DHSC: Open consultation

Home use of both pills for early medical abortion up to 10 weeks gestation

Question: Do you consider that the temporary measure has had an impact on the provision of abortion services for women and girls accessing these services with particular regard to safety?

a) Yes, it has had a positive impact

b) Yes, it has had a negative impact **X**

c) It has not had an impact

d) I don't know

The absence of a face to face consultation:

1) removes the physical examination and routine scanning that would confirm gestation dates

The 'pills by post' process relies on the woman being able to recall the first day of her last period. Studies report that approximately one half of women do not accurately recall their LMP.[1] Evidence from the DHSC[2] confirms that pregnancies that are well past 9 weeks and 6 days are being terminated at home, with increased safety risks, particularly haemorrhage, as a consequence.

2) removes examination and scanning that would reveal if a pregnancy is ectopic

A ruptured ectopic pregnancy is a surgical emergency. For all women this is of serious concern, but for those living remotely it can be a matter of life and death.

3) removes the opportunity to clarify and supervise the timing and method of taking the two medicines

For example, one of the pills (Misoprostol) is designed to be absorbed from the mouth by keeping the pill between the cheek and gum for a full 30 minutes. Swallowing the pill whole converts it to an oral dose, which is associated with reduced efficacy and increased failure rates.[3]

4) removes a safe place for a woman under coercion to speak freely

Vulnerable women in abusive relationships may be forced into taking the abortion pills.

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[1]https://www.healthcare.uiowa.edu/familymedicine/fpinfo/OB/OB2017/ACOG%20redating%20gestational%20age.pdf page 2.

[2] https://www.gov.uk/government/statistics/abortion-statistics-during-the-coronavirus-pandemic-january-to-june-2020

[3] Scottish Abortion Care Providers Network. Abortion − improvement to existing services − approval for misoprostol to be taken at home. Scottish Government Health and Social Care Directorates 26 October 2017. https://bit.ly/2DFZi7y; Raymond EG et al. First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review. Contraception 2013; 87:26-37 https://bit.ly/2S10BRF; Winikoff B et al. Two distinct oral routes of misoprostol in mifepristone medical abortion: a randomized controlled trial. Obstetrics and Gynecology December 2008;112(6):1303-10

5) allows impersonation

Is the woman requesting abortion the same woman that will take the medicines?

A nationwide undercover investigation, commissioned by Christian Concern, showed that 'home abortion schemes are wide open to abuse' and are 'leading to dangerous and illegal 'DIY' abortions.' Kevin Duffy, ironically a former Global Director of Clinics Development at Marie Stopes International, who led the investigation, said: 'The investigation clearly demonstrates that abortion at home, by pills-by-post, is not safe and on many occasions oversteps legal boundaries without any proper scrutiny... It is deeply concerning that the abortion industry has been allowed to take this service this far during an already highly vulnerable time for pregnant women. The process of wholly relying on telemedicine must be withdrawn urgently.'[4]

6) removes the opportunity to check that the patient has another adult present who will raise the alarm if things go wrong, and that emergency medical support is at hand.

Manufacturers clearly understand these risks: the data sheet supplied with Medabon's 'Combipack' of Mifepristone with Misoprostol states:

'Because it is important to have access to appropriate medical care if an emergency develops, the treatment procedure should only be performed where the patient has access to medical facilities equipped to provide surgical treatment for incomplete abortion, or emergency blood transfusion or resuscitation during the period from the first visit until discharged by the administering qualified medical professional.'[5]

A Swedish study which looked at all abortions from one hospital from 2008 to 2015 reported an overall complication rate of 7.3% in medical abortions under 12 weeks. The commonest complication was incomplete abortion.[6] A significant finding was that the rate of complications associated with medical abortions increased from 4.2% in 2008 to 8.2% in 2015, possibly associated with a shift from hospital to home medical abortions.

7) removes an opportunity for reflection – time to consider options in a non-pressurising context

The BBC has reported[7] concerns over the negative impact on women's health of not being able to access in-person abortion counselling.

