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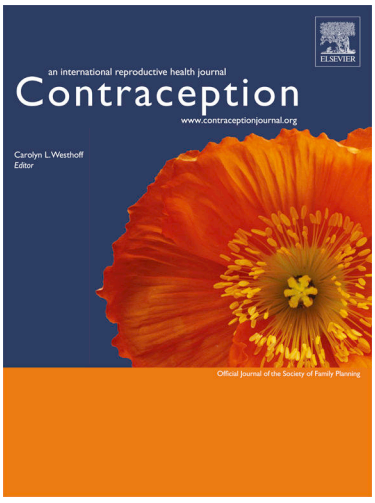

Original Research Article

Effectiveness of self-managed medication abortion between 13 and 24 weeks gestation: a retrospective review of case records from accompaniment groups in Argentina, Chile, and Ecuador

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Title: Effectiveness of self-managed medication abortion between 13 and 24 weeks gestation: a retrospective review of case records from accompaniment groups in Argentina, Chile, and Ecuador

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Abstract (word count: 250)

Objectives: In settings where abortion is legally restricted or inaccessible, grassroots feminist networks provide evidence-based information and support to individuals who self-manage abortions—a model of care known as abortion accompaniment. This study aims to fill a gap in existing evidence about out-of-clinic abortion beyond 12 weeks gestation.

Study design: We conducted a retrospective analysis of anonymized case records from accompaniment groups based in Argentina, Chile, and Ecuador of abortions supported between 13-24 weeks gestation. We report on the reproductive histories of individuals who underwent accompanied abortions, as well as medication regimens, and outcomes.

Results: Between 2016 and 2018, 316 individuals received accompaniment support for 318 medication abortions between 13-24 weeks gestation. Individuals most commonly used mifepristone-misoprostol (n=297, 93%), with sublingual misoprostol administration (n=288, 88%). Medication alone resulted in 241 complete abortions (76%); 37 (12%) people underwent manual vacuum aspiration or dilation and curettage within the formal health system, and 16 people (5%) required an additional medication abortion attempt at a later date, resulted in ongoing pregnancy, or were lost to follow-up. After accounting for additional interventions or monitoring at a healthcare facility, 302 of 318 (95%) abortion attempts completed overall. We had complete information regarding complications only from Chile (n=78); of these, 12 (15%) experienced potential complications, including delayed placental expulsion and/or heavy bleeding (n=5, 6%), high fever (n=3, 4%), and hypotension, panic attack, or vomiting (n=3, 4%). No abortions resulted in transfusion or hysterectomy.

Conclusions: Self-managed medication abortion, with accompaniment group support and linkages to the formal health system in the event that complications arise, may be an effective and safe option for abortion beyond the first trimester – particularly in legally restrictive settings.

Keywords: second-trimester abortion; later abortion; self-managed abortion; medication abortion; accompaniment; Latin America;

Implications: (word count: 49)

These results build on an emerging body of evidence suggesting that self-managed medication abortion beyond 12 weeks gestation, conducted with accompaniment support and referrals to formal health care services as needed, can be an effective model of abortion care – and may provide a safe alternative to clandestine surgical procedures.

1. Introduction

Worldwide, an estimated 10-15% of induced abortions occur after 12-weeks gestation[1, 2]. Abortions occur after 12-weeks gestation for a variety of reasons, including delays such as later discovery of pregnancy, time required to gather funds for abortion services, the need to arrange childcare or time off work, and distance to a provider[3-9]. Legal restrictions focused on gestational age limits further compound these barriers to abortion care, resulting in a higher proportion of abortions beyond 12-weeks taking place outside of the formal healthcare sector[10].

Increasing awareness and access to safe medications, through local pharmacies, the Internet, community health workers, activist groups, telemedicine models, and more, have enabled more people to have the tools to safely self-manage abortion regardless of geography or legal context[11-16]. As a result, in some regions, the proportion of global abortions considered "unsafe" has declined in recent years, a shift that researchers attribute directly to increasing use of misoprostol, alone or in combination with mifepristone[17], as an alternative to less-safe and potentially life-threatening methods[18-20].

In some legally restricted settings, self-described feminist networks that pioneered the model of abortion accompaniment—a model that can be described as the provision of evidence-based protocols, information, and support, virtually or in-person, throughout the abortion process to individuals who self-manage abortions – have begun to support people seeking to use medication for abortion beyond 12 weeks gestation[21]. Most accompaniers lack formal medical training, but have been trained by network leaders, regional and international organizations, and local medical professionals, to provide evidence-based, comprehensive, compassionate pregnancy options and abortion counselling - using World Health Organization (WHO)

medication abortion protocols according to gestational age – to individuals self-managing a medication abortion[14, 15, 21, 22]. Accompaniers meet regularly as a collective to share lessons learned, and stay up to date on revisions to medication abortion protocols[21].

