THE HIGH COURT OF JUSTICE **CO/1402/2020**

QUEEN'S BENCH DIVISION

ADMIN COURT

IN THE MATTER OF AN APPLICATION FOR JUDICIAL REVIEW

R

(on the application of

CHRISTIAN CONCERN)

Claimant

-v-

SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

Defendant

DEFENDANT'S EVIDENCE BUNDLE

Government
Legal Department

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INDEX TO DEFENDANT'S EVIDENCE BUNDLE

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WITNESS STATEMENT OF ANDREA DUNCAN

I, **ANDREA DUNCAN**, of the Department for Health and Social Care, 39 Victoria Street, London, SW1H 0EU will say as follows:

1. I am the Head of policy for Alcohol, Sexual and Reproductive Health (which includes abortion policy) and Physical Activity in the Healthy Behaviours Team in the Department of Health and Social Care. I have been a civil servant for over 30 years and prior to my current role led policy on sexual and reproductive health in DHSC for over 15 years. I have worked in the team which leads on abortion policy within the Department for a number of years and my role includes managing policy on home use for early medical abortion.

2. I make this statement to explain the decision, published on 30 March 2020, to grant approval for two temporary measures in England to ensure continued access to

abortion services, as follows: (1) women and girls are able to take both pills (Mifepristone and Misoprostol) for early medical abortion up to 10 weeks gestation in their own homes, without the need to first attend a hospital or clinic (subject to eligibility following a telephone or e-consultation with a clinician); and (2) registered medical practitioners are able to prescribe both pills for the treatment of early medical abortion up to 10 weeks from their own homes (the "**Decision**") [**JR/38**]. In my role, I was closely involved in the events leading to the Decision.

3. Except where indicated otherwise, the matters contained in this witness statement are within my own knowledge and are true. Where I refer to matters which are not within my own knowledge, I believe them to be true and indicate the source of my information.

4. References in this statement:

    a. to [**JR/x**] are to page references in the judicial review bundle

    b. to [**DB/x**] are to page references in the Defendant's material which has been provided at the same time as this statement.

Abortion legislation and guidance

5. The 1967 Abortion Act sets out the legal framework under which abortions can be performed in England and Wales. In accordance with section 1(3) of the Abortion Act 1967, all independent sector clinics wishing to perform termination of pregnancy must be approved by the Secretary of State for Health and Social Care. The Secretary of State's approval is conditional upon the provider's compliance with the Abortion Act, the Health and Social Care Act 2008, and the Department's Required Standard Operating Procedures ("RSOPs"):

    https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/874241/Procedures_for_approval_of_independent_sector_places_for_abortion.pdf

6. The RSOPs make explicit the conditions and requirements for independent sector places to be approved by Secretary of State to perform termination of pregnancy. Failure to comply can lead to withdrawal of approval at any time. The RSOPs have been developed to:

- Ensure compliance with all legal requirements,
- Provide the best quality of care for patients, and
- Provide sound management, organisational and clinical governance arrangements including issues such as child and adult safeguarding.

7. Providers must also comply with the regulatory framework set out in the Health and Social Care Act 2008 and accompanying regulations and guidance. The Care Quality Commission ("CQC") is responsible for implementing the regulatory framework set out in the regulations made under the Act. The (Regulated Activities) Regulations 2014 provides that the termination of pregnancy is a regulated activity. All providers of regulated activities must be registered with the CQC and meet fundamental standards of quality and safety as set out in Part 3 to the 2014 regulations. Registered providers must also meet the requirements set out in the Care Quality Commission (Registration) Regulations 2009. CQC registration must be in place before the Secretary of State will consider an application for approval.

8. In 2014 my team developed "*Guidance in Relation to Requirements of the Abortion Act 1967 for all those responsible for commissioning, providing and managing service provision:"*

   https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/313459/20140509_-_Abortion_Guidance_Document.pdf.

9. The intention of the guidance was to provide support for doctors. The guidance dealt with a number of issues including the role of the certifying doctors and the steps they should take to assess risk to the woman's physical or mental health, the role of the multi-disciplinary team and consultations via webcam or telephone. In relation to the latter, a key extract is set out below:

   > "6. Although there is no legal requirement for at least one of the certifying doctors to have seen the pregnant woman before reaching a decision about a termination, the Department's view is that it is good practice for this to be the case. It is recognised however that, with technological advances, this

may well mean that a doctor does not physically see the woman, e.g. there could be a discussion by phone or over a webcam…"

10. Service provision in England has for some years included remote consultations, with women then subsequently attending a service for treatment. Certification takes place before the woman attends for treatment.

11. The Royal College of Obstetricians and Gynaecologists ("RCOG") have published a series of guidance documents in response to the Covid-19 pandemic, including guidance for healthcare professionals on Covid-19 infection and abortion care services (the latest version of this was published on 9 April 2020).

    https://www.rcog.org.uk/globalassets/documents/guidelines/2020-04-09-coronavirus-covid-19-infection-and-abortion-care.pdf

12. The guidance sets out that during the Covid-19 pandemic access to normal healthcare processes will be disrupted, and that to ensure safe and effective abortion care, greater use of remote consultations and medical abortion at home may be necessary. It outlines an evidence-based approach to delivering best practice care using well established models that are already widely used, but may have been limited or restricted in UK practice.

13. The development of this guidance followed a meeting which the Department led on 10th March (see below).

14. The guidance also includes a flow-chart which summaries the care pathway for management of EMA during COVID-19. The guidance includes the circumstances in which women will not be eligible for remote treatment.

Early medical abortion

15. Early medical abortion ("**EMA**") involves taking two different tablets, Mifepristone and Misoprostol, which are most effective with a time gap between taking the first and second pill of 24-48 hours.

16. For a number of years there were calls for the Secretary of State to use powers in Section 1(3A) of the Abortion Act 1967 to approve English homes as a class of place where EMA could be performed. This would mean that women would only attend clinic once where they would take Mifepristone and be supplied with the Misoprostol to take in their home 24-48 hours later. These calls were based on: international evidence as to home use being effective, safe and acceptable for EMA; many women preferring to have the choice to take pills at home to help balance family and personal needs; and, because of concerns around patient safety, where women returning home for self-management after taking Misoprostol in the clinic may begin to abort whilst travelling home, which could be traumatic. Simultaneous administration of pills, which was commonly chosen by women to avoid a second visit, also has a higher risk of side effects and reduced effectiveness.

17. Scottish Ministers approved "Scottish homes" as a class of place for EMA on 26th October 2017. This was followed by Welsh Ministers on 27th June 2018. DHSC Ministers announced, on 25th August 2018 [**JR/96**], that they would approve homes in England as a place where the second stage of EMA could be performed and that this change would come into force by the end of 2018. There was no consultation prior to those approvals.

18. The announcement highlighted that the Department would work with the RCOG to develop clinical guidance for all professionals to follow for home use.

19. The approval was published on 27th December 2018 – [**JR/98**]. Clinical guidance was published on 3 January 2019. This set out recommendations for best practice, which includes identification and management of vulnerable groups.

20. Following publication of the approval, women and girls have been able to take the second pill for early medical abortion in their own homes. Typically in these cases, the individual will contact the provider and will be offered a consultation, prior to which she will be emailed written information about the procedure. The woman will then have a video or telephone consultation where the clinician – which might be a nurse or midwife, working as part of a multidisciplinary team - will gather through sensitive questioning information about the woman including her health and personal circumstances. The woman will also have the opportunity to ask

questions. Informed consent for the procedure can then take place. Two doctors will then consider whether there are grounds under the Abortion Act 1967 for treatment to proceed. If this is the case, the woman attends the clinic to take the first pill and then returns home to take the second pill 24-48 hours later.

Pre-existing evidence on approving homes as a class of place where EMA could be performed

21. A systematic review of home-based abortion published by the World Health Organisation (WHO) in 2011 concluded that home use of abortion pills was safe provided certain safeguards (such as telephone support from health professionals) are in place. Guidance subsequently published in 2012 from WHO "Safe Abortion: technical and policy guidance for health systems" states that "home use of misoprostol is a safe option for women". For some years, women have been supplied with exactly the same medicines used in medical abortions to complete miscarriage at home. Home use of EMA has been routine in the USA since 2000 and in Sweden and France since 2004.

22. In 2019, the National Institute for Health and Care Excellence's evidence review on "Abortion care: [A] Accessibility and sustainability of abortion services" (September 2019) was published. At pp. 39-41 and 44, it found that there was no difference in satisfaction between women who received abortion services by telemedicine compared to face-to-face services. Moreover, the quantitative and qualitative evidence showed that telemedicine services may improve access to abortion services. They commented that there was the potential to reduce inequalities associated with groups who find it difficult to travel to abortion services. By way of example, it would improve access to those who suffered from threats of violence, controlling circumstances and cultural backgrounds that accept honour-based violence. Finally, it found that telemedicine services were likely to be cost-saving rather than lead to increased resources being used.

Impact of Coronavirus

23. On 3rd March 2020, I was copied into a letter from Ann Furedi, Chief Executive of the British Pregnancy Advisory Service (BPAS), addressed to the Secretary of State for Health, the Minister for Care (Helen Whately) and the Chief Medical Officer, Prof. Chris Whitty [**DB/45**]. This highlighted the work that BPAS were doing to prepare for the Coronavirus pandemic including "risk-assessing the continued provision of our services in circumstances where women who need to terminate a pregnancy may be unable to attend treatment units, and also when units may be short of staff, or need to close".

24. Ms Furedi went on to say that:

> "an obvious measure we have identified would be for the Secretary of State to use his power now to enable both the medications involved in early medical abortion (EMA) to be taken at home. Precedent has been established already with the approval for the home-use of misoprostol, which has resulted in a significant improvement to services. The same action regarding mifepristone would allow us to provide the entire procedure without the need for the woman to visit a facility, using proven telemedicine protocols….."

25. A telephone meeting was arranged for 10th March, which was attended by BPAS, Marie Stopes UK (MSUK), National Unplanned Pregnancy Advisory Service (NUPAS), the Royal College of Obstetricians and Gynaecologists, Public Health England and Scottish and Welsh Government officials. The readout of the meeting is at [**DB/32**]. It recorded the view of the external bodies who attended that there ought to be home use for both abortion pills for EMA up to 10 weeks gestation. The view was that this was supported by clinical evidence and the necessary infrastructure was already in place, but that there needed to be appropriate safeguarding of vulnerable patients. It was also agreed that doctors ought to be able to prescribe from home, and there was also support for midwife / nurse prescribing.

26. Following the meeting, stakeholders continued to flag issues with provision of abortion services: see [**DB/34 to 35**].

27. A submission was sent to Ministers on 18 March 2020 recommending that the power to approve women's homes as a class of place where both abortion pills

could be taken for early medical abortion, and for the home of a registered medical practitioner (a doctor; "RMP") as a class of place where both abortion pills can be prescribed for the treatment of early medical abortion" [**DB/36**].

28. This action was agreed by the Minister of State for Care. It was assumed that the Secretary of State was also content, as his office had been copied into the submission, and abortion matters had been delegated to the Minister for Care for decision under ordinary Ministerial arrangements. The approval was published on GOV.UK on 23 March 2020 (not 20 March 2020 as the Claimant's Statement of Facts and Grounds states).

29. On the evening of 23 March, my media colleagues were alerted by the Secretary of State's office that he had become aware of the publication of the approval and had asked for it to be withdrawn immediately. They informed me that he had not seen the submission and did not agree that changes needed to be made. I attach an e-mail of 24 March 2020 timed at 13.13 from the Secretary of State's private office which confirmed this [**DB/75**].

30. As a result, the approval was withdrawn from the GOV.UK website and a message appeared as follows: "*The information on this page has been removed because it was published in error. This was published in error. There will be no changes to abortion regulations*".

31. That accurately explained things because we obviously would not have proceeded to publication if we were aware that our Secretary of State was not content. Unfortunately, an error was made and he had not had sight of the submission. That is clearly regrettable. However, I should also say that the Department was dealing with a completely unprecedented set of events at this time. I cannot recall anything similar in the whole of my career**.** Ministers, their offices and the wider Department were working long hours and having to adapt to working to manage the COVID-19 pandemic. Many urgent decisions were being taken and there were large volumes of issues and email traffic to manage.

The Coronavirus Act 2020

32. Around the same time that we were considering the granting of approval under s1(3A) of the Abortion Act 1967, we were approached by RCOG by e-mail, dated 18th March [**DB/64**]. They asked for urgent consideration to be given to using the emergency legislation - the Coronavirus Bill - going through Parliament to relax the rule that two doctors must certify an abortion during the current COVID-19 crisis. Instead, they wanted to allow for one doctor, nurse or midwife to certify that the grounds had been met.

33. We understand that Peers also approached Lord Bethell – the Parliamentary Under-Secretary of State – about this matter. On 18th March 2020, a second submission was sent to Ministers [**DB/66**] asking them to indicate whether they wanted us to urgently pursue avenues to use the Coronavirus Bill to relax the two-doctor certification rule. As things turned out, this was overtaken by events, as described below.

34. RCOG continued to press for an amendment to be included in the Bill to relax the requirements on certification and over the weekend wrote a formal letter to the Secretary of State's office asking for the certification requirements to be relaxed [**DB/69**].

35. In the early afternoon of 24th March 2020, the Secretary of State made a statement to the House of Commons to update the House on COVID-19. In response to questions, the Secretary of State confirmed that there were no plans to change abortion regulations due to COVID-19. This reflected the Secretary of State's position at that time, as set out above.

36. The amendment to the Bill was tabled in the House of Lords by Baroness Barker and Baroness Bennett late in the evening of 24 March and this sought:

    - To allow one doctor (rather than two) to certify that the grounds have been met for an abortion to be performed and additionally allow one nurse of midwife to certify abortions;

- To allow nurses and midwives to perform abortions;
- To classify women's homes as a place where both stages of medical abortion could be performed (England and Wales only); and,
- To allow doctors, nurses or midwives to prescribe medication for abortion from their home (E&W only).

37. This amendment would have made significant changes to the current legislative framework, in particular permitting nurses and midwives to perform abortions, certify that the grounds had been met and prescribe medication for abortion from their homes. Whilst nurses and midwives are likely to be part of a multi-disciplinary team providing abortion services, this is a different role from that of the RMP.

38. The Government's response to the amendment is on record in the speech by Lord Bethell on 25 March 2020. The amendment was withdrawn following debate. Lord Bethell committed to keeping the position under review in light of the concerns raised by the Baroness Barker and Baroness Bennett over access to services. He stated that:

> "Her point on monitoring the situation is exactly the one that the noble Baroness, Lady Watkins, made earlier. I commit the department to monitoring it. We will remain engaged with the Royal College of Obstetricians and Gynaecologists and other stakeholders. She is absolutely right that we can return to the subject with two-monthly reporting back, and it can be discussed in Parliament in the debates planned on a six-monthly basis."

Further developments

39. The withdrawal of the approval on 23rd March 2020, so as not to allow both stages of EMA to be performed at home, caused concern among abortion service providers and other groups, such as RCOG.

40. On 25th March 2020, the Secretary of State's Private Office requested a short note on other potential options for women accessing abortion services in light of

concerns raised by stakeholders. A note was sent to the Minister for Care and the Secretary of State's private office on 25th March 2020 [**DB/76**].

41. The Department and Ministers received a number of representations following the withdrawal.

42. On 25th March 2020, we received am email from Ms Ann Furedi at BPAS, stating that:

- "Across **BPAS**, over a quarter of clinics (23/73) have closed as of 25th March due to staff shortages. We have 85 members of staff either diagnosed with actual or suspected COVID infection - or self-isolating.
- **Nupas anticipates 60-70% of its services will close down within days at current rates of sickness and isolation.**
- **MSI – around 12% (54) of staff have been self-isolating. Women who have booked but been unable to attend appointments has doubled.**
- **NHS – many services have staff self-isolating or services reduced withdrawn because spare capacity is needed.** Hospitals are seeing a contraction in their services because of the need to take anaesthetic machines out of theatre to use as ventilators OR take over clinical spaces for early surgical for mgmt. of COVID+ patients or staffing issues – they need to ramp up EMA but can't because of miso upper gestation restrictions and delivery remotely but can't because of home mife restriction
- **Independent providers** not been able to access some of the locations where we normally provide EMAs (like GP surgeries) – this and number 1 mean there are fewer actual places for people to go.
- Access to surgical abortion is reducing due to
    - Hospitals taking back their theatres to use the ventilators
    - Surgeons self-isolating
    - Anaesthetists and surgeons being called into the NHS to care for COVID patients
- We are getting increasing numbers of messages via social media from women who **cannot leave their homes or will be pushed over the limit for EMA during isolation**. Without the ability to provide EMA at home some will be forced to continue their pregnancies.
- Forced pregnancy is bad enough at the best of times but infinitely worse in the midst of a healthcare crisis. Some will be pushed into gestations where they need surgical – see above." (original emphasis)

43. On 27th March 2020 we were informed by Ms Ann Furedi at BPAS that:

"…

1. As of today 25 out of 71 units are closed. Some due to staff shortages, some because health centres that we operate from are not functioning normally.
2. In total through clinic closures and staff shortages we cancelled 1,120 appointments."

