20 February 2021

Abortion Consultation
Ministerial Correspondence and Public Enquiries Unit
Department of Health and Social Care
39 Victoria Street
London
SW1H 0EU
United Kingdom

Dear Sir/Madam

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

We, the undersigned, are responding to the consultation on behalf of Christians in Pharmacy (CiP). CiP is a growing network of 127 pharmacists, pharmacy technicians, pharmaceutical scientists, and non-technical professionals working in all areas of Pharmacy and in the pharmaceutical world.

In terms of the process, a draft was prepared by the undersigned, who are members of the leadership team. This was then circulated to the leadership team of four pharmacists (one of whom is retired). After receiving preliminary comments, the draft response was then circulated to the entire membership for comments and suggestions. After the closing period for this internal consultation, the final draft (as attached) is now sent to you as the official response from the Christians in Pharmacy network.

In summary, we believe that the government should **IMMEDIATELY END** the temporary measure to allow women to perform their own abortions at home. We base our opinion on medical, ethical, professional, safeguarding and legal reasons (as detailed in the attached document). We believe, based on the information presented below, that continuing to allow this practice puts the welfare of women and women's health in jeopardy.

Please note that, for the convenience of the reader, many of the references supporting the statements made in the document also contain clickable links.

Yours faithfully,

David Clapham (Mr.) *BPharm*.

Chik Kaw Tan (Dr.) *BPharm MSc PhD PgCertMedEd PgCertPsychTherap*

On behalf of Christians in Pharmacy

1. INHERENT MEDICAL RISKS

1.1 Complications of medical abortion

Even under conditions where abortifacients are administered (at least for the 1st part of the treatment) under close medical supervision, complications after medical abortion are four times higher than after surgical abortion[1]. We believe the risk to women is substantially increased beyond this level primarily due to the use of remote consultations and the unsupervised administration of all the tablets at home.

1.2 Pre-screening.

Prior to treatment being initiated (as required by the licensing agreement for Mifepristone and Misprostolol)[2] a number of checks are required to ensure that the health of the mother is not compromised. These include checks that are not possible to undertake without a visit to a suitably equipped clinic, with the relevant professional staff. For example:

- Pregnancy must be confirmed by gynaecological examination, ultrasound scan or biological tests. Even where a positive pregnancy test is confirmed the possibility of ectopic pregnancy exists.
- Confirmed or suspected extra uterine pregnancy must be excluded. This can only be assured if the patient is examined. Use in the case of ectopic pregnancy can lead to serious side effects including severe bleeding. Should this be the case, immediate treatment may well be needed that will not be readily available in the patient's home.

  According to the Miscarriage Association UK, around 1 in 80 pregnancies is ectopic and for some women, it can be life-threatening[3]. Statistics provided in the government consultation document states the following[4,5]: "Between April and June 2020, there were 23,061 medical abortions where both pills for EMA were administered at home under the temporary approval, representing 43% of abortions during this time. The percentage of abortions using this method increased between April and June, accounting for 33% of abortions in April and increasing to 51% of abortions in June". Of the projected 69000 DIY abortions from April to December 2020, there is the potential possibility of 860 cases of ectopic pregnancy. The safety of pregnant women must be a serious consideration in any piece of health policy.

- In the case of female genital mutilation (FGM) a physical examination must be performed by a qualified and trained medical professional to exclude any anatomical obstacles to medical abortion[2]. Clearly this cannot be achieved via telemedicine but the woman requesting the abortion may not self-report her FGM.
    - FGM is illegal in the UK. There is little information on the number of women who've had FGM performed illegally or before their emigration to the U.K, whether voluntarily or coerced. In either case they may not report due to fear of legal and social consequences.
    - A significant number of them may not have sufficient command of English and need an interpreter, family member, or friend/acquaintance to speak on their behalf. This raises potential problems with safeguarding issues.
    - They may not consider it relevant.

