

Original research article

Community-based distribution of misoprostol for early abortion: evaluation of a program along the Thailand–Burma border[☆]

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Abstract

Background: Although abortion is legal in Thailand for a number of indications, women from Burma residing in Thailand are rarely able to access safe services. We evaluated the outcomes of a community-based distribution program that provides migrant, refugee, and cross-border women from Burma with evidence-based information about and access to misoprostol for early pregnancy termination.

Methods: After determination of eligibility based on self-report and counseling, trained Network members instructed women to vaginally administer two 800-mcg doses of misoprostol 24 h apart and a third dose one week later, if needed. We systematically reviewed data from monitoring logbooks recorded over a three-year period to examine pregnancy outcomes. We also conducted in-depth open-ended interviews with the three leaders of the two Networks to understand better their perceptions and experiences as providers and counselors. We analyzed logbook data using descriptive statistics and interviews for content and themes using both deductive and inductive techniques.

Results: From January 2012 through December 2014, 918 women received early abortion care using misoprostol through the community-based distribution program. Of these, 885 women (96.4%) were not pregnant at follow-up, 29 were pregnant at follow-up (3.2%), and four women were lost to follow-up (0.4%). Our interviews revealed that providers are motivated to participate due to concerns surrounding unsafe abortion in the community and frame their work as a public health intervention.

Conclusions: The documented outcomes from this initiative may be valuable for those working to reduce harm from unsafe abortion in other legally restricted, low-resource, and/or conflict-affected settings.

Implications: Our findings demonstrate that community-based distribution of misoprostol can be a safe and effective strategy for increasing access to safe abortion, even in a legally restricted, low-resource setting. Determining if similar strategies can be successfully employed in other contexts appears warranted.

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1. Introduction

Decades of civil conflict and an overarching lack of economic development in Burma have resulted in population dislocation, disruption of services, and shortages in trained health service personnel.¹ These dynamics have had

significant consequences for sexual and reproductive health outcomes [1]. In conflict-affected Eastern Burma, the best available evidence suggests a maternal mortality ratio of around 1,000 deaths per 100,000 live births [2]. Women in this region lack access to a full range of contraceptive methods and unintended pregnancy is common [3–7].

In Burma, abortion is legally permissible only if the pregnancy threatens the woman's life [8]. This legal exception has long been narrowly interpreted and there is no evidence that safe and legal abortions are being performed. Providers and women risk fines and imprisonment for performing and/or having an unauthorized abortion [8]. However, several studies have documented that women use various unsafe methods to terminate unwanted

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¹ Although the country's official name is Myanmar, there are many who question the legitimacy of the military government's decision to rename the country more than 25 years ago. Out of respect for the terminology used by many refugees and migrants living in Thailand, we use Burma throughout this article.

pregnancies [3,5,9–11]. In conflicted-affected areas, unsafe abortion is likely a leading cause of maternal death [12].

Conditions in Burma have led more than 1.5 million people to relocate to Thailand as either registered residents of nine unofficial refugee camps or migrants of varying legal status. Further, people living in Eastern Burma routinely enter northern Thailand to obtain goods and services, a population referred to as “cross-border.” Cross-border populations, refugees, and migrants face significant barriers to accessing reproductive health services, including abortion care, in Thailand [3,5–7,11,13–15].

Thai law permits abortion for a range of indications. Current interpretations allow legal abortion when a pregnancy endangers the life of the woman, threatens the woman’s physical or mental health, involves a fetal abnormality, resulted from rape or incest, or occurred when the woman was age 15 or younger [16,17]. The Thai Medical Council further regulates abortion procedures, which must be provided by a physician, certified or approved by a second physician, and detailed in the medical record [18]. Importantly, women do not face criminal penalties for obtaining or inducing an unauthorized abortion. In December 2014, the Thai government approved mifepristone for hospital-based provision by qualified Thai medical doctors for research purposes [18]. However, trained providers in Thai government hospitals and private clinics often use misoprostol-alone regimens to terminate early pregnancies [19]. Although misoprostol is a “hospital only” medication by regulation, the drug is widely available in clinics, pharmacies, and drug shops throughout Thailand. In contrast, as of early 2017, mifepristone was not available in non-hospital settings and remained highly regulated.

Legal and safe abortion services are available throughout Thailand through government hospitals and private sector facilities. However, facilities interpret the law differently such that Thai women face considerable regional, urban/rural, and socioeconomic disparities in accessing timely and affordable care [16–18,20]. These dynamics are further exacerbated for women from Burma; refugees and migrants generally cannot access safe abortion care, even for cases that fall clearly within the legal exceptions [3,11,21,22]. Despite recent efforts to expand access to safe and legal abortion care in the region [13,19], women from Burma on both sides of the border suffer significant morbidities as a result of unsafe abortion [3,9,10,21,22].

