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

Consultation questions

Impact of home use of both pills for EMA up to 10 weeks gestation on delivery of abortion services

Service delivery has been transformed across the whole health and care system during the pandemic. Abortion services are no exception, and we're taking this opportunity to reflect on the changes that have been implemented over the last eight months to ensure service provision remains safe and accessible, meets legal requirements, meets the needs of women and girls and is of high quality going forward.

We're therefore seeking views and evidence on the impact of the temporary measure enabling home use of both pills for EMA up to 10 weeks gestation during the COVID-19 pandemic.

We're particularly keen to hear views from those who have direct experience of accessing or providing abortion services during the pandemic.

Question 1: 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

c) It has not had an impact

d) I don't know

We believe it is important to find a balance between increasing access / reducing inequalities on the one hand and safeguarding / patient safety on the other.

The recently published evidence[1] shows that significant adverse events are rare for women accessing the pills via a telemedicine service and clinical outcomes with telemedicine are equivalent to in-person care. In addition, in all cases where the gestational age after abortion was reported as being greater than the expected 10 weeks, the medical abortion was completed at home without additional medical complications.

There was a slight increase in effectiveness in the group that received telemedicine and this may be due to the ability of patients to better control the timing at which they took the medication.

Abortion is safer and better for women the earlier it is performed, and telemedicine has resulted in a drop in average gestation and abortions being performed earlier than ever before. According to recent DHSC data, since the introduction of telemedicine, 30% of abortions now happen before 6 weeks' gestation, compared to only 13.5% in the same period in 2019.

Anecdotally, we have heard that staff involved in triaging patients consider that the service is continuing to be delivered to a high standard

We note that a small number of cases have occurred where a complication might have been avoided if the woman had been seen in person and the learning from these cases needs to be discussed. It is essential that this learning is shared across services in England and that any recommended safety steps are introduced by all services.

The safe and effective use of medicines should underpin these arrangements. This includes mifepristone, misoprostol and analgesia, as well as anti-emetics, prophylactic antibiotics and ongoing contraception where used. Therefore, it is essential that all services have clear arrangements in place

[1] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3742277

for confirming each medicine, including analgesia, is appropriate and safe for an individual patient. Where services are being provided remotely, remote access to clinical information and a discussion with the patient will be key components of confirming the safe use of medicines.

Also essential to the safe use of medicines is women receiving clear information about how to take their medicine and when to seek further help. Information may need to be provided in multiple formats, recognising an individual woman's level of literacy, health literacy and languages spoken. Work should be undertaken with patient representative groups and health literacy experts to ensure information resources are fully accessible. In addition, consultations should be structured to confirm a patient's understanding of the information, especially as this may be more challenging in a remote consultation.

In addition, some women may find remote consultations impossible to access (e.g., lack of privacy at home for a remote consultation) and therefore alternative options should be available, and we would advocate patient choice.

The postal or courier delivery service needs to be robust to ensure that there is no risk of delivery to the wrong person and that confidentiality is maintained. There is potentially a risk that the ease of access could be viewed as reducing the seriousness of the decision and it is important to ensure that this is an informed choice.

Question 2: 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

c) It has not had an impact

d) I don't know

It is clear from the data in the consultation paper that accessibility has improved. The evidence shows that the new telemedicine-hybrid model improved access as the rate of women seeking abortion medication outside the formal healthcare setting reduced significantly in the UK following implementation of telemedicine.

Before this change, women had to attend a licensed clinic which may be a long distance from their home, requiring public transport to access, needing women to take time off work, pay for childcare, and often bring a partner or friend with them. This meant that abortion care often had quite a high cost to women. Telemedicine has removed these barriers.

Question 3: 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

c) It has not had an impact

d) I don't know

It is likely that the benefits identified in relation to improved access and reduction in need to travel may have a positive impact for rural communities. Being able to remotely access services from the privacy of home may be especially significant for women in remote communities, since having to

travel away from home to access care is difficult to keep private in a small community. However, the ability to access urgent care should any adverse outcomes occur may be even more challenging in remote locations and therefore arrangements must be put in place for this before women in remote locations are supplied with medical abortion treatments as part of contingency plans.

More than half of women who had an abortion in 2019 had to attend a clinic or hospital that was targeted by anti-abortion protesters. These women often report being watched, observed, and being made the feel guilty. Multiple women report knowing a protester outside the clinic, compromising their privacy. Telemedicine reduces the number of women exposed to this damaging activity.

However, not all women and girls will have access to an electronic device in order to be able to undertake a remote consultation.

Question 4: 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

c) It has not had an impact

d) I don't know

Time, resources and training are required to undertake video or telephone consultations, and this should continue to be available to those providing the service. The time spent in consultations with patients, whether provided in person or remotely, is likely to be similar. However, remote consulting enables greater workforce flexibility, for example, in cases of staff shielding and access to a wider pool of staff across a larger geographical area.

Question 5: Have other NHS services been affected by the temporary measure?

a) Yes [please provide details of which services]

b) No

c) I don't know

BPAS data from April – July 2020 shows that complications for Early Medical Abortions declined compared to the same period in 2019. The risk of continuing pregnancy after treatment fell by three-quarters to 0.28%, down from 1.12%, potentially as the result of women being able to choose the best time for them to start the procedure, rather than having to fit it around their commitments in addition to the in-clinic appointment for the first medication

The same data shows that the risk of major complication (usually the only kind of complication that need hospital care) fell by 2/3rds from 0.09% to 0.03% thereby reducing pressures on NHS Trusts.