  Medical abortion is highly risky for this group and clearly poses a threat to vulnerable ethnic and religious minority groups.
- The genital tract is more susceptible to ascending infection when the cervix is dilated after abortion or childbirth. Any reproductive tract infections (especially STIs) should be treated before the medical abortion regimen is administered. Telemedicine consultations may well miss the possible need to co-administer antibiotics with possible serious long term sequalae for future fertility. Severe Pelvic Inflammatory disease is a risk to some patients.
- A range of other contraindications and warnings must be excluded before treatment begins such as[2]:
    - severe asthma uncontrolled by therapy
    - well controlled asthma may need adjustment of treatment since the anti-glucocorticoid activity of mifepristone can reduce the efficacy of long-term corticosteroid therapy (including inhaled corticosteroids)

- chronic adrenal failure
- inherited porphyria
- renal failure
- hepatic failure
- malnutrition

  It is again possible that these aspects will be missed under a telemedicine consultation whereas many can be picked up in a face-to-face consultation with a trained medical professional.
- There is a small risk of allergic reaction to prostaglandins or hypersensitivity to one of the active ingredients or excipients. Any such allergic reaction could well constitute a medical emergency with the potential requirement for resuscitation.

Given the above medical and pharmacological risks there is a clear need that medical abortions "should only be performed where the patient has access to medical facilities equipped to provide surgical treatment for incomplete abortion or emergency blood transfusion or resuscitation"[2] if required. Clearly a patient's home is not such an environment.

Another aspect that needs to be considered here is that studies have shown that valid NHS numbers for the clients are not obtained by abortion providers (as confirmed in a 'mystery client' report[6]). As the medical history of the client cannot be confirmed, the abortion provider is entirely dependent on the client's knowledge of her medical condition which may be limited or inaccurate. In view of the contraindications listed above, remote consultation is medically unacceptable. All women need to have an in-clinic assessment as part of their abortion care pathway. Failure to do so risks damage to the woman's health and wellbeing and has worrying potential professional and legal implications for health care professionals. Please also see sections 4 and 5.

1.3. Gestational age.

Medabon (the combination abortion treatment pack containing mifepristone and misoprostol) "**should never be prescribed in pregnancy beyond 63 days of amenorrhoea**"[2]. This is a legal and therapeutic requirement.

The implementation of a fully remote telemedicine process means that assessing the gestational age now depends solely on the woman's accurate and honest recall and disclosure of the first day of her last period. Previously, the use of an ultrasound scan would have confirmed an accurate gestational age. To rely solely on self-assessment, on so serious and irreversible a course of action, is inherently unsafe.

The gestational age may not be correct due to genuine error of recall. Pregnancy can be a stressful time and, under extreme stress, it may be very difficult for the woman to accurately recall the exact date of her last period. This is even more difficult for those whose periods are normally irregular.

However, unless the person presenting is seen by a medical professional there is a clear risk that the client may deliberately misrepresent the gestational age either for themselves or even potentially on behalf of someone else.

Compliance with this time limit can be vital for the health of the woman. BPAS data[7]indicates that there is a disproportionate exponential increase in serious side effects that can result from giving the medicine just within 7 days after 9 weeks of pregnancy:(see Table below)

	Up to 9 weeks	9-10 weeks
Take 1st medication (mifepristone)	In clinic, by mouth	In clinic, by mouth
Take 2nd medication (misoprostol)	1-2 days interval in the vagina or between cheek and gum	1-2 days interval in the vagina or between cheek and gum
Complete abortion	97 in 100	93 in 100
Potential risks		
Continuing pregnancy	1 in 100	3 in 100
Retained pregnancy tissue	2 in 100	3 in 100
Needing surgical treatment to complete abortion	3 in 100	7 in 100
Side effects		
Nausea	29 in 100	50 in 100
Vomiting	9 in 100	46 in 100
Diarrhoea	5 in 100	17 in 100
Warmth/chills	15 in 100	33 in 100
Headache	18 in 100	18 in 100
Dizziness	9 in 100	7 in 100
Follow-up	Self assessment with pregnancy test in 2 weeks or In-clinic ultrasound scan in 1-2 weeks	In-clinic ultrasound scan in 1-2 weeks

Although it might be expected that patients would respect the need to conform to the gestational time limit, there is growing evidence that this may not be the case. A Freedom of Information request to the DHSC revealed 52 incidences[8] of these pills being taken illegally after 10 weeks' gestation**.** Of these there was a small number of cases where medical abortion at home took place far beyond this cut off time; these include a child aborted at 28 weeks in the Midlands[9], another at

30 weeks, and another born at 32 weeks which was treated as a murder investigation[10]. None of these were recorded in official statistics.