An abundance of global evidence indicates that misoprostol is between 75% and 90% effective in inducing an abortion in the first 9 weeks of pregnancy and thus a key alternative in low-resource settings [23–25]. Although interventions using misoprostol have been discussed as an important harm reduction strategy for unsafe abortion [26,27], few published case studies examine the feasibility of community-based distribution of misoprostol for early abortion. This article presents the results of an evaluation of a community-based misoprostol program established along the Thailand-Burma border. We document pregnancy outcomes

over a 3-year period and explore perceptions of key informants involved in distribution.

2. Project description and methods

Despite the regulatory status of misoprostol in Thailand, clinics in the Thailand-Burma border region routinely use the drug for post-partum hemorrhage prevention and treatment, post-abortion care, and the management of intra-uterine fetal demise. In addition, back pack health care workers and Burma Medical Association clinics in Eastern Burma use misoprostol for post-partum hemorrhage prevention. In 2011, a multi-disciplinary North American team facilitated the establishment of two Networks to provide Burmese- and Karen-speaking women seeking an abortion with information about misoprostol as well as free medication. A Burmese physician who provides primary care to both migrant and refugee women through a local Community-Based Organization (CBO) led Network A. As the program expanded, this leader trained two additional health workers from Burma. A Karen counselor from Eastern Burma originally led Network B. As the project expanded, this leader trained two health workers and a social worker from Burma. The social worker later became the point person for Network B. Individuals within Network B were affiliated with a number of different CBOs that serve cross-border, refugee, and migrant populations throughout northern Thailand. All providers in both Networks were well known within their communities.

The overarching program included training, technical assistance, a supply of medication, and logistical support. The North American team used a train-the-trainer model for the two Networks. The leader of each Network received initial training on the legal status of abortion and the regulatory status of misoprostol in both Thailand and Burma, options counseling, a standard misoprostol-only regimen, and clinical expectations, side effects, complications, and conditions warranting follow-up. The training also included information about where women could obtain post-abortion care and/or contraception. The North American team also provided each Network leader with ongoing mentorship and technical assistance including an on-call expert who could discuss complicated cases or review protocols when needed. As counterfeit and expired medications are common in this region [28], the North American team regularly supplied both Networks with misoprostol obtained directly from a vetted pharmaceutical company in South Asia in its original packaging. Finally, both Network leaders received logistical support with respect to record keeping and phone/in-person follow-up with women obtaining misoprostol through the Networks.

All providers in both Networks volunteered their time and for the first 2 years of the initiative the two Networks operated independently from each other. Program leaders for each Network were responsible for training new members

and collating outcomes information for all women who received misoprostol. They also regularly checked-in with members of the North American team to discuss challenging cases or situations and provide updated information about the supply of misoprostol.

With respect to the process, after learning about the Network through personal relationships or by word-of-mouth in the community, a woman with a self-reported unwanted pregnancy of 9 weeks or less based on her recollection of the first day of her last menstrual period (LMP) contacts a Network provider. She then receives in-person counseling at a mutually convenient time and place regarding pregnancy options, the legal status of abortion in Thailand (and Burma, if relevant), use of misoprostol, expected symptoms, conditions warranting clinic/hospital follow-up, and the process by which to report the outcome. The Network provider gives her 12 misoprostol tablets (200mcg each) and instructs her to vaginally take 800mcg followed 24 h later with another 800mcg dose and a third 800mcg dose one week after the initial administration, if needed.² The Network provider also gives the woman contact information and requests that she contact him/her via cell phone with questions or concerns. Network providers follow up with women by phone or in person after 1 month if they do not hear from the woman about the outcome. This overarching “no touch” process relies exclusively on self-reported information.

In order to ensure that women obtaining misoprostol through this initiative are in the first trimester of pregnancy, women who identify themselves as having a pregnancy beyond 9 weeks during the initial contact with the provider are not eligible. Network providers counsel these women on the legal indications for abortion in Thailand and refer women with more advanced pregnancies to a pilot program in the border region that refers eligible women from Burma to a Thai government hospital for safe and legal abortion care [13]. However, Network providers also use their judgment and occasionally offer misoprostol to women who they believe are within a few days of the gestational age cutoff but still well within the first trimester of pregnancy.