44. On the same day, correspondence was received through Ms Nadine Dorries MP, Minister of State for Patient Safety, Mental Health and Suicide Prevention, from Lucy Allan MP, detailing BPAS's concerns about the deteriorating situation [**DB/79**].

45. Also on 27th March 2020, a letter was sent to the Secretary of State from Mr Richard Bentley at Marie Stopes UK, stating that:

> "…By way of information, we currently have 68 out of 400 of our team members away from work self-isolating because of the virus; I understand other independent providers are also experiencing a similar deteriorating position. Given the ongoing number of people visiting our clinics, this is only set to increase. If we, the independent sector, are increasingly unable to provide services and the NHS is diverting resources to treating COVID-19 cases, abortion services will very soon be in a critical state across the country.
>
> Activity at our centres is showing no sign of abating; in fact, our nurses, midwives, doctors and call centre teams are being asked to take on higher caseloads in support of NHS Trusts, which are having to suspend termination of pregnancy services and re-direct resources. As things stand, we have been approached by 15 NHS Trusts & CCGs to ask if we can support them to deliver services. One of these is **West Suffolk Hospital**, which, I understand is within your own constituency." (original emphasis)

46. An updated note was sent to Ministers on 27 March 2020 [**DB/80**].

47. On 28th March 2020, we received an open letter signed by 55 public health specialists urging the Secretary of State to enable telemedicine for EMA so that women would not have to leave their houses [**DB/84**].

48. On the evening of Saturday 28th March 2020, the Secretary of State agreed to grant approval for women to take both abortion pills at home. This is recorded in an e-mail from the Secretary of State's private office timed at 21.45, which also records the detailed briefing which was being given to the Sunday Times [**DB/88**].

49. At that time, there remained an issue about whether RMPs could prescribe the medicine from their homes, and we were asked to send up a further submission.

50. In response to a submission sent on 29th March 2020 [**DB/89**], the Secretary of State confirmed that he agreed to approve the home of an RMP as a class of place where both abortion pills could be prescribed [**DB/98**].

51. The approval was published on GOV.UK on 30th March 2020 [**JR/38**].

52. DHSC are monitoring how home use of abortion pills up to 10 weeks is working in practice, and the necessity of this temporary measure, through regular engagement with abortion providers and RCOG. CQC are also continuing to monitor the provision of abortion services following the approval.

Conclusion

53. Temporary approvals of women's homes as a place where both stages of EMA up to 10 weeks gestation and doctor's homes as a place where medication for medical abortion can be prescribed are now in place during the COVID-19 pandemic. Ministers have taken difficult decisions at pace in an unprecedented and changing climate. They have taken account of clinical advice and women's safety and wellbeing has been at the forefront of their decision making.

I believe that the facts stated in this witness statement are true.

SIGNED:

DATED: 12 May 2020

THE HIGH COURT OF JUSTICE **CO/1402/2020**

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SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

Defendant

WITNESS STATEMENT OF IMOGEN STEPHENS

I, **IMOGEN STEPHENS** FRCOG, FFSRH, FPH, of Public Health England, Wellington House,133-155 Waterloo Road, London, will say as follows:

1. I am a consultant in Public Health Medicine and a Fellow of the Royal College of Obstetricians and Gynaecologists ("**RCOG**"). I have clinical, research, commissioning, corporate and government-level experience. I have particular expertise in revalidation, quality, clinical governance and improvement of health service delivery, in particular for women's reproductive health. From 2013-2019, I was Deputy Medical Director at Public Health England. From 2017 until July 2019, I was Medical Director and Responsible Officer for Marie Stopes UK, a leading provider of NHS-funded abortion.

2. I am currently a Clinical Advisor to the Department for Health and Social Care (the "**DHSC**") and the Northern Ireland Office. I am also advising on implementation of abortion provision in Northern Ireland.

3. Except where indicated otherwise, the matters contained in this witness statement are within my own knowledge, and are true. Where I refer to matters which are not within my own knowledge, I believe them to be true and indicate the source of my information.

4. References in this statement to [JR/x] are to page references in the judicial review bundle.

5. I make this statement to set out the clinical evidence supporting the decision, made on 30 March 2020, to grant approval for two temporary measures in England to ensure continued access to abortion services, as follows: (1) women and girls being able to take both pills (Mifepristone and Misoprostol**)** for early medical abortion up to 10 weeks gestation in their own homes, without the need to first attend a hospital or clinic (subject to eligibility following a telephone or e-consultation with a clinician); and (2) registered medical practitioners being able to prescribe both pills for the treatment of early medical abortion up to 10 weeks from their own homes (the "**Decision**").

6. I also make this statement to address and respond to issues raised by the Claimant and in the Statement of Dr Gregory Gardner.

Abortion arrangements before the COVID-19 pandemic

7. Abortion prior to 10 weeks gestation is termed Early Medical Abortion ("**EMA**"). This now usually occurs with the taking of two medicines – Mifepristone and Misoprostol – either at a 24-48 hours interval (which is associated with fewer adverse events, including reduced risk of ongoing pregnancy) or simultaneously. The regime used depends on the clinical and organisational aspects in place at the provider level and on the woman's preference. Mifepristone works by blocking the hormone progesterone. Without progesterone, the lining of the uterus breaks down and the pregnancy cannot continue. Misoprostol makes the uterus contract,

causing cramping, bleeding and the loss of the pregnancy in a similar way to a miscarriage.

8. Before these medicines are administered, many women would normally have a remote teleconsultation with a nurse or midwife. The purpose of this would be to obtain information from the pregnant woman as to the reasons for the abortion and to ensure there are no medical issues, or contra-indications to abortion in general or EMA in particular. Issues relating to, for example, safeguarding and mental capacity would be explored. It would also be a chance for the pregnant woman to ask questions about the procedure. In order to fulfil the statutory requirements of the Abortion Act 1967, two registered medical practitioners in England, Wales and Scotland must sign to certify and specify that grounds have been met for an abortion. Guidance from the DHSC (2014) states that a registered medical practitioner can rely on the information obtained by other members of their team when certifying an abortion. This certification could therefore be performed remotely, including through use of an electronic signature.

9. It used to be the case that both Mifepristone and Misoprostol would then be administered in a clinical setting. Taking Misoprostol at home, however, was introduced as part of EMA provision in December 2018 following approval by the Secretary of State. This enables women, at the time of the Mifepristone being administered, also to be handed the Misoprostol pill which can then be taken at home. This avoids the risks of experiencing pain and heavy bleeding whilst travelling back from the clinic. There has been no observed increase in complications as a result of this change. It is likely, in fact, that the risks of ongoing pregnancy have been reduced, since many women opted for the convenience of taking both Mifepristone and Misoprostol simultaneously when required to attend a clinical setting.

10. Regulated access to abortion ensures services are provided to women in accordance with nationally agreed standards of clinical care and quality governance.

11. Standards of care for abortion provision in England are clearly described in recent NICE guidance NG140 'Abortion Care' (2019)[1]. Even before the pandemic, these supported self-referral and recommended the use of telephone and video consultations in clinical assessment where appropriate, with appropriate information governance safeguards in place. The basis of these recommendations (i.e. self-referral and use of teleconsultation) was to minimise delay in the abortion process, to ensure women have more options available, to decrease adverse events, and improve women's experience. In addition, there was strong evidence that substantial cost savings can be achieved when women present earlier, as this increases the likelihood that women can have a medical rather than a surgical abortion.

Reasons why COVID-19 pandemic required change in approach

12. Abortion is an urgent, time-sensitive clinical procedure. This means that any upset in access to abortion services is liable to have substantial negative impacts for women.

13. The COVID-19 pandemic had multiple impacts on abortion treatment and that this would be the case was evident from, at the latest, mid-March 2020. First, fewer women were willing or able to travel to abortion services because of the danger to themselves in contracting COVID-19 and the difficulties faced in leaving home by those with young children or living in coercive and abusive relationships. Second, the incidence of staff illness within some providers had reduced the availability of provision of services and lengthened waiting times. Third, abortion services themselves were being withdrawn because spare capacity was needed for patients suffering from COVID-19.

14. Not making any changes to abortion rules, such as that made by the Decision, would have led to the following potential harms:

    a. Women who were intent on having EMAs would have been forced to leave their homes and travel to clinical settings in order to take Mifepristone and obtain Misoprostol. This would have increased the

[1] NICE guidance NG140: Abortion Care; 2019.

possibility of them being infected with Covid-19 as well as tending to increase the spread of that disease. In 2018, 131,838 EMAs were carried out in England. Prior to the temporary change in approval of class of place, each of these women would have attended a clinic or NHS service at least once, and sometimes on 2 or more occasions. The increased use of teleconsultation and telemedicine will therefore have a significant impact on travel and social interaction and thus play a part in reducing transmission of infection during the pandemic;

b. Alternatively, women seeking abortions would not have been able to take Mifepristone and Misoprostol, either because they did not want to leave their homes, or, even if they had been willing to, would not be able to access treatment because clinics had closed. The result of this would have been:

- Women missing the 10-week deadline meaning that they would be having later terminations leading to greater health complications. The clinical risks of EMA are significantly less than abortions at later stages;[2]
- There would be a build-up of desired abortion treatments swamping capacity when more women felt able to leave their homes; and,
- Women seeking to undertake illegal, unsafe abortions.

15. In my view, these risks far outweigh any risks posed by women taking both Mifepristone and Misoprostol at home following a remote consultation. A detailed review of the evidence in support of self-administration of Mifepristone and Misoprostol by WHO[3] in 2015 recommended the option of women managing Mifepristone and Misoprostol medication without direct supervision of a health provider in circumstances where women have a source of accurate information and access to a health provider should they need or want it at any stage of the process.

[2] Harris L & Grossman D. N Engl J Med 2020;382:1029-40.
[3] Health worker roles in providing safe abortion care and post-abortion contraception: Evidence-to-decision framework, WHO, 2015.

More women report the method to be satisfactory when it is self-managed. Women find the option acceptable and feasible and providers also find the option feasible.

16. This was supported more recently by an evidence review conducted by the National Institute for Health and Care Excellence's, titled "Abortion care: [A] Accessibility and sustainability of abortion services" (September 2019, pp39-41 and 44).

Abortion arrangements in light of the COVID-19 pandemic

17. Following the Decision, in England (and also in Wales and Scotland following similar decisions made in those areas), providers can now offer a complete EMA service with the consultation taking place via video or teleconferencing and, if appropriate, a treatment package either sent to the woman's home or made available for her to collect from an abortion service provider.

18. Additional guidance for abortion care during the current COVID-19 pandemic response, including in relation to telemedicine and EMAs, was published by RCOG[4] on 9 April 2020 to ensure continuation of essential services when acute services are disrupted and/or women or clinical staff may be self-isolating (the "**RCOG COVID-19 Guidance**").

19. For women requesting an EMA, the RCOG COVID-19 Guidance only requires her to attend in person where the clinician judges that the benefit of doing so outweighs the risk of Covid-19 exposure and transmission, for example where there are safeguarding, language or capacity concerns, or when she is unsure of her gestation.

20. As before, in order to fulfil the statutory requirements of the Abortion Act 1967, an abortion must still be signed-off by two registered medical practitioners in England, Wales and Scotland. There is no change to this nor to the fact that a registered medical practitioner will often rely on the information obtained by other members of their team when certifying an abortion.

[4] RCOG Coronavirus (Covid19) infection and abortion care: information for healthcare professionals, 2020.

21. Counselling is available for all women undergoing EMA at any point in the care pathway, including post-abortion.

Response to issues raised by the Claim

22. I address here the various issues which have been raised by the Claimant in relation to the measures introduced by the Decision, which is being challenged in this claim. Where necessary, I also directly rebut the claims made in the Statement of Dr Gregory Gardner, dated 15 April 2020. I have used the same sub-headings as those used by Dr Gregory Gardner.

(a) Risks of physical complications

23. Dr Gardner sets these risks out at §§10-16 of his Statement. I disagree with his assessment and do not consider that these are good reasons for requiring women to take Mifepristone in a clinical setting, at least during the COVID-19 pandemic.

24. On infections, the RCOG guidance from that Dr Gardner refers to, at §10, has been superseded by NICE guidance 140 (Abortion Care, 2019) which does not recommend routine antibiotic prophylaxis for EMA. This is because the risk of ascending infection is very low in a non-surgical abortion and at early gestations. In line with guidance from the Chief Medical Officer, this approach also helps to prevent further development of antimicrobial resistance.

25. Pelvic Inflammatory Disease (PID) and subsequent infertility is unlikely following EMA, since ascending infection is not a risk.

26. The NICE guidance does not recommend routine screening for Chlamydia and other sexually transmitted diseases sexually transmitted infections (STIs) for women having EMA, but if STI screening is part of NHS commissioning it can be safely and easily performed by telemedicine: a swab kit is posted to the woman, who then sends this to the relevant laboratory, who then notify the provider. If treatment is required this can be sent by post. Sexual health services are increasingly provided in this way (e.g. by SH24, a well-known provider of telehealthcare).

27. On haemorrhage and subsequent surgical evacuation, the evidence does not support Dr Gardner's position.

28. The first Finnish registry-based study cited by Dr Gardner, at §13 of his Statement, looked at complications following medical abortions to 20 weeks gestation in adolescents compared with older adults. It was not designed to demonstrate gestation-related risks of 'haemorrhage' (which was not clearly defined) and the quoted risks are therefore not relevant to the risks of women undergoing medical abortions to 10 weeks gestation only.

29. The second Finnish registry-based study cited compared immediate complications following surgical versus medical abortion to 9 weeks gestation only, but again did not clearly define 'haemorrhage'. Medical abortion regimens in this study included those using Misoprostol alone, which is known to have a lower success rate and consequent increased risk of prolonged bleeding. The techniques used for surgical abortion inevitably produce less bleeding as the procedure is designed to be more immediately complete. Despite this, the incidence of significant haemorrhage (requiring further surgical evacuation) was only 2.9% in the EMA group.

30. The Swedish study, referred to at §14 of his Statement, categorised either heavy bleeding lasting longer than 12 hours or longstanding bleeding (> 21 days) as a bleeding complication, or haemorrhage. Only 1.9% (72 women) out of 3696 undergoing medical abortion <12 weeks were deemed to have had haemorrhage.

31. Finally, the Australian study, referred to at §15, included a subset of 947 women undergoing EMA to 9 weeks gestation, of whom only 6 (0.6%) experienced a clinically significant complication (haemorrhage, sepsis, treatment failure).

(b) <u>Risks of psychological trauma</u>

32. Dr Gardner sets these risks out at §§17-19 of his Statement. I disagree with this assessment.

33. An extensive systematic review of the association between induced abortion and adverse mental health outcomes in 2011 conducted by the National Clinical Collaborating Centre for Mental Health concluded that when studies with weak

design and quality were excluded: "*rates of mental health problems will be largely unaffected whether she has an abortion or goes on to give birth*."[5]

34. The Sullins study from the Catholic University of America, cited in §18 of his Statement, considered all abortion gestations and cannot be considered authoritative for women undergoing EMA.

35. In any event, as already set out above, telemedicine consultations were common well before the pandemic and so Dr Gardner's concerns are not material to the Decision.

(c) Communication risks

36. Dr Gardner sets out his concerns at §§20-22 of his Statement. I disagree with his assessment.

37. All abortion providers who have experience in the use of teleconsultation and telemedicine already have well developed and effective systems for assessing and managing risks (medical, psychological, safeguarding). Whenever any risks or concerns are identified or considered possible the woman is required to attend for face-to-face consultation.

38. Following the temporary change in approval of place, and in line with RCOG and NICE guidance, providers have instigated a thorough process of informed verbal consent which ensures that all women have access to detailed web-based and written information, which is then discussed with them in detail by the registered medical professional performing the relevant stage of the teleconsultation process. This is clearly documented in electronic case records and signed electronically by the registered medical professional.

39. If there are any identified language understanding concerns, the woman may be offered a 3rd party interpreter as part of the teleconsultation process or be required to attend for a face-to-face consultation.

[5] Academy of Medical Royal Colleges and National Clinical Collaborating Centre for Mental Health: Induced abortion and mental health: a systematic review (2011), p125.

