



*A roadmap for research on
self-managed abortion in the
United States*

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Introduction

Media coverage and research data show a growing awareness of the option to self-manage (or self-induce or self-source) abortion outside of the formal health care system; we are learning more about people's experiences with self-managed abortion, and how often people choose this option in the United States. Recent evidence indicates between one and seven percent of abortion patients (see below) have taken or done something to try to end their current pregnancy. In addition, in 2015, there were more than 700,000 Google searches using terms related to self-induced abortion in the United States.¹ The reasons women attempt to self-manage an abortion are varied, but they are often related to barriers accessing clinic-based care, as well as a preference for self-care.²

At the same time, many in our field recognize that facility-based provision of medication abortion in the United States is overly medicalized, although it has certainly become less medicalized over the 17 years since mifepristone was approved by the US Food and Drug Administration (FDA). For example, protocols now allow for women to take both mifepristone and misoprostol at home. But medication abortion could be even further demedicalized through pharmacy dispensing and expansion of telemedicine models—or even making it available over the counter (OTC)—which have the potential to expand access greatly.

We are now seeing a groundswell of interest among advocates and clinicians in efforts to make progress on two different but complementary goals. The first is to understand better what women and all people who need access to abortion care in the United States are actually doing as they access medication abortion on their own, ensure that they are doing so safely, and explore ways to support people who self-manage their abortions. Evidence is needed to understand how best to get people the information and resources they need, as well as to help clinics adapt to this changing landscape. The second goal is to work toward demedicalizing care and expanding access to medication abortion within facility-based, legal medical services. Research is necessary to understand and document alternative models of medication abortion provision, as well as to develop and test technologies that support demedicalized care models. Progress on these two goals would significantly improve the quality of abortion care in the United States.

Clearly many similarities exist between self-managed abortion and formal demedicalized care. Critics often have the same concerns about both—especially fears about the safety of abortion with less clinical supervision. Evidence that helps to allay those fears, including research to document experiences with self-managed abortion from a range of contexts in the United States and in other countries, will serve both to improve quality of care for people who choose to self-manage abortion now and to lay the foundation for future simplified medication abortion service delivery models.

Together, Advancing New Standards in Reproductive Health (ANSIRH), Gynuity Health Projects, and Ibis Reproductive Health have collaborated to develop this forward-looking research agenda around self-managed and demedicalized abortion in the United States. Below we describe four research priorities that we believe will significantly advance our goals to support people who self-manage abortion to do so safely and to generate critical evidence to remove unnecessary restrictions and provide medication abortion in user-friendly and accessible ways across the United States.

Priority #1: Understand the current landscape of self-managed abortion in the United States

This priority focuses on understanding the current and potential practice of self-managed abortion in the United States and the impact on service delivery, as well as women's interest in demedicalized abortion care. This work is central to understanding the scope of self-managed abortion in the United States (including aspects of safety); informing advocacy efforts and initiatives that support women with information and clinical back-up; and shaping our efforts to develop less medicalized models of care. This research may also be useful in advocacy efforts aimed at removing restrictive policies. At the same time, we must avoid framing self-managed abortion as a negative result of such policies, especially when women are using safe and effective methods. In addition, this research may help abortion clinics understand the scope of this phenomenon and aid them in adapting their services in light of this new reality.

Prior research has shown that a small proportion of US women attempt to self-induce abortion.^{3,4} In a 2014 national survey of abortion patients, 1.3% said they had ever used misoprostol to try to end a pregnancy or bring back their period, and 0.9% had ever used another substance, such as vitamin C or herbs.⁵ By comparison, a study of abortion patients in Texas found that seven percent had taken or done something to try to end the pregnancy before coming to the clinic.⁶ A representative survey of Texas women aged 18-49 estimated that at least 100,000 women in that state had attempted to self-induce an abortion at some point in their lives.⁷ This survey also found that women who reported that they had ever found it difficult to obtain reproductive health services, as well as Latinas living near the Mexican border, were more likely to report knowing someone who had attempted to self-manage an abortion or to have done so themselves.