These last two late abortions were revealed in an e-mail[10] sent by a senior midwife at the NHS, which confirms that women are presenting at hospital with complications after taking the tablets later than the gestational limit (see Appendix). The same e-mail includes a report of one woman who had unfortunately died at home the morning after starting the process and another who died after presenting at A&E with sepsis.

1.4 Risks even when tablets are taken correctly

Even when used correctly the treatment is subject to a significant level of side effects which can range from distressing to life threatening. These may not be explained properly to the client in a telemedicine procedure and even if they are, it is not possible to pick up on the non-verbal cues that can confirm a proper understanding by the client.

Where it is not just confined to the strengths used in Medabon both the active ingredients have received a significant number of reports of adverse events using the "yellow card" (Report of Suspected Adverse Drug Reaction) reporting scheme. This scheme allows a member of the public or a healthcare professional to alert the MHRA of a suspected adverse drug reaction. Not all adverse events are reported via the scheme. However, the data that is provided via this route allows the MHRA to monitor the safety of treatment in practice. Access is freely available[11] and there are no 'log in' restrictions. Summary data from this source shows a rather large number of reports including serious adverse drug reactions (ADR):

Mifepristone[12]

- Total number of reactions: 843 - Total number of ADR reports: 294
- Total number of serious ADR reports: 253 - Total number of fatal ADR reports: 17
- Reports processed up to: 31-Dec-2020

Misoprostol[13]

- Total number of reactions: 4338 - Total number of ADR reports: 2315
- Total number of serious ADR reports: 1043 - Total number of fatal ADR reports: 70
- Reports processed up to: 31-Dec-2020

There have been increasing admissions to hospitals of women suffering from complications arising from taking abortion pills at home, including haemorrhage and sepsis[14]. The Summary of Product Characteristic (SPC/SmPC)[2] for Medabon states that 'Heavy bleeding occurs in up to 5% (i.e. 5 in 100) of the cases and may require haemostatic curettage and blood transfusion in up to 1.8% (1.8 in 100) of the cases'.

Another issue is that there is a small but significant risk of treatment failure. The SPC for Medabon[2] states that there is a "non-negligible risk of failure, which occurs in 4.5 to 7.8% (i.e. 4.5 in 100 to 7.8 in 100) of the cases"[2]. Between April and June 2020, there were 23,061 medical abortions where both medicines (mifepristone and misoprostol) were administered at home[4,5]. Of the projected 69000 DIY abortions from April to December 2020, there were likely to be between 3100 to 5400 such cases.

Due to this risk of failure of complete abortion it may be necessary to give additional tablets that are unlikely to be available in a patient's home or to follow up with surgical intervention. In either case a follow up appointment is required to ensure that complete abortion has been achieved. Indeed the SPC for Medabon[2] states this: "The non-negligible risk of failure…. makes the follow-up visit mandatory in order to check that abortion is complete." This follow up is unlikely to be carried out under the current 'pills at home' arrangements. Retention of 'products of conception' can lead to life threatening infection.

Another less serious, but very common, side effects is pain. For this reason, Codeine is often co-prescribed for pain relief. Patients are also advised to use Paracetamol or Ibuprofen purchased 'over-the-counter' if they assess the pain is such that it does not require treatment with Codeine. Each of these medicines (for abortion and for pain) comes with its specific instructions and carry its specific sets of risks and contraindications. There is a risk of dependence with the use of codeine[15] and effects on gastric motility can lead to constipation and possible disruption of the absorption of some other medications. Thus there is a need for suitable counselling on administration of this analgesic which is unlikely to be given in the case of delivery of tablets by post.

All these side effects carry a significant risk of adversely affecting the woman's mental health at a time which is already characterised by high levels of stress. Therapeutic and pharmacological risks must never be downplayed. The issues of access should never over-ride the safety of the woman.