40. Finally, there is growing evidence[6] that, in EMA, it is not necessary to perform a scan to assess the gestation of the pregnancy if the woman is certain of the date of her last menstrual period.

(d) Relaxation of safeguards: clinical

41. Dr Gardner sets out his concerns at §§23-32 of his Statement. I disagree with his assessment.

42. Dr Gardner asserts that the safeguards for use of EMA medication such as access to emergency and follow up facilities have not been considered in granting the temporary approval.

43. Teleconsultation is a longstanding feature of abortion provision for EMA. All women are given information about aftercare, have access to a 24-hour helpline and are given information about the nearest acute gynaecology emergency centre to attend if necessary.

44. Women are informed about the failure rate for EMA as part of the informed consent process, and advised what to look for, including the relevance and importance of prolonged bleeding and/or pain.

45. All women are asked to perform self-follow up within 14-21 days through use of a low sensitivity pregnancy test which will detect residual b-HCG if at clinically significant levels. This has been standard clinical practice for several years in abortion provision and is not associated with adverse clinical outcomes or increased rates of ongoing pregnancy. All women undergoing EMA have access to 24 hr helpline support and advice. 'Remote' follow up following EMA has been found to be both highly acceptable and safe. [7]

46. All women are screened at teleconsultation for a range of pre-existing medical conditions which may mean they are not suited for early medical abortion. This

[6] Upadhyay U & Grossman D. Telemedicine for medication abortion. Contraception (100) 351-353. 2019.
[7] Bracken H. et al. RU OK? The acceptability and feasibility of remote technologies for follow-up after early medical abortion. Contraception 2014 (90) 29-35.

would include conditions such as anaemia or hypocoagulability, history of female genital mutilation and a range of other conditions.

(e) Safeguarding and risk of coercion

47. The Claimant asserts that the new system introduced by the Decision carries with it significant medical and ethical risks, in particular relating to the adequacy of safeguarding assessments. There is a particular concern about vulnerable women being pressured into having an abortion by an abusive partner: SFG, §22. Dr Gardner also deals with this in his Statement, at §33. I disagree with this assessment.

48. Independent Sector Providers, who provide the majority of NHS-commissioned abortion services in England and are approved places for this purpose, have been performing clinical assessment and 'remote' prescribing for EMA for many years: since 2006 in the case of one major provider. Providers are therefore highly experienced in clinical and safeguarding risk assessments by teleconsultation and telehealthcare, which must meet the requirements of commissioners and in which their use has not historically been associated with increased adverse effects. In response to the Decision, providers have enhanced still further their safeguarding screening processes during remote consultation, for example by requiring detailed videoconsultation if concerns are identified during screening, or by requiring face-to-face attendance if any concerns are identified. These practices are in line with the RCOG COVID-19 guidance.

49. As already set out, at §18 above, RCOG published the RCOG COVID-19 Guidance in light of the pandemic and following the Decision. This followed the guidance published alongside the approval in 2018 allowing Misoprostol to be taken at home: NICE guidance (NG140) Abortion Care (September 2019).

50. The RCOG COVID-19 Guidance has a whole section, titled "*Consent and Safeguarding with remote consultations"* (Section 4). For example, at p21, it states:

> "Safeguarding is an essential part of the assessment for abortion care, and providers should follow their processes and assess each case on an individual basis. However there is no automatic need to have to do this in person if adequate assessment is possible via remote consultation,

> although it is recommended that this should be tailored to the individual. 35 The clinician should be confident that the woman is not being coerced and that she is able to discuss any concerns privately."

51. Under the new arrangements, face-to-face consultation is still required should any clinical or safeguarding concerns be identified, or if it is felt that the woman has language, literacy or mental capacity difficulties that would hinder the assimilation of information in order to provide Montgomery-compliant consent. The temporary changes aim to reduce the need for women to travel at a time when this may not be possible, due to local clinic closures and/or self-isolation.

52. All service providers ensure that women have 24 hr access to online and telephone support, including counselling, should this be necessary, including at any time following an abortion procedure.

(f) Longer term risks

53. Dr Gardner raises these concerns at §§34-35 of his Statement. They do not relate to the Decision. The same points could be made, for example, of the EMA where both medicines are taken in a clinical setting.

54. In any event, I disagree that the evidence stands for the proposition he asserts.

55. The Decision makes no difference to the necessity or appropriateness of raising these issues in consultation.

(g) Self-regulation

56. Dr Gardner raises this concern at §36 of his Statement. He asserts that, 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. This is not a concern that relates specifically to the Decision.

57. In any event, I am aware that only 9 are rated as 'inadequate' for safety.

58. Furthermore, the Claimant asserts that taking both Mifepristone and Misoprostol at home is unsafe: SFG, §48(e). I disagree.

59. There is international evidence that 'home abortion' is safe.[8]

60. The safety of 'home abortion' is further assured by the pre-existent experience of abortion providers in England in carefully assessing suitability for 'home abortion' through longstanding professionally developed teleconsultation practices.

61. As to the suggestion that the Decision somehow undermines the regulatory regime, I disagree: SFG, §§58-60. Both NHS and ISP providers remain subject to CQC registration and oversight.

62. Teleconsultation and teleprescribing are not new approaches to abortion provision, having been in use for many years by ISPs.

63. EMA resembles, physiologically, a spontaneous abortion (miscarriage), a common outcome of early pregnancy where the abortion or miscarriage would normally take place within the woman's own home. Induced abortion at home incurs no additional hygiene risks or skill requirements.

(h) Systemic risks

64. Dr Gardner raises this concern at §37 of his Statement. I disagree. There is no increased risk of complications when women take both pills at home for EMA. Moreover, women are already able to complete their abortion at home following the approval in 2018 to take Misoprostol at home and there has been no observed increase in complications. (cite ref 13),

65. In fact, the option for women not to be required to attend a healthcare setting, together with the approval of the home of a registered medical practitioner as a class of place for prescribing the medicines for EMA, reduces the pressure on health services at this difficult time.

66. There has been no relaxation in the requirement for two medical practitioners to certify and specify the grounds which determine a patient's suitability for abortion and there has been no downgrading of assessment as suggested at §37 of Dr

[8] Aiken A et al. 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.

Gardner's Statement. Therefore, it is unlikely that there would be any increase in the risk of medical error.

(i) Other risks

67. Most of the concerns raised by Dr Gardner at §38 of his Statement have already been dealt with above.

68. The Claimant states that the doctor has no control as to when the patient will take the drugs: SFG, §44. This leads to the alleged risks of taking the medicine after 10 weeks, handing the drugs to other women and the sale of these drugs on the black-market. I disagree that these are new concerns which arise as a result of the Decision.

69. These concerns would apply equally to the taking of Misoprostol at home, a policy which has now been in place since January 2019 and has not led to any identified clinical compliance or other concerns. It is also worth saying that the same argument could be made for many prescribed drugs that are taken at home.

70. The outcome of any clinical assessment between clinician and patient ultimately rests on trust. There is no evidence that a teleconsultation, carefully and professionally performed, negatively impacts upon this important relationship in abortion care. The issue of abortion is highly sensitive and deeply personal: women who attend abortion service providers are highly motivated to complete their abortion.

Conclusion

71. Ultimately, Dr Gardner concludes, in §39 of his Statement, that the new arrangements are "*more likely than not to depart from the essential tenets of duty of care through proper clinical assessment, thereby raising the risk of serious injury and harm being done to women self-administering Mifepristone and Misoprostol at home*." As will be clear from my evidence above, I fundamentally disagree. In my experience, the measures which have been introduced are necessary to secure the safety of women and practitioners during the pandemic, and to ensure that

there is a continued ability for women to access abortion provision. The adverse consequences of them not being able to do so would be significant, as I have explained. In developing the new arrangements, important steps have been taken to ensure safety, as I have explained above.

I believe that the facts stated in this witness statement are true.

SIGNED:

DATED: 12 May 2020

Direct telephone: +44 (0)207 772 6345
Email: president@rcog.org.uk

Royal College of Obstetricians & Gynaecologists

Dr Edward Morris
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Department of Health and Social Care
39 Victoria Street
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SW1H 0EU

12 May 2020

RE: HOME USE OF MIFEPRISTONE

On behalf of the Royal College of Obstetricians and Gynaecologists, I would like to endorse the statement made by Dr Imogen Stephens FRCOG.

With best wishes,

Dr Edward Morris, President
Royal College of Obstetricians and Gynaecologists

From: [redacted]
Sent: 12 March 2020 16:00
To: Duncan, Andrea [redacted]@dhsc.gov.uk>; [redacted]@bpas.org>; [redacted]@mariestopes.org.uk>; [redacted]@nupas.co.uk>; [redacted]@bpas.org>; [redacted] (MANCHESTER UNIVERSITY NHS FOUNDATION TRUST) [redacted]@nhs.net>; [redacted]@exeter.ac.uk>; [redacted]@RCOG.ORG.UK>; [redacted]@nhs.net; [redacted]@phe.gov.uk>; [redacted]@phe.gov.uk>; [redacted]@phe.gov.uk>; [redacted]@gov.scot; [redacted]@gov.wales; [redacted]@nupas.co.uk; [redacted]@nupas.co.uk; [redacted]@nupas.co.uk; [redacted]@phe.gov.uk>
Cc: [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@governmentlegal.gov.uk>; [redacted]@governmentlegal.gov.uk>
Subject: RE: COVID 19 AND ACCESS TO ABORTION

Hi all,

Thanks for your time earlier this week to discuss continuation of access to abortion services in the context of COVID-19.

I've provided a readout of the five key issues raised at the meeting below, supported by the specific points raised. These issues have now been fed into the wider work within DHSC on planning for COVID-19 and will be subject to wider decisions on management of COVID-19 at a national level. We will of course keep you updated with any progress and do keep us updated if new issues emerge at your side.

Best wishes,
[redacted]

***

1. *Abortion should be designated as an essential service if there is going to be a mandate to stop non-essential services.*

2. *Ensuring access to early medical abortion in cases where women and/or doctors are self-isolating (either with a COVID-19 diagnosis or not)*
    - Support for BPAS proposal for home use for both abortion pills for early medical abortion up to 10 weeks (9 + 6) gestation. This is supported by clinical evidence and the infrastructure is already in place for this to happen. Need to ensure safeguarding of patients who are vulnerable to ensure only appropriate patients are assessed via telemedicine. The detail of BPAS' proposal would need to be tailored to work for other providers.
    - Support for extending home use provisions so that this can occur after 10 weeks gestation.
    - It was raised that if women in self-isolation cannot access services, it is likely that they may attempt to access pills online.

3. *How to ensure access to later abortions in cases where women are self-isolating (either with a COVID-19 diagnosis or not)*

- Consensus from attendees that women seeking later-term abortions would need to be treated in isolation in NHS services. BPAS are working to establish how many NHS services that they refer into have isolation facilities for treatment and will send through these figures once they have them. Need for clear comms about protocol for women in these situations.
- Consensus from attendees that providers do not want to state to women that they should wait two weeks in isolation before accessing services. This would be particularly detrimental for women who are 22 weeks pregnant and would therefore be pushed over the gestational limit.

4. *Where abortion pills can be prescribed by Doctors*
    - Support for expanding this to Doctors homes (to cover a scenario where doctors are self-isolating but able to work) and call centres.
    - Support for expanding to nurses and midwives.

5. *How to ensure continuity of drug supply*
    - Support for exploring with MHRA whether restrictions could be lifted on where packing down of pills can take place, as at the moment this is restricted to one NHS Trust.
    - Support for escalation of approval of medabon by MHRA.

[redacted]
Abortion and Sexual Health

From: [redacted]@RCOG.ORG.UK>
Sent: 17 March 2020 10:46
To: [redacted]@dhsc.gov.uk>
Subject:

Hi [redacted]

RCOG is currently putting together some guidance to help with managing abortion care during COVID-19.

Sorry to chase, but following the announcement yesterday, I've had lots of providers telling me that they are inundated with queries around accessing services.

Not sure if you have heard back from the national response team yet?

If we can't deliver mifepristone from home, the sector is likely to go into standstill, and women will be presenting at NHS premises requiring care.

Best wishes

[redacted]

[redacted]
Political Adviser to the President

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Switchboard: +44 20 7772 6200

From: [redacted]@bpas.org>
Sent: 17 March 2020 11:55
To: [redacted]@dhsc.gov.uk>; Duncan, Andrea [redacted]@dhsc.gov.uk>
Subject: Urgent: EMA decisions

Dear both,

Sorry to press, but please would you let me know when a decision will be taken about home use of miso. We need to move to this immediately for two reasons. Firstly, we have a growing number of staff required to self isolated home - 35 as of today. Secondly, we know that NHS services are under extreme pressure and we anticipate demand increasing. (Not your geographical area I know, but we know that the NHS hospital in Cardiff has requested use of our unit because they have lost the theatre time for their abortion list)

So - the request is for a decision asap - and immediate advice on when that will be.

Thanks.

Hope you and yours are fit and well,

[redacted]

CLEARANCE CHECKLIST

Inclusion of this checklist is mandatory. Please complete the whole list and private office will remove before putting submission in the box. A submission without it will be sent back.

***Note**: Contact names provided must have seen and approved the submission.*

Finance:
Does this involve any spending or affect existing budgets?
☐ If yes, named official:
Click here to enter text.
☑ No

Legal:
[redacted]

Communications:
Could this generate media coverage, or a response from the health sector?
☐ If yes, named official:
Click here to enter text.
☐ No

Analysis and data fact-checking:
Does this include complex data, statistics or analysis?
☐ If yes, named official:
Click here to enter text.
☐ No

Devolved Administrations:
Will this affect Scotland, Wales or Northern Ireland?
☐ If yes, named official:
Click here to enter text.
☐ No

Fraud:
Have you considered fraud risks?
☐ If yes, named official:
Click here to enter text.
☐ No

Commercial:
Does this include commercial or contractual implications?
☐ If yes, named official:
Click here to enter text.
☐ No

Strategy Unit:
Does this relate to cross-cutting or longer-term implications for wider DH strategy?
☐ If yes, named official:
Click here to enter text.
☐ No

Implementation Unit:
Does this relate to one of the Secretary of State priorities?
☐ If yes, named official:
Click here to enter text.
☐ No

Legislation:
Does this include options that may require secondary legislation?
☐ If yes, do you have a prioritisation reference number? *(contact Parly or SOPL if unsure):*
Click here to enter text.
☐ No

Duties, Tests and Appraisals:
The following tests apply and have been considered.

☐ Secretary of State Statutory Duties, including on health inequalities
☐ Public Sector Equality Duty
☐ Family test
☐ Other(s) (please specify)
Click here to enter text.

To: MS(C), SofS

From: [redacted]
Clearance: Andrea Duncan
Date: 18/03/2020
Copy: [redacted]
Private Office Submissions Copy List

COVID-19: Access to early medical abortion services

Issue	This submission seeks approval of two measures to reduce transmission of COVID-19 and ensure continued access to early medical abortion services in the context of increasing self-isolation measures and NHS capacity.
Timing	Urgent (two working days) Urgent approval will enable the below measures to come into force as soon as possible and prevent delay for women accessing services.
Recommendation	To limit transmission of COVID-19 and ensure that women and girls are able to access early medical abortion services, we recommend that you use your powers under the Abortion Act 1967 to temporarily approve: • women's homes as a class of place where both abortion pills can be taken for early medical abortion. • the home of a registered medical practitioner (a doctor) as a class of place where both abortion pills can be prescribed for the treatment of early medical abortion.

Discussion

1. This submission recommends that you approve two non-legislative temporary measures to limit the transmission of COVID-19 and ensure that women and girls are able to access early medical abortion services.

2. In England and Wales in 2018 the total number of abortions was 200,608 – just under 4,000 per week. Four out of every five abortions (80%) were carried out under 10 weeks gestation.

3. The Abortion Act 1967 permits abortions to be performed under certain grounds by doctors in an NHS hospital or place approved by the SofS. In England, around two-thirds of NHS-funded abortions are performed at approved independent sector clinics (clinics are approved by DHSC Ministers).

4. Since January 2019 women living in England have been able to take the second pill (misoprostol) for early medical abortion up to 10 weeks gestation in their own home. Women attend a clinic where they take the first pill (mifepristone), and then have the option of either returning to the clinic to take the second pill, or taking the second pill at home. Women living in Scotland and Wales are also able to take the second pill for early medical abortion at home, although no gestational

limit is set and clinicians instead rely on NICE guidance, which recommends home use for early medical abortion up to 10 weeks gestation.

5. Access to abortion services is an urgent matter: the procedure's risk increases at later gestations; the Abortion Act 1967 sets legal gestational limits for accessing services, so if women present to services near to the gestational limit they may only have a short time to access services; and any disruption to normal business (i.e. women not being able to access services for several weeks due to self-isolation) will have a major impact on the future system's capacity, and it is also inevitable that vulnerable women will be forced to continue with unwanted pregnancies.

