Infectious complications post termination of pregnancy include endometritis and pelvic inflammatory disease.

Women presenting with symptoms and/or signs of endometritis post termination of pregnancy should be managed in line with the HSE antibiotic prescribing guidelines: https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/conditions-and-treatments/pregnancy-infections/

Women presenting with symptoms and/or signs of pelvic inflammatory disease post termination of pregnancy should be managed in line with the HSE antibiotic prescribing guidelines: https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/conditions-and-treatments/genital/pelvic-inflammatory-disease/pelvic-inflammatory-disease-pid-.html

All women who test positive for chlamydia or gonorrhoea should be managed in line with the HSE antibiotic prescribing guidelines and offered testing for other STIs, including serology for HIV, Hepatitis B and syphilis. Hepatitis C testing should be undertaken in line with national Hepatitis C testing guidelines: https://health.gov.ie/wp-content/uploads/2017/08/HepC-NCG-15_Summary_v8.pdf

Further information on the management of chlamydia is available here: https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/conditions-and-treatments/genital/chlamydia-trachomatis/chlamydia-trachomatis.html
Further information on the management of gonorrhoea is available here: https://www.hse.ie/eng/services/list/2/gp/antibiotic-prescribing/conditions-and-treatments/genital/gonorrhoea/gonorrhoea.html

Recommendation
Women presenting with infectious complications of termination of pregnancy should be managed in line with the HSE antibiotic prescribing guidelines.

Recommendation
Women diagnosed with a chlamydia or gonorrhoea should be offered full Sexually Transmitted Infection screening, including serology for HIV, Hepatitis B, syphilis and Hepatitis C (where indicated).

Recommendation
Women diagnosed with chlamydia or gonorrhoea should be managed in line with the HSE antibiotic prescribing guidelines.

8.0 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. Patients 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.

At the time of finalising this guidance document, limited information was available from the HSE regarding how the above process would occur. As part of a review of this guidance document early next year, the disposal of fetal tissue will need to be clarified.

9.0 Pre- and Post- Termination of Pregnancy counselling

9.1 Pre-TOP counselling

The majority of women have made a clear decision on termination of pregnancy before they present to their doctor. In one Scottish study, only 18 (9%) of the 201 women surveyed reported using pre-termination counselling (Baron, Cameron & Johnstone 2015). Most women did not feel counselling was necessary because they were already certain of their decision (Baron, Cameron & Johnstone 2015).

The World Health Organisation (2012) has published comprehensive information and guidance on various aspects of TOP services including the following on counselling:

"Providing information and offering counselling can be very important in helping the woman consider her options and ensuring that she can make a decision that is free from pressure. Provision of counselling to women who desire it should be voluntary, confidential, non-directive and by a trained person. Many women have made a decision to have an abortion before seeking care, and this decision should be respected". Women should be offered appropriate counselling but a woman cannot be compelled to attend counselling. Counselling is a voluntary process. It is not a requirement under the Act and cannot be applied as a condition precedent to a termination under the Act.

Recommendation

Many women have decided to have a termination of pregnancy before seeking care, and this decision should be respected. A woman should not be compelled to attend mandatory counselling.

At a minimum, pre-termination counselling should include information on:

- what will be done during and after the procedure
- 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
- any follow-up care

Certification of pregnancy can proceed at the first visit if dates are certain or following an ultrasound scan report confirming dates. The medical practitioner should clearly convey to the woman her number of weeks pregnant, the three-day waiting period, the 12 week limit and the implications these have for her abortion care.

Patients who decide to continue with pregnancy

Health-care workers should also provide information and referral for antenatal care to women who decide to carry the pregnancy to term and/or consider adoption. In some circumstances, the woman may be under external pressure others to have a termination. Unmarried adolescents, women in abusive relationships and women living with HIV may be particularly vulnerable to such pressure. If health-care workers suspect coercion, they should talk with the woman alone, or refer her for

additional counselling. If staff know or suspect that the woman has been subjected to sexual violence or other abuse, they should offer her referrals for other counselling and treatment services as appropriate. In some cases, women (and partners) may need more than one counselling session before coming to a decision. There is no limit to the amount of counselling sessions a woman (and her partner) may have.

