



OPEN ACCESS

Self reported outcomes and adverse events after medical abortion through online telemedicine: population based study in the Republic of Ireland and Northern Ireland

Abigail R A Aiken,^{1,2} Irena Digol,^{3,4} James Trussell,^{5,6} Rebecca Gomperts⁷

¹LBJ School of Public Affairs, University of Texas at Austin, TX 78713, USA

²Population Research Center, University of Texas at Austin, TX 78712, USA

³Women on Web International Foundation, Amsterdam, Netherlands

⁴Centre for Reproductive Health and Medical Genetics, Chisinau, Moldova

⁵Office of Population Research, Princeton University, NJ 08544, USA

⁶Chalmers Centre, University of Edinburgh, Edinburgh EH3 9ES, UK

⁷Women on Web International Foundation, Amsterdam, Netherlands

Correspondence to: A Aiken araa2@utexas.edu

Additional material is published online only. To view please visit the journal online.

Cite this as: *BMJ* 2017;357:j2011 <http://dx.doi.org/10.1136/bmj.j2011>

Accepted: 20 April 2017

ABSTRACT

OBJECTIVES

To assess self reported outcomes and adverse events after self sourced medical abortion through online telemedicine.

DESIGN

Population based study.

SETTING

Republic of Ireland and Northern Ireland, where abortion is unavailable through the formal healthcare system except in a few restricted circumstances.

POPULATION

1000 women who underwent self sourced medical abortion through Women on Web (WoW), an online telemedicine service, between 1 January 2010 and 31 December 2012.

MAIN OUTCOME MEASURES

Successful medical abortion: the proportion of women who reported ending their pregnancy without surgical intervention. Rates of adverse events: the proportion who reported treatment for adverse events, including receipt of antibiotics and blood transfusion, and deaths reported by family members, friends, or the authorities. Care seeking for symptoms of potential complications: the frequency with which women reported experiencing symptoms of a potentially serious complication and the proportion who reported seeking medical attention as advised.

RESULTS

In 2010-12, abortion medications (mifepristone and misoprostol) were sent to 1636 women and follow-up information was obtained for 1158 (71%). Among these, 1023 women confirmed use of the medications, and follow-up information was available for 1000. At the time women requested help from WoW, 781 (78%) were <7 weeks pregnant and 219 (22%) were 7-9 weeks pregnant. Overall, 94.7% (95% confidence interval 93.1% to 96.0%) reported successfully ending their pregnancy without surgical intervention. Seven women (0.7%, 0.3% to 1.5%) reported receiving a blood transfusion, and 26 (2.6%, 1.7% to 3.8%) reported receiving antibiotics (route of administration (IV or oral) could not be determined). No deaths resulting from the intervention were reported by family, friends, the authorities, or the media. Ninety two women (9.3%, 7.6% to 11.3%) reported experiencing any symptom for which they were advised to seek medical advice, and, of these, 87 (95%, 87.8% to 98.2%) sought attention. None of the five women who did not seek medical attention reported experiencing an adverse outcome.

CONCLUSIONS

Self sourced medical abortion using online telemedicine can be highly effective, and outcomes compare favourably with in clinic protocols. Reported rates of adverse events are low. Women are able to self identify the symptoms of potentially serious complications, and most report seeking medical attention when advised. Results have important implications for women worldwide living in areas where access to abortion is restricted.

Introduction

About a quarter of the world's population lives in countries with highly restrictive abortion laws.¹ Women in these countries often resort to unsafe methods to end their pregnancies. Globally, each year an estimated 43000 women die as a result of lack of access to safe legal abortion services through their countries' formal healthcare systems.² Millions more have complications.³ Worldwide, the fourth leading cause of maternal mortality is unsafe abortion.⁴

Yet in many countries, self sourced medical abortion provides a vital alternative to dangerous methods such as using sharp objects or noxious substances. Women source mifepristone and misoprostol (or misoprostol alone) themselves and use the medications outside the formal healthcare system. In some settings, women buy the medications from pharmacies or markets.⁵ In other settings, they can self source using online telemedicine

WHAT IS ALREADY KNOWN ON THIS TOPIC

In many countries where abortion through the formal healthcare system is restricted, self sourced medical abortion through online telemedicine provides an alternative to methods such as sharp objects or noxious substances

Little is known about the safety and effectiveness of medical abortion provided through this online pathway

Previous studies have been limited by small sample sizes, high losses to follow-up, and inability to examine self screening for potentially serious complications

WHAT THIS STUDY ADDS

This study is based on women's self reports of outcomes and complications of medical abortion and provides the best evidence to date that self sourced medical abortion through online telemedicine is highly effective and that rates of adverse events are low

Reported rates of successful medical abortion are comparable with protocols in clinics, and women report successfully self screening for potentially serious complications and seeking medical assistance when necessary

For the millions of women worldwide living in areas where access to abortion is restricted, the findings show the vital role played by self sourced medical abortion in providing an option with high effectiveness rates and few reported adverse outcomes

initiatives that provide medications as well as help and support by email or instant messaging.⁶

