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Date: 5 January 2021 – Scottish Government

Consultation: *Future Arrangements for Early Medical Abortion at Home*

Consultation response on behalf of the Scottish Council on Human Bioethics:

The **Scottish Council on Human Bioethics** (SCHB) is an independent registered Scottish charity composed of doctors, lawyers, biomedical scientists, ethicists and other professionals from disciplines associated with medical ethics.
The principles to which the Scottish Council on Human Bioethics subscribes are set out in the ***United Nations Universal Declaration of Human Rights*** which was adopted and proclaimed by the UN General Assembly resolution 217A (III) on the 10th of December 1948.
The SCHB is very grateful to the Scottish Government for this opportunity to respond to the consultation on the ***Future Arrangements for Early Medical Abortion at Home.*** It welcomes its intention to promote public consultation, understanding and discussion on this topic.

Response to the Questions

Are you responding as an individual or an organisation?

Individual
X Organisation

Full name or organisation's name: **Scottish Council on Human Bioethics**
Phone number: **07 83 83 84 904**
Address: **15 North Bank Street, Edinburgh EH1 2LS**
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Where are you resident? (Please see one of the options below)

X Scotland Rest of the UK Rest of the world

The Scottish Government would like your permission to publish your consultation response. Please indicate your publishing preference:

X Publish response with name
Publish response only (without name)
Do not publish response

We will share your response internally with other Scottish Government policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for Scottish Government to contact you again in relation to this consultation exercise?

X Yes
No

Background

The Abortion Act 1967 requirements

The *Abortion Act 1967* ('the Act') sets out the legal requirements which should be met before an abortion can be carried out lawfully in Scotland. This Act still applies across Great Britain, although policy on abortion is now a devolved matter, meaning that the Scottish Parliament could potentially enact legislation on abortion in the future.

The present Act requires two registered medical practitioners (doctors) to certify that they are of the opinion that at least one of the grounds under the Act for an abortion have been met.[1] This will often – but not always – be the GP and the doctor at the clinic where the abortion will take place.
Except in an emergency (situations where an abortion is immediately necessary to save the life or prevent grave permanent injury to the physical or mental health of the pregnant woman), an abortion can only be carried out in an NHS hospital or in a place approved by Scottish Ministers.

Section 1(3A) of the Act clarifies that Ministers can approve a 'class of places' where medical abortions can be undertaken. This allows women's homes to be approved as places where abortion treatment can be administered.

Scottish Context

In Scotland, abortion was viewed, before the *Abortion Act 1967*, as a Common Law offence without strictly defined limits. In other words, it was settled law that any improper act *"by the mother or any other person calculated to destroy the fetus or cause its premature expulsion from the body of the mother constitutes a common law crime, that of abortion".*[2] The only exception to this was medical necessity, where the need to terminate the pregnancy was in the interests of the health of the mother. In these circumstances a physician, using his or her own clinical judgment, could undertake a legal abortion.

This means that it was possible to interpret the law differently than in England. Abortions were illegal in Scotland but could be carried out if certain medical criteria existed and when physicians believed they were acting in good faith and, for the most part, when there was a serious risk to the life of the mother. This remained the general consensus of medical practitioners in Scotland at the time.

At present, an abortion continues to be a crime in Scotland if criminal intent can be demonstrated with the burden of proof lying with the legal prosecution. Additionally, in Scots Law, the victim of the crime of abortion or attempted abortion is the prenatal child. It is obvious, therefore, that in Scots Law the prenatal child has always been given a status of personhood, with the right to life.[3] But since the *Abortion Act 1967,* physicians are not prosecuted for undertaking an abortion in certain circumstances.

Early Medical Abortion at Home – developments over time

A medical abortion takes place in the first 12 weeks of gestation and the woman takes two sets of pills to end the pregnancy. The first pill (mifepristone) blocks the main hormone, progesterone, that makes the lining of the uterus (womb) suitable for the early embryo to implant. The second medication (misoprostol), which is taken about two days later, causes the lining of the womb to break down and the woman to terminate the pregnancy. This second medicine causes cramping and bleeding, often with clots which may be much more important than in a normal period. The cramps usually start 2 to 4 hours after the pills are inserted and may last for 3 to 5 hours.[4]

[1] Abortion Act 1967, section 1.

[2] Butterworths (1987) *The Laws of Scotland: Stair Memorial Encyclopaedia*

[3] Ought Scots law recognise the distinct legal personality of a foetus? An international, interdisciplinary conference of the Centre for Responsibilities, Rights and the Law McGroarty, J.P. (2008).

[4] Isle of White NHS Trust, Your guide to Early Medical Abortion, September 2020, https://www.iow.nhs.uk/Downloads/Patient%20Information%20Leaflets/Early_Medical_Abortion-Guide.pdf

The heavy bleeding will usually settle once the abortion is complete, however, the woman may continue to get some bleeding for 9–16 days and it may stop and start several times and can persist up to the next period. [5]

In 1992, 16% of all terminations were medical abortions in Scotland and, within five years, this rose to over a third. By 2002 half of all terminations were medical abortions, rising to 88% of all 13,583 terminations in Scotland in 2019.[6]

Until late 2017, women were required to attend a clinic twice to take both medical abortions drugs (24 to 48 hrs apart) and, in most cases, women self-administered both pills. In the case of the second drug misoprostol), a healthcare professional would give the women 4 small tablets to put in into her vagina (or a member of staff could do this). They were then expected to stay between 6 and 8 hours and occasionally longer, especially if they were over 9 weeks pregnant, or had complications. Different women would also vary in their reaction to this treatment with some having significant bleeding and pain. Some women may, in addition, experience diarrhoea, sickness, headache, dizziness, and hot flushes or chills.

