

INTEGRATING SELF-MANAGED MEDICATION ABORTION WITH MEDICAL CARE: A BRIEFING PAPER

April 26, 2021

EXECUTIVE SUMMARY

This briefing document about self managed medication abortion (SMMA) offers a framework that emphasizes context and integration of SMMA with medical care. It was written in 2020 by Global Doctors for Choice, an international network of physicians who advocate for reproductive health care and rights. Its primary goal is to provide physicians and other healthcare providers with a synthesis of evidence from around the world to inform their clinical practice and their advocacy. The advent of medication abortion has enabled some women to end their pregnancies with little or no clinician involvement. There are a range of perspectives on self-managed medication abortion. Some emphasize the liberatory advances for women's autonomy, others are concerned about possible adverse health consequences. Since Global Doctors for Choice supports doctors working in different contexts around the world, this document highlights clinical concerns and advocacy opportunities for clinicians in both low- and high-resource settings, and in places with varying legal and administrative restrictions on abortion.

Several recent global developments are salient. During to the Covid-19 pandemic, access to abortion care has been compromised, pushing health systems to adopt more self-managed care options. Over the past several years, medical standard setting bodies have endorsed "patient centered care," which is respectful and responsive to patient preferences, needs and values, and supports patient participation in their own care, be it diabetes, asthma, or labor and delivery. Concurrently, distrust and dismissal of science and scientists has surged across a wide range of issues, from climate change, to vaccines, to wearing masks during the Covid-19 pandemic. Global Doctors for Choice asserts the value of medical and public health science and methods, and considers clinicians to be valuable players who meld their evidence based credibility with familiarity with the harms caused by lack of access to care and their fiduciary responsibility to promote patients' interests.

INTENDED AUDIENCE

GDC hopes that a range of stakeholders, such as public health policymakers and civil society organizations, find this document useful. However, our primary aim is to provide physicians and other healthcare providers with an empirical foundation from which to advocate for systemic improvements to access to safe medication abortion within their health systems. To this end, we have categorized models of SMMA care according to the degree of involvement of clinicians and the formal health care system. In our view, abortion is an essential component of comprehensive health care and should not be siloed as a categorical service.

THE EVIDENCE

This briefing concerns self-managed medication abortion, defined broadly as the use of a combination of mifepristone and/or misoprostol where *varied components of the abortion process* (drug procurement, eligibility assessment, ingestion, support and management of complications, and follow up) proceed *without direct contact with a supervising clinician*. The term 'self-managed abortion' is used imprecisely in research literature. To help physician advocates understand the existing landscape of SMMA, we have created five categories of SMMA ([see descriptions and a table](#)), each of which describes an existing model of care. These categories are descriptive, and range from a model of care with no clinical involvement to telemedicine-based medication abortion.

In light of the wide variety of working environments in which clinicians may encounter SMMA, we enumerate the [broad contextual factors](#) that facilitate and constrain equitable access to safe abortion such as level of resource and infrastructure, including internet and telemedicine health access, health system characteristics and coverage, and legal and political climate. We present [evidence](#) regarding the medical concerns relating to these categories, such as eligibility, gestational age assessment, safety and efficacy, and post-abortion follow up, as well as [data regarding other critical concerns](#), including medication quality, access to comprehensible accurate information, and patient preferences.

CLINICAL CONCERNs AND RECOMMENDATIONS FOR PHYSICIAN ADVOCACY

The final section summarizes [evidence-based clinical concerns for each category of SMMA and pairs them with concrete recommendations for advocacy](#). Our hope is that physicians and other healthcare providers will find advocacy recommendations here that match their working conditions on the ground. These recommendations provide evidence-based ideas about how to improve health systems to facilitate patient access to medication abortion. Healthcare providers are in a unique position to advocate for systems that support patient-centered abortion care, which provides the services and information people need in a way that respectfully supports autonomy, dignity, privacy, and physical and emotional safety.^{1,2} The recommendations promote safe, accessible, and equitable abortion care that accords with women's circumstances and preferences and benefits from the expertise of health professionals and the resources of formal health systems.

Global Doctors for Choice wants to:

Equip clinicians to make context specific evidence-based clinical decisions.

Advocate for pathways to safe medication abortion as one element of essential, comprehensive healthcare.

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This briefing document about self managed medication abortion (SMMA) was written in 2020 by Global Doctors for Choice, an international network of physicians who advocate for reproductive health care and rights. This document therefore primarily addresses physicians and other healthcare providers in order to inform their clinical practice and their advocacy. As Global Doctors for Choice represents doctors from around the world and thus has a keen appreciation of context, the document highlights clinical concerns and advocacy opportunities for clinicians in both low- and high-resource settings, and in places with varying legal and administrative restrictions on abortion.

Several recent global developments are salient. During to the Covid-19 pandemic, access to abortion care has been compromised, pushing health systems to adopt more self-managed care options. Over the past several years, medical standard setting bodies have endorsed “patient centered care,” which is respectful and responsive to patient preferences, needs and values, and supports patient participation in their own care, be it diabetes, asthma, or labor and delivery. Concurrently, distrust and dismissal of science and scientists has surged across a wide range of issues, from climate change, to vaccines, to wearing masks during the Covid-19 pandemic. Global Doctors for Choice asserts the value of medical and public health science and methods, and considers clinicians to be valuable players who meld their evidence based credibility with familiarity with the harms caused by lack of access to care and their obligation to promote patients’ interests.

Our aim is to provide physicians and other healthcare providers with an evidence base from which to advocate for systemic improvements to access to safe medication abortion within their health systems. To this end, we have categorized models of SMMA care according to the degree of involvement of clinicians and the formal health care system. In our view, abortion is an essential component of comprehensive health care and ideally should not be siloed as a categorical service.

DEFINITIONS

These definitions reflect the evidence summarized in the following document.

SAFETY

In the evidence outlined below, safety refers to any measure of abortion-related medical complications, including serious adverse events and complications that may affect physical health.³ Determination that a is “safe” is a judgement based on all available safety-related outcome measures, and specific measures are not consistently assessed in all the studies reviewed below. Our goal in this document is not to make recommendations about the safety of self-managed abortion, but to summarize evidence regarding safety. This document does not use the WHO framework of “safe,” “less safe,” and “least safe” abortion, but we recommend this framework to readers interested to know more about regional classifications of abortion by safety.⁴

EFFICACY

A successful abortion refers to expulsion of an intrauterine pregnancy without surgical intervention.⁵ Assessment criteria for successful abortion vary widely between studies (including no gestational sac on ultrasound and a negative urine pregnancy test). Other outcomes used to evaluate the efficacy of medication abortion in the studies below include continuing pregnancy, incomplete abortion, and complete abortion.⁶ As with the safety of medication abortion, this document does not make independent assessments of efficacy. Readers should note that while a successful pregnancy may be the most important outcome for individual patients and clinicians, outcomes such as rates of surgical intervention or repeat doses of medication are important for systems-level issues such as the allocation of resources.

TELEMEDICINE MEDICATION ABORTION

This term refers to a medication abortion where any of the following functions are administered or accessed via telecommunications technology: assessment, counselling, prescription, and/or information. In studies of “telemedicine medication abortion,” the component(s) of care that were delivered via telecommunications are not consistent. Telemedicine is a broad term that encompasses both synchronous and asynchronous interaction between patients and providers. Further, telemedicine medication abortion services operate both within and outside of formal healthcare systems.⁷ When occurring within the formal healthcare system, medication abortion provision via telemedicine should comply with ethical standards set by professional bodies.^a

CATEGORIES OF SELF-MANAGED MEDICATION ABORTION (SMMA)

The term ‘self-managed abortion’ is used imprecisely in research literature, is practiced in a wide range of legal contexts, and may apply to a variety of circumstances with differing outcomes. The studies outlined below define “self-managed” in reference to one or more of the following components of the medication abortion process.

1. **How** and **where** the drugs are procured
2. **How**, **by whom**, and **where** eligibility was determined
3. The **location** where medications are ingested
4. **Who** administers the drugs
5. What clinical **supervision or supports** were available before, during, and after the procedure
6. **How**, **by whom**, and **where** abortion completion was assessed

Studies often examine one or more of these facets while leaving the others unspecified. *Of particular interest to physician advocates—and the aim of this briefing—is to summarize the evidence regarding safety and efficacy according to*

^a See the World Medical Association Statement on the Ethics of Telemedicine (2018), at <https://www.wma.net/policies-post/wma-statement-on-the-ethics-of-telemedicine/>.

degree of physician involvement in each of these six components of medication abortion. To that end, we have broken down the imprecise term “self-managed abortion” into five categories, roughly organized by the *extent of formal health system and physician involvement* in the process. The numbers associated with each category (1-5) are descriptive, and should not be understood as a ranking of relative models of medication abortion provision.