Evidence from clinical settings has demonstrated that, when compared to first trimester abortions, abortions at later gestations carry a higher risk of complications (specifically retained placenta, hemorrhage and mortality)[23], require additional time, and cost more[24]. Nonetheless, evidence evaluating the safety and effectiveness of abortions that occur outside of clinical settings has, to date, predominantly documented abortions that occur in the first 12-weeks gestation, and levels of safety and effectiveness do not appear inferior to abortions that occur in clinical settings [11, 12, 25, 26].

Only a limited number of studies have documented out-of-clinic abortion care beyond 12-weeks gestation[15, 21, 27, 28]. Given the demonstrated need for abortion after 12-weeks worldwide—a need that is likely more acute in restricted legal settings—and that abortions beyond 12-weeks gestation do carry an increased health risk relative to first trimester abortions, research that evaluates the safety and effectiveness of self-managed medication abortion at this stage of pregnancy is of critical importance[23, 29, 30]. The purpose of this study is to describe the population that accessed accompaniment support for an abortion between 13-24 weeks gestation, the medication protocols used, abortion outcomes, and any safety events related to the abortions.

2. Materials and methods

2.1 Study setting

This is a retrospective analysis of anonymized case records for accompanied medication abortions from 13 to 24 weeks in Argentina, Chile, and Ecuador. In all three countries, abortion is legally restricted with few exceptions[31].

In each setting, individuals find information about the accompaniment groups via word-of-mouth, posters or fliers, online, or elsewhere, and contact the accompaniment groups by telephone, email, social media, or secure messaging apps. During an initial screening call, accompaniers assess the gestational age of the pregnancy based on last menstrual period (LMP) or, for all pregnancies above 12 weeks, an independently acquired ultrasound, and rule out any contraindications to medication abortion. During the initial call, accompaniers provide in-depth counseling and detailed information on the medication regimen, discuss options for accessing reliable medication abortion pills, what to expect, how to assess abortion completeness, options for managing products of conception, potential risks, how to identify warning signs of potential complications, when to seek formal healthcare services, and how to minimize legal risk in communications with healthcare providers. Accompaniers counsel participants to self-administer mifepristone at 200 mg orally 24-48 hours prior to the first dose of misoprostol; with misoprostol usually dosed at 800 mcg initially (sublingually or vaginally), followed by either (1) misoprostol at 400 mcg (sublingually) every three hours until expulsion of the fetus, or (2) misoprostol at 400 mcg (sublingually) every three hours for 12 hours (five doses of misoprostol, regardless of whether fetus is expelled prior to the fifth dose)[22].

Individuals are instructed to contact the accompanier after taking the first dose of mifepristone. For abortions that are accompanied in-person, approximately 24 hours after the first dose of mifepristone, 2-3 accompaniers will join the person in a secure location, and be with them throughout the abortion process to provide informational, emotional, and physical support,

following standard protocols and systematically documenting the abortion in an individual case record form that is then securely stored. Those who are accompanied virtually are in regular contact with the accompanier (hourly or with greater frequency when needed/wanted) by phone, text, or secure chat. The entire process, from first dose of mifepristone through expulsion of the pregnancy and completion of the accompaniment support generally lasts between 1-3 days.

2.2 Data source

We extracted data for this analysis from anonymized case records of individuals who had abortions at 13- 24 weeks gestation with accompaniment support in Argentina, Chile, and Ecuador between 2016 and 2018. Although each group uses a slightly different system of documentation, all three groups recorded sociodemographic characteristics (collected at the initial screening), timing and use of medication and dosage, side effects and symptoms of the abortion process itself, abortion outcomes, and any related healthcare seeking. In Chile, accompaniers documented events during the medication abortion itself and approximately 72 hours after; whereas accompaniers from Argentina and Ecuador remained in contact with individuals for one to three weeks following the abortion. Limited follow-up data beyond 72 hours were also available for individuals with a failed medication abortion—defined for the purposes of this study as taking medication abortion pills and not expelling the fetus.

In all three settings, accompaniers verbally inquired about each person's medical history. If individuals reported standard medication abortion contraindications such as prostaglandin allergy, suspected ectopic, intra-uterine device (IUD), or hemorrhagic disorder, the accompaniers did not proceed with supporting the medication abortion. Accompaniers did not consistently

document other relevant medical conditions, such as history of cesarean section or anemia; these are not contraindications, but potential risks with medication abortion.

