

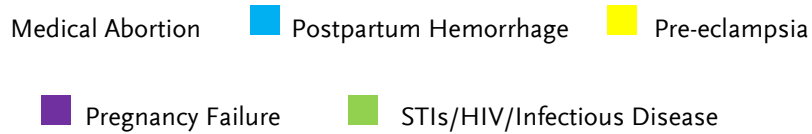
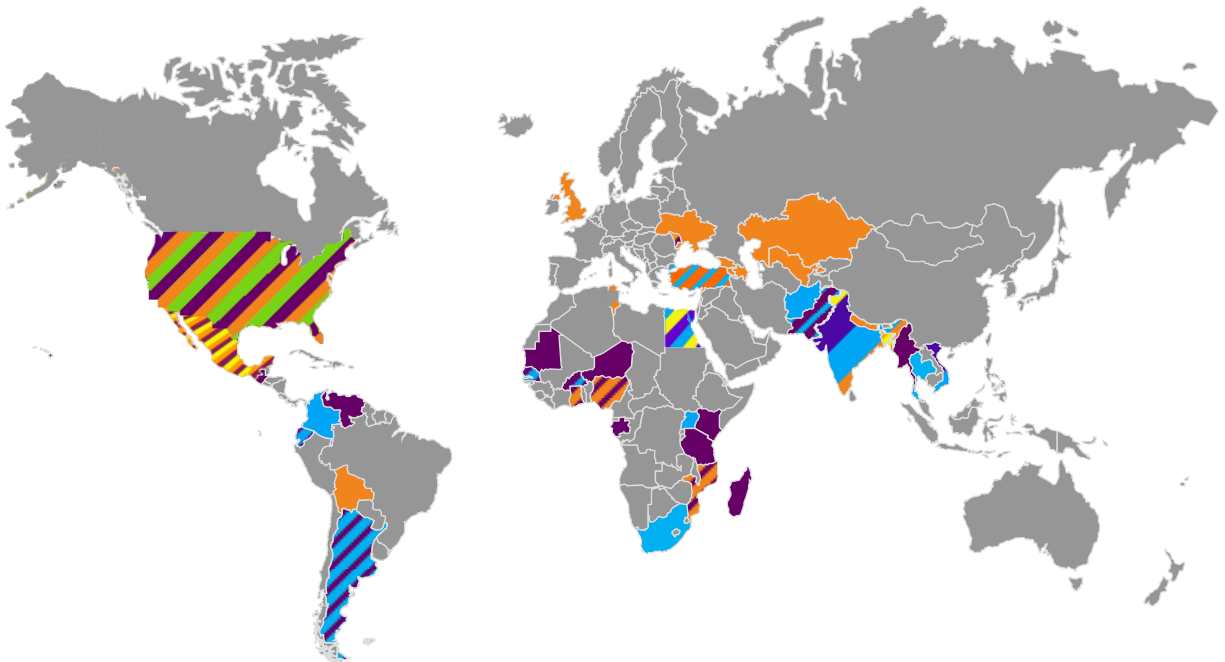
CLINICAL AND OPERATIONS RESEARCH

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 and operations 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,
- 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

- Simplified medical abortion screening: a pilot demonstration project
- Use of a semi-quantitative pregnancy test after early medical abortion
- Outpatient medical abortion through 77 days of gestation

- Pilot studies of outpatient medical abortion 71-84 days' LMP
- Acceptability and feasibility of mifepristone+misoprostol for menstrual regulation in public sector facilities in Bangladesh

Medical abortion regimens for pregnancy termination in the second trimester

- Effectiveness of mifepristone and repeated doses of sublingual misoprostol for abortion 13-22 weeks gestation
- RCT trial comparing sublingual to buccal misoprostol regimens after mifepristone for abortion 13-21 weeks gestation

Pregnancy Failure and Miscarriage

Treatment of missed abortion

- Comparing mifepristone + misoprostol vs. misoprostol alone for the treatment of missed abortion (tertiary level)

Treatment of intrauterine fetal death

- Mifepristone and misoprostol versus misoprostol alone for treatment of fetal death at 14-28 weeks of pregnancy: A randomized, placebo-controlled double-blinded trial

Misoprostol for post-abortion care

- Introduction of misoprostol as first-line treatment for incomplete abortion

Postpartum Hemorrhage

Misoprostol for postpartum hemorrhage

- Examining two strategies for postpartum hemorrhage prevention in communities: Misoprostol and Oxytocin in Uniject™
- A study of safety and effectiveness of self-administered oral misoprostol (600 mcg) versus placebo in home delivery settings for prevention of postpartum hemorrhage
- Two community strategies comparing use of misoprostol for secondary prevention to universal prophylaxis (primary prevention) for postpartum hemorrhage
- Comparing 800 mcg sublingual misoprostol vs. placebo + standard of care (primary health care level)
- Comparing 800 mcg sublingual misoprostol + standard of care vs. placebo + standard of care following 600 mcg misoprostol as postpartum hemorrhage prophylaxis (home births)
- Treatment of Postpartum Hemorrhage with Misoprostol: Whom do we treat? Who will develop fever?