1.5 Risk of poor treatment compliance

Non-compliance with drug treatment is widespread. When patients are given medication by their doctors, nearly half do not take the drug or do not take it as prescribed[16]. Lack of compliance with the correct treatment protocol will only worsen the risks outlined above. The failure rate will no doubt be exacerbated by women who are unfamiliar with the optimum way to take the medication correctly if unsupervised. The dosage regimen, whilst not overly complicated, does involve the use of two products (mifepristone and misoprostol) which must be taken in the correct sequence, at the correct interval, and in the manner instructed (orally, buccally and/or intravaginally). Together with these, there are instructions for use of the pregnancy test device, along with the overall plethora of instructions. There is a strong likelihood of non-compliance with the regime for a woman at home, as they are: without the professional support they would have had in an in-clinic environment, potentially without privacy, potentially in the presence of an abusive partner or coercive family members. This can lead to therapeutic failure and increased side-effects.

2 ETHICAL ISSUES

2.1 Trivialising the risks

Talking to The Radio Times[17] in September, Clair Murphy, head of public affairs at the British Pregnancy Advisory Service (BPAS), stated (amongst other things) that home abortion is safe. "The safety of this medication (mifepristone and misoprostol) is absolutely establishment. It's safer than many medications that you get in a pharmacy. It's safer than Viagra for example and no one is calling for safer restrictions than that… There are absolutely no safety concerns about this".

This comment cannot be quantified and is not backed up evidence. Further, the statement seriously understates the risks of this procedure and misleads the public; women are not prepared for what the treatment actually entails.

Given the variability of human biology, it is not true for any medicine that "there are absolutely no safety concerns about this". The data given in the SPC[2] (Summary of Product Characteristics) clearly indicates otherwise. The use of medication can be undertaken only **RELATIVELY** safely and only in strictly defined and appropriate circumstances. Medabon is commonly associated with gastrointestinal disturbances such as nausea, sickness, diarrhoea, stomach cramps, and the potentially more serious side effect of heavy vaginal bleeding and incomplete abortion. Specifically, the health of the mother is compromised in severe and prolonged heavy bleeding. This will require immediate medical intervention which will not be possible in a patient's home environment.

Other misleading or incorrect statements are made on the BPAS web site (under the heading "Pills by Post – Abortion Pill treatment at home" [18]. In the section on "Significant unavoidable or frequently occurring risks" statements are made that do not concur with the SPC for Medabon. For example

- Failure rate

BPAS: Continuing pregnancy (less than 1 in 100, up to 3 in 100 between 9 and 10

weeks' gestation)
SPC for Medabon: Under "Warnings": The non-negligible risk of failure, which occurs in 4.5 to 7.8% (i.e. 4.5 in 100 to 7.8 in 100) of the cases.

- Haemorrhage

BPAS: Haemorrhage – very heavy bleeding (2 in 1,000)
SPC for Medabon: Under "Warnings": heavy bleeding requiring haemostatic curettage (a surgical procedure) occurs in 0.2 to 1.8% (i.e., 2 in 1000 to 18 in 1000).
Under "Undesirable side-effects" this statement is made: Heavy bleeding occurs in up to 5% (i.e., 50 in 1000) of the cases and may require haemostatic curettage and blood transfusion in up to 1.8% (18 in 1000) of the cases.

For such a serious and irreversible decision, it is vital that accurate and unbiased information is made available to the woman in a readily understood format. Even if proper information is provided there is no mechanism to ensure that it is understood by the patient without a face-to-face interaction with a trained healthcare professional.

2.2 Informed Consent - lack of assurance of validity

Consent to treatment means a person must give permission before they receive any type of medical treatment; this principle is an important part of medical ethics and international human rights law. For consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision. In the case of consent given over the phone or video, a number of issues arise:

- Has consent been given **voluntarily**? The abortion provider cannot be certain that the woman is not being coerced to give consent by an abusive partner, coercive family members, or even a well-meaning friend. Vulnerable women cannot properly consent if their home environment is not conducive to it.
- Is the consent given adequately **informed**? For example, is the home environment conducive to privacy and confidentiality, whereby a client feels free to ask questions? Does the person understand the information provided, given the lack of proximity of the professional to gauge understanding? In a clinic face-to-face clinic environment, confidentiality and lack of coercion can be ensured, along with the non-verbal signals which can indicate to the healthcare professional whether the patient has understood the risks and potential complications of medical abortion.
- Has the woman the **capacity** to give consent? Valid NHS numbers for the clients are not obtained by abortion providers during a remote consultation (as confirmed in a 'mystery client' report[6] commissioned by Christian Concern). If providers cannot confirm the identity of the woman requesting the abortion pills, the social and medical history of the person is unknown. The abortion provider cannot, therefore, be certain of the capacity of the person in question (without the medical history).