Accompaniment group leaders securely transferred completed case records to the study team via photographs of the paper forms (Chile), electronic text documents (Chile and Ecuador), or pre-formatted in a password protected electronic database (Argentina). Study investigators hand extracted data from Chile and Ecuador's paper records, and merged these with Argentina's dataset into a single electronic database. Inclusion criteria included all individuals who used abortion medications with support of one of the three accompaniment groups, and were 13-24 weeks gestation at the time of misoprostol ingestion. The Allendale Investigational Review Board (IRB) in the United States (US) reviewed and approved this study. Concerns about the study subject matter and potential legal risk to the accompaniment groups and accompaniers themselves resulted in a unanimous decision among the study team not to seek in-country IRB approval, and to instead rely on an international IRB in the US, where the lead research organization is based.

2.3 Measures

The primary outcome of interest is complete abortion with medication alone. We considered abortions to be complete when records indicated that a person had expelled all products of a pregnancy within ~72 hours and had not received additional doses of medication (beyond the protocol described above) or any surgical interventions to facilitate completion of the abortion. We created a second variable to capture whether the intended outcome of the attempted medication abortion was achieved — i.e., the person was no longer pregnant at the end of follow-up, regardless of additional medical or surgical intervention. For this measure,– we

constructed a dichotomous outcome variable categorized as *positive* for anyone who was no longer pregnant at the end of the ~72 hours, regardless of having required monitoring or surgical intervention in a health facility, and *negative* for anyone who had an ongoing pregnancy or required an additional abortion attempt at a later date.

We also analyzed data related to secondary outcomes of interest including: medication regimen used to terminate the pregnancy; route of medication administration; interactions with formal healthcare services; surgical intervention; abortion complications; and time to expulsion. We categorized *route of medication administration* as: sublingual, vaginal, buccal, or a combination of sublingual and buccal use. We categorized those who interacted with formal health care services within ~72 hours of the medication abortion as having *sought formal healthcare services*, regardless of medical indication. We did not discriminate between local health unit, urgent care or hospital setting – we considered all to be "formal healthcare". For those who did seek care, when possible, we extracted information regarding any type of additional medication received or procedure performed. We categorized *surgical intervention* as "None," "Manual Vacuum Aspiration" or "Dilation & Curettage" based on the accompanier's documentation. We classified an event as an *abortion complication* if the record indicated the occurrence of retained placenta, heavy bleeding (as assessed by the accompanier), blood transfusion, uterine rupture or hysterectomy, or severe side effects from the medications. Expected side effects from mifepristone and misoprostol, such as abdominal pain, nausea, vomiting, diarrhea, or elevated temperature were not included as complications, unless the person's temperature was >38°C or symptoms were severe enough to warrant seeking medical care. Information regarding these potential complications was available for Chilean cases only. We measured *time to expulsion* as the time between ingestion of the first dose of misoprostol and

passage of the gestational sac/fetal expulsion, in number of hours (for Chile only), and in doses of misoprostol taken before the pregnancy expelled.

We obtained the following characteristics from case records: age, number of previous abortions and live births, gestational age of the index pregnancy, and insurance status. We reported insurance status as a marker of access to formal health care. Accompaniers in Argentina and Ecuador, but not Chile, systematically collected data on insurance status, and previous attempts to interrupt the pregnancy. For Chilean data, the study team recorded previous abortion attempts during the index pregnancy only if explicitly documented in case records; otherwise, we report this variable as missing for Chilean participants.

2.4 Data analysis

The denominator for most study outcomes is the total number of accompanied abortion attempts, not the number of pregnant individuals. Two people in our sample had two accompanied medication abortion attempts for the same pregnancy, in which the first accompanied abortion failed and the individual chose to reattempt a second accompanied medication abortion beginning again with mifepristone >7 days later; thus, 316 individuals with 318 medication abortion attempts. All participant and abortion data are reported by gestational age categories. We reported frequencies, means, and ranges for numeric variables. We generated a Kaplan-Meier curve to evaluate time-to-expulsion of the gestational sac/fetus in terms of hours among a sub-group of abortions.

3. Results

3. 1Accompaniment records

From services provided in 2016 to 2018, we obtained 455 case records from three accompaniment groups in Argentina, Chile, and Ecuador. The case records obtained from Argentina include all cases from the time period. The case records obtained from Chile and Ecuador include only those cases for which the accompaniers filled out the tracking form; prior to 2018, case records were not mandatory. While Chile and Ecuador could not provide a definitive count of the accompaniments provided prior to 2018, it is estimated that the majority of records are included in this analysis. Of these, we excluded 131 records with no data beyond the initial screening call (Figure 1). Based on gestational age on the day of the medication abortion, we excluded four persons with pregnancies <13 weeks gestation and two pregnancies ≥24 weeks gestation from analysis (Figure 1).