A study of women from Sweden who had home abortions in 2016 noted that 'one-third of the women stated that they lacked information in different areas like bleeding, pain, the abortion process, expulsion of the embryo, and the opportunity to see a counsellor. Lack of or insufficient information about bleeding was most frequently mentioned.'[8] Home abortion instructions given by phone or video are more likely to be misunderstood and therefore carry greater potential for harm. This would be especially true if the woman did not have English as a first language.

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[4] https://christianconcern.com/news/undercover-investigation-exposes-diy-abortion-service-breaking-the-law/

[5] Electronic Medicines Compendium (accessed 10.02.2021). 2020 [cited; Available from: https://www.medicines.org.uk/emc/product/3380/smpc

[6] Carlsson I, Breding K, Larsson PG. Complications related to induced abortion: a combined retrospective and longitudinal follow-up study. BMC Womens Health 2018;18(1):158.

[7] https://www.bbc.co.uk/news/uk-wales-54423710

[8] Hedqvist M, Brolin L, Tyden T, Larsson M. Women's experiences of having an early medical abortion at home. Sex Reprod Healthc 2016;9:48-54.

8) increases the risk of psychological trauma

The American Psychological Association's report[9] identified fifteen risk factors for post abortion psychological injury, including suicidal ideation. Reardon notes that the list is one of the shortest that has been developed,[10] emphasising how unlikely it is that consultations done by phone or video link will be able to fully assess the risk of an abortion to a woman's psychological health. About half the women who have abortions in England and Wales each year have had at least one abortion previously. The incidence of repeat abortion is therefore high. Sullins found a compounding effect of repeat abortion on suicidal ideation and substance misuse.[11]

9) allows abortions to be carried out without any record being kept

Women can obtain NHS funded abortions at home without having to apply through their GP. A direct approach to the abortion provider is possible. The provider is not obliged to inform the client's GP and the client can request that confidentiality be observed. As a result, the abortion may never appear on that patient's medical notes. Future care decisions may therefore be made in ignorance – this cannot be in the patient's best interests of safety

10) prevents screening for sexually transmitted diseases (STDs)

The Royal College of Obstetricians and Gynaecologists (RCOG) recommends screening for Chlamydia and other STDs in all women having abortion.[12] This cannot be done other than by a face to face appointment. The lack of provision for this under the emergency provisions therefore increases further the risk of personal injury to the woman.

11) entrusts safety into the hands of those whose practices have been found unsafe

The Care Quality Commission found examples of malpractice at Marie Stopes centres in 2016. In answer to a Parliamentary question in February 2020, it was reported that 121 facilities performing abortions (59% of the total) required improvement for safety.[13] The proposal to make permanent the emergency regulations will lower safety standards. If abortion providers were already compromising on safety standards, then lowering those standards will likely result in further compromises.

12) increases the risk of under-reporting of complications

In response to an FOI request, the Government reported that 'Between April and June 2020, there were 23,061 medical abortions performed on residents of England and Wales where both medicines (antiprogesterone and prostaglandin) were administered at home. Of the 23,061 abortion notification forms received, one form reported a complication.'

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[9] Report of the APA Task Force on Mental Health and Abortion. Washington DC: American Psychological Association; 2008.

[10] Reardon DC. The abortion and mental health controversy: A comprehensive literature review of common ground agreements, disagreements, actionable recommendations, and research opportunities. SAGE Open Med 2018;6:2050312118807624

[11] Sullins DP. Abortion, substance abuse and mental health in early adulthood: Thirteen-year longitudinal evidence from the United States. SAGE Open Med 2016;4:2050312116665997.

[12] The care of Women Requesting Induced Abortion London: Royal College of Obstetricians and Gynaecologists; 2011

[13] https://questions-statements.parliament.uk/written-questions/detail/2020-02-27/21971.

Commenting on this report, Sally-Ann Hart MP pointed out:

'This would mean that the average rate of complication for medical abortions at a similar gestation over the past five years was over seventeen times higher than the complication rate for home abortions earlier this year.

'This is not only highly unlikely – that complications would radically reduce in a home setting versus a medical setting – but, some may say, ridiculous.

