United Kingdom Data Deficiencies Influencing U.S. FDA Decisions

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ABSTRACT: The U.S. FDA has permanently removed the in-person prescribing requirements that previously safeguarded the use of mifepristone/misoprostol medical abortions, allowing prescribing through telemedicine or on-line ordering and distribution through the mail and pharmacies, without standard pre-abortion testing. This will increase the risk of complications due to failure to adequately determine the gestational age or rule out ectopic pregnancy by ultrasound or physical exam, failure to perform labs to document whether RhoGAM is indicated, and failure to obtain appropriate informed consent to prevent unwanted abortions, among other concerns. The FDA justified this action by referencing flawed studies with significantly undercounted complications. The details of these study deficiencies are examined in this paper.

Background

In April 2021, Janet Woodcock, Acting Commissioner of the U.S. Food and Drug Administration (FDA), approved the temporary exercise of "enforcement discretion" for the in-person prescribing requirement for mifepristone due to the Covid-19 pandemic. These changes were made

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permanent in December 2021. These actions allowed mifepristone, used along with misoprostol in the two-drug abortion pill regimen, to be dispensed through the mail or by mail-order pharmacy, without an in-person visit or the standard pre-abortion testing of ultrasound, laboratory testing or physical examination.[1]

We, and many others, have expressed concern about the potential harms of such a prescribing regimen.[2] Failure to perform ultrasound prior to providing abortion drugs may lead to a missed diagnosis of ectopic pregnancy, which is not effectively treated by mifepristone and misoprostol,[3] and may progress to a ruptured Fallopian tube, catastrophic internal hemorrhage, and even maternal death. Moreover, the similarity of symptoms can result in delayed presentation of the rupture, which is one of the primary factors in maternal death resulting from ectopic pregnancy.[4]

Failure to correctly diagnose gestational age by physical examination or ultrasound will lead to more failed abortion complications,[5] including a living fetus and/or failure to evacuate all the pregnancy tissue, if gestational age is underestimated. It can—and has—also subjected women and girls to the medical risks of unattended second and third-trimester deliveries,[6] and the legal risks of subsequent neonatal deaths, with a sharp rise in prosecutions—previously virtually unheard of—since the same policy approved by the FDA was introduced in the United Kingdom.[7] Additionally, omission of ultrasound and physical examination may fail to diagnose other factors that may complicate

1 US Food and Drug Administration (2023). 'Postmarket Drug Safety Information,' available online at https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation, accessed January 24, 2024.

2 Miller, C (2023). 'The safety of self-managed abortion: a dearth of good-quality evidence and a wealth of misrepresentation,' *Issues in Law and Medicine*, 38(1): 3-25; Miller, C (2022). 'Telemedicine abortion: why it is not safe for women,' in Colgrove, N, Blackshaw, BP and Rodger, D (eds.) *Agency, Pregnancy, and Persons: Essays in Defense of Human Life*. New York: Routledge.

3 World Health Organization (2012). *Safe abortion: technical and policy guidance for health systems*, 2nd ed. Geneva: World Health Organization.

4 Health Services Safety Investigations Body (2020). *Investigation Report: The diagnosis of ectopic pregnancy*. Available online at https://www.hssib.org.uk/patient-safety-investigations/the-diagnosis-of-ectopic-pregnancy/investigation-report/, accessed February 19, 2024.

5 ACOG estimate that 40% of women estimate their gestational age incorrectly using last menstrual period alone. See American College of Obstetricians and Gynecologists (2017). 'Methods for estimating the due date,' available online at https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/05/methods-for-estimating-the-due-date, accessed February 19, 2024.

6 National Network of Designated Healthcare Professionals for Children (NNDHP) (2021). 'Position Statement: Early Medical Abortions: Safeguarding Young People'.

7 Aspinall, G (2024). 'The terrifying rise in British women being prosecuted for abortion,' *Grazia Daily*, available online at https://graziadaily.co.uk/life/in-the-news/abortion-prosecutions-uk/, accessed February 19, 2024.

an abortion such as uterine abnormalities of fibroids or septum, molar or multiple pregnancies, fetal demise, or pre-existing infections.[8]

Failure to perform laboratory testing to screen for Rh-D negativity and provide RhoGAM prophylaxis, if indicated, may lead to alloimmunization, a maternal immune response directed against future unborn children, which can lead to life-threatening complications of severe fetal and neonatal anemia, brain damage and stillbirth or neonatal death.[9] Although abortion advocates have recently stated that RhoGAM is not necessary in the first trimester,[10] alloimmunization has been documented in the first trimester,[11] and the failure to accurately determine the gestational age by ultrasound will lead to underestimation of gestational age in some cases, causing some women to fail to receive indicated RhoGAM in the second or third trimester.[12] Additionally, failure to perform labs for sexually transmitted infections will miss the diagnosis of chlamydia and other infections that may place a woman's future fertility at risk, with a large drop in chlamydia screening documented in the U.K. since telemedicine abortion was introduced.[13] Failure to exclude women with anemia will cause some women to need transfusions if they experience significant blood loss.

