

MEDICAL ABORTION

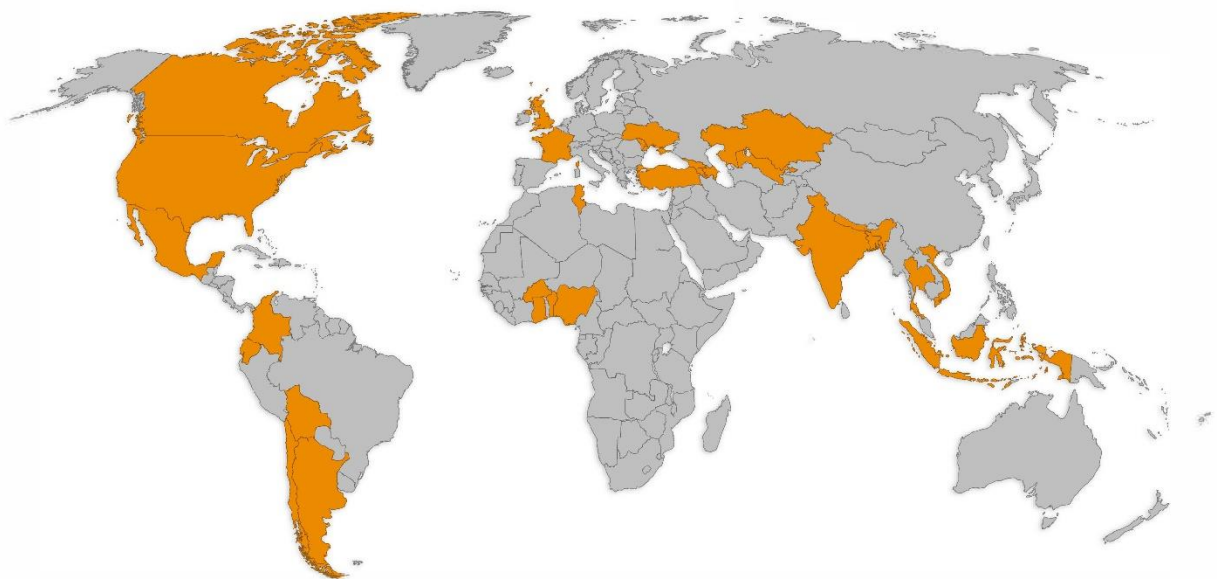
OVERVIEW

For almost three decades, medical abortion using mifepristone and misoprostol has proven to be a safe, effective, and desirable option for terminating pregnancies. Millions of women have chosen to have medical abortions because they wished to avoid surgery or because they felt the method was more natural and afforded greater autonomy and privacy. Medical abortion is an important choice for all women; in low-resource settings and where access to abortion services is limited, medical abortion has the potential to reduce morbidity and mortality dramatically from the estimated 21 million unsafe abortions that occur each year.¹ Gynuity's work improving access to medical abortion has been influential globally in simplifying service delivery and in making safe abortion more accessible.

Our primary goal is to increase access to medical abortion by improving medical abortion regimens and services through *Research*, creating local expertise through *Training*, and offering *Technical Assistance* to policy makers and advocates to incorporate evidence-based information into reproductive health guidelines and services. We also create *Resources* for varied audiences (health care providers, policy makers, and women) and undertake *Policy and Advocacy* activities to promote and preserve access to medical abortion. We collaborate with pharmaceutical companies to facilitate the registration of abortion medicines. This program brief describes our most recent endeavors. Further information about our previous achievements can be found on our website www.gynuity.org.

LOCATIONS

Gynuity Health Projects works in all regions of the world. The map below highlights previous and present medical abortion project countries.



RESEARCH

We conduct research to provide the data that makes change possible on a large scale. The research questions we ask are practical ones, derived from extensive experience and close observation of national services and international dialogue. Some of the important innovations in medical abortion practice that we have fostered through our research include the use of misoprostol and mifepristone at home, extending the gestational age limit for medical abortion in the first trimester, standardizing regimens for second trimester procedures, and documenting the provision of medical abortion by non-physician health providers.