Informed consent also requires that the woman be given fair and unbiased advice that other options are available and should be considered before the final decision to undergo an abortion. There is no evidence that women are being offered advice and information around alternative options to abortion when faced with an unwanted pregnancy. A telemedicine consultation is focussed on medical treatment rather than information and support.

2.3 Lack of safety

Although dealt with in detail above it is worth repeating that all women need to have an in-clinic assessment as part of their abortion care pathway. The SPC for Medabon[2] clearly gives the following statement of warning: "Because it is important to have access to appropriate medical care if an emergency develops, the treatment procedure should only be performed where the patient has access to medical facilities equipped to provide surgical treatment for incomplete abortion, or emergency blood transfusion or resuscitation during the period from the first visit until discharged by the administering qualified medical professional." It is ethically irresponsible to fail to provide this care.

It is worth noting that the pandemic does not make it impossible to see patients – many providers are ensuring patients with a range of conditions are seen face-to-face when necessary, using precautions such as temperature checking and use of PPE. Access is less important than the safety of women.

2.4 Treatment by stealth

In a 'mystery client' report[6] clients gave a number of legally invalid reasons for wanting an abortion and these were accepted without question by the abortion providers in the study. In terms of safety and the remit of the drug licence, this current service can be danger to women. One of the study authors, a former director of Marie Stopes International, stated that 'abortion providers are operating as if abortion on-demand for any reason is legal'. It is not.

2.5 Risk to society

More than 42 million abortions took place around the world in 2019[19]. Just between January to June 2020, there were 109,836 abortions performed on residents of England and Wales[5]. This is unacceptable and tragically high; even people who are not against abortion cannot but feel aghast at so many abortions. It says something about the prevailing attitude of British society, and the British government, that the U.K. is more concerned about greater ease of access to medical abortion, and normalising the practice into daily life, than it is at the astronomical number of abortions and the risk to women's health.

3 SAFEGUARDING ISSUES

3.1 Abuse or coercion

Domestic abuse has increased during the lockdown associated with the current pandemic. Society needs to protect vulnerable women from abusive partners, coercive family members, and even well-meaning friends who might be putting pressure on women, even adolescents and teenagers, to abort their pregnancy. The ease of obtaining the abortion pills can increase the likelihood of abuse of these pregnant women.

It must be remembered that pregnancy is already a stressful time for pregnant women. This puts them at greater risk of being coerced into having an abortion.

The government has a duty to help safeguard vulnerable pregnant women from making decisions they will regret later. This is particularly true in the harsh economic climate that many of the populace face. The lack of face-to-face support or the privacy of an in-clinic consultation renders this risk more likely.

There is widespread concern about the health, safety and welfare of women during the lockdown associated with the current pandemic.

3.2 Psychological harm

The psychological impact on a woman having an abortion at home has not been assessed. The literature reports a significant level of mental distress and regret from women who have undergone an abortion but later wish they had not. This may require a significant level of counselling and support.

Home abortion is a painful and traumatic experience for many women and their loved ones. Many women regret having had an abortion; how much more the impact of women having an abortion at home and seeing 'retained products of conception" (which are foetal and/or placental tissue that remains in the uterus after an abortion). The psychological impact of this can be devastating not only for the woman, but for a loving partner in a committed relationship.

Incidences of serious side effects (which are not rare) can have a severe psychological impact on the women concerned and their family members and spouses/partners.

The psychological and physical health and welfare of women must be paramount.

4 LEGAL ISSUES

4.1 Liability

It is not clear where legal liability lies if a patient experiences serious adverse events when taking their tablets. It is not clear how registered medical practitioners can realistically 'remain in authority and take responsibility throughout the process' as required by the Abortion Act 1967 under the current 'temporary' arrangements where consultations are via remote consultation alone. It is also not clear what liability, if any, will attach to the immediate provider of the drugs used in this procedure (such as pharmacists or other staff). When at least the 1st part of the treatment is provided in a supervised environment appropriate control can be maintained to some extent. When a patient carries out both parts of the treatment in her own home, supervision is not possible

4.2 Possibly illegal operation procedures

Licensing requirements for the drugs used cannot be guaranteed. Consent given by a woman may be invalid (see sections 2 and 3) and 'Duty of Care' requirements may be breached. The principle of duty of care means that the government and the NHS have an obligation to avoid acts or omissions which could be reasonably foreseen to injure or harm other people. This means that they must anticipate risks for their patients and clients and take due care to prevent them coming to harm. This harm encompasses both physical and emotional harm. In practice it means that the temporary measure of permitting medical abortion at home abrogates this duty of care for the following reasons: medical risks, therapeutic and pharmacological risks, non-compliance/adherence of therapeutic regime, safeguarding, psychological distress.