Serious safeguarding concerns also exist as to whether adequate informed consent can be obtained when a remote prescriber, prescribing through telemedicine or merely by a website form, is unable to discern whether a woman is seeking abortion freely, without coercion. Concerns about coercion and domestic abuse going undetected by telemedicine have been raised even by those promoting telemedicine abortion.[14] Additionally, if a woman does experience a complication following remotely prescribed, medically unsupervised, medical abortion, she may have trouble finding a provider to care for her emergency in the U.S, where remote "healthcare deserts" without available emergency services have been documented.[15] The opportunity for contraceptive counseling to help a woman avoid future undesired pregnancies and abortions will also

8 World Health Organization (2012).

9 Zipursky, A and Paul, VK (2011). 'The global burden of Rh disease,' Archives of Disease in Childhood: Fetal & Neonatal, 96(2): F84-85.

10 Horvath, S et al. (2022). 'Society of Family Planning committee consensus on Rh testing in early pregnancy,' *Contraception*, 114:1-5.

11 Miller (2023); de Haas, M et al. (2014). 'Anti-D prophylaxis: past, present and future,' *Transfusion Medicine*, 24(1): 1-7; Bowman, J (2003). 'Thirty-five years of Rh prophylaxis,' *Transfusion*, 43(12): 1661-1666.

12 American College of Obstetricians and Gynecologists (2017). 'Practice Bulletin 181: Prevention of Rh D Alloimmunization,' *Obstetrics & Gynecology*, 130(2): 481-483.

13 Miller (2023).

14 Miller (2023).

15 Skop, I (2019). 'Medical abortion: What physicians need to know,' *Journal of American Physicians and Surgeons*, 24(4): 109-113; Skop, I (2022). 'Chemical abortion: risks posed by changes in supervision,' *Journal of the American Physicians and Surgeons*, 27(2): 56-61.

be missed in the absence of such counseling—the U.K. also saw a large drop in highly effective long-acting reversible contraceptive (LARC) uptake with the onset of telemedicine abortion.[16]

For reasons such as these, leading pro-choice medical and safeguarding authorities in the U.K.—including the Royal College of Paediatrics and Child Health[17] and the National Network of Designated Healthcare Professionals for Children[18]—have made unprecedented political interventions seeking the repeal of telemedicine abortion. The U.K. government—likewise pro-choice—recognized these concerns and announced a repeal of their own policy but was overruled by a parliamentary vote.[19]

The U.K. is not the only secular, pro-choice country to exhibit such concerns. Most European countries never introduced telemedicine abortion at all and attempts in the Netherlands—one of the most pro-choice countries in the world—were halted when leading pro-abortion authorities themselves opposed telemedicine abortion. The Minister for Medical Care and Sport responded to an appeal from Women on Waves to allow telemedicine as follows: "Abortion care requires careful consideration of different interests and must be carried out carefully, safely and medically responsibly. Providing medication by post does not fit with this view. In addition, I would like to emphasize once again that I have not currently received any signals from the abortion sector that require an adjustment to the current policy."

StiSAN, the federation of co-operating abortion clinics in the Netherlands, soon afterwards confirmed:

> "In the Netherlands, 30,000 abortions take place annually… There are no signals from the clinics that women cannot receive the care they want… None of the clinics have seen a decline in the numbers of clients visiting the clinics…No signal has been received from the clinics that women are being influenced by this corona crisis…
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> StiSAN, but also NVGA [Dutch Society of Abortion Doctors], strongly advise against giving pills to women and girls for an early medical abortion up to

16 Miller (2023).

17 Royal College of Paediatrics and Child Health (2022). 'Lords consideration stage briefing on home early medical abortion provisions in the Health and Care Bill,' available online at https://www.rcpch.ac.uk/sites/default/files/2022-04/RCPCHBriefingHealthandCareBillPositiononHomeEarlyMedicalAbortion5April2022.pdf, accessed February 16, 2024.

18 National Network of Designated Healthcare Professionals for Children (NNDHP) (2022). 'Early medical abortions: safeguarding young people (second position statement: April 2022)'.

19 Royal College of Obstetricians and Gynaecologists (2022). 'Parliament votes to make telemedicine for early medical abortion permanent in England,' available online at https://www.rcog.org.uk/news/parliament-votes-to-make-telemedicine-for-early-medical-abortion-permanent-in-england/, accessed February 16, 2024.

> 10 weeks at home via any route other than the abortion clinic. For termination of pregnancy up to 10 weeks, the same procedure applies as for local treatment with or without anesthesia, i.e. first a decision-making interview on the basis of which decision-making can be made. In addition, the pros and cons of medical abortion are discussed and contraceptive measures are discussed to prevent a repeat abortion. This knowledge is not available among pharmacists or general practitioners. The gestational age must also be determined by making an ultrasound. Providing an abortion pill after 10 weeks can have far-reaching medical consequences for a client. Consider complications that could occur that would require referral to a hospital."[20]

NGVA, the Dutch Society of Abortion Doctors, also took the side of the state in refusing to allow telemedicine abortion. As a result of these interventions, the courts flatly rejected an appeal from Women on Waves to allow telemedicine abortion, ordering them to pay court costs.[21]

The FDA's Reliance on Poor-Quality Data

In a letter to the leaders of the American College of Obstetricians & Gynecologists (ACOG) and Society of Maternal-Fetal Medicine (SMFM),[22] Dr. Woodcock identified four studies that the FDA reviewed to justify its decision to remove the in-person prescribing requirements.[23] Most were small and incomplete (with follow-up data not available on all women) and did not replicate the conditions of use that the FDA approved (because they all included at least some women who received routine pre-abortion testing). Although the FDA justified removing the in-person requirements in order to facilitate telemedicine abortions during the Covid-19 pandemic, the changes do not prohibit on-line abortion provision, often from out-of-state or out-of-country prescribers, without the ability to perform any pre-abortion testing at all.