[Category 1] Medication abortions using mifepristone and/or misoprostol, **self-sourced** and ingested without medical guidance, or with guidance of unknown provenance or reliability.

[Category 2] Medication abortions obtained **outside of the formal healthcare system** using personal social networks, at pharmacies, from drug sellers, or online, where some form of support is provided by non-health system intervention such as an accompaniment service,⁸ a safe abortion hotline^{9,10,11} or online resource.^{12,13}

[Category 3] A hybrid approach to medication abortion provision in **legally restricted settings**, where physicians may date pregnancy, provide detailed information about medications used to induce abortion, and warning signs of complications and post-abortion care, but medication is self-sourced (e.g. from personal social networks, drug sellers, or over the counter at a pharmacy). This category is exemplified by a “**harm reduction**” approach pioneered in Uruguay, when abortion was severely restricted.¹⁴

[Category 4] Medication abortions using the abortifacient drugs mifepristone and/or misoprostol **in a context of legal or access restrictions**, prescribed by a clinician via telemedicine **outside of the formal healthcare system**, with no in-person clinical encounters.^{15,16} An example of this model is [Women on Web](#), which allows women in countries with restricted access to abortion to obtain abortion medications online. Requests are reviewed by a physician who provides a prescription for mifepristone and misoprostol following WHO recommended dosages. Medications are delivered via mail and a 24 hour telephone hotline with trained non-medical staff is available to provide support and instructions on medication use. Individuals are advised to visit clinical or emergency services for symptoms of potentially serious complications.

[Category 5] Medication abortions using the abortifacient drugs mifepristone and/or misoprostol **prescribed within the formal healthcare system by a clinician via telemedicine**, where *all* medication is taken at home. Procedures for screening and follow-up vary within this category (see Table 1 below).

[Category 6] Medication abortions using the abortifacient drugs mifepristone and/or misoprostol **prescribed within the formal healthcare system, by a clinician in person**, where at least one medication is taken at home. This category includes **outpatient medical abortion**, where screening and mifepristone administration happens in clinic but misoprostol is taken at a location of the patient’s choice (e.g. at home) and post-abortion evaluation happens in-clinic. In 2016, the FDA approved self-administration of misoprostol.^b

^b <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information>

TABLE 1. CATEGORIES OF SELF-MANAGED MEDICATION ABORTION

	Procurement – how and where	Gestational Age Assessment	Screening for Contraindications	Where were drugs taken?	Support and Management of Complications	Assessment of abortion success
Category 1	Self-sourced	Self-assessed	Unknown	Outside of a formal medical setting (e.g. at home)	None/unknown	None/unknown
Category 2	Self-sourced via online pharmacy, OTC, drug seller, or personal network	Self-assessed	Unknown	Outside of a formal medical setting (e.g. at home)	Lay support, incl. written guidance, in-person accompaniment, safe abortion hotline, websites/mobile apps.	Self-assessment based on resources or guidance provided by lay support, pharmacy worker, or community health worker
		Assessed using LMP with support of trained layperson (e.g. community health worker, pharmacy worker)	Assessed in consultation with trained layperson (e.g. community health worker, pharmacy worker)			
Category 3	Self-sourced via online pharmacy, OTC, drug seller, or personal network	In-person or virtual, clinical assessment (within formal healthcare system)	In-person, clinical assessment	Outside of a formal medical setting (e.g. at home)	Advance guidance from clinicians, could include lay support (e.g. written guidance, in-person accompaniment, safe abortion hotline,	In-person or remote clinical assessment (within formal healthcare system)
						Self-assessment based on resources or guidance from pharmacy worker/community

					websites/mobile apps)	health worker (outside of formal healthcare system)
Category 4	Prescribed by physician remotely (outside formal healthcare system)	Review of patient-reported LMP by physician	Online intake form with clinical symptoms/medical history reviewed by physician	Outside of a formal medical setting (e.g. at home)	Access to 24-hr hotline staffed by trained, lay support	Self-assessment based on resources or guidance provided by medical and lay support team
Category 5	Prescribed by physician remotely (within formal healthcare system)	Ultrasound or physical examination with results sent to prescribing physician	In-person testing if indicated with results sent to prescribing physician	Outside of a formal medical setting (e.g. at home)	Remote access to physician or clinic, including formal referrals to care.	Formal ultrasound assessment
		Remote assessment by physician using patient-reported LMP	Remote telephone or video assessment using clinical symptoms/medical history			In-person serum or urine HCG test
Category 6	Prescribed by physician in person	In-person clinical exam using ultrasound or bimanual examination	In-person testing if clinically indicated	At least one medication/dose taken at home	Standard in-person clinical support	In-person clinical assessment

CONTEXTUAL FACTORS TO CONSIDER

The evidence reviewed in this briefing should be assessed alongside careful consideration of the many contextual variables—listed below—that facilitate and constrain equitable access to a full range of safe abortion methods across the globe. These variables may themselves be the target of physician system-level advocacy (e.g. working to decriminalize abortion provision in healthcare settings) or they may be underlying socioeconomic or geographic conditions that need to be accounted for when proposing interventions. For example, in a region where most individuals have limited access to telecommunications technologies, efforts to expand telemedicine may not be an appropriate advocacy goal. Conversely, if a region suffers from poor transportation infrastructure, advocates may decide to focus on interventions that reduce the need for in-person clinic visits, such as developing evidence-based protocols for remote screening and follow up that include clear pathways for referrals in the event of a complication. The following are some of the legal, socioeconomic, geographic, and health system variables that should inform physician advocacy regarding SMMA.^c These are critical details that might be amassed in the “Information Gathering” phase of advocacy.^d

- Sources of regulation of abortion (e.g. criminal or civil law, Constitutional amendment, health code).
- Legal and/or administrative restrictions on abortion, including:
 - Gestational age limits.
 - Mandatory waiting periods.
 - Mandatory reporting of illegal abortion.
 - Criminalization of abortion provision, including self-administration of abortion medications.
 - Third party authorization (e.g. parental consent, court proceedings, medical panels).
 - Policies limiting facilities and/or medical professionals allowed to provide abortion medications or perform surgical abortions.
 - Mandatory but medically unnecessary clinical tests or diagnostic procedures (e.g. ultrasound) or multiple consultations.
 - Burdensome administrative restrictions on abortion medications, including restrictions on registration, eligible prescribers, restraints on prescription (e.g. only in-hospital prescriptions, limits on pharmacy or mail order prescribing).
- Measures of sexual and reproductive health, including unintended pregnancy, access to contraception, rates of post-abortion contraception, STI rates, rates of pregnancy-related complications (e.g. ectopic pregnancies), abortion-related morbidity and mortality
 - Disparities within these indicators based on relevant population characteristics (i.e. urban/rural, socioeconomic status, race/ethnicity, age)
- Qualitative and quantitative data on abortion-related stigma and conscientious objection among health professionals.
- Geographic distribution of health infrastructure, particularly numbers of abortion providers.

^c Many of these details can be found via the WHO’s database of safe abortion laws, policies, health standards, and guidelines. Available at: <https://abortion-policies.srhr.org/>.

^d See Global Doctors for Choice physician advocacy training programs. Available at: <https://globaldoctorsforchoice.org/resources/training-resources/>.

- Existing telemedicine infrastructure, including mobile phone and Internet reach and coverage.
- Existing curricula from medical schools and residency programs with SRH contents (including abortion provision techniques).
- Existing national or local systems of monitoring and evaluation of SRH services, including abortion.
- Existing pathways for referrals and communication between healthcare facilities.
- Outdated protocols for surgical and medication abortion provision (e.g. routine use of sharp curettage)
- Patient costs, insurance coverage, and provider compensation for abortion provision.
- Availability and cost of tests or technology to aid in determining eligibility and follow up.
 - Regional availability and cost to patient of ultrasonography.
 - Commercial availability of urine pregnancy tests.
- Systems for procurement, distribution, storage, quality assurance, and registration of abortion medications.
- Local attitudes towards medical care and health system, physicians, privacy, and abortion self-care.

Physician advocates should read this document with an awareness of these contextual factors in mind. Evidence that supports the safety and efficacy of entirely remote telemedicine abortion provision in the United States may be helpful to physicians in countries with a similarly robust health infrastructure. For others, evidence regarding training pharmacy workers to safely provide off-label misoprostol may be more relevant. This document presents a broad landscape of evidence that physician advocates should consider when working towards safe, equitable access to medication abortion within the legal and health systems of their own countries.

