

Hospital Treatments for Complications from Early Medical Abortion.

1. Introduction.

In this briefing we bring you three new sets of data about early medical abortion services being provided across England and Wales. Our analysis will help to inform those responding to government consultations, which ask for your views on whether or not the temporary measure introduced during the COVID-19 pandemic, allowing women and girls to take both pills for an early medical abortion at home, should be made permanent. In summary:

- a) Data from a freedom of information (FOI) request to the Care Quality Commission (CQC) show that it investigated 29 serious incidents where women who had accessed early medical abortion (EMA) had suffered complications; 17 of these women had accessed the pills-by-post process, in which the abortion treatment is posted to a woman after only a phone consultation.
- b) These CQC data reveal 19 cases in which women were being treated in hospital for complications arising from early medical abortion in which the gestational age (GA) of the pregnancy was greater than the legal limit for EMA of 9-weeks-6-days, including four cases in which the GA was beyond 24 weeks. The CQC disclosed that 11 of these 19 cases were resulting from women accessing the pills-by-post process; each of these 11 cases were in breach of the temporary approval given by the Secretary of State for the Department of Health and Social Care on 30 March 2020.
- c) Data from FOI requests to NHS Ambulance Services indicate that on average 36 women make 999 calls every month seeking medical assistance for complications arising from the taking of abortion pills; each month across England and Wales there are an average of 20 ambulance emergency responses for complications related to medical abortion at home.
- d) FOI data from NHS Hospital Trusts reveal that every month 495 women attend hospital with complications arising from retained products of conception (RPOC), which is when the abortion pills have failed to complete the abortion and parts of the embryo/fetus and/or the placenta remain in the uterus. Each month, 250 women using the abortion pills at home will require hospital treatment to surgically remove retained products of conception (ERPC). Our analysis shows a 2020 rate of 2.4 ERPC per 100 medical abortions, which is consistent with previously published rates.
- e) FOI data from NHS Hospital Trusts reporting on the numbers of women being treated for complications of haemorrhage and sepsis arising after medical abortion suggest a complications rate of 7.5 per 1,000, five times higher than the rate reported by the DHSC (1.5 complications per 1,000 medical abortions).

These data tell a different story from the one being published by the major abortion providers, often quoting a DHSC report of just one complication in 23,000 abortions using the pills-by-post process during Q2 2020.^{1 2} We show that these data are being underreported; the CQC states at least 13 complications arising from pills-by-post in the same time period and the ambulance service reports 20 emergency responses each month to women at home with complications arising from the administration of abortion pills.

¹ Source: <https://www.newstatesman.com/politics/health/2020/12/how-pandemic-revolutionised-abortion-access-uk>

² Source: <https://www.bpas.org/media/3417/england-ema-consultation-template-response-december-20.pdf>

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It would be simple for the DHSC to gather these data from NHS Hospitals and Ambulance services and to use these alongside the data on the HSA4 forms from the abortion providers when it is considering the safety and effectiveness of medical abortion at home. Continuing to conduct a public consultation without fully considering and assessing all available data does not seem to be a prudent or proper approach.

2. Freedom of Information Request to CQC.

We made a Freedom of Information Act (FOIA) request to the Care Quality Commission (CQC) on 4 December 2020 and received a response on 6 January 2021. This FOI request followed on from an earlier email exchange between our researcher and the CQC in late November 2020.

During the period 1 April to 30 November the CQC was notified by NHS England and Improvement of 29 serious incidents³ in which women who had accessed early medical abortion had suffered complications; 17 of these were cases in which the women had used the pills-by-post process. The CQC notes that such incidents are those requiring hospital treatment for complications such as delivery of fetuses of unexpected gestation, incomplete abortion with retained products of conception, and ectopic pregnancies.