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20 Civil Court of The Hague, Netherlands (2020). ECLI:NL:RBDHA:2020:3551. Available online at https://uitspraken.rechtspraak.nl/details?id=ECLI:NL:RBDHA:2020:3551, accessed February 16, 2024; translation by Google.

21 Ibid.

22 Woodcock, J (2021). Letter from Janet Woodcock to Drs. Maureen Phipps and William Grobman. Available online at https://www.aclu.org/wp-content/uploads/legal-documents/fda_acting_commissioner_letter_to_acog_april_12_2021.pdf, accessed February 16, 2024.

23 Chong E, et al. (2021). 'Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic,' *Contraception*, 104(1): 43-48; Kerestes C, et al. (2021). 'Provision of medication abortion in Hawai'i during COVID-19: practical experience with multiple care delivery models,' *Contraception*, 104(1): 49-53; Aiken A et al (2021). 'Effectiveness, safety and acceptability of no-test medical abortion provided via telemedicine: a national cohort study. *British Journal of Obstetrics and Gynaecology*, 128(9): 1464-1474; Reynolds-Wright JJ et al. (2021). 'Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during the COVID-19 pandemic,' *BMJ Sexual & Reproductive Health*, 47(4): 246-251.

Of note, in the letter sent to ACOG and SMFM, Dr. Woodcock also remarked that the small number of adverse events reported to the FDA in 2020 demonstrated medical abortion's safety. She neglected to mention that in 2016, the FDA removed the requirement for prescribers to report non-lethal medical abortion complications. In other words, the FDA declined to mandate data unless the abortion pills killed a woman.[24] Thus, the complications known by the FDA are only those voluntarily reported by abortion providers and other physicians who care for injured women, yet common sense and experience suggests that abortion providers are unlikely to voluntarily report complications that contradict the common safety narrative for their product.[25]

How comprehensive is the data from the four studies that the FDA relied upon? The extremely small study by Kerestes, et al. analyzed medical abortions in 330 Hawaiian women and documented similar failure rates requiring surgery between the groups (3.2% failures after telemedicine with in-person distribution, 2.9% failures after telemedicine with mailed distribution and 6.4% failures after traditional in-person visits). Of note, 2/3 of the women had pre-abortion ultrasounds, and 12.2% were lost to follow-up with outcomes unknown.[26]

Reynolds-Wright et al. evaluated abortions in 663 Scottish women, explicitly noting that "the study size... is still too small to detect changes in rare events." 8.4% were lost to follow-up at two weeks, and 2.4% required emergency hospital visits, in addition to 8.4% requiring an urgent clinic assessment, mostly for signs or symptoms of continuing pregnancy. This, along with the survey methodology, suggests that the 2% failure rate they report was subsequent to follow-up treatment, including emergency evacuation of retained products of conception (ERPC). The need for urgent clinic appointments more than tripled from 2.7% in prior studies. The authors note that some of these may have been prompted by the researchers' phone calls for the follow-up survey—meaning that in a non-experimental setting, these women's care might have been delayed further and resulted in an emergency hospital visit. Only one patient had an ectopic pregnancy, meaning conclusions cannot be meaningfully drawn about the safety of telemedicine abortion for women with ectopic pregnancies. Only 71.3% said they would use telemedicine again, suggesting nearly a third experienced a fundamentally incomplete service, and many felt they were

24 Food and Drug Administration (2021). 'Response Letter from FDA CDER to American Association of Pro-Life Obstetricians and Gynecologists and American College of Pediatricians,' available online at https://www.regulations.gov/document/FDA-2019-P-1534-0016.

25 Cirucci, CA et al. (2021). 'Mifepristone adverse events identified by Planned Parenthood in 2009 and 2010 compared to those in the FDA Adverse Event Reporting System and those obtained through the Freedom of Information Act,' *Health Services Research and Managerial Epidemiology*, 8: 23333928211068919.

26 Kerestes et al. (2021).

only 'somewhat' prepared for the abortion from the telemedicine service. The authors documented a huge drop in the initiation of highly effective LARC use after the abortion, compared to before telemedicine, raising the risk of recurrent unintended pregnancies leading to subsequent abortions.[27]

Chong mailed 1,390 abortion drug packages to women in thirteen U.S. states, and documented that 5% failed requiring surgery, 6% had emergency room visits, 7.8% had other outpatient visits, and 0.9% had serious adverse events, including 0.4% who required transfusions. Half of this patient population had routine in-person screening and standard pre-abortion testing-the only remote component for these women was that they were mailed abortion pills rather than given them in person. Seventeen percent were lost to follow-up with outcomes unknown.[28]

Hence these three studies, in general, did not replicate the conditions of use the FDA approved, and in any case showed considerable rates of failures requiring surgery, as well as many women lost to follow-up with unknown outcomes. The measurement of additional complications across these studies was inconsistent and scant, with minimal measurement of infections, hemorrhage not requiring transfusion, missed ectopic pregnancies, and no attempts to measure Rh alloimmunization in future pregnancies. The studies likewise did not attempt to capture safeguarding concerns or incidents such as coercion—yet these were the primary (but not only) concern among pro-choice medical authorities and politicians in the U.K. Other concerns—for example, that telemedicine would reduce the use of more reliable long-acting contraceptives after the abortion—were vindicated.[29]