A 2008 qualitative study of 30 women recruited from health care facilities in four US cities examined the experiences of women who had ever attempted to self-induce an abortion.⁸ The study found that women had used a range of methods, including herbs, vitamin C, birth control pills, various food products, and misoprostol to attempt to end their pregnancies. Study participants reported several reasons for choosing to attempt to self-manage an abortion, including being unable to afford the cost of clinic-based abortion care, wanting to avoid clinic-based care, and being young and therefore not knowing how or whether they could obtain a clinic-based abortion; others preferred self-management because they thought it was easier or more natural, or more like bringing their period back.

A number of important research projects to advance this effort are underway, including:

- A nationally representative survey of US women to estimate the prevalence of self-managed abortion, as well as women's interest in online and OTC access to medication abortion pills and advance provision of medication abortion pills.
- Surveys of abortion patients in five "bad-policy" states (Arkansas, Louisiana, North Dakota, Oklahoma, and Texas), and in as many as ten states where telemedicine is allowed, about their interest in online and OTC access to medication abortion pills and advance provision of medication abortion pills.
- Research on self-managed abortion among abortion patients and the general population of women in Texas.
- Documentation of experiences among women seeking/using self-managed abortion in the United States recruited from community providers and online sites offering medication abortion services.
- An online survey using Google AdWords to recruit women who are searching for information about abortion, some of whom have explored self-managed abortion.
- Research to estimate the prevalence of self-managed abortion among prenatal care patients in Louisiana and Baltimore.

We are now planning more comprehensive documentation in other states with restrictive policies, such as Louisiana and Mississippi, and more widespread research using innovative strategies, such as using Google AdWords, to recruit participants who seek information about where to obtain an abortion online, to understand how practices vary within different communities and networks, and to draw upon lessons learned from other countries. These projects include:

- Research on self-managed abortion in communities where people face significant barriers in the United States, such as Louisiana and Mississippi (including prevalence of, reasons for, and experiences with self-managed abortion).
- In-depth surveys of women who are searching for abortion pills or a clinic online, recruited using Google AdWords, to assess the prevalence of self-managed abortion among this population.
- Research and repackaging of data to respond to the needs of advocates and lawyers.
- A landscape analysis of existing research on self-managed abortion from other countries, packaged for US settings.
- Research on users' preferences for demedicalized models or self-managed abortion outside the formal health system.

Priority #2: Support self-managed abortion with information and improved digital technology

This priority focuses on evaluating novel ways to inform women who choose self-managed abortion about the safest and most effective methods, as well as developing linkages to clinical services if needed, to improve quality of care. Access to high-quality, acceptable, and safe self-managed abortion in the United States will in large part depend on whether people who access medications for self-managed abortion have accurate and digestible information about medication regimens and what to expect, as well as clear information about adverse effects and signs of serious complications that require medical care. Information about legal, facility-based care is also critical to ensure people seeking abortion care know their options. A broad range of new and innovative information delivery models exists, and research is needed to assess the acceptability and utility of these different approaches.

In settings where abortion is legally restricted, as well as where it is permitted by law but not widely accessible, women are increasingly choosing mifepristone and/or misoprostol to terminate their pregnancies outside of the formal health care system.⁹ Increasing use of these safe and effective medications for abortion in legally restrictive settings has been associated with reductions in abortion-related morbidity and mortality.¹⁰

In the late 1990s, advocates and clinicians in Uruguay working to reduce mortality and morbidity from unsafe abortion developed an innovative, clinic-based strategy to provide women with evidence-based information from the World Health Organization about how to safely terminate their own unwanted pregnancies using misoprostol,¹¹ and adopted the terminology of public health harm reduction programs. Decades of experience with the “harm reduction model” in Uruguay and elsewhere demonstrated that women who have access to evidence-based information about misoprostol for safe abortion can be empowered to terminate their own pregnancies with very low rates of complications,^{12,13} and innovations on the abortion harm reduction model have evolved around the globe, including safe-abortion hotlines, telephone accompaniment models, internet-based telemedicine counseling for abortion, and web-based information and pill delivery platforms.

