Evaluating the community-based distribution of misoprostol for early abortion in Pakistan

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Abstract

With nearly 13% of maternal deaths being attributed to unsafe abortion there is a need to implement new strategies to improve access to safe services. As developing regions and legally restricted areas lead these numbers, further evidence must be presented demonstrating tailored and actionable strategies for these settings. In Pakistan abortion is legally restricted and the country continues to face a high burden of maternal death and disability, much of which is directly or indirectly attributable to unsafe abortion. The community-based distribution of misoprostol for early abortion has the potential to reduce harm from unsafe abortion in Pakistan and other low-resource settings where abortion is legally restricted. This study employed a multi-methods approach to evaluate this intervention in Sindh, Pakistan and consisted of a logbook review, interviews with lay providers, and in-depth interviews with program beneficiaries. Our results suggest that the community-based distribution of misoprostol is an effective and promising strategy for improving access to safe abortion care. Efforts to implement or strengthen similar programs appears warranted.

Résumé

Avec jusqu'à 13% des morts maternelles étant liées aux avortements à risques, de nouvelles stratégies sont nécessaires afin d'améliorer l'accès aux avortements sécurisés. Outre, la majorité des avortements à risques sont pratiqués dans les pays en développement, et ceux avec une législation restrictive. Le Pakistan est un des pays avec une législation la plus restrictive face aux avortements et souffre d'un taux de mortalité et de morbidité maternelle élevée. La distribution communautaire du misoprostol pour des avortements sécurisés peut réduire les conséquences provoquées par les avortements clandestins au Pakistan, et dans d'autres contextes de faibles ressources et où l'accès à l'avortement est limité. Cette étude a employé une approche de méthodes multiples afin d'évaluer une intervention au Sindh, Pakistan. Cette approche a été composée d'entretien avec les fournisseurs de programme et les bénéficiaires. Nos résultats démontrent que la distribution communautaire du misoprostol est une stratégie efficace d'améliorer l'accès aux avortements sécurisés. Plus de soutien doit être fourni afin de renforcer ou d'établir des programmes similaires dans d'autres contextes.

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List of abbreviations and acronyms

CPR	Contraceptive prevalence rate
DNC	Dilation and curettage
IDI	In-depth interview
KII	Key-informant interview
LHW	Lady health worker
LMP	Last menstrual period
M&E	Monitoring and evaluation
MVA	Manual vacuum aspiration
NGO	Non-governmental organization
NSAID	Non-steroidal anti-inflammatory drug
PI	Principal Investigator
PPH	Postpartum hemorrhage
REB	Research Ethics Board
SAC	Safe abortion care
SDGs	Sustainable Development Goals
SRH	Sexual and reproductive health
SRHR	Sexual and reproductive health and rights
WHO	World Health Organization

Chapter 1: Introduction

1.1 Background

1.1.1 Unsafe abortion in the world today

Throughout the past several decades there has been a significant global effort towards reducing maternal mortality rates (1,2). Governments and international organizations have promoted research and health interventions addressing some of the top causes of maternal deaths including hemorrhage, infection, blood pressure disorders, and obstructed labour (3). However, there has been notably much less emphasis on addressing unsafe abortion and its contribution to maternal death and disability (4). Roughly 1/12 of maternal deaths are associated with unsafe abortion and it is one of the only causes that is almost completely preventable (5). As abortion continues to be a vital part of how individuals choose to control their fertility, ensuring access to safe services should be at the forefront of all sexual and reproductive health (SRH) responses (6).

Recent estimates suggest that worldwide there are approximately 25 million unsafe abortions that occur each year; they are sub-categorized as “less safe” or “least safe” based on two criteria (7). If an outdated method is performed by a trained health professional, or a World Health Organization (WHO) recommended method is performed by an untrained provider, the abortion is considered “less safe” (7). If an outdated method is performed by an untrained provider, it is considered “least safe” (7). These account for 31% and 14% of abortions respectively (7). Complications resulting from an unsafe abortion include incomplete abortion, hemorrhage, vaginal, cervical, and uterine injury, and infection and can result in long-term disability or death (8). While procedures performed following WHO guidelines are very safe and rates of

complications and death are negligible, women and girls often face considerable legal and socio-cultural barriers preventing them from accessing safe care (9,10).

Abortion laws fall along a scale from completely prohibited to permissible without any restrictions (11). As of today, there are 125 countries with highly restrictive abortion laws, meaning abortion is either completely prohibited or only permissible to preserve the woman's life or health. Roughly 42% of women and girls of reproductive age reside within these regions (8). Least safe abortions occur in a much higher proportion in more legally restrictive settings, from fewer than 1% of abortion cases in the least-restrictive countries to 31% in the most-restrictive (8). Although restrictive abortion laws play a crucial role in limiting women's ability to access safe services, other factors must also be considered (12). Even in areas where abortion is broadly legal, lack of availability and affordability, stigmatization, and gender inequality, prevent women from terminating their pregnancies safely (13). These challenges are further exacerbated in the Global South where over 88% of unsafe abortions occur (8).

Abortion rates have largely remained stagnant in the Global South, contrasting their steady decline in the Global North (14,15). Major contributors to this variability are inadequate delivery systems of contraceptive methods, restrictive laws, socio-cultural stigma surrounding abortion, and limited health infrastructures for comprehensive post-abortion care (16). Unsafe abortion has widespread and significant effects on social, financial, and health structures and must therefore be made safe, legal, and accessible (17–19). Such progress will not only protect women's lives and health, but will also bring the global community closer to achieving target 3.7 of the

Sustainable Development Goals (SDGs) which centres on access to comprehensive SRH care (20).

1.1.2 Misoprostol for early abortion

Misoprostol is a prostaglandin E_1 analogue that was initially developed for the purpose of preventing gastric ulcers caused by non-steroidal anti-inflammatory drug (NSAID) use (21). More recently, misoprostol has been studied and more widely used for obstetric indications such as inducing labour, treating intrauterine fetal demise, and preparing the cervix for instrumentation (22). In the last decade, misoprostol has been included in the WHO list of essential medicines for the prevention and treatment of postpartum hemorrhage (PPH), as well as the management of incomplete abortion (23). Given its few contraindications, as well as its affordability, availability, and drug stability, misoprostol has proven to be advantageous in low resource settings (21,24).

Off-label use of misoprostol is widespread, particularly for inducing early abortion (25). Off-label use is defined as a drug being used for purposes other than what is included on the approved label and is justified when there is substantial, high-quality evidence that supports the practice (26,27). Typically, the gold standard for medication abortion is a combination of a dose of mifepristone followed by the use of misoprostol (28,29). This regimen has been shown to be around 98% effective in terminating a pregnancy of 9 weeks or less (30). However, because mifepristone is almost exclusively used to induce abortion, its registration and distribution is limited, and it is unavailable in most settings where abortion is legally restricted. Although not as

effective as the gold standard, misoprostol-only regimens have been shown to be important alternatives when mifepristone is unavailable or inaccessible (31,32).

The recommended misoprostol-only regimen for early abortion consists of taking three 800 mcg doses of misoprostol 3-12 hours apart (10). Misoprostol can be administered buccally, sublingually, or vaginally, where it then acts by softening the cervix and inducing uterine contractions (10). While misoprostol is 75-90% effective at a gestational age of 9 weeks or less, misoprostol is also safe and effective at terminating pregnancies at later gestational ages (10,33,34). The most common side effects noted following misoprostol use in early pregnancy include nausea, vomiting, diarrhea, chills, fever, and dizziness (35). Further, although incidences of fetal abnormalities following in-utero exposure to misoprostol have been documented, they are rare (21,36).

The public health implications of expanding access to medication abortion are substantial. A study conducted in 2006 estimated that if 60% of unsafe abortions were replaced by a misoprostol-only regimen, there would be a 45% reduction in mortality, saving 30,500 lives each year (37). Expanding knowledge and availability of misoprostol is a demonstrated harm reduction strategy as this offers a safer alternative for women who would otherwise resort to unsafe methods (38).

1.1.3 Setting the context: Pakistan

Pakistan, officially the Islamic Republic of Pakistan, is situated in Southern Asia and is bordered by India, Iran, China, Afghanistan, and the Arabian Sea (39). The majority of the population is

Muslim (96%), with the remaining 4% consisting primarily of Hindus and Christians (40). Ranking as the sixth most populous country in the world, Pakistan encompasses a rich diversity of culture, ethnicity, and language separated into four provinces, two autonomous territories, and one federal territory (map provided as Appendix A) (40). Each province is distinct and wide sociocultural variations exist (41).