The fourth and largest of these peer-reviewed studies relied upon data obtained from British Pregnancy Advisory Service (BPAS), MSI-Reproductive Choices (MSI-RC) (formerly Marie Stopes International) and National Unplanned Pregnancy Advisory Service (NUPAS), the three largest independent abortion providers commissioned by the National Health Service (NHS) in the United Kingdom. Performed by Texas pro-abortion researcher, Abigail Aiken, and coauthored by Patricia Lohr, Medical Director of BPAS; Nabanita Ghosh, Medical Director of NUPAS; and controversial abortion advocate Jonathan Lord, Medical Director of MSI-RC;[30] this study reported that within the

27 Reynolds-Wright et al. (2021).

28 Chong et al. (2021).

29 Reynolds-Wright et al. (2021).

30 Searles, M (2024). 'Royal College advice not to report illegal abortions written by Marie Stopes director,' The Telegraph, available online at https://www.telegraph.co.uk/news/2024/01/24/royal-college-marie-stopes-illegal-abortions-advice/ accessed February 16, 2024; Adams, S (2021). 'Woman in her 40s felt 'scared and pressured' by Marie Stopes when quizzed about 'abortion reversal' treatment she received from pro-life medic,' Daily Mail, available online at https://www.dailymail.co.uk/news/article-9753587/Woman-40s-felt-scared-pressured-quizzed-abortion-reversal-treatment.html accessed February 16, 2024.

telemedicine-hybrid cohort (which included those who had medical abortions without ultrasound either via telemedicine or in-person) telemedicine abortion resulted in 99.2% effectiveness in the telemedicine part of the cohort and 98.1% effectiveness for the in-person part of the cohort.[31] The study encompassed nearly all (approximately 95%) of the total number of abortions examined by the FDA and cited in support of their decision.[32] Dr. Aiken and colleagues studied 52,142 abortions, whereas the other three articles studied a combined total of only 2,387 abortions.

At first glance, Aiken's data appears hard to refute, because single-payer abortion coverage and a socialized medical system could in theory create high-quality abortion data. Record-linkage studies from some European countries with socialized medical systems, for example, have been considered the gold standard in abortion research. It is noteworthy that such studies have consistently demonstrated far more complications from medical abortions than reported by U.S. researchers linked to the abortion industry.[33]

U.S. studies are often of poor quality because most abortions are paid for privately and women are often hesitant to report a preceding abortion if they have a complication, due to shame, or in some cases because they have been advised by the abortion provider or encouraged by abortion advocacy groups to omit this information,[34] allowing emergency physicians to assume that a miscarriage instead of an abortion led to the complication. Additionally, many studies are plagued by large numbers of women lost to follow-up, for whom abortion outcomes are unknown. In the U.S., there are no federal mandatory complication reporting requirements or accurate centralized systems collecting data related to abortion—leading to substantial uncertainty of the numbers, complications and deaths following abortion.[35] It might be assumed

31 Aiken et al. (2021).

32 Skop, I (2023). 'What is the Truth about the Alliance for Hippocratic Medicine vs U.S. Food and Drug Administration Lawsuit,' available online at https://lozierinstitute.org/what-is-the-truth-about-the-alliance-for-hippocratic-medicine-v-u-s-food-and-drug-administration-lawsuit/, accessed January 9, 2024.

33 Niinimaki, M et al. (2009). 'Immediate complications after medical compared with surgical termination of pregnancy,' *Obstetrics & Gynecology*, 114(4): 795-804; Mentula, M et al. (2011). 'Immediate adverse events after 2nd trimester termination of pregnancy,' *Human Reproduction*, 26(4): 927-932.

34 ZawnVillines (2022). 'A guide to surviving in a post-Roe world: advice from doctors, midwives, & experts on Abortion,' Daily Kos, available online at https://www.dailykos.com/stories/2022/5/19/2098906/-A-Guide-to-Surviving-in-a-Post-Roe-World-Advice-from-Doctors-Midwives-Experts-on-Abortion, accessed February 16,2024; Safe2Choose (2024). 'Will medical staff be able to notice that I am having an abortion?,' available online at https://safe2choose.org/faq/medical-abortion-faq/during-abortion-with-pills/will-medical-staff-be-able-to-notice-that-i-am-having-an-abortion, accessed June 6, 2023.

35 Comparing the total number of abortions reported by the abortion research organization Guttmacher Institute, the U.S. Centers for Disease Control and Prevention (CDC) reporting

that the British data would avoid these deficiencies, because it relies upon a single-payer healthcare system that would fund most abortions and pay for the treatment of most complications.

The Quality of the U.K. Data

Aiken et al. explicitly highlight concerns with underreporting of complications in their paper. They write, "The main limitation of this study is that we were unable actively to follow up patients after their abortion. There is a potential gap in the consistency of reporting incidents, due to some complications not meeting the threshold of serious incidents, multiple routes of entry into the NHS and informal communication between the NHS and abortion providers. Although it is possible that some patients presented to other providers and a significant adverse event was not reported in our dataset, the risk management and reporting systems within the NHS are well defined, with serious incidents being routinely shared... No additional cases were identified from regulators that were not already recorded by the providers' clinical incident processes. More importantly, there is no reason that any under-reporting would be systematically more likely in either cohort to introduce bias...Although patient behavior may have been altered in the pandemic, it seems unlikely patients would not have reported problems to their provider given that there is immediate access to help via 24-hour telephone services. It is also possible that with NHS acute services (e.g. early pregnancy units) harder to access, patients would be more likely to engage with their abortion provider first."