4.3 Remote clinical assessments

Although in a different context, that of using virtual assessments to section people under the Mental Health Act, the legality of remote assessments has been challenged and ruled inappropriate. It was reported in the online version of the Guardian on 30 January 2021[20] that hospital trusts in England have been told to stop using virtual assessments to section people under the Mental Health Act after a judge ruled them unlawful.

The Department of Health and Social Care had issued guidance in November indicating that this method could be used as part of an evaluation during the pandemic. However, concerns about the legality of the practice have now been upheld.

In a similar manner, we believe that remote consultations for home use of abortion pills via webcam or telephone may not be legal.

Further, there is a current legal challenge to the government's DIY abortion policy being petitioned at the Supreme Court by Christian Concern. The aforementioned ruling on a core mental health assessment practice raises, not only legal issues, but grave safety and safeguarding concerns.

5. PROFESSIONAL REASONS

5.1 Coercion of Pharmacy and non-Pharmacy staff

There are hospital and clinic staff who have strong ethical and religious reasons for not wanting to be involved with the abortion process. For example, pharmacists and pharmacy technicians who are conscientious objectors may be coerced into the clinical review and supply of the abortion drugs. Even non-pharmacy staff may be forced to participate in the posting of the abortion pills.

5.2 Invidious position of medical staff

Based on the procedures for home use of both pills for early medical abortion, doctors are put in a difficult professional, clinical, and legal position on two counts:

5.2.1 Remote prescribing

The GMC guidance on remote prescribing[21] (via telephone, video-link or online) is that a doctor *"must satisfy yourself that you can make an adequate assessment, establish a dialogue and obtain the patient's consent in accordance with the guidance…".* Further the doctor may prescribe only when *"you have adequate knowledge of the patient's health"* and consider *"the need for physical examination or other assessments"* and *"whether you have access to the patient's medical records."*

5.2.2 Off-label prescribing

The use of Medabon (combination of Mifepristone and Misoprostol), based on the procedures for home use of both pills for early medical abortion, is clearly outside the terms of its UK licence[2]. Using drugs "off-label" is often linked with increased risk. Hence, when prescribing an unlicensed medicine, the GMC guidance[21] states that the doctor must "*take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment".* (The term 'unlicensed medicine' is used to describe medicines that are used outside the terms of their UK licence or which have no licence for use in the UK.).

The importance of informed consent is emphasised in the guidance[21]. Good practice requires a prescriber informing patients that they are taking the medicines "off-label".

Similarly, before using a medicine "off-label", the MHRA advises prescribers to *"take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring and follow-up."*[22] Informed consent is emphasised.

In addition the clinicians prescribing and dispensing are liable for their use. The dispensing pharmacy may also legally share some of this liability (see 4.1)

In SUMMARY, we believe that the temporary measure allowing for home use of both pills for early medical abortions (EMA) up to 10 weeks' gestation:

- Is unsafe,
- Does not provide the best quality of care for patients,
- Does not provide sound management, organisational and clinical governance arrangements including issues such as child and adult safeguarding,
- Risks seriously damaging women's health and well-being,
- Is potentially illegal.

We therefore urge the government to **END IMMEDIATELY** the temporary measure enabling home use of both pills for EMA.

Appendix

From: [redacted] (NHS ENGLAND & NHS IMPROVEMENT - X24)
[mailto:[redacted]@nhs.net]
Sent: 21 May 2020 09:34
Subject: FW: URGENT Information and Action re: Pills in the Post ToP service
Importance: High

Please be vigilant when reading emails. To reduce the risk of virus infections, only access links that you are confident are safe and are from known sources.