9.2 Counselling during home medical termination

A study by Cameron *et al*. (2015) found that 13% (n= 224/1726) of women made contact with a helpline after taking home misoprostol prior to 9 weeks. The majority of those that telephoned were reassured (84%, n=188) whereas a minority (16% n=36) were advised to attend for emergency medical review. Overall, only 2% (36/1726) of women attended for emergency review after home misoprostol prior to 9 weeks (Cameron *et al.* 2015). This study emphasises the need for expert clinical advice to be available 24/7 for women having an early medical termination at home.

Recommendation

It is important that women have access to a trained professional 24/7 to answer clinical queries during home medical termination of pregnancy.

9.3 Post TOP Counselling

At the second visit when medication is given, and at the third visit if the woman returns for a check-up post procedure, information should be given on counselling services and how to access them.

Immediately after a termination, women have physical and emotional reactions due to hormonal changes. This is normal, and usually settles with the resumption of menstrual cycles in four to six weeks. However, a woman's psychological reaction to having a TOP will vary depending on many factors including uncertainty as to her decision, partner support, personal support from family and/ or friends, previous pregnancies, and previous TOPs.

There is no limit as to the amount of session's available post TOP. Partners of women who have had a TOP can also attend.

The American Psychological Association (APA) Task force on mental health and abortion (2008) made the following findings in relation to psychological sequalae of abortion:

- Women may experience sadness, grief, and feelings of loss following TOP
- Women whose crisis pregnancies did not proceed to TOP also experienced distress
- Overall, the incidence of mental illness is similar in women who have a single, legal first trimester abortion for non-therapeutic reasons to those who continue with an unplanned pregnancy in the same circumstances
- An increase in mental ill-health was noted in women who had multiple TOP. However positive associations between multiple TOPs and poorer mental health may be linked to co-occurring risks that predispose a woman to both multiple unwanted pregnancies and mental health problems
- Some women do experience clinically significant disorders, including depression and anxiety. Several factors were identified that are predictive of more negative psychological responses following first-trimester TOP. These factors included a prior history of mental health problems, feelings of stigma, perceived need for secrecy, and low perceived or anticipated social support for the abortion decision. Across studies, prior mental health emerged as the strongest predictor of post-abortion mental health

In the context of providing TOP 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.

Recommendation

Counselling should be available promptly and provided by appropriately trained individuals to all pregnant women who request this service, prior to, during and post termination of pregnancy.

Recommendation

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.

10.0 Contraception

A discussion on contraception is considered an important part of an abortion consultation to minimise the risk of further crisis pregnancy. This position is also upheld by WHO, Royal College of Obstetricians and Gynaecologists, 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 abortion contraception is part of abortion provision and after-care.

Ovulation can return as early as eight days following TOP (Schreiber *et al.* 2011). Often, re-initiation of sexual intercourse precedes ovulation, therefore putting people at increased risk of another unintended pregnancy. Immediate initiation of contraception reduces this risk. The benefits of immediate initiation of contraception post-TOP are numerous. Motivation to prevent another crisis pregnancy is usually very high post-TOP, making it an ideal and effective time to start, or change (in the case of a failed method) contraception. Also, studies have shown increased uptake of contraception at 6 months post TOP following immediate initiation of contraception, compared to delayed initiation (Okusanya, Oduwole & Effa 2011, Saav, Stephansson & Gemzell-Danielsson 2012).

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". Ideally, all forms of contraception should be discussed, with an emphasis on the superior efficacy of Long Acting Reversible Contraception (LARC), and a plan established for provision of the desired contraceptive method if the woman is keen for immediate initiation. However, 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 TOP 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.

Recommendation

After surgical or medical termination of pregnancy, all women should be offered contraceptive information and, if desired, the contraceptive method of their choice or referral for this service.

Recommendation

It is important for health care professionals to recognise that some women prefer to discuss contraceptive options after the termination is completed.