One setting in which online telemedicine has dramatically changed women's access to abortion is in the Republic of Ireland and Northern Ireland. Abortion laws in both the Republic and Northern Ireland are among the most restrictive in the world.¹ Abortion is allowed only to save a woman's life and, in Northern Ireland only, her permanent physical and mental health.^{7,8} Although Northern Ireland is part of the UK, the Northern Irish legislature did not adopt the 1967 Abortion Act, which legalised abortion carried out by registered medical practitioners in England, Scotland, and Wales. As a result, abortion under most circumstances remains illegal there under the Offences Against the Person Act of 1861, which provides a maximum penalty for the woman undergoing the abortion of life imprisonment.⁹

Women from the Republic and Northern Ireland who do not want to, or feel they cannot, continue with a pregnancy have traditionally had three options: those with the requisite financial and logistical means can travel abroad to access abortion in a clinic, while those who do not must either self induce using an unsafe method or continue their unwanted pregnancy. For the past decade, however, women of all financial means have also had the option to self source early medical abortion through online telemedicine.^{10,11}

Despite having been used by thousands of women in the Republic and Northern Ireland¹¹ and tens of thousands of women worldwide,¹² little is known about the outcomes of these self sourced medical abortions. Two existing studies have examined data from telemedicine initiatives: one across various settings⁶ and the other in Brazil.¹³ These studies showed encouraging results with respect to efficacy but were limited by small sample sizes and relatively high losses to follow-up. Moreover, no study has examined whether women are able to safely manage their own abortions by identifying the symptoms of serious complications and presenting for medical advice when appropriate.

Using data from an online telemedicine initiative, we conducted a population based analysis of women in the Republic of Ireland and Northern Ireland who self sourced medical abortion during a three year period. We examined self reported outcomes and complications after medical abortion through online telemedicine and assessed women's ability to self screen for the symptoms of potentially serious complications of abortion and their propensity to seek medical attention. In light of current policy debates,^{9,14} the Republic and Northern Ireland provide a particularly important and timely opportunity to examine women's self reported outcomes.

Methods

We examined data from Women on Web (WoW), a non-profit organisation that provides early medical abortion through online telemedicine in countries where access to safe abortion is restricted. The service is currently available for women up to 10 weeks' gestation at the

time of request. To make a request, women fill out a consultation form on the WoW website (www.womenonweb.org/en/i-need-an-abortion).¹⁵ A doctor reviews the medical information on the form and, if clinical criteria are met, provides a prescription according to the WHO recommended dose regimen for medical abortion.¹⁶ Mifepristone and misoprostol are sent through the mail by a partner organisation. Women either make a donation to support the service or, if they cannot afford to do so, the service is donated to them. Real time instruction about how to use the medications, as well as help and support during and after the abortion process, are provided by a multilingual specially trained helpdesk team.⁶ Women are invited to share their experiences four weeks later using an online evaluation form or by emailing the helpdesk.

Our dataset includes all women in the Republic and Northern Ireland who filled out an online consultation form and to whom mifepristone and misoprostol were sent from 1 January 2010 to 31 December 2012. We chose this date range for three reasons. Firstly, although WoW began providing online telemedicine abortion in 2006, changes to the software used to handle requests mean that data are available only from 1 January 2010 onwards. Secondly, in January 2013, a change to the evaluation form reduced the level of detail available on symptoms of potential complications and help seeking behaviour. Thirdly, WoW was the only telemedicine service operating in the Republic and Northern Ireland in 2010-13. Our sample therefore represents all women accessing medical abortion through online telemedicine during this period. Overall, 2150 women contacted the WoW helpdesk to request an abortion from 1 January 2010 to 31 December 2012. Among these, 514 cancelled their request or discontinued contact with the helpdesk, and no medications were sent to them. The analytic sample size was determined by the number of women remaining to whom medications were sent and who subsequently confirmed using them and provided follow-up information about the outcome of their abortion.

We did not distinguish between women who live in the Republic and Northern Ireland in our analyses. All women living in the Republic who access abortion through WoW have their medications sent to an address outside the Republic because the import by mail of prescription medications is prohibited and all incoming medications are confiscated by Irish customs.¹⁷ Some women from the Republic are already aware of the customs situation and select Northern Ireland as their country of origin on the consultation form. The border between the two countries, however, is, at present, barely discernible and fully open to travel. Moreover, the practicalities women face in terms of accessing abortion in the two countries is similar.

The online consultation form includes self reported information about age, weeks' gestation, feelings about the decision to have an abortion, and any medical contraindications or conditions requiring additional screening. We categorised age as <20, 20-24, and into 5 year increments thereafter, with a final group of ≥45.

Gestational age was reported as <7 weeks' or 7-9 weeks', which represents gestational age at the time of the consultation. During the time period of our study, WoW collected data on gestational age according to these categories to reflect the change in the registered use of mifepristone from up to 7 weeks' to up to 9 weeks' gestation in 2009.¹⁸ In our sample, 58% of women reported having gestational age confirmed through ultrasonography, and the remainder used a pregnancy calculator based on the date of their last menstrual period, which has been shown to be an accurate method of determining gestational age for early medical abortion.¹⁹ The estimated time for the medications to arrive in the Republic/Northern Ireland is between five and seven days, and 94% of women who used them reported doing so less than a week after they arrived. Thus, while we do not have information on women's exact gestational ages at the time they took the medications, we can estimate that for most women it was less than two weeks after the consultation.