In essence, they claim that:

1) Patients are more likely to report complications to their abortion provider than to e.g. NHS providers at hospitals, clinics, etc.
2) Abortion providers therefore are likely to have a relatively comprehensive database of complications following abortion.
3) Abortion complication reporting systems within the NHS are 'well defined', suggesting that the NHS has a cogent, consistent and comprehensive system for capturing abortion complications.
4) Under-reporting of complications is not more likely in the telemedicine cohort compared to the in-person cohort.

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accounts for 309,833 fewer abortions, meaning the federal agency's abortion total is 30% lower than that of the private organization. See Longbons, T and Steupert, M (2023). 'Five things we don't know about abortion in the U.S. (but could with better reporting),' available online at https://lozierinstitute.org/five-things-we-dont-know-about-abortion-in-the-u-s-but-could-with-better-reporting/, accessed February 16, 2024. Regarding the many issues contributing to poor quality of data of maternal mortality due to abortion, see especially Skop, I (2023). 'Handbook of maternal mortality: addressing the U.S. maternal mortality crisis, looking beyond ideology,' available online at https://lozierinstitute.org/handbook-of-maternal-mortality-addressing-the-u-s-maternal-mortality-crisis-looking-beyond-ideology/, accessed February 16, 2024.

5) The regulators they consulted did not identify any additional complications that were previously unknown to the abortion providers.

As we will demonstrate from the U.K. government report on abortion complications, claims 1-4 are categorically false. Claim 5 is presumably true, but only underscores how poor the NHS regulators' complication reporting is, since the abortion providers demonstrate massively underreported complications. Moreover, other more reliable U.K. data sources from the same period show an order of magnitude more complications than reported by Aiken et al., confirming that their sources severely underreport complications.

In England, abortions are paid for by the National Health Service. NHS protocols allow medical abortion to be performed at home after telephone or e-consultation until 10 weeks' gestation,[36] in-hospital medical abortion throughout pregnancy, surgical suction aspiration abortion until 14 weeks and surgical dilation and evacuation abortion after 14 weeks.[37] Thus, it would be possible to perform a record-linkage study if an accurate system existed for recording abortion complications and if the patient abortion records could be linked to subsequent records documenting complications for the same patient.

A U.K. governmental review by the Department of Health and Social Care (DHSC), however, recently demonstrated that there are many data deficiencies in the U.K.'s abortion complication reporting.[38] There are two disparate systems in the U.K. that record abortion complications. The Abortion Notification System (ANS) is data collected from HSA4 forms containing demographic data, submitted by all abortion providers in England and Wales, within 14 days of the abortion, to the DHSC.[39] NHS identification numbers are not obligatory for these forms, resulting in an inability to correlate subsequent medical encounters in the NHS system with the preceding abortion report.

Another system, the Hospital Episode Statistics (HES), provides details of all admissions, Accident and Emergency (A&E) attendances and outpatient appointments to treat abortion complications at NHS hospitals in England. No identifier (NHS number or other form of identification) is linked to these records either, further hampering the ability to link known abortions through the ANS system to subsequent complications in the HES system. Thus, a

36 Royal College of Obstetricians and Gynaecologists (2022). 'RCOG and FSRH welcome telemedicine for early medical abortion care being made permanent in England,' available online at https://www.rcog.org.uk/news/rcog-and-fsrh-welcome-telemedicine-for-early-medical-abortion-care-being-made-permanent-in-england/, accessed February 16, 2024.

37 Royal College of Obstetricians and Gynaecologists (2011). *The Care of Women Requesting Induced Abortion*. London: RCOG Press.

38 UK Department of Health and Social Care (2023a). 'Complications from abortions in England, 2017 to 2021,' available online at https://www.gov.uk/government/statistics/complications-from-abortions-in-england-2017-to-2021, accessed February 16, 2024.

39 Ibid.

critical component allowing a record-linkage study to be performed, comparing data from the two databases, is missing, often on both ends.

Underestimation of Complications in the ANS Data

Because the HSA4 form is usually completed before a woman leaves the abortion facility, the ANS typically records only immediate complications witnessed by healthcare providers in person.[40] Prior to 2019, both mifepristone and misoprostol were administered in the clinic for medical abortions less than ten weeks' gestation. However, since 2019, women have been allowed to take the misoprostol at home after taking the mifepristone in-clinic. Since 2020, both pills have been allowed to be taken at home in the "telemedicine pills-by-post" protocol. As a consequence, even when prescribed in-clinic, many or most of the HSA4 forms are completed and submitted before the woman has self-administered the misoprostol at home, leading to very low reported rates of complications in this system.[41]

Between the two systems, there is no common definition of what constitutes an abortion complication. ANS considers hemorrhage, sepsis, cervical tears, and uterine perforation to be the only reportable abortion complications, although it does have a category called "other, unspecified." Thus, they omit the most common complication of medical abortion: retained pregnancy tissue (RPOC), as well as some of the biggest concerns following telemedicine as discussed above: undiagnosed ectopic pregnancy, underestimation of gestational age, coercion and Rhesus alloimmunization. Hemorrhage comprised two-thirds of the reported complications, but there is no standard definition of what constitutes a hemorrhage. Some researchers wishing to minimize complication rates in telemedicine abortion studies only count cases requiring transfusion,[42] whereas others seeking to maximize complication rates (for example, when attempting to discredit abortion pill reversal) use subjective measures or lesser degrees of bleeding to define hemorrhage.[43]

Notably, cervical tears and uterine perforation are complications usually resulting from instrumentation in surgical abortion, and sepsis is usually a

40 Moreover, it has been found that UK abortion providers have been prone to illegally pre-filling the forms even before meeting the woman, reducing their overall reliability, but especially for events occurring after the abortion. See Huffington Post (2012). 'One in five abortion clinics 'illegally pre-signing blank forms,' available online at https://www.huffingtonpost.co.uk/2012/03/23/one-in-five-abortion-clinics-illegally-signing-forms_n_1374431.html, accessed February 16, 2024.