The CQC confirmed that it had also been notified of two maternal deaths in this period. One woman attended a clinic for a medical abortion on 20 March 2020 and died in hospital on 11 April 2020. The other woman attended a clinic for a medical abortion on 24 March 2020 and died at home later the same day. The CQC has clarified that neither of these women had used the telemedicine abortion service or received pills by post. We asked the CQC to provide copies of the coroners' post-mortem reports for both of these cases and received the following response:

“ We are withholding this information in accordance with section 41 of FOIA (information obtained in confidence).

However, I can advise you that the coroner's findings for the two deaths were sudden cardiac death in one case (noting that toxicology did not indicate an alternative cause of death) and Streptococcus sepsis in the other case.

The data shared by the CQC show that 19 of these serious incidents involved the delivery of a fetus with a gestation greater than expected (GGTE); 11 of which were cases in which the woman had used the pills-by-post process. The expected gestation for early medical abortion is one that is less than 10 weeks and the legal limit for use of the abortion pills at home is 9-weeks-6-days.

³ The FOI response from the CQC lists 32 serious incidents. These include two maternal deaths and one near miss, hence the noted 29 serious incidents.

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Cases with gestation greater than expected	
10-16 weeks	1
16-20 weeks	5
20-24 weeks	9
>24 weeks	4
Total cases	19

This table shows the actual gestation in the incidents being investigated.

The 11 cases arising from the use of pills-by-post can be considered illegal; even though the registered medical practitioners would have been acting in good faith when certifying these cases and prescribing the abortion pills for use at home, each case is beyond the legal limit set when the DHSC gave its temporary approval on 30 March 2020.

It is worth asking the question of how in the other eight cases, which were managed with at least one in-clinic consultation, the abortion provider could have missed the later gestation; this may indicate some gaps in training or in adherence to clinical protocols.

Four of the serious incidents were cases in which women presented at their local hospital Emergency Department with retained products of conception (RPOC), bleeding, and abdominal pain.

There are six cases in which women who had accessed an early medical abortion needed to attend hospital to receive surgical treatment for an undiagnosed ectopic pregnancy. We don't know how many of these six women used pills-by-post or how many first attended the abortion clinic. When using phone consultations, the abortion provider relies on the woman to self-assess if she has any indications suggesting an ectopic pregnancy. During an in-clinic consultation the abortion provider should be better able to spot these indications and confirm any concerns using an ultrasound scan. That said, this case rate is broadly consistent with the statement on the BPAS website⁴ that undiagnosed ectopic pregnancy might be expected in 1 in 7,000 early medical abortions.

It is worth noting that these 29 cases are only those which are known to the CQC, having been reported to it by NHS England and Improvement. There may be other incidents being managed at hospitals which are not reported to the CQC or are yet to be reported. There may be some cases in which women present with the same complications but do not disclose having taken the abortion pills, but present as if having a miscarriage – these cases would not be included in this response.

What do we learn from this?

This response from the CQC and the data it has shared confirms that the writer of the leaked NHS email, dated 21 May 2020 was correct to raise concerns about an escalating risk around the pills-by-post process, noting incidents arising from undiagnosed ectopic pregnancy and the delivery of fetuses of unexpected gestation. The CQC has provided helpful clarification about the two maternal deaths mentioned in the same email.

The CQC response shows that women will access and use the abortion pills at home beyond the legal limit of 9-weeks-6-days and some will, as a result, suffer complications requiring hospital treatment. It is worth noting that the DHSC, in

⁴ Source: <https://www.bpas.org/abortion-care/abortion-treatments/the-abortion-pill/abortion-pill-up-to-10-weeks/>

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response to FOI-1250644, reported 52 cases in the first six months of 2020 in which the gestational age was beyond the 10-week limit; 12 of these were pills-by-post cases. What we learn from the CQC response is that sometimes women having a medical abortion at these later gestational ages end up in hospital needing treatment for complications arising from these later gestations.