MEDICAL CONCERNS

Medication abortion (also called medical abortion) can refer to the use of mifepristone and/or misoprostol to manage voluntary induced abortion, spontaneous abortion, incomplete abortion, or intrauterine fetal demise. The WHO recommends a regimen of 200 mg of oral mifepristone followed at least 24 hours later by 800 mcg of vaginal, sublingual, or buccal misoprostol. This combination regimen is effective at < 84 days gestation (12 gestational weeks) with repeat doses of misoprostol administered as needed in the late first trimester. Gestational age limits on medication abortion within the first trimester are in flux as evidence emerges about the safety and efficacy of late first trimester medication abortion.^{17,18} Although it is less effective than the combination regimen, a regimen of 800 mcg of misoprostol administered vaginally, sublingually, or buccally (with repeat doses as indicated) up to 12 gestational weeks (GW) is also recommended by the WHO.¹⁹

In a 2015 guideline, the WHO usefully distinguishes between self-management of the entire process of medication abortion—for which there is no direct supporting evidence—and self-management of its associated subtasks, including assessment of eligibility, administration of drugs, and self-assessment of abortion completion and need for follow-up care.^e Evidence supports the safety and efficacy of Category 5 of self-managed medication abortion up to 10 weeks: self-

^e A systematic review of the evidence WHO used to make its recommendations regarding self-management can be found on pages 116-124 of *Health worker roles in providing safe abortion care and post-abortion contraception*, Web Supplement 2 (2015): https://apps.who.int/iris/bitstream/handle/10665/177626/WHO_RHR_15.11b_eng.pdf?sequence=1.

administered mifepristone and misoprostol when ingested after a clinical assessment of eligibility with the option of self-assessment of abortion success.^{20,21} WHO clarifies that they support self-management of abortion as “an active extension of health systems and health care” but that their recommendations “are NOT an endorsement of clandestine self-use by women without access to information or a trained health-care provider/health-care facility as a backup. All women should have access to health services should they want or need it” (p. 42).²¹ Evidence for Category 5 is limited for more than 10 weeks gestation.^{17,19,22} There are also fewer studies about any Category of self-managed medication abortion with a misoprostol-only regimen, with higher rates of ongoing pregnancy observed.^{23,23–25} A 2019 systematic review found approximately 78% of abortions with misoprostol alone (n=13,000) had a complete abortion in the first trimester without surgical intervention, and over 93% (n=13,000) of pregnancies were successfully terminated.²⁶ Misoprostol alone is less effective than the combined regimen for first-trimester abortions. However, misoprostol is more accessible than mifepristone. It is also more widely used in low-resource contexts where safe, reliable backup care is also less readily available.^{27,28,17}

Below, we summarize evidence regarding screening and eligibility, safety and efficacy, and follow up for SMMA, referencing the relevant category when possible.

SCREENING AND ELIGIBILITY

Questions about eligibility for medication abortion include screening for contraindications, gestational age, use of ultrasound, and rhesus testing. Contraindications for medication abortion include allergies to the medications, chronic adrenal failure, bleeding disorders, inherited porphyrias, suspected ectopic pregnancy, and having an IUD in place.¹⁹

SCREENING FOR CONTRAINDICATIONS

[Category 1] [Category 2] There is limited evidence about self-assessment or lay assessment of contraindications for medication abortion.^{21,29}

[Category 4] [Category 5] Telemedicine is compatible with clinician screening for contraindications to medication abortion. A prospective study in Moldova, Mexico, and the United States (n=365) found that medication abortions could be offered safely and effectively without in-person pretreatment tests by using a detailed telemedicine screening for risk factors and contraindications.³⁰ Studies examining outcomes of Women on Web users note that individuals seeking abortion medications answer questions about medical history and are flagged for additional screening by a physician if they report a potential contraindication.¹⁵ Women on Web tells users that they should be able to get to a hospital or healthcare facility within an hour, and to have someone available to help them during the abortion.³¹

GESTATIONAL AGE

Gestational age is a concern for SMMA because after 63 days GA (9 GW), repeat doses of misoprostol may be needed.¹⁷ If GA is underestimated, individuals may not be provided with the proper dosage, increasing the possibility of an ongoing pregnancy or more serious complications.

SELF-ASSESSMENT OF GESTATIONAL AGE

If the medication abortion will not include any in-person visits, gestational age must be self-assessed based on the first day of the last menstrual period. Studies of varied research designs have found that the majority of people are able to accurately report their last menstrual period.^{32–35} Notably, this does not take into account the possibility of post-conception spotting/bleeding, which may be perceived as if it were a menstrual period. A 2014 systematic review including studies of poor to fair quality found that individuals are more likely to overestimate rather than underestimate their gestational age.³⁴ According to the same review, the percentage of individuals whose self-assessments put them below 63 days (a common eligibility cut-off for early medication abortion) but whose ultrasounds dated their pregnancies as >63 days ranged in studies from 2.8% to 11.5%.³⁴

TELEMEDICINE ASSESSMENTS OF GA

[Category 4] The telemedicine service Women on Web does not accept requests from people with pregnancies beyond 9 weeks gestation. The website includes gestational age calculator and requests (but does not require) that clients submit ultrasound imaging so that GA can be assessed by a physician. Data are not available on outcomes of those not eligible for Women on Web's services.

[Category 5] Telemedicine-based medication abortion (within the formal health system) uses a range of practices to assess gestational age, some of which incorporate in-person medical testing or require testing only in the presence of risk factors. For example, in Australia, a telemedicine abortion service serving women at <8 GW required women to obtain in-person screening tests, including ultrasound at a local facility.³⁶ This may not be a feasible model for providers who serve rural patients or work within poorly resourced health systems.

PRETREATMENT ULTRASOUNDS

Pre-abortion ultrasounds are typically used to assess eligibility for medication abortion, particularly to assess gestational age. Routine ultrasound has not been shown to improve the safety or efficacy of early medication abortion as gestational age can be assessed with patient-provided LMP and/or a bimanual exam.^{30,34,37,38} Ultrasound requirements may also function as barriers to abortion access, especially in resource-poor settings.

In up-to-date protocols for medication abortion, pre-abortion ultrasounds are indicated only under limited circumstances, such as the presence of risk factors for an ectopic or otherwise abnormal pregnancy.^f

^f For a detailed decision aid for early medication abortion without ultrasound, see

<https://www.rcog.org.uk/globalassets/documents/guidelines/2020-06-04-decision-aid-for-early-medical-abortion-without-ultrasound.pdf>.

ECTOPIC PREGNANCIES

Ectopic pregnancies occur in 1-2% of pregnancies globally and ultrasound to screen for an ectopic is only recommended in the presence of risk factors.³⁹ Diagnosed ectopic pregnancies are a contraindication for medication abortion. However, if an ectopic pregnancy cannot be ruled out but the client is asymptomatic and low-risk, protocols recommend that an early medical abortion can safely proceed with close follow up, often citing the low incidence of ectopic pregnancies among women presenting for early medical abortion.⁴⁰ Further, proceeding with an early medical abortion and revealing an ectopic when the patient experiences no bleeding may be safer overall than delaying care out of fear of a possible ectopic pregnancy. Rates of ectopic pregnancies are not well documented outside of high-resource countries, and the WHO considers a suspected ectopic to be a contraindication for medication abortion.⁴¹

RHESUS TESTING

Recent studies suggest that routine Rh screening and provision of anti-D immunoglobulin is not necessary for medication abortion, especially in the early first trimester.^{42,43} The WHO safe abortion guidelines state that "determination of Rh status and the offer of anti-D prophylaxis are not considered prerequisites for early medical abortion" (WHO Safe Abortion Guidelines, 2012). In recent years, professional bodies have updated recommendations to reflect the WHO position, although gestational age cut-offs for consideration of Rh status differ slightly between protocols. For example,

- In the United Kingdom, the most recent (2019) National Institute for Health and Care Excellence (NICE) guidelines recommend routine anti-D prophylaxis only for abortions after 10 weeks gestation.⁴⁴
- In 2019, the U.S. National Abortion Federation (NAF) determined that clinicians could reasonably forgo Rh testing and anti-D administration for medication abortion under 8 weeks gestation.⁴⁵

SAFETY AND EFFICACY

SAFETY AND EFFICACY TO 10 WEEKS

[Category 1] There are limited data regarding the safety and efficacy of abortion medications when they are entirely self-sourced and self-administered, in part due to the challenges associated with recruiting and following up with women outside of the formal healthcare system and in contexts of restrictive abortion laws. Outcome data in this category of SMMA are subject to selection bias because most data come from people who visit healthcare facilities because of side effects or complications. Researchers have highlighted the need for more evidence on outcomes following self-use of abortion medications in these categories, and proposed methodologies to mitigate some of these challenges.^{6,46} As will be discussed later in this document, evidence suggests that women who obtain abortion medications without prescriptions

via online or in-person pharmacies receive little information about how to safely use the medications, including little information about proper dosages, side effects, or signs of potential complications.^{9,47}

- In a recent prospective cohort study in Lagos, Nigeria 227 drug sellers recruited women seeking abortion (n=501). 78% (n=391) of women completed all three telephone surveys involved in the study.²⁷ At the final 1 month follow up, 95% reported no longer being pregnant (return of regular menstruation). 20% (n=77) reported problematic bleeding, 4% (n=15) reported signs of possible infection, and 7% (n=29) of women reported that they wanted medical care. Of women who sought medical care (6%, n=24), most received pain medication or an ultrasound. One woman received a blood transfusion and a surgical abortion.²⁷

[Category 2] As with Category 1 above, data about SMMA interventions outside of the formal healthcare system are limited by the challenges of recruiting and following up with women outside of the formal healthcare system and in contexts of restrictive abortion laws.