11.0 Education and training

All clinical staff, including medical, midwifery, nursing and support workers should receive 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 receive training on:

- Outline of legal context, model of care and location of services
- Early medical TOP
- Early surgical TOP including Manual Vacuum Aspiration
- Electric Vacuum Aspiration
- Frequency and management of complications of termination of pregnancy
- Values clarification
- Post termination 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 TOP care, there are many opportunities for collaborative learning. To identify opportunities for collaboration, develop shared content, and to support the co-ordination of activities, an ICGP & IOG Joint Training Committee will be established. Nursing and midwifery staff both in primary and secondary care have an important role in caring for women with crisis pregnancy and collaborative multi-disciplinary training should be considered. It is also critical that the training needs of other staff, both clinical and non-clinical are addressed.

12.0 Conscientious objection

Many patients' first point of contact will be their primary healthcare physician. Where patients are unsure if their doctor is a conscientious provider, they will likely contact the 24-hour helpline to direct them to a conscientious provider. Section 22(1) of the Act provides, that any medical practitioner, nurse or midwife shall not be obliged to carry out, or to participate in carrying out a termination of pregnancy in accordance with section 9 (risk to life or health), section 11 (condition likely to lead to death of foetus) or section 12 (early pregnancy) to which he or she has a conscientious objection.

However, this is qualified by section 22(2) of the Act which states that section 22(1) shall not be construed to affect any duty to participate in a termination of pregnancy in accordance with section 10, i.e. where there is an immediate risk to the life, or of serious harm to the health, of the pregnant woman and it is immediately necessary to carry out the termination in order to avert that risk.

Therefore, in emergency situations, a medical practitioner, nurse or midwife must provide treatment to the pregnant woman, irrespective of any conscientious objection that the medical practitioner, nurse or midwife may have.

At the time of writing this guidance document, it was noted that 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.

Recommendation

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

Recommendation

A termination may be carried out by a medical practitioner where, having examined the pregnant woman, the medical practitioner 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, of the pregnant woman and it is immediately necessary to carry out the termination of pregnancy in order to avert that risk. In an emergency, the patients' care must be made a priority and the necessary treatment must be provided. This remains the position irrespective of any conscientious objection of the medical practitioner.

13.0 Notification to the Minister for Health

The Health (Regulation of Termination of Pregnancy) Bill 2018 specifies that:

(1) 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.

At the time of finalising this guidance document, no information was available from the Department of Health regarding how the above process would occur. It is expected that forms will be made available via the HSE in January 2019.

Disclaimer:

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

Appendices

Appendix 1 – Letter from Department of Health (Three-day period)

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

12th December 2018

Mr Pat Healy
National Director, Community Strategy and Planning
Health Service Executive
Dr Steevens' Hospital
Dublin 8

Re: Clinical Guidelines for Termination of Pregnancy – Three-day period

Dear Pat

I refer to an issue that has arisen in relation to the three-day period required under Section 12 of the Health (Regulation of Termination of Pregnancy) Bill 2018.

For the avoidance of doubt, I wish to clarify that the legislation provides that the termination of pregnancy may be provided after a period of "not less than three days has elapsed" from the date of certification.

What that means in practice is that the day on which the doctor certifies that the pregnancy has not exceeded 12 weeks counts as the first day. The termination may then be carried out after the third day has "elapsed".

A practical illustration of how a doctor would certify that a pregnancy has not exceeded 12 weeks would be as follows:

A woman visits a doctor on a Monday and the doctor certifies that the pregnancy has not exceeded 12 weeks. Monday would count as the first day; Tuesday and Wednesday would be the second and third days. Once Wednesday (being the third day) has "elapsed", the termination may take place, so it may be carried out at any time from Thursday onwards, once 12 weeks of gestation have not been exceeded.

I trust this clarification will be of assistance.

Yours sincerely

Dr Tony Holohan
Chief Medical Officer

c.c. Dr Cliona Murphy, Chair, Institute of Obstetricians and Gynaecologists, RCPI
Mr Leo Kearns, CEO, RCPI
Dr John O'Brien, President, ICGP
Mr Fintan Foy, CEO, ICGP

Appendix 2 – Letter from Department of Health (Definition of 12 weeks)

An Roinn Sláinte
Department of Health

27 November 2018

FAO: Dr Cliona Murphy; Chair, Institute of Obstetricians and Gynaecologists, RCPI
Dr John O'Brien; President, ICGP

c.c. Mr Fintan Foy; CEO, ICGP

Re: Clinical Guidelines for Termination of Pregnancy
Definition of 12 weeks

Dear all

I refer to the development of clinical guidelines and the issue that has arisen in relation to the definition of 12 weeks.

