

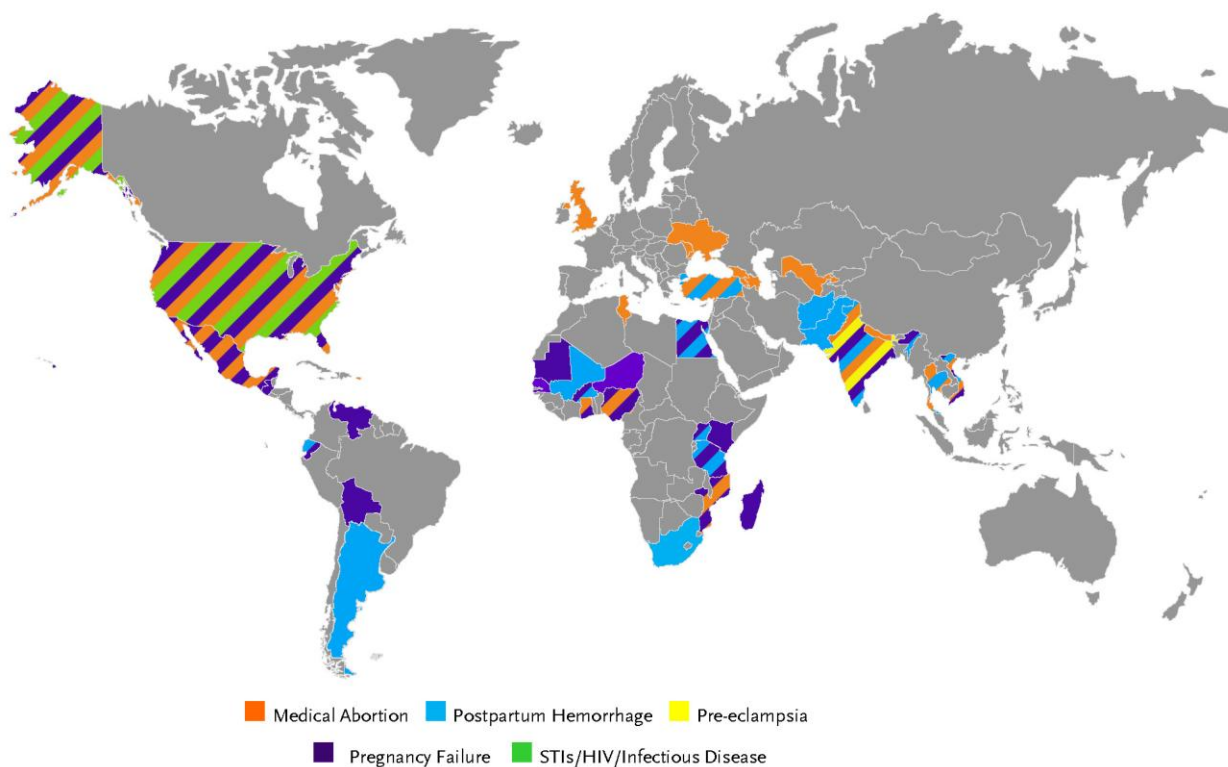
CLINICAL RESEARCH

Gynuity works with researchers and clinical care providers in the United States and internationally to conduct research on critical women’s health issues. Our aim is to reduce morbidity and mortality related to some of the most significant health problems facing women, such as unsafe abortion and postpartum hemorrhage. We work predominantly in low-resource settings, where access to adequate health care can be challenging.

Some of the specific objectives of our clinical research include:

- refining clinical protocols for existing reproductive health technologies to increase convenience, safety, and acceptability, and to reduce costs,
- testing treatments in different service delivery contexts and settings,
- providing women and health care providers the opportunity to learn about and evaluate new technologies, and
- generating data for regulatory filings and working with regulatory agencies.

The following map demonstrates the countries and topic areas in which we currently work, or have completed research



CURRENT RESEARCH

Medical Abortion

Expanding options with mifepristone for early medical abortion

- National expansion study of medical abortion to 14 regions of Tunisia: Protocol of 400 mcg sublingual misoprostol after 200 mg mifepristone up to 63 days' LMP.
- Uptake and acceptability of home use of mifepristone for medical abortion.
- Comparing two doses of 800 mcg buccal misoprostol alone to the combined regimen of 200 mg mifepristone followed by 800 mcg buccal misoprostol for gestations up to 63 days' LMP.
- Testing buccal administration of 800 mcg misoprostol following 200 mg mifepristone up to 63 days' LMP.
- Open-label study comparing the efficacy, safety, and acceptability of mifepristone and 800 mcg buccal (in U.S.) or 400 mcg sublingual (Republic of Georgia, India, Tunisia, Ukraine) misoprostol between 57-63 days' vs. 64-70 days' LMP.
- Testing buccal administration of 400 mcg misoprostol following 200 mg mifepristone up to 63 days' LMP.
- Exploring alternatives to a routine follow-up visit after early medical abortion.
- Simplifying medical abortion provision: Exploring the role of at-home semi-quantitative pregnancy tests for medical abortion follow up.