Prior to its independence in 1947, Pakistan was a constituent of British ruled India (42). The history of the partition can be traced back to the 1930s when a Muslim Indian philosopher, Sir Muhammad Iqbal, argued that the four northwestern provinces should be joined and serve as an independent homeland for Muslim Indians (43). In 1933 the name Pakistan was coined from an acronym of the territories in which it hoped to encompass (Punjab, Afghania, Kashmir, Indus-Sind) (42). The motivation driving the independence movement stemmed from decades of feeling underrepresented in British ruled India, with a religious Hindu majority; thus began the push for a separate, self-governing state (44).

Following World War II and the termination of British authority in India, Pakistan achieved independence as a dominion within the Commonwealth in August of 1947 (42). The partition of India led to one of the largest mass migrations in modern history with millions of refugees fleeing both sides of the divide (45). The accompanying riots and sectarian violence led to many casualties, with estimates ranging from a few hundred thousand to two million (45). This historical event is considered to be a defining moment in Pakistan's history, with its influence still being felt today.

The new state of Pakistan held its first democratic election in 1970. However the military establishment that had been ruling over the past two decades refused to relinquish power to the newly elected party (42). This was partly due to the elected political party being in favour of the Bengali nationalist movement, ultimately leading to a war of liberation which cost millions of civilian lives (46). Pakistan surrendered the war in 1971 and Bangladesh gained its sovereignty (47). Since its independence, Pakistan has suffered through important challenges including political turmoil, military coups, and civil war (48). Although the country has made advances in stabilizing the country it continues to face some significant development challenges including terrorism, poverty, illiteracy, and corruption (49).

1.1.4 Women's sexual and reproductive health and rights in Pakistan

In recent years Pakistan has made numerous important advances in women's rights and has engaged in both international and national commitments to promote gender equality (50). Despite these commitments, Pakistan continues to be ranked as the third lowest in the world for gender equality (51). Discriminatory laws and policies and gender-specific cultural norms pose huge barriers for women's rights and autonomy, which in turn impact their health outcomes and development.

The perpetuation of gender-based discrimination is reinforced by social processes at multiple levels of the social order (52). From within the home there is often asymmetrical distribution of power in marriage, with the husband being the primary voice of authority (53). Husbands or fathers often determine the health needs of women in the household, including when or if they should seek health care (54). In addition to this, resources such as food are often shared

unequally within the home; women and girls are given lower priority compared to their male counterparts (55). Male dominant values are also present within the community, such as through disadvantageous allotment of services in the health sector, unequal access to education, and limited opportunities for employment (56). Principal factors determining women's and girls' health outcomes are illiteracy, poor nutrition, early marriage, and multi-parity (57). These disparities in combination with social pressures place women at a significant disadvantage, minimizing their independence and their ability to advocate for women's health issues. One of the most effective and powerful ways to reduce health inequities and promote egalitarian societies is promoting women's rights to health, including their control over their bodies and fertility (58). There remains a clear and pressing need for the integration of gender equity and rights into current health programs and initiatives in Pakistan.

Between the 1980s and 2015, Pakistan witnessed a rapid decline in total fertility, from more than 6 children per woman to 3.8 (59). Despite the decline in the total fertility, the contraceptive prevalence rate (CPR) has remained relatively low at 35.4% (60). This low CPR has largely been attributed to service delivery and socio-cultural barriers leading to significant unmet contraceptive need (61). One marker of this unmet need is the prevalence of abortion. In 2012, there were roughly 9 million pregnancies in Pakistan (60). Of these, 46% were unintended and 54% of those were resolved with abortion; this resulted in 2.2 million induced abortions (60). A study conducted by the Health Systems and Policy Department in Pakistan found that the major reasons underlying women's decisions to terminate their pregnancies were that they were financially unstable, that they already had young children, and/or that their husbands were unwilling to have another child (62).

Although abortion is relatively common, it is also legally restricted. Currently, abortion offences are split into two categories depending on gestational age: 1) Before the fetus has formed organs or limbs, abortion is prohibited unless performed in good faith to provide necessary treatment or to save the woman's life; and 2) After organs or limbs are formed abortion is permitted only to save the woman's life (63). Although the legal repercussions are solely directed towards the provider of the abortion and not the women who seek one, women may face social repercussions from their partners, families, and communities. Women must then prioritize secrecy over safety and turn to clandestine and unsafe methods (64).

1.1.5 The intervention: Community-based distribution of misoprostol

In 2018, Dr. Angel M. Foster received a Grand Challenges Canada grant to create and evaluate a community-based distribution program of misoprostol for early abortion. The goal of this project was to expand access to safe abortion in legally restricted and low-resource settings. Based on a successful pilot project conducted in Northern Thailand, this initiative involved working with local organizations to establish a community-based distribution network (65,66). In consultation with Women Help Women and based on a number of overarching considerations regarding geographic, linguistic, socio-cultural-religious, and population diversity, Dr. Foster identified local project partners in the Democratic Republic of the Congo, Nigeria, and Pakistan to undertake this multi-year initiative. In the summer of 2018, the University of Ottawa partnered with a local non-governmental organization (NGO), Peace Foundation, that currently provides SRH services in Sindh, Pakistan. Although the local NGO had some experience with the use of misoprostol for a variety of indications and had integrated counselling about misoprostol into

their community health programs, the Grand Challenges Canada project resulted in the formalization of a community-based distribution model to expand access to misoprostol for early abortion. Because of its common use in inducing labour and preventing PPH, misoprostol is not classified as an abortion-inducing drug and is therefore fairly accessible in Pakistan.

After disseminating information about the program through various community channels and word-of-mouth, women with a self-reported unwanted pregnancy with a gestational age of ≤ 10 weeks present themselves to a centre and meet with a lay provider. Gestational age is estimated based on their recollection of the first day of their last menstrual period (LMP). Lay providers handle cases of women who are beyond the 10-week limit on a case-by-case basis and refer if possible. However, lay providers use their own judgment on whether or not to give these women the misoprostol tablets if they believe they are close to the 10-week cut-off. Lay providers are well respected, established women who have been elected by members of their communities to take on this role. Centres are typically run from within or nearby their homes and are often available 24/7.

Once they present themselves, women receive in-person counselling to discuss options, the legal status of abortion in Pakistan, how to use misoprostol, what to expect in terms of symptoms, and when to seek medical attention (if necessary). The lay provider then places four 200 mcg tablets of misoprostol sublingually and instructs them to take two more 800 mcg doses sublingually every three hours for a total of three 800 mcg doses. On a case-by-case basis, they either stay at the facility and complete the abortion there, or they take the first dose at the facility and complete the remaining doses at home. This is dependent on individual security risks and the distance

between their residence and the facility. Women either return to the facility or the lay provider seeks them out for a follow-up, typically within a week after taking the first misoprostol dose. As part of the overarching project, we provided continuous monitoring of the program activities and conducted a rigorous multi-methods evaluation.

1.2 Study rationale

Studies on abortion in Pakistan are few and far between. Despite the global interest in developing strategies to reduce harm from unsafe abortion, there is limited research evaluating these interventions within legally restricted and low resource areas. In 2012 Dr. Foster and her research group worked with community organizations in Northern Thailand to implement and evaluate a community-based distribution of misoprostol program along the Thailand-Burma border (65,66). This pilot study provided promising results demonstrating the value and benefit of employing misoprostol within a low resource context. However, there was a need to develop similar evaluated interventions in other settings that present barriers to safe abortion care (SAC). The project outlined in this thesis contributes to the evidence supporting misoprostol as a harm reduction strategy for unsafe abortion in low resource and legally restricted settings and builds on these previous efforts.

1.3 Research questions and objectives

There is a notable lack of research documenting women's experiences with abortion in Pakistan and an even greater gap in documentation highlighting potential intervention strategies. The evaluation of the community-based distribution program combines a logbook review, key

informant interviews, and in-depth interviews with program beneficiaries to answer three primary questions:

1. What are the factors influencing the success and feasibility of this strategy?
2. What are women's experiences and perceptions of this program?
3. What efforts could be undertaken to improve and expand access to safe abortion services in low resource and legally restricted areas?