PROJECT COUNTRIES

Moldova, U.S.
Bolivia, Mexico, India, Tunisia, U.S.
Azerbaijan, Mexico, Republic of Georgia, U.S., Vietnam

Tunisia, Vietnam
Bangladesh

Ukraine, Uzbekistan

Armenia, Nepal, Tunisia

Gabon, Pakistan, Argentina, Mexico

Vietnam

Ecuador, Egypt, Mexico, Myanmar, Senegal

Senegal

Uganda

Egypt, India

Egypt

Afghanistan, Pakistan

Latin America

CURRENT RESEARCH

PROJECT COUNTRIES

Postpartum Hemorrhage continued

Oxytocin in the third stage of labor for prevention of postpartum hemorrhage

- Effectiveness of oxytocin delivered either IV bolus, IV infusion or IM as postpartum hemorrhage prophylaxis

Ecuador, Egypt, Turkey, Vietnam

Pre-eclampsia

Diagnosis and prediction of pre-eclampsia: The clinical utility of the Congo-red dot test

- With Ohio State University, testing the hypothesis that pre-eclampsia is characterized by urine congophilia, which can be rapidly identified using a simple paper-based test (named the Congo Red Dot [CRD] test).

Bangladesh, Mexico

Assessing the usability and clinical utility of the Congo Red Dot Test: A case-control study and survey

- Assessing the usability and clinical utility of the Congo Red Dot Test

Mexico

Treatment of severe pre-eclampsia with magnesium sulfate regimens

- A randomized trial comparing treatment of severe pre-eclampsia with a magnesium sulfate regimen administered with the Springfusor® infusion pump to a continuous (IV) regimen

Egypt

Induction of labor with Foley catheter or Misoprostol (INFORM) Study

- With University of Liverpool and Government Medical College, Nagpur, comparing the Foley balloon catheter with oral misoprostol for induction of labor in pre-eclamptic women

India

Oral antihypertensive regimens for management of acute hypertension in pregnancy

- With the University of British Columbia and Government Medical College, Nagpur, comparing the efficacy, safety and side effects of nifedipine, methyldopa, and labetalol for management of hypertension in pregnant women

India

STIs/HIV/ Infectious Disease

Immune modulation with different routes of misoprostol

- With Vanderbilt University, assessing immune modulation by vaginal vs. buccal misoprostol

U.S.

COMPLETED RESEARCH**Medical Abortion***Medical abortion (MA) regimens in the first trimester*

Increasing acceptability and accessibility: Armenia, Azerbaijan, Bangladesh, Ghana, India, Kazakhstan, Mexico, Moldova, Mozambique, Nepal, Nigeria, Puerto Rico, Republic of Georgia, Tunisia, Turkey, Ukraine, U.K., U.S., Uzbekistan, Vietnam

Measuring adherence and side effects associated with antibiotic use following MA

U.S.

Comparing two regimens of ibuprofen for minimizing pain in first trimester MA

U.S.

Home-use of mifepristone in MA

Armenia, Azerbaijan, Moldova, Nepal, Republic of Georgia, U.S.

Alternatives to a routine follow-up visit after early MA

Mexico, Moldova, Tunisia, U.K., Uzbekistan

Comparing mifepristone-misoprostol regimens to misoprostol-alone regimens in the second trimester

Moldova, Tunisia, Vietnam

RCT trial comparing mifepristone and misoprostol dosing initiated simultaneously versus a 24h interval for abortions 13-22 weeks LMP

Vietnam

Pregnancy Failure and Miscarriage*Misoprostol for post-abortion care*

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

Misoprostol for second trimester intra-uterine fetal death

U.S., Vietnam

Postpartum Hemorrhage*Misoprostol for prevention of postpartum hemorrhage*

Pakistan, Uganda

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 techniques

India

Pre-eclampsia*Magnesium sulfate for treatment of pre-eclampsia*

India

STIs/HIV/ Infectious Disease*Woman-controlled products for vaginal health*

U.S.

Clostridium sordellii and Clostridium perfringens carriage

U.S.

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.

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