For the avoidance of doubt, I wish to clarify that the legislation states "...that the pregnancy concerned has not exceeded 12 weeks".

Twelve weeks plus 1 day exceeds 12 weeks. Therefore, 12 weeks is 12 weeks plus 0 days.

I trust this clarification will be of assistance.

Yours sincerely

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Appendix 3 – Communication from Department of Health (Completion of termination of pregnancy)

Re: Early pregnancy Section 12 of the Health (Regulation of Termination of Pregnancy) Bill 2018

When the Bill is enacted it will be lawful, under section 12, to carry out a termination of pregnancy , which includes the prescribing of a drug, before the pregnancy has exceeded 12 weeks (and at least three days has elapsed from the date of certification).
It is recognised that in some circumstances the process of completion of the termination may extend beyond 12 weeks.

Regards Geraldine

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Offences
23. (1) It shall be an offence for a person, by any means whatsoever, to intentionally end the life of a foetus otherwise than in accordance with the provisions of this Act.

(2) It shall be an offence for a person to prescribe, administer, supply or procure any drug, substance, instrument, apparatus or other thing knowing that it is intended to be used or employed with intent to end the life of a foetus, or being reckless as to whether it is intended to be so used or employed, otherwise than in accordance with the provisions of this Act.

(3) *Subsections (1)* and *(2)* shall not apply to a pregnant woman in respect of her own pregnancy.

(4) It shall be an offence for a person to aid, abet, counsel or procure a pregnant woman to intentionally end, or attempt to end, the life of the foetus of that pregnant woman otherwise than in accordance with the provisions of this Act.

(5) A person who is guilty of an offence under this section shall be liable on conviction on indictment to a fine or imprisonment for a term not exceeding 14 years, or both.

(6) A prosecution for an offence under this section may be brought only by or with the consent of the Director of Public Prosecutions.

(7) Nothing in *subsection (4)* shall operate to prevent or restrict access to services lawfully carried out in a place outside the State.

Offence by body corporate
24. (1) Where an offence under this Act is committed by a body corporate and it is proved that the offence was committed with the consent or connivance, or was attributable to any wilful neglect, of a person who was a director, manager, secretary or other officer of the body corporate, or a person purporting to act in that capacity, that person shall, as well as the body corporate, be guilty of an offence and may be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(2) Where the affairs of a body corporate are managed by its members, *subsection (1)* applies in relation to the acts and defaults of a member in connection with his or her functions of management as if he or she were a director or manager of the body corporate.

Appendix 5

Table 1: The mean fetal crown-rump length (CRL) measurements (+ 2 standard deviations) in mm for a given gestational age. ROV=range of variation for a given CRL measurement in days.

Study	**Mean CRL (+ 2SD) mm at 12+0 weeks**	**ROV**
Robinson 1975	54.7 (8.6)	95% CI is + 4.7 days
Drumm 1976*	54.5 (5.2)	5 days
Pedersen 1982	53	6 days
Lasser 1993	51.5	95% CI is ± 4 days
Daya 1993	54	95% CI is ± 3 days

Appendix 6

Table 3: Dosing regimens used for medical TOP in other jurisdictions compared with Irish guideline