Safe-abortion hotlines, web-based services, and other digital technologies have become central to women’s access to information about safe medication abortion in restrictive legal contexts around the globe.^{14,15,16} In the United States, given the stigmatized and politically polarized nature of abortion, in addition to the large number of complex state-level legal restrictions and the unknown legal risks of self-managed abortion, it is not surprising that evidence is scarce regarding who accesses information about medications for abortion outside of formal health care settings, their abortion experiences, and critical information gaps. We also know little about what platforms are used and trusted, and what

digital technologies would best facilitate access to reliable information and linkages to health systems when needed.

At present, efforts are underway to develop a smartphone app to meet the sexual and reproductive health and self-managed abortion information needs of women in the United States. To complement this research, we are planning to evaluate novel platforms with the potential to improve quality of care, including:

- Conducting a large-scale, mixed-methods study to document and explore who seeks information about self-managed abortion through online platforms (Safe2Choose, Women Help Women, Women on Web); reasons for seeking information about self-managed abortion; information about legal facility-based services; if, where, and how they have abortions; their abortion experiences, outcomes, and interactions with the formal health system; abortion preferences; and information gaps.
- Better understanding and evaluating the Self-managed Abortion Safe and Supported (SASS) model of providing tailored counseling to those seeking information and support for self-managed abortion in the United States by analyzing service statistics from the first year of SASS services. Additionally, prospectively recruiting women contacting the service for a qualitative study exploring their abortion experiences and outcomes; awareness of legal facility-based services; feelings of preparedness; perceptions of the quality of the information/services they receive; links/referrals to the formal health system for follow-up care when necessary; privacy concerns; and abortion preferences.
- Documenting and evaluating the impact of the smartphone app that has been developed for comprehensive sexual and reproductive health (which includes information about self-managed abortion) on abortion experiences and outcomes through a large-scale prospective study among facility-based and self-managed abortion users of the app.
- Developing and testing standardized materials in collaboration with communities that face barriers to abortion care about evidence-based protocols for self-managed abortion for dissemination to a range of audiences including abortion funds, pregnancy options hotlines, and grassroots advocacy organizations.

Priority #3: Countering clinical concerns with evidence

This priority focuses on building the evidence base to address commonly cited potential “risks” of medication abortion, which limit support for self-managed abortion and other demedicalized approaches. This work aims to improve medication abortion care both within and outside of the formal health care system. Information that addresses the concerns of the medical community about self-managed abortion is critical to building support for innovations to expand access and reduce unnecessary medicalization. The more we identify and address the layers of professional opposition to self-use with good science, the more likely practices can change both inside and outside of clinics. It is also possible that addressing the concerns of the medical community will help to reduce scrutiny of women’s use of medication abortion outside of facilities—and may lead to fewer prosecutions of women and those who assist them.

In the United States, providers commonly use ultrasound (and less commonly, pelvic examination) to determine gestational age and exclude ectopic pregnancy before starting the treatment. These examinations are costly, uncomfortable, and must be performed by personnel with specialized skills and equipment. Eliminating these tests could increase access by decreasing cost, expanding who could offer the service, and enhancing telemedicine delivery of medication abortion. Although the medical community is generally resistant to eliminating ultrasounds or pelvic exams before medication abortion, evidence has demonstrated that these tests are unnecessary. Women can estimate with reasonable accuracy from menstrual dating whether or not they fall within the current accepted limit for outpatient medication abortion.^{17,18,19} In addition, a recently completed study evaluated the safety and acceptability of medication abortion in selected women without an ultrasound or pelvic exam, and found that no serious adverse events occurred that would have been prevented by performing those tests.²⁰

Another concern with self-managed abortion or simplified screening is that women may (intentionally or not) take the medications at a gestational age past the current upper limit, when there is less evidence on the optimal regimen that should be used. While it is well established that the standard outpatient regimen of mifepristone and misoprostol works well up to 70 days LMP, one large study has shown that efficacy drops slightly in the 11th week (71-77 days LMP).²¹ A retrospective chart review in Mexico City suggests that adding a second dose of misoprostol can significantly boost success rates in the 11th week,²² but more research is needed in both the 11th and 12th weeks.