During the study period, 316 individuals received accompaniment support for 318 medication abortions between 13 to 24 weeks gestation.

3. 2 Characteristics of accompanied individuals, gestational age, and medication protocol

Individuals who had accompanied abortions beyond 12 weeks were young, most had a previous pregnancy, and nearly one in five (n=61, 19%) reported a previous abortion (Table 1). Prior to contacting the accompaniment group, at least 59 individuals (18%) had previously attempted to interrupt the index pregnancy, four of whom had two prior attempts. Accompaniers did not systematically record data on the specifics of these prior attempts.

At the time of beginning the accompanied medication abortion, 153 (48%) cases were 13-16 weeks gestation, 107 (34%) were 16-20 weeks, with the remaining 58 (18%) between 20-24 weeks. The vast majority of abortions (n=297, 93%) used a combined mifepristone-misoprostol regimen (Table 2); and administered misoprostol sublingually (n=281, 88%).

259

260 3.3 Accompanied abortion outcomes

261 Two hundred and forty one of 318 (76%) accompanied abortions successfully completed
262 with the accompanied medication abortion attempt alone (Table 2). After additional intervention,
263 302 abortions (95%) resulted in a non-pregnant state (Table 2). Among the 16 unsuccessful
264 abortion attempts (5%), 12 repeated a self-managed medication abortion, two received additional
265 medication in the hospital, and two opted to carry the pregnancy to term. When stratified by
266 country, 72%, 89%, and 74% of abortions (in Argentina, Chile, and Ecuador, respectively) were
267 completed with mifepristone and misoprostol alone. After additional intervention (medication or
268 procedure or monitoring in a healthcare facility), the proportion increased to 95%, 94%, and
269 100%, in Argentina, Chile, and Ecuador, respectively. Except for the two that chose to continue
270 the pregnancy, all subsequent abortion attempts (n=316, 99%) were successful. Chile measured
271 the duration of the abortion process with most detail: the pregnancy expelled within 12 hours of
272 taking the first dose of misoprostol in 70% of Chilean abortions (Figure 2).

273

274 3. 4 Health-care seeking during or after the abortion process

275 Just over one third of accompanied abortions (n=111, 35%) resulted in interactions with
276 the formal healthcare system within ~72 hours of taking mifepristone and misoprostol (Table 2).
277 In 61 (55%) of the 111 abortions for which individuals sought healthcare, the pregnancy had
278 fully expelled prior to arriving to healthcare. In those cases, the person sought healthcare not for
279 additional intervention, rather, for reassurance or confirmation from the clinician that the
280 abortion was complete.

We had complete information regarding complications only from Chile (n=78). Delayed placental expulsion occurred in three abortions (4%), heavier vaginal bleeding concerning for hemorrhage in three, including one individual who also had delayed placental expulsion (4%), and severe side effects from misoprostol, including fever >38 °C (n=3, 4%), extensive vomiting (n=1, 1%), panic attack (n=1, 1%), and hypotension with convulsion (n=1, 1%). Of the five abortions (6%) with documented possible hemorrhage and/or delayed placental expulsion, five (100%) sought healthcare. No one in this analysis faced any legal issues or repercussions from the accompanied abortion.

4. Discussion

This analysis presents new evidence from Argentina, Chile, and Ecuador that the accompaniment model of providing evidence-based information and support for self-managed medication abortion between 13-24 weeks gestation, together with links to formal sector health services when needed or desired, may be safe and effective. In this analysis, approximately 76% of accompanied abortions were complete with the initial medication regimen alone, and 95% of abortions were complete after additional healthcare intervention, within ~72 hours of initial medication use.

These data build on an emerging body of evidence documenting the safety and effectiveness of self-managed abortion beyond 12 weeks gestation [15, 21, 27, 28]. Our findings are consistent with a recent retrospective record review from a safe abortion hotline in Indonesia, which reported 93% of medication abortions between 13 and 22 weeks gestation completed on the first attempt, after accounting for healthcare intervention [15]. A retrospective case review from 2014 found that 44.8% of individuals in Brazil who contacted an online telemedicine

