Ibis Reproductive Health

Medication Abortion

Brief 1: Making protocols and regimens more user friendly

Brief

Highlights

- Current evidence supports simplifying medication abortion protocols and regimens to make them more user friendly.
- Ibis has evaluated innovations including self-assessment of gestational age before abortion and urine pregnancy tests to verify successful termination of pregnancy.

Ibis Reproductive Health aims to improve access to medication abortion for women around the world. Using clinical and social science research, we test ways to make protocols and regimens—including both mifepristone and misoprostol and misoprostol-alone options—more user friendly; explore ways to improve access to medication abortion services and service delivery; and examine global policy related to medication abortion. We also strive to improve access to medication abortion by providing medically accurate information about this service to diverse audiences. We work in many different contexts, including where abortion is legal and where it is restricted, low-resource settings, and places where rates of unsafe abortion are high.

Review of the evidence for making medication abortion more user friendly

Mifepristone and misoprostol medication abortion was originally approved as a three-visit regimen in settings where abortion is legal, with the first visit to assess the woman's eligibility and dispense mifepristone, the second visit to administer misoprostol, and the third visit to confirm that the abortion was complete and rule out complications. Researchers have been examining ways to simplify the regimen so it is easier for women to access.

With colleagues from Gynuity Health Projects and the Department of Family and Social Medicine of the Montefiore Medical Center/ Albert Einstein College of Medicine, Ibis reviewed the evidence on ways to simplify medication abortion provision and outlined areas for further research. Research has clearly shown the effectiveness of a two-visit strategy, which gives women the option of taking misoprostol at home instead of at the clinic, and this approach has largely become standard of care. The review covered a number of other modifications designed to streamline service delivery, lower cost, and increase access to care while maintaining high levels of safety, efficacy, and acceptability. The following regimen and protocol improvements are supported by research evidence, but not yet incorporated into standard of care:

- Clinical exam in combination with a woman's report of her last menstrual period can be safely substituted for routine ultrasound when determining gestational age before medication abortion, assuming that there are no discrepancies between the woman's report and the bimanual examination.
- Serial serum hCG measures can be substituted for routine ultrasound when confirming termination of pregnancy and ruling out rare conditions such as ectopic pregnancy and gestational trophoblastic disease.

Additional modifications, such as self-assessment of eligibility for abortion and alternatives for post-abortion follow-up (including alternatives to ultrasound or blood tests in a clinic setting and self-assessment for follow-up care), have the potential to further increase the accessibility of medication abortion for women but require further research. See the article *Can mifepristone medical abortion be simplified? A review of the evidence and questions for future research* by Clark et al. 2007 for more information.

Where we work

Ibis works in a number of countries in diverse contexts, including in Latin America and the Caribbean, the Middle East and North Africa, sub-Saharan Africa, and the United States. In this brief, we feature work completed in Mexico and South Africa.

Eliminating the need for routine ultrasound before medication abortion

Routine use of ultrasound examination for determination of pregnancy duration limits women's access to medication abortion by restricting provision of the method to facilities with ultrasound equipment. Eliminating the need for this procedure before a woman can receive a medication abortion could increase access, particularly in low-resource settings. Here we highlight two of Ibis's studies which examine the possibility of replacing ultrasound with women's or providers' estimates of gestational age before medication abortion and find promising results.

Evaluation of women's and clinicians' estimates of gestational age

In South Africa, access to reproductive health care is included in the Constitution and abortion is permitted up to 20 weeks without restriction; nurses and midwives provide most abortions up to 12 weeks gestation. Mifepristone is approved for early abortion up to 56 days from the last menstrual period (LMP). As part of a study on women's and providers' attitudes towards medication abortion conducted in collaboration with colleagues at Gynuity Health Projects, the Philadelphia Hospital in Mpumalanga, the Population Council, the Reproductive Health and HIV Research Unit of the University of Witwaterstrand in Soweto, and the Women's Health Research Unit of the University of Cape Town, we collected data on women's, providers', and ultrasound assessments of gestational age and analyzed results from more than 600 abortion clients. We calculated women's and providers' estimates in three ways: clinical exam, women's report of LMP, and women's estimation of pregnancy duration. Estimates of duration of pregnancy based on

clinical exams were, on average, only two days different than ultrasound estimates, a clinically insignificant difference. A small proportion of women, approximately 10%, would have been identified as eligible for medication abortion based on a clinical exam, but were not eligible based on ultrasound findings. It is important to note that as gestational age increases additional counseling and support are needed to manage the side effects, but efficacy does not drop off precipitously at the cut-off so the majority of these women could likely have safely used medication abortion. Using a clinical exam to determine eligibility for medication abortion could greatly expand access to the method in South Africa, and we are currently working with advocates and policymakers to change guidelines and practice to use clinical exam as the main way to determine eligibility with ultrasound on referral if needed. More information on the study is available in the article *A comparison of women's, providers' and ultrasound assessments of pregnancy duration among termination of pregnancy clients in South Africa* by Blanchard et al. 2007.

