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# Misoprostol in the era of COVID-19: a love letter to the original medical abortion pill

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## Introduction

Timely and equitable access to safe, high-quality abortion is a core component of ensuring reproductive autonomy and upholding the tenets of reproductive justice.<sup>1</sup> The coronavirus 2019 (COVID-19) pandemic, coupled with increased demands on national public health systems and restrictions on travel and movement, are exacerbating existing inequities in abortion access.<sup>2,3</sup> Nonsurgical abortion methods – which can be performed by a wider cadre of providers than surgical abortion methods, require fewer resources, and can be utilised in a range of settings, including one's home – are key to safeguarding access to safe abortion during and after the pandemic. Now, more than ever, it is imperative to harness the potential for medical abortion, particularly misoprostol, a safe, World Health Organization (WHO) recommended medication for pregnancy termination,<sup>4</sup> to expand access to abortion care for everyone, when and where they need it.

While the discovery of medical abortion methods revolutionised safe abortion access for many, systemic inequities in access persist. The consequences of inequitable abortion access include loss of bodily autonomy, forced childbearing, increased morbidity and mortality from use of unsafe methods,<sup>5</sup> and long-term economic, social, and emotional impacts.<sup>6</sup> Long histories of racism, gender inequality, homophobia, and numerous other systems of oppression have resulted in these consequences being disproportionately experienced by communities that have been systematically marginalised. For example, people

living in countries that have experienced centuries of colonialism (where the majority of unsafe abortions occur), transgender and gender nonbinary people (who often face discrimination or outright refusals of care), Black, Indigenous, and other people of colour in the United States (who are disproportionately impacted by community disinvestment, abortion restrictions, and federal funding restrictions), and those living in poverty (who face numerous barriers often related to cost and inaccessibility of local services), are more likely to be negatively impacted.<sup>1,5,7,8</sup>

Major societal disruptions, such as economic recessions, conflict, and the current pandemic, further amplify inequities in access to care. Disruptions in global contraception supply chains, resource shortages and diversion of sexual and reproductive health facilities to providing COVID-19 care, as well as the impact of severe economic distress on individuals' livelihoods, compound already existing inequities in access to preferred and reliable methods of contraception and clinic-based abortion care.<sup>2,3</sup> As this pandemic continues, these inequities will worsen. Previous evidence suggests that during humanitarian crises, sexual and reproductive health care needs rise.<sup>9</sup> It is likely the current pandemic will increase the number of people in need of safe abortion services, as disruptions in contraception access, changes in family structure and dynamics, increased prevalence of sexual violence, and economic insecurity may limit people's reproductive autonomy and ability to prevent pregnancy.<sup>10</sup>

Faced with the ongoing crisis of COVID-19, fully utilising all WHO-recommended abortion methods is essential to expanding and maintaining access to abortion. The WHO recommends two regimens for safe and effective abortion care throughout pregnancy: misoprostol on its own, and mifepristone in combination with misoprostol.<sup>4</sup> These medications, when used correctly, successfully terminate 80–95% of pregnancies without the need for surgical intervention, depending on regimen and pregnancy duration.<sup>11,12</sup> Misoprostol, an essential component of both regimens, was originally developed as a treatment for gastric and duodenal ulcers; in the late 1980s, women in Brazil, unable to obtain abortions in the formal healthcare system, discovered its use as a safe and effective abortifacient.<sup>13</sup> Clinical trials soon followed, and misoprostol was incorporated into clinic-based standards for abortion care around the world.