- A noninferiority study in Nepal assessed a model where pharmacy workers were trained in safe OTC medication abortion provision. Researchers concluded that trained pharmacy workers were able to provide MA at levels of safety and efficacy (reported adverse events and rates of abortion completion) comparable to the standard of care in Nepali healthcare settings, where medication abortions are provided up to 9 GW.⁴⁸
- A study carried out at the Thai-Burma border assessed a model of community provision of misoprostol to improve access to safe abortion care in the region, where equitable access to safe abortion care is compromised by uneven interpretation of the law, socioeconomic status, and urban/rural disparities in healthcare access.⁴¹ Trained community health workers distributed misoprostol sourced directly from a pharmaceutical company to ensure quality. A gestational age limit of 9 weeks was screened for using self-reported LMP, and pregnancy status was self-reported. Over the course of three years, 96.4% (n=885) of 918 women who received misoprostol were not pregnant at a one-month follow up. Three women were diagnosed in-clinic with ectopic pregnancies, and two women required additional medications beyond the three doses of misoprostol.⁴¹

[Category 3] This hybrid category comprises interventions within the formal healthcare system, typically in a context of legal restrictions on safe abortion care.⁴⁹

- Beginning in 2001—a time when abortion was criminalized—Uruguayan physicians and health professionals implemented a harm reduction model for “lower risk abortion.” In 2006, after demonstrated success, the model was adopted in hospitals across the country. Physicians examined women, and counselled them about options, including termination using medications, and informed them about the signs and symptoms that would require medical involvement. In an implementation study, 1717 individuals were seen for unwanted pregnancy over two years (68.7% <= 10 GW, 9.5% > 12 GW). Only 27% (n=729) of women returned for a postabortion visit; 92% of these reported having self-administered misoprostol. 6.3% of misoprostol users had mild complications (bleeding or infection) not requiring hospitalization.¹⁴ In the 15 years following the intervention, maternal mortality related to unsafe abortion and emergency room visits for postabortion complications decreased significantly.⁵⁰
- In direct response to the success of the Uruguayan model, a cohort study evaluated a similar model in Peru, where abortion is illegal except when there is a threat to the life or health of the mother. 500 women who received pre-abortion harm reduction counselling participated in the study, about half (n=253) were available for follow up. 88% (n=220) took misoprostol. 88.6% (n=195) of these reported a complete abortion at follow up. 8% (n=17) reported adverse events (hemorrhage, infection, or severe pain). Almost a quarter (n=49) of women who took

misoprostol subsequently had a surgical abortion, but data were not available on the medical justifications for surgical intervention.^{51,52}

[Category 4] [Category 5] These categories are presented together because research about their safety and efficacy has been combined in recent systematic reviews. A 2019 systematic review of telemedicine for medication abortion, based on limited and largely self-reported data, found rates of complete abortion between 93.8% and 96.4% and rates of continuing pregnancy between 0 and 1.9% for pregnancies ≤ 10 weeks (compared to mean rates of complete abortion for in-clinic medication abortion of 96.7% at 9 weeks gestation and 93.1% at 10 weeks).⁷

This review found that surgical evacuation rates after telemedicine medication abortion ≤ 10 weeks were very inconsistent, ranging from 0.9 to 19.3%.⁷ Rates of surgical evacuation for in-person medication abortion care (with a combined mifepristone-misoprostol regimen) range from 1.8-4.2%.⁷ In the same review, complication rates for abortions ≤ 10 weeks were not significantly different from those for in-person medication abortions ≤ 10 weeks. Other outcome measures included hospitalization (0.07-2.8%), blood transfusion (0-0.7%), severe hemorrhage (0.03%-0.6%), and heavy bleeding (3.4-5.2%). All of these figures are comparable to safety outcomes following in-person medication abortion.⁷ Importantly, the authors note that only middle- and high-income study groups were represented in the review, limiting the generalizability of the results. Further, all available studies of telemedicine for medication abortion are for the combined mifepristone-misoprostol regimen.⁵³

- A recent study in the United States found that telemedicine medication abortion is non-inferior to clinic-based medication abortion up to 10 weeks GA.⁵⁴ In this study, women were screened by clinic staff for eligibility, had physician consultations via video conference, and abortion completion was confirmed at a clinic visit. Medications were dispensed remotely and taken at home. The same study found that after telemedicine provision became available, abortions were more likely to occur before 12 weeks. In other words, the introduction of telemedicine MA corresponded with a decline in second trimester abortions.⁵⁴

[Category 6] A 2020 Cochrane review compared the safety and efficacy of self-administered (at least one drug taken without provider present) and provider-administered (drugs taken in presence of provider) medical abortion in 18 studies (2 RCTs, 16 non-randomized). The majority of reviewed studies (16 of 18) were conducted in low-to-middle resource contexts. Based on the two RCTs, the review found no differences in rates of successful abortion (RR 0.99, 95% CI, n = 919). Based on very low-certainty evidence from non-randomized studies, study authors found that the chance of having any complication requiring surgical intervention with self-administered medical abortion is 4.4% (82/1880) compared with 2.6% (15/572) with provider-administered medical abortion (RR 2.14, 95% CI 0.80 to 5.71; 3 studies, 2452 women). The studies reviewed reported very few instances of hospitalization, hemorrhage, or infection, with no statistically significant differences in these outcomes between the two groups. Pooled analyses of dichotomous measures did not find any differences in instances of side effects between the self-administered and provider-administered groups.⁵⁵

A 2011 systematic review of prospective cohort studies found that there were no differences in rates of abortion completion for home-based compared with clinic-based misoprostol administration (86-97%, n=3478 home, 80-99%, n=1044 clinic; OR = 0.8, 95% CI). All study participants received an initial dose of mifepristone in the clinic and had the choice of taking the follow-up dose of misoprostol at home or coming back to the clinic. As in the Cochrane review, study authors note that side effects and complications were reported inconsistently across studies. Across all studies reviewed, serious adverse events were very rare and conclusions could not be drawn about their association with the location of misoprostol administration.⁵⁶

A 2015 study in India compared the safety and efficacy of home use of misoprostol with clinic-administered misoprostol for pregnancies ≤ 9 weeks ($n = 731$). This study is notable because of its high success rate of at-home medication abortion in a low-resource setting among a group of mostly rural women without formal education. All participants were assessed in-clinic by a physician and then given 200 mg of misoprostol. They then chose to administer the second dose of misoprostol at home ($n=342$) or to come back to the clinic ($n=389$). Outcome data was available for 700 women: 94.2% of at-home abortions were completed, and 94.4% of in-clinic abortions were completed. There were no significant differences between the home administration and clinic administration groups in rates of ongoing pregnancy, incomplete abortion, or surgical intervention.⁵⁷ Using the same data, a 2016 paper found that 18.6% of home users experienced complications compared with 12.6% of clinic users. The most frequently cited side effect among home-use patients was excessive bleeding (7.2% home admin, $n=21$, compared with 3.6% clinic admin, $n=12$). Pain and vomiting lasted 0.3 days longer in home-based abortions. There were two adverse events reported, 1 in each group.²⁸

SAFETY AND EFFICACY AT OR ABOVE 10 WEEKS

Some studies have compared safety outcomes for SMMA by gestational age and found higher rates of in-person hospital or clinic visits and increased surgical intervention post-abortion for telemedicine-based SMMA after 9 GW compared with SMMA at 9 weeks or less.^{6,7,58} Globally, a higher proportion of complications and deaths from unsafe abortion occur after the first trimester.^{59,60} Rates of incomplete abortion (defined as abortions requiring additional intervention beyond the initially prescribed dosage of medications), continuing pregnancy, and surgical evacuation are significantly higher after 12 weeks GA compared to rates of incomplete abortion ≤ 12 GW.⁷ Compared with in-clinic medical abortion after 12 GW, telemedicine medical abortion is associated with higher rates of continuing pregnancy and surgical evacuation.⁷ The authors of a systematic review note that repeat doses of misoprostol, routinely administered in hospital settings for incomplete abortion, are less likely to be readily available to women obtaining medication abortion via telemedicine.⁷