'There is either a serious problem when medical abortions are provided in a clinical environment with direct medical supervision – leading to vastly more complications in clinics than in homes – or a substantial issue with the overall quality of reporting and recording the real impact of 'at-home' medical abortions on women's health.'[14]

13) prevents accurate assessment of outcomes and hinders research

Abortion providers are not obliged to record NHS numbers and women are not required to report adverse outcomes to their abortion provider. So systematic, objective analysis of the outcomes for women post abortion is prevented by the absence of full records linking women's health to prior abortion. Accurate records, systematic review and robust audit are essential to safe practise. How is the effectiveness of the present system, were it to be made permanent, to be assessed? How will we learn from mistakes if longitudinal analysis is impossible? It is essential that there be a record of EMAs at home, and a mandatory consultation and assessment would facilitate this.

14) threatens the validity of consent

Even at the best of times, the decision to terminate a pregnancy is a profoundly significant one. From the earliest days of her pregnancy, a woman's intuition is to provide a welcome and a safe place in her womb for her baby. The choice to abort is costly and may lead to later regret.

But these are not the best of times. The pressures of isolation, and fears and anxieties around jobs, vulnerable family members, education etc have had a profound effect on the mental health of many. These are not good times for people to be making far-reaching decisions. To have to do so without the opportunity to talk things over in person with trusted medical carers is to make an already difficult situation intolerable. Evidence already cited confirms that women requesting EMA at home are less likely to be given clear and comprehensive information and advice. As a result, consent to the procedure is not fully informed and therefore not valid.

We believe that the initial consultation should be with the patient's doctor and that that doctor should routinely have to account for his or her decision to another doctor, who may affirm or resist their colleague's decision.

We believe that this level of care and involvement is essential to the patient's best interests in providing a confidential setting where any coercive factors can be safely discussed, and fears and anxieties gently explored. Only in this way can informed and free consent be assured. We believe this is sufficiently important to justify the very small risk of COVID transmission when undertaken in a COVID secure environment with appropriate PPE and distancing measures.

[14] https://www.politics.co.uk/comment/2021/01/06/home-abortions-a-disservice-to-women/

A temporary measure to deal with an unforeseen national emergency should not become the norm. It is putting lives at risk. There has been no review by an independent body of the safety of remote consultations.

The UK government has no systematic, objective data analysis of the outcomes for women post 'abortion at home', no evidence base for the safety of the process, no comparison with outcomes prior to the sanctioning of home abortion. Even if such an analysis existed, helpful as it would be, in such a short timeframe it would not cover longer term psychological consequences.

Abortion providers should not be relied upon to provide unbiased data – remote consultations are clearly easier for them and cut costs.

To press ahead with plans to make the emergency provisions permanent, without supportive evidence, appears driven more by ideology than science or public health concerns.

Question: Do you consider that the temporary measure has had an impact on the provision of abortion services for women and girls accessing these services with particular regard to accessibility?

a) Yes, it has had a positive impact

b) Yes, it has had a negative impact **X**

c) It has not had an impact

d) I don't know

Increased accessibility may be of benefit to those living in remote areas, but the greater speed and ease of access generally is not necessarily helpful. By 'streamlining' the process, the essential need for a period of calm reflection and access to non-directive counselling is denied. It is inevitable that this will lead to more women regretting decisions made in a hurry and without information and support.

If counselling is only offered by those agencies that are also providing the abortion, there is a significant risk of the advice being skewed by unconscious bias, especially with an ethically polarised issue such as abortion.

In their February 2019 Abortion policy statement, the Family Planning Association states: 'Free, non-directive pregnancy counselling and post-abortion counselling should be accessible to everyone who wants or needs it.'[15]

We appeal strongly for the mandatory provision of independent and non-directive information, counsel and support to be built into the process for all women considering an abortion. This should be followed by a 'cooling-off' period of at least 48 hours for reflection. This is one of the most important decisions any woman will make, with implications that will last her lifetime, not to mention the implication for her baby. Women facing such a decision should be able to access in-person support, information, and counselling in a setting free from coercive or commercial pressures.