Feelings about the decision to have an abortion were reported as "I can cope with my feelings regarding my decision" and "I have some worries about my decision and would like further information." Women who expressed worries were directed to appropriate sources of information. Questions on medical history included the presence of any contraindications (such as bleeding disorders, inherited porphyrias, allergies to mifepristone or misoprostol) or medical conditions that required additional medical screening (such as hypertension and diabetes).

We retrieved follow-up information for as many women as possible through either an evaluation form sent out four weeks after the medications were sent or email follow-up through the helpdesk. The evaluation form is based on similar follow-up instruments used in the clinical setting. Available information included the number of women who confirmed delivery of mifepristone and misoprostol, the number who confirmed whether or not they had used the medications, and, among those who confirmed use, the outcome of the abortion. The number of women who confirm using the medications is inevitably lower than the number to whom the medications are sent because some experience a spontaneous miscarriage, decide travel to obtain an abortion abroad, decide to continue with their pregnancy, or simply do not respond to follow-up from the helpdesk.

Women who confirmed using the medications were asked whether or not they are still pregnant, whether they received any surgical intervention (dilatation and evacuation or vacuum aspiration), and whether they received any other treatment after their abortion, including antibiotics and blood transfusion. Women were also asked if they experienced any symptoms of potentially serious complications, including: "bleeding requiring more than two maxi pads an hour for more than two hours"; "fever over 39°C or abnormal vaginal discharge"; and "persistent pain continuing for several days after the abortion." They were then asked whether they went to a hospital or to see a doctor. WoW advises

women to seek medical attention if any of the above symptoms arise.

For women who completed medical abortion at home and for whom self reported information on outcome was available, we first examined the age distribution, gestational age, feelings about abortion, and prevalence of contraindications and comorbidities. We then examined the proportion for whom medical abortion was successful according to the standard definition of success in the Medical Abortion Reporting of Efficacy (MARE) Guidelines—that is, the proportion who were able to expel their pregnancy without the need for surgical intervention.²⁰ Next, we examined the prevalence of reported adverse events, following to the extent possible the categories defined by Cleland and colleagues.²¹ Information was available on antibiotics, blood transfusion, and death. The highly politicised nature of abortion in the Republic and Northern Ireland means that any death suspected to be related to abortion would be extremely high profile news. We think it is likely that WoW would either have known if the woman in question had accessed their service or would have been notified by the authorities or the woman's family or friends. Finally, we examined the prevalence with which women reported symptoms of possibly serious complications and the frequency with which those who reported such symptoms sought medical attention.

Data analysis was conducted with Stata version 13.1 (StataCorp. 2013. College Station, TX). We calculated point estimates and exact binomial 95% confidence intervals for the overall population and for the binary categories of gestational age available in our dataset. Characteristics and outcomes by category of gestational age were compared with the Fisher-Freeman-Halton test and Fisher's exact test, respectively. Findings were considered significant at an α level of 0.05. Anonymised data were provided to us by WoW.

Patient involvement

Patients were not involved in the design or conduct of the study. The follow-up that WoW provides, however, is designed to deal with the priorities and experiences of women who access the service. Thus, though this study is an analysis of secondary, anonymised data, with no direct participant involvement, the research questions were informed by the needs of women who rely on WoW to access abortion.

Results

From 1 January 2010 to 31 December 2012, WoW sent 200 mg mifepristone and 1200 μ g misoprostol to 1636 women living in the Republic and Northern Ireland (fig 1). Among these, 1181 women confirmed subsequent use or non-use of the medications. Among the remainder, 24 women confirmed delivery but offered no further follow-up information, while 431 neither confirmed delivery nor offered further follow-up information. Among the 1181 women who confirmed use or non-use of the medications, 1023 used the pills, and 158 did not. Follow-up information on abortion outcome (that is, whether or not a woman was still pregnant after using

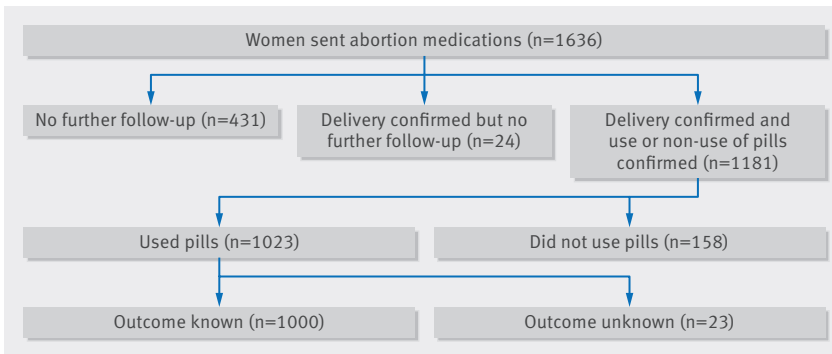


Fig 1 | Women accessing medical abortion through WoW (Women on the Web)

the medications) was available for 1000 of the 1023 women who confirmed use of the medications. Thus, outcome data were available for 1158 women who were sent mifepristone and misoprostol, representing 71% follow-up. Reasons for not using the medications included having had a spontaneous miscarriage in the meantime, accessing abortion through another pathway such as travelling abroad, and deciding to continue the pregnancy. One woman elected not to use the medications because she discovered her pregnancy was ectopic. No other ectopic pregnancies were reported either before or after use of the medications.