To: GM CYP Clinical Director's and Heads of Nursing

Dear All,

Below is some feedback from the CMO in [redacted] about an issues which is building linked to the Pills in the Post ToP service.

[redacted] the CMO for [redacted] met with the CQC on behalf of all Regional CMO's yesterday and has since shared that the CQC have been aware of an escalating risk around the 'Pills by Post' process for TOP during Covid, especially the process linked to 3 independent providers, BPAS, Marie Stopes and NPAS, since the 1st May 2020. This led to an abortion task force meeting last week and a review by the RCOG also last Friday. There was an indication that there had been a judicial review that Ministers are also being kept updated.

[redacted] shared that the CQC indicated that they are aware of 13 incidents related to this process, which when compared to the number of TOPs using Pills by Post (circa 16,000 since March) is a very small number, though recognising that the impact of poor outcomes for women is tragic.

[redacted] herself had been made aware of 10 incidents across 6 organisations on her DOMs calls and forwarded the list of those incidents to the CQC so that they can x-ref with their list if they are already known. In [redacted] we are aware that there have been 2 maternal deaths linked to this issue also. One case where a woman was found at home the morning after starting the process and the second where a woman presented with sepsis and died very quickly in the A&E dept. Neither of these women were known to our maternity or gynae services as far as we are aware.

The incidents in [redacted] range between women attending ED with significant pain and bleeding related to the process through to ruptured ectopics, major resuscitation for major haemorrhage and the delivery of infants who are up to 30 weeks gestation. There was also a near miss where a woman had received the pills by post and then wished for a scan so attended a trust and was found to be 32 weeks. There are 3 police investigations in [redacted] linked to these incidents and one of those is currently a murder investigation as there is a concern that the baby was live born. The PM is being undertaken by a home office pathologist.

[redacted] reports that it was clear on the call that the only reporting of incidents, to the CQC, from this sector are those that are significant i.e. babies that are found to be a late TOP, as all the other outcomes are seen to be a complication of the process which could occur in any setting. There is therefore no data to compare current outcomes to.

Given the perceived small numbers of incidents there is concern that there is a risk of changing the process and that having a greater impact on women and girls choices. There is therefore a real need for us to better understand the outcomes for the women who are presenting to NHS services. The balance of risk both physically , mentally and for safeguarding is challenging especially without data.

The CQC will present the issue to Nigel Acheson as Deputy Chief Inspector of Hospitals and the link to the RCOG to consider a joint letter being sent to all NHS Trusts about this concern and will be setting up a reporting process. As this may take some time to set up, therefore an interim process is needed.

I have therefore been asked as the Regional Chief Midwife to:

1. Request that the D/HoMs alert the ED, EPAU, Obstetric team and paediatric services within the trust to be aware of any presentations of girls and women to their services with complications of this process

2. Ask if the D/HOMs would capture any reports from their organisation

3. Request that all the incidents collected by the D/HoMs is passed to the Regional Chief Midwife who can pass the incident to me for onward dissemination to the team who are working on this

I would be grateful for your support with this request.

Finally I would like to ask any of you who may be aware of any such similar cases already, that I am not aware of to please contact me asap so we can keep a record of the issues in [redacted] pertaining to this issue and if necessary inform the CQC.

BW
[redacted]

[redacted] Regional Chief Midwife
Professional Midwifery Advocate
NHS England & NHS Improvement

Email: [redacted]@nhs.net Mobile: [redacted]
Twitter: @[redacted] https://twitter.com/[redacted]

Links to online resources COVID-19

[redacted]	RCOG – Landing Page for all Infection and Pregnancy guidance	Link
[redacted]	RCM - Landing Page for all covid-19 guidance	Link
[redacted]	Refer patients for help from NHS Volunteer Responders	Link
[redacted]	SBLCBv2: Covid-19 information	Link
[redacted]	Revised Guidance PPE – from PHE Infographic PPE	Link Link
[redacted]	HEE - Landing Page for Covid-19 training programme for health and care workforce	Link
[redacted]	NHS Specialty guidance during the pandemic - landing page for all specialties	Link

References

1. Skop I. Medical Abortion: What Physicians Need to Know. *Journal of American Physicians and Surgeons* 2019; **24** (4): 109-113. *https://jpands.org/vol24no4/skop.pdf* (accessed 5 February 2021)

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