The use of misoprostol in self-managed abortion, defined here as when a person performs their own abortion without clinical supervision, has risen globally, and is credited with declines in maternal morbidity and mortality.<sup>14</sup> Many features of misoprostol make it well suited for self-use: it is low-cost, available in many places without a prescription, relatively stable at different temperatures, and is straightforward to use, provided the individual has accurate information. Over the past 40 years, online telemedicine services, safe abortion hotlines, feminist networks, and other community-based distribution models have further facilitated the rise of self-managed abortion using both medical abortion regimens, and have expanded access to people in need of abortions around the world, regardless of legal context, by providing empathetic and evidence-based information about how to procure medication, accurate timing and dosing, what to expect, how to confirm completion, and how and when to seek necessary health care.<sup>8</sup> The organisations involved, which primarily operate in countries where abortion is highly restricted and/or unavailable through formal healthcare systems, are committed to serving those who face the most barriers to abortion access and providing support to those with limited financial resources or other support systems with information that is clear and easy to understand.

Given the higher efficacy documented in clinical trials, the combined regimen (mifepristone and misoprostol) is considered the preferred method for medical abortion care in countries where mifepristone is registered as a pharmaceutical product.

However, in countries where mifepristone is not registered, or where abortion access is highly restricted, the majority of medical abortions are carried out with misoprostol-only regimens. We briefly review the evidence on the effectiveness of misoprostol-only abortions, highlight the advantages of the misoprostol-only regimens compared to the combined regimen, and raise important considerations.

### *Effectiveness of misoprostol-only regimens*

The WHO-recommended protocol for misoprostol-only abortions for pregnancies with gestations below 12 weeks is as follows: 800 micrograms ( $\mu\text{g}$ ) of misoprostol tablets administered sublingually (under the tongue), vaginally (inserted in the vagina), or buccally (between the cheek and gums), every three hours for up to three doses (2400  $\mu\text{g}$  total). For pregnancies above 12 weeks gestation, the WHO-recommended protocol is 400  $\mu\text{g}$  of misoprostol tablets administered sublingually, vaginally, or buccally every three hours until foetal and placental expulsion.<sup>4</sup> For more advanced gestations (beyond 24 weeks), lower misoprostol doses with a longer timing between doses are recommended.

In the largest randomised trial evaluating different misoprostol-only regimens in 2066 women with pregnancies below nine weeks, 84% of the 1033 participants randomised to receive three doses 800  $\mu\text{g}$  misoprostol administered sublingually or vaginally every three hours had a complete abortion without surgical intervention at two-week follow-up, 11% had a surgical intervention to treat an incomplete or missed abortion, and 5% had an ongoing pregnancy.<sup>15</sup> Data is limited for effectiveness of misoprostol-only regimens for pregnancies between nine and 13 weeks gestation, although there is evidence suggesting similar levels of effectiveness.<sup>16</sup> A meta-analysis of 38 studies with 12,829 evaluable women with pregnancies below 13 weeks gestation found that 78% (95% CI: 74.5–81.2%) of study participants had a complete abortion without need for surgical intervention, although the studies varied widely in the misoprostol-only regimens used and time period under observation.<sup>12</sup> In general, effectiveness was higher with more doses of misoprostol, non-oral routes of administration (vaginal, buccal, or sublingual), and a longer time period to evaluate completion prior to surgical intervention. Method failure (ongoing viable pregnancy at the time of

follow-up) occurred in 6.8% (95% CI: 5.3–8.5%) of study participants (weighted meta-analytic estimate).<sup>12</sup> Across 12,184 evaluable women in the review, only 26 were hospitalised or received blood transfusions (meta-analytic estimate 0.7%, 95% CI 0.4–1.0%), and no deaths were reported.<sup>12</sup>

Studies exploring the efficacy of misoprostol for terminating pregnancies beyond 13 weeks gestation have found that 72–95% of participants had a complete abortion without need for surgical intervention at 48 hours after the first misoprostol dose (regimen: up to five doses 400 µg misoprostol administered sublingually or vaginally at three-hourly intervals, and repeated if there is no effect after 24 hours).<sup>17–21</sup> In a randomised trial of 681 women with pregnancies between 13 and 20 weeks, 2.1% with vaginal administration and 5.6% with sublingual administration had an ongoing pregnancy 48 hours after the first misoprostol dose.<sup>20</sup> While the evidence from clinical trials suggests that vaginal administration of misoprostol has the highest efficacy, sublingual administration is often equivalent or similar; people should choose appropriate routes based on their context, personal preference, cultural considerations, and legal risks.