[15] https://www.fpa.org.uk/sites/default/files/abortion-policy-statement.pdf

This must not be left purely to the abortion providers to supply; it has been amply demonstrated that those who profit from abortion cannot provide truly unbiased information and support.[16]

Question: Do you consider that the temporary measure has had an impact on the provision of abortion services for women and girls accessing these services with particular regard to privacy and confidentiality of access?

a) Yes, it has had a positive impact

b) Yes, it has had a negative impact **X**

c) It has not had an impact

d) I don't know

Of course, every patient should be able to have confidence that his or her medical details will be treated as confidential. But it is not in a woman's best interests for there to be no record in her medical notes of pregnancy, abortion or related surgery, as may be the case under the provisions for Early Medical Abortion (EMA) at home.

Abortion providers are not obliged to record NHS numbers and women are not required to report adverse outcomes to their abortion provider. So systematic, objective analysis of the outcomes for women post abortion is undermined in the UK by the absence of full records linking women's health to prior abortion. How is the effectiveness of the present system, were it to be made permanent, to be assessed? How will we learn from mistakes if longitudinal analysis is impossible? That the DHSC can say, as they do on their website, they are 'carefully monitoring the impact,' without putting in place even the most rudimentary scrutiny procedures, beggars belief.[17]

As things stand, an abortion at home will not be recorded on a patient's NHS record. Without that information available to them, clinicians may unwittingly interpret subsequent symptoms, and/or institute treatment, inappropriately. Privacy and confidentiality should not include a failure to keep a patient's medical records updated; it is in that patient's interests that clinicians, who may be called upon to treat her for subsequent illness, have access to a full history.

Question: Do you consider that the temporary measure has had an impact on the provision of abortion services for those providing services? This might include greater workforce flexibility, efficiency of service delivery, value for money etc.

a) Yes, it has had a positive impact

b) Yes, it has had a negative impact **X**

c) It has not had an impact

d) I don't know

[16] https://www.independent.co.uk/news/uk/home-news/abortions-marie-stopes-clinic-bonuses-persuade-women-investigation-a8012171.html

[17] https://www.gov.uk/government/consultations/home-use-of-both-pills-for-early-medical-abortion/home-use-of-both-pills-for-early-medical-abortion-up-to-10-weeks-gestation

The overwhelming majority of healthcare professionals are highly motivated to deliver the best care possible for their patients. An induced abortion, even at an early stage, is a traumatic experience, emotionally as well as physically, even when it is without complication. Caring professionals will want to be alongside their patients at such times, and COVID-19 restrictions have prevented them from doing the best by their patients.

This has caused healthcare professionals both frustration and injury to their personal moral intuitions. To perpetuate this one week longer than COVID-19 security necessitates would be harmful. Offering appropriate care and support will always trump 'service efficiency' for healthcare professionals.

The temporary arrangements may well have recruited new personnel into the pipeline of provision, for example those asked to package and post the EMA pills out to patients. Among these will be some whose sincerely held beliefs, religious or otherwise, prohibit them from participating in the abortion process for reasons of conscience. Hopefully, reasonable accommodation at local level will mean that nobody is required to act against their own conscience. We urge the UK government to provide statutory protection for conscience in this situation if the temporary arrangements become permanent.

Question: Have other NHS services been affected by the temporary measure?

a) Yes **X**

b) No

c) I don't know

The majority of EMAs are arranged through private abortion providers like BPAS and Marie Stopes, though funded by the NHS. However, when complications arise during home abortions, that require surgical intervention, it is not these providers that step in, but the NHS. According to BPAS's own figures,[18] 3% of women having abortion at home before 9 weeks will require surgical intervention to complete the abortion. This figure rises to 7% for pregnancies of 9-10 weeks' gestation.

Such complications may present as emergencies, requiring ambulances, blood transfusions, rapid access to surgical theatres and personnel, with implications for other services.

Question: What information do you consider should be given to women around the risks of accessing pills under the temporary measure if their pregnancy may potentially be over 10 weeks gestation?