SUMMARY OF CLINICAL AND OPERATIONS RESEARCH STUDIES

| Topic | Rationale | Studies |
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| <i>Extending the gestational age limit in late first trimester</i> | Previous research has established the safety and efficacy of outpatient medical abortion through 70 days since LMP. However, there remains a gap in the literature for the 11th and 12th weeks of gestational age. (Most second trimester protocols start at 13 weeks.) In order to improve the quality of care for women seeking later first trimester medical abortions, we are seeking to develop simple standardized treatment regimens and service delivery protocols. | A series of pilot studies in Tunisia and Vietnam demonstrated that outpatient medical abortion services were feasible for the late first trimester. These data helped inform the planning of larger studies of safety and efficacy. In 2016, we completed a study of outpatient mifepristone-misoprostol abortion at 64-70 days and 71-77 days' LMP in Azerbaijan, Mexico, Republic of Georgia, the U.S. and Vietnam. |
| <i>Simplifying screening for medical abortion</i> | In many settings, ultrasound and/or pelvic exam is standard before medical abortion to determine the duration and location of the pregnancy. These procedures can limit access to the treatment as they are costly, time-consuming, invasive and uncomfortable, and require the presence of a specially trained clinician in an equipped medical facility. | A recently completed study in Moldova, the U.S. and Mexico evaluated medical abortion without initial ultrasound or pelvic examination. The study found no serious complications or adverse events attributable to the omission of the screening ultrasound or exam, and the simplified procedures were highly acceptable to women. We are beginning research to understand the necessity of routine screening and administration of Rh immune globulin to Rh negative women. We are also in the very early stages of developing a urine or serum based test for gestational age dating without ultrasound and/or a clinic visit. The evidence we generate from these two streams of research will help determine future policies and service delivery strategies in settings, including telemedicine, where Rh tests and ultrasound for gestational age dating are not routinely available. |

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| <i>Using medical abortion drugs to treat ongoing pregnancy after initial medical abortion failure</i> | The recommended treatment for ongoing pregnancy following medical abortion is usually vacuum aspiration. Limited data demonstrate that additional misoprostol can terminate ongoing pregnancy, but there is no published literature on the repeat use of a combined mifepristone-misoprostol regimen. Anecdotal evidence indicates that some providers repeat the combined regimen in the event of an initial failure. | We are conducting a randomized controlled trial to assess the effectiveness of a repeat course of 200 mg mifepristone and 800 mcg buccal misoprostol compared to two doses of 800 mcg buccal misoprostol for treatment of ongoing pregnancy. Our findings may reveal medication alternatives to vacuum aspiration, which could be important for women who seek to avoid surgical intervention and for clinical settings where these interventions are not feasible. |
| <i>Pain management during outpatient medical abortion</i> | Medical abortion causes pain and cramping in almost all women, which can sometimes be intense. Despite current clinical protocols that include NSAIDs or even narcotic analgesics, women consistently report high pain scores and cite pain as a negative feature of medical abortion. Alternative pain management strategies are needed to improve women's comfort and acceptability of the method and, in turn, the overall quality of their medical abortion experience. | We recently completed a survey in the U.S. to document the methods women use to manage pain, nausea, and anxiety during first trimester medical abortions (with a particular focus on marijuana) and to ascertain their perceptions on the effectiveness of these pain control methods. |
| <i>New technologies for follow-up after medical abortion</i> | Since the vast majority of women abort successfully with medical abortion and do not require in-person follow-up, it is important to explore ways to determine which women need to return for clinic-based care. Sequential use of a multi-level pregnancy test (MLPT) that monitors trends in hCG levels in urine could feasibly replace clinic-based follow up for most women. Research is needed to ascertain whether women can use and comprehend test results outside of clinics, in both legal and limited legal access settings, and to determine how best to integrate this tool into service delivery. | We are exploring the feasibility and acceptability of using an MLPT at home in lieu of routine clinic follow-up to identify ongoing pregnancies after medical abortion services working in a range of settings such as: Bolivia, Ecuador, Kazakhstan, Mexico, Pakistan and the United States. We also evaluated its use in conjunction with an interactive telephone system using serial MLPTs. We published a meta-analysis of 7 of our studies summarizing the data on the effectiveness of using the MLPT to rule out ongoing pregnancy in women ≤ 63 days' gestation. The test sensitivity in identifying ongoing pregnancy and the negative predictive value were both 100%. |