More specifically this study aims to:

1. Assess the feasibility of a community-based distribution program of misoprostol to reduce harm from unsafe abortion in Pakistan;
2. Identify the strengths and the weaknesses of this form of intervention;
3. Document women's perceptions and experiences with the program;
4. Identify avenues for expanding and/or improving access to safe abortion services in low resource and legally restricted settings.

1.4 Thesis structure

This thesis is organized as a "thesis by articles" and is divided into six chapters. Chapter 1 provides an introduction to the study with a review of relevant literature pertaining to abortion in fragile settings as well as an overview of the study site. It is also in this chapter that we include the study rationale, outline of the objectives and research questions, outline of the thesis, and statement of contributions. Chapter 2 describes the methodology of the study and provides in depth explanations of the methods used; logbook review, key informant interviews (KIIs) with

the lay providers, and in-depth interviews (IDIs) with beneficiaries. This chapter also outlines the analytical approaches used and the conceptual framework employed.

Chapter 3, 4, and 5 present three original research manuscripts. The first article presented in chapter 3 provides an overview of the outcomes associated with the community-based distribution. We have submitted this article to *Contraception* and the manuscript conforms to the standards of this peer-reviewed journal (brief article format).

Chapter 4 presents a description of the program and findings from the KIIs with lay providers. This article centres on the lay providers' experiences with and perceptions of the program. We have formatted this article for submission to *International Perspectives on Sexual and Reproductive Health* and it conforms to the standards of this peer-reviewed journal.

Chapter 5 focuses on women's abortion experiences with misoprostol and their experiences with the community-based distribution program. This article centres on the findings from the IDIs with women who have obtained misoprostol through this intervention. This article has been formatted for submission to *Contraception* and conforms to the standards of this peer-reviewed journal (original research article).

The final chapter (Chapter 6) of this thesis integrates and triangulates the results from all three components of the study and presents the final evaluation of the program. This is followed by the significance and implications of this study, future directions, and the study limitations. The thesis ends with a concluding statement and a complete list of references and appendices.

1.5 Statement of contribution

As the Study Coordinator for this project, I completed this study in partial fulfillment of the requirements of the Master of Science in Interdisciplinary Health Sciences program at the University of Ottawa. This study is informed by the pilot project completed in Northern Thailand, where Dr. Foster served as the Principal Investigator (PI) (65,66). I worked with my supervisor to adapt the study design to the Pakistan context and revised the study instruments.

Following a two-day qualitative research workshop led by my supervisor with the local collaborating team from Peace Foundation in Doha, Qatar, I led all primary data collection and data analysis for the project. While in Pakistan I worked closely with the local project team. I contributed to the article included as chapter 3 and led the drafting of the manuscripts included as chapters 4 and 5. My supervisor reviewed and supervised me through all components of this project and provided invaluable guidance and training.

Chapter 2: Methods

This chapter will begin by outlining the overall study design and then proceed to describe the three primary components of this qualitative study; logbook review, KIIs, and IDIs with beneficiaries. I will then detail the analytical approach and end the chapter discussing the theoretical framework and ethical considerations for this project.

2.1 Study design

This project and the overall evaluation of the program is informed by the pilot project completed in Northern Thailand (65,66). We decided to undertake a qualitative multi-methods approach that comprised three components: 1) A review of program logbooks; 2) Key informant interviews with lay providers; and 3) In-depth interviews with women who have obtained misoprostol through this initiative. We completed primary data collection over a two-month period in the Sindh province of Pakistan.

2.2 Data collection

2.2.1 Logbook review

At the beginning of the project we sought out to record the treatment outcomes of at least 100 women who had received misoprostol through the community-based distribution program. We developed a data collection sheet specifically for this project and shared with all 12 lay providers. We chose the selected indicators in consultation with the NGO leaders with the intention that this would serve as a tool for ongoing monitoring and evaluation (M&E) of their programmatic activities. These indicators included; age, marital status, number of previous pregnancies, number of children, number of abortions, results of the pregnancy test (if taken),

gestational age (in weeks), if the patient was still pregnant at follow-up, if any other methods to abort the pregnancy were used in conjunction with the misoprostol, and if any complications requiring medical intervention occurred.

The local NGO translated the sheets into Urdu and Sindhi to accommodate each lay provider's language capacity and distributed the tool to each of them. We asked lay providers to collect this information for all incoming misoprostol patients starting from November 1, 2019, until at least 100 total cases were recorded.

2.2.2 Key informant interviews with lay providers

Between October and December 2019, I conducted in-depth, semi-structured interviews with the 12 lay providers with the help of a local research assistant. In most instances, we held the interview in the centre where the program operates; often a designated space within her home. Due to security limitations, we had to hold interviews with lay providers operating within the Tharparkar District in Mirpurkhas at a secure and private location. We conducted each interview in the participant's language of choice (Urdu or Sindhi).

We began the interview by discussing the current SRH situation within the lay provider's respective community, and the main priorities for which she tends to focus her work. We then discussed abortion and how women managed their unwanted pregnancies prior to the introduction of the misoprostol program and what the situation has been since the provision of misoprostol began. We then turned to discussions about the lay provider's personal motivation

for getting involved in the program, as well as her own views and perspectives on this initiative, including how she believed the program could be improved and/or expanded.

We followed each interview with a debriefing session between myself and the interpreter and I formally memoed to reflect on the interviewer-interpreter-participant dynamic. An interview lasted approximately 45 minutes and with the permission of the participant, we audio-recorded the interaction and a staff member of the local NGO interpreted throughout. We then transcribed and translated the interview at a later date. A second member of the University of Ottawa research group verified the translation.

2.2.3 In-depth interviews with women

We conducted 30 in-depth, open-ended, semi-structured interviews with women who had obtained misoprostol through the community-based distribution program. All participants had used misoprostol to terminate a pregnancy within the previous month. We were able to recruit women from all but one of the facilities and were therefore able to get a more holistic view of the program in all operating settings.

We began the interview by gathering general background information and learning more about the participant's daily routine. We then moved to a discussion of her SRH history, the circumstances surrounding the unwanted pregnancy, and how she came to reach the centre. We then asked her to recount her abortion experience(s), as well as her retrospective feelings about both her decision and the experience itself. Finally, we asked the participant about how she felt

the program could be improved and if she would recommend the program and/or misoprostol to other women.

We conducted the interview in the participant's language of choice (Urdu, Sindhi, Hindi) with the help of an interpreter. Interview lasted roughly 45 minutes and with the permission of the participant, we audio-recorded and later transcribed and translated the discussion. A member of the University of Ottawa research team verified the translation.

2.3 Data analysis

We first analyzed each component of the project separately. We analyzed logbook data using descriptive statistics to determine frequencies and cross tabulations, in addition to analyzing open-ended comments for content and themes.

Our analytic process for the qualitative components was iterative, and we managed all qualitative data with ATLAS.ti. The analytic memos and briefing sessions with the interpreter allowed us to identify early themes and begin the analytic process (67). We employed content and thematic analyses to engage with both sets of interviews. Graneheim and Lundman's (2004) guidelines for qualitative content analysis (68) informed our analytic approach in which we systematically developed codes and categories to ultimately identify threads of underlying meaning (68).

Following Graneheim and Lundman's (2004) approach to qualitative content analysis, we familiarized ourselves with the data through reviewing transcripts and memos to obtain a sense of the whole (68). We began extracting the participants' experiences and bringing them together

in one text which formed our unit of analysis. We then divided our unit of analysis into meaning units which we then condensed and labelled into a code. Through a process of reflection, we compared codes and sorted them into categories and sub-categories. This coding process focused on the manifest content of the interviews. After finalizing the coding process, we engaged in a more interpretive process of identifying potential primary and sub-themes. By reviewing categories and identifying the underlying meaning, or latent content, we formulated categories into themes. The final phase of the analytic process for this project involved integrating the three study components. We specifically looked for points of concordance and discordance. We report these results through two journal articles in chapters 4 and 5 of this thesis.

2.4 Theoretical framework

Practical action research serves as the theoretical foundation for this project, which is situated within an interpretivist paradigm (69). As is characteristic of action research generally, the design embraces the planning, acting, observing, and reflecting cycle that occurred throughout the life of the project (70). In consultation with local stakeholders, we have defined the practical concern for which we are addressing. We designed this project to empower participants and their communities, acquire knowledge, prioritize collaboration and capacity building through participation, and effect social change.