41 UK Department of Health and Social Care (2023b). 'Abortion statistics for England and Wales: January to June 2022,' available online at https://www.gov.uk/government/statistics/abortion-statistics-for-england-and-wales-january-to-june-2022, accessed February 16, 2024.

42 E.g. Aiken et al. (2021).

43 E.g. Creinin, MD et al. 'Mifepristone antagonization with progesterone to prevent medical abortion: a randomized controlled trial,' *Obstetrics & Gynecology*, 135(1): 158-165.

delayed diagnosis, as it takes time for a severe infection to manifest. When complications from medical abortions occur, they are almost always delayed, not immediate, and thus it is unlikely that medical abortion complications would be noted before leaving the abortion facility, especially if the regimen is not completed in the abortion clinic, or if a woman never enters the facility when obtaining "pills by post." The ANS data reflects this deficiency, demonstrating four times as many complications reported after surgical abortion compared to medical abortion. Whereas other high-quality studies, in fact, document the opposite-four times as many complications following medical compared to surgical abortion.[44]

The ANS form specifically states that "an evacuation of retained products of conception (ERPC) is not a complication," categorically excluding the most common complication following medical abortion. It is odd that this consequence would not be considered a complication by the health system and researchers, because it would undoubtedly be considered a complication by a woman choosing a medical abortion in hopes of avoiding surgery, and in other settings, the NHS has listed it as a complication.[45] The inability of a woman's body to completely expel the pregnancy tissue, the object of the abortion, will inevitably lead to a prolongation of her symptoms. Her uterus will continue to contract in a vain attempt to expel the tissue, leading to continued pain and bleeding. The necrotic tissue can become infected, in rare cases leading to fulminant sepsis from *Clostridium sordellii*, a cause of some maternal deaths.[46] Sometimes an additional dose of misoprostol results in complete expulsion, but in many cases an emergency surgical procedure is necessary. Tellingly, the "pills by post" packages contain 1,200 mcg of misoprostol rather than the clinically recommended 800 mcg, an implicit demonstration that providers are aware medical abortions often do not evacuate uterine tissue well and extra doses of misoprostol are often required, but in this case taken at the woman's discretion and without medical oversight.

The DHSC acknowledges that complications after discharge (when the form has been sent) are unlikely to be recorded on the HSA4 form, and explicitly states that abortions at home are unlikely to have complications reported (contrary to Aiken et al.'s claim 4). They state, "If the abortion provider is informed (of a complication), they would need to have documented the relevant HSA4 form identification number and contact DHSC to ask for the form to be returned to them or updated with the relevant information. In 2022 there was

44 Niinimaki et al. (2009).

45 UK National Health Service (2020). 'Risks: abortion,' available online at https://www.nhs.uk/conditions/abortion/risks/, accessed February 16, 2024.

46 Fischer, M et al. (2005). 'Fatal toxic shock syndrome associated with Clostridium sordellii after medical abortion,' *New England Journal of Medicine*, 353(22): 2352-2360.

no evidence of this occurring."[47] They note that even if the provider wanted the form back, they would have to have the relevant identification number, which is by no means guaranteed.

Moreover, evidence has emerged more recently from the same hospital regulators Aiken, et al. supposedly consulted (the Care Quality Commission) that abortion providers such as BPAS do fail to highlight and notify the relevant authorities of serious incidents.[48]

Aiken, et al. relied on broadly the same data as the ANS system—complications known to and reported by abortion providers. But what is clear from this discussion is that abortion providers are frequently unaware of complications, since most women experiencing complications present directly to NHS providers, and even if they become aware of complications, it is rare that they would notify the relevant authorities: in the case of HSA4 forms, there was 'no evidence of this occurring'. Moreover, some of the most frequent complications (e.g. incomplete abortion) are not considered complications by them at all, and others are deliberately defined with higher thresholds than in other circumstances. Other concerns (e.g. Rhesus disease, safeguarding) were not addressed at all.

Thus, Aiken, et al.'s complications' data are demonstrably unreliable and, as such, useless in establishing the safety of mifepristone by telemedicine. As will be demonstrated below, Freedom of Information requests addressed directly to hospitals show far higher complication rates nationally in the same period Aiken et al. studied—using broadly the same sample. Other telemedicine studies show similarly high failure rates.

Even despite this massive underreporting, the study found that ectopic pregnancies detected *after* the abortion were three times more common with telemedicine than with the traditional model, vindicating our aforementioned concerns about the failure to exclude ectopic pregnancy with pre-abortion testing. Likewise with abortions of a gestational age greater than legally and medically permitted, which did not occur in the 'traditional' group but occurred in 11 reported cases (and likely far more unreported) in the telemedicine group. For the reasons described, these are both likely vastly underestimated in the ANS dataset.[49] Hence even if Aiken et al.'s data are taken to be reliable,

47 UK Department of Health and Social Care (2023a).

48 Care Quality Commission (2021). BPAS—Doncaster. Available online at https://api.cqc.org.uk/public/v1/reports/bc49d8d2-46df-4b00-8d9f-965383c0be81?20211104080100, accessed February 16, 2024; Care Quality Commission (2021). BPAS—Merseyside. Available online at https://api.cqc.org.uk/public/v1/reports/b1211e17-f487-48a2-acde-00007f702a50?20211102080239, accessed February 16, 2024; Care Quality Commission (2021). BPAS—Middlesbrough. Available online at https://api.cqc.org.uk/public/v1/reports/beb7e1f3-b0f7-458e-bc2f-c74df1e76b87?20211104080100, accessed February 16, 2024.