Enabling women and girls to take both abortion pills at home

6. As above, since January 2019 women living in England have been able to take the second pill for early medical abortion up to 10 weeks gestation in their own home. However, all women must attend a clinic or hospital in person at least once, to take the first pill.

7. To limit transmission of COVID-19 and enable women to access abortion services if they are self-isolating, **our recommendation is that you use your powers under the Abortion Act 1967 to temporarily approve women's homes (their permanent address or place where they usually reside) as a class of place where both abortion pills can be taken for early medical abortion**.

8. We recommend not specifying a gestational limit of 10 weeks in the approval, and recommend instead directing providers and clinicians to NICE guidance, which recommends home use for up to 10 weeks gestation. This will provide clinicians with the ability to apply their clinical judgement and discretion in the context of COVID-19.

9. This approval would enable a woman to be assessed via telemedicine, following which both abortion pills would be prescribed, dispensed by a pharmacist and posted to the woman. The consultation would be equivalent to the current in-person consultations. The woman would then take both abortion pills at home, removing the need to attend a clinic or hospital in person and therefore reducing transmission of COVID-19.

10. This proposal has been tested with abortion providers, the Royal College of Obstetricians and Gynaecologists (RCOG) and PHE and has received strong consensus support. Home use for both abortion pills is supported by clinical evidence, and telemedicine is supported by NICE abortion guidance. Providers have stated that there is the infrastructure in the independent sector and NHS to commence this new practice immediately. Given 80% of abortions in England and Wales in 2018 were carried out under 10 weeks gestation, approval of this approach would ensure continuity of access for the vast majority of women.

11. One of the main abortion providers in England, the British Pregnancy Advisory Service, has written to SofS on this subject, requesting that women should be able to take both abortion pills for early medical abortion in their homes and providing a draft guideline for delivering early medical abortion by telemedicine. These documents are attached at **Annex C and D**.

12. To note that this approval would also enable a woman who is not self-isolating to attend a clinic or hospital and subsequently take both abortion pills home. This has been deemed appropriate given the supporting clinical evidence and avoids

the need for a woman to attend clinic or hospital even if they are asymptomatic, given increasing social distancing advice.

Enabling doctors to prescribe medication for early medical abortions at home

13. The Abortion Act 1967 permits abortions to be performed in NHS hospitals or a place approved by the SofS, and the courts have ruled that this includes the whole course of treatment (including prescribing). The Act also sets out that abortions can only be carried out by doctors. This means that a doctor has to be located within an approved clinic or hospital in order to prescribe medication.

14. As a further measure to limit transmission of COVID-19 and enable women to access abortion services, we **recommend that you use your powers under the Abortion Act 1967 to temporarily approve the home of a registered medical practitioner (a doctor) as a class of place where both abortion pills (Mifepristone and Misoprostol) can be prescribed for the treatment of early medical abortion.** Given the increasing self-isolation measures, this would enable doctors who are self-isolating but well enough to work to prescribe medication from their home. Their home would be approved as a class of place only for prescribing the medication.

15. Approval of this measure alongside approval of home use for both abortion pills (see paras 6-12) would enable medication to be prescribed by the doctor in their home in the following circumstances:

    a. A woman has attended a consultation in a clinic or hospital;

    b. A woman has had a consultation with a clinic or hospital via video link, telephone or other electronic means;

    c. A woman has had a consultation with a doctor (who is self-isolating in their home) via video link, telephone or other electronic means.

16. Increasing flexibility to enable doctors to prescribe from their homes has been tested with abortion providers, RCOG and PHE and has received strong consensus support. As above, the use of telemedicine is supported by NICE abortion guidance.

Timing and next steps

17. **Our recommendation is immediate approval of both of the above measures on a temporary basis (option 1).** This would enable women to take both abortion pills at home and for doctors to prescribe medication at home; continuing access to early medical abortion whilst reducing risk of COVID-19 transmission. If you agree, the relevant approval for agreement is at **Annex A**.

18. An alternative approach (option 2) would be to first enable women to take both abortion pills at home, and then enable doctors prescribe medication at home later down the line. This is not recommended. Given the increasing self-isolation measures, our view is that it is necessary to implement both measures immediately, as to do otherwise would be to delay the inevitable. However, if you were minded to approve this two-staged approach, you would need to agree to the approvals at both **Annex A and Annex B**. The approval at Annex B would be communicated to the sector first, followed by Annex A at a later date.

19. Following your agreement an urgent letter communicating this change will be sent from a senior DHSC official to providers, following which the letter will be published on gov.uk. These are temporary measures in the context of COVID-19

so we will provide advice in due course as to when these measures should be switched off. We are however, likely to be pressed to maintain similar access in the future.

20. RCOG are developing urgent guidance on managing access to abortion in the context of COVID-19 and we are working with them closely on this to ensure alignment of messaging.

Risks

21. Key risks of the above temporary measures are set out below:

    a. These measures will be viewed as controversial by pro-life organisations and MPs as they are likely to be seen as a loosening of regulation around abortion provision. However, our view is that these measures are proportionate in the COVID-19 context and are in line with clinical evidence. We will also be clear that these are temporary measures that will be switched off in due course.

    b. These measures will be supported by pro-choice organisations, including abortion providers, and it is likely that these organisations will put pressure on DHSC to extend these measures after COVID-19, particularly as they are supported by clinical evidence. We will mitigate this risk by being clear that these are temporary measures to manage transmission of COVID-19 and ensure access to abortion services during this time. Any proposal to implement this practice as a permanent measure would need to follow a proper process.

    c. There is a need to ensure that consultations on the phone/via video appropriately take into account the need to safeguard vulnerable women. This will be for individual providers to take forward as per their usual protocols and training.

Devolved Administrations

22. The approvals you are being asked to agree will only apply to England. We have engaged with Scottish and Welsh officials and understand that they are likely to advise their Ministers to agree to equivalent approvals in Scotland and Wales, to prevent transmission of COVID-19 and ensure access to services.

23. The situation for Northern Ireland (NI) is more complex. We will return to you shortly with further advice on this. Regulations setting out a new legal framework for abortion in NI are due to be laid early next week. However, as the Department of Health in NI do not anticipate that abortion services will be available on the ground in NI for some time, you have agreed to continue the DHSC-managed scheme enabling women to travel to, and access abortion services in, England for a year. Given the increasing self-isolation measures and the very real possibility of reduced travel between NI and England, we are exploring urgently with NI officials how to ensure access to services for women resident in NI in the context of COVID-19.

Access to later term and surgical abortions

24. Whilst the measures in this submission will enable the vast majority of women to continue to access early medical abortions, in 2018 29% of abortions in England and Wales were surgical procedures.

25. Stakeholders are raising concerns as to how we will ensure women will continue to access abortion surgical and later term abortions, and we are urgently progressing discussions with RCOG, PHE and the central DHSC COVID-19 team. We will provide further advice to you shortly.

Legal [redacted]

26. [redacted]

27. [redacted]

28. [redacted]

Communications [redacted]

29. We anticipate that relaxing the rules around early abortion will generate widespread media interest, given the increased scrutiny on government policy around limiting the spread of coronavirus.

30. When the NHS announced the cancellations of non-urgent surgery on the 17 March due to the ongoing COVID19 situation, the coverage was reported straight, underlining that there was a need for flexibility in light of the current pandemic.

31. Abortion often gets covered by the media, for example on the 4th March ONS stats revealed that a record proportion of pregnancies were ending in abortion, which led to calls by Marie Stopes UK for increased access to contraception. The stats, reported by The Times and Daily Mail, highlighted regional disparities as women in more deprived areas of the country were twice as likely to have an abortion. A survey on the 25 February by Marie Stopes and YouGov revealed that nine in ten adults in the UK identify as pro-choice.

32. We will handle media queries reactively making it clear that patient safety is the priority and that people feel supported during this unprecedented time. We will also prepare a robust Q&A.

Conclusion

33. To limit transmission of COVID-19 and ensure that women and girls are able to access early medical abortion services, we recommend that you use your powers under the Abortion Act 1967 to temporarily approve:

a. women's homes as a class of place where both abortion pills can be taken for early medical abortion.

b. the home of a registered medical practitioner (a doctor) as a class of place where both abortion pills can be prescribed for the treatment of early medical abortion.

[redacted]

HEALTHY BEHAVIOURS TEAM

The Abortion Act 1967 - Approval of a Class of Places

This approval supersedes the approval of xxxx 2020

The Secretary of State makes the following approval in exercise of the powers conferred by section 1(3) and (3A) [1]of the Abortion Act 1967[2]:

Interpretation

1. In this approval –

"home" means, in the case of a pregnant woman, the place in England where a pregnant woman has her permanent address or usually resides or, in the case of a registered medical practitioner, the place in England where a registered medical practitioner has their permanent address or usually resides;

"approved place" means a hospital in England, as authorised under section 1(3) of the Abortion Act 1967 or a place in England approved under that section.

Approval of class of place

2. The home of a registered medical practitioner is approved as a class of place for treatment for the termination of pregnancy for the purposes only of prescribing the medicines known as Mifepristone and Misoprostol to be used in treatment carried out in the manner specified in paragraph 4.

3. The home of a pregnant woman who is undergoing treatment for the purposes of termination of her pregnancy is approved as a class of place where the treatment for termination of pregnancy may be carried out where that treatment is carried out in the manner specified in paragraph 4.

4. The treatment must be carried out in the following manner-

a) the pregnant woman has-

i) attended an approved place;

ii) had a consultation with an approved place via video link, telephone conference or other electronic means, or

iii) had a consultation with a registered medical practitioner via video link, telephone conference or other electronic means; and

(b) she is prescribed Mifepristone and Misoprostol to be taken for the purposes of the termination of her pregnancy.

[1] Section 1(3A) was inserted by section 37(3) of the Human Fertilisation and Embryology Act 1990 (c. 37).
[2] 1967 c. 87

The Abortion Act 1967 - Approval of a Class of Places

This approval supersedes the approval of 27 December 2018.

The Secretary of State makes the following approval in exercise of the powers conferred by section 1(3) and (3A) [1]of the Abortion Act 1967[2]:

Interpretation

1. In this approval –

"home" means the place in England where a pregnant woman has her permanent address or usually resides;

"approved place" means a hospital in England, as authorised under section 1(3) of the Abortion Act 1967 or a place in England approved under that section.

Approval of class of place

2. The home of a pregnant woman who is undergoing treatment for the purposes of termination of her pregnancy is approved as a class of place where the treatment for termination of pregnancy may be carried out where that treatment is carried out in the manner specified in paragraph 3.

3. The treatment must be carried out in the following manner-

(a) the pregnant woman has-

i) attended an approved place, or

ii) had a consultation with an approved place via video link, telephone conference or other electronic means; and

(b) she is prescribed Mifepristone and Misoprostol to be taken for the purposes of termination of her pregnancy.

[1] Section 1(3A) was inserted by section 37(3) of the Human Fertilisation and Embryology Act 1990 (c. 37).
[2] 1967 c. 87

Rt Hon Matt Hancock MP
Secretary of State
Department of Health and Social Care
39 Victoria Street London
SW1H 0EU

2nd March 2020

Dear Rt Hon Matt Hancock MP,

As you will know BPAS is now responsible for almost 100,000 of abortions under commissioning arrangements with the NHS, and we are particularly concerned about our continuing ability to continue to provide this time-sensitive care during the current situation with COVID19.

One simple measure, which would allow us to treat women safely in the early weeks of pregnancy without requiring them to attend a clinic would be for you to use your power under conferred by section 1(3) and (3A) of the Abortion Act 1967 (as amended 1990) to enable the use of both sets of medications required for early medical abortion at home.

This would remove the requirement for women up to 9 weeks and 6 days of pregnancy, who have already been assessed as suitable for treatment in a tele-consultation, to attend a treatment unit for the sole purpose of ingesting the mifepristone tablets. Clearly, the geographical location in which she swallows tablets makes no clinical difference, but it is currently a requirement of the Abortion Act 1967. Fortunately, it is one that you have the power to amend at any time. There is widespread clinical support for this measure: recent RCOG and NICE guidance see telemedical services for early abortion care as sensible and safe.

Early medical abortion involves the use of two medications: **mifepristone** which blocks the pregnancy hormones and **misoprostol**, which causes the expulsion of the products of conception. You have already used the powers in section 1 (3) and (3A) to allow the use of the misoprostol at home, which has significantly improved services and demonstrated that women are capable of following instructions for home-use.

BPAS has been preparing to ask for the home-use of both drugs to be considered in any case, in the light of the development of remote counselling provision, but the current circumstances make the need for action urgent.

The current restrictions will prevent the treatment of women subject to quarantine requirements, putting their health at further risk, and by insisting that the large number of women attend clinics as they do at present causes them to be at increased risk at a time when they are experiencing the vulnerability of pregnancy.

I have attached a draft Guideline under which we would intend to work.

I would be pleased to meet your Minister, and or officials with the BPAS Medical Director to discuss how this urgent risk management measure can be progressed as quickly as possible.

Yours faithfully,

[redacted]
British Pregnancy Advisory Service (BPAS)

Delivering Early Medical Abortion by Telemedicine

Date of Current Issue: February 2020

Related Policies & Procedures

Consent to Examination and Treatment
Contraception Counselling and related method-specific contraception guidelines
Ectopic Pregnancy
Generic Guideline for All Abortions
Clinical Incident Policy and Procedure
Management of Suspected Retained Products of Conception
Record Keeping
Suitability for Treatment at BPAS
Telephone Consultation Procedures
Women's Wishes Regarding the Fetus

Introduction

1. This guideline would enable women to access safe abortion care at home, in accordance with recommendations from NICE and the Royal College of Obstetricians and Gynaecologists

2. It describes an early medical abortion (EMA) service comprised of a telephone and online assessment and posting of mifepristone and misoprostol for use at home to women at risk

3. The service would be available initially up to 56 days of gestation or less when a woman meets screening criteria confirming that an ultrasound is not needed or is available before treatment

This Guideline Applies To

Clients with pregnancies at 56 days of gestation or less who want an EMA

Procedures

Booking

1. Clients call 03457 30 40 30 to book a consultation
2. If screening questions determine they are suitable they will be referred to an initial telephone consultation.

Consultation and Treatment

1. Nurse/midwife, with support of a Client Care Coordinator if needed, to follow care pathway in Appendix 1
2. It is imperative that if client is considering EMA, staff determine medical eligibility as per Appendix 2 before proceeding
3. If client desires and is eligible for EMA, follow all steps in the Screening Algorithm (Appendix 3) to determine eligibility

a. Eligibility depends on
    i. Meeting screening criteria for treatment without an ultrasound (2) **or** the client providing an ultrasound report confirming an intra-uterine pregnancy (IUP) with a gestational age of 56 days or less on the day of consultation.
    ii. Able to undergo a consultation without the need for a translation service
    iii. Ability to undertake part of the consultation by video call using WhatsApp

4. For clients proceeding follow the steps in the Treatment Algorithm (Appendix 4)
    a. Nurse/midwife to document inform consent
        i. Email client a PDF of the consent form and a link to consent information on BPAS website
        ii. Refer to outcomes data in Appendix 5
        iii. Obtain verbal consent for Pills-by-Post
        iv. Nurse/midwife to sign consent form
        v. Email signed form to the client
        vi. Confirm receipt with client and document confirmation in case record
    b. Text WhatsApp video call link
    c. Initiate WhatsApp video call
        i. If there is any concern that the client is under 18 ask for identification with proof of age
        ii. Client may email this or show ID on screen
        iii. If under 18, revert to care pathway management for under 18s
    d. Provide information on process and self-management in Appendix 6

5. By 3pm each day, scan and upload case record and consent to BIS and to shared file
    a. Records should be identified by BIS number
    b. Shared file should have records in sub-folders organised by date
    c. If there are records completed after 3pm, they should go into the folder for the next day
6. By 5pm each day, 2 doctors review records in the dated folder in shared file
    a. If treatment approved
        i. HSA forms signed by both doctors
        ii. Doctor prescribes Medabon and codeine (if no contraindications) using standard prescription form (Appendix 7)
        ii. Doctor saves prescription in shared file and emails a copy to pharmacy.

    b. If treatment is not approved
        i. Doctor will complete a Treatment Declined form (Appendix 8) and save it in the shared drive with requested action
7. When pharmacy receives prescription, it will
    a. Send pack and instructions by Next Day Delivery to client
    b. Email a dispatch notification to an administrative assistant at BPAS Remote Services for each client
8. Client takes mifepristone 200 mg orally when pills received and before gestational age reaches 63 days
9. 1-2 days later client uses 800 mcg misoprostol buccally or vaginally
10. An administrative assistant at BPAS Telephone Services will check the shared files each day for prescriptions and Treatment Declined forms

a. Treatment Declined forms will be actioned as per Doctor's instruction b. Prescriptions to be uploaded to client's BIS record

11. After a dispatch notice for the medications has been received, a paper set of notes is created by an administrative assistant at BPAS Telephone Services and sent for storage and the documents held in the shared file are deleted.