2.5 Ethics

This study received ethical approval from the University of Ottawa Social Sciences Research Ethics Board (REB) (File #09-16-19). The letter of approval from the University of Ottawa REB can be found in Appendix B. An ad hoc committee at Peace Foundation also reviewed the study

protocol and instruments and determined that the study met local standards of research and the protection of human subjects.

Chapter 3: Community-based distribution of misoprostol for early abortion: Outcomes from a program in Sindh, Pakistan

We submitted this brief research article to the peer-reviewed journal, *Contraception* in November 2020.

Community-based distribution of misoprostol for early abortion: Outcomes from a program in Sindh, Pakistan

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Abstract

Objective: To evaluate the outcomes of a community-based distribution program in which lay providers offer women in Sindh, Pakistan misoprostol for early abortion.

Methods: We reviewed monitoring logbooks to examine pregnancy outcomes and analyzed logbook data using descriptive statistics.

Results: In late 2019, 120 women obtained abortion care through this program. None of the women (n=0, 0%) were pregnant at follow-up and none (n=0, 0%) experienced serious adverse outcomes or complications requiring medical intervention.

Conclusions: The outcomes from this initiative may be valuable for those working to expand access to misoprostol for early abortion in other settings.

1. Introduction

In Pakistan, the legal permissibility of abortion depends on gestational age. Prior to the formation of fetal organs or limbs, abortion is legally permissible to save the life of the woman or provide "necessary treatment". After the formation of fetal organs or limbs, abortion is only permitted to save the life of the woman [1]. Although both "necessary treatment" and fetal development markers can be variably interpreted, most of the more than 2 million induced abortions that occur in Pakistan each year are defined as unsafe and unsafe abortion is a major contributor to maternal death and disability [2-3].

The World Health Organization (WHO) recommends the use of misoprostol alone for first trimester induced abortion when alternative medication abortion regimens and/or aspiration abortion services are unavailable [4]. In recent years, both international and local non-governmental organizations (NGOs) around the world have undertaken a number of efforts to increase access to medication abortion information and services and reduce harm from unsafe abortion in low resource and/or legally restricted settings [5-8]. Modelled after a successful community-based distribution of misoprostol for early abortion program in Northern Thailand [9-10], in 2019 a North American Research team partnered with a local NGO to establish a similar program in Sindh, Pakistan. In this article, we document the outcomes of that initiative.

2. Program description and methods

In mid-2019, the staff of the local NGO trained 12 lay providers in the Mirpurkhas (n=7) and Tharparkar (n=5) districts of Southeastern Pakistan to offer misoprostol through a community-based distribution model. Local communities previously identified these women to serve as

community health workers and these lay providers were already engaged in providing primary sexual and reproductive health services, including contraceptive, prenatal, and postnatal care, out of “centres” attached to their homes. Lay providers received a stipend to incorporate misoprostol for early abortion into their services, a cell phone to follow up with women seeking care, and a supply of misoprostol.

Women with an unwanted pregnancy of 10 weeks gestation or less are eligible to obtain misoprostol through the program. Lay providers address the needs of women beyond 10 weeks on a case-by-case basis. Women establish their gestational age by self-reporting the first day of their last menstrual period (LMP) and in most cases the lay providers confirm the existence of a pregnancy with a urine pregnancy test. Lay providers then provide women with in-person information about the legal status of abortion, pregnancy options, the use of misoprostol and the expected abortion process, conditions warranting immediate follow-up, and post-abortion contraception. Lay providers administer the first 800 mcg misoprostol dose sublingually and gives the woman two additional doses to take at home. Lay providers ask women to call or return to the centre within two weeks or if they have any questions or problems. Lay providers follow-up with women after four weeks if they do not hear from them about the outcome.

Lay providers received logistical support to maintain standardized logbooks. Out of an abundance of caution given the legal status of abortion, logbooks contain limited non-identifiable demographic information about women who present with an unwanted pregnancy and the outcome of the misoprostol-only treatment. This includes information whether or not the woman

used additional methods to end the pregnancy, experienced complications warranting medical intervention, or was pregnant at follow-up. Lay providers also make specific case notes.

Lay providers began recording cases on November 1, 2019, and we reviewed the outcomes for the first 10 women who presented to each centre for 120 total cases. We used descriptive statistics to analyze the outcomes data and reviewed all notes. We followed up with individual lay providers when information was unclear. The local NGO approved the community distribution program and both this NGO and the Research Ethics Board at the University of Ottawa approved the evaluation.

3. Results

The 120 women who obtained misoprostol through the community-based distribution program averaged 27 years of age and all were married with at least one living child. Roughly half of the women had at least one prior abortion. Women presented at an average gestational age of eight weeks. A summary of demographic information is presented in Table 1.

At four weeks after the initiation of the misoprostol regimen, none of the women were pregnant (n=0, 0%). Lay providers reported that seven women (6%) were likely still pregnant at initial follow-up, at which time they received an additional dose of misoprostol. None of the women who received misoprostol through the community distribution program experienced complications warranting medical intervention (n=0, 0%). Women reported a range of side effects that were expected and transient, including diarrhea, vomiting, and fever.

Initially, one of the lay providers did not provide outcome information. Rather, she used the logbook to share information about the women's lives and pregnancy histories. When the research team met with her to clarify the outcomes, she explained that all of the abortions were successful and that recording that information was "uninteresting". She decided to provide information about each woman because she wanted the study team to understand why women made the decisions that they did. We went through each case in detail and annotated to the logbook to reflect pregnancy outcomes. Otherwise, there was no difference in outcomes between the clients who received care from different lay providers.

Table 1: Demographic information about the study population (N=120)

Demographic classification	**n (%)**
Age	
≤18	1 (1%)
19+	119 (99%)
Marital Status	
Married	120 (100%)
Unmarried	0 (0%)
Previous pregnancies	
0	0 (0%)
1-2	45 (38%
3+	75 (62%)
Number of children	
0	0 (0%)
1-2	80 (67%)
3+	40 (33%
Number of prior abortions	
0	111 (92%)
1-2	7 (6%)
3+	2 (2%)
Gestational age	
≤ 4 weeks	30 (25%)
5-8 weeks	74 (62%)
9+ weeks	16 (13%)

4. Discussion

The outcomes from this initiative are reassuring and align with those from the program in Northern Thailand [9]. Taken together these evaluations suggest that the community-based distribution of misoprostol through lay providers can be a highly successful strategy to increase access to safe abortion care in low resource, legally restricted settings. Providing additional misoprostol and reporting outcomes four weeks after initiating the abortion process likely explains the high "success" rate associated with this initiative compared to the 75%-90% effectiveness of misoprostol alone cited by the WHO [4]. However, we did not lose any women to follow up and thus we are confident that we did not miss any serious adverse events. Identifying ways to scale up this initiative in Pakistan and expand community-based distribution programs to other low resource and/or legally restricted settings appears warranted.

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Chapter 4: Lay providers' perspectives on expanding access to safe abortion care through the community-based distribution of misoprostol in Sindh, Pakistan

We have formatted this original research article for the peer-reviewed journal, *International Perspectives on Sexual and Reproductive Health.* We intend to submit this manuscript once the article presented in Chapter 3 has been accepted.

Lay providers' perspectives on expanding access to safe abortion care through the community-based distribution of misoprostol in Sindh, Pakistan

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Abstract

Introduction: Unsafe abortion directly contributes to 8%-15% of maternal deaths worldwide and there is a significant need to implement new strategies to improve access to safe services, particularly in low resource and legally restricted settings such as Southeastern Pakistan. Expanding access to misoprostol has the potential to reduce harm from unsafe abortion practices.

Methodology: In mid-2019, a Canadian research team partnered with a local non-governmental organization in Sindh, Pakistan to develop, implement, and evaluate a program dedicated to the community-based distribution of misoprostol for early abortion. In late 2019 as part of a multi-methods evaluation, we conducted interviews with all 12 lay providers involved in the program to understand their experiences with misoprostol provision, motivations for becoming involved, and perspectives on the value of the program and how it could be improved. We analyzed interviews for content and themes using inductive and deductive techniques.

Results: Our interviews with lay providers elicited three key themes: 1) Lay providers view the community-based distribution of misoprostol as the only viable option for expanding access to safe abortion care in their communities; 2) Lay providers believe misoprostol is the safest and easiest method for early abortion; and 3) Lay providers felt their involvement with the program had positive impacts on both their own lives and on their communities.