49 Aiken et al.'s final significant claim, that abortions occurred significantly earlier with

they show preliminary evidence of serious safety issues which the FDA should have taken into account.

Underestimation of Complications in the HES Data

Higher complication numbers are documented by the HES system, which records hospital episodes in general, including complications when women present to a hospital or clinic for help after an abortion. Yet even the government report on abortion complications using HES examines only four ICD-10 diagnostic codes referencing complications following completed abortions (infection, hemorrhage, embolism and unspecified: ICD-10 codes O04.5-O04.8). As with the ANS, incomplete medical abortion resulting in retained products of conception (RPOC) is specifically *not* considered an abortion complication.

When including incomplete abortions (RPOC) as a complication, HES expands their search to an additional four codes (O04.0-O04.8)—incomplete abortion followed by the same complications. But even then, they ignore ten other codes for complications following spontaneous abortion or miscarriage (O03.0-O03.9), even though it has been documented extensively—including in the report itself—that women often misrepresent a medical abortion complication as resulting from a miscarriage (sometimes at the encouragement of the abortion provider as documented earlier[50]). Record-linkage, if it could be performed, would demonstrate when incorrect coding was used following medical abortions. Additionally, they inexplicably exclude *another* eleven codes referencing failed abortions (O04.4 incomplete medical abortion, without complication; O04.9 complete or unspecified medical abortion, without complication; O07.0 failed medical abortion, complicated by infection; O07.1 failed medical abortion, complicated by hemorrhage; O07.2 failed medical abortion, complicated by embolism; O07.3 failed medical abortion, other unspecified; O07.4 failed medical abortion without complications; O07.5 unspecified failed attempted abortion, complicated by infection; O07.6 unspecified failed attempted abortion, complicated by hemorrhage; O07.8 unspecified failed attempted abortion, other and unspecified complications; O07.9 unspecified failed attempted abortion, without complication). Thus, whether or not a complication was included in the government report depended on which codes the researchers chose to include, and whether these matched those used by the hospital coding department. If the hospital coding department happened to

telemedicine, therefore becoming safer, is refuted in Miller (2023).

50 Studnicki, J et al. (2021). 'A longitudinal cohort study of emergency room utilization following mifepristone chemical and surgical abortions, 1999-2015,' *Health Services Research and Managerial Epidemiology*, 8: 23333928211053965; Studnicki, J et al. (2022). 'Post hoc exploratory analysis: induced abortion complications mistaken for miscarriage in the emergency room are a risk factor for hospitalization,' *Health Services Research and Managerial Epidemiology*, 9: 233333928221103107.

choose the included codes, the complication would be reported. If they used a code excluded from the report, it would not be reported—artificially lowering the complication rates in the report.

Nonetheless, when researchers expanded their search to include (some, but far from all) incomplete abortion complication codes, in 2021, the HES documented 19.3 complications per 1000 abortions (approximately two percent) requiring hospital admissions after medical abortions; five times higher than the HES rate when incomplete abortions were not counted and 10 times higher than the rate reported by ANS.[51]

In addition to omitting a wide variety of relevant codes, the report also omits all complications treated in A&E or as an outpatient, or at the abortion provider. It only includes the cases in which the woman was admitted as an inpatient, typically for surgical ERPC. It also does not include women with RPOC who were treated with additional doses of misoprostol or managed expectantly at home. The proportions in which each of these three treatments might be used may depend upon the perceived severity of bleeding/pain and on the availability of trained medical staff able to perform the evacuation of retained products of conception (ERPC) as well as the availability of inpatient beds.[52]

The HES data also noted that all abortion complication rates rose as women aged,[53] and all abortion complication rates also rose as gestational age increased, with a woman nearly sixty times as likely to experience a complication after twenty weeks compared to one who had an abortion in the first nine weeks of pregnancy, once again demonstrating the critical need to rule out a more advanced pregnancy by ultrasound or exam prior to prescribing abortion drugs.[54]

In summary, even the HES, which estimates ten times the complication rate of the ANS abortion providers' data that Aiken et al. relied upon, is prone to significant underestimation of abortion complications from an accumulation of multiple data biases.[55] This is just for the abortion complications it measures: other complications—such as missed ectopic pregnancy and underestimated gestational age—it does not appear to measure at all.

51 UK Department of Health and Social Care (2023a).

52 Percuity (2024). 'Abortion Complications—new official statistics,' available online at https://percuity.blog/2024/01/10/abortion-complications-new-official-statistics/, accessed February 16, 2024.

53 UK Department of Health and Social Care (2023a).

54 Ibid.

55 The government report also explains that multiple abortion complications would be coded as a single admission in the HES system, further underestimating the number of complications.