- **[Category 2]** One study of records from volunteer accompaniment groups in Argentina, Chile, and Ecuador reported complete abortions from medication alone in 76% percent of 318 self-managed abortions between 13 and 24 weeks.³⁰
- **[Category 2]** A retrospective analysis of records from a safe abortion hotline in Indonesia found that 91% (83 of 91) women reporting pregnancies >12 weeks had successful terminations without further medical intervention.¹³
- **[Category 4]** A retrospective cohort study of women in Poland who used the telemedicine medication abortion service Women on Web found women at > 9 weeks ($n=188$) had almost fourfold higher risk of in-person clinical visits within 0-1 days of the abortion compared with women at ≤ 9 weeks ($n=427$).⁵⁸
- **[Category 4]** A retrospective cohort study of women in Brazil who used the telemedicine medical abortion service Women on Web found that rates of surgical intervention differed significantly by gestational age: 19.3% (40/207; 95% CI 14.5–25.2) of women at ≤ 9 GW, 15.5% (11/71, 95% CI 8.9–25.7) of women at 10, 11 or 12 weeks; and 44.8% (13/29, 95% CI 28.4–62.5) of women at 13 weeks or more ($p=0.006$).¹⁶

FOLLOW UP PROCEDURES

ASSESSING ABORTION COMPLETION

The WHO does not recommend routine follow-up care for medication abortions using mifepristone and misoprostol.¹⁹ Although posttreatment ultrasound can be used to rule out a continuing pregnancy, alternative assessment strategies are effective and acceptable to patients. These alternative assessment options include clinical assessment of patient history and symptoms, patient self-assessment, serum hCG measurements, urine pregnancy tests.^{61,62} A 2020 systematic review of low quality evidence found similar clinical outcomes when comparing in-clinic ultrasound assessment to remote assessment strategies (multi-level pregnancy tests and high-sensitivity pregnancy tests) up to 10 GW. The review found that a majority of women in these studies preferred remote assessment to in-person assessment.⁶³

A systematic review of four RCTs (n=5493) found that there was no significant difference in complete termination of pregnancy between in-clinic assessment and self-assessment (with a urine pregnancy test and follow-up contact).⁶⁴ Studies in a wide range of contexts have demonstrated the efficacy of a combined regimen: follow-up contact *and* either a low-sensitivity pregnancy test (LSPT),^{57,65,66} high-sensitivity pregnancy test (HSPT),⁶⁷ or semiquantitative multi-level pregnancy test (MLPT).^{68–72} Methods that test for a drop in hCG levels (semiquantitative tests) may require an initial in-clinic assessment to produce the baseline measurement. This would not be a feasible option for an entirely remote SMMA, particularly because MLPTs are not yet commercially available on a broad scale. Although low- and high-sensitivity pregnancy tests have higher false positive rates than MLPTs, they are more accessible.^{73,74}

- **[Category 2]** A 2020 RCT compared women's experiences with SMMA using a smartphone app or a safe abortion hotline. After at least 24 days, 74.8% (n=170) participants reported a complete abortion, 7.9% (n=17) reported an incomplete abortion, and 17.3% (n=37) were unsure, with no difference in abortion completion between study arms ($P=0.772$). 75% (n=177) of participants reported having taken only misoprostol, which is associated with a longer duration of bleeding than the combined regimen.⁷⁵

The WHO notes that more research is needed to evaluate the efficacy of self-assessment of abortion completion with a misoprostol-only regimen, and recommend a routine follow-up visit when this regimen is used.²¹

POST-ABORTION CONTRACEPTION

Postabortion contraceptive information provision and counselling are important features of medically supervised abortion care that are lost when abortion is self-managed outside of the formal healthcare system. There are many documented barriers to postabortion contraceptive access within the formal healthcare system, particularly in low-and-middle income countries.⁷⁶ Further reducing in-person care for medication abortion provision therefore risks compounding existing disparities in access to the contraceptive methods best suited to individual needs. Long-acting reversible contraceptives (LARCs) may be particularly difficult to integrate into a model of telemedicine service provision. There have been efforts to increase postabortion contraceptive uptake using mobile technology,⁷⁷ but research is needed into the efficacy of remote postabortion contraceptive counselling when the abortion is managed entirely via telemedicine. In particular, there is a need for large comparative studies that assess contraceptive uptake, timing of initiation, and continuation rates following remote compared to in-person postabortion care. Obviously, contraceptives need to be available.

- **[Category 3]** The hybrid model used in Uruguay integrated contraception counselling into in-person postabortion care; 75.5% of 729 women who received in person postabortion counselling in family planning methods began using a safe contraceptive method following their follow-up visit.¹⁴
- **[Category 5]** An RCT in India compared a group of women randomized to assess their medication abortion outcome at home with a group who had their abortion outcome assessed in a primary care clinic. Contraceptive use was measured as a secondary outcome. At a two week follow up (n=556), 53% of women in the clinic group had initiated contraception compared with 25% of in the home assessment group. However, there was no difference in overall contraceptive use at 3 months between the two groups.⁷⁸
- **[Category 6]** An RCT in India compared a group of women randomized to assess their medical abortion outcome at home with a group who had their abortion outcome assessed in a primary care clinic. Contraceptive use was measured as a secondary outcome. Of the women available at a two week follow up (n=556), 53% of women in the clinic group had initiated contraception compared with 25% of in the home assessment group. A subset of participants (n=114) were called 3 months later for follow-up interviews about contraceptive methods (the copper IUD, injection, or oral pill). Women in the 3 month in-clinic follow up group (n=62) were more likely to begin contraceptive use at the follow-up appointment, whereas women from the home assessment group (n=52) were more likely to begin contraceptive use after their next menstrual period. However, there was no difference in overall contraceptive use at 3 months between the two groups.⁷⁸

MONITORING AND EVALUATION

Self-managed abortion that occurs outside of formal health systems (i.e. self-sourced abortions using pills procured without prescription online, OTC at a pharmacy, or from drug sellers) by definition cannot be monitored by public health officials or systematically evaluated for quality and safety. Studies on self-sourced medication abortion rely on self-reported data or complication rates of women who visited a healthcare facility after self-administering medication, both of which are subject to undercounting and selection bias. As a result, we lack rigorous data to assess the safety, efficacy and acceptability of Categories 1-4 of SMMA.

OTHER CONCERNs

MEDICATION QUALITY

International and domestic regulatory systems are responsible for assuring the quality of physician-prescribed misoprostol, mifepristone, and combined mife/miso products. There are many manufacturers and brands of mifepristone, misoprostol, and the combipack (which packages the two drugs together). The IPPF's Medical Abortion Commodities Database currently includes 20 misoprostol brands, 43 mifepristone brands, and 14 combipack brands

(<https://www.medab.org/summary-information>, as of 30 June 2020).⁹ But medication quality and compliance with storage requirements are not assured when abortion medications are obtained through unregulated sources such as online pharmacies or unlicensed drug sellers. In addition, because misoprostol is sold for a variety of indications, off-label purchases may not contain adequate dosages.

- A study in Malawi demonstrated that misoprostol samples contained as low as 12% of the active pharmacological ingredient (API) instead of the 90% minimum requirement.⁷⁹
- A study exploring the feasibility of obtaining abortion medications via unregulated online pharmacies in the United States obtained 20 products via 16 websites (a convenience sample) at a cost of \$110 to \$360. All products contained the correct active ingredients but only 73% contained the WHO recommended quantity of each compound. All mifepristone pills were within 8% of 200 mg, but only 30% of misoprostol pills were within 10% of 200 mcg (mifepristone range: 185.4 mg/pill – 204.1 mg/pill; misoprostol range: 34.1mcg/pill – 201.4mcg/pill).⁸⁰

MODE OF ACCESS

Accurate information and instructions are an integral component of safe medication abortion care. Concerns about inadequate or inaccurate information are most pronounced when drugs are purchased without eligibility screening via online pharmacies, drug sellers, or over the counter. Even drugs that contain the correct active ingredient and dose may not be accompanied by reliable written information or directions for use.⁴⁶

ONLINE ACCESS TO MEDICATIONS

Studies of internet search patterns suggest that people are increasingly seeking abortion medications online, particularly in regions where there are abortion restrictions.^{58,81} Mifepristone and misoprostol are available for purchase from online vendors (which are distinct from online telemedicine services). In a study in the United States, online pharmacies did little to no eligibility screening of potential purchasers of abortion medications: none of the sites required a prescription, only two questioned the medical history of the purchaser, and none ascertained gestational age or contraindications for mifepristone. No products arrived with any written materials of any kind.⁸⁰ Online procurement of abortion medications can involve lengthy or delayed shipping times. If online purveyors do not screen for gestational age or do not take processing and shipping into account, a user may end up taking the medication after the recommended gestational age limit.