Among the 1000 women who used the medications and for whom we had information about the outcome of the abortion, 781 (78%) reported being <7 weeks pregnant at the time of requesting help from WoW, and 219 (22%) reported being 7-9 weeks pregnant (table 1).

Almost a third (n=306) of women were aged 30-34, 236 were 35-39, and 195 were 25-29, 79 were aged ≤24, and 184 were ≥40. Virtually all (997) reported being able to cope with their decision to have an abortion. None had any contraindications to medical abortion, and 23 had a medical condition that required extra screening to ensure that it could be carried out safely. Comparison of the characteristics of the 1158 women for whom follow-up information was available versus the 478 women for whom no follow-up information was available showed no clinically or statistically significant differences between the two groups (see appendix).

Virtually all women (99.2%, 95% confidence interval 98.4% to 99.7%) reported having ended their pregnancies, and 94.7% (93.1% to 96.0%) reported a successful medical abortion (that is, ending their pregnancies with no surgical intervention) (table 2). Women with a reported gestational age of 7-9 weeks at the time they requested an abortion more commonly reported receiving a surgical intervention than women with a reported gestational age of <7 weeks (7.3% (4.2% to 11.6%) v 3.7% (2.5% to 5.3%), respectively, P=0.04). There were, however, no statistically or clinically significant differences by gestational age in the proportions reporting a successful medical abortion (95.4% (93.7% to 96.8%) v 92.2% (87.9% to 95.4%); P=0.09).

Among the 1000 women for whom information about the outcome of their abortion was available, information about adverse events and symptoms of potentially serious complications was available for 987 (99%). Rates of self reported treatment for adverse events were low: 3.1% (95% confidence interval: 2.1% to 4.4%)

Table 1 | Medical and demographic characteristics of women conducting self sourced medical abortion through online telemedicine. Figures are number (percentage) of women

Characteristic	All gestations (n=1000)	<7 weeks' gestation (n=781)	7-9 weeks' gestation (n=219)	P value
Age (years):				
<20	4 (0.4)	3 (0.4)	1 (0.5)	0.17
20-24	75 (7.5)	53 (6.8)	22 (10.1)	
25-29	195 (19.5)	146 (18.7)	49 (22.4)	
30-34	306 (30.6)	238 (30.5)	68 (31.1)	
35-39	236 (23.6)	190 (24.3)	46 (21.0)	
40-44	135 (13.5)	115 (14.7)	20 (9.1)	
≥45	49 (4.9)	36 (4.6)	13 (5.9)	
Gestational age (weeks):				
<7	78 (78.0)	—	—	—
7-9	22 (22.0)	—	—	—
Feelings about decision to have an abortion:				
I can cope with my feelings	997 (99.7)	778 (99.7)	219 (100.0)	0.36
I have some worries about my feelings	3 (0.3)	3 (0.3)	0 (0.0)	
Contraindications to abortion:				
No contraindication	1000 (100.0)	781 (100.0)	219 (100.0)	1.0
Comorbidities:				
Heart disease	1 (0.1)	1 (0.1)	0 (0.0)	0.62
Epilepsy	1 (0.1)	1 (0.1)	0 (0.0)	
Hypertension	4 (0.4)	3 (0.4)	1 (0.5)	
Diabetes	4 (0.4)	2 (0.3)	2 (0.9)	
Hepatic disease	1 (0.1)	1 (0.1)	0 (0.0)	
Renal disease	0 (0.0)	0 (0.0)	0 (0.0)	
Thyroid disease	13 (1.3)	10 (1.3)	3 (1.4)	
Any co-morbidity	23 (2.3)	17 (2.2)	6 (2.7)	

Table 2 | Outcome of abortion reported by women conducting medical abortion through online telemedicine. Figures are number of women (percentage, 95% confidence interval)

Abortion outcome	All gestations (n=1000)	<7 weeks' gestation (n=781)	7-9 weeks' gestation (n=219)	P value
Pregnancy				
No longer pregnant	992 (99.2, 98.4 to 99.7)	774 (99.1, 98.2 to 99.6)	218 (99.5, 97.5 to 100.0)	1.0
Surgical intervention				
Reported surgical intervention*	45 (4.5, 3.3 to 6.0)	29 (3.7, 2.5 to 5.3)	16 (7.3, 4.2 to 11.6)	0.04
Successful medical abortion				
No longer pregnant and no surgical intervention	947 (94.7, 93.1 to 96.0)	745 (95.4, 93.7 to 96.8)	202 (92.2, 87.9 to 95.4)	0.09

*Dilatation and evacuation; vacuum aspiration.

Table 3 | Treatment for adverse events reported by women conducting medical abortion through online telemedicine. Figures are number of women (percentage, 95% confidence interval)

Treatment	All gestations (n=987)	<7 weeks' gestation (n=768)	7-9 weeks' gestation (n=219)	P value
Antibiotics	26 (2.6, 1.7 to 3.8)	19 (2.5, 1.5 to 3.8)	7 (3.2, 1.3 to 6.5)	0.63
Blood transfusion	7 (0.7, 0.3 to 1.5)	4 (0.5, 0.1 to 1.3)	3 (1.4, 0.3 to 4.0)	0.19
Death	0 (0, 0.0 to 0.4)	0 (0, 0.0 to 0.5)	0 (0, 0.0 to 1.7)	1.0
Any adverse event	31 (3.1, 2.1 to 4.4)	21 (2.7, 1.7 to 4.1)	10 (4.6, 2.2 to 8.2)	0.19

reported any treatment for a possible adverse event (table 3). Overall, 2.6% (1.7% to 3.8%) reported receiving antibiotics by any route of administration, 0.7% (0.3% to 1.5%) reported receiving a blood transfusion, and no deaths were reported by family, friends, the authorities, or the media. Rates of reported adverse events were not significantly more prevalent in the 7-9 week group than in the <7 weeks group (4.6% (2.2% to 8.2%) v 2.7% (1.7% to 4.1%), respectively, P=0.19).