Usually, the woman will use a bedpan every time she uses the toilet so that the nurses can check to see if she has passed the pregnancy. The pregnancy is likely to be passed with clots of blood, and the embryo/foetus may be identifiable, especially if the woman is over 7 weeks pregnant. It is recommended that if the woman does not want to see the result of the abortion that she should not look at what she passes.

Before the woman goes home, she will usually have a vaginal examination to check that the abortion is complete. Occasionally it may be necessary to arrange an ultrasound scan to check this.
Moreover, in some cases, a woman may leave the clinic straight after taking misoprostol so she can pass her pregnancy at home.[7]

Since October 2017, Scotland's Chief Medical Officer indicated that the second drug misoprostol could be taken by women outside of a clinical setting.[8] The woman will then be given the first medication tablet (mifepristone) in the clinic but given a medication pack to take home containing the vaginal tablets which she inserts at home two days later as well as painkillers. She will then have heavy bleeding and pass the pregnancy at home, usually a few hours after the vaginal tablet are taken.[9]

To be suitable for early medical abortion at home, a woman will need to meet certain criteria, including:

- Be less than or equal to 9 weeks + 6 days confirmed pregnant on the day of mifepristone administration.
- Be 16 years or over;
- Be in good general health, with no significant previous pregnancy problems;
- Have someone at home with the woman for the whole day;
- Have a telephone;
- Have access to transport so that she can go back to hospital if she is concerned;
- Be able to speak and read appropriate English;
- Be within 30 minutes travel time of a hospital with an A&E department;
- Be able to give a follow-up contact number;
- Agree to do a follow-up test after 3 weeks;

[5] Isle of White NHS Trust, Your guide to Early Medical Abortion, September 2020, https://www.iow.nhs.uk/Downloads/Patient%20Information%20Leaflets/Early_Medical_Abortion-Guide.pdf

[6] Public Health Scotand, Termination of pregnancy, Year ending December 2019, https://beta.isdscotland.org/media/5320/2020-08-25-terminations-2019-report.pdf, p. 14.

[7] In addition, many other women who have sadly suffered a miscarriage have been taking misoprostol at home for some time for pregnancies which ended under 13 weeks of gestation.

[8] See https://www.sehd.scot.nhs.uk/cmo/CMO(2017)14.pdf (Annex A) for a copy of the October 2017 approval.

[9] See Finch et al – 'Impact of self-administration of misoprostol for early medical abortion: a prospective observational cohort study'. BMJ Sexual and Reproductive Health, 2019. WHO – 'Medical Management of Abortion' - https://www.who.int/reproductivehealth/publications/medicalmanagement-abortion/en/.
Nice guidelines on abortion care - https://www.nice.org.uk/guidance/ng140

As a result, almost half of the about 12,000 medical terminations in Scotland in 2019 involved self-administration of misoprostol in the home setting compared to 30% in 2018.[10]

Current COVID-19 arrangements

Since the 31st of March 2020, in light of COVID-19 and the importance of minimising risks of spreading the virus, abortion care providers in Scotland have allowed women having an early medical abortion to take both sets of pills at home, where this is considered appropriate and the woman wishes to do so. The Scottish Abortion Care Providers have produced guidelines for staff to help them decide, where suitable, when they need to see a woman in person, such as when they need an ultrasound scan.

This means women can have an appointment with a doctor or nurse remotely via a telephone or video call to discuss their options and the process, and their own circumstances, such as the timing of their last menstrual period and whether they have any medical conditions which need to be taken into consideration. If the woman wishes to have their abortion at home and the doctor or nurse is satisfied that they meet the criteria for this, they can be prescribed both drugs to be taken at home.

During their appointment (and in the medication pack), women receive clear instructions about how and when to take their medication and the circumstances when they should get in touch for help and who to contact – for example if they experience any complications or if they believe they may still be pregnant. Women can either have their medication pack delivered to them (normally either by NHS Board staff or a courier) or in some areas they need to come and collect their pack from a clinic reception.

While some women are still being seen in person for at least one appointment, this means many women are now able to stay at home to minimise any physical contact with others. Feedback from NHS Boards suggests, where they have carried out surveys, that the great majority of women prefer to have their abortion in the comfort and privacy of their own home. Some NHS Boards have also found it has helped to reduce the waiting times for women to have their appointment and, if they wish to proceed, their abortion. This, it is suggested, may both help improve service delivery, but also enable more women to have their abortion at an earlier gestation stage; this is considered beneficial as the earlier the gestation the less bleeding and pain and the lower the risks of any significant complications from the procedure.

It is also noted that women are able to take mifepristone and misoprostol at home for early medical abortion in a number of other countries, either during the COVID-19 pandemic or longer term.

CONSULTATION QUESTIONS

Based on the evidence so far, while there are some additional risks due to not having an appointment in person, the Scottish Government is satisfied, following discussions with Scottish Abortion Care Providers, that these risks are low and are outweighed by the risks of spreading the virus if all women must have in-person appointments. Therefore, given that most women prefer to remain at home where possible, the Government is comfortable that the current approval remains appropriate while COVID-19 poses a significant risk to public health in Scotland.

However, the Scottish Government believes that it is now time to start considering future arrangements for abortion services in the longer term. Initial feedback suggests some NHS Boards would like to continue to enable women to take mifepristone at home without an in-person appointment to make abortion services easier to access, particularly for those who find it difficult to travel to a hospital clinic for an appointment for any reason. For example, research highlights difficulties for some women in accessing abortion care in remote and rural Scotland.[11]

However, the Scottish Government is aware that some people have concerns that there are a number of risks in not having in-person appointments. In particular they feel there are risks that women may

[10] Public Health Scotand, Termination of pregnancy, Year ending December 2019, https://beta.isdscotland.org/media/5320/2020-08-25-terminations-2019-report.pdf, p. 15.

[11] See Heller et al – 'Barriers to accessing termination of pregnancy in a remote and rural setting: a qualitative study', BJOG, 2016

underestimate the gestation of their pregnancy and that services may be less likely to detect if women are victims of domestic abuse or human trafficking if they do not see the woman in person.