PHARMACY PROVISION

Pharmacies (a term used by researchers to encompass any licensed or unlicensed business that sells drugs) are a common source of abortion medications in many low- and middle-income countries, particularly those where abortion cannot be legally provided.⁴⁷ For example, a review article found that between 78 and 90 percent of Mexican pharmacies and 72 percent of Zambian pharmacies surveyed had misoprostol available.⁴⁷ Because misoprostol is indicated for several medical conditions, it is often accessible over the counter. Combination

⁹ See the Medical Abortion Commodities Database for details on the availability of products that meet strict quality inclusion criteria across 100 countries (medab.org).

mifepristone-misoprostol products were more frequently available in South Asia in countries where mifepristone has been approved for medication abortion.⁴⁷ However, a systematic review (including 7 high quality, 11 medium, and 4 low quality studies) found that pharmacy workers—regardless of the legal status of medication abortion or the knowledge level of pharmacy workers—did not provide users with adequate information about abortion medications, did not offer consistent advice regarding complications, did not routinely screen for eligibility or require a prescription, and reported low rates of referral to other providers in the event of a complication.⁴⁷ Studies have also found misoprostol sold in doses below WHO recommendations (see below for an example).⁸²

- **[Category 1]** In Bangladesh, legal abortion is highly restricted but mifepristone and misoprostol can be purchased over the counter. A prospective cohort study assessed self-reported outcomes among Bangladeshi women who purchased abortion medications from pharmacies. The study found insufficient information was provided to women by pharmacy workers. Among a sample of 109 women (response rates were low at 30% and the intended sample size was not reached), 89.9% of women were not screened by pharmacy workers for eligibility, 40.4% women received no information about the medications, and 80.4% were not informed of any warning signs of potential complications. Inconsistent doses of misoprostol were sold, implying that women who took only misoprostol (n=20) may have had doses that were inadequate to achieve a complete abortion.⁸³
- **[Category 1]** In a prospective cohort study in Lagos, Nigeria, 44% of 172 women who obtained misoprostol from drug sellers received less than the WHO recommended dosage of 800 mcg and only 20% received an adequate dosage. 77.9% of women (n=307) received any instructions on how to take the medication. 38.6% (n=152) were instructed to administer the drugs orally, which is considered a suboptimal route. Researchers developed a 9-item measure of screening questions and information that should be provided by drug sellers. Women reported an average of 3.3 items were covered. Importantly, 72% did not use any other source of information to manage their abortion.²⁷

Several interventions have specifically targeted pharmacy workers' knowledge and practices regarding abortion medication sales in regions with less restrictive abortion laws.⁴⁸ These interventions were effective at increasing knowledge, but did not include systematic monitoring and evaluation. Researchers note the increased efficacy of ongoing, routine training rather than one-off courses.⁴⁷

LITERACY AND LABEL COMPREHENSION

When abortion medications are obtained without a prescription and used without clinical oversight, it is obviously essential that the product label alone provide comprehensible information about gestational age requirements, possible contraindications, dosage instructions, and warning signs of complications. Therefore, product labels must be written for audiences of varying literacy levels.

- **[Category 1]** A pilot study to investigate abortion medication's suitability for over the counter use assessed women's comprehension of a combination mifepristone-misoprostol product label. A convenience sample of 100 South African women (ages 16 and older) were presented with a OTC format product label for Mifeprex and asked questions that measured comprehension of indications for the product, assessment of GA, screening for ectopic pregnancies, identifying contraindications, instructions for use, when to seek medical care, and how to use a pregnancy test to follow-up the procedure. Average scores ranged from 60-80% per item and did not meet the

80% target indicating adequate comprehension. Literacy levels (rather than education levels) proved to be the most important predictor of label comprehension for all concepts.⁸⁴

INFORMATIONAL QUALITY OF LABEL/PACKAGE INSERTS

Product labels and package inserts for abortion medications must contain accurate, up-to-date information. Labels and inserts are particularly important in cases of self-managed abortion without provider involvement, as the medication packaging (i.e. the dosage included in a single pack and the label/written insert describing the drug) may be users' only guide to taking the drugs. Because misoprostol is indicated for other medical issues, the packaging information may not be relevant to an user seeking to induce abortion.⁸⁵

- **[Category 1]** In a cross-sectional analysis of 41 mifepristone, misoprostol, and combipack inserts from 20 low- and middle-income countries (a nonrandom sample), researchers found that 5 of 27 misoprostol products listed medication abortion as an indication for use. The study also found substantial inconsistencies in the information the product packages included, including medical indications for the drugs, eligibility, storage instructions, and regimens. Misoprostol inserts provided more inconsistent information about contraindications and dose regimens than did the mifepristone and combipack inserts. Several of the inserts were also extremely out of date.⁸⁵

IMPROVING ACCESS TO INFORMATION

Risks associated with self-sourcing and ingesting abortion medications without provider oversight (Category 3, Category 4) may be mitigated through interventions such as safe abortion hotlines that provide accurate information about managing a medication abortion. In settings where the health system has integrated some degree of self-managed abortion into its standards of care, patient-centered mobile health (mHealth) interventions have shown promising results in improving feelings of preparedness during a SMMA.⁸⁶ Similar mHealth interventions could be implemented in contexts where abortion medications are obtained from pharmacies or telemedicine services.

- **[Category 3]** In Bangladesh, Marie Stopes set up a call center staffed by mid-level health providers to field questions and concerns from individuals who purchased OTC or off-label abortion medications from pharmacies.⁹ The call center received 287,095 calls over a four year study period, with call volume increasing substantially over that period. After two years, the call center number began to be printed on the packaging of several abortion medications, including a combination pack of mifepristone and misoprostol that was labeled for menstrual regulation and included accurate written instructions. The majority of calls were made before individuals took the medications, a promising sign that call centers could prevent harm from unsafe use. The call center also offered advice and referral information for individuals experiencing possible complications (2.83% of calls). These results suggest that call centers can be an effective and scalable way to improve access to information for those obtaining abortion medications and may provide an alternative to the time and resource-intensive approach of training pharmacy workers in safe provision; 43.1% of calls were from health care or pharmacy workers.⁹ A qualitative study in Bangladesh found that 15 of 24 women who had used menstrual regulation products, did not use their mobile phones to get information about menstrual regulation provision, and were not aware of existing resources such as safe abortion hotlines.⁸⁷

- **[Category 6]** An RCT in South Africa assessed a telemedicine intervention to provide remote support via SMS text messages to women taking misoprostol at home after receiving mifepristone in-clinic (232 women were randomized to receive the intervention, 235 received the standard of care). Women received 13 texts with reminders about taking medication and information about side effect management and potential complications. Researchers measured changes in feelings of anxiety and emotional discomfort as well as preparedness for symptoms of abortion. There were significant differences found between the two groups in preparation for bleeding (OR=2.9; 95% CI=1.6 to 5.1), pain (OR=1.6; 95% CI=1.0 to 2.6), and other side effects (OR=1.8, 95% CI 1.1 to 2.9). The mobile intervention was designed as a supplement to standard in-clinic care, but it could be transferred to contexts where women obtained abortion medications from pharmacies or through telemedicine services.⁸⁶

A 2018 paper outlining a research agenda for SMMA identified a research gap regarding women's access to and preferences regarding abortion information, particularly "how literacy level and the quality of information received make a difference to a woman's experiences and outcomes with medical abortion."⁴⁶ There are basic instructions for SMMA available in multiple languages via organizations including HowToUse, Safe2Choose, Women on Waves, Women on Web^h; these resources are largely contingent on access to the Internet.

For individuals seeking guidance about medication abortion online, there is a wide range in the quality of information available and it falls to the individual user to judge which seem trustworthy. A 2019 review of online access to abortion medications includes several examples of online abortion services with incomplete and sometimes dangerous advice, even when the websites claimed to be operated by medical providers.⁸⁸

Regional organizations such as Mobilizing Activists around Medical Abortion (MAMA) in Sub-Saharan Africa (<https://mamanetwork.org/>) offer resources on medication abortion for both providers and users, including written guidelines and links to regional safe abortion helplines.

TISSUE DISPOSAL

When carried out in clinical settings, the tissue removed during an abortion is treated as medical waste and disposed of through standard medical protocols. In pregnancies up to 10 weeks, fetal tissue is generally not recognizable and can be disposed of similarly to menstrual products or using indoor plumbing. For later first trimester and second trimester abortions, people supporting home use of abortion medications should be aware of local laws regulating the disposal of fetal remains and women should be alerted to these and advised accordingly.

ACCEPTABILITY OF AND PREFERENCES FOR SMMA

^h <https://www.womenonwaves.org/en/page/2592/safe-abortion-low-literacy>; <https://www.womenonweb.org/en/page/11873/how-to-do-an-abortion-with-pills>; <https://womenhelp.org/en/information>; <https://www.howtouseabortionpill.org/howto/>; <https://safe2choose.org/abortion-pills/>.