304 helpdesk for information on how to self-manage a medication abortion beyond 12 weeks
305 completed their abortion without surgical intervention; and after surgical intervention, 93% were
306 no longer pregnant [28]. The higher proportion of complete abortions with medication alone in
307 our analysis (76% versus 44.8%) could reflect an additional benefit of the accompaniment model
308 beyond the information and support provided by the telemedicine model, including guidance on
309 care-seeking, or it could simply reflect differences in study location, timing, or medication
310 choice. All three studies demonstrate nearly identical levels of pregnancy termination success
311 when accounting for additional intervention[15, 28] – levels that mirror those found in clinical
312 studies[32, 33]. Similarly, in all three studies, warning signs of potential complication were
313 relatively rare, and healthcare was sought in the majority of cases of a potential complication.
314 Of note, over one-third of people in our sample sought care at a health facility at some
315 point during or after the abortion, but more than half had expelled the pregnancy prior to seeking
316 care. Rather than signaling concern, this finding may be reflective of strong ties developed
317 between accompaniment groups and clinicians at various health facilities[21]. Among those who
318 had not expelled the pregnancy prior to arrival, care seeking could additionally indicate a
319 preference for expelling the fetus in a health facility – rather than a medical indication for care
320 [21]. It is encouraging that links to the formal healthcare system are in place, and that a
321 substantial proportion of individuals felt comfortable accessing care if desired or needed.
322 Where facility-based abortion care is effectively unavailable or illegal, the
323 accompaniment model beyond 12-weeks gestation may provide an important alternative to
324 clandestine and/or unsafe procedures which are often the only available option in restrictive legal
325 settings. Previous literature has often situated similar abortion support services within a harm
326 reduction framework [34-36]. However, the harm reduction framework has the potential to

exclude the exploration of a legitimate role for accompaniment models in legal settings as well[16, 37-39]. More research is needed to understand the preferences and interpersonal experiences of those who have abortions with accompaniment support, and comparisons between experiences with and preferences for accompaniment versus clinician-led telemedicine support for medication abortion.

This study is limited by a number of factors. Accompaniers did not use standardized measures related to complications and drug regimens. Despite a general protocol that all pregnancies beyond 12 weeks require a confirmatory ultrasound, gestational age for some pregnancies was assessed by self-report of LMP, which could have led to some incorrect dating of pregnancies. We are unable to discern which measurements were based on LMP versus ultrasound. Further, because not all individuals were followed for more than 72 hours after abortion completion, it is possible that we could have missed some complications -such as infection – that take time to develop. We were also constrained in our ability to assess indication for seeking formal healthcare services, or surgical indication for those who underwent MVA or D&C. We cannot distinguish medical need from patient request or provider-driven confirmatory assurance. Research on medication abortion would benefit from a consensus among investigators of standardized, validated indicators that medically and non-medically trained providers alike could use to address the need for further management.

Despite some limitations, this study is an important contribution to building the evidence base for de-medicalized, out-of-clinic models of medication abortion care. Findings suggest that accompaniment models could represent a safe and effective model of abortion care beyond the first 12 weeks of pregnancy, when linkages to formal health care exist.

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References:

1. Berer M. Abortion Law and Policy Around the World: In Search of Decriminalization. Health Hum Rights. 2017;19(1):13-27.
2. Gemzell-Danielsson K, Lalitkumar S. Second Trimester Medical Abortion with Mifepristone–Misoprostol and Misoprostol Alone: A Review of Methods and Management. Reprod Health Matters. 2008;16(sup31):162-72.
3. Baum S, DePiñeres T, Grossman D. Delays and barriers to care in Colombia among women obtaining legal first- and second-trimester abortion. Int J Gynaecol Obstet. 2015;131(3):285-8.
4. Foster DG, Kimport K. Who seeks abortions at or after 20 weeks? Perspect Sex Reprod Health. 2013;45(4):210-8.
5. Foster DG, Jackson RA, Cosby K, Weitz TA, Darney PD, Drey EA. Predictors of delay in each step leading to an abortion. Contraception. 2008;77(4):289-93.
6. DePiñeres T, Raifman S, Mora M, Villarreal C, Foster DG, Gerdts C. 'I felt the world crash down on me': Women's experiences being denied legal abortion in Colombia. Reproductive Health. 2017;14(1):133.
7. Kiley JW, Yee LM, Niemi CM, Feinglass JM, Simon MA. Delays in request for pregnancy termination: comparison of patients in the first and second trimesters. Contraception. 2010;81(5):446-51.
8. Drey EA, Foster DG, Jackson RA, Lee SJ, Cardenas LH, Darney PD. Risk factors associated with presenting for abortion in the second trimester. Obstet Gynecol. 2006;107(1):128-35.
9. Finer LB, Frohwirth LF, Dauphinee LA, Singh S, Moore AM. Timing of steps and reasons for delays in obtaining abortions in the United States. Contraception. 2006;74(4):334-44.
10. Harris LH, Grossman D. Confronting the challenge of unsafe second-trimester abortion. Int J Gynaecol Obstet. 2011;115(1):77-9.
11. Aiken ARA, Digol I, Trussell J, Gomperts R. Self reported outcomes and adverse events after medical abortion through online telemedicine: population based study in the Republic of Ireland and Northern Ireland. BMJ. 2017;357:j2011.
12. Foster AM, Arnott G, Hobstetter M. Community-based distribution of misoprostol for early abortion: evaluation of a program along the Thailand Burma border. Contraception. 2017;96(4):242-7.
13. Footman K, Keenan K, Reiss K, Reichwein B, Biswas P, Church K. Medical Abortion Provision by Pharmacies and Drug Sellers in Low- and Middle-Income Countries: A Systematic Review. Stud Fam Plann. 2018;49(1):57-70.
14. Gerdts C, Hudaya I. Quality of Care in a Safe-Abortion Hotline in Indonesia: Beyond Harm Reduction. Am J Public Health. 2016;106(11):2071-5.
15. Gerdts C, Jayaweera RT, Baum SE, Hudaya I. Second-trimester medication abortion outside the clinic setting: an analysis of electronic client records from a safe abortion hotline in Indonesia. BMJ Sex Reprod Health. 2018.
16. Moseson H, Herold S, Filippa S, Barr-Walker J, Baum SE, Gerdts C. Self-managed abortion: A systematic scoping review. Best Pract Res Clin Obstet Gynaecol. 2019.
17. Ganantra B, Gerdts C, Rossier C, Johnson Jr B, Tuncalp O, Assifi A, et al. Global, regional, and subregional classification of abortions by safety, 2010-14: estimates from a Bayesian hierarchical model. Lancet. 2017;390:2372-81.