<u>Question 1</u>. What impact do you think that the current arrangements for early medical abortion at home (put in place due to COVID-19), have had on *women accessing abortion services*? Please answer with regards to the following criteria:

a) **safety**

	No impact
	Positive impact
X	**Negative impact**
	The impacts are mixed
	I don't know

b) **accessibility and convenience of services**

	No impact
	Positive impact
	Negative impact
	The impacts are mixed
X	**I don't know**

c) **waiting times**

	No impact
	Positive impact
	Negative impact
	The impacts are mixed
X	**I don't know**

Comments (optional):

<u>*Scottish Council on Human Bioethics Response:*</u>

Deciding whether to have an abortion is one of the most important and momentous life or death decisions a woman will probably make during her lifetime. She is literally deciding whether her prenatal child lives or dies. The consequences of this are far from trivial. Whatever her beliefs about the moral status of the prenatal child, she will need to live with the decision for the rest of her days. As the 2020 NHS-Inform-Scotland leaflet for women indicates:

> "*Women vary greatly in their emotional response to having an abortion. Some women feel relieved, others feel sad or guilty, and many women feel a combination of these.*"[12]

This is why the leaflet adds:

> "*Making a decision about whether to undergo abortion may not be easy. Before deciding, you may wish to discuss your situation with healthcare professionals, such as your GP*".[13]

Thus, any decision about a possible termination must be done only after appropriate face to face counselling with a healthcare professional, which must be of a very high standard. Physicians and Counsellors know how important it is to see someone face to face when making such decisions. Phone or video calls, are completely inadequate. The healthcare professional and the woman need to sit down and discuss the options in a relational and non-judgmental way that gives proper respect to the person making

[12] https://www.nhsinform.scot/tests-and-treatments/surgical-procedures/abortion#introduction

[13] https://www.nhsinform.scot/tests-and-treatments/surgical-procedures/abortion#introduction

the decision and allows space for reflection. Significant risks for the woman would exist if this did not happen, including:

1. Full home abortions may be illegal

The SCHB is very concerned that, with home abortions, women may realise that it is themselves who are now responsible for terminating their prenatal child and that they may also, unintentionally, see the dead embryo/foetus.

In this context, it has come to the attention of the Scottish Council on Human Bioethics that current arrangements for early medical abortion at home (put in place due to COVID-19), and discussed in the Scottish Government's consultation, may be illegal. This is because women may be committing an offence under the *Abortion Act 1967* if they are now taking both the early abortion drugs, mifepristone and then misoprostol at home. Indeed, it is the woman wanting an abortion who is basically terminating the pregnancy and not a registered medical practitioner as required by Section 1(1) of the *Abortion Act 1967*, which indicates:

> *"Subject to the provisions of this section, a person shall not be guilty of an offence under the law relating to abortion when a pregnancy is terminated by a registered medical practitioner if two registered medical practitioners are of the opinion …"*[14]

The SCHB notes that the requirement that a registered medical practitioner be the person who terminates the pregnancy was examined in the Scottish courts in the context of the possible provision of the second drug (misoprostol) at home. In this regard, the Scottish Court of Session stated in 2019:

> *"We do not accept that the doctor's control or supervision over the treatment differs in any material way between the situation of taking the tablet within the clinic and then leaving; and that of delaying the taking of the tablet to allow the woman to travel home. Both result in the termination of the pregnancy taking place outside of the clinic. In each case the Registered Medical Practitioner can properly be described as taking responsibility for the treatment of the termination of the pregnancy and control in the appropriate sense is maintained."*[15]

But providing both drugs at home is a completely new state of affairs because the registered medical practitioner may no longer be considered as the principal actor in the termination. Indeed, the Scottish Court of Session recognised that any further changes to the original setting of the abortion would need further legal clarification:

> *"[W]hilst we accept that there is a requirement for the Registered Medical Practitioner to have responsibility for the treatment and to retain a degree of control over it, what will satisfy that requirement will be a matter of fact and degree according to the nature of the process involved in the treatment.*" [16]

Moreover, in 2005, Lady Hale in a UK Supreme Court decision indicated:

> *"The more difficult question is what is meant by "to participate in" the course of [a termination] treatment in question… A narrow meaning would restrict it to "actually taking part", that is actually performing the tasks involved in the course of treatment."*[17]

[14] https://www.legislation.gov.uk/ukpga/1967/87/section/1

[15] SPUC Pro-Life, Court of Session Decision, [2019]CSIH 31, paragraph 34. https://www.scotcourts.gov.uk/docs/default-source/cos-general-docs/pdf-docs-for-opinions/2019csih31.pdf?sfvrsn=0

[16] SPUC Pro-Life, Court of Session Decision, [2019]CSIH 31, paragraph 31. https://www.scotcourts.gov.uk/docs/default-source/cos-general-docs/pdf-docs-for-opinions/2019csih31.pdf?sfvrsn=0

[17] Doogan v Greater Glasgow Health Board [2015] SC (UKSC) 32, Paragraph 37. https://www.supremecourt.uk/cases/docs/uksc-2013-0124-judgment.pdf

She then added: *"In my view, the narrow meaning is more likely to have been in the contemplation of Parliament when the Act was passed. … "Participate" in my view means taking part in a "hands-on" capacity."*[18]

In this regard, the Scottish Court of Session also noted: *"[I]t was a matter of agreement that prescription of the [abortifacient] medication was not sufficient to constitute treatment*."[19]

Moreover, in law, the identity of the person responsible for the actual act of terminating life very much matters as demonstrated, for example, between the different legislations on euthanasia and assisted suicide in a number of countries. Even in Scotland a difference exists between (1) euthanasia (whereby a person directly ends the life of another) which would generally be considered as a form of murder and (2) assisting someone to commit suicide by giving him or her, for example, a lethal drug or pills that he or she can take himself or herself, which may be considered as a form of culpable homicide.