Existing DHSC provisions ensure that independent abortion care providers (who provide roughly 75% of all abortion care in England) provide follow-up care for women who access care with them. They have 24-hour aftercare phone line staffed by trained clinical staff, they provide in-clinic appointments for women with suspected incomplete abortions or retained products of conception, and they provide post-abortion counselling where a woman requires it. Telemedicine has not changed this. Uptake of pre and post counselling is low and has been provided via a telephone service prior to the telemedicine service being initiated.

The reduction in gestation means more women are able to access early medical abortion, reducing the need for surgical services and releasing capacity for other medical procedures

Question 6: 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?

Abortion providers include this information in discussions with clients in the same way as other kinds of risks and complications of abortion treatment. Doctors and nurses are the best people to determine what they need to discuss with their patients and will ensure all individuals have the relevant information to make an informed choice.

The risk of this complication is very low, according to a large-scale analysis of abortion provision before and after the change in regulation, 0.04% of abortions appeared to have been provided at over 10 weeks' gestation. More recent assessments indicate that the risk within the BPAS service is lower, at around 1 in 3285. This is roughly 14 times lower than the risk of a pregnancy ending in stillbirth.

The large-scale analysis of care pre- and post-regulatory change reports that all post-10-week abortions were completed at home without additional medical complications.

Question 7: 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

b) Yes, disadvantages

c) No

d) I don't know

There is a real danger that safeguarding issues or coercion may be more difficult to detect via a remote, non-face to face, consultation. We note that the preferred option for women in one survey is for telephone consultation rather than video consultations yet some other services specifically recommend use of video consultations to reduce the risk of coercion (e.g., moving the camera to check who else is in the room with the patient). Where there are safeguarding issues that cannot be resolved remotely, women should be seen in person. The preference for use of telephone vs video consultations may need further research to mitigate against any safeguarding and coercion risks.

However, we are aware that every woman is asked by abortion providers whether they are safe at home. This is a routine part of abortion care, no matter how or where care is provided.

Some women seeking access to services are in relationships or home environments where their behaviour and travel are monitored which means travelling to an abortion clinic is difficult or dangerous. Telemedicine enables these women to access abortion care without risking their personal safety.

Assurance that abortion services will continue to provide in-person care where telephone consultations raise safeguarding concerns such as safety or privacy at home, ability to consent, or wider safety concerns surrounding existing children or statutory concerns such as Female Genital Mutilation is needed.

Abortion providers report that providing care remotely led to increases in the number of women disclosing problems at home. BPAS reported that in the first three months of their Pills by Post service, 10% of clients underwent an enhanced safeguarding risk assessment which is a 12% increase compared to March 2020.

Clinicians providing abortion services report that telemedicine has made women more willing to disclose concerns about safety when in the privacy and familiarity of their own surroundings, as opposed to a clinical environment

Public sector equality duty

As part of the consultation, we're inviting views on the impact of making permanent home use of both pills for EMA on people with protected characteristics and steps that could be taken to mitigate against any adverse impact, against the government's duties under the Equality Act 2010.

Protected characteristics are:

age

gender reassignment

being married or in a civil partnership

being pregnant or on maternity leave

disability

race including colour, nationality, ethnic or national origin

religion or belief

sex

sexual orientation

Question 8: 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?

Based on the information available it is difficult to determine the impact on age (for example, younger women may have less privacy at home) and it is unclear if there is any impact on ethnicity or disability. Any changes made must be responsive to individual patient needs

Socioeconomic considerations

In addition to the protected characteristics as discussed above, we're also seeking views on the potential for making permanent home use of both pills for EMA to reduce or increase inequality in health outcomes experienced by different socioeconomic groups.

Question 9: 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?

By giving women more choice about how to access care this could have a positive impact on socio-economic equality.

There is also a financial benefit by reducing the costs of travel to clinics

Whether to make home use of both pills for EMA a permanent measure

As set out above, the current approval allowing home use of both pills for EMA up to 10 weeks gestation is not permanent. It will currently expire on the day on which the temporary provisions of the Coronavirus Act 2020 expire, or the end of the period of 2 years beginning with the day on which it is made, whichever is earlier. We're seeking views on whether this should be made permanent (noting

that, as with any other healthcare service, the measure would be kept under review should new evidence or information emerge), and if not, when the temporary measure should end.

It is important to note that the options for the future of the temporary measure set out in question 10 will be subject to any considerations regarding the COVID-19 pandemic that are relevant at the time the decision is taken.

Question 10: 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?

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]?

More evidence of the impact of the change to this service needs to be collated and shared before a permanent change is made. Any national guidelines that are in place should be regularly reviewed and changed as appropriate based on good practice or in response to a safety incident.

Abortion care should be evidence-based and reflect the best possible care available to women. Telemedicine is potentially able to provide up to date, high quality care going forward.

Further research, particularly on acceptability, will be necessary post pandemic.

Question 11: Have you any other comments you wish to make about whether to make home use of both pills for EMA a permanent measure?

We have concerns that it will be more difficult to pick up any emotional and safeguarding issues via a remote consultation.

The remote consultation also provides the ability for a woman or girl to access the service and obtain the pill for a friend.

Women and girls who are confident in their decision need to be supported around accessing these types of services and reducing any barriers to access will help this. But this needs to be done in a way that helps them, rather than seen as a route without the emotional help and support that they might need to access in either making the decision in the first place, or the after effects of doing so.