Aftercare

1. Follow algorithm in Appendix 9
2. If no or minimal bleeding in the 24 hours after misoprostol use
    a. Treated without a scan
        i. If client reports unilateral lower abdominal pain or other symptoms suggestive of ectopic pregnancy refer to EPAU or A and E
        ii. In the absence of symptoms: provide reassurance and a reminder of when to seek advice or emergency care (i.e. ectopic symptoms)
    b. Treated with a scan
        i. Advise client that bleeding may start in the next few days and to undertake the self-assessment as planned 2 weeks after mifepristone
3. If bleeding and cramping proceeds as expected, client to perform the following self-assessments 2 weeks after mifepristone administration
    a. Low sensitivity urine pregnancy test (LSPT) (Quadratec Check4®-hCG (hl) 1000 mIU/ml), **and** symptom checklist
    b. Treatment is completed if LSPT/self-assessment negative
    c. Client to contact BPAS if
        i. If LSPT is positive, invalid, or they cannot interpret it;
        ii. **or** LSPT was negative, and they had ***any*** of the following
            1. Fewer than 4 days of bleeding
            2. Persistent symptoms of pregnancy (e.g., nausea, breast tenderness, increased abdominal girth)
            3. No menstrual period by 4 weeks after treatment

Clients who Change Their Minds after Mifepristone and/or Misoprostol

1. Clients who are considering continuing their pregnancy after mifepristone and misoprostol must have it explained to them that mifepristone is not known to increase the risk of teratogenesis in humans, but that fetal malformations have been reported after first trimester use of misoprostol
2. Document this conversation in the case record
3. If a client is uncertain about what to do or decides to continue the pregnancy after counselling, provide the standard information sheet in Appendix 11

4. A client who opts to continue the pregnancy is to be advised to inform her antenatal care provider of exposure
5. Information can be given to the client and/or her care provider on the risks of exposure. Articles on this topic are available on the BPAS intranet in the "Advice for GPs" folder (bpas Intranet>Libraries>Policies, Procedures and Guidelines>Operational and Clinical>Advice for GPs)

Adverse Drug Reactions

Suspected reactions should be reported using the Medicines and Healthcare products Regulatory Agency (MHRA)/Committee on Safety of Medicines yellow card system. Online reporting can be performed at http://www.mhra.gov.uk.

Incident Reporting

Any staff identifying a complication at any point in the client pathway must complete a Datix entry on the day the incident is identified. If diagnosis and treatment of a complication occurs at different units, the treating team should ensure that the incident has been reported. If in any doubt, report. Duplicate submissions will be managed at Head Office.

References

1. Aiken ARA, Gomperts R, Trussell J. Experiences and characteristics of women seeking and completing at-home medical termination of pregnancy through online telemedicine in Ireland and Northern Ireland: a population-based analysis. BJOG An Int J Obstet Gynaecol. 2017 Jul 1;124(8):1208–15.
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3. Sääv I, Fiala C, Hämäläinen JM, Heikinheimo O, Gemzell-Danielsson K. Medical abortion in lactating women - Low levels of mifepristone in breast milk. Acta Obstet Gynecol Scand. 2010;89(5):618–22.
4. Misoprostol [Internet]. Drugs and Lactation Database (LactMed). 2006 [cited 2019 Dec 10]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/30000496

Appendix 1

Care Pathway: EMA by telemedicne

Appendix 2

Medical Eligibility for Early Medical Abortion

1. Contraindications
    a. Chronic adrenal failure
    b. Severe asthma uncontrolled by therapy
    c. Porphyria
    d. Known adverse drug reaction to mifepristone or prostaglandins
    e. Bleeding disorder or current anticoagulants (e.g., warfarin)
    f. Suspected ectopic pregnancy/absence of a gestational sac on ultrasound
    g. Intrauterine contraception in place (remove before taking mifepristone)
2. Cautions
    a. Kidney disease
    b. Liver disease
    c. Malnutrition
3. Considerations
    a. BMI >35 kg/m^2
        i. A high BMI is not a contraindication to EMA
        ii. Consideration of BMI is important because approximately 5% of clients will need surgical uterine evacuation due to a complication of treatment such as an incomplete abortion or continuing pregnancy
        iii. Be aware of the BMI limits for conscious sedation and general anaesthesia (as appropriate) or if there are any locally imposed BMI limits for aspiration under local anaesthesia
        iv. Tell clients if a hospital referral will be required for a surgical evacuation
4. Refer to the Suitability for Treatment at BPAS guideline or obtain advice from a doctor on suitability is uncertain

Appendix 3

Screening Algorithm: EMA by telemedicine

Appendix 4

Treatment Algorithm: EMA by telemedicine

Appendix 5

Early Medical Abortion Outcomes by Gestational Age

Counselling point	
Medication interval	1-2 days
Misoprostol route	Vaginal or buccal
Complete abortion without surgical intervention and without continuing pregnancy	97 in 100
Continuing pregnancy	1 in 100
Uterine aspiration (any reason)	3 in 100
Uterine aspiration (incomplete abortion or retained non-viable sac)	2 in 100
Serious complications (transfusion, IV antibiotics, hospitalisation)	2 in 1000
Nausea	29 in 100
Vomiting	9 in 100
Diarrhoea	5 in 100
Warmth/chills	15 in 100
Headache	18 in 100
Dizziness	9 in 100
Outcome assessment	Self-assessment + pregnancy test

Advice for Clients Receiving Pi

1. Tell client they will receive a package by Next Day Delivery directly from the pharmacy
2. Tell client the package contents
    a. Medabon: a combipack with 1 tablet of mifepristone (200 mg) and 4 tablets of misoprostol (800 mcg)
    b. Instructions for use of Medabon and self-assessment
    c. 14 tablets of 30mg plain codeine (if no contraindications)
    d. A low-sensitivity pregnancy test
3. Instruct client how and when to take the mifepristone
    a. The single mifepristone tablet is taken by mouth with water
    b. Client may take the mifepristone table at a time and place of their choosing on or before the date when the gestation of the pregnancy reaches 63 days (9 weeks and 0 days)
    c. Provide client with the date gestation will reach 63 days
4. Instruct the client how and when to use the misoprostol
    a. Use 4 misoprostol tablets 1-2 days after mifepristone
    b. Misoprostol may be taken at a place of their choosing
    c. Tell client how to administer the misoprostol
        i. Vaginal: Insert 4 tablets as high as possible in the vagina; the exact location is not important only that they do not fall out, or
        ii. Buccal: Place 4 tablets in the mouth between the upper cheek and gum (2 on each side) and allow the tablets dissolve for 30 minutes (any undissolved tablets should then be swallowed with water)
5. Discuss expectations of treatment and management of side effects
    a. Timing, amount and quality of bleeding
        i. Bleeding may occur after mifepristone but is usually light
        ii. Approximately 5% of clients abort with mifepristone alone when there is an interval of 24 hours or more between mifepristone and misoprostol
        iii. The chance of bleeding between mifepristone and misoprostol increases with the duration of the interval between these medications
        iv. Misoprostol should still be used even if client has bleeding during interval between medicines
        v. Most bleeding occurs after administration of misoprostol and usually begins within 2-4 hours; however, it may occur sooner
        vi. Bleeding is typically heavier than menses and is greater as gestational age increases
        vii. It is likely that the client will pass clots, normally smaller than a lemon
        viii. Clients usually then experience bleeding like a menstrual period for 7-14 days, but spotting may continue to the next menstrual period
        ix. Some clients may experience an episode of heavy bleeding 3-5 weeks after medication administration and/or have a heavier than normal period with the next cycle.
        x. Advise client to obtain a supply of sanitary pads in order to be able to monitor blood loss in the first 24-48 hours after using misoprostol
    b. Pain and pain management
        i. Pain is typically described as cramping

ii. Pain typically begins 1-2 hours after using misoprostol
iii. Pain is most severe in the 2-4 hour period during expulsion, after which it usually subsides
iv. The client may use over-the-counter ibuprofen for mild-moderate pain; refer to client information for doses and intervals
v. The client may use plain codeine (30mg) for moderate-severe pain if no contraindications; refer to client information for doses and intervals

c. Side effects
   i. Side effects of mifepristone are uncommon, but some bleeding or cramping can occur between mifepristone and misoprostol
   ii. Most side effects occur after misoprostol
   iii. Side effects include nausea, vomiting, diarrhoea, feeling dizzy, headaches, fever and chills
   iv. Tell client that the buccal route of misoprostol
      1. Is associated with a higher risk of nausea, vomiting, and diarrhoea than vaginal administration, and
      2. May taste unpleasant and have a "chalky texture
   v. Advise on use of paracetamol, over-the-counter anti-diarrhoeals and anti-emetics as needed for side effects
   vi. Side effects should be transient. If they continue 24 hours after misoprostol use, advice should be sought from BPAS

d. What they may see at the time of expulsion
   i. Up to 6 weeks of gestation, an embryo is ≤5mm long (about the size of a lentil)
   ii. At 7 weeks, it is about the size of a blueberry (1 cm)
   iii. At 8 weeks, it is about the size of a raspberry (1.6 cm)
   iv. In most cases the embryo/fetus cannot be seen without magnification
   v. Clients may see other tissue at the time of the abortion, including the gestational sac, which is white and fluffy in appearance, and decidua, which looks like brown-red tissue

e. How to dispose of the tissue at home; see Women's Wishes Policy and Procedure

6. Tell client how and when to perform self-assessment of outcome
   a. Tell client that bleeding alone is not enough to confirm expulsion
   b. Tell client the low sensitivity urine pregnancy test (Quadratec Check4®-hCG (hl) 1000 mIU/ml) and complete the symptom checklist 2 weeks after mifepristone administration
   c. Tell client that they are responsible for contacting BPAS if
      i. Their pregnancy test is positive, invalid, or they cannot interpret it; **or**
      ii. Their pregnancy test was negative, and they had any of the following
         1. Fewer than 4 days of bleeding
         2. Persistent symptoms of pregnancy (e.g., nausea, breast tenderness, increased abdominal girth)
         3. No menstrual period by 4 weeks after treatment
      iii. Tell client that in case of an ongoing pregnancy, misoprostol may have teratogenic effects
7. Tell client that they will receive a post-treatment evaluation by email 2 weeks after treatment
   a. The survey is to be returned after they have confirmed the abortion is compete which may be
      i. Following a negative self-assessment
      ii. Following another confirmation of completion if self-assessment

was not negative
   b. If BPAS has not received an evaluation response, it will be resent at 4 and 6 weeks post-treatment
8. Discuss access to advice and emergency care
   a. Tell clients they need to have access to a telephone and transportation in order to call for medical help and get to a medical facility equipped to provide emergency treatment of complications if they occur
   b. Provide details of Post Treatment Support Line
9. Tell clients about what symptoms that warrant contacting the Post Treatment Support Line
   a. Soaking 2 or more sanitary pads per hour for 2 consecutive hours
   b. Sustained fever or onset of fever (≥ 38º C) in the days after misoprostol
   c. Abdominal pain or discomfort, or "feeling sick" including weakness, nausea, vomiting, or diarrhoea more than 24 hours after taking misoprostol
   d. Abdominal pain that is not controlled with oral pain medications in the recommended dosages and intervals
   e. Foul smelling vaginal discharge
   f. No bleeding 24 hours after using misoprostol
10. Provide additional advice as specific to client's circumstances
   a. Breastfeeding
      i. Tell clients that both mifepristone and misoprostol enter the breastmilk, but the amounts are small and would not be expected to cause any adverse effects in breastfed infants (3) (4)
      ii. Tell clients that no special precautions are required; breastfeeding may continue uninterrupted following mifepristone or misoprostol
   b. Chronic diarrhoea (including irritable or inflammatory bowel disease (Crohn's or Ulcerative colitis)
      i. Tell clients who suffer from chronic diarrhoea that diarrhoea may worsen during treatment, as it can be a side effect of misoprostol
   c. Nausea and vomiting of pregnancy
      i. Advise client to obtain an over-the-counter anti-emetic to use prior to taking mifepristone
      ii. Tell client that if mifepristone is vomited within 1 hour of ingestion treatment may be less effective but can continue with misoprostol and self-assessment as planned
   d. Travelling after treatment
      i. Travelling is not ideal in the first 24 hours after using misoprostol
      ii. Tell clients who intend to travel within 24 hours of misoprostol use that they may develop symptoms while in transit and must be prepared and able to manage them
      iii. Tell clients who intend to travel that they also need to know when and how to access emergency services in case of a complication or in case a continuing pregnancy is suspected

Appendix 7

Prescription pad

Dr Name:		**Patients name:**	
Dr surgery address:		**Address:**	
Post code:		**Post code:**	
Tel No:		**Tel No:**	
GMC No:		**DOB(dd/mm/yy):**	

Drug name:		**Strength:**	
Size etc:			
Dosage instructions:			

Drug name:		**Strength:**	
Size etc:			
Dosage instructions:			

Drug name:		**Strength:**	
Size etc			
Dosage instructions:			

Dr signature		**Date:**	

Appendix 8

Treatment Declined Form

Date Treatment Declined:	
Client Initials:	
Index Number:	
Consultation Date:	

DECISION TO DECLINE TREATMENT MADE BY:	
*Consultation/Treatment Doctor:	

REASON DECLINED:
ACTION

Appendix 9

Aftercare Algorithm EMA by telemedicine

Appendix 10

Early Medical Abortion Follow-up Letter Template

INSTRUCTIONS:- 1. SUPPLY THE INFORMATION IN THE **BLUE** SECTIONS.
2. DELETE THE PARAGRAPHS and or WORDS IN **RED** THAT ARE NOT APPLICABLE.
3. DELETE THESE INSTRUTIONS BEFORE PRINTING.

DATE

Private & Confidential

NAME
ADDRESS
ADDRESS
ADDRESS

Dear NAME

Re: Treatment Follow Up

You were scheduled for an appointment on DATE at BPAS UNIT NAME to determine whether your treatment was successful and to confirm that you are no longer pregnant. Unfortunately you did not attend this appointment.

Please contact the clinic on TELEPHONE NUMBER as soon as possible to reschedule, so that we can be sure your treatment has been successful.

Yours sincerely

SIGNATURE
NAME
BPAS TITLE

CC Client Notes

For BPAS - NAME OF UNIT
ADDRESS
ADDRESS
ADDRESS
UNIT TELEPHONE NUMBER AND OPENING HOURS.

Appendix 11

Information for Clients Who Have Had a Medical Abortion and the Pregnancy is Continuing

Mifepristone

This is the first drug that is given by mouth as part of an early medical abortion. Studies that have been done so far appear to show that mifepristone is not associated with an increased risk of fetal abnormality.

Misoprostol

This is the second drug given usually vaginally or sometimes in between the cheek and gum. When an early pregnancy is exposed to misoprostol there is an increase in the risk of some birth defects and specifically a set of abnormalities called Möbius syndrome. People with Möbius syndrome are born with facial paralysis and the inability to move their eyes from side to side. They may also have other abnormalities, such as clubbed feet or missing toes or fingers.

Background Rate of Fetal Abnormality

In the general population, between 1 and 2 in 100 babies are born with some sort of congenital abnormality, admittedly some minor. Studies indicate that the risk of anomalies related to misoprostol exposure in early pregnancy is less than 10 malformations per 1,000 births.

Background Rate of Miscarriage

Up to 13 in 100 pregnancies miscarry. If you include pregnancies in which the fetus is known to be abnormal, then the rate is higher. Taking mifepristone and/or misoprostol is likely to increase the chance of miscarriage even if the pregnancy is normal. The chance of miscarriage cannot be predicted.

Antenatal care

It is advisable to book in for antenatal care as soon as possible and to tell the doctor and midwife exactly which drugs you have taken. You will be offered an anomaly scan at around18-20 weeks of pregnancy and it is important you attend for this. Some of the abnormalities that can be caused by misoprostol, like Möbius syndrome, cannot be seen on ultrasound scan.

We can provide further information to your care provider with your permission. The Treatment Unit can be reached on the following telephone number if you would like us to speak with your antenatal care provider:

Name of Treatment Unit: _____

Treatment Unit Telephone Number: _____

From: [redacted]@RCOG.ORG.UK>
Sent: 18 March 2020 14:33
To: Duncan, Andrea [redacted]@dhsc.gov.uk>
Cc: [redacted]@RCOG.ORG.UK>
Subject: Re: Certification

Thanks Andrea, know you're working at breakneck speed. May find the below amendment helpful if successful!