Thus, the SCHB would like to ask the Scottish Health Department to clearly confirm that when both drugs are prescribed for home abortion, the registered medical practitioner is still actually undertaking the abortion and/or whether his or her participation is direct, indirect or inconsequential in law and that the woman terminating a pregnancy is not breaking the law.

The *Abortion Act 1967* was enacted, amongst other reasons, to address illegal and dangerous backstreet or home abortions. It is completely unacceptable, therefore, for the Scottish Government to suggest in the present Government consultation to go back to a situation which may be similar. A situation which may lead women to consider inappropriately supervised abortions which may actually be illegal.

The SCHB is also very surprised that the present Scottish Government public consultation on home abortions is taking place when a Judicial Review, submitted by *Christian Concern* (in October 2020), on the topic is pending in the UK Supreme Court. Expenses, time and energy of the Scottish Government and those responding to the consultation should not be misused.

2. The possible existence of undue pressures

The assumption is often made that all abortion requests are autonomous and free from coercion. But one SCHB GP with 27 years of experience estimated that in a quarter to a third of cases, when given an opportunity to express the reasons for requesting a pregnancy termination, the patient would respond with a phrase such as: "*My boyfriend says he will leave me otherwise*" or "*My mother would kill me*."

Coercion of some kind is not at all infrequent in unplanned pregnancy. At least in a face-to-face consultation with the patient, the woman can speak freely without the coercing party being there or listening-in. Even with a video consultation, a third party can easily be in the room just out of view of the camera. The possibility of such third-party intervention is obviously even greater if the consultation is by other electronic means such an email.

Only a few studies exist that have explored the incidence of coerced abortion in partner abuse, but in one of these, 7 out of 13 women reported having experienced some kind of coercion to have an abortion.[20] In a larger US study of 954 women, one third of participants reported pressure to abort.[21] Such instances of abuse are not usually disclosed if women are not in a place where confidentiality and privacy can be assured. In the coronavirus pandemic, recent news reports also confirm a rising reported incidence of domestic abuse in the UK[22] since restriction of movement was introduced.

[18] Doogan v Greater Glasgow Health Board [2015] SC (UKSC) 32, Paragraph 38.

[19] SPUC Pro-Life, Court of Session Decision, [2019]CSIH 31, paragraph 8. https://www.scotcourts.gov.uk/docs/default-source/cos-general-docs/pdf-docs-for-opinions/2019csih31.pdf?sfvrsn=0

[20] Hathaway J E, Willis G, Zimmer B, Silverman J G. 2005. Impact of partner abuse on women's reproductive lives, *J of the American Women's Medical Association* 60 42-45.

[21] Chibber KS et al 2914 The role of intimate partners in women's reasons for seeking abortion. Women's Health Issues 24:e131–38.

[22] Kelly J, Morgan T 2020 Coronavirus: Domestic abuse calls up 25% since lockdown, charity says www.bbc.co.uk/news/uk-52157620

Thus, a real risk exists that the woman may be under pressure to self-administer an abortion with an abusive relationship or from relatives who will not support her. Such situations are only discussed and discerned properly with face to face meetings with a physician. Only then is it possible to discuss options such as help from a crisis pregnancy centre or the possibility of allowing the child to be adopted. Perhaps the woman does want to keep the child, and this may be the only opportunity for her to confidentially express her wishes. In this regard, the UK Health Minister, Lord Bethell, told the House of Lords on 25 March 2020:

> *"We believe that it is an essential safeguard that a woman attends a clinic, to ensure that she has an opportunity to be seen alone and to ensure that there are no issues. Do we really want to support an amendment that could remove the only opportunity many women have, often at a most vulnerable stage, to speak confidentially and one-to-one with a doctor about their concerns on abortion and about what the alternatives might be? The bottom line is that, if there is an abusive relationship and no legal requirement for a doctor's involvement, it is far more likely that a vulnerable woman could be pressured into have an abortion by an abusive partner."*[23]

3. Misunderstanding of the psychological risks of having an abortion

Because it is now the woman who seems entirely responsible for the death of her embryo/foetus (and not the registered practitioner) this may have dramatic effects on her psychological wellbeing. In this respect, a danger exists that the woman considering an abortion may not fully understand the trauma of undergoing such a procedure, potentially all alone, at home. This is frequently a very unpleasant and painful experience to go through and needs to be carefully discussed. In addition, the woman may unintentionally see the embryo/foetus, which she then has to flush away down the toilet herself without any emotional support. The foetus could be up to 3-6 cm in size at about 10 weeks of gestation. This is acknowledged by the Sandyford clinic in Glasgow which states: *"[T]he pregnancy is likely to be identifiable, especially if you are over 7 weeks pregnant. If you do not want to see this it is important not to look at what you pass*."[24]

Thus, having a home abortion may significantly increase the risks psychological trauma and feeling of loneliness for the woman. For some women, it may even be extremely traumatic. This means that concern should be shown to such women who should always be offered counselling to cope with the aftermath. If support is not provided to ensure their safety, the Scottish Government may significantly be failing in its duty of care.

4. Misunderstanding of the medical risks involved

Another danger is that the woman may not fully understand the biological risks involved. It is, therefore, highly questionable whether appropriate informed consent can always be obtained for such a procedure over the phone.