Another common test that is conducted for clinic-based abortion care is Rhesus (Rh) factor testing. Women presenting for abortion are tested if their status is unknown and all women are offered Rh immune globulin if their blood type is negative. This practice is based on expert opinion and extrapolation from the outcomes of full-term pregnancies. In fact, the actual likelihood of early medication abortion triggering sensitization and subsequent fetal morbidities is unknown, and most providers agree that it is quite low. Further evidence is needed on the necessity of searching for and

“treating” Rh negativity after early abortion. Simplifying (or even eliminating) this practice would help demedicalize medication abortion, including self-managed abortions.

Despite the extremely high efficacy rate of medication abortion in the first trimester, providers commonly ask women to have a follow-up visit to confirm pregnancy termination with ultrasound, pelvic examination, or serum pregnancy testing. One hurdle to having providers support self-managed abortion, or eliminating the follow-up visit, is lack of confidence that women can self-identify ongoing pregnancy in a timely manner. A well-studied strategy uses the multi-level urine pregnancy test (MLPT), which measures the approximate concentration of hCG hormone. A decline in concentration indicates that no ongoing pregnancy exists, whereas a stable or rising concentration suggests a need for further evaluation. A recent meta-analysis²³ looked at seven studies using this strategy, and concluded it is highly reliable and efficient up to 63 days gestation, and can allow the large majority of women to avoid an in-person follow-up visit to the abortion facility. Although the MLPT is not yet registered in the United States, work is underway to support its registration and strategize on how best to integrate it into services.

Below is an illustrative list of issues to be addressed:

- Whether women can assess gestational age accurately enough for safe use and to know what tools they may need.
- Documentation of what happens if women use medication abortion past 70 days (inside or outside of formal health services).
- Identification of safe and effective medication abortion regimens for use beyond ten weeks of pregnancy and development of accompanying information and support for people after 12 weeks of pregnancy.
- Research to understand if the standard medication abortion regimen can effectively treat ectopic pregnancies.
- Research to ascertain whether use of medication abortion without screening for ectopic pregnancy might delay diagnosis and treatment of an ectopic pregnancy and worsen outcomes.
- Studies to better understand and evaluate whether women identify ongoing pregnancy after taking the medications and know what tools they may need to do this effectively.
- Studies to understand if Rhogam is needed after early medication abortion and to clarify the real world risks of not providing Rhogam to Rh-negative women.

To advance this effort, we are planning to:

- Develop a point-of-care (including home) urine (or even blood) test to help women assess gestational age eligibility.
- Research outcomes and experiences with medication abortion past 70 days.
- Document outcomes and experiences of medication abortion services without ultrasound.
- Assess information on how Rh-negative women with early pregnancy loss are managed and when treatment is needed to avoid sensitization, and develop and disseminate best practices on the management of Rh-negative women undergoing medication abortion and whether treatment with Rhogam is needed.
- Research ectopic pregnancy in the context of medication abortion, including actual incidence among very early abortion patients, possible ways to predict/detect ectopic pregnancies, and assessment of whether mifepristone-misoprostol might actually prevent incipient ectopic

implantations and reduce the risk of ectopic pregnancy. (There is early suggestive evidence that very early use of mifepristone-misoprostol may decrease the number of ectopic pregnancies in a population; this issue needs further exploration.)

- Document women's ability to use and interpret the MLPT without provider instruction and disseminate information about and support registration of a multi-level pregnancy test for home follow-up after medication abortion.

Priority #4: Normalizing self-managed abortion services

This priority focuses on documenting the safety, effectiveness, and feasibility of client-directed and novel models of providing medication abortion, including pharmacy dispensing, direct-to-patient telemedicine, advance provision of medication abortion pills, and OTC access. This research will inform our understanding of the safety and effectiveness of self-managed abortion and move self-managed abortion into legally and medically sanctioned normalized health care. It will also potentially dramatically improve access to medication abortion in the United States.

For years, researchers, clinicians, and advocates have argued that medication abortion could be provided in simpler, less medicalized ways.²⁴ Research over the past decade has demonstrated conclusively that more than one routine visit to an abortion provider to obtain medication abortion is unnecessary. Women can take the misoprostol at home,²⁵ and they can confirm abortion success at home using urine pregnancy tests.^{26,27,28} Contraceptives, including implants and depot medroxyprogesterone acetate injections, can be effectively provided on the day of mifepristone.^{29,30} Elimination of the need for routine in-person follow-up has been endorsed by many normative bodies,^{31,32} including implicitly by the FDA in its 2016 approval of a new label for Mifeprex®.