18. Harper CC, Blanchard K, Grossman D, Henderson JT, Darney PD. Reducing maternal mortality due to elective abortion: Potential impact of misoprostol in low-resource settings. Int J Gynaecol Obstet. 2007;98(1):66-9.
19. Winikoff B, Sheldon WR. Use of medicines changing the face of abortion. International Perspect Sex Reprod Health. 2012;38:164-6.
20. Aiken ARA, Digol I, Trussell J, Gomperts R. Self reported outcomes and adverse events after medical abortion through online telemedicine: population based study in the Republic of Ireland and Northern Ireland. The BMJ. 2017;357:j2011.
21. Zurbriggen R, Keefe-Oates B, Gerdts C. Accompaniment of second-trimester abortions: the model of the feminist Socorrista network of Argentina. Contraception. 2018;97(2):108-15.
22. WHO. Medical Management of Abortion. Geneva, Switzerland: World Health Organization; 2018. Available from: https://www.who.int/reproductivehealth/publications/medical-management-abortion/en/
23. Calvert C, Owolabi OO, Yeung F, Pittrof R, Ganatra B, Tunçalp Ö, et al. The magnitude and severity of abortion-related morbidity in settings with limited access to abortion services: a systematic review and meta-regression. BMJ Global Health. 2018;3(3):e000692.
24. Roberts SC, Gould H, Kimport K, Weitz TA, Foster DG. Out-of-pocket costs and insurance coverage for abortion in the United States. Womens Health Issues. 2014;24(2):e211-8.
25. Endler M, Beets L, Gemzell Danielsson K, Gomperts R. Safety and acceptability of medical abortion through telemedicine after 9 weeks of gestation: a population-based cohort study. BJOG. 2019;126(5):609-18.
26. Gomperts R, 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 - Reply. BJOG. 2008;115(12):1588.
27. Constant D, Grossman D, Lince N, Harries J. Self-induction of abortion among women accessing second-trimester abortion services in the public sector, Western Cape Province, South Africa: an exploratory study. S Afr Med J. 2014;104(4):302-5.
28. 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(2):129-33.
29. Kapp N, Blanchard K, Coast E, Ganatra B, Harries J, Footman K, et al. Developing a forward-looking agenda and methodologies for research of self-use of medical abortion. Contraception. 2018;97(2):184-8.
30. Center for Reproductive Rights. Understanding The World's Abortion Laws Map 2019 Available from: https://www.worldabortionlaws.com/questions.html.
31. Ronald Johnson B, Mishra V, Francheska Lavelanet A, Khosla R, Ganantra B. A global database of abortion laws, policies, health standards and guidelines. Bull World Health Organ. 2017;95:542-4.
32. Borgatta L, Kapp N, Society of Family P. Clinical guidelines. Labor induction abortion in the second trimester. Contraception. 2011;84(1):4-18.
33. Ngoc NT, Shochet T, Raghavan S, Blum J, Nga NT, Minh NT, et al. Mifepristone and misoprostol compared with misoprostol alone for second-trimester abortion: a randomized controlled trial. Obstet Gynecol. 2011;118(3):601-8.
34. Tasset J, Harris LH. Harm Reduction for Abortion in the United States. Obstet Gynecol. 2018;131(4):621-4.