5. Misuse of the abortion pills

A significant risk may exist that the woman does not adhere to the precise and very important time intervals between taking the two drugs for home abortions. Taking the second drug incorrectly increases complications for the woman who may even require surgery. For example, in Sweden, as many as half of all recommended protocols for prescription drug use are not followed, or not followed correctly.[25]

[23] https://hansard.parliament.uk/Lords/2020-03-25/debates/3C266E78-4BB7-4330-9199-D361CDBAE2AD/CoronavirusBill, Column 1762

[24] https://www.sandyford.scot/sexual-health-services/abortion/abortion-services-information/

[25] Hovstadius B & Petersson G (2011) Non-adherence to drug therapy and drug acquisition costs in a national population – a patient-based register study. BMC Health Services Research 11:326

It may be possible that, without any examination, the woman will receive the abortion pills for a pregnancy that is over 10 weeks gestation, which is the legal limit for such home abortions. A 2020 report already exists of a woman at 28 weeks gestation taking the pills and delivering a baby which subsequently died.[26] In addition, there are numerous examples of women receiving both sets of abortion pills far beyond the 10 weeks deadline.

Moreover, some women may abuse the system and obtain the pills for someone else. Some abusers may also order the pills by email and force their partners to take them. The dispensing of abortion pills for self-administration removes any control over who takes the pills, at what gestational age they are taken, where they are taken, whether they are taken, when in the process they are taken or in the case of a minor, if an adult is present. In other words, it is not clear how the NHS or independent clinics could ensure the pills are taken at home, by the individual they are provided to, and within the appropriate time frame.

6. Possibility of regret in taking the first pill

Some women may regret taking the first pill. A number of GPs in Scotland have weekly requests for abortion reversal after women have taken the first pill (mifepristone). This is happening because the women are changing their mind, are undecided, feel pressurised into the decision or realise that they are now the actual ones terminating the life of the embryo/foetus rather than the physician.

Moreover, because the right to withdraw consent is an integral part of the principle of informed consent, women should be able to stop an abortion procedure, after a reflection and cooling off period, if no other reasons exist for the abortion to continue. This means that women should be provided with information on how to get a reversal or that a starter pack of progesterone pills, which can reverse the effects of mifepristone, should be provided with the other drugs to take home.[27] Indeed, the effects of mifepristone (which works as an antagonist of progesterone - a hormone essential for a successful pregnancy) may be counteracted by quickly giving the woman large and repeated doses of progesterone, by mouth, vaginally, or by injection, every day until the end of the first trimester (that is about 14 weeks). The reversal procedure must be started no later than 48 hours after the mifepristone pill has been taken.[28]

No clinical trials have been undertaken with such reversals. It is not approved by the Food and Drug Administration in the US and is not recommended by the American Congress of Obstetricians and Gynaecologists. Side effects, though minor, include insomnia and nausea. Critics maintain that there is no clear evidence that the procedure actually works. For example, in about 30% to 50% of women who take mifepristone alone, the pregnancy will continue. Thus, it may be that doing nothing and just waiting to see what happens may be just as effective as undertaking a course of progesterone treatment.[29]
It should also be noted that embryonic and foetal development effects such as clubfoot, limb and cranial nerve abnormalities have been reported in pregnancies that continue to birth following the taking of mifepristone.[30]

7. Medical complications increase with unsupervised abortions

The evidence to support the claim that: "*If performed in the first 10 weeks, a medical abortion carries a very small risk of complications*"[31] predominantly comes from research on medical abortions carried out in appropriately supervised conditions. In such a situation, the complication rate of early medical abortion is

[26] https://www.dailymail.co.uk/news/article-8349739/Police-investigate-death-unborn-baby-woman-took-abortion-drugs-home-28-weeks-pregnant.html

[27] Delgado G, Condly SJ, Davenport M, Tinnakornsrisuphap T, Mack J, Khauv V, Zhou PS. A case series detailing the successful reversal of the effects of mifepristone using progesterone. *Issues Law Med*. 2018. 33(1):21-31.

[28] George Delgado, Mary Davenport, Progesterone Use to Reverse the Effects of Mifepristone (December). 2012, *Annals of Pharmacotherapy* 46(12).

[29] Shannon Firth, Reversing Abortion Pill: Can It Be Done?, *MedPage Today*, 24 February 2015, https://www.medpagetoday.com/obgyn/generalobgyn/50164

[30] See: http://www.misoprostol.org/misoprostol-teratogenicity/

[31] Women on web https://www.womenonweb.org/en/page/6907/complications-of-medical-abortion

low but not negligible. In one Swedish retrospective, longitudinal study[32] of 3694 medical abortions under 12 weeks, the overall complication rate was 4.2% in 2008 but this rose to 8.2% for 2015, which was the final year of the study. The authors state that the cause of this increase "*is unknown but it may be associated with a shift from hospital to home medical abortions*." Other research has suggested that unsupervised medical abortion can lead to increased risks, including maternal morbidity and mortality.[33]

The most common complications related to medical abortions under 12 weeks included:

- An ongoing viable pregnancy (1.1%)[34]
- Heavy prolonged bleeding (15.4%)[35]
- Infection (1.2%)[36]
- Gastrointestinal discomfort (50%)[37]

In a 2019 study of telemedicine, the incidence of reported complications for home abortions under 10 weeks is generally low. Rates relevant to completion, safety, and acceptability of outcomes for women under 10 weeks' of gestation ranged from: [38]

- 0 to 1.9% for continuing pregnancy,
- 0.9 to 19.3% eventually completion with surgical evacuation *(which is certainly not negligible)*,
- 0 to 0.7% need for blood transfusion,
- 0.07 to 2.8% for hospitalization.

Other researchers analysed, in 2017, self-reported outcome data submitted to a telemedicine clinic by 1000 women four weeks after receipt and use of mifepristone and misoprostol to end an early pregnancy (among a total of 1636 who were sent these drugs, 158 (nearly 10%) of whom confirmed not using the drugs). The women lived in the Republic of Ireland or Northern Ireland, where abortion laws, at the time, were among the most restrictive in the world. Almost 95% reported ending their pregnancy, 0.7% required a blood transfusion, 2.6% required antibiotics, and overall, 9.3% experienced symptoms potentially requiring medical attention which were significant, especially if no medical support is provided or is available. There were no deaths.[39]

The most recent Cochrane Systematic Review, in 2020, urges some caution over the current data regarding unsupervised abortion at home, which could be due to the intrinsic shame or secrecy surrounding such procedures. The review states: "*Data are limited by the scarcity of high-quality research study designs and the presence of risks of bias. This review provides insufficient evidence to determine the safety of self-administration when compared with administering medication in the presence of healthcare provider supervision*."