Medical abortion regimens for pregnancy termination in the second trimester

- Comparing a combination of mifepristone and buccal misoprostol to buccal misoprostol used alone for termination of pregnancies 14-21 weeks' gestation.

Pregnancy Failure and Miscarriage

Misoprostol for post-abortion care

- Introduction of 400 mcg sublingual or 600 mcg oral misoprostol as first-line treatment for incomplete abortion.

Misoprostol for second trimester intra-uterine fetal death

- Comparing two different doses of buccal misoprostol (200 mcg vs. 100 mcg) as a treatment for fetal death at 14 – 28 weeks' gestation.

PROJECT COUNTRIES

Tunisia

Moldova, Nepal, U.S.

Tunisia, Vietnam

Armenia, Azerbaijan, Mexico

Republic of Georgia, India, Tunisia, Ukraine, U.S.

Republic of Georgia

Moldova, U.K., Uzbekistan, Vietnam

U.S.

Moldova, Puerto Rico, Tunisia, Turkey

Ecuador, Egypt, Guatemala, Madagascar, Mexico, Niger, Senegal

U.S.

Postpartum Hemorrhage

Misoprostol for prevention of postpartum hemorrhage

- Two trials comparing 10 IU oxytocin IM (Uniject®) to 600 mcg oral misoprostol for PPH prevention at community-level (1 at primary level, 1 for home deliveries). India, Mali, Vietnam
- With University of Liverpool and Makerere University, Uganda: Pilot study on safety and effectiveness of self-administered oral misoprostol (600 mcg) versus placebo in home delivery settings for prevention of PPH. Uganda
- Misoprostol for primary prevention versus early treatment/secondary prevention of postpartum hemorrhage: A comparison of two community strategies of misoprostol use to reduce postpartum hemorrhage. Egypt, India

Misoprostol for treatment of postpartum hemorrhage

- RCT comparing 800 mcg sublingual misoprostol vs. placebo + standard of care (primary health care level). Egypt, Kenya
- RCT comparing 800 mcg sublingual misoprostol vs. placebo + standard of care following 600 mcg misoprostol as PPH prophylaxis (home births). Afghanistan, Pakistan

Pre-eclampsia

Magnesium sulfate for treatment of pre-eclampsia

- Testing the low-tech SpringFusor pump for introduction of IV magnesium sulfate. India

STIs/HIV/ Infectious Disease

Woman-controlled products for vaginal health

- Testing a topical estrogen cream for vaginal self-protection. U.S.

Clostridium sordellii and perfringens infection

- Estimating prevalence of vaginal and rectal colonization in women of reproductive age. U.S.
- Evaluating changes in vaginal and rectal carriage following medical and surgical abortion. U.S.
- Estimating the efficacy of doxycycline vs. placebo in eliminating vaginal or rectal carriage. U.S.

COMPLETED RESEARCH

Medical Abortion

Expanding options with mifepristone for early medical abortion:

Ghana, India, Moldova, Mozambique, Nepal, Nigeria, Puerto Rico, Republic of Georgia, Thailand, Tunisia, Turkey, Ukraine, U.S. , Uzbekistan, Vietnam

Medical abortion regimens for pregnancy termination in the second trimester

Vietnam

Pregnancy Failure and Miscarriage

Misoprostol for post-abortion care :

Burkina Faso, Ecuador, Egypt, Ghana, India, Kenya, Madagascar, Mauritania, Moldova, Mozambique, Niger, Nigeria, Senegal, Tanzania, Uganda, Venezuela, Vietnam

Postpartum Hemorrhage

Misoprostol for prevention of postpartum hemorrhage:

Pakistan

Misoprostol for treatment of postpartum hemorrhage:

Burkina Faso, Ecuador, Egypt, Turkey, Vietnam

Misoprostol for adjunct treatment of postpartum hemorrhage:

Argentina, Egypt, South Africa, Thailand, Vietnam

Blood measurement:

India

For a detailed list of completed research protocols please write to pubinfo@gynuity.org. We invite you to visit our website for additional information about our research activities, and to read abstracts of published peer-reviewed articles for many of the completed studies in the Resources section.

26-Nov-10