Among the 987 women for whom we had information on self reported symptoms, 9.3% (95% confidence interval 7.6% to 11.3%) reported experiencing symptoms of a potentially serious complication (table 4). The prevalence of reporting any such symptom was higher in the 7-9 weeks group than the <7 weeks group (13.7% (9.4% to 19.0%) v 8.1% (6.2% to 10.2%), respectively, P=0.02). Bleeding requiring more than two maxi pads an hour for more than two hours was the most commonly reported of the symptoms (5.2%, 3.9% to 6.7%). Overall, 95% (87.8% to 98.2%) of women who reported symptoms of a potentially serious complication for which they were advised to seek medical assistance said they went to a hospital or clinic. There were no substantive or significant differences in the proportions of women who sought advised medical attention by reported gestational age (94% (84.3% to 98.2%) in the <7 weeks group v 96.7% (82.8% to 99.9%) in the 7-9 weeks group, P=1.0). None of the five women who did not seek

medical help reported an adverse outcome or treatment for a complication, and none of the women who did not report symptoms of a potentially serious complication reported an adverse event.

Discussion

Among women in the Republic of Ireland and Northern Ireland, early medical abortion provided through online telemedicine was highly effective. The reported rate of successful medical abortion compares favourably with the rates of those carried out within the formal healthcare system, both when mifepristone and misoprostol are administered in clinic and when mifepristone is administered in clinic and misoprostol is taken at home.²² The reported prevalence of adverse events is low, and, critically, when women reported experiencing symptoms of a potentially serious complication, almost all reported seeking medical attention as advised.

Limitations and strengths of study

The main limitation of our study is that we relied on women's self reports with respect to the outcome and complications of abortion. Many studies in the clinical setting, however, have the same limitation as women often do not return to the clinic and either self report by phone or are simply lost to follow-up. Moreover, as the women in our study are by definition conducting their

Table 4 | Reported symptoms and care seeking for potentially serious complications among women conducting medical abortion through online telemedicine. Figures are number of women (percentage, 95% confidence interval)

	All gestations	<7 weeks' gestation	7-9 weeks' gestation	P value
Reported symptoms:				
No of women	987	768	291	—
Bleeding >2 maxi pads/hr for >2 hours	51 (5.2, 3.9 to 6.7)	33 (4.3, 3.0 to 6.0)	18 (8.2, 4.9 to 12.7)	0.02
Fever >39°C or abnormal vaginal discharge	17 (1.7, 1.0 to 2.7)	10 (1.3, 0.6 to 2.4)	7 (3.2, 1.3 to 6.5)	0.07
Persistent pain continuing several days after abortion	24 (2.4, 1.6 to 3.6)	19 (2.5, 1.5 to 3.8)	5 (2.3, 0.8 to 5.3)	1.0
Any of above symptoms	92 (9.3, 7.6 to 11.3)	62 (8.1, 6.2 to 10.2)	30 (13.7, 9.4 to 19.0)	0.02
Advised to seek medical care given reporting any of above symptoms:				
No of women	92	62	30	—
Sought medical care as advised	87 (95.0, 87.8 to 98.2)	58 (94.0, 84.3 to 98.2)	29 (96.7, 82.8 to 99.9)	1.0

abortions outside the formal healthcare setting, self report is the only possible method of follow-up. While self reporting could be subject to recall or social desirability bias, the short time period between the abortion and the collection of follow-up information should minimise recall bias. A previous large randomised controlled trial showed that self assessment of the outcome of medical abortion was non-inferior to clinical follow-up, indicating that women are capable of determining on their own whether or not their abortion has been successful.²³ Although judgment of the symptoms of potentially serious complications is subjective, and not all will actually be indicative of an adverse event, it is reassuring that virtually all women who reported experiencing such symptoms said they sought medical advice. It is also unlikely that women had much incentive to give inaccurate reports of adverse events or complications. WoW was their main source of advice during their abortion, and so women who reported problems tended to have communicated with the helpdesk.