Discussion: Findings from this study may help inform future initiatives aimed at reducing harm from unsafe abortion in similarly low resource and legally restricted areas. Efforts to expand the reach of such programs appears warranted.

1. Introduction

Unsafe abortion remains a neglected sexual and reproductive health (SRH) issue even though the global evidence is clear that there are significant consequences associated with the practice (1). According to the World Health Organization (WHO), abortions are deemed unsafe if they are either performed by a provider without the appropriate training or skills or if they are performed in an environment that does not meet minimum medical standards, or both (2). Unsafe abortion leads to an estimated 22,800-31,000 maternal deaths and millions of complications annually (3). The most common complications caused by unsafe abortion include uterine perforation, genital tract and bladder injuries, gastrointestinal injuries, gas gangrene, renal failure, and hemorrhage (4). These complications often lead to long-term disability and contribute to high rates of maternal morbidity (4). In addition to these immediate consequences on women's health, unsafe abortion poses substantial financial and social burdens on local systems as well as on the women and their families (1). These challenges disproportionately impact developing economies and low resource settings, where nearly 88% of all unsafe abortions are performed (3). This gross disparity is largely due to inadequate delivery systems of contraceptive methods, restrictive abortion laws, poor quality post-abortion care, and socio-cultural stigma surrounding abortion (5). Priority must be placed on improving access to safe services, particularly in the Global South where challenges are more pronounced.

Since independence in 1947, Pakistan has faced many complex challenges including political instability, civil war, domestic terrorism, and corruption (6). In addition, women in Pakistan face significant gender-based discrimination, placing them at a great social and institutional disadvantage (7). These injustices are intertwined with restricted social mobility and result in

limited access to basic health care, including comprehensive SRH services (8). Socio-cultural norms and poor service delivery have led to a slow uptake of modern contraceptive methods and a subsequent high rate of unintended pregnancy (1). Recent data indicate that there were approximately 4.2 million unintended pregnancies in Pakistan in 2012; more than half of these (54%) resulted in an induced abortion (9).

The current law in Pakistan permits abortion within narrow, but somewhat ambiguous, parameters. Abortion is legally permissible to save the woman's life throughout pregnancy, but in earlier pregnancy abortion is also legally permissible to provide "necessary treatment" (10). In 2012, there were an estimated 2.25 million induced abortions in Pakistan (11). However, the majority of these abortions were performed under unsafe conditions putting many women at risk of post-abortion complications, including death (12). A lack of appropriate post-abortion care services further exacerbates the negative impact of unsafe abortion. It is estimated that globally, complications from unsafe abortion costs over USD550 million (13). This costly expenditure further drains an already fragile health system and places a substantial economic burden on women and their families. The situation in Pakistan is no exception.

When abortion is legal, safe, and easily accessible, women's health dramatically improves, as has been demonstrated in several settings (14). Although the legalization of abortion is a necessary step in achieving comprehensive SRH services for all and reaching target 3.7 of the Sustainable Development Goals (SDGs), this is not sufficient. Several factors lead women to seek or induce unsafe abortions. These include restrictive laws and policies as well as the financial costs of abortion procedures, sociocultural-religious attitudes towards abortion, gender

inequality, and most importantly the availability of safe abortion services (15). For instance, in countries like India where abortion has been legally permissible since 1971, researchers estimate that 2-11 illegal abortions are performed for every legal abortion (16). This is largely due to the limited availability and accessibility of safe services (16). In order to create meaningful change and attain SGD target 3.7, ensuring adequate access to safe abortion care regardless of context and legal status is critical.

Misoprostol, a prostaglandin E_1 analogue, has been the subject of much research over the last few years. Although not as effective as the combination of mifepristone and misoprostol, the WHO states that the misoprostol-only regimen is 75-90% effective at ending a pregnancy of 9 weeks or less (2). However, recent studies demonstrate that misoprostol is effective through 12 weeks (17,18). Further, because misoprostol was developed as a therapy to prevent stomach ulcers, misoprostol is more widely available than mifepristone. Consequently, misoprostol is a promising substitute for the medication abortion gold standard when mifepristone is not available. A previous interventional study in Northern Thailand highlighted the effectiveness of a strategy for distributing the misoprostol-only regimen for early abortion in a legally restricted setting and relatively low resource setting (19). The mobilization of misoprostol for early abortion can improve access to safe services and holds the potential for attenuating the impact of unsafe abortion and its effect on global health. This pilot informed the current project and we have reported on the outcomes previously (20). Based on ongoing monitoring and a multi-methods evaluation, in this paper we provide a description of the program, examine lay providers' perspectives on the program, and offer lessons learned from implementation.

2. Methodology

In the summer of 2019, a research team from the University of Ottawa in Canada collaborated with Peace Foundation, a local NGO that provides sexual and reproductive health services in Sindh, Pakistan, to develop, implement, and evaluate a community-based distribution of misoprostol for early abortion program. Because misoprostol is commonly used to induce labour and prevent postpartum hemorrhage in this region, it is not classified as an abortion-inducing drug and is therefore fairly accessible in Southeastern Pakistan. By employing a community-based distribution model, this program relies on lay providers. In this setting, lay providers are well respected, established women who have been elected by members of their communities to serve as community health workers. This network of providers have long provided contraceptive, prenatal, and postpartum care as well as miscarriage management services. Most lay providers operate a "centre" out of or near their homes, thus ensuring that services are available locally and often 24/7.

Description of the community-based distribution program

With respect to the community-based distribution of misoprostol program, women with a self-reported, unwanted pregnancy of 10 weeks or less can present themselves to one of the centres to meet with a trained lay provider. Women determine gestational age based on their recall of the date of the first day of their last menstrual period (LMP). Once the lay provider establishes the existence of a pregnancy through a urine pregnancy test, the woman receives in-person information and counselling regarding the legal status of abortion in Pakistan, pregnancy options, the misoprostol-only regimen and the expected abortion process, side effects and potential complications, conditions warranting urgent follow-up, when to follow up with the lay provider,

post-abortion contraception, and other general support. The lay provider then administers four 200 mcg tablets of misoprostol sublingually and instructs the woman to take two more 800 mcg doses sublingually every three hours for a total of three 800 mcg doses. On a case-by-case basis, the woman either stays at the centre and completes the abortion there, or she takes the first dose at the centre and completes the remaining doses at home. This is dependent on individual security risks and the distance between the woman's residence and the facility. Either women return to the centre or the provider follows up by phone or in-person within a week of administering the first dose of misoprostol. Lay providers handle cases of women who are beyond the 10-week limit on a case-by-case basis and either refer the woman to a safe abortion provider or use their own judgment to offer the woman misoprostol per the standard protocol.

Program monitoring and evaluation

Twelve lay providers participated in the community distribution program. All lay providers completed a targeted training about abortion, misoprostol, and the parameters of the community-based distribution program offered by Peace Foundation and led by M.A. As part of the program, lay providers kept logbooks at each site that included basic demographic and outcomes information about program beneficiaries (20). Lay providers also received a cellular phone in order to follow-up with women who had questions or concerns after using misoprostol.

As part of the program evaluation, we conducted semi-structured interviews with all lay providers affiliated with the program in November and December 2019. K.M, a Canadian master's student focused on health sciences, led the open-ended, in-depth interviews after receiving training from A.M.F., an American medical doctor and medical anthropologist with

extensive experience in both abortion-related research and program evaluation. A.M.F and K.M adapted an interview guide used in Northern Thailand (19) for use in this setting and N.S., a Pakistani woman fluent in both Urdu and Sindhi, served as the interpreter. N.S. contacted lay providers and scheduled a time to meet in-person for the interview. After reviewing the project's aims and purpose, participants verbally consented to both participate in the interview and for K.M. to audio-record the interactions.

Interviews with providers focused on the current SRH situation and the most important challenges they face within their respective communities. The interviews then turned to a discussion of how they perceive the community-based distribution program, how unwanted pregnancies were managed prior to the introduction of misoprostol, their personal motivations for involvement, how the program could be improved, and how to expand the program to other areas in Southeast Pakistan and beyond.