Best wishes

[redacted]

After Clause xxx

Insert the following new Clause—

"Amendment to the Abortion Act 1967

In the Abortion Act 1967—

1. In section 1, subsection 1, leave out "if two registered medical practitioners are" and insert ", nurse or midwife if one registered medical practitioner, nurse, or midwife is"
2. In section 1, subsection 4, leave out "two registered medical practitioners" and insert "a registered medical practitioner, nurse or midwife"
3. In section 1, subsection 4, after "practitioner" insert ", nurse or midwife"
4. In section 2, subsection 1, paragraph b, after "practitioner" insert ", nurse or midwife"
5. [In section 5, subsection 1, after "practitioner" insert ", nurse or midwife"]

[redacted]
Political Adviser to the President
Royal College of Obstetricians and Gynaecologists
T: [redacted]
E: [redacted]@rcog.org.uk
Website: www.rcog.org.uk

27 Sussex Place, Regent's Park, London, NW1 4RG, UK
Switchboard: +44 20 7772 6200
Registered Charity No: 213280

From: Duncan, Andrea <[redacted]@dhsc.gov.uk>
Sent: 18 March 2020 12:09
To: [redacted]@RCOG.ORG.UK>
Subject: RE: Certification

Thanks [redacted]

I am picking up and will do our best.
BW
Andrea

From: [redacted]@RCOG.ORG.UK>
Sent: 18 March 2020 12:02
To: Duncan, Andrea [redacted]@dhsc.gov.uk>
Subject: Certification

Hi Andrea

Thanks for your time. On certification, one argument could be to amend the legislation to one signature and not specify doctor. So amend medical practitioner to healthcare professional. But to time limit this to 23+6 weeks gestation if there's any pushback. A bit messier but might help the argument with the ministers.

Best wishes

[redacted]

[redacted]
Political Adviser to the President
Royal College of Obstetricians and Gynaecologists
T: [redacted]
M: [redacted]

CLEARANCE CHECKLIST

Inclusion of this checklist is mandatory. Please complete the whole list and private office will remove before putting submission in the box. A submission without it will be sent back.

***Note**: Contact names provided must have seen and approved the submission.*

Finance:
Does this involve any spending or affect existing budgets?
☐ If yes, named official:
Click here to enter text.
☑ No

Legal:
[redacted]

Communications:
Could this generate media coverage, or a response from the health sector?
☐ If yes, named official:
Click here to enter text.
☐ No

Analysis and data fact-checking:
Does this include complex data, statistics or analysis?
☐ If yes, named official:
Click here to enter text.
☐ No

Devolved Administrations:
Will this affect Scotland, Wales or Northern Ireland?
☐ If yes, named official:
Click here to enter text.
☐ No

Fraud:
Have you considered fraud risks?
☐ If yes, named official:
Click here to enter text.
☐ No

Commercial:
Does this include commercial or contractual implications?
☐ If yes, named official:
Click here to enter text.
☐ No

Strategy Unit:
Does this relate to cross-cutting or longer-term implications for wider DH strategy?
☐ If yes, named official:
Click here to enter text.
☐ No

Implementation Unit:
Does this relate to one of the Secretary of State priorities?
☐ If yes, named official:
Click here to enter text.
☐ No

Legislation:
Does this include options that may require secondary legislation?
☐ If yes, do you have a prioritisation reference number? *(contact Parly or SOPL if unsure):*
Click here to enter text.
☐ No

Duties, Tests and Appraisals:
The following tests apply and have been considered.

☐ Secretary of State Statutory Duties, including on health inequalities
☐ Public Sector Equality Duty
☐ Family test
☐ Other(s) (please specify)
Click here to enter text.

To: MS(C), PS(I), PS(P), SofS

From: Andrea Duncan
Healthy Behaviours

Date: 18/03/2020

Copy: [redacted]
Private Office Submissions Copy List

COVID-19: ABORTION ACT AND TWO SIGNATURE REQUIREMENT

Issue	The Royal College of Obstetricians and Gynaecologists (RCOG) have asked that urgent consideration be given to using the emergency legislation going through Parliament to relax the rule that two doctors must certify an abortion during the current COVID-19 crisis.
Timing	Urgent (two working days) Urgent as the Bill is about to go through Parliament.
Recommendation	That you indicate whether you want us to urgently pursue avenues to relax the two-doctor certification rule for abortions in the Bill.

Discussion

1. Under the provisions of the 1976 Abortion Act two registered medical practitioners must certify that there are grounds for an abortion to take place. It is a criminal offence for doctors not to comply with this provision.

2. We have been working with the RCOG to consider how we can ensure that women can continue to access abortions during the current COVID-19 crisis. Finding two doctors to certify each procedure may become increasingly challenging as staff are shifted to other areas or become ill themselves.

3. The RCOG have therefore requested that we urgently consider whether the rule can be relaxed so that one doctor provide the certificate. In addition, that registered nurses and midwives be allowed to provide the certificate. This was also strongly pressed by Baroness Jolly in the peer pre-legislative scrutiny process for the Bill.

4. We consider there is merit in considering this measure and such a step could be justified in relation to the current situation. In England and Wales in 2018 the total number of abortions was 200,608 – just under 4,000 per week.

5. Access to abortion services is an urgent matter: the procedure's risk increases at later gestations; the Abortion Act 1967 sets legal gestational limits for accessing services, so if women present to services near to the gestational limit they may only have a short time to access services; and any disruption to normal business (i.e. women not being able to access services for several weeks due to self-isolation) will have a major impact on the future system's capacity, and it is also inevitable that vulnerable women will be forced to continue with unwanted pregnancies.

Timing and next steps

6. We would welcome an urgent steer as to whether you wish us to identify ways to include this provision in the Bill, even at this late stage. If so, we will work with the Bill team to take forward if possible.

Risks

7. The key risk is that the measure will be viewed as controversial by pro-life organisations and MPs as this will be seen as a loosening of regulation around abortion provision. However, our view is that this measure would be proportionate in the COVID-19 context. We will also be clear that this is a temporary measure that will be switched off in due course.

Devolved Administrations

8. If introduced the relaxation will only apply to England and Wales. In Scotland the legislation is devolved. In the new legal framework for Northern Ireland, one signature (of a doctor, nurse or midwife) is required to confirm gestation up to 12 weeks. After that two signatures to agree grounds are required.

Conclusion

9. That you indicate whether you want us to urgently pursue avenues to relax the two-doctor certification rule for abortions in the COVID-19 Bill.

Andrea Duncan

HEALTHY BEHAVIOURS TEAM

Royal College of Obstetricians & Gynaecologists

FSRH The Faculty of Sexual & Reproductive Healthcare

THE ROYAL COLLEGE OF MIDWIVES

MARIE STOPES UK

NUPAS national unplanned pregnancy advisory service

bpas British Pregnancy Advisory Service

BSACP BRITISH SOCIETY OF ABORTION CARE PROVIDERS

Rt. Hon. Matthew Hancock MP
Secretary of State for Health and Social Care
39 Victoria Street
Westminster
London
SW1H 0EU

[redacted]
Political Adviser to the President
Royal College of Obstetricians and Gynaecologists
10-18 Union Street
London
SE1 1SZ

22nd March 2020

RE: Two doctors' signatures to certify abortion during Covid-19

Dear Secretary of State,

We are writing at this time of crisis to urge you to amend the Coronavirus Bill currently before Parliament to allow nurses and midwives to ensure that women needing abortions in the coming weeks and months will be able to access care.

In the next 13 weeks prior to the best estimates of Covid-19's peak impact on the UK, 44,000 women in England and Wales will need access to an Early Medical Abortion.

As you are aware, the current law on abortion requires that two doctors provide signatures to certify that the abortion being carried out does not breach the terms of the Abortion Act 1967. These signatures are all that stands between healthcare professionals and the threat of a life sentence for performing an abortion outside the law. **In the next 13 weeks, 88,000 signatures will be needed for abortions prior to 12 weeks' gestation.**

It is important to note that this requirement is legal and not clinical – that many Early Medical Abortion services are nurse- and midwife-led, that these healthcare professionals are qualified, experienced, and registered with the Nursing and Midwifery Council. Despite being the people who meet face to face with women, that take medical histories, that obtain informed consent to treatment, that hand over the medication, they are legally unable to certify an abortion.

In normal circumstances, the requirement for two doctors' signatures – particularly in the NHS – means that women may be asked to return to a clinic more than once, that they may be asked to come via their GP so that their GP can sign the form, or that once they are sat in our waiting rooms, our doctors have to physically walk around the hospital to find a doctor willing to provide a second signature.

In normal circumstances, this aspect of the law may be clinically unnecessary but it is the law nonetheless and we make the best of the situation.

In the current circumstances with Covid-19 meaning doctors are self-isolating or off sick and the NHS under immense pressure, it wastes valuable time, puts everyone at greater risk of spreading or contracting coronavirus and risks our ability to provide abortion care at all.

Currently, 72% of all abortions are provided in the independent sector. During this crisis and given the pressure on hospitals, we expect this proportion to rise. To sign off abortions, these abortion services rely on the dedicated provision of only 20 FTE doctors. Of these doctors, 70% also work within the NHS, as GPs, or in sexual health clinics – meaning that they are likely to come into contact with patients who are exhibiting the symptoms of Covid-19 and may well be left unable to work for periods of time.

In the NHS, many Early Medical Abortion services operate as standard with only two doctors (supported by registered nurses). If one is required to self-isolate then the service will be unable to run.

In the Coronavirus Bill, there is a recognition that in the highly unusual circumstances presented by Covid-19, there may be occasions where two mental health professionals are not available to detain somebody under the Mental Health Act 1983. However, there is no recognition of the similar pressures on the abortion service.

In 2018 there were more than 200,000 legal abortions in England and Wales. As Secretary of State for Health and Social Care, regardless of how controversial a topic you may consider this to be, you must recognise the unacceptable impact on any woman forced to continue a pregnancy for want of a second doctor to sign off a form.

We are asking you to amend the legislation currently before the House to enable a single registered medical practitioner, nurse, or midwife to perform and certify an abortion under the Abortion Act 1967.

We are not asking for a permanent change to this provision, nor a change to the underlying criminalisation of abortion – **we are asking you for a simple but essential measure to ensure that no woman in England or Wales is forced to continue with an unwanted pregnancy during the Covid-19 epidemic.**

Yours sincerely,

Professor Dame Lesley Regan | Chair, RCOG Abortion Taskforce

Dr. Edward Morris | President, Royal College of Obstetricians and Gynaecologists (RCOG)

Dr. Asha Kasliwal | President, Faculty of Sexual and Reproductive Healthcare (FSRH)

Gill Walton | Chief Executive, Royal College of Midwives

Dr. Suzanne Tyler | Executive Director, Services to Members, Royal College of Midwives

Katharine Gale | Chair, Royal College of Nursing's Women's Health Forum

Debra Holloway | Fellow, Royal College of Nursing | Fellow, RCOG

Joanne Fletcher | Co-Chair, British Society of Abortion Care Providers

Jonathan Lord | Medical Director, Marie Stopes | Co-chair, British Society of Abortion Care Providers

Tracey Masters | Lead for Abortion Service at Homerton University Hospital

Dr. Patricia Lohr | Medical Director, BPAS

Michael Nevill | Director of Nursing, BPAS

Dr. Nabanita Ghosh | Medical Director, NUPAS

PROVISION OF SIGNATURES FOR HSA1 FORMS DURING COVID-19
20TH MARCH 2020

20 FTE doctors working for Independent Service Providers signing off Early Medical Abortion forms
44,000 women will need an Early Medical Abortion in the next 13 weeks
88,000 signatures from doctors will be needed to make these abortions legal

Proposal

Given the pressure on abortion services during Covid-19, and the potential impact on the very small number of doctors responsible for signing off abortion forms, the requirement for two doctors' signatures is an insurmountable bottleneck in the system. The law needs to be temporarily changed to enable one doctor, nurse, or midwife to sign off an abortion.

Current law

Section 1 of the Abortion Act 1967 requires two registered medical practitioners to certify that a woman meets the legal grounds for an abortion.

Any abortion performed (except in an emergency) without these two signatures constitutes a crime under s58 of the Offences Against the Person Act 1861 which carries a life sentence for both the woman and the healthcare professional.

Abortion workforce

Under established case law, doctors who sign off abortions do not need to see women face to face or treat them personally. Most abortion services are nurse-led with provisions in place for doctors to review notes and provide legally-required signatures. In the Independent Sector, this is generally via remote review.

72% of abortions in England and Wales in 2018 were provided by Independent Service Providers and funded by the NHS.

With the upcoming availability of mifepristone at home (enabling telemedicine) and the pressure on the NHS expected as a result of Covid-19, there is an expectation that the proportion of abortions performed in the Independent Sector will increase.

Signing doctors

The three main independent service providers in England and Wales are the British Pregnancy Advisory Service (BPAS), Marie Stopes, and NUPAS.

These three organisations currently employ 33 doctors equivalent to 20 FTE to sign off Early Medical Abortions.

Of these employed doctors, 24 also work within the NHS, as GPs, or in sexual health clinics.

In the next 13 weeks to Covid peak, each of these FTEs will have to review patient notes and provide 4400 signatures.

This is prior to accounting for self-isolation or sickness.

NHS services

NHS services do not have the provision for remote reviewing and signing of HSA1 forms. This means that in NHS abortion services, two doctors have to be physically present.

Several services encourage patients to attend with one doctor's signature already – primarily by encouraging patients to come via GP referral.

For patients that present without an initial signature, NHS services either send patients away to return at a later date when a second signature has been obtained within the service or physically walk around the hospital to find a doctor from another service who is willing to sign the form. This entails longer waits for patients – sometimes in mixed waiting rooms which will in the coming weeks present an infection hazard. It can also mean that some women, sent away because they don't have an initial signature, are pushed over the Early Medical Abortion limit and forced to travel for a more expensive surgical treatment.

Many NHS Early Medical Abortion services operate as standard with only two doctors (supported by registered nurses). If one is required to self-isolate then the service will be unable to run.

Consent and safeguarding

Obtaining two doctors' signatures is completely separate from the obtaining of informed consent from the woman and from the safeguarding that takes place as part of the consultation.

It is a legal requirement and not a clinical one.

Solution

In line with the current proposals in the Coronavirus Bill for the reduction in the number of medical professionals required to section an individual, **the law needs to be temporarily changed to enable individual nurses and midwives to sign off and provide abortions.**

In practice, this is what these healthcare professionals do already – but legally they are unable to provide the necessary signatures.

This would not change the underlying legal position of abortion in which it remains a crime.

This would bring England and Wales temporarily into line with the proposed position in the Northern Ireland regulations in which one healthcare professional is able to certify an abortion up to 12 weeks.

There is already support from the Opposition frontbench and from the Liberal Democrat frontbench. This would not be a controversial measure in the House.

Attached is a proposed amendment to the Coronavirus Bill. We are asking the Government to include this as an amendment at Committee Stage.

New Clause x

To move the following Clause—

"Temporary modification of abortion legislation

Schedule (*Abortion provision*) contains temporary modifications of the Abortion Act 1967, and related provision."

New Schedule y

To move the following Schedule—

"Abortion provision

PART 1
INTRODUCTORY PROVISION ETC.

Interpretation

1

(1) References in this Schedule to sections are to sections of the Abortion Act 1967 ("the 1967 Act).

(2) "Registered medical practitioner" means a person on the Register of the General Medical Council established by the Medical Act 1983.
"Registered nurse or midwife" means a person on the Register of the Nursing and Midwifery Council, with the meaning given to it by s5(5) of The Nursing and Midwifery Order 2001

Forms

2 Where any form prescribed for use in connection with a provision of the 1967 Act is inconsistent with a modification made by Part 2 of this Schedule, the form—

(a) may, in connection with the provision as so modified, be used with appropriate amendments;

(b) is otherwise, for use in that connection, to be read with such amendments as are necessary to reflect the modification.

PART 2
MODIFICATIONS TO THE ABORTION ACT 1967

Certification of abortion

1

(1) During a period in which this paragraph has effect, the provisions in section 1 apply to a pregnancy terminated by a registered medical practitioner, nurse or midwife.

(2) During a period in which this paragraph has effect, an opinion under section 1 may be formed by one registered medical practitioner, nurse or midwife, if the professional considers that compliance with requirement under that section for the opinion of two registered medical practitioners is impractical or would involve undesirable delay.