Another important limitation is that we were unable to ascertain whether the treatment women received for potential adverse events was appropriate and necessary. Previous work has shown that rates of surgical intervention after medical abortion provided through online telemedicine vary widely by setting.²⁴ The surgical intervention rate of 4.5% that we found is similar to equivalent rates found in studies of medical abortion in the clinical setting (which typically range from 3% to 5%).²² It is possible, however, that providers in countries where abortion is highly restricted might intervene inappropriately because of lack of experience or over-cautious management. They could also cause further complications through unnecessary or inappropriate interventions, and we are unable to distinguish these from adverse events relating to the abortion itself (for example, surgical intervention could lead to the need for a blood transfusion). The rate of reported receipt of an antibiotic in our sample was higher than previous reports of receipt of intravenous antibiotics after medical abortion in a clinic.²¹ We could not distinguish between antibiotics administered intravenously versus orally, the latter being much more common after medical abortion. Additionally, some healthcare professionals might provide oral antibiotics “just in case” or for an incidentally discovered urinary tract or sexually transmitted infection. Our rate of reported blood transfusion was also higher than in previous large studies of abortion in a clinic^{21 25} but still low at less than 1%. We also lacked information on two other adverse events—hospital admission and emergency room treatment.²¹ Previous studies, however, have shown considerable overlap between these events and the receipt of blood transfusion or antibiotics,²⁶ both of which we were able to include.

Key strengths of our study include the large sample size and high follow-up rate, which is comparable with or, in some cases, better than studies of abortion within the formal healthcare setting.²⁷ Additionally, we included data on the entire population of women in the Republic and Northern Ireland who accessed medical

abortion through online telemedicine. While we must acknowledge the limitations of necessary reliance on self reporting and incomplete follow-up, the questions we sought to answer about medical abortion provided outside the formal healthcare system in a setting where abortion is highly restricted cannot be dealt with by a randomised controlled trial, clinical trial, or prospective cohort study. We have drawn on the best available “real world” data to answer these important questions.

We consider that the rates of reported complications and successful abortion in our study might be conservative estimates. A previous study using telephone follow-up among a smaller sample of women who self sourced their own abortions using WoW shows that those to whom medications were sent but who did not spontaneously provide follow-up information by email or an online evaluation form were less likely to have experienced complications and more likely to have had a successful medical abortion.⁶ This possibility must still be balanced against the biases discussed above. We are also unable to definitively identify gestational age at the time of abortion, and some women might have had higher gestational ages than they were willing to disclose or might have experienced delays in receipt of the medications. Thus, we might reasonably expect the reported rates of adverse events to be slightly higher than those reported in clinical studies of medical abortion, which generally include gestational ages up to a maximum of 7 or 9 weeks.^{21 22 25 26} Moreover, a systematic review of the safety of regimens of medical abortion at home up to 8 weeks’ gestation indicates average rates of transfusion of 0.1%, which although higher than for studies of medical abortion in a clinic, is still considered low.²²

It is also important to view the rates of self reported adverse events shown in this study in the context of the other options available to women in the Republic and Northern Ireland who have an unwanted pregnancy. The complication rates we found are lower than the risk of equivalent complications during delivery in the UK.²⁸ They are also much lower than the equivalent risks associated with unsafe methods of abortion.³ While some could also raise ethical questions about the provision of medications without formal in person consultation with a doctor, it is worth noting that similar models of telemedicine are used in the US to prescribe and dispense numerous other medications (with the exception of controlled substances)²⁹ and that both mifepristone and misoprostol are on the WHO list of essential medicines.³⁰ Additionally, one might view the provision of abortion medications by telemedicine as an ethical response to the unethical practice of criminalising women for choosing abortion. A growing body of literature documents the negative health impacts experienced by women denied a wanted abortion and forced to continue an unwanted pregnancy compared with those who were able to access an abortion.^{31 32} In 2016, the United Nations Human Rights Council found Ireland in violation of its human rights obligations, stating that its abortion laws subject women to “suffering and discrimination.”³³

Applicability

Our results might not be generalisable to all settings where women self source using online telemedicine. A recent review of the acceptability of self managed abortion in both legal and legally restricted contexts emphasises the role of local attitudes surrounding abortion on women's experiences.³⁴ Higher levels of education and medical knowledge as well as better access to healthcare compared with women in developing settings might mean that women in the Republic and Northern Ireland are more likely to use the medications correctly and to seek follow-up care. The stigma surrounding abortion experienced by Irish women, however, is considerable. Women in both countries face the possibility of prosecution and jail sentences if they are found to have conducted an abortion at home. Recently, several women in Northern Ireland have been charged after being reported to the authorities by housemates or medical staff.^{35 36} Women who have had a self sourced abortion and those who have had an early pregnancy loss are clinically indistinguishable, but these events raise the concerning possibility of a chilling effect, whereby women might be reluctant to seek care for fear of being reported.

On average, women who access abortion through online telemedicine are older than women who access abortion in a clinic setting in the UK.³⁷ This difference might be because younger women are less likely to recognise their pregnancy sufficiently early to choose medical abortion if they have not been pregnant before, or they might be more likely to be able to travel abroad to access abortion because of parental assistance or fewer childcare commitments, or they might already be overseas pursuing higher education. Alternatively, older women might be more likely to have had abortions or deliveries before and thus be more confident about self managing their abortion at home. A previous study examining the decision making and experiences of Irish women who self sourced medical abortion through WoW indicated that some do so because they lack the financial or social resources to travel elsewhere.¹¹ Thus, our sample could be less socioeconomically advantaged than women who travel to access abortion care. The same study also showed, however, that others access abortion through online telemedicine because they prefer the privacy of using the medications at home, they lack the required documentation to travel, or they prefer medical abortion to a surgical alternative.¹¹

Implications and conclusions

Our results have important implications for the perception of abortion self sourced outside the formal health system using online telemedicine. Firstly, they clearly show that not at all abortions taking place outside the law are unsafe abortions. Secondly, they add an important dimension to existing evidence that women themselves report abortion through online telemedicine as a positive experience with benefits for health and wellbeing.¹¹ Millions of women worldwide live in countries where self sourced medical abortion

is a potentially lifesaving option, and strengthening services outside the formal healthcare setting could be a vital component of strategies to reduce maternal mortality from unsafe abortion. Finally, given the trajectory of abortion policy in Europe and the US, the visibility and importance of self sourced medical abortion will continue to increase. There are already reports of women seeking abortion outside the formal healthcare setting in the US.³⁸ Investigating women's experiences, preferences, outcomes, and unmet needs in various settings is a critical goal for future research.