Gestation	UK	Europe	US	World	Ireland
TOP 7 weeks (0 - 49 days)	RCOG 2015 Mifepristone 200mg PO 24-48 hours later Misoprostol 800ucg PO/PV/BU Then Misoprostol 400ucg 3hlry	CNGOF Mifepristone 200mg PO Misoprostol 400ucg PO SL BL PV Repeat after 3h	IPPF/WHO Mifepristone 200mg PO Misoprostol 400ucg PO Repeat Misoprostol 800ucg	Canada Mifepristone 200mg PO Misoprostol 800ucg BL WHO Mifepristone 200mg Misoprostol 800ucg PV BU SL & PO	Mifepristone 200mg Misoprostol 800mcg BL taken at home 24-48 hours later
TOP 7- 9 weeks (50-63 days)	RCOG 2015 Mifepristone 200mg Misoprostol 800ucg PO/PV/BU COCHRANE Mifepristone 200mg Misoprostol PV best Single dose 800ucg BPAS Mifepristone 200mg Misoprostol 800ucg	Norway Mifepristone 200-600mg Misoprostol 800ucg PV FIAPAC reports RCOG/WHO Mifepristone 200mg PO Misoprostol 800ucg PV BL SL CNGOF Mifepristone 200mg PO Misoprostol 800ucg BL SL PV NVOG Netherlands Mifepristone 200mg Misoprostol 800ucg PV	CPG NAF Mifepristone 200mg PO Misoprostol 800ucg BL SL PV Repeat x 1 IPPF/WHO Mifepristone 200mg PO Misoprostol 800ucg PO PV Bl SL Repeat Misoprostol 800ucg x 1 ACOG Mifepristone 200mg PO Misoprostol 800ucg PV/BL/SL Repeat x 1	WHO Mifepristone 200mg Misoprostol 800ucg PV BU SL Canada Mifepristone 200mg PO Misoprostol 800ucg BL SL PV Repeat miso x1	Mifepristone 200mg Misoprostol 800 mcg BL taken at home 24-48 hours later Repeat Misoprostol 400mcg buccal if no bleeding within 4 hours
TOP 9-12 weeks	RCOG 2015 Mifepristone 200mg	CNGOF Mifepristone 200mg		WHO Mifepristone 200mg PO	Ireland Mifepristone 200mg

	Misoprostol 800ucg PV/PO/BU stat + then Misoprostol 400ucg 3hrly	Misoprostol 800ucg BL SL PV Then Misoprostol 400ucg 3hrly x 5doses BL SL PV		Misoprostol 800ucg PV Then Misoprostol 400ucg PV SL 3hrly X 4	Misoprostol 800 mcg buccal 24-48 hours later Repeat Misoprostol 400mcg 3 hourly x 4 doses until bleeds heavily All elements of treatment (including Misoprostol) must be completed by 12+0