By reporting 11 serious incidents, when using pills-by-post, which have arisen from the delivery of a fetus with a greater than expected gestation, the CQC is confirming that even when the abortion provider is acting in good faith, they cannot be certain of the actual gestational age when relying on the woman's self-assessment during the phone consultation. One would hope that had these women had an in-clinic assessment that their later gestational age would have been confirmed and they might thus have avoided the unnecessary additional trauma of a later delivery and subsequent hospital treatment. Again, we should note that these 11 are just the serious incidents reported to the CQC, there may be others in which the gestational age was beyond 10 weeks but not reported as a serious incident to the CQC.

Given that the regulators and the abortion providers acknowledge complications arising from women taking the abortion pills at home when their pregnancies are beyond the 10-week limit, it would be better for the safety and wellbeing of women to revert to the prior arrangements in which women must have an in-clinic assessment for eligibility before being prescribed the abortion pills.

In this response the CQC details 13 serious incidents in the period 1 April to 30 June, in which complications arising from the self-administration of the abortion pills at home, using the pills-by-post process, needed to be treated in hospital. This can be compared to the one complication reported by the DHSC using the HSA4 forms from the abortion providers, in the same period; data which were revealed in response to FOI-1260054⁵. This might support an assertion that the DHSC is underreporting the incidence of complications because of timing; the HSA4 forms are submitted before the self-administration of the abortion pills at home and thus before the subsequent complications start.

3. West Midlands Police Enquiry.

Our researcher asked the West Midlands Police about the police investigations mentioned in the leaked NHS email, dated 21 May 2020. The following response was received on 30 November 2020.

“ In April this year [2020], we were alerted to a stillbirth in Erdington that may have been caused from medication being taken to induce a miscarriage, despite the mother knowing they were too far gone to have an abortion. Enquiries into this remain ongoing.

Our subsequent requests for further information and clarification were answered:

“ We're unable to comment as the investigation is ongoing.

⁵ Source: <https://www.gov.uk/government/statistics/abortion-statistics-during-the-coronavirus-pandemic-january-to-june-2020>

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4. Ambulance Service NHS Trusts FOI Request.

We made FOI requests to the Ambulance Service NHS Trusts across England and Wales asking for data on calls received and responses made, for cases in which the problem stated by the caller included references to the words 'abortion Pills', 'mifepristone' or 'misoprostol'.

To date we have received responses from NHS Trusts which provide ambulance services to a total 13.7% of the population of England and Wales. Data has been received for the periods April to December in 2020 and also in 2019. The following table show these data extrapolated annually across England and Wales.

England and Wales	
2019 Emergency Calls Received	282
2019 Ambulance Responses	203
2020 Emergency Calls Received	435
2020 Ambulance Responses	242

It is worth noting that the calls in 2020 are 54% higher than the same period in 2019. Ambulance responses are 19% higher year-on-year, notwithstanding the fact that ambulance responses in general are down by 25% during the lockdowns in 2020 when compared with the same period in 2019.

What do we learn from this?

Based on official DHSC data⁶, the five-year average for complications treated in hospital is 1.6 complications per 1,000 abortions, when counting all abortions. When just considering early medical abortion this rate is lower, 0.74 per 1,000.

We don't know if the women making these calls had first attended an abortion clinic for a medical abortion or had used the pills-by-post process, nor do we know the gestational age of their pregnancy at the time of the abortion. We do know that the reason given by the callers was complications arising from a medical abortion.

Using DHSC data for all medical abortions⁷ and applying these to the population served by the responding NHS Trusts, we find 1.3 complications requiring hospital treatment for every 1,000 women having a medical abortion.

One might expect that those women taking both abortion pills in a clinic or hospital might not be the ones phoning for an ambulance, so when these women are discounted, the rate is 1.9 complications requiring hospital treatment for every 1,000 women having a medical abortion, where one or both of the abortion pills are taken at home.

These rates in the range 1.3 - 1.9 complications per 1,000 abortions are similar to the average 1.6 reported by the DHSC over the last five years.⁸ We note that this is

⁶ Source: <https://www.gov.uk/government/collections/abortion-statistics-for-england-and-wales>

⁷ All medical abortion including those taking both pills at home, those taking the first pill in a clinic followed by the second at home, and those taking both pills in a clinic or hospital.