Notification

2

(1) During a period in which this paragraph has effect, the requirement to give notice of the termination in subsection 2(b) applies to any registered nurse or midwife

Protection from prosecution

3

(1) During a period in which this paragraph has effect, the provisions in subsection 5(1) also apply to any registered nurse or midwife."

From: psmatthancock <[redacted]@dhsc.gov.uk>
Sent: 24 March 2020 13:13
To: [redacted]@dhsc.gov.uk>; psmatthancock <[redacted]@dhsc.gov.uk>; Duncan, Andrea [redacted]@dhsc.gov.uk>; pshelenwhately <[redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; PsBethell [redacted]@dhsc.gov.uk>
Cc: Marron, Jonathan <[redacted]@dhsc.gov.uk>; Davies, Mark <[redacted]@dhsc.gov.uk>; [redacted]@governmentlegal.gov.uk>; [redacted]@governmentlegal.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; E[redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; Jones, Elin [redacted]@dhsc.gov.uk>; McMordie, Adam <[redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; Reeve, Simon <[redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>
Subject: RE: URGENT SUBMISSION: COVID19 AND ABORTION ACCESS

Hi [redacted],

The Secretary of State has just reviewed the submission and has decided that he does not want any changes to abortion.

He has asked for a letter to be sent to all of the recipients of the first letter along the lines of: Sorry, this letter was sent in error. This change is not happening.

Thanks,

[redacted]

25 March 2020

Access to abortion services – COVID-19

This note follows the submission of 18/03/2020 which set out possible measures to increase access to early medical abortion services in light of COVID-19.

We remain concerned about access to abortion services in light of COVID-19. Around 4,000 women have an abortion each week in England and Wales and access to abortion services is urgent:

- The procedure's risk increases at later gestations;

- The Abortion Act 1967 sets gestational limits for accessing services, so if women present to services near to the gestational limit they will have only a short time to access services. Women who present later in pregnancy are more likely to be vulnerable, so delays will likely mean that vulnerable women will be forced to continue with unwanted pregnancies.

- Any disruption to normal business (i.e. women not being able to access services for several weeks) will have a major impact on the future system's capacity. Surgical abortions require surgical facilities, so ensuring as many women as possible can access early medical services will reduce the strain on hospital facilities.

Key concerns

1. **All women must attend a clinic or hospital in person at least once**. In light of COVID-19, our advice is that travel to abortion clinics or hospitals is classed as essential travel, however this remains a concern for the following reasons:

    - The majority of women accessing abortions will travel on public transport, increasing their risk of COVID-19 transmission. Many women do not have a local clinic so these journeys will often be very long, and following the recent school closures, with children (over 50% of women accessing abortions have given birth to children previously).

    - The need to travel to a clinic will be a particular issue for **women who are shielding, those who have COVID-19 symptoms or those with children** (as clinics can't accommodate children). Providers have told us that in these circumstances, women will be forced to continue with unwanted pregnancies or obtain abortion pills unlawfully online.

2. Providers have informed DHSC that **large numbers of clinic staff are self-isolating and that clinics are having to close in light of this, given doctors are unable to prescribe abortion medication from home**. We have been informed of at least two NHS hospitals where the only available doctors are self-isolating and if they cannot prescribe from home the service will stop. We have been told that ensuring there is a continued level of service provision in clinics and hospitals will be challenging or simply impossible. Clinic closures also mean that women will need to travel longer distances to access services if their nearest clinic closes, increasing concerns around travel outlined above.

Options considered

We have engaged with abortion providers and stakeholders (including the Royal College of Obstetricians and Gynaecologists) to consider a range of options to ensure women and girls are able to access services in the context of COVID-19. The range of options that have been considered are outlined in the table below, along with a DHSC view on each.

Temporary measure to ensure access	DHSC view
1. DHSC to work with abortion providers to provide whatever support we can to ensure continued service provision. This includes clear messaging that abortion is an essential service that must continue and that we expect providers to work together to maintain service provision as far as possible.	This work is ongoing.
2. Using their powers under the Abortion Act, DHSC Ministers approve that **women can take both abortion pills for early medical abortion in their own homes** so that no travel is necessary (currently women can take the second pill in their home, but must attend the clinic or hospital to take the first). This is supported by clinical evidence.	Ministers have not approved.
3. Using their powers under the Abortion Act, DHSC Ministers approve that **doctors can prescribe both pills for early medical abortion from their own homes**, to ensure doctors can prescribe when self-isolating.	Ministers have not approved.
4. Amend the Abortion Act to enable **one doctor to certify** abortions (under the Abortion Act two doctors must certify), to respond to concerns around reduced doctor capacity.	Ministerial view that this should not be progressed. We expect doctors to work flexibly to ensure certification is timely and doesn't delay treatment. Assessment can take place via telemedicine, webcam or on the phone.
5. Amend the Abortion Act to **enable nurses, midwives and nurses to perform and certify abortions**, to respond to concerns around reduced doctor capacity.	This was not be progressed given Ministerial steer to not to accept amendments on abortion. We do not think it is right that midwives and nurses are suddenly expected to take on expanded roles without proper training and guidance in place.

Next steps

Due to the restrictions in the Abortion Act, options for changing service provision are limited.

- Ministers have powers under the Abortion Act to approve additional places where abortions may be performed. Approval of additional locations (other than the options

outlined in the table above) would not in practice improve access. For example, approving GP practices would mean that a woman could in theory attend her local GP in person to access services, however GPs are not trained to provide abortions and women would still need to travel. GPs are likely to be very reluctant to take on a new service during the current time.

- We have been asked to consider what support could be provided to women to address concerns about women travelling to services on public transport. In our view options here are limited. For example, if Ministers were minded to fund taxis for high risk women (e.g. those who are shielding) to access services, it would be difficult to ensure that taxi drivers did not have COVID-19 infection. However, if Ministers are minded to pursue this option further then we can provide further advice and work with colleagues to see what is being done to enable vulnerable groups to access other healthcare services.

- As you have decided to require women to attend clinics in person to access services it is critical that we ensure adequate service provision to ensure women are not forced to continue with unwanted pregnancies. If the situation escalates and services are increasingly unavailable, we recommend that we return to you with further advice on whether to approve home use for early medical abortion and home prescribing of abortion pills (i.e. options 2 and 3 above), to prevent unwanted pregnancy or women being forced into taking actions which are illegal.

The Hon. Nadine Dorries MP
Minister for Patient Safety and Women's Health
Department for Health and Social Care
39 Victoria Street
London SW1H 0EU

25 March 2020

Dear Nadine

I have been contacted by the Telford branch of the British Pregnancy Advisory Service (BPAS), who have raised a number of concerns about the ongoing operation of their services.

BPAS has informed me that under the current circumstances, thousands of women will be unable to access abortion care during the next three months, and thousands more will have no option but to travel to healthcare clinics for unnecessary appointments, further straining the healthcare system. I understand that one in four of BPAS's clinics have been closed due to staff shortages and illness. This includes the Telford clinic in my constituency, and many women are now having to travel to Stafford or Cannock to access BPAS services.

In particular, BPAS has explained that under the law, 500 women a day have to travel to abortion clinics to take a pill before self-managing the abortion at home. BPAS has stated that this is not clinically required and contradicts Government guidance on non-essential travel. They have asked if the Government would consider allowing BPAS to provide telemedicine services to ensure women can continue to access their advice and support.

I would appreciate if you would look into this matter and provide any assurances for BPAS and women around the UK who rely on their pregnancy services, so that they can continue to support women's access to abortions and pregnancy throughout this time.

Thank you in advance.

Yours ever,

Lucy Allan MP
Member of Parliament for Telford

25 March 2020

Access to abortion services – COVID-19

This note follows the submission of 18/03/2020 which set out possible measures to increase access to early medical abortion services in light of COVID-19.

We remain concerned about access to abortion services in light of COVID-19. Around 4,000 women have an abortion each week in England and Wales and access to abortion services is urgent:

- The procedure's risk increases at later gestations;

- The Abortion Act 1967 sets gestational limits for accessing services, so if women present to services near to the gestational limit they will have only a short time to access services. Women who present later in pregnancy are more likely to be vulnerable, so delays will likely mean that vulnerable women will be forced to continue with unwanted pregnancies.

- Any disruption to normal business (i.e. women not being able to access services for several weeks) will have a major impact on the future system's capacity. Surgical abortions require surgical facilities, so ensuring as many women as possible can access early medical services will reduce the strain on hospital facilities.

Key concerns

1. **All women must attend a clinic or hospital in person at least once**. In light of COVID-19, our advice is that travel to abortion clinics or hospitals is classed as essential travel, however this remains a concern for the following reasons:

    - The majority of women accessing abortions will travel on public transport, increasing their risk of COVID-19 transmission. Many women do not have a local clinic so these journeys will often be very long, and following the recent school closures, with children (over 50% of women accessing abortions have given birth to children previously). Clinic closures as set out in paragraph two will make these journeys even harder.

    - The need to travel to a clinic will be a particular issue for **women who are shielding, those who have COVID-19 symptoms or those with children** (as clinics can't accommodate children). Providers have told us that in these circumstances, women will be forced to continue with unwanted pregnancies or obtain abortion pills unlawfully online.

2. Providers have informed DHSC that **large numbers of clinic staff are self-isolating and that clinics are having to close in light of this, given doctors are unable to prescribe abortion medication from home**. For example, Marie Stopes UK have written to SoS to say that 68 of their 400 staff are now self-isolating or showing symptoms. They have also been asked to take on work from 15 areas covered by the NHS given their staff have been re-deployed. BPAS have informed us that 20% of their staff are currently absent. We have been informed of at least two NHS hospitals where the only available doctors are self-isolating and if they cannot prescribe from home the service will stop. We have been told that ensuring there is a continued level of service provision in clinics and hospitals will be challenging or simply impossible.

Clinic closures also mean that women will need to travel longer distances to access services if their nearest clinic closes, increasing concerns around travel outlined above.

Options considered

We have engaged with abortion providers and stakeholders (including the Royal College of Obstetricians and Gynaecologists) to consider a range of options to ensure women and girls are able to access services in the context of COVID-19. The range of options that have been considered are outlined in the table below, along with a DHSC view on each.

Temporary measure to ensure access	DHSC view
1. DHSC to work with abortion providers to provide whatever support we can to ensure continued service provision. This includes clear messaging that abortion is an essential service that must continue and that we expect providers to work together to maintain service provision as far as possible.	This work is ongoing.
2. Using their powers under the Abortion Act, DHSC Ministers approve that **women can take both abortion pills for early medical abortion in their own homes** so that no travel is necessary (currently women can take the second pill in their home, but must attend the clinic or hospital to take the first). This is supported by clinical evidence.	**Pros:** • Ministers have the powers to approve homes as places where both pills can be taken. • Providers are ready to go if the approval is given. • Would enable access to women who are self-isolating and or who have symptoms. **Cons:** • Secretary of State does not currently support this approach. • Is controversial and we will be faced accusation of "DIY" abortions. • Concerns about safeguarding women if they are no physically seen in a clinic.
3. Using their powers under the Abortion Act, DHSC Ministers approve that **doctors can prescribe both pills for early medical abortion from their own homes**, to ensure doctors can prescribe when self-isolating.	**Pros:** • Ministers have the powers to approve doctors' homes as places where treatment for early medical abortion can be prescribed. • Providers are ready to go if the approval is given. • Would enable doctors who are self-isolating or who only have mild symptoms to continue to work from home. **Cons:** • Secretary of State does not currently support this approach.

4. 4. Ministers approve a wider range of settings, including GP surgeries, to maintain access to services	**Pros:** • Ministers have the power approve GP surgeries or any other premises where abortions can legally be performed. • GP surgeries are more local for women than abortion services. **Cons:** • Prescribing would need to be undertaken physically within the surgery and women would still need to leave their home to collect the medication, including those with symptoms and those who are self-isolating. The first pill would need to be taken at the surgery. • GPs may be reluctant to undertake this work at rapid pace given they currently are not involved in abortion care. • We do not know how many GPs would conscientiously object to providing abortion care. • Funding issues would need to be addressed. • Abortion services have 24-hour helplines in place so that women can seek advice on managing pain and bleeding. It is not clear how this would be provided in a GP run service.
5. Pharmacy provision including home deliveries	**Pros:** • May ensure quick access and most women live near a pharmacy. • Ministers have the power to approve pharmacies as a place where abortions can legally be performed. **Cons:** • **Legally only a doctor can perform an abortion** which includes prescribing the medication. Primary legislation is required to amend this. Ministers did not support an attempt to amend the emergency bill to allow nurses and midwives to perform abortions and the amendment was withdrawn. • Home deliveries would involve both pills being taken at home and would require women's homes to be approved as above.

Other Issues/ Options

Due to the restrictions in the Abortion Act, options for changing service provision are limited.

- We have been asked to consider what support could be provided to women to address concerns about women travelling to services on public transport. In our view options here are limited. For example, if Ministers were minded to fund taxis for high risk women (e.g. those who are shielding) to access services, it would be difficult to ensure that taxi drivers did not have COVID-19 infection. However, if Ministers are minded to pursue this option further then we can provide further advice and work with colleagues to see what is being done to enable vulnerable groups to access other healthcare services.

- As you have decided to require women to attend clinics in person to access services it is critical that we ensure adequate service provision to ensure women are not forced to continue with unwanted pregnancies. If the situation escalates and services are increasingly unavailable, we recommend that we return to you with further advice on whether to approve home use for early medical abortion and home prescribing of abortion pills (i.e. options 2 and 3 above), to prevent unwanted pregnancy or women being forced into taking actions which are illegal.

28 March 2020

Open letter to: Rt Hon Matt Hancock MP, Secretary of State for Health

Dear Secretary of State,

Request for immediate introduction of telemedical abortion services to reduce coronavirus transmission

First let us express our best wishes for a speedy recovery from your illness and apologise for having to bring another issue to your attention at this challenging time.

We are writing to you as public health specialists to implore you to advise the Prime Minister, and the wider government, on the capacity of telemedical abortion services to help curb the COVID-19 pandemic and protect wider public health.

- Despite instruction to avoid any unnecessary travel by the Prime Minister, in the next 13 weeks as the pandemic is predicted to reach its peak, at least 44,000 women will have to leave their homes needlessly to access early medical abortion care, with an increasing number of clinic closures forcing them to travel long distances across the country exposing themselves and others to COVID-19.
- This equates to over 3,000 journeys per week, with each woman making multiple contacts during her journey and during her time in both independent clinics and high-risk NHS settings. Telemedical early abortion services would eliminate all such contact and therefore protect the health of the wider population, our health system, and our healthcare workers.
- The government is repeatedly refusing to follow advice from scientific and professional bodies to enable telemedicine for early medical abortion so women can be safely cared for in their own homes whilst fulfilling their moral obligation to protect the health of others.
- Comprehensive regulations on permitting telemedicine for early medical abortion were introduced by the Department of Health on Monday, on the advice of healthcare bodies including the Royal College of Obstetricians and Gynaecologists (RCOG) and the Royal College of Midwives (RCM), and then inexplicably retracted the same evening.
- Telemedicine for abortion has been recommended by NICE.

We believe that the impact of failing to implement this service on both individuals and the wider population will be grave, and services are currently at the brink of collapse.

- Women with severe health issues who have been told to self-isolate for 12 weeks say they are being forced to choose between risking their health by leaving their house and being compelled to continue an unwanted pregnancy that also threatens their health.
- Vulnerable women are already turning outside the regulated healthcare system for help from online providers, breaking the law and foregoing the inbuilt safeguarding and support provided by regulated services.

- A quarter (23%) of abortion clinics run by bpas, which cares for 100,000 women per year, were closed on the 24th of March due to staff sickness and isolation, with further closures expected across NHS funded services today.
- Surgical abortion lists are being cancelled across the UK as operating theatres are being used as ICUs. Women who cannot access a safe early medical abortion will have no back up later in their unwanted pregnancy.
- Abortion services are at risk of collapse if the Prime Minister does not act swiftly.

We urge you to act immediately to protect the health of individuals, the wider population, and our healthcare workers.