35. Grossman D, Baum SE, Andjelic D, Tatum C, Torres G, Fuentes L, et al. A harm-reduction model of abortion counseling about misoprostol use in Peru with telephone and in-person follow-up: A cohort study. PLoS One. 2018;13(1):e0189195.
36. Fiol V, Briozzo L, Labandera A, Recchi V, Piñeyro M. Improving care of women at risk of unsafe abortion: Implementing a risk-reduction model at the Uruguayan-Brazilian border. I Int J Gynaecol Obstet. 2012;118(S1):S21-S7.
37. Aiken ARA, Padron E, Broussard K, Johnson D. The impact of Northern Ireland's abortion laws on women's abortion decision-making and experiences. BMJ Sex and Reprod Health. 2019;45(1):3-9.
38. Foster A. Exploring Polish women's experiences using a medication abortion telemedicine service: A qualitative study. Eur J Contracept Reprod Health Care. 2018;23:59-60.
39. Ramos S, Romero M, Aizenberg L. Women's experiences with the use of medical abortion in a legally restricted context: the case of Argentina. Reprod Health Matters. 2015;22(44 Suppl 1):4-15.

468 **Figure 1.** Flow chart diagraming health-care seeking and abortion outcomes across all 318
469 accompanied abortion attempts.
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472 **Table 1.** Characteristics of individuals who self-managed an abortion with medications with
473 support from an accompaniment group in Argentina, Chile, and Ecuador over 318 abortion
474 attempts, and separately by gestational age
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	Gestational age at time of medication abortion			
	13 – 15 weeks	16 – 19 weeks	20- 24 weeks	Total
	n (%)	n (%)	n (%)	n (%)
Total	*153 (48)*	*107 (34)*	*58 (18)*	*318 (100)*
Country				
Argentina	133 (87)	63 (59)	25 (43)	221 (70)
Chile	13 (9)	38 (36)	27 (47)	78 (25)
Ecuador	7 (5)	6 (6)	6 (10)	19 (6)
Year				
2016	64 (42)	21 (20)	1 (2)	86 (27)
2017 & 2018	89 (58)	86 (80)	57 (98)	232 (73)
Age				
≤14	1 (1)	1 (1)	0 (0)	2 (1)
15 - 19	18 (12)	12 (11)	4 (7)	34 (11)
20 - 29	48 (41)	36 (34)	17 (29)	101 (32)
30 - 39	9 (6)	6 (6)	6 (10)	21 (7)
≥40	1 (1)	2 (2)	0 (0)	3 (1)
Missing	76 (50)	50 (47)	31 (53)	157 (49)
Prior term pregnancy				
Yes	93 (61)	53 (50)	25 (43)	171 (54)
Missing	2 (1)	7 (7)	7 (12)	16 (5)
Previous abortion	26 (17)	21 (20)	14 (24)	61 (19)
Health insurance				
Uninsured	84 (55)	47 (44)	19 (33)	150 (47)
Missing	13 (9)	38 (36)	27 (47)	78 (25)
Number of previous abortion attempts for this pregnancy				
0	54 (35)	31 (29)	20 (34)	105 (33)
1	27 (18)	22 (21)	6 (10)	55 (17)
2	1 (1)	2 (2)	1 (2)	4 (1)
Missing	71 (46)	52 (49)	31 (53)	154 (48)

476 **Figure 2.** Kaplan-Meier curve for time-to-expulsion of the gestational sac/fetus timed from the
477 first dose of misoprostol. Data from Chilean accompaniments (n=71) where the gestational
478 sac/fetus was successfully passed with medication only.
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Table 2. Medication abortion regimen, outcomes, and healthcare seeking among all accompanied abortion outcomes by gestational age occurring in Argentina, Chile, and Ecuador