Our focus now is on addressing the requirement for even a single in-person visit to a clinical facility to obtain medication abortion. Some foundation for removing this requirement has been laid. Home use of mifepristone has been established as safe³³ and is sanctioned by the National Abortion Federation and the Planned Parenthood Federation of America and again, implicitly, by the FDA. Experience with clinician-to-clinic telemedicine services has shown that a remote abortion provider can adequately counsel and evaluate a patient located in a separate clinical facility by reviewing her screening test results and speaking to her by videoconference and that this model increases access and patient satisfaction.^{34,35} Direct-to-patient telemedicine services, which go a step farther in enabling women to communicate by phone, internet, or videoconference with an abortion provider from home and then to receive medication abortion pills by mail, have been successful and acceptable in Canada,³⁶ Ireland,³⁷ and Australia,³⁸ as well as several other countries.³⁹ An ongoing project in the United States is showing encouraging results.⁴⁰ Studies in Australia and the United States have indicated that allowing distribution of mifepristone in pharmacies rather than only in clinicians' offices can enhance the availability of the drug by increasing the number of drug outlets⁴¹ and the number of clinicians willing to provide medication abortion.⁴² Finally, as mentioned above, substantial data indicate that at least for some women, eligibility for medication abortion can be determined entirely by history without ultrasound or other tests.^{43,44}

In the United States, some of these approaches to provision of medication abortion are currently prohibited by federal and state laws and regulations. The FDA Risk Evaluation and Mitigation Strategy for Mifeprex® requires that prescribers pre-register with the drug distributor and prohibits sale of the drug in retail pharmacies.⁴⁵ Laws in some states either directly or indirectly ban telemedicine. Reversing these regulations will be critical to expanding medication abortion options in this country.

Several lawsuits contesting these restrictions have been filed, but further evidence would help to support these challenges and to fight or prevent the introduction of additional similar regulations. In addition, research projects can serve to provide innovative services to women while the legal decisions are pending. As a community, we must develop, implement, and evaluate several new options for medication abortion in the United States and build the evidence base against restrictive laws and regulations. Specifically, we plan to assess the benefits, risks, and feasibility of the following:

- Sale of medication abortion pills by brick-and-mortar and online pharmacies with a prescription.
- Provision of medication abortion pills in advance to women in case of future need.
- Different models for providing medication abortion by direct-to-patient telemedicine.
- Provision of medication abortion pills OTC.

A number of critical research projects to advance this effort are underway, and include studies of: in-person pharmacy dispensing of mifepristone, clinician-to-clinic telemedicine, direct-to-patient telemedicine, an assessment of demand for and interest in advance provision of medication abortion pills, and the pilot of a label comprehension study for an OTC mifepristone-misoprostol product. Additional research is needed to document the safety, acceptability, and feasibility of a range of direct-to-patient telemedicine innovations. The work we are planning aims to:

- Expand direct-to-patient telemedicine with various options, such as:
 - Use of phone rather than videoconferencing.
 - Web-based interface for patient interactions and for recording clinical and research data.
 - Provision of medication abortion pills from a central pharmacy rather than from each clinician's office.
 - Elimination of the requirement for screening ultrasound and lab tests (i.e., implement screening based entirely on history).
 - Home-based follow-up methods using urine pregnancy testing.
- Study the uptake, safety, and effectiveness of advance provision of medication abortion pills.
- Undertake an OTC label comprehension study and develop and implement an actual use study in a simulated OTC environment.
- Identify ways to improve access in legally restricted settings using data from research with online providers and smartphone apps.

Closing

The research roadmap above describes an ambitious and impactful program of research activities that address many of the key issues preventing our field from taking a bolder stance on using medication abortion pills with limited clinical support. We believe the results of the research we outline will provide critical evidence to move toward formally recognizing and expanding access to demedicalized medication abortion models, and to support people who self-manage their abortions to do so safely.

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