Signed:

Professor Maggie Rae, President of the Faculty of Public Health

Professor Helen Ward, Professor of Public Health, Imperial College London

Professor Trish Greenhalgh, Professor of Primary Care Health Sciences, Nuffield Department of Primary Care Health Sciences, Medical Sciences Division, University of Oxford

Dr Edward Morris, President, Royal College of Obstetricians and Gynaecologists. Consultant in Obstetrics and Gynaecology, Norfolk and Norwich University Hospital, Norwich

Dame Lesley Regan, Professor Obstetrics & Gynaecology, Imperial College; Chair RCOG Abortion Task Force and Past President RCOG

Professor Martin McKee, Professor of European Public Health, London School of Hygiene and Tropical Medicine

Professor Jim McManus, Vice-President, Association of Directors of Public Health

Professor Majid Ezzati, Chair in Global Environmental Health, Imperial College London

Professor David McCoy, Professor of Global Public Health, Queen Mary University of London

Professor Paul Roderick, Professor of Public Health, University of Southampton

Professor Nicola Shelton, Professor of Population Health, University College London

Professor Allyson Pollock, Professor of Public Health, Newcastle University

Professor Mark S Gilthorpe, Professor of Statistical Epidemiology, University of Leeds

Professor Elio Riboli, Chair in Cancer Epidemiology and Prevention, Imperial College London

Professor Lefkos Middleton, Chair in Clinical Neurology, Imperial College London

Dr Rochelle Burgess, Lecturer in Global Health, University College London

Dr Miriam Orcutt, Senior Research Fellow, University College London

Dr Cleone Rooney, retired Consultant in Public Health and Health Protection

Professor Steph Taylor, Professor in Public Health and Primary Care, Barts and The London School of Medicine and Dentistry, Queen Mary University of London

Professor Adrian Martineau, Professor of Respiratory Infection and Immunity, , Barts and The London School of Medicine and Dentistry, Queen Mary University of London

Professor Ernestina Coast, Professor of Health and International Development, London School of Economics & Political Science

Professor Guiqing Lily Yao, Professor of Health Economics, University of Leicester.

Dr Jocalyn Clark, Executive Editor, The Lancet; Assistant Professor of Medicine, University of Toronto

Dr Geordan Shannon, Lecturer in Global Health, University College London

Dr Rishita Nandagiri, LSE Fellow in Health and International Development, London School of Economics and Political Science

Professor Cicely Marston, Professor of Public Health, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Rebecca French, Associate Professor of Sexual & Reproductive Health Research, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Professor Oona Campbell, Professor of Epidemiology and Reproductive Health, Faculty of Epidemiology and Population Health, London School of Hygiene & Tropical Medicine

Dr Alexis Palfreyman, Research Fellow in Global Health, University College London

Professor Deborah Ashby, Director of the School of Public Health, Imperial College London

Dr Rachel Scott, Research Fellow in Demography, London School of Hygiene and Tropical Medicine

Dr Francesca Cavallaro, Research Fellow in Maternal and Child Health Epidemiology, University College London

Dr. Neha Singh, Assistant Professor, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Heini Vaisanen, Lecturer in Social Statistics and Demography, Department of Social Statistics and Demography, University of Southampton

Professor Veronique Filippi, Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine

Professor Caroline Free, Professor of Primary Care and Epidemiology. General Practitioner.

Dr Rudiger Pittrof, NHS Consultant in Community Sexual Health and HIV, GSTT,

Dr Sam Miles, Research Fellow, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Professor Mark Petticrew, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Professor Nicholas Mays, Professor of Health Policy, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Alicia Renedo, Assistant Professor, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Helen Burchett, Assistant Professor, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Jennie Gamlin, Senior Research Fellow, UCL Institute for Global Health

Professor Susannah Mayhew, Faculty of Public Health and Policy, London School of Hygiene & Tropical Medicine

Martine Collumbien, Associate Professor of Sexual Health Research, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Dina Balabanova, Associate Professor, Health Systems/Policy, London School of Hygiene & Tropical Medicine

Dr Ruth Lewis, Research Fellow, University of Glasgow

Dr Nambusi Kyegombe, Assistant Professor, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Carrie Purcell, Research Fellow, MRC/CSO Social and Public Health Sciences Unit, University of Glasgow

Dr Fiona Bloomer, School of Applied Social and Policy Sciences, Ulster University

Dr Jenevieve Mannell, Lecturer, Institute for Global Health, University College London

Dr Ruth Ponsford, Assistant Professor, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine

Dr Susannah Woodd, Research Fellow, Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, General Practitioner

Harriet Ruysen, Research Fellow: London School of Hygiene & Tropical Medicine & Midwife: Dumfries and Galloway Royal Infirmary

Professor Sam Rowlands, Visiting Professor, Dept of Medical Sciences and Public Health, Bournemouth University

From: psmatthancock
Sent: 28 March 2020 21:45
To: pshelenwhately [redacted]@dhsc.gov.uk>; [redacted]@dhsc.gov.uk>; Duncan, Andrea [redacted]@dhsc.gov.uk>; psmatthancock [redacted]@dhsc.gov.uk>
Cc: Covid19 Comms [redacted]@dhsc.gov.uk>; Miller, Stuart [redacted]@dhsc.gov.uk>; Davies, Mark [redacted]@dhsc.gov.uk>
Subject: RE: Urgent - lines on abortion

Hi All,

Just had an update from Jamie. He has briefed the Sunday times along the following lines:

- We will be allowing the home use of abortion pills, with the following stipulations:
  - Any abortion will require a telephone or e-consultation with a doctor
  - This change will be made on a temporary basis only and is time limited for two years, or until the crisis is over, on the same timetable as the emergency legislation. It is not permanent.
  - This applies for medical abortions up to 10 weeks as it is currently.

Jamie said No.10 were happy with this, and the ST are reflecting this in their copy. It is likely we will have fall out tomorrow depending on how this lands with the ST, so would be grateful if officials could be on hand tomorrow morning.

I appreciate this doesn't answer your question on doctors prescribing these pills from home. I think SofS will need to review the policy options on doctors prescribing from home sent up in the original sub last week again. **So would you be able to prepare a short sub for tomorrow morning on the doctors prescribing from home policy options given the new steer please?** Really sorry about the timings of this!

Just to let you know, [redacted] will be covering the Covid work in SofS office tomorrow morning.

Thanks,

[redacted]

Department of Health & Social Care

[redacted]
Covid response - SofS Private Office
(Rota system with [redacted])
E: [redacted]@dhsc.gov.uk
T: [redacted] M: [redacted]

CLEARANCE CHECKLIST

Inclusion of this checklist is mandatory. Please complete the whole list and private office will remove before putting submission in the box. A submission without it will be sent back.

***Note**: Contact names provided must have seen and approved the submission.*

Finance:
Does this involve any spending or affect existing budgets?
☐ If yes, named official:
Click here to enter text.
☐ No

Legal:
[redacted]

Communications:
Could this generate media coverage, or a response from the health sector?
☑ If yes, named official:
[redacted]
☐ No

Analysis and data fact-checking:
Does this include complex data, statistics or analysis?
☐ If yes, named official:
Click here to enter text.
☐ No

Devolved Administrations:
Will this affect Scotland, Wales or Northern Ireland?
☐ If yes, named official:
Click here to enter text.
☐ No

Fraud:
Have you considered fraud risks?
☐ If yes, named official:
Click here to enter text.
☐ No

Commercial:
Does this include commercial or contractual implications?
☐ If yes, named official:
Click here to enter text.
☐ No

Strategy Unit:
Does this relate to cross-cutting or longer-term implications for wider DH strategy?
☐ If yes, named official:
Click here to enter text.
☐ No

Implementation Unit:
Does this relate to one of the Secretary of State priorities?
☐ If yes, named official:
Click here to enter text.
☐ No

Legislation:
Does this include options that may require secondary legislation?
☐ If yes, do you have a prioritisation reference number? *(contact Parly or SOPL if unsure):*
Click here to enter text.
☐ No

Duties, Tests and Appraisals:
The following tests apply and have been considered.

☐ Secretary of State Statutory Duties, including on health inequalities
☐ Public Sector Equality Duty
☐ Family test
☐ Other(s) (please specify)
Click here to enter text.

To: SofS

From: [redacted]
Clearance: Mark Davies
Date: 29 March 2020
Copy: [redacted]
Private Office Submissions Copy List

COVID-19 AND ABORTION: APPROVAL OF WOMEN'S HOMES FOR EARLY MEDICAL ABORTION AND DOCTOR'S HOMES FOR PRESCRIBING

Issue	Following your agreement to a temporary approval of home use of both abortion pills for early medical abortion up to 10 weeks gestation, this submission seeks a steer on whether doctors should be able to prescribe both pills for treatment of early medical abortion from their homes and the terms of the approval that will be sent to providers.
Timing	Urgent (two working days) An urgent steer is required as a new temporary approval needs to be sent to providers and stakeholders as soon as possible.
Recommendation	To limit transmission of COVID-19 and ensure access to early medical abortion services, we recommend that you use your powers under the Abortion Act 1967 to temporarily approve the home of a doctor as a class of place where both abortion pills can be prescribed for the treatment of early medical abortion up to 10 weeks and agree the updated temporary approval at annex A.

Discussion

1. You have agreed to use your powers under the Abortion Act 1967 to temporarily approve women's homes as a class of place where both abortion pills can be taken for early medical abortion up to 10 weeks. This is a temporary approval and is time limited (see paragraph 4).

2. This submission seeks a decision on whether you are content to also approve, on a temporary time limited basis, the home of a registered medical practitioner (a doctor) as a class of place where both abortion pills can be prescribed for the treatment of early medical abortion up to 10 weeks. This will also be a temporary approval (see paragraph 4). This approach was previously supported by No10 and MS(C). Providers and stakeholders are likely to seek urgent clarification on this point. It was included in the temporary approval circulated on Monday 23 March that has now been withdrawn.

3. If you are content to approve, the temporary approval at Annex A will be sent to abortion providers from a senior DHSC official and also to stakeholders and published on gov.uk. This will include approval of both: women's homes as a class of place where both abortion pills can be taken for early medical abortion up to 10 weeks gestation; and the home of a doctor as a class of place where both abortion pills can be prescribed for the treatment of early medical abortion up to 10 weeks. Providers must also ensure that a telephone or e-consultation with a

doctor takes place as part of the certification process. As with existing practice, this may be a consultation with a nurse or midwife acting under the instruction of a doctor (currently only doctors are allowed to perform abortions, but midwives and nurses sometimes undertake the consultation acting under the instruction of a doctor). Two doctors must always review the information from the consultation and agree that there are grounds under the Abortion Act 1967 before the abortion can proceed.

4. The temporary approval at Annex A sets out that the approval of women's homes for taking both abortion pills and doctors home's for prescribing medication up to 10 weeks gestation **is not permanent**. The temporary approval at Annex A sets out that **the approval expires 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**.

Enabling doctors to prescribe medication for early medical abortions at home

5. The Abortion Act 1967 permits abortions to be performed in NHS hospitals or a place approved by the SofS. The courts have ruled that this includes the whole course of treatment (including prescribing). The Act also sets out that abortions can only be carried out by doctors. This means that a doctor has to be located within an approved clinic or hospital in order to prescribe abortion medication.

6. We have been told that large numbers of doctors are now self-isolating. **We therefore recommend that you agree to include in the updated temporary approval the home of a registered medical practitioner (a doctor) as a class of place where both abortion pills (Mifepristone and Misoprostol) can be prescribed for the treatment of early medical abortion. We will be clear that the temporary approval expires 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**.

7. This will enable doctors who are self-isolating but well enough to work to prescribe medication from their home. Their home would be approved as a class of place only for prescribing the medication. Approval of this measure alongside would enable medication to be prescribed by the doctor in their home in any of the following circumstances:

    a. A woman has attended a consultation in a clinic or hospital; or

    b. A woman has had a consultation with a clinic or hospital via video link, telephone or other electronic means; or

    c. A woman has had a consultation with a doctor (who is self-isolating in their home) via video link, telephone or other electronic means.

8. This approach has strong consensus support from abortion providers, the Royal College of Obstetricians and Gynaecologists and PHE. As above, the use of telemedicine is supported by NICE abortion guidance.

9. Whilst this measure is less controversial than home use for both abortion pills, it may still be viewed as controversial by pro-life organisations and MPs. However, our advice is that this measure is necessary in the COVID-19 context and is in line with clinical evidence. This measure will be supported by pro-choice organisations and it is likely that these organisations will put pressure on DHSC to extend this measure after COVID-19. As with home use for both abortion pills,

we will be clear that the temporary approval at Annex A is not permanent, and expires 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.

Legal [redacted]

10. [redacted]

11. [redacted]

12. [redacted]

Public Sector Equality Duty

13. In making any decisions or exercising any other functions, ministers must comply with the public sector equality duty ("PSED") in section 149 of the Equality Act 2010. When exercising functions relating to the NHS, the SofS must also comply with general duties under the NHS Act 2006 and with the Families Test.

14. This policy will have a positive impact on the need to eliminate discrimination between sexes. It is important to note that women and girls still have the option of attending a clinic to take the first, or both, abortion pills, which will foster good relations between different groups of women and girls. This policy forms a part of our efforts to ensure no groups are disadvantaged in the current COVID-19 crisis. A more detailed PSED analysis is being developed.

Communications – [redacted]

15. The abortion guidance, and its subsequent change this week, has received significant media interest from the majority of nationals over the past few days, with several journalists asking for our response on the guidance changes. We

anticipate that this further amendment will also receive interest from both stakeholders and media.

16. If this is agreed to, Media Relations will prepare a robust reactive line emphasising this importance of this new guideline, but also that patient safety is still a priority and this is a temporary measure. We will also prepare a Q&A for use in case approached by media on the specifics. Everything will be cleared appropriately through SpAds and No.10.

17. External Affairs will pre-brief relevant stakeholders ahead of the new guidance being published, so that they're aware of the changes being made and can inform their members accordingly.

Conclusion

18. To limit transmission of COVID-19 and ensure access to early medical abortion services, we recommend that you:

    a. Use your powers under the Abortion Act 1967 to temporarily approve the home of a doctor as a class of place where both abortion pills can be prescribed for the treatment of early medical abortion.

    b. Agree the draft temporary approval for early medical abortion which includes women's homes for taking both treatments and doctors home's for prescribing medication up to 10 weeks gestation at Annex A.

Department of Health & Social Care

The Abortion Act 1967 - Approval of a Class of Places

This approval supersedes the approval of 27 December 2018. This approval has effect until the earlier of the end of the period of 2 years beginning with the day on which it is made or the day on which the temporary provisions of the Coronavirus Act 2020 expire.

The Secretary of State makes the following approval in exercise of the powers conferred by section 1(3) and (3A) [1]of the Abortion Act 1967[2]:

Interpretation

1. In this approval –

"home" means, in the case of a pregnant woman, the place in England where a pregnant woman has her permanent address or usually resides or, in the case of a registered medical practitioner, the place in England where a registered medical practitioner has their permanent address or usually resides;

"approved place" means a hospital in England, as authorised under section 1(3) of the Abortion Act 1967, or a place in England approved under that section.

Approval of class of place

2. The home of a registered medical practitioner is approved as a class of place for treatment for the termination of pregnancy for the purposes only of prescribing the medicines known as Mifepristone and Misoprostol to be used in treatment carried out in the manner specified in paragraph 4.

3. The home of a pregnant woman who is undergoing treatment for the purposes of termination of her pregnancy is approved as a class of place where the treatment for termination of pregnancy may be carried out where that treatment is carried out in the manner specified in paragraph 4.

4. The treatment must be carried out in the following manner-

a) the pregnant woman has-

i) attended an approved place;

[1] Section 1(3A) was inserted by section 37(3) of the Human Fertilisation and Embryology Act 1990 (c. 37).
[2] 1967 c. 87.

ii) had a consultation with an approved place via video link, telephone conference or other electronic means, or

iii) had a consultation with a registered medical practitioner via video link, telephone conference or other electronic means; and

b) the pregnant woman is prescribed Mifepristone and Misoprostol to be taken for the purposes of the termination of her pregnancy and the gestation of the pregnancy has not exceeded nine weeks and six days at the time the Mifepristone is taken.

Mark Davies

Director, Population Health

20 March 2020

Department of Health & Social Care

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b) the pregnant woman is prescribed Mifepristone and Misoprostol to be taken for the purposes of the termination of her pregnancy and the gestation of the pregnancy has not exceeded nine weeks and six days at the time the Mifepristone is taken.

Mark Davies

Director, Population Health

20 March 2020

From: psmatthancock <[redacted]@dhsc.gov.uk>
Sent: Sunday, March 29, 2020 8:50 pm
To: [redacted] Duncan, Andrea; psmatthancock; pshelenwhately
Cc: DL - Private Office Submissions Copy List; Davies, Mark; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]
Subject: RE: Urgent abortion submission - doctor's homes and temporary approval

Hi [redacted],

Thank you for working on this. SofS has approved doctors' homes as places where abortion prescriptions can take place. He wants to use the approval titles "option 2" aswell. He has asked that it go tomorrow morning.

Thanks,

[redacted]

Department of Health & Social Care

[redacted]

Covid response - SofS Private Office

(Rota system with [redacted])

E: [redacted]@dhsc.gov.uk

T: [redacted] M: [redacted]