The program launched in January 2012 and we tracked outcomes over a three-year period through a review of logbooks maintained by the point person for each Network. Logbooks contained limited nonidentifiable demographic information about women who presented with an unwanted pregnancy and the outcome of the misoprostol-only treatment. This included information about whether or not the woman was pregnant at follow-up and whether or not the woman presented at a health facility and/or received treatment as a result of using misoprostol. Network leaders also made specific case notes, when relevant. We used descriptive statistics to analyze the outcomes data and reviewed all notes.

To supplement information about patient outcomes we conducted interviews with the three leaders of the two Networks to understand better their perceptions of the program, personal motivations for involvement, challenges with operating the Network, and opinions on how to improve access to misoprostol. We summarized, transcribed, and coded interviews using both *a priori* codes from a pre-determined codebook and inductive codes that emerged during review [29].

The Steering Committee of a local CBO approved the community distribution program and both this CBO Steering Committee and the Research Ethics Board at the University of Ottawa approved the evaluation. To protect individuals and organizations involved with the Networks, we have removed and/or masked all personally identifiable information, including gender, as well as all CBO names.

3. Results

Between January 1, 2012, and December 31, 2014, 918 refugee, migrant, and cross-border women with unwanted pregnancies received a medication abortion with misoprostol-alone through the community-based distribution program. We present the outcomes in Fig. 1. Of these 918 women, 885 (96.4%) were not pregnant at follow-up. Within this group, there were no major complications, including no hospitalizations and no bleeding that required a transfusion.

Twenty-nine women (3.2%) remained pregnant at follow-up. In three of these cases (0.3%), the absence of expected bleeding led the woman to seek care at a clinic where she was diagnosed with an ectopic pregnancy; these ectopic pregnancies were subsequently managed with standard clinic protocols. In two cases (0.2%), the woman presented to the Network provider within 6 weeks LMP and experienced scant bleeding and cramping after using three doses of misoprostol. Because these women were still within 9 weeks, the Network leader helped them obtain mifepristone/misoprostol from the telemedicine service Women on Web [30]; in both instances the women were not pregnant at follow-up. The remaining 24 women all continued their pregnancies to term and all of these pregnancies resulted in a live birth; no women reported fetal anomalies.

In addition, four women (0.4%) were lost to follow-up. In three cases the Network provider suspected that the woman returned to Burma after receiving the medication to have the abortion beyond the gaze of the migrant community and could not afford international phone charges to report follow-up. Network leaders estimate that 10% of all women followed up with providers more than 4 weeks after the initial misoprostol administration.

Our interviews with Network leaders reveal considerable enthusiasm for the program. All three leaders described the community-based distribution program as a successful initiative and as a means of addressing the unmet need for safe abortion options in migrant and refugee communities.

² This was a widely accepted evidence-based regimen at the time [38].

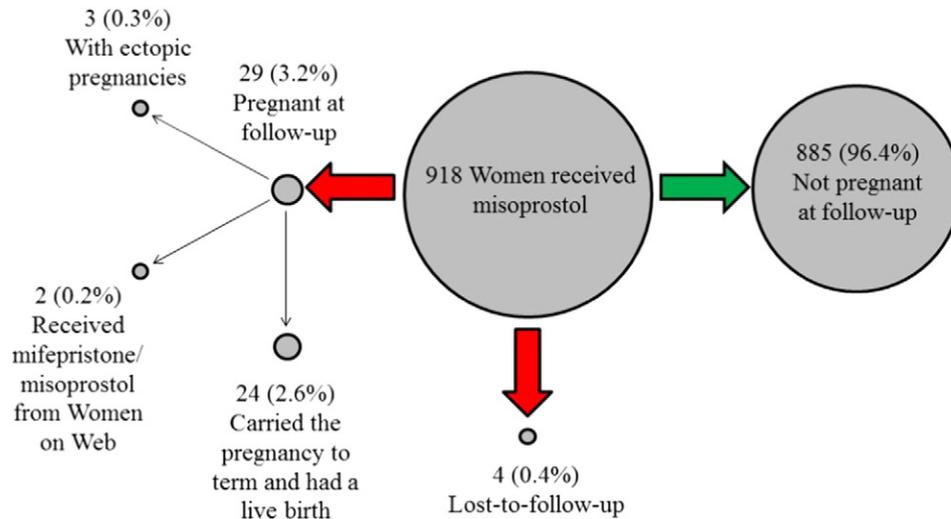


Fig. 1. Outcomes of the community-based distribution misoprostol program.

Although personal motivations for involvement differed, each provider described how witnessing the suffering that results from unsafe abortion in their communities was a critical factor in their decision-making. As described by the counselor who led Network B:

I feel [committed to the program] because I see [unsafe abortion] with my eyes and I see women die. So many do not see it directly — it makes a big difference to see it [rather] than just hearing about it.