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[32] Carlsson I, Breding K, Larsson P G 2018 Complications related to induced abortion: a combined retrospective and longitudinal follow-up study BMC Women's Health https://bmcwomenshealth.biomedcentral.com/articles/10.1186/s12905-018-0645-6

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Thakar R V et al 2014 Self-medication of abortion pill; Women's health in jeopardy NHL Journal of Medical Sciences 3 26-31.

[34] Raymone E G et al 2013 First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review Contraception 87 26-37

[35] Niinimaki M et al 2011 Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: population register based study BMJ 342 https://doi.org/10.1136/bmj.d2111

[36] Carlsson, I., Breding, K. & Larsson, P. Complications related to induced abortion: a combined retrospective and longitudinal follow-up study. *BMC Women's Health* **18,** 158 (2018).

[37] Lui, M-W, Ho P-C 2020 First trimester termination of pregnancy Best Practice & Research Clinical Obstetrics & Gynaecology 63:13-23

[38] Endler M, Lavelanet A, Cleeve A, Ganatra B, Gomperts R, Gemzell-Danielsson K. Telemedicine for medical abortion: a systematic review. BJOG. 2019 Aug;126(9):1094-1102.

[39] Aiken ARA, Digol I, Trussell J, Goperts R. Self reported outcomes and adverse events after medical abortion through online telemedicine: population based study in the Republic of Ireland and Northern Ireland. *BMJ* 2017;357:j2011.

It concludes: "*[I]t remains unclear whether self-administration of medical abortion is effective and safe*."[40]

<u>Question 2.</u> What impact do you think that the current arrangements for early medical abortion at home (put in place due to COVID-19), have had for *those involved in delivering abortion services*? (For example, this could include impacts on workforce flexibility and service efficiency.)

	No impact
	Positive impact
X	**Negative impact**
	The impacts are mixed
	I don't know

<u>Scottish Council on Human Bioethics Response:</u>

The current arrangements for home abortions (put in place due to COVID-19) may result in the following negative consequences for those involved in delivering of abortion services:

1. Misunderstanding the woman's intention

It is likely that, in some cases, the physician may misunderstand the actual wishes of the woman if only a telephone or video call is used. Indeed, in such a call, what she may say might not fully represent her real wishes, and this may go unnoticed. For example, physicians who have been involved in reversal requests have indicated that they were contacted by women who were unsure what to do. Indeed, when they discovered they were pregnant, they had at first phoned the clinic to discuss their doubts and possible help with their decision, but found it was more or less presumed that they had phoned with the intention of obtaining an abortion. Moreover, despite making enquiries, these women had not been provided with appropriate counselling or even a listening ear.[41]

It has been suggested that about 55% of communication is body language, 38% is the tone of voice, and 7% is the actual words spoken.[42] Of course, such statistics cannot be applied to all and every situation. But they are useful if inconsistencies are noticed between attitudes communicated verbally and through body language. In this regard, it is accepted that the postural component should dominate in determining the inferred message. But this is not possible over the phone and is only limited using a video call.

2. Compassion and empathy for the woman are difficult to communicate with telemedicine

Many physicians, patients and their families find it very difficult to hear or discuss challenging news over the phone or in a video-call. For example, some doctors are already describing the heart wrenching phone calls they are making to critically ill patients and their relatives during the Covid-19 lockdown. Previously, they would always have shared bad news face to face.[43] This is because no amount of technology will supplant the benefits of the human presence and physical expression of compassion and empathy. One commentator indicated that: "*Empathy's greatest benefit is by being displayed live, not televised*."[44] This may especially be difficult for physicians to share in life and death decisions such as with an abortion.

3. Difficulty in determining the stage or site of pregnancy

Usually, when a woman goes to see a healthcare professional about a possible abortion, a scan would be undertaken to determine the stage of pregnancy. But in the case of home abortions, there is no way to verify how long a woman has been pregnant over the phone/video/other electronic means. This means,

[40] Cochrane Library, Self-administered versus provider-administered medical abortion www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013181.pub2/abstract
[41] Personal communication from SCHB member.

[42] Mehrabian, A. (1972). Nonverbal Communication. New Brunswick: Aldine Transaction.

[43] https://www.walesonline.co.uk/news/wales-news/doctor-describes-devastating-phonecalls-constantly-18132235

[44] <u>https://www.fastcompany.com/90318752/doctors-are-using-hospital-robots-to-tell-patients-theyre-dying-sparking-an-outcry</u>

that a higher risk exists that women will be given an inaccurate gestation estimation and that she would be prescribed abortion pills after the 10-week limit. Thus, the lack of accurate diagnosis of gestational age makes it possible to breach the legal time-limit on home abortions. There is also the danger that the pregnancy is ectopic, which carries its own medical risks and which may be enhanced by an unsupervised termination.

4. Difficulty in making sure that appropriate informed consent is being given

Because the physician taking the phone or video call may not always know the woman and be able to fully appreciate her age or mental ability, it may not be possible for this physician to be certain that she can give consent to such an important life or death decision. Moreover, if the woman comes from abroad and does not speak or understand sufficient English, it may be especially difficult for the physician to be confident that they understand each other and that the woman can give appropriate informed consent.

5. The physician may feel less responsible for the termination

Again, because the final actual act of terminating the life of the embryo/foetus may no longer be seen as the responsibility of the physician in home abortions, this may be considered from this physician's perspective as a welcome development. However, this may also lead him or her to feel less responsible that the whole procedure takes place in an appropriate manner.