Contributors: ARAA conceived the original research question, conducted the statistical analyses and prepared the tables and figures, and wrote the first draft of the manuscript. ARAA, RG, and JT contributed to the study design. RG and ID provided the de-identified data. ARAA and JT did the initial data interpretation. All authors contributed to final data interpretation, revised first and subsequent drafts critically for intellectual content, and approved the final manuscript. All authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. ARAA is guarantor.

Funding: This study was funded by a grant from the Society of Family Planning (SFPRF10-J12) and was supported in part by the Eunice Kennedy Shriver National Institute of Child Health and Human Development of the NIH through grant R24HD04284 to the population research centre at the University of Texas at Austin, and in part by grant P2C HD047879 to the office of population research at Princeton University. The funders played no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the article for publication. The authors are completely independent from the funding sources. The content of this article is solely the responsibility of the authors and does not necessarily represent the official views of the Society of Family Planning or the National Institutes of Health.

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare grants from the Society of Family Planning (ARAA) and infrastructure support from the National Institutes of Health (JT and ARAA); RG is founder and director of Women on Web, ID is a prescribing physician for Women on Web, JT serves on the Board of the Women on Web Foundation; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: The University of Texas at Austin institutional review board reviewed and approved study protocols and declared the use of the de-identified database for research purposes exempt from full board review. All women consented to the anonymised use of their data at the aggregate level for research purposes.

Transparency: The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained

Data sharing: No additional data available.

This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

- Center for Reproductive Rights. World abortion laws. <http://worldabortionlaws.com/>
- Kassebaum NJ, Bertozzi-Villa A, Coggeshall MS, et al. Global, regional, and national levels and causes of maternal mortality during 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 2014;384:980-1004. doi:10.1016/S0140-6736(14)60696-6.
- Grimes DA, Benson J, Singh S, et al. Unsafe abortion: the preventable pandemic. *Lancet* 2006;368:1908-19. doi:10.1016/S0140-6736(06)69481-6.
- Say L, Chou D, Gemmill A, et al. Global causes of maternal death: a WHO systematic analysis. *Lancet Glob Health* 2014;2:e323-33. doi:10.1016/S2214-109X(14)70227-X.