Physical risks escalate quickly if the pills are taken beyond 10 weeks. These include the risks of incomplete abortion, leading to persistent, sometimes heavy, bleeding; infection, with the associated risk of subsequent subfertility; sudden collapse, pain and bleeding associated with a ruptured, undiagnosed ectopic pregnancy; uterine rupture. These are dangerous complications that could be life-threatening in a remote location where emergency assistance is distant.

There are also psychological risks to consider. We suggest that it is every woman's natural intuition to offer a welcome in her womb as soon as she knows she is pregnant. To contemplate abortion flies in the face of that instinct and inevitably provokes internal conflict. The time pressures for women

[18] https://www.bpas.org/abortion-care/abortion-treatments/the-abortion-pill/abortion-pill-up-to-10-weeks/

nearing 10 weeks' gestation may mean that little thought is given to the long-term psychological impact. Decisions taken in the heat of the moment may be regretted for a lifetime. The longer the pregnancy has continued, the more the woman has to try to repress her maternal instincts in order to go through with the abortion. Access to support, non-directive information and counsel is essential in every case, but all the more so where the pregnancy is more advanced.

A woman using the pills by post scheme and who may be over the 10-week limit should also be warned of the potentially shocking sight of the recognisably human form of her baby in the toilet. She should be strongly advised to arrange for the support of a mature adult through the process.

Question: Outside of the pandemic do you consider there are benefits or disadvantages in relation to safeguarding and women's safety in requiring them to make at least one visit to a service to be assessed by a clinician?

a) Yes, benefits **X**

b) Yes, disadvantages

c) No

d) I don't know

1. Confirmation of dates

The timing of the two pills, both in relation to the gestation of the pregnancy and to the period between the two pills being taken, is crucial.

Usually, the last menstrual period (LMP) is used to estimate gestational age, but LMP alone is not the best obstetric estimate because it assumes a regular menstrual cycle. Studies report that approximately one half of women do not accurately recall their LMP.[19] Examination by a clinician will confirm a correlation between dates and the size of the pregnant uterus or suggest the need for an ultrasound scan to confirm.

2. Exclusion of ectopic pregnancy

In many obstetric centres, ultrasound scanning to exclude ectopic pregnancy, as well as to confirm dates, is a routine procedure. Exposing an undisclosed ectopic pregnancy to the effects of the abortion pills may produce torrential bleeding resulting in a surgical emergency. At home, with inexperienced support, this would be as terrifying as it would be life-threatening.

3. Ensuring the validity of 'consent'

For consent to be valid, it must be fully informed and free of duress or coercion. Even at the best of times, the decision to terminate a pregnancy is a profoundly significant one. But these are not the best of times. The pressures of isolation, and fears and anxieties around jobs, vulnerable family members, education etc have had a profound effect on the mental health of many. These are not good times for people to be making far-reaching decisions. To have to do so without the opportunity to talk things over in person with trusted medical carers is to make an already difficult situation intolerable.

[19]https://www.healthcare.uiowa.edu/familymedicine/fpinfo/OB/OB2017/ACOG%20redating%20gestational%20age.pdf page 2.

We believe that the initial consultation should be with the patient's doctor and that that doctor should routinely have to account for his or her decision to another doctor, who may affirm or resist their colleague's decision.

We believe that this level of care and involvement is essential to the patient's best interests in providing a confidential setting where any coercive factors can be safely discussed, and fears and anxieties gently explored. Only in this way can informed and free consent be assured. We believe this is sufficiently important to justify the very small risk of COVID transmission when undertaken in a COVID secure environment with appropriate PPE and distancing measures.

4. Uncovering abuse, coercion or impersonation

Telemedicine cannot reveal the presence of coercion. Only in a secure, supportive and confidential setting, away from the abusive relationship, may a woman find the courage to open up and to make a free choice about her pregnancy.

'Pills by post' cannot guarantee that the person requesting the pills will be the person taking them. There is also the concern that pills may be being procured for underage girls and/or victims of sexual abuse. Retaining face-to-face visits would retain the chance for these girls to raise the alarm and receive help.