6. The physician remains entirely responsible for the termination

On the other hand, if something goes wrong during the termination itself, the physician remains entirely responsible in law for all the stages of the termination of pregnancy. However, this may then deter physicians to prescribe both drugs for home abortions since they would no longer have any control over circumstances while remaining legally responsible. The Scottish Court of Session indicated, in 2019, in this regard:

> *"We agree with the Lord Ordinary … that: "patients who self-administer medication at home may still be described as being treated by their medical practitioner who remains in charge of that treatment.""* [45]

However, the Court of Session then indicated:

> *"The fundamental point, made by Lord Diplock …, is that: "the requirements of the subsection are satisfied when the treatment for termination of a pregnancy is one prescribed by a registered medical practitioner carried out in accordance with his directions and of which a registered medical practitioner remains in charge throughout.""*[46]

The SCHB would like to receive confirmation from the Scottish Government that the registered medical professional is indeed always still in charge, throughout, and legally responsible when both drugs are provided for home abortions. This is especially important since an abortion is legally considered as a crime in Scotland. It is only when certain specific individuals fulfil certain conditions in accordance with the *Abortion Act 1967* that they are then not "*guilty of an offence"* and not prosecuted.

7. Concerns relating to the disposal of the embryo/foetus remains

The SCHB is also very concerned about the disposal of the remains of the embryo/foetus in home abortions. When a natural abortion takes place in a clinic or hospital, these remains are usually placed in an individual box, and will then be sent to the hospital mortuary to be forwarded to a local crematorium for cremation (though cremated remains (ashes) from the pregnancy will not be available). To do this, consent will be obtained from the woman by signing a consent form asking permission for suitable disposal of the

[45] SPUC Pro-Life, Court of Session Decision, [2019] CSIH 31, paragraph 33. https://www.scotcourts.gov.uk/docs/default-source/cos-general-docs/pdf-docs-for-opinions/2019csih31.pdf?sfvrsn=0

[46] SPUC Pro-Life, Court of Session Decision, [2019]CSIH 31, paragraph 32. https://www.scotcourts.gov.uk/docs/default-source/cos-general-docs/pdf-docs-for-opinions/2019csih31.pdf?sfvrsn=0

remains of the prenatal child. If she wishes to make her own arrangements for disposal of the pregnancy, the woman can also speak to the doctor or nurse at the clinic.[47]

With home abortions, however, appropriate and sensitive respect for the disposal of the remains of the embryo/foetus does not generally take place since these are usually flushed down the toilet or discarded as waste in another manner. An outcome which may cause considerable distress to some vulnerable women having an abortion as well as the eventual persons supporting them at home. This may happen because of their possible grief, especially when they see the dead embryo/foetus, which is up to 3-6 cm in size at about 10 weeks of gestation and which ends up in the sewage. It may also create very significant trauma to other professionals, such as sewage and plumbing professionals, if they ever encounter these thousands of dead human embryos/foetuses in the course of their work.

In addition, Scottish law has never considered the remains of an embryo/foetus, or those of a deceased person who was born, as worthless waste because of the respect ascribed to past lives. A respect which would be completely undermined if the remains of the dead were considered as being just waste or even rubbish.

Moreover, in Scotland, deciding the value and worth of an embryo/foetus, or a person who has been born, has never been the responsibility of a single or a few individuals. Instead, it has always been the remit of society as a whole. This happens to protect it from degenerating into barbarity or into a moral wilderness. Scottish society cannot, therefore, continue to let the remains of embryos/foetuses simply be discarded as worthless waste.

Question 3. What risks do you consider are associated with the current arrangements for early medical abortion at home (put in place due to COVID-19)?
How could these risks be mitigated?

Scottish Council on Human Bioethics Response:

See answers to Question 1 and 2. It is difficult to see how the risks can be mitigated.

Women who share a protected characteristics:

As part of this consultation, the Scottish Government also wishes to consider the likely or possible impacts (both positive and negative) on different groups of women, of allowing the current arrangements to continue permanently. This includes women who share a protected characteristic as defined by the *Equality Act 2010,*[48] including disabled women, younger women, minority ethnic women and women who share a particular religion or belief, as well as women who have childcare or other caring responsibilities. The Scottish Government also wishes to consider the likely or possible impacts (both positive and negative) on trans men who require access to abortion services, of allowing the current arrangement to continue.

Question 4. Do you have any views on the potential impacts of continuing the current arrangements for early medical abortion at home (put in place due to COVID- 19) on equalities groups (the protected characteristics of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation)?

X **Yes**
No
I don't know

If yes, please outline possible impacts below. Please be as specific as you can and include any resources or references to evidence on this topic that we should consider.

In addition to the groups discussed above, the Scottish Government also wants to seek views on the potential for making permanent home use of both pills for early medical abortion to reduce or increase

[47] https://www.sandyford.scot/sexual-health-services/abortion/abortion-services-information/

[48] See https://www.equalityhumanrights.com/en/equality-act/protected-characteristics

inequality in health outcomes experienced by different socioeconomic groups. This is in particular to help ensure it meets its responsibilities under the Fairer Scotland Duty[49] to help tackle inequalities caused by socioeconomic disadvantage.

Scottish Council on Human Bioethics Response:

The SCHB believes that appropriate informed consent should always be given by a person wanting a termination in order to protect the important concept of autonomy and voluntarism. This will then inform the individual of the possible risks and consequences of a procedure, such as an abortion, while ensuring that this person is capable of understanding the nature of such a life and death decision. Thus, appropriate informed consent should be required which includes:

1. Competence: A person's capacity for decision making.
2. Disclosure: The content of what a person is told during the consent discussion.
3. Comprehension: How much given information the person understands.
4. Voluntariness: The ability for a person to make a choice without being unduly pressured or influenced to make a particular choice.
5. Implementation: The ability for a person to implement his or her decision.