- 5 Costa SH. Commercial availability of misoprostol and induced abortion in Brazil. *Int J Gynaecol Obstet* 1998;63(Suppl 1):S131-9. doi:10.1016/S0020-7292(98)00195-7.
- 6 Gomperts RJ, Jelinska K, Davies S, Gemzell-Danielsson K, Kleiverda G. Using telemedicine for termination of pregnancy with mifepristone and misoprostol in settings where there is no access to safe services. *BJOG* 2008;115:1171-8. doi:10.1111/j.1471-0528.2008.01787.x.
- 7 Daniels P, Campbell P, Clinton A. The current state of abortion law and practice in Northern Ireland. *Br J Nurs* 2013;22:326-8. doi:10.12968/bjon.2013.22.6.326.
- 8 Wicks EA, B, C v Ireland: Abortion Law under the European Convention on Human Rights. *Hum Rights Law Rev* 2011;11:556-66doi:10.1093/hrlr/ngr015.
- 9 Dyer C. Abortion in Northern Ireland: is change on the cards? *BMJ* 2016;352:i629. doi:10.1136/bmj.i629.
- 10 Rowlands S. Abortion pills: under whose control? *J Fam Plann Reprod Health Care* 2012;38:117-22. doi:10.1136/jfprhc-2011-100232.
- 11 Aiken A, Gomperts R, Trussell J. Experiences and characteristics of women seeking and completing at-home medical termination of pregnancy through online telemedicine in Ireland and Northern Ireland: a population-based analysis. *BJOG* 2016. doi:10.1111/1471-0528.14401.
- 12 Women on Web. 10 Year Anniversary Press Release <http://www.womenonweb.org/en/page/11876/>
- 13 Gomperts R, van der Vleuten K, Jelinska K, da Costa CV, Gemzell-Danielsson K, Kleiverda G. Provision of medical abortion using telemedicine in Brazil. *Contraception* 2014;89:129-33. doi:10.1016/j.contraception.2013.11.005.
- 14 Irish Citizens' Assembly. The Eighth Amendment of the Constitution <http://www.citizensassembly.ie/en/The-Eighth-Amendment-of-the-Constitution/>.
- 15 Women on Web. <https://www.womenonweb.org/en/i-need-an-abortion>.
- 16 Safe abortion: technical and policy guidance for health systems. 2nd ed. World Health Organization, 2012 http://apps.who.int/iris/bitstream/10665/70914/1/9789241548434_eng.pdf.
- 17 Sheldon S. How can a state control swallowing? The home use of abortion pills in Ireland. *Reprod Health Matters* 2016;24:90-101. doi:10.1016/j.rhm.2016.10.002.
- 18 World Health Organization. Model List of Essential Medicines. 2010. http://www.who.int/medicines/publications/essentialmedicines/Updated_sixteenth_adult_list_en.pdf.
- 19 Schonberg D, Wang LF, Bennett AH, Gold M, Jackson E. The accuracy of using last menstrual period to determine gestational age for first trimester medication abortion: a systematic review. *Contraception* 2014;90:480-7. doi:10.1016/j.contraception.2014.07.004.
- 20 Creinin MD, Chen MJ. Medical abortion reporting of efficacy: the MARE guidelines. *Contraception* 2016;94:97-103. doi:10.1016/j.contraception.2016.04.013.
- 21 Cleland K, Creinin MD, Nucatola D, Nshom M, Trussell J. Significant adverse events and outcomes after medical abortion. *Obstet Gynecol* 2013;121:166-71. doi:10.1097/AOG.0b013e3182755763.
- 22 Ngo TD, Park MH, Shakur H, Free C. Comparative effectiveness, safety and acceptability of medical abortion at home and in a clinic: a systematic review. *Bull World Health Organ* 2011;89:360-70. doi:10.2471/BLT.10.084046.
- 23 Oppegaard KS, Qvigstad E, Fiala C, Heikinheimo O, Benson L, Gemzell-Danielsson K. Clinical follow-up compared with self-assessment of outcome after medical abortion: a multicentre, non-inferiority, randomised, controlled trial. *Lancet* 2015;385:698-704. doi:10.1016/S0140-6736(14)61054-0.
- 24 Gomperts R, Petow SA, Jelinska K, Steen L, Gemzell-Danielsson K, Kleiverda G. Regional differences in surgical intervention following medical termination of pregnancy provided by telemedicine. *Acta Obstet Gynecol Scand* 2012;91:226-31. doi:10.1111/j.1600-0412.2011.01285.x.
- 25 Upadhyay UD, Desai S, Zlidar V, et al. Incidence of emergency department visits and complications after abortion. *Obstet Gynecol* 2015;125:175-83. doi:10.1097/AOG.0000000000000603.
- 26 Gatter M, Cleland K, Nucatola DL. Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days. *Contraception* 2015;91:269-73. doi:10.1016/j.contraception.2015.01.005.
- 27 Grossman D, Ellertson C, Grimes DA, Walker D. Routine follow-up visits after first-trimester induced abortion. *Obstet Gynecol* 2004;103:738-45. doi:10.1097/01.AOG.0000115511.14004.19.
- 28 Knight M, Kenyon S, Brocklehurst P, Neilson J, Shakespeare J, Kurinczuk JJ, eds, on behalf of MBRACE-UK. Saving Lives, Improving Mothers' Care - Lessons learned to inform future maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2009-12. National Perinatal Epidemiology Unit, University of Oxford, 2014.
- 29 Friedman MA, Schueth A, Bell DS. Interoperable electronic prescribing in the United States: a progress report. *Health Aff (Millwood)* 2009;28:393-403. doi:10.1377/hlthaff.28.2.393.
- 30 World Health Organization. List of Essential Medicines. 19th ed, updated November 2015. http://www.who.int/medicines/publications/essentialmedicines/EML_2015_FINAL_amended_NOV2015.pdf?ua=1
- 31 Biggs MA, Upadhyay UD, McCulloch CE, Foster DG. Women's Mental Health and Well-being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study. *JAMA Psychiatry* 2017;74:169-78. doi:10.1001/jamapsychiatry.2016.3478.
- 32 Roberts SC, Biggs MA, Chibber KS, Gould H, Rocca CH, Foster DG. Risk of violence from the man involved in the pregnancy after receiving or being denied an abortion. *BMC Med* 2014;12:144. doi:10.1186/s12916-014-0144-z.
- 33 United Nations News Centre. Ireland: UN experts urge amending abortion ban subjecting women to suffering and discrimination. 9 June 2016. <http://www.un.org/apps/news/story.asp?NewsID=54180#WJZxgRiZ09Y>
- 34 Wainwright M, Colvin CJ, Swartz A, Leon N. Self-management of medical abortion: a qualitative evidence synthesis. *Reprod Health Matters* 2016;24:155-67. doi:10.1016/j.rhm.2016.06.008.
- 35 McDonald H. Northern Irish woman given suspended sentence over self-induced abortion. *The Guardian*, 4 April, 2016. <https://www.theguardian.com/uk-news/2016/apr/04/northern-irish-woman-suspended-sentence-self-induced-abortion>.
- 36 Fenton S. Second Northern Irish woman faces jail under abortion laws after helping daughter have termination. *The Independent*, 7 April, 2016. <http://www.independent.co.uk/news/uk/crime/second-northern-irish-woman-to-stand-trial-on-abortion-charges-a6972726.html>.
- 37 Department of Health. Abortion Statistics, England and Wales: 2015. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/523623/Abortion_Stats_2015.pdf
- 38 Redden M. *The Guardian*, 21 November, 2016. <https://www.theguardian.com/us-news/2016/nov/21/home-abortions-emails-secret-world>.

Appendix: Supplementary table