RCOG - *Royal College of Obstetricians and Gynaecologists*

CNGOF - *Collège National Des Gynécologues et Obstétriciens Français*

ACOG – *American College of Obstetricians and Gynaecologists*

IPPF - *International Planned Parenthood Federation*

CPG-NAF - *Clinical Policy Guidelines - National Abortion Federation*

WHO - *World Health Organisation*

BPAS - *British Pregnancy Advisory Service*

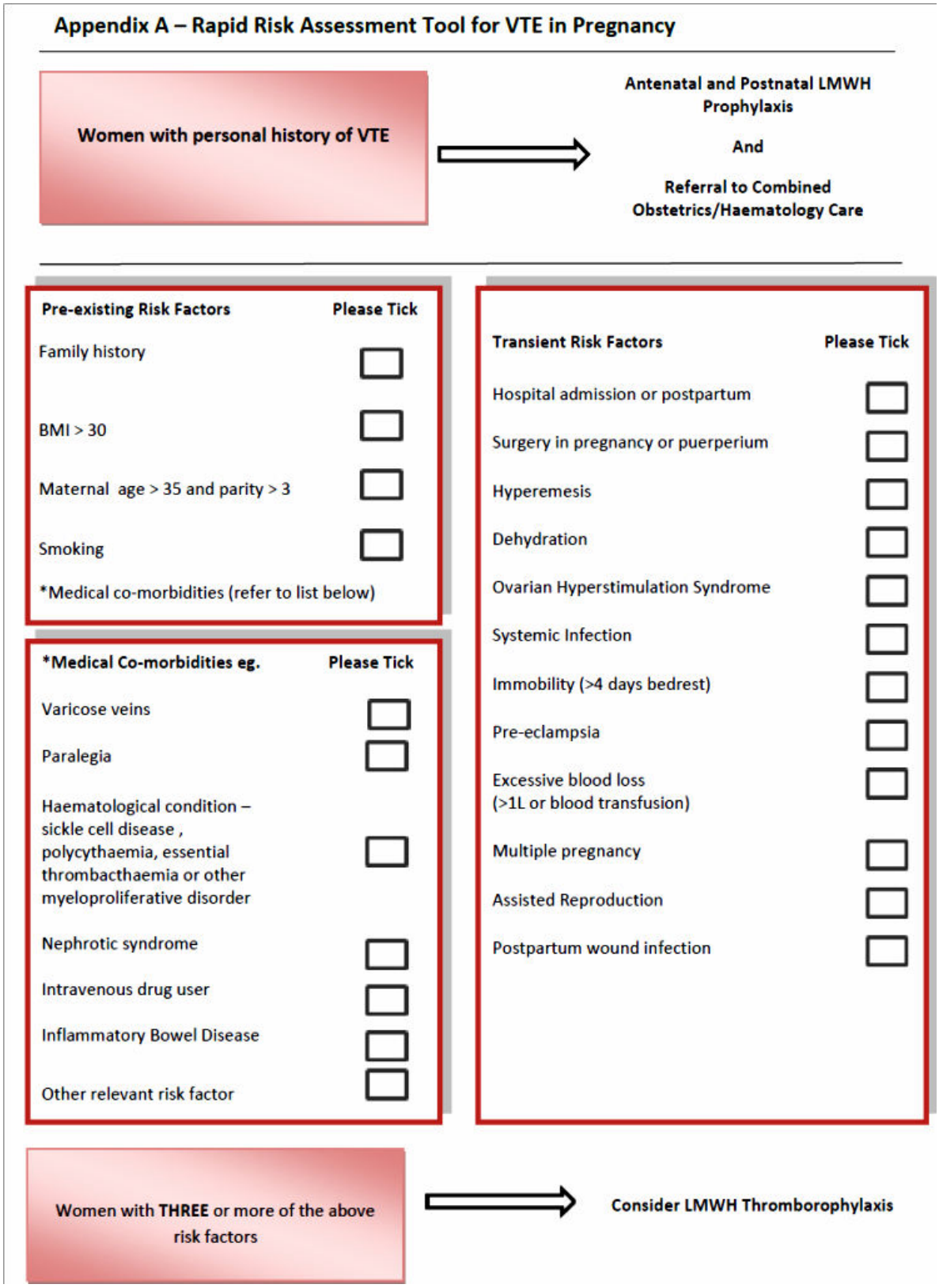
FIAPAC – *International Federation of Professional Abortion and Contraception Associates*

NVOG - *Nederlandse Vereniging voor Obstetrie en Gynaecologie*

Appendix 7

Figure 2: Venous Thromboembolism Assessment Checklist

Clinical Practice Guideline Venous Thromboprophylaxis in Pregnancy (HSE/IOG 2013)



Glossary

ACOG	American College of Obstetricians and Gynecologists
ART	Assisted reproductive technology
BV	Bacterial vaginosis
CDC	Centre for Disease Control
CNGOF	Collège National Des Gynécologues et Obstétriciens Français
CMO	Chief Medical Officer
CO	Conscientious objection
CPG-NAF	Clinical Policy Guidelines - National Abortion Federation
CRL	Crown rump length
D&E	Dilatation and evacuation
DOH	Department of Health
ERPC	Evacuation of retained products of conception
FBC	Full blood count
GA	Gestational age
GDG	Guideline development group
GP	General Practitioner
hCG	Human chorionic gonadotrophin
HSE	Health Service Executive
HTN	Hypertension
ICGP	Irish College of General Practitioners
ISUOG	International Society of Ultrasound in Obstetrics & Gynaecology
IOG	Institute of Obstetricians and Gynaecologists
IUD	Intrauterine device
LARC	Long acting reversible contraception
LMP	Last menstrual period
MDT	Multi-disciplinary team
MTOP	Medical termination of pregnancy

MVA	Manual vacuum aspiration
NPEC	National Perinatal Epidemiology Centre
PCRS	Primary care reimbursement service
PG	Prostaglandin
PID	Pelvic inflammatory disease
RCOG	Royal College of Obstetricians and Gynaecologists
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Rh	Rhesus
ROV	Range of variation
STD/STI	Sexually transmitted disease/infection
STOP	Surgical termination of pregnancy
TOP	Termination of pregnancy
VTE	Venous thromboembolism
WHO	World Health Organization

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