Fulfilling these informed consent stages, however, may be difficult for vulnerable women who are, for example, not psychologically robust. It would indeed be a mistake to consider all women as being equal or similar when facing the prospect of ending the life of their embryo/foetus. In addition, the following women may be at greater risk:

1. Under 18-year olds

The SCHB notes that girls of any age can have an abortion without telling their parents, as long as two doctors believe it is in her best interests and she fully understands what is involved. However, it is very unlikely that girls under 18 years of age can fully understand the implication of the momentous life and death decisions associated with abortions. Thus, it is very unlikely that they can give appropriate informed consent.

In addition, adolescence and young adulthood are characterised by pronounced changes in motivated behaviour. This includes an emphasis on potential rewards which may result in an increased tendency to approach novel experiences bringing potential for positive reinforcement, but which may also result in risky behaviour. In addition, their social development, while at a very important formative phase, can be affected by the many experiences of getting on with peers, self-confidence and cognitive development.

Brain regions can actually be identified which are involved in processing rewards in adolescents as well as young adults and functional changes in reward-related brain activity can be examined. As a result, young persons have been found to be less averse to risk than more mature adults and have different cognitive control. This is also one of the reasons why it is suggested that under-25s should be kept out of adult prisons. Two important neurodevelopmental mechanisms are thought to play a role in the genesis of risk-taking behaviours in adolescence and young adulthood: the significant secretion of sex hormones (affecting also the brain) at the beginning of puberty and the delayed maturation of cognitive control.

Because the brains of adolescents and young adults are continuing to develop with the associated behavioural changes, it is unlikely that they will have the same capacity for decision making, voluntariness and the ability to make balanced decisions as more mature adults. This means that they may not be able to give appropriate informed consent for certain momentous decisions requiring mature reflection such as with an abortion. That adolescents have not reached full maturity is also reflected in that individuals under 18 years of age cannot:

- Vote in General Elections in the UK.
- Stand for election as a local councillor, MP or MSP.
- Serve as a juror.

[49] See https://www.gov.scot/publications/fairer-scotland-duty-interim-guidance-public-bodies/pages/1/

- Buy alcohol in licensed premises and consume alcohol in a bar.
- Buy cigarettes & tobacco.
- Buy a lottery ticket.
- See, rent or buy any film.
- Buy or possess fireworks.
- Place a bet.
- Get tattooed.
- Hire or buy a sunbed.
- Hold a licence to drive a medium-sized goods vehicle.
- Become a policeman or policewoman.
- Train to become an army officer.
- Claim Benefits

In other words, just because people want more rights under the age of 18 does not mean they have the maturity to understand the responsibilities associated with such rights. Moreover, if it is a criminal offence to make a false declaration over the phone, what would happen to the persons who make such a declaration?

As a result, the SCHB does not believe that persons below the aged 18 can consent to life or death decisions associated with abortion.

2. Mentally disabled women

It may be very difficult for a physician to determine the ability of a woman to consent to an abortion if she has a mental disability, especially if he or she does not know the woman in question and the conversation is taking place through a phone or video call.

3. Women who do not speak good English

Again, it may be very difficult for a physician to determine whether a woman has understood all the implications of abortion which are required in obtaining informed consent if significant language barriers exist and the discussion is only taking place over the phone.

Question 5. Do you have any views on potential impacts of continuing the current arrangements for early medical abortion at home (put in place due to COVID-19) on socio-economic equality?

X **Yes**
No
I don't know

If yes, please outline possible impacts below. Please be as specific as you can and include any resources or references to evidence on this topic that we should consider.

Scottish Council on Human Bioethics Response:

See answers to Question 4.

Question 6. Do you have any views on potential impacts of continuing the current arrangements for early medical abortion at home (put in place due to COVID-19) on women living in rural or island communities?

X **Yes**
No
I don't know

If yes, please outline possible impacts below. Please be as specific as you can and include any resources or references to evidence on this topic that we should consider.

Scottish Council on Human Bioethics Response:

Accessing abortion in rural or island communities is challenging. However, because of the critical nature of the decision whether to have an abortion, it is vital that the woman is protected and supported in a healthcare setting.

Whether to make current early medical abortion arrangements a permanent measure

As set out above, we are seeking views on whether the current flexibilities should be made permanent or not.

Question 7. How should early medical abortion be provided in future, when COVID- 19 is no longer a significant risk? [select one of the options below]

~~a) Current arrangements (put in place due to COVID-19) should continue – in other words allowing women to proceed without an in-person appointment and take mifepristone at home, where this is clinically appropriate.~~

~~b) Previous arrangements should be reinstated – in other words women would be required to take mifepristone in a clinic, but could still take misoprostol at home where this is clinically appropriate.~~

c) Other (please provide details):

The evidence for the safety of medical abortion under supervised conditions by a health care professional cannot be extrapolated to unsupervised conditions. The SCHB also notes that when carried out correctly at the right gestational age, medical abortion still has low but not negligible rates of physical risks.

In addition, the administration of both drugs at home offers no opportunity for the women to speak face to face in person with a health care professional. Appropriate informed consent may then not be clearly verifiable. This is likely to lead to a greater incidence of inappropriate consent being obtained and coerced abortions being undetected. Thus, women should be required to take mifepristone and misoprostol in a clinic.

Moreover, in order for the Scottish Parliament to prepare an informed view on the matter, the SCHB would like to ask the Scottish Government to publish the relevant data relating to the medical and psychological safety concerns and unintended consequences of home abortions in Scotland which have been available since 2017, when the second drug (misoprostol) could be taken at home.

The SCHB would also like to see the evidence of the initial feedback, mentioned by the Scottish Government in the consultation, which suggests that some NHS Boards would like to continue to enable women to take the first drug, mifepristone, at home without an in-person appointment.