5. 'Cooling off period' for non-directive information and reflection

Decisions made in haste may be regretted for a lifetime. Consent is not fully informed if it is given under duress, or on the basis of only partial understanding of the options available. A supportive environment and access to non-directive counselling before and, if abortion happens, after abortion, are essential to the consent process, we believe.

6. Ensuring that mature adult help and available back up emergency services are in place

No woman should have to face disposing of the recognisably human form of her aborted baby alone. Help should be on hand for any physical or emotional needs.

7. Arrangement for a follow up pregnancy test to confirm full expulsion of uterine contents, and to discuss contraception options

8. Offsetting the risk of under-reporting of complications

See answer, part 12), to Q1 above

9. Ensuring an audit trail to assess outcomes and aid research

Abortion providers are not obliged to record NHS numbers and women are not required to report adverse outcomes to their abortion provider. So systematic, objective analysis of the outcomes for women post abortion is prevented by the absence of full records linking women's health to prior abortion. Accurate records, systematic review and robust audit are essential to safe practise. How is the effectiveness of the present system, were it to be made permanent, to be assessed? How will we learn from mistakes if longitudinal analysis is impossible? It is essential that there be a record of EMAs at home, and a mandatory consultation and assessment would facilitate this.

Question: To what extent do you consider making permanent home use of both pills could have a differential impact on groups of people or communities? For example, what is the impact of being

able to take both pills for EMA at home on people with a disability or on people from different ethnic or religious backgrounds?

Nobody should be required to participate in enabling abortion at home, for example by posting pills, if to do so would conflict with their sincerely held beliefs, religious or otherwise. We urge the UK government to extend respect for conscience to cover all related procedures.

Question: To what extent do you consider that making permanent home use of both pills for EMA would increase or reduce the difference in access to abortion for women from more deprived backgrounds or between geographical areas with different levels of disadvantage?

England does not have the large number of small, remote island communities that Scotland does, but it does have many remote, rural village settings where public transport may be intermittent and house calls by GPs may be limited. We appreciate that not having to wait for a GP to visit such a community could be viewed as a significant advantage. However, we would argue that it is better to be inconvenienced early on than be put at risk later in the process when emergency help might not be at hand.

On balance we believe that women living in remote communities would be better served, and safer, under a provision that mandated face-to-face consultations, and would suggest that financial assistance be made available to women in poverty to enable them to travel to those consultations.

Question: Should the temporary measure enabling home use of both pills for EMA [select one of the below]

a) Become a permanent measure?

b) End immediately? **X**

c) As set out in the current temporary approval, be time limited for 2 years or end when the temporary provisions of the Coronavirus Act 2020 expire, whichever is earlier?

d) Be extended for one year from the date on which the response to this consultation is published, to enable further data on home use of both pills for EMA and evidence on the temporary approval's impact on delivery of abortion services to be gathered?

e) Other [please provide details]?

Question: Have you any other comments you wish to make about whether to make home use of both pills for EMA a permanent measure?

It is our view that the emergency provisions, intended to cover lockdown, should be discontinued immediately. Clinics have re-opened, and access is restored. We believe that initial face to face clinical assessment by a healthcare professional, provision of non-directive information and support, pre-decision counselling and time for reflection, and follow-up support including a check pregnancy test, should all be routine and be reinstated immediately. Both pills should be taken in a clinic. Following misoprostol, the woman should remain in the care of the clinic until the abortion is

deemed by clinicians to be complete. Resuscitation equipment, and staff trained to use it, must be on hand throughout.

We believe the small risk of COVID-19 transmission this would involve is outweighed by the safety risks of continuing with the emergency regulations.

For reasons given above, non-directive information, counsel and support should not be left to abortion-providers alone to supply.

(It is possible to conceive of a situation where there may be insuperable barriers to accessing normal face to face abortion care, [for example, where there is domestic abuse that is preventing a woman from leaving the house], such that her choice is between no care and telemedicine. In this situation, we would see remote care as the 'lesser of two evils.' This should not be interpreted as approval of the current blanket proposal, that we strenuously oppose, but as hesitant openness to the use of telemedicine in exceptional circumstances.)