A literature review of women's preferences for medication abortion and barriers to medication abortion care included 45 quantitative and qualitative studies from 32 countries in Asia, Africa, Europe, North America, and Latin America. The authors found that women's preferences for medication vs. surgical abortion are highly contingent on contextual factors such as those laid out earlier in this briefing, including abortion laws and medical protocols. In Italy, preferences are shaped by the relative ease of obtaining a surgical abortion—which requires just a single appointment—compared with a medication abortion, which requires a three-day hospital stay. Women's opinions and preferences are also colored by their sources of information. The authors cite studies where physicians demonstrated poor knowledge about the safety and efficacy of medication abortion or expressed a clear preference for one method over the other based on familiarity, or religious or moral principles (with doctors more willing to fill a prescription than perform a surgical termination). Satisfaction is higher where women are able to choose their method of abortion in the context of a supportive healthcare system. Dissatisfaction with medication abortion was associated with increased gestational age and with experiencing side effects such as severe pain or bleeding. Women who expressed a preference for medication abortion saw it as more "natural" and safer than surgery or preferred the privacy, control, and reduced dependence on the healthcare system; these factors were especially valued in contexts of legal restriction, high levels of abortion stigma, or "where infrastructure and gendered social values limit women's mobility."⁸⁹

- **[Category 1]** A small qualitative study of university students in Ghana (n=32) found that despite knowledge of safe abortion services in the formal healthcare system, social stigma and concerns about disclosure prompted young people to self manage their abortions by purchasing misoprostol from pharmacies as it was seen as more affordable, direct, and acceptable than medication abortion overseen by a provider.⁹⁰
- **[Category 1]** A small qualitative study of experiences with safe abortion care and pharmacy abortion medication provision in Nepal found that those who obtained medications at pharmacies (n=10) expressed concerns about the lack of referral information available to them in case of complications and about the safety of the process.⁹¹
- **[Category 4] [Category 5]** A systematic review of telemedicine for medication abortion found eight studies that included quantitative measures of acceptability with rates of satisfaction ranging from 64% to 100%, and rates of dissatisfaction ranging from 0.2% to 2.3%. In a study that compared acceptability among women who received abortion services in-person and via telemedicine, there was no difference in rates of satisfaction or dissatisfaction. 90 to 98% of women would recommend telemedicine for medication abortion.⁷
- **[Category 6]** A 2016 study in India found that among 731 women from primarily rural areas without formal education, women who administered misoprostol at home (n=378) after receiving mifepristone at a primary care clinic were significantly more likely to be satisfied than those who returned to the clinic to administer misoprostol (n=389). 90.2% of home users would choose home administration for a future abortion compared with 79.2% of who would opt for clinic administration ($p = 0.0002$).

In a review of research on online access to abortion medications, women in several studies reported that online access offered convenience, privacy, and quicker access to care. In particular, reviewers found a high level demand for online abortion services that offer interactive care and guidance from a trusted source of medical advice (in contrast to noninteractive online services).^{88,92}

SMMA AND COVID-19

The Covid-19 pandemic has been used as a pretext to limit abortion services in many countries, ostensibly to free up hospital beds and equipment, even though abortion requires minimal biosafety equipment and rarely results in hospitalization. As medical resources have been routed to care of those infected, travel and contact restrictions have further aggravated the difficulties for many to obtain healthcare. All of these features of the pandemic have heightened the urgency of ensuring access to safe medication abortion with minimal in-person contact.^{93,94} In some cases, administrative regulations on telemedicine and remote prescribing have been temporarily suspended to make abortion medications more accessible and protocols have been modified for medication abortion provision during the pandemic.^{i,95} These experiences may yield data to support these new approaches after the pandemic.

KEY CLINICAL CONCERNS AND RECOMMENDATIONS FOR PHYSICIAN ADVOCACY

The summary below details key clinician concerns and advocacy opportunities for physician advocates. The advocacy suggestions listed below comprise examples of realistic system-level reforms that would incrementally integrate self-managed abortion into the formal healthcare system while responding to key clinical concerns. These recommendations are not exhaustive, but provide physician advocates with empirically-based ideas about how to work systematically toward safe, accessible, and equitable abortion care that benefits from the expertise of health professionals and the resources of formal health systems.

In some instances, we have tailored suggestions for advocacy to specific legal environments and resource levels in an effort to make these recommendations useful for physician advocates working in different contexts around the globe. However, we recognize that these are crude distinctions. Working or living in a high resource country does not always guarantee access to resources at a local level. Even in countries with liberal abortion laws, issues of cost, accessibility, and stigma may prompt individuals to seek abortion medications outside of the formal healthcare system. However, it is unfortunately the case that those most in need of SMMA because of constrained resources or laws are those most at risk for the very same reason.

Some advocacy needs transcend the specifics of legal climate and resource availability. Foremost among these is working towards universal coverage of abortion services.

IN ALL RESOURCE CONTEXTS AND LEGAL ENVIRONMENTS, GDC URGES PHYSICIAN ADVOCATES TO:

1. *Advocate for information about medication abortion to be incorporated into curricula in medical schools and other clinical training programs (midwifery, nursing, pharmacy, and others).*

ⁱ For example, Centro de Estudios y Sociedad (CEDES) and Gynuity Health Projects (along with partner organizations) developed evidence-based guidance for misoprostol administration with limited clinic visits. See <https://womenhelp.org/en/page/1218/ma-covid-en-print>.

2. Advocate for professional societies, national health department, and other standard-setting bodies to endorse evidence-based protocols for pre- and post-abortion care. In contexts with legal restrictions on abortion provision, advocates may be able to build on the existing post-abortion care consensus.
3. Advocate for workforce development efforts led by clinical education bodies to encourage collaboration and task-sharing with other cadres of providers.

CATEGORIES 1, 2, AND 4

	Procurement – how and where	Gestational Age Assessment	Screening for Contraindications	Where were drugs taken?	Support and Management of Complications	Assessment of abortion completion
Category 1	Self-sourced	Self-assessed	None/unknown	At home	None/unknown	None/unknown
Category 2	Self-sourced via online pharmacy, OTC, drug seller, or personal network	Self-assessed	None	At home	Lay support, incl. written guidance, in-person accompaniment, safe abortion hotline, websites/mobile apps.	Self-assessment based on resources or guidance provided by lay support, pharmacy worker, or community health worker
		Assessed using LMP with support of trained layperson (e.g. community health worker, pharmacy worker)	Assessed in consultation with trained layperson (e.g. community health worker, pharmacy worker)			
Category 4	Prescribed by physician remotely (outside formal HC system)	Review of patient-reported LMP by physician	Online intake form with clinical symptoms/medical history reviewed by physician	At home	Access to 24-hr hotline staffed by trained, lay support	Self-assessment based on resources or guidance provided by medical and lay support team

Note: These three categories (the details of which are in the table on page 4) are presented here as a group because they present a shared set of concerns for clinicians and opportunities for advocacy. In all three models of SMMA, medications are obtained outside of the formal healthcare system. As a result, patients typically interface with the formal health system solely in the context of a concern or complication. Grouping Categories 1, 2, and 4 together is not a comment on the relative safety or efficacy of these models of SMMA.

KEY CONCERNS

MANAGING COMPLICATIONS: Clinicians may only come into contact with individuals who have complications that prompt them to visit a doctor. Clinicians should therefore be aware of the signs, symptoms, and management of post-abortion complications, particularly at later gestational ages. Clinicians should also be alert for signs of ectopic pregnancy.

ADVOCACY OPPORTUNITIES:

- **If medication abortion is legally restricted,**
 - Advocate for a reporting system to track complications (perhaps an anonymous system to avoid putting clinicians or patients at risk of criminal sanction).
 - Forge partnerships with community-based organizations, including advocates for self-managed abortion and safe abortion hotlines, to share information about the signs and symptoms of potential complications of medication abortion and to strengthen links to needed medical services.
 - Explore the utility of training pharmacy workers in safe abortion provision, including signs and symptoms of potential complications and referrals to emergency care.
 - **In low-resource contexts,**
 - advocate for adequate training and health system readiness (complications, equipment, medications, evidence-based protocols) at routine points of contact with the health system (especially emergency departments).
- **If medication abortion can be legally provided,**
 - Gather data about why individuals are seeking abortion medications outside of the health system to usefully inform advocacy strategies. How can the medical system better serve the needs of individuals seeking abortion? What points of access or elements of doctor-patient interaction can be improved? Answers to these questions will differ depending on available resources, as will the advocacy goals that follow. For example, **in low-resource contexts**, explore the utility of training pharmacy workers in safe medication abortion provision, including signs and symptoms of complications and referrals to medical care. In **high resource contexts**, see advocacy opportunities in Category 5.

INFORMATION QUALITY: The information patients receive from outside sources (medication packaging, pharmacies, friends, online) may be inaccurate.

ADVOCACY OPPORTUNITIES:

- Promote evidence-based information by cultivating partnerships between trusted community-based organizations—including lay-run abortion support services—and clinicians to ensure that available information is evidence-based.
- Advocate to get accurate information printed on abortion medication packaging.