It is important to note that effectiveness may be even higher outside the confines of a clinical trial. In clinical trials, incomplete, missed, or failed abortion events are typically treated surgically rather than with additional doses of misoprostol, and the time period to assess completion is relatively short. Prospective cohort studies of misoprostol-only regimens in self-managed contexts with virtual or in-person support provide useful data, as participants may be less inclined to seek early medical intervention and protocols typically allow for repeat doses before referral to additional care. One study of 918 women on the Thai-Burma border found that 96.4% successfully self-managed their abortions with misoprostol only, assessed after one month (regimen: two doses 800 µg administered vaginally, 24 hours apart, additional dose of 800 µg if needed after one week).<sup>22</sup> Evidence from a pilot study of 202 callers to safe abortion hotlines in South America, Southeast Asia, and West Africa found that 92.6% of the 94 callers with pregnancies below 12 weeks who self-managed their abortion with misoprostol-only reported a complete abortion without the need for surgical intervention at 21-day follow-up (regimen: three doses 400–800 µg administered sublingually every three hours, with additional doses or

subsequent attempts as needed).<sup>23</sup> A prospective study of 394 women in Nigeria who purchased misoprostol from drug sellers found that 94% reported a complete abortion without surgical intervention about a month after taking the medications, despite receiving incomplete or inadequate counselling from the drug seller (regimen: varied).<sup>24</sup> By comparison, clinical studies typically use a one or two-week follow-up, and do not allow for additional doses in their protocol – many “incomplete” or “missed” abortions might have resulted in a complete abortion without the need for surgical intervention with additional time or additional doses.

### *Advantages of misoprostol-only regimens*

Misoprostol-only regimens carry many advantages over the combined regimen. Misoprostol is less costly, more widely available, and carries fewer restrictions for use than mifepristone. In the United States, provision of mifepristone is bounded by the Food and Drug Administration’s Risk Evaluation and Mitigation Strategy (REMS) guidance, which limits the number and type of providers who can prescribe mifepristone, and requires in-person clinic visits for provider-observed administration of this pill. While these restrictions are already burdensome, they become insurmountable barriers to clinic-based abortion care under current circumstances. Around the world, the COVID-19 pandemic has resulted in restrictions on travel which limit people’s ability to provide or receive care, the closure of abortion clinics under anti-choice emergency declarations, school and childcare closures, and economic conditions that, together, further exacerbate the challenges of paying or travelling for abortion care.

In countries where abortion is legally restricted, mifepristone is often not registered for use and largely unavailable in the formal healthcare system. However, misoprostol is considered an essential medicine in most countries and is available over the counter due to its numerous other medical indications (treatment for gastric ulcers, postpartum haemorrhage, arthritis), and often available via informal channels. While global shifts in availability of essential medications may impact access to misoprostol, it is less likely to be as affected as mifepristone, given its registration in most countries and other medical indications for use. The wide-spread global availability of misoprostol and documented safety and effectiveness

throughout pregnancy, coupled with fewer restrictions on its use, highlight the salient role that misoprostol can play in expanding and maintaining abortion access during and after these unprecedented times.