Evaluation of a pregnancy wheel tool

In Mexico, where abortion is highly restricted except in the capital city and where many women self-medicate with misoprostol to terminate pregnancies, we worked with the Population Council Mexico to pilot test a pregnancy-wheel tool that women can use to estimate their gestational age and suitability for abortion in the first trimester. Use of this tool would not only make medication abortion less onerous by eliminating the need for pre-abortion ultrasound, but would also make it safer for women in legally restricted and resource-poor settings by giving women who choose to self-medicate a reliable way to determine their eligibility for medication abortion.

Eliminating the need for routine ultrasound after medication abortion

Routine follow-up visits after medication abortion are recommended or required by most medication abortion protocols, primarily to diagnose ongoing pregnancies. Although pelvic ultrasonography is not required by the United States Food and Drug Administration-approved mifepristone label, many health care facilities employ it to detect ongoing pregnancy. Here we highlight two of Ibis's projects that examine alternative ways to identify ongoing pregnancies after medication abortion, and suggest ways to further increase access to medication abortion.

Evaluation of a semi-quantitative urine pregnancy test in settings where ultrasound equipment is not available

Levels of hCG decline in the body after pregnancy and serum hCG measurements from blood tests can be used as an alternative to ultrasound to verify successful termination of pregnancy in a clinic setting. Use of a urine pregnancy test to measure hCG levels and detect ongoing pregnancy would further simplify medication abortion. With collaborators from the Instituto Nacional de Ciencias Medicas y Nutrición Salvador Zubirán, the Instituto Nacional de Perinatología Isidro Espinosa de los Reyes, and the Population Council, we evaluated a urine dipstick pregnancy test with four possible outcomes [negative, hCG<1000 IU/L, hCG>1000 IU/L (indicating ongoing pregnancy), or indeterminate] with 97 women at a hospital and private clinic in Mexico and compared its accuracy to serum hCG measurements from blood tests. We found the test to be reasonably accurate; sensitivity (ability to correctly identify ongoing pregnancies) was 88.6% and specificity (ability to correctly identify women without ongoing pregnancies) was 71.7%. Further work is needed to refine the test and testing algorithm and to determine sensitivity in settings where the less effective misoprostol-alone regimen is used, but the test shows promise as a way to screen for ongoing pregnancy after medication abortion. More information is available in the article *Accuracy of a semi-quantitative urine pregnancy test compared to serum beta-hCG measurement: A possible screening tool for ongoing pregnancy after medication abortion* by Grossman et al. 2007.

Systematic review of alternatives to ultrasound for follow-up after medication abortion

We conducted a systematic review of alternative ways to diagnose ongoing pregnancies after first-trimester medication abortion. Our search identified eight articles that compared two or more follow-up modalities, including women's self-assessment, clinicians' assessment, serum hCG measurements, urine pregnancy tests, and combinations of the above. The most promising modalities included serum hCG measurements, standardized assessment of women's symptoms combined with low-sensitivity urine pregnancy testing, and standardized telephone consultation (perhaps followed by high-sensitivity urine pregnancy test). These follow-up modalities were highly accurate at identifying ongoing pregnancies (the proportions of women with ongoing pregnancies who were correctly identified were all ≥90%, and the proportions of women who tested negative who did not have an ongoing pregnancy were all ≥99%). Furthermore, the proportions of women who were diagnosed with ongoing pregnancy by the follow-up modality and would therefore be referred for further evaluation, such as by ultrasound, were low, ≤33%. Additional research is needed to demonstrate the accuracy, acceptability, and feasibility of these alternative follow-up modalities in practice, in particular of home-based urine testing combined with self-assessment and/or clinician-assisted assessment. However, these findings indicate that alternatives to routine ultrasound after medication abortion are accurate at diagnosing ongoing pregnancy. More information is available in the article *Alternatives to ultrasound for follow-up after medication abortion: A systematic review* by Grossman and Grindlay 2010.

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Ibis Reproductive Health

Ibis Reproductive Health aims to improve women's reproductive autonomy, choices, and health worldwide.

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