Freedom of Information Data in the UK

Further demonstrating the underestimation of complications in U.K. data sources, Freedom of Information Act (FOIA) requests by Kevin Duffy of Percuity indicated that more than 10,000 women (1 in 17 or 5.9%) who used "pills by post" in 2020 needed hospital treatment. These rates were calculated by determining the percentage of the nation's people served in a Trust (hospital) compared to national abortion numbers, to determine the approximate number of abortions in each trust, checked against the reported abortions in the population served by each trust. Between April 2020 and September 2021, 180,182 women requested "pills by post" medical abortions, and 5.5 to 6.2% presented for emergency care due to RPOCs, and half of these (2.7-3%) were admitted as in-patients for a surgical evacuation of retained products of conception (ERPC), the others being treated as out-patients with either expectant management or additional doses of misoprostol.[56]

Additionally, it was independently documented that as medically unsupervised "pills by post" increased, ambulance dispatches and 999 calls responding to abortion pill concerns rose 64% from 2019-2022.[57] These figures fit the much higher complication rates reported for medical abortion and telemedicine abortion elsewhere (e.g. as high as 21% surgical intervention rates in Endler's systematic review).[58]

Sadly, the U.K. public health response to the abundantly documented frequent complications following medical abortion pills was much the same as has been demonstrated by the U.S. FDA—a refusal to protect women from the dangerous misuse of drugs. On March 30, 2020, in response to the Covid-19 pandemic, the U.K. government amended its regulations to allow women to consume abortion pills at home without medical supervision, overriding even their own ministers' concerns, as well as those of the professional bodies with

56 Maddox, D (2021). 'Abortion pill horror: 10k women needed hospital treatment over side effects,' Daily Express, available online at https://www.express.co.uk/life-style/health/1527888/Abortion-pill-diy-nhs-warning, accessed February 16, 2024; Duffy, K (2021). 'FOI investigation into medical abortion treatment failure,' available online at https://percuity.files.wordpress.com/2021/10/foi-ma-treatment-failure-211027.pdf, accessed February 16, 2024.

57 Evans, T (2022). 'Ambulance dispatches and 999 calls responding to abortion pill concerns have risen by 64% since 2019—GB News investigation,' GB News, available online at https://www.gbnews.com/news/ambulance-dispatches-and-999-calls-responding-to-abortion-pill-concerns-have-risen-by-64-since-2019-gb-news-investigation/359311, accessed February 16, 2024.

58 Endler, M et al. (2019). 'Telemedicine for medical abortion: a systematic review,' *British Journal of Obstetrics and Gynaecology*, 126(9): 1094-1110; Marie Stopes Australia (2021). Impact Report: 2020. Melbourne: Marie Stopes Australia.

expertise in safeguarding described above.[59] Harm to women from these "pills by post" was almost immediately documented in a May, 2020 leaked email from a regional chief midwife.[60] Nonetheless, the U.K. Court of Appeals, refusing to hear evidence of harms, rejected a lawsuit to limit these dangerous unsupervised medical abortions,[61] and the policy was made permanent in August 2022.

Conclusion

Some of the most pro-choice countries in Europe have practices and data relevant to the relaxation of mifepristone safeguards. While in Sweden, at-home medical abortion was associated with a significant increase in complications,[62] in the Netherlands it was abortion clinics and doctors who led the campaign *against* telemedicine abortion because of medical safety concerns.

This paper has examined the flaws in the studies the U.S. FDA relied upon to make sweeping changes removing in-person safeguards, demonstrating both the underreporting of medical abortion complications in U.S. data, and also known limitations in the U.K. data collecting systems. When higher quality, more robust data is considered in the U.K., examining all available ICD-10 codes that reference complications, and defining a failed abortion resulting in retained pregnancy tissue as a complication, it appears there were at least five to ten times as many complications in reality as initially reported—and likely many more.

The reported complications do not include all the other complications and risks not captured by the available ICD-10 abortion-related codes: for example, missed ectopic pregnancies, Rhesus alloimmunization, second and third-trimester abortions happening without medical supervision, and the safeguarding concerns around domestic abuse and coerced abortion which have been entirely unstudied, yet remain prevalent concerns among the relevant (pro-choice) safeguarding professionals.

When examined thoroughly, the United Kingdom data shows that medical abortion with mifepristone and misoprostol has significantly higher

59 Christian Concern (2024). 'DIY abortions,' available online at https://christianconcern.com/cccases/diy-abortions/, accessed February 16, 2024.

60 Regional Chief Midwife (2020). Letter from Regional Chief Midwife to GM CYP Clinical Director's [sic] and Heads of Nursing. Available online at https://christianconcern.com/wp-content/uploads/2018/10/CC-Resource-Misc-Judicial-Review-Abortion-200729-NHS-email-2.pdf, accessed February 16, 2024.

61 R (Christian Concern) v SSHSC. Available online at https://christianconcern.com/wp-content/uploads/2018/10/CC-Resource-Misc-Abortion-JR-CoA-Judgment-200925.pdf, accessed February 16, 2024.

62 Carlsson, I et al. (2018). 'Complications related to induced abortion: a combined retrospective and longitudinal follow-up study,' *BMC Women's Health*, 18: 158.

complication rates than the Aiken, et al. study referenced by the FDA suggests, especially when these pills are distributed without standard pre-abortion testing and without medical supervision, AKA "pills by post." Moreover, the U.K. data the FDA used did not even attempt to study some of the most serious safeguarding and safety concerns raised by various credible organizations. The U.S. FDA was remiss in its duty by relying on compromised U.K. data, misrepresented by a biased U.S. pro-abortion researcher, assisted in her deception by co-authors representing the U.K. abortion industry, in order to justify removing critical in-person safeguards on medical abortion.