

Studying Accompaniment Feasibility and Effectiveness (SAFE) study: An introduction to self-managed abortion and a research primer

What is self-managed abortion (SMA)?

- Self-managed abortion (SMA) is anything a person does to end a pregnancy without clinical support.
- Self-managed <u>medication abortion</u> is when a person uses one of two WHO-recommended medication regimens to end a pregnancy without clinical supervision. The two regimens are:
 - 1. <u>Mifepristone</u>, which blocks the hormone necessary to continue pregnancy, followed by
 - misoprostol 24-48 hours later which causes the uterus to contract and expel the pregnancy.
 - 2. <u>Misoprostol</u> alone
- Self-managed medication abortion with <u>accompaniment</u> involves non-clinically trained abortion counselors who provide evidence-based information about the use of medication abortion, as well as compassionate emotional (and sometimes physical) support, throughout an individual's self-managed medication abortion process. Abortion accompaniment is provided over the phone, through secure digital messaging platforms, and/or in person.
 - While accompaniment groups largely operate outside the health system, some have established collaborations with friendly clinicians who facilitate access to in-clinic care if or when needed during and after a person's self-managed medication abortion process.
- Self-managed abortion with medication began in Brazil in the late 1980s. In a country where abortion was criminalized, individuals discovered the abortifacient properties of misoprostol and began to use it to end their pregnancies at home.

What is the SAFE study?

- The <u>Studying Accompaniment Feasibility and Effectiveness (SAFE) study</u> is a first of its kind study designed to evaluate the effectiveness of self-managed medication abortion with accompaniment support.
- The SAFE study recruited over 1,000 people who contacted a safe abortion accompaniment group in Argentina or Nigeria, followed them for approximately one month, and measured outcomes on their SMA experiences, with abortion completion as the primary outcome.
- Safe abortion advocates at <u>Colectiva Feminista La Revuelta de Neuquén</u> (Argentina), <u>GIWYN</u> (Nigeria), and in Southeast Asia, together with researchers at <u>Ibis Reproductive Health</u>, designed and implemented the SAFE study.

What are the key findings from the SAFE study?

- SMA with medications is **very effective**.
 - 93.8% of those who used the mifepristone + misoprostol regimen had a complete abortion without surgical intervention.
 - 98.8% of those who used the misoprostol alone regimen had a complete abortion without surgical intervention.
- SMA with medications is **no less effective than medication abortion in a clinical setting**, for pregnancies <9 weeks duration.
- SMA with misoprostol alone is highly effective, and warrants renewed attention.

- Abortion completion following use of the misoprostol alone regimen was substantially higher than has previously been reported in clinical studies, but similar to the effectiveness found in other studies conducted in self-managed contexts.
- SMA with medications is **safe**.
 - 0 No deaths or major adverse events took place among SAFE study participants.
 - Only 20% of all participants visited a health facility during and after their abortion process, primarily to confirm that their abortion was complete and not because of any symptoms or worries about a complication.
- These findings reinforce an existing body of evidence that, with accurate information, people themselves can safely and effectively use medications to terminate their own pregnancies.
- Our findings also support a renewed look at misoprostol alone regimens for medication abortion, no longer as a second-tier method, but one that offers similar effectiveness, and often greater accessibility, than the mifepristone + misoprostol regimen.
- Finally, these findings support the use of remote models of early abortion care, including telemedicine, as is being considered in several countries as a result of the COVID-19 pandemic.

How do these findings compare to prior research on SMA?

- There have only been a handful of prospective studies on SMA effectiveness, and all have found similarly high levels of effectiveness of SMA with medications (~95%).
- Retrospective reviews of SMA experiences also find high effectiveness, including for pregnancies up to 24 weeks.
- Notably, only our pilot study focused on effectiveness with accompanied self-managed abortion—the others focused on pharmacy-supported or community health worker supported SMA.
- Additional studies:
 - Moseson H, Jayaweera R, Raifman S, et al. Self-managed medication abortion outcomes: Results from a prospective pilot study. *Reprod Health*. 2020;17(1):164. <u>https://doi.org/10.1186/s12978-020-01016-4</u>
 - Stillman M, Owolabi O, Akinyemi A, et al. Women's self-reported experiences using misoprostol obtained from drug sellers: A prospective cohort study in Lagos State, Nigeria. *BMJ Open.* 2020. <u>10.1136/bmjopen-2019-034670</u>
 - Footman K, Scott R, Taleb F, et al. Feasibility of assessing the safety and effectiveness of menstrual regulation medications purchased from pharmacies in Bangladesh: A prospective cohort study. *Contraception*. 2018;97(2):152-159. https://doi.org/10.1016/j.contraception.2017.08.002
 - Foster AM, Arnott G, Hobstetter M. Community-based distribution of misoprostol for early abortion: Evaluation of a program along the Thailand-Burma border. *Contraception*. 2017;96(4):242-247. <u>https://doi.org/10.1016/j.contraception.2017.06.006</u>