⁸ Source: <https://www.gov.uk/government/collections/abortion-statistics-for-england-and-wales>

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in contrast to the claimed reduction in the complications rate being reported by BPAS.^{9 10}

The DHSC, in its response to FOI-1257670¹¹, reported one complication requiring hospital treatment for 23,061 early medical abortions in which both pills were taken at home, the pills-by-post process, during the three months April to June 2020. In a footnote to its response the DHSC says:

“ Note: complications are reported up to the time of discharge from the place of termination. Therefore complications that occur after discharge may not be recorded.

“ Note: this data should be treated as provisional, meaning that it may be subject to revision if DHSC receives further information from hospitals and clinics on missing information from HSA4 forms, or more forms are received.

The data shared by the NHS Ambulance services suggest that a rate of 1 complication in 23,061 early medical abortions is significantly underreporting the actual number of women being treated in hospital for complications arising from EMA – just as the DHSC itself has noted, complications are occurring after women have been discharged by the abortion providers; the HSA4 forms are submitted before the self-administration of the abortion pills at home and thus before the subsequent complications start.

It is important to note that some women might make their own way to their local NHS A&E rather than calling an ambulance and that some callers might not admit to abortion on the phone and say instead that they are having a miscarriage, both of which might mean that these data are not a complete record of all cases of complications arising from early medical abortion requiring hospital treatment. That said, based on these data alone, we find that each month across England and Wales there are an average of 20 ambulance emergency responses for complications related to medical abortion at home.

Daniel Kawczynski MP, asked the following written question:

“ To ask the Secretary of State for Health and Social Care, how many 999 ambulance calls were received nationwide from distressed women having taken mifepristone and misoprostol at home between 30 March and 30th November 2020; and how many ambulances were sent out.

To which Helen Whately MP, on 08 February 2021, gave the following response on behalf of the Department of Health and Social Care:¹²

“ This information is not held centrally.

⁹ Source: <https://www.newstatesman.com/politics/health/2020/12/how-pandemic-revolutionised-abortion-access-uk>

¹⁰ Source: <https://www.bpas.org/media/3417/england-ema-consultation-template-response-december-20.pdf>

¹¹ Source: <https://www.gov.uk/government/statistics/abortion-statistics-during-the-coronavirus-pandemic-january-to-june-2020>

¹² Source: <https://www.theyworkforyou.com/wrans/?id=2021-02-02.147798.h>

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It would be simple for the DHSC to gather data from the Ambulance services and to use these alongside the data on the HSA4 forms from the abortion providers when it is considering the safety and effectiveness of medical abortion at home.

5. NHS Hospital Trusts FOI Request.

We made a freedom of information request to NHS Hospitals across England and Wales, asking for numbers of women who were treated for retained products of conception (RPOC) after an early medical abortion. This was asked in the context of the March 2020 approval by the DHSC for both abortion pills to be taken at home after a phone consultation.

Women might have retained products after either a medically induced abortion or after a natural miscarriage. The complications arising and the treatments used are the same for both a spontaneous or missed abortion (miscarriage) and for a medically induced abortion.

Retained products of conception is when parts of the embryo/fetus and/or the placenta remain in the uterus. It is important that such remains are fully removed otherwise the woman may continue to bleed and risks infection. Sometimes the body will pass these products naturally after waiting some more days, though this needs to be monitored in case of infection or haemorrhage. Sometimes a medical intervention is required; this can be administration of additional misoprostol tablets or a surgical procedure which is referred to as an evacuation of retained products of conception (ERPC). In case of a miscarriage this treatment is sometimes called surgical management of miscarriage (SMM).

We took care to ensure that the data being reported are only for those cases of induced medical abortion.

To date, we have received responses detailing the numbers of treatments for women presenting with retained products of conception after a medical abortion, from 17 Trusts serving a total population of 11,300,000, representing 19% of the population across England and Wales.