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| <i>The TelAbortion Project</i> | Many women in the U.S. face significant barriers in reaching an abortion clinic. Innovative, high quality service delivery models for abortion are urgently needed. | <p>We started a pilot project in 2016 to evaluate the feasibility and acceptability of a model to provide medical abortion by telemedicine. Women receive counseling via videoconference, obtain screening tests at facilities close to them, and if eligible, are sent mifepristone and misoprostol through the mail. The pilot operates in four U.S. states: New York, Hawaii, Oregon, and Washington. We intend to expand to additional states.</p> <p>We are also exploring the feasibility of telemedicine abortion models outside of the U.S.</p> |
| <i>Introducing and integrating second-trimester medical abortion into service delivery systems in new geographies</i> | Since many countries offer limited legal access to abortion, the quality of second trimester services may need strengthening. We are committed to introducing second trimester medical abortion services in new settings by increasing provider experience with medical methods in later gestations, contributing to guideline development and creating a local evidence base of the safety, efficacy and acceptability of medical abortion in the second trimester. | We are at present carrying out open label studies in Burkina Faso and Benin to evaluate the feasibility and acceptability of medical abortion in the second trimester. We will also collect data to inform global efforts to expand task-sharing in abortion care by documenting the roles of ob-gyns, midwives and nurses in service delivery. |
| <i>Developing a second-trimester medical abortion day procedure</i> | Over the past five years, we have developed a significant body of evidence on regimens for medical abortion in the second trimester. We recently conducted a pooled analysis of these data to help assess the feasibility of providing second medical abortion as an outpatient “day service.” We believe that if these later abortions can be managed mostly as outpatient procedures, the abortion process will be simpler and less burdensome for women and health care delivery systems. | Using the supportive evidence generated in our pooled analysis, we have developed an innovative model for an outpatient “day procedure” for medical abortion in the second trimester. We are currently piloting this service delivery innovation at hospitals in Nepal where we will enroll women seeking abortion at 13 – 18 weeks’ gestational age. To help bolster international evidence on task-sharing in medical abortion, we will also document the tasks performed by special doctors, other doctors, junior doctors and nurses in the provision of services. |
| <i>Assessing potential demand for menses-inducing drugs</i> | In some countries women with early missed periods who do not wish to be pregnant use mifepristone and/or misoprostol without confirming their pregnancy status – a service that has been termed “medical menstrual regulation” or MMR. | In the U.S. we are currently studying potential demand for “missed period pills” using an anonymous survey with women presenting for reproductive health services in two states– one in which abortion is relatively unrestricted (New Jersey) and another in which it is more restricted (Michigan). We are currently planning new work to assess the safety, feasibility and acceptability of using missed period pills among women and providers in the U.S. |

TRAINING AND TECHNICAL ASSISTANCE

Gynuity conducts trainings for health care providers typically paired with service delivery research to enhance the quality, effectiveness, accessibility, and/or coverage of programs. In April 2016, Gynuity celebrated 15 years of medical abortion use in Tunisia with the Tunisian *Office Nationale de la Famille et de la Population*, key partners in the introduction and extension of the method nationally. In Mexico City, due in part to Gynuity's efforts since 2007, medical abortion now accounts for over 80% of abortion procedures in the first trimester. Mifepristone and misoprostol are offered as outpatient services through 10 weeks of pregnancy throughout the Mexico City Secretariat of Health public sector network.



Health care providers in Mexico.

Gynuity provides technical assistance to global health entities such as the International Federation of Gynecology and Obstetrics (FIGO) and the World Health Organization (WHO) to encourage inclusion of evidence about medical abortion into clinical guidelines. Gynuity staff also participate in WHO advisory groups to create and update abortion guidelines. For example, we are members of a collaborative working group, Supporting Expanded Roles for safe Abortion care by Health workers (SERAH), established in 2016, that works to disseminate the WHO 2015 Guide on Health Worker Roles in Providing Safe Abortion Care and Post-abortion Contraception. These collaborative efforts inform our work with national public and private sector entities to influence clinical practice guidelines, a service we have provided in dozens of countries. In many of these places and others we have played a large role in the registration of mifepristone for medical abortion.

POLICY AND ADVOCACY

In June 2015, Gynuity launched the Coalition to Expand Access to Mifepristone in the United States. As of May 2017, 115 organizations and 264 individuals were involved in the Coalition. Members include researchers, advocates, clinicians, and other reproductive health professionals. The goal is to ensure that mifepristone is available in pharmacies and accessible to all U.S. women who need it. Activities to date include celebrating the fifteenth anniversary of the FDA approval of mifepristone in the U.S. and advocating for evidence-based changes to the mifepristone product label, most of which were included in the revised FDA approved label issued in March 2016. We have also launched a small grant initiative to encourage innovative thinking and dynamic projects that support the Coalition's goals.

RESOURCES

Gynuity has been producing informational resources for health care providers and women's health advocates since 2003. We continue to have demand for *Providing Medical Abortion in Low-resource Settings: An Introductory Guidebook*, 2nd Edition (2009), available in 10 languages and as an e-publication in English. We produce materials for users of the method to enhance their understanding of the process, and we adapt images and concepts to the varied contexts in which we work. Many of these images will be made available via an image bank on our website.



For more information consult www.gynuity.org or for copies of our publications, please contact pubinfo@gynuity.org.

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¹ Sedgh, G. et al "Induced abortion: incidence and trends worldwide from 1995 to 2008" Lancet (2012); Feb 18;379(9816):625-32.

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