MEDICATION QUALITY: Because of unregulated quality and dosage of self-sourced abortion medications, clinicians should be attentive to indications that post-abortion patients may have taken an inappropriate dose.

ADVOCACY OPPORTUNITIES:

- Increase community awareness about the possibility of inadequate doses when abortion medications are self-sourced, including community education about signs of possible complications or incomplete abortion.
- **If medication abortion can be legally provided,**
 - advocate for medication registration and the removal of burdensome regulatory restrictions on mifepristone and misoprostol.

ASSESSING SUCESSFUL ABORTION: Clinicians should be prepared to advise patients about how to use a urine pregnancy test at home, or to advise patients about how to obtain and use a commercially available urine pregnancy test.

ADVOCACY OPPORTUNITIES

- **If medication abortion is legally restricted,**
 - partner with community-based organizations—including lay-run abortion support services—to disseminate information about how to determine abortion completion and how to safely seek emergency care for a possible incomplete abortion.
 - explore the utility of training pharmacy workers in safe abortion provision, using commercial urine pregnancy tests to assure the person is not pregnant.
- **If medication abortion can be legally provided,**
 - Advocate for professional societies and standard-setting bodies to endorse evidence-based self-assessment protocols using remote follow up and urine pregnancy tests.

POST-ABORTION CONTRACEPTION: Clinicians should be aware that individuals who obtain abortion medications outside of the formal healthcare system may be in need of post-abortion follow up, including contraceptive information and or counselling..

ADVOCACY OPPORTUNITIES:

- Strengthen systems of referral and access points for linkages to care to ensure equitable access to post-abortion contraception.

- Forge community partnerships to promote evidence-based information about contraceptive methods (see WHO medication eligibility criteria^j).

CATEGORY 3

	Procurement – how and where	Gestational Age Assessment	Screening for Contraindications	Where were drugs taken?	Support and Management of Complications	Assessment of abortion completion
Category 3	Self-sourced via online pharmacy, OTC, drug seller, or personal network	In-person, clinical assessment (within formal HC system)	In-person, clinical assessment	At home	Advance guidance from clinicians, could include lay support (e.g. written guidance, in-person accompaniment, safe abortion hotline, websites/mobile apps)	In-person or remote clinical assessment (within formal HC system)

KEY CONCERNS

SCREENING FOR GESTATIONAL AGE AND CONTRAINDICATIONS: In health systems where there are hybrid frameworks for reducing the risk of unsafe abortion in the context of legal restrictions, clinicians should tailor information about abortion medications to the patient's gestational age and any other risk factors.

ADVOCACY OPPORTUNITIES:

^j Available at https://apps.who.int/iris/bitstream/handle/10665/181468/9789241549158_eng.pdf?sequence=9.

- Physician advocates should forge partnerships with community-based organizations, including advocates for self-managed abortion and safe abortion hotlines, to increase awareness that it is safe and legal to visit a physician for counseling, screening and gestational age assessment.

MANAGING COMPLICATIONS: Clinicians should be trained in recognizing and managing post-abortion complications and prepared to refer patients to emergency care when needed.

ADVOCACY OPPORTUNITIES:

- Advocate for a reporting system to track complications that avoids putting clinicians or patients at risk of criminal sanction.
- Forge partnerships between clinical facilities and community-based organizations and safe abortion hotlines to share information about the signs and symptoms of potential complications of medical abortion and to strengthen links to needed medical services.
- Explore the utility of training pharmacy workers in safe abortion provision, including signs and symptoms of potential complications and referrals to emergency care.
- ***In low-resource contexts,***
 - advocate for adequate training and health system readiness (complications, equipment, medications, evidence-based protocols) at routine points of contact with the health system (especially emergency departments).

INFORMATION QUALITY: Patients may not have accurate information about abortion medications. When counseling patients with unwanted pregnancies, clinicians should provide them with comprehensive information about medication abortion (within the limits of the law) and share additional resources such as hardcopy or online guidance or the number of a local safe abortion hotline.

ADVOCACY OPPORTUNITIES:

- Promote evidence-based information by cultivating partnerships between trusted community-based organizations—including lay-run abortion support services—and clinicians to ensure that available information is evidence-based.

MEDICATION QUALITY: Clinicians should inform patients about the risks associated with unregulated quality and decreased potency of self-sourced abortion medications.

ADVOCACY OPPORTUNITIES:

- Advocate for programs run by health departments or clinical facilities to educate the community about the possibility of inadequate doses when abortion medications are self-sourced, including information about signs of possible complications or incomplete abortion, and when to seek follow up or emergency care.

ASSESSING SUCCESSFUL ABORTION: Clinicians should be prepared to advise patients about how to use a urine pregnancy test at home, or to advise patients about how to obtain and use a commercially available urine pregnancy test.

ADVOCACY OPPORTUNITIES:

- Forge partnerships between community-based organizations (including lay-run abortion support services), professional societies, and state agencies to promote information about how to determine abortion completion and when to seek emergency care.

POST-ABORTION CONTRACEPTION: Clinicians should be aware that individuals who obtain abortion medications outside of the formal healthcare system may be in need of post-abortion follow up, including contraceptive information and or counselling.. Clinicians should incorporate post-abortion contraceptive access into any follow-up visits, including referrals for options that require in-person care (e.g. LARCs).

ADVOCACY OPPORTUNITIES:

- Strengthen systems of referral and access points for linkages to care to ensure equitable access to post-abortion contraception.

CATEGORY 5

	Procurement – how and where	Gestational Age Assessment	Screening for Contraindications	Where were drugs taken?	Support and Management of Complications	Assessment of abortion completion
Category 5	Prescribed by physician remotely (within formal HC system)	Ultrasound or bimanual examination with results sent to prescribing physician	In-person testing if indicated with results sent to prescribing physician	At home	Remote access to physician or clinic, including formal referrals to care.	Formal ultrasound assessment
		Remote assessment by physician using patient-reported LMP	Remote telephone or video assessment using clinical symptoms/medical history			In-person serum or urine HCG test
						Urine test performed at home in combination with self-assessment of symptoms and/or remote clinical assessment of symptoms

KEY CONCERNS

MANAGING COMPLICATIONS AND FOLLOW UP CARE: Clinicians should be prepared (training, equipment, etc.) to manage post-abortion complications at routine points of contact (e.g. emergency departments), and to refer patients to needed care for complications or follow up.

ADVOCACY OPPORTUNITIES:

- Advocate for firm links to care between inpatient and outpatient services.
- Advocate for well-designed studies on each component of telemedicine-provision of medication abortion, including patient and physician satisfaction and the effectiveness and acceptability of telemedicine post-abortion contraception provision.
- Advocate for investment to streamline and extend the reach of telemedicine technologies and infrastructure.
 - In low-resource health systems with high levels of mobile phone use, advocate for funding of health system-supported mHealth services to reduce the cost barrier to hospital-based abortion provision.
- Advocate within clinical facilities and health departments for equitable access to telemedicine services that are secure, private, and confidential.
- Ensure that telemedicine options are recognized as legitimate healthcare services under regulatory schemes (including malpractice coverage, payment mechanisms, regulations on prescribing, and insurance reimbursement).
- Advocate that professional clinical societies and licensing bodies incorporate timely updates to models of care in response to new evidence, including the removal of medically unnecessary barriers to care.

CATEGORY 6

	Procurement – how and where	Gestational Age Assessment	Screening for Contraindications	Where were drugs taken?	Support and Management of Complications	Assessment of abortion completion
Category 6	Prescribed by physician in person	In-person clinical exam using ultrasound or bimanual examination	In-person testing if clinically indicated	At least one medication/dose taken at home	Standard in-person clinical support	In-person clinical assessment

KEY CONCERNS

MANAGING COMPLICATIONS AND FOLLOW UP CARE: Clinicians should be prepared (training, equipment, etc.) to manage post-abortion complications at routine points of contact (e.g. emergency departments), and to refer patients to needed care for complications or follow up.

ADVOCACY OPPORTUNITIES:

- Advocate that professional clinical societies and licensing bodies update models of care in response to evidence supporting the home administration of abortion medications to remove unnecessary barriers to access.

CONCLUSION

This document provides physicians and other healthcare providers with the latest evidence base regarding different approaches to self-managed medication abortion. Health systems must be responsive as new evidence become available and laws and social practices evolve. Our goal is to optimize existing models of SMMA to support health and safety, which requires the decriminalization of abortion and removal of medically unnecessary restrictions on access. We emphasize here the importance of melding respect for patient ***participation, autonomy and dignity*** with ***evidence based clinical expertise*** and the ***obligation of health systems*** to provide meaningful access to safe and equitable abortion care and reiterate that all of these vary with ***context***.

Global Doctors for Choice is committed to promoting an equitable, respectful approach to safe abortion provision, in which abortion is integrated into the formal healthcare system so that abortion may serve as a window for engagement with the full spectrum of essential medical care.

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