Interviews averaged 45 minutes in length. As lay providers received a stipend to participate in the community-based distribution program, we did not compensate them for participating in the interview. However, we did offer refreshments during the interview and covered any travel-related costs associated with the interview. K.M. took notes throughout the interview, debriefed with N.S. after each interaction, and formally memoed to reflect on the interviewer-interpreter-participant dynamic and initiate the analytic process (21). N.S., K.M., and a local research assistant transcribed and translated the interviews; a second member of the University of Ottawa study team verified the translations.

Data analysis

We used an iterative approach to analyze the interviews for content and themes. We began analyzing the data as we collected them; the analytic memos and debriefing sessions between K.M. and N.S. allowed us to identify early themes (21,22). We analyzed data for content and themes using both *a priori* codes from a predetermined codebook that K.M. generated, as well as inductive codes that emerged as we familiarized ourselves with the data (22,23). We managed our qualitative data, including transcripts, notes, and memos, using ATLAS.ti.

Ethics

We received ethics approval from the University of Ottawa's Social Sciences and Humanities Research Ethics Board. Peace Foundation also approved this project and determined that the design met local ethical and research standards. To protect participants' confidentiality, we have removed or masked all personally identifying information.

3. Results

The 12 lay providers involved in the community-based distribution program had little formal or specialized medical training. However, seven of the 12 providers had completed at least some high school; the other five lay providers had completed some primary school or had not received any formal schooling. Only one lay provider had completed a nursing degree and had prior experience as a staff nurse. All of the providers had received extensive training on misoprostol and had acquired knowledge through experience; most had experience as birth attendants or untrained midwives prior to becoming involved in Peace Foundation's program.

Interviews with lay providers elicited several key themes: 1) Lay providers view the community-based distribution of misoprostol as the only viable option for expanding access to safe abortion care in their communities; 2) Lay providers believe misoprostol is the safest and easiest method for early abortion; and 3) Lay providers felt their involvement with the program had positive impacts on both their own lives and on their communities.

Misoprostol is the only viable option for early pregnancy termination

All of the lay providers we interviewed asserted that the community-based distribution program was the only viable option for many women to obtain safe abortion care and was thus meeting a significant need. Interviewees highlighted a number of factors that severely limit women's ability to access safe abortion care, including financial and infrastructural obstacles that are mitigated by the community-based distribution program.

In the Mirpurkhas district of Sindh lay providers explained that the primary barrier preventing women from accessing safe abortion services was cost. In part due to the legal restrictions on abortion and a lack of providers, women have to pay exorbitant amounts for an abortion, which could likely be of highly variable safety and quality. One lay provider described the situation before the introduction of misoprostol:

> If women had need [they] would go to hospital and they would do [a dilation and curettage] with instruments and [doctors] would demand a lot of money. They would get 9,000-10,000 rupees [USD56-USD63]. [Women] would sell everything they had, cows, goats, and then would go to the hospital. [The program] work is very good and supports people. They can't afford fees. And those women have need to abort and they can't afford anything else, so misoprostol helps them.

Another lay provided echoed this sentiment, “Misoprostol is good, it is a cheap price. It is not expensive, and women can save money.” Thus according to lay providers in the Mirpurkhas District, clinic-based abortion care is available in the region and there are providers of various quality. However, with costs exceeding more than 10% of the average annual income, obtaining care from these providers was prohibitively expensive for most women in the region.

In contrast, lay providers from the more rural Tharparkar District focused on the overall lack of infrastructure as being the most significant barrier to safe abortion care. Out of the five Tharparkar based lay providers, only one noted that there was a health facility within a reasonable distance. Thus lay providers in this region explained that their centres were not only the only option for safe abortion care, they were the only option for an array of women’s health services. One lay provider described how she needed to walk 5 km to reach the closest road and then hitchhike for another hour to reach the nearest basic health unit. Physical distance is aggravated by women’s lack of social mobility; women in this region are generally not permitted to drive a car or motorbike and must rely on rides from men in the community or travel on foot. As stated one interviewee working in Tharparkar: “We have no road and no vehicle for women. So, because of this we are facing many problems.” Thus, lay providers in both rural and more urban areas identified the community-based distribution strategy as filling an essential need and allowing women from their communities to overcome the infrastructural and financial barriers to access.

Misoprostol is the safest and easiest method for early pregnancy termination

Throughout the interviews with lay providers we heard time and again how misoprostol was easy and safe. When asked about their experiences with misoprostol, providers resoundingly stated that one of the benefits to a misoprostol-only regimen for early abortion was that it was very easy for them to physically administer the treatment. Many of the lay providers work in conditions with limited resources, often in regions without electricity or running water. Misoprostol enabled these providers to offer women a method to terminate their pregnancies that did not require advanced facilities or specialized equipment.

Lay providers also viewed misoprostol as extremely safe. They evaluated safety both objectively and in relation to other practices. Notably, lay providers not only compared the safety of misoprostol to unsafe self-induction practices, they also favourably compared the safety of misoprostol to the use of existing dilation and curettage practices. Lay providers in the Mirpurkhas District reported that there has been very little update of manual vacuum aspiration of electric vacuum aspiration techniques among physicians. As a result, physicians who provide abortion care rely on outdated techniques and often lack adequate training to ensure safety. As one interviewee explained:

> Before misoprostol we have only the DNC [dilation and curettage] process and it is very difficult for women. Because as I said, they have no clean instruments. Because of this, women have many, many difficulties after that process...sometimes, women do not get pregnant [again]. I know of one woman who used to live here…she got hepatitis after DNC because of instruments.

Interviews told many stories of women who had become infertile or contracted serious infections due to unsafe instrumentation practices. Lay providers also recounted stories of women who were not given anesthesia during clinic-based abortion processes and subsequently experienced

considerable pain. From the perspective of lay providers, this made the availability of misoprostol all the more valuable. As explained by one interviewee: “Women believe in misoprostol. They know that if they use [the drug] they can terminate without any complications. Misoprostol saves women’s lives.”

Involvement in the community-based distribution program positively impacted the lives of lay providers

Lay providers were motivated to participate in the community-based distribution program for a variety of reasons. However, the most common impetus was a desire to meet the need in the community for safe abortion care. As illustrated in one lay provider’s account:

> Before [this program], I worked at [another NGO] and I worked in villages. And here you can see 3-4 women in my centre, but if you go to villages you can see many women in terrible conditions. And I see their conditions in the villages, and women say, “Please help us.” I want to support them. I saw conditions of these people in villages and after that I decided I needed to continue this work.

Witnessing the frequency and consequences of unsafe abortion impacted provider's views and motivated them to be involved in this program. However, our interviews with lay providers also revealed that their involvement with the community-based distribution program went beyond the realm of safe abortion care. Although the primary motivation for involvement stemmed from wanting to help others, lay providers also described the empowerment that they felt through participating in this initiative. Interviewees repeatedly expressed how they, as women, faced discrimination and were often not seen as valuable members of society. As described by one woman: “Women here, we are not people. We are like a goat or cow. We are not respected people in society.” However, once women became involved within this program, they felt that

their value within the community increased, and that this work provided them with a greater purpose. Another provider describes her experience before the program and after:

> Before [this program], people only saw me as an old birth attendant. But now, through [Peace Foundation], I have contraceptives, I have misoprostol, so I feel like I am a big doctor. Men, women come to me to solve their problems and I do. They see me, I am important.

Recruiting women from within the community as lay providers proved to help in establishing trust between the program and the community, as well as fostered a sense of empowerment among the lay providers.

Discussion

Global evidence demonstrates that misoprostol can be used effectively as a solo early abortifacient (2, 24) that is acceptable to women (25). However, few published studies highlight the potential and value of the community-based distribution of misoprostol in low resource and/or legally restricted settings. This study provides evidence that this strategy for expanding access to safe abortion care is acceptable to lay providers. Lay providers repeatedly extolled the benefits of the program and the safety of misoprostol. The perspectives align with the outcomes; at the time of our interviews with the lay providers, more than 120 women had obtained misoprostol through the community-based distribution program and all of these program beneficiaries had experienced a complete abortion without complications (20). The experience of lay providers in Sindh, Pakistan is also consistent with the experiences of lay providers involved in a community-based distribution program in Northern Thailand (19).

Our study also demonstrates that the community-based distribution program had an impact that went beyond its primary purpose of providing safe abortion care. Women lay providers who were involved in this initiative reported feeling a greater sense of purpose and having greater capacity to empower other women in their communities as a result. These secondary benefits align with efforts to support gender transformative interventions and are likely to have enhanced sustainability.