### ***Important considerations***

Some providers, advocates, and individuals may have concerns around the efficacy of misoprostol-only compared to mifepristone and misoprostol in combination. In contexts where mifepristone is available and accessible, the combination regimen is a valid and effective option. However, there are many contexts in which this is not the case. Reassuringly, a wide body of evidence, some of which is discussed above, has demonstrated that the vast majority of those using misoprostol-only regimens will have a complete abortion without the need for further treatment or follow-up after taking the requisite number of doses. However, based on the data summarised above, around 10–15% may need additional doses of misoprostol to completely expel the products of conception; this should be considered part of the standards of care and as an expected and anticipated outcome. Counselling – either at the point of purchase, from a medical provider, or lay support person – should adequately prepare individuals to expect this. Some may not wish to continue taking medications, either because they find the prolonged bleeding and cramping uncomfortable or worrisome, or cannot procure additional pills; for these individuals, referral for surgical intervention to complete the abortion is appropriate. In contexts where abortion is legally restricted in the formal healthcare system, and/or self-managed abortion is criminalised, counselling for people who self-manage should adequately prepare them to seek medical care, if needed. Symptoms, presentation, and treatment of a medical abortion in process are identical to that of a spontaneous abortion (miscarriage); even in restrictive contexts, care for spontaneous abortion is often available in the formal healthcare system. In these settings, it is important to emphasise the advantages of sublingual and buccal administration to ensure that tablet remnants are not present in the vagina in the instance of a pelvic examination, as a means to avoid detection and minimise the risk of criminalisation.

For the approximately 5% of those for whom misoprostol has no effect and results in an ongoing

pregnancy, the regimen can be repeated, as misoprostol is a safe and effective abortion method throughout pregnancy. Those who continue not to experience any bleeding and who did not confirm the location of their pregnancy via ultrasound may need referral to additional care as method failure may be a sign of an ectopic pregnancy.

In self-managed contexts, additional counselling and support should be provided to those with pregnancies beyond 12 weeks, particularly related to the physical process and expectations around expelling the products of conception, as important considerations around monitoring of potential warning signs of complications and appropriate management of the products of conception are vital.<sup>25</sup>

While misoprostol-only medical abortion is medically safe, there are possible legal or social risks. For those who self-manage, there may be risks for those who want or need to hide their abortion from people they live with, risks of criminal prosecution if the pregnant person seeks needed medical care at any point during their process and self-managed abortion is suspected, or, for those who are terminating at later gestations, risks if the products of conception are discovered by others. However, legal advocacy efforts, wider availability of evidence-based information about medical abortion, advanced planning support regarding care-seeking strategies for those who self-manage, and training around legal obligations to report self-managed abortion for providers can mitigate these risks.

Lastly, re-imagining what it means to have a “successful” abortion is critical to our field’s understanding and interpretation of abortion self-care. The clinical endpoints that currently define a successful abortion, such as the proportion of individuals with complete uterine evacuation seven days after taking a pre-specified number of doses, are helpful metrics when establishing medication efficacy and recommended protocols. However, these endpoints do not encompass the full range of considerations that people weigh when prioritising or selecting one method over another. People base their abortion preferences and “decisions” around a wide variety of factors – comfort with surgical procedures, length of the process, setting where the abortion will occur, prior experiences, influence from providers or social support networks, cost, ease of use, and accessibility, among others. For some, a “successful” abortion may mean self-managing at home with misoprostol purchased

from their local pharmacy, with support from a non-clinical abortion accompanier. Others may prefer to take medication at a health facility under the guidance of a physician or advanced practice clinician, with additional doses of misoprostol if needed. Some may prefer to begin their medical abortion at home with accompaniment support, and expel the products of conception in a health facility with support from a medical provider who treats them with dignity and respect, or may prefer a manual vacuum aspiration if their bleeding is prolonged. Whatever the circumstances, a “successful” abortion is one that results in the desired outcome (termination of pregnancy); is safe, accessible, and timely; and prioritises the dignity, autonomy, privacy, and preferences of the individual.

### Conclusion

In every country, there have always been individuals for whom facility-based abortions were out of reach, or not preferred – the COVID-19 global pandemic has only exacerbated this divide. While medical abortion is not a panacea for all of the disparities and inequities in access to timely, safe, affordable, and

non-judgmental abortion care, it has the potential to vastly expand access to many, both in clinical and self-managed settings. Misoprostol-only is a safe, effective, and acceptable regimen for providing abortion care in a variety of contexts, and should not be overlooked during or after these extraordinary times.

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*No potential conflict of interest was reported by the author(s).*

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