Further, all three participants explained that they framed this effort as a public health initiative with both individual and community benefits and all three described their participation as a moral responsibility. The doctor who led Network A described his/her participation as follows:

I don't consider [providing misoprostol] as not being right. The big problem is if I don't give [women] it, or don't do this work, they will still go, pay much money and get many problems. Therefore, this is my duty.

Although hundreds of women have received abortion care through the Networks, providers reiterated that challenges due to legal restrictions persist and prevent open discussion of the program. As a result, community knowledge of the program appears to arise primarily from word-of-mouth. Network leaders shared that many new clients are accompanied to their counseling session by a friend or family member who has already received an early abortion through the program. However, despite challenges relating to the current legal status of abortion in general, and misoprostol in particular, all leaders agreed that expanding community-based distribution of misoprostol in other areas along the border is warranted.

4. Discussion

Global efforts to provide women with medically accurate information about medication abortion, including misoprostol-alone regimens, have inspired harm reduction programming, dissemination of medically accurate information through telemedicine services and websites, and the establishment of call centers in contexts where access to safe services is limited or unavailable [30–36]. This initiative demonstrates similar successful outcomes and indicates that expanding access to safe abortion care through community-based distribution of misoprostol is feasible, even in a legally restricted, low-resource, conflict-affected setting.

Clinical trials generally report that misoprostol-alone results in a complete abortion in 75% to 90% of cases [23–25]. Yet over 96% of women who obtained misoprostol through this community-based distribution program were not pregnant at follow-up. A number of factors may have led to this comparatively high “success” rate. First, the protocol used throughout the initiative included three 800mcg doses of misoprostol as Network leaders deemed asking women to return for a third dose in this setting impractical. Some early clinical trials assessed completion after only two 800-mcg doses [37]. This likely accounts for some of the observed difference. Second, follow-up with Network providers took place at least 1 month after the initial contact for a significant proportion of women. This follow-up period is much longer than is standard in traditional clinical trials and clinic-based studies, resulting in more time for the abortion to complete. Third, uterine evacuation at the provider or the woman's request, an intervention that constitutes a treatment failure in clinical trials, is not available in this setting. Finally, women established their pregnancies by self-report and Network providers rarely confirmed pregnancy status. Some women may not have been pregnant at the time they took the

misoprostol. These dynamics will likely characterize any community-based distribution program in legally restricted settings where pregnant at follow-up versus not pregnant at follow-up is the measured outcome. Consequently, success rates associated with community-based distribution strategies may be higher than those derived from clinical trials and clinic-based intervention studies.

The extremely low loss-to-follow-up rate gives us confidence that the Network leaders did not miss significant adverse events. However, this rate is also exceptional. That women entered the Networks through word-of-mouth and had personal relationships with providers likely generated a greater sense of obligation to follow-up. Further, Network providers proactively followed up with women by calling, stopping by their homes, or visiting them in factories. This is not the typical protocol for studies in clinical settings. Finally, a significant number of the women reside in refugee camps and a number were affiliated with a network for survivors of human trafficking. These populations are easier to reach than women in the general population. Community-based distribution models, at least when initially launched, may feature follow-up rates higher than typically seen in clinical interventions through formal health systems.

This study has several limitations. Given legal restrictions on provision of misoprostol outside hospital settings, Network leaders collected minimal information. Thus, the evaluation does not assess full case reports and client/patient histories as would be expected in a clinical trial or a standard chart review. Further, women self-reported their outcomes and clinical confirmation did not take place. We also do not have information about whether or not women used misoprostol in conjunction with other practices. Further research would benefit from obtaining the perspectives of women using misoprostol through community-based distribution initiatives. Finally, although seven individuals provided misoprostol through the two Networks, to minimize legal risk only the Network leaders engaged with those outside of the Networks about their activities. Consequently, we conducted interviews only with the point people for the two Networks.

5. Conclusions

Despite these limitations, the success of the misoprostol distribution initiative is reassuring. Moving forward the Networks intend to expand their reach in northern Thailand. Possible avenues include engaging with traditional birth attendants, distributing low literacy materials related to the use of misoprostol-alone, and connecting those women who experience continued pregnancy to a growing referral program designed to facilitate women's access to safe and legal services [13,15,19]. Identifying other ways to scale up this initiative appears warranted. Further exploration of the experiences of women served by the Networks, as well as monitoring and reporting of long-term trends, could also

prove valuable. Finally, the success of this program — both in terms of outcomes and evaluation — could inform harm reduction efforts in other settings with limited access to safe and legal abortion care.

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