	Gestational age at time of medication abortion			
	13 – 15 weeks n (%)	16 – 19 weeks n (%)	20 – 24 weeks n (%)	Total n (%)
Total	*153 (48)*	*107 (34)*	*58 (18)*	*318 (100)*
Medication used				
Mife+Miso	145 (95)	101 (94)	51 (88)	297 (93)
Oxaprost (miso + diclofenac)	1 (1)	0 (0)	0 (0)	1 (1)
Missing	7 (5)	6 (6)	7 (1)	20 (6)
Route of misoprostol administration				
Buccal	1 (1)	0 (0)	0 (0)	1 (0.3)
Sublingual	133 (87)	99 (94)	49 (84)	281 (88)
Vaginal	11 (7)	1 (1)	0 (0)	12 (4)
Combo, SL + Buccal	1 (1)	1 (1)	3 (5)	5 (2)
Missing	7 (5)	6 (6)	6 (10)	19 (6)
Complete after only mife & miso				
Yes	118 (77)	81 (76)	42 (72)	241 (76)
Missing	14 (9)	5 (5)	1 (2)	20 (6)
Did the person pass the gestational sac?				
No	4 (3)	3 (3)	6 (10)	13 (4)
Btwn the 1st and 2nd dose	0 (0)	6 (6)	1 (2)	7 (2)
Btwn the 2nd and 3rd dose	24 (16)	16 (15)	3 (5)	43 (14)
After the 3rd dose	120 (78)	79 (74)	47 (81)	246 (77)
Could not confirm	4 (3)	2 (2)	0 (0)	6 (2)
Missing	1 (1)	1 (1)	1 (2)	3 (1)
Visited medical care within ~72 hours after taking medication				
Yes	55 (36)	41 (38)	15 (26)	111 (35)
Missing	1 (1)	1 (1)	0 (0)	2 (1)
Surgical intervention within ~72 hours after taking medication				
Yes - MVA	6 (4)	12 (11)	5 (9)	23 (7)
Yes - D&C	8 (5)	4 (4)	2 (3)	14 (4)
Missing	40 (26)	22 (21)	2 (3)	64 (20)
Complete abortion after accompaniment support, with or without surgical intervention	146 (95)	105 (98)	51 (88)	302 (95)

Table 3. More detailed information on medication dosing, time to expulsion, health care seeking, and potential complications from a sub-group analysis of Chilean accompaniments only (n=78) (as Chilean records contain more detail on these topics than data from other sites).

	Gestational age at time of medication abortion			
	13-15 weeks	16-19 weeks	20-24 weeks	Total
	n (%)	n (%)	n (%)	n (%)
Total	*13 (17)*	*38 (49)*	*27 (35)*	*78 (100)*
Hours from 1st mifepristone to 1st misoprostol (mean ± SD)				
	38 ± 4	38 ± 6	43 ± 6	40 ± 6
Total mifepristone use (mg)*				
200	10 (77)	17 (45)	10 (37)	37 (47)
400	1 (8)	5 (13)	7 (26)	13 (17)
600	0 (0)	0 (0)	1 (4)	1 (1)
Missing	2 (15)	16 (42)	9 (33)	27 (35)
Total misoprostol dose (mcg)				
800	0 (0)	8 (21)	3 (11)	11 (14)
1200	7 (54)	10 (26)	1 (4)	18 (23)
1600	2 (15)	6 (16)	8 (30)	16 (21)
2000	1 (8)	7 (18)	8 (30)	16 (21)
2400	2 (15)	4 (11)	6 (22)	12 (15)
2800	0 (0)	1 (3)	0 (0)	1 (1)
3200	0 (0)	0 (0)	1 (4)	1 (1)
Missing	1 (8)	2 (5)	0 (0)	3 (4)
Hours between 1st dose of misoprostol and passing the pregnancy?**				
<3	0 (0)	6 (16)	0 (0)	6 (8)
3 - <6	5 (38)	9 (24)	0 (0)	14 (18)
6 - <9	3 (23)	9 (24)	7 (26)	19 (24)
9 - <12	0 (0)	4 (11)	12 (44)	16 (21)
12 - <15	0 (0)	3 (8)	5 (19)	8 (10)
15 - <18	1 (8)	1 (3)	0 (0)	2 (3)
18 - <21	0 (0)	1 (3)	1 (4)	2 (3)
Missing	4 (31)	5 (13)	2 (7)	11 (14)
Potential complications?				
None	9 (69)	31 (82)	23 (85)	63 (81)
Possible hemorrhage	2 (15)	0 (0)	1 (4)	3 (4)
Retained placenta ± bleeding***	1 (8)	3 (8)	1 (4)	3 (4)
Severe side effects	0 (0)	4 (11)	2 (7)	6 (8)
Unspecified	1 (8)	0 (0)	0 (0)	1 (1)
Visited medical care within ~72 hours				
Yes	2 (15)	4 (11)	2 (7)	8 (10)
Missing	0 (0)	1 (3)	0 (0)	1 (1)

** The WHO protocol followed by accompaniers recommends only a single dose of mifepristone. However, due to case-by-case variations, there were instances in which individuals took more than one mifepristone pill.*

491 ** *Among abortions that successfully completed with medication only.*
492 *** *One individual experienced both delayed placental expulsion and bleeding concerning for*
493 *hemorrhage, and is represented in each respective row.*