The success of the community-based distribution program for misoprostol is also consistent with an emerging body of evidence that suggests community-based distribution models and efforts to support self-care are important strategies for expanding access to SRH services more generally. Research from multiple countries in Sub-Saharan Africa has demonstrated the efficacy of using community-based distribution strategies to expand access to modern contraceptive methods and reduce costs (26-29). However, to date community-based distribution programs of misoprostol for early abortion have only been implemented and evaluated in Asia (19,25). Efforts to explore community-based distribution programs to expand safe abortion care in Sub-Saharan Africa contexts should be considered.

Limitations

As is true of qualitative research in general, our findings are not generalizable. However, given the strength of the themes we believe the results are transferable and have import beyond the immediate study population. The research team's positionalities, including educational level, language capacity, and nationality, undoubtedly influenced the interviewer-participant-interpreter interactions. Through formal memoing, team debriefing, and consistent and ongoing

reflection we aimed to understand these dynamics and minimize their impact on our interpretation; we believe these processes strengthened the credibility and trustworthiness of this study.

Conclusion

Our findings demonstrate that the community-based distribution of misoprostol for early abortion is a highly accepted and valued method of improving access to safe abortion care in Sindh, Pakistan. Efforts to expand the geographic reach of the program in Southeastern Pakistan and develop similar efforts in other low resource and legally restricted settings appear warranted.

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Chapter 5: "It is good for women and women need to know more about it": Exploring women's experiences with the community-based distribution of misoprostol for early abortion in Pakistan

We have formatted this original research article for the peer-reviewed journal, *Contraception.* We intend to submit this manuscript once the article presented in Chapter 3 has been accepted.

"It is good for women and women need to know more about it": Exploring women's experiences with the community-based distribution of misoprostol for early abortion in Pakistan

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Abstract

Objective: In Pakistan, abortion is legally restricted and unsafe abortion is a major contributor to maternal death and disability. In 2019, a local non-governmental organization developed and implemented a community-based distribution program of misoprostol for early abortion to reduce harm from unsafe abortion in the Sindh region and expand access to safe abortion care. We undertook this qualitative study to explore women's experiences with this program.

Methods: In October-December 2019, we conducted 30 in-depth interviews with women who had obtained misoprostol through this program. We audio-recorded, transcribed, and translated to English all interviews and used ATLAS.ti to manage our data. We analyzed the interviews for content and themes using deductive and inductive techniques.

Results: Overall, women felt positively about their experiences with the program and the overall initiative. Women remained certain of their decisions to have an abortion and were satisfied the misoprostol-only regimen and the abortion process. Women reported that the program filled a significant need and that they would recommend the program to others.

Conclusion: The community-based distribution of misoprostol is a culturally resonant and acceptable strategy for improving access to safe abortion care in Sindh, Pakistan. Expanding the reach of the program and engaging in efforts to increase awareness of and provide women with accurate information about safe abortion care appears warranted.

Implications

Over the last decade, organizations around the world have launched programs to expand access to medication abortion with the misoprostol-only regimen. Our findings indicate that providing misoprostol through a lay provision model in a legally restricted context is not only safe and effective but is also culturally resonant.

1. Introduction

Pakistan became a sovereign state in 1947 with the hope of serving as an independent homeland for Muslim Indians [1]. However, since its independence Pakistan has endured military coups, civil unrest, and domestic terrorism and continues to face complex development challenges [2]. Although the country has made advances towards overarching security and stability, there continues to be significant social inequities between different geographic regions and widespread gender discrimination. Combined with socio-cultural taboos and limitations on women's and girls' mobility, the overall context shapes healthcare decision-making, access, and outcomes. Promoting gender equity and women's rights is widely recognized as an important mechanism to reduce these health inequities [3].

Discriminatory laws and policies and gender-specific cultural norms severely inhibit women's reproductive autonomy, including control over fertility, in Pakistan. The legal status of abortion in Pakistan is complicated and depends on the stage of fetal development [4]. Before the fetus has formed organs or limbs, abortion is legally prohibited unless performed in good faith to provide necessary treatment or to save the woman's life. After the formation of fetal organs or limbs abortion is legally permitted only to save the woman's life [4]. The ambiguity of both the term "necessary treatment" and the stage of fetal development complicates the provision of abortion care, discourages providers from offering safe abortion services, and leads many women to resort to unsafe practices. In addition, abortion stigma is pervasive and research indicates that women fear that they will experience social repercussions from their families and communities, further compelling them to turn to clandestine abortions [5].

Many studies have documented the effectiveness of using a misoprostol-only regimen for early abortion [6–8]. Although not as effective as the gold standard mifepristone-misoprostol regimen, the World Health Organization states that misoprostol alone is 75-90% effective in ending a pregnancy of 9 weeks or less [9] Although abortion is legally restricted in Pakistan, misoprostol is often used to induce labour and to treat postpartum hemorrhage and is therefore widely available and relatively easy to access. Beginning in the 2010s, a local non-governmental organization (NGO) began to incorporate the use of misoprostol into several programs related to women's health in the Sindh region of Pakistan. In mid-2019, this program expanded to provide safe abortion care through the community-based distribution of misoprostol and in partnership with a research team at the University of Ottawa (Canada) we conducted a comprehensive evaluation of this intervention. We have reported on both the outcomes and design of this program previously [10–11]. In this article, we present on the results of a qualitative study that aimed to document Pakistani women's experiences using this service and their perspectives on how the program could be improved.

2. Materials and methods

2.1 Study setting and program description

Peace Foundation is an NGO located in the Southeast region of Pakistan. Peace Foundation provides safe abortion care through the community-based distribution of misoprostol via a network of community health workers located at 12 sites. In addition to providing the misoprostol tablets, trained lay providers offer counselling, information about the legal status of abortion in Pakistan, and information about the abortion process and conditions warranting

follow-up, all of which is free of cost. Any women with a self-reported unwanted pregnancy can present themselves to one of the lay providers and access these services.

The lay provider establishes pregnancy with a urine pregnancy test and a gestational age estimate based on the woman's recollected date of the first day of her last menstrual period (LMP). Women at a gestational age of less than 10 weeks are eligible for the misoprostol-only treatment. They then receive three 800 mcg doses of misoprostol, which they take sublingually, three hours apart. Women who present after 10 weeks' gestation are handled on a case-by-case basis; in some cases they received misoprostol and in other cases they are referred to a known and reputable abortion provider.

2.2 Data collection

In October-December 2019, we conducted a qualitative study to document women's experiences with the misoprostol distribution program. With the help of the lay providers, we invited women who obtained care through each of the 12 sites to participate in an in-person interview.[1] Women were eligible to participate in the interview if they had received misoprostol through the community-based distribution program at least one month before the date of the interview. We chose this timeframe to ensure that women would know the outcomes of the treatment. We held interviews at a mutually convenient time and at a secure and private location.

[1] We recognize that not all people who want, need, and have abortions identify as women. However, use of more gender-inclusive language would have been confusing and linguistically challenging. Thus, we used gendered language throughout the project and this is reflected in the terminology we use in this paper.

K.M, a white Canadian who was completing her Master's in Interdisciplinary Health Sciences at the University of Ottawa, led all in-depth, open-ended, semi-structured interviews after receiving training from A.M.F., a white American medical doctor and medical anthropologist who has conducted abortion-related research in dozens of fragile and humanitarian settings. K.M. worked closely with N.S., a Pakistani program manager at Peace Foundation who is fluent in Urdu and Sindhi and served as the interpreter. With the help of N.S., K.M. reviewed the project's aims and purpose with participants who then verbally consented both to participate in the interview and to audio recording.

Using a guide tailored specifically to this context, the interview began with a discussion of the participant's current living situation, daily routines, and general background. The interview then shifted to focus on the participant's sexual and reproductive health (SRH) history, current SRH status, and use of SRH services. The interview then turned to the circumstances surrounding the index pregnancy, the participant's experience accessing the community-based distribution program, and the abortion process and outcomes. We ended interviews with a discussion of how the current program could be improved and how safe abortion care could be expanded in the Sindh region.