NHS Hospital Trust	2020	
	RPOC	ERPC
Blackpool Teaching Hospitals	128	50
Croydon University Hospital	73	55
Gateshead Health	24	19
King's College Hospital	34	15
Liverpool Women's Hospital	180	40
Royal Derby Hospital	62	27

When responding to FOI requests, hospitals are careful not to identify any patients and so when the case count is less than five, they report it as <5, rather than the actual count. In our analysis, we counted <5 cases as one.

This table shows a sample of the results for the full year 2020.

When calculating the case rates, we used the total count for all medical abortions rather than the lower counts of early medical abortion or those using pills-by-post.

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From these FOI responses, for the calendar year 2020 across England and Wales, we found:

- The number of women attending a hospital with complications arising from retained products of conception after a medical abortion is 16 per day, 495 per month.
- The average rate of surgical procedures to remove retained products of conception after a medical abortion is 2.4 procedures per 100 medical abortions.

What do we learn from this?

When extrapolated for the whole of England and Wales, and using the most recent DHSC data reporting the numbers of women self-administering both abortion pills at home, pills-by-post, and also those taking misoprostol at home after an in-clinic consultation, we find:

- Each month, 340 women having an early medical abortion at home will subsequently attend hospital with complications arising from retained products of conception.
- Each month, 250 women using the abortion pills at home, will require hospital treatment to surgically remove retained products of conception.

The average rate for ERPC from these FOI responses is 2.4 surgical procedures per 100 medical abortions. This rate is consistent with the data table shown by BPAS [here](#)¹³. What this tells us is that notwithstanding the continued move towards lower gestational age at the time of administering the abortion pills, whether at home or in-clinic, the rate of incomplete abortions requiring removal of pregnancy tissue (RPOC) still remains at the same rate as previously published. There is nothing in these FOI responses to suggest that the rate of complications from incomplete abortions has reduced in 2020.

It is worth noting that as advised by the Royal College of Obstetricians and Gynaecologists, the pills-by-post treatment packs include an additional 2 x 200mcg of misoprostol to be taken if the woman suspects that her abortion is not complete after taking the first dose of 4 tablets. So, women being treated in hospital are most likely to have taken a total of six misoprostol tablets, 1,200 mcg, which one would have expected to reduce the incidence of incomplete medical abortion.

6. DHSC Reporting of Complications.

The DHSC, in its response to FOI-1257670¹⁴, reported complications arising from medical abortions, which needed hospital treatment, including haemorrhage and sepsis: a total of 231 complications in 2019 and an annual equivalent of 214 in 2020.

¹³ Source: <https://www.bpas.org/abortion-care/abortion-treatments/the-abortion-pill/abortion-pill-up-to-10-weeks/>

¹⁴ Source: <https://www.gov.uk/government/statistics/abortion-statistics-during-the-coronavirus-pandemic-january-to-june-2020>

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As discussed above in section 4: 'Ambulance Service NHS Trusts FOI Request.', the DHSC notes that these are complications reported to it on the HSA4 forms and might not be a complete record of all such complications because the forms may have been submitted by the abortion providers before some complications arise. One might find a scenario in which an abortion provider submits a client's HSA4 form at about the same time as the abortion pills are posted to that woman and thus before the treatment is administered and before any subsequent complications start.

In a parliamentary written answer on February 05, 2021 Helen Whatley confirmed that the DHSC uses no method other than HSA4 forms, which are submitted by the abortion providers, for collecting data on medical abortions at home.¹⁵

Women using the pills-by-post telephone process, are told by the abortion providers to look out for the warning signs of complications such as bleeding too heavily or not bleeding enough and thus risking an incomplete abortion. The volunteers making these calls for our mystery client investigation were each told, that in such an event, to go immediately to their local A&E department rather than calling the abortion provider. It seems plausible that the abortion providers do not know about many of the complications arising from abortion at home which are subsequently managed by the NHS Ambulance Services and Hospitals. It has been noted that because the woman's NHS number is not included on the HSA4 form submitted by the abortion provider, it is difficult to associate subsequent hospital treatments with the earlier provision of the abortion treatment. To ensure the completeness of the reported data, the DHSC should mandate the inclusion of the NHS number on the HSA4 form.

In response to our FOI requests, six hospitals provided data related to treatment for complications, (haemorrhage and sepsis), for women who had taken the abortion pills. In 2020, these six hospitals provided treatment for 69 women diagnosed with haemorrhage or sepsis after taking the abortion pills. Based on population numbers, this rate of complications is more than five times higher than the rate reported by the DHSC in 2019 and 2020.

This is important when considering the safety of early medical abortion; the DHSC reported rate of 1.5 complications per thousand medical abortions is incomplete, the actual rate is likely to be much higher, our FOI data suggest a rate closer to 7 per 1,000.

7. CQC's Follow-up with Abortion Providers.

In response to our researcher's email, the CQC included the following statement on 30 November 2020:

“ Nigel Acheson, CQC's Deputy Chief Inspector of Hospitals, said: *We are aware of a small number of serious incidents where women who have accessed early medical abortion have suffered complications. We have followed up directly with the providers concerned, and continue to work closely with NHS England and Improvement, the Department of Health and Social Care and the Royal College of Obstetricians and Gynaecologists to ensure the*

¹⁵ Source: <https://www.theyworkforyou.com/wrans/?id=2021-02-01.146769.h>

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appropriate safeguards are in place to protect women accessing this service.

“ *Follow up with the three main abortion providers (MSI, BPAS and NUPAS) has prompted steps to significantly strengthen the premedical abortion screening process.*

We asked the CQC to expand on its follow-up with the main abortion providers and to outline any specific actions taken; we received the following response:

“ *We have reviewed all of the information provided to us and followed up directly with the providers concerned. In each case we contacted the provider to understand the circumstances surrounding the incident, the process they had followed to investigate and what that investigation had found. We sought assurance of the steps they were taking to mitigate any future risks. All three providers have strengthened their screening process following the initial concerns – this has included additional steps to ensure more specific details about menstrual periods are obtained prior to any medical abortion.*

Let's address the last sentence in the above statement.

A mystery client investigation¹⁶ commissioned by Christian Concern, conducted in June-July 2020, revealed gaps in the abortion providers' screening process being used at that time to assess a caller's eligibility for early medical abortion at home, before taking her verbal consent to the procedure, prescribing the medical abortion treatment, and posting this to her home. Specifically, the investigation found:

- Abortion providers were unable to verify the identity of the caller.
- Abortion providers did not act appropriately to ensure that the given NHS registration details were valid.
- Abortion providers relied on the woman's stated date of her last period in order to assess the gestational age of her pregnancy. In 26 out of 26 cases our callers were provided the abortion treatment at home even though they were not pregnant. In four out of four cases, the abortion provider allowed the caller to change the stated date in order to remain within the legal limit of 9-weeks-6-days.
- The abortion providers were unable to discover when the woman was being coerced by her abusive partner sitting beside her during the call.
- The abortion providers do not know if it is the woman on the call who will be the one using the posted abortion treatment.
- The abortion providers do not know when the woman will self-administer the abortion pills after receiving these at home, in some cases this will be well beyond the ten-week limit.

In the light of the CQC's November statement about the remedial actions agreed with the abortion providers to strengthen the screening process, we conducted a new set of mystery client calls. Over the three months, November 2020 to January

¹⁶ Source: <https://christianconcern.com/resource/abortion-at-home-a-mystery-client-investigation/>

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2021, we repeated the calls using similar case details as before. In each case we found all of the same gaps as before. Our volunteers noted no change in the abortion providers' screening process between this most recent cycle of calls compared to those conducted in the summer of 2020.

It is important that Nigel Acheson and his team at the CQC note that nothing has changed; the remedial actions which he agreed with BPAS and MSI have not mitigated the identified risks in this abortion by telemedicine process.