Interviews averaged 45 minutes and we provided participants with PKR1000 (about USD6) as a thank you for participating in the study. We also covered all travel costs for women to come to the secure and private interview location and provided and meals and refreshments when appropriate. K.M. took notes throughout each interview, debriefed with N.S. immediately afterward, and formally memoed to engage in a reflexive process and initiate analysis [12]. We

used thematic saturation as an endpoint for data collection [13] and we believed we had reached thematic saturation after 21 interviews. However, we also wanted to interview at least a few women who had obtained misoprostol from each of the 12 sites. Thus, we completed additional interviews for confirmation, for maximum variable, and to respect the arrangements we had made with lay providers and interviewees. N.S. and K.M. worked together to transcribe and translate the interviews; a second member of the University of Ottawa team reviewed the translation to improve accuracy.

2.3 Data analysis

We analyzed the interviews for content and themes using both predetermined and emergent codes [14–15]. Data analysis was iterative and occurred alongside data collection. K.M. developed an initial codebook and served as the principle coder. Team meetings guided our interpretation of the results; we resolved all disagreements through discussion. In this article, we organize our results around key themes. We use illustrative quotes to showcase these themes. We also present several narrative vignettes to provide a more comprehensive glimpse of our participants' lives.

2.4 Ethics

We received approval to conduct this study from the Research Ethics Board at the University of Ottawa. An ad hoc committee at Peace Foundation also reviewed the study protocol and all instruments and determined that the project met local ethical and research standards. To protect both those who participated in the program and those lay providers offering abortion care with

misoprostol, we have removed or masked all personally identifying information and use pseudonyms throughout.

3. Results

3.1 Study participants and abortion characteristics

We interviewed 30 women who had obtained misoprostol through the community-based distribution program to terminate 33 early pregnancies. All of our participants were between the ages of 22 and 46 years old (average 28.6 years) at the time of the interview. However, this is a rough estimate as many women were unsure of their exact age. At the time of the interview, half of the participants were living in villages and half resided in small towns. Twenty-two participants resided in Mirpurkhas or neighbouring districts; the remaining eight of the resided in the Tharparkar desert district.

Women successfully aborted all 33 pregnancies within one month of receiving the misoprostol; none reported any complications requiring medical assistance. Based on their recollected LMP, women were 4-10 weeks gestation when they initiated the regimen; the majority (67%) was at a gestational age of six or more weeks. Ten of the women had used a form of modern contraception, including the contraceptive implant, Depo-Provera, oral contraceptive pills, and/or condoms, at some point in their reproductive lives prior to the index pregnancy. Twenty women had never used a modern method of contraception prior to their most recent abortion but most had since initiative a method or were in the process of starting one.

[Figure 1 about here]

3.2 Women felt positive about their abortion experience and the abortion decision

We received resoundingly positive feedback about misoprostol and the community-based distribution program. The ease of the process and tolerable side effects were some of the benefits that women mentioned most frequently. Given the lack of available health services in their immediate catchments and women's limited mobility, women reported that having a more accessible option that did not require them to travel to a city to reach a hospital or health clinic was especially important. Further, having minimal side effects and being able to abort in a relatively short amount of time allowed women to return to their daily activities such as fieldwork, house chores, and tending to children, without disrupting their routines. As described by one participant: "I terminated without any complications. No need to spend a lot of time for the abortion. I have a family and I have to take care of my family. With [misoprostol] I have no need to go to hospital and spend time at the hospital." Being able to access misoprostol allowed women to secure a safe abortion independently and conveniently.

As showcased in Azizah's story (Fig. 1), women in our study felt certain about their decision to have an abortion and believed that having an abortion was the best option for themselves and their families. Women report that the primary reasons for choosing to have an abortion were poverty, their health, and their feeling that already had enough children. In general, women's confidence in the decision added to their positive recollection of the experience. However, for a small number of women the decision was more difficult. As one woman explained: "The decision was not easy. I feel sad sometimes. But because of my living situation [poverty] and my husband's condition I had to do it. I feel sad but it was my need."

[Figure 2 about here]

3.3 Women felt strongly that the community-based distribution program saved their lives

Women in our study repeatedly spoke about how women in Pakistan face many challenges when trying to access safe abortion services. Several participants described unsafe abortion as a common occurrence and spoke of the experiences of family members, neighbours, and other women in the community. One woman described the experience of her sister-in-law who obtained an abortion from an untrained lady health worker (LHW) and died from complications.

> Many untrained women in villages are doing very bad things to women. Once my relative she went and she died. An untrained lady health worker in [a village] she curetted her uterus and she curetted and curetted and she also curetted her intestines. We went to the Civil Hospital, and she was in very serious condition. They did an internal check-up, and the nurse had her intestines on her fingers.

Given this context, many participants believed the community-based distribution of misoprostol saved their lives because it offered a safe alternative to unsafe abortion methods. However, as reflected in Amira's story (Fig. 2) women and girls face risks to their safety if they become pregnant as a result of illicit sex. Having an abortion is therefore protective but only if it can be secured discretely. As one woman explained: "If we go to hospital everyone knows why you're going and what you are doing, and if we come here nobody else knows about your problems. [Provider's name] saved me. Misoprostol saves women's lives." Women expressed that because of the community-based distribution program, they were able to abort safely and discreetly and avoid negative repercussions within their familial or social networks.

3.4 Women would recommend misoprostol for early abortion to other women

All of the women whom we interviewed stated that they would recommend misoprostol and the specific community-based distribution program to other women. In fact, almost all had already been recommending misoprostol, in general, and the program, in particular, to family members and other women in their villages. Although many expressed some hesitation about openly talking to others about their own experiences, all of them agreed that if someone were to reach out to them and ask for advice that they would encourage them to visit one of the 12 sites and terminate with misoprostol. As one woman stated: "I told women in the village, and also when I go to other villages to cut crops, in other districts, I tell them too about misoprostol and now they come here."

In the interviews, women repeatedly focused on the importance of spreading the message and making others aware of misoprostol. Women were adamant that spreading information about misoprostol was the best way to reduce harm from unsafe abortion in the region. When asked what she thought should be done to improve access to safe abortion care in Pakistan one woman responded:

> It is good for women and women need to know more about it. If their health is good, they can do many things. In my village, women are not aware about anything to do with family planning or [misoprostol] so they need to learn more. Women need to know about misoprostol in all of Pakistan, and you need to spread misoprostol in all of Pakistan.

4. Discussion

Misoprostol has been shown to not only be an effective means for inducing an early abortion, but is also a promising strategy for improving access to safe abortion care in legally restricted and/or

low resource settings in Asia [16–18]. Our study provides a snapshot of women's experiences obtaining an abortion through a community-based distribution of misoprostol program in rural Pakistan. Our findings confirm the results of previous work that indicates that women who obtain abortion care with misoprostol alone through lay providers reflect positively on those experiences and support the initiative.

Indeed, our study suggests that this form of intervention is both highly acceptable and culturally responsive. Being able to access the program easily and close to home, experience minimal side effects, and terminate discreetly were the most positive aspects of this program. Given the pervasiveness of unsafe abortion in the region and widespread fear of experiencing stigma or violent reprisals if there is proof of having had illicit sex, women felt that misoprostol allowed them to circumvent negative physical and social health outcomes. Thus, the program not only reduces harm from unsafe abortion but reduces harm from the laws, policies, and social-cultural dynamics that place women's and girls' lives and health at risk.

Given women's overall satisfaction with the initiative and the successful outcome, exploring avenues for expanding the community-based distribution program appears warranted. Spreading the word about the program, and about misoprostol more generally, would be an important first step. As the initiative expands, recruiting lay providers from a wider array of ethnic and linguistic backgrounds and from more geographic areas could prove useful in meeting the needs of a broader range of women and girls.

Our study has several limitations. First, as is true for all qualitative research, our study is not generalizable or representative. This is an exploratory study that focuses on individual program beneficiaries' experiences, perceptions, and opinions. Second, we only interviewed women who had successful abortion through the community-based distribution program. Although we intended to speak with women who did not successfully abort after using misoprostol, at the time we were conducting interviews all participants in the community-based distribution program had successfully induced an abortion with the misoprostol-alone regimen. Future research would benefit from the perspectives of those whose outcomes were less successful. Third, Pakistan is a diverse country both culturally and linguistically. Our team operated in English, Urdu, and Sindhi, there are over 70 languages spoken in the country and some participants were communicating in a non-dominant language. We appreciate that some nuance and subtlety may have been lost in translation. Finally, we acknowledge that the study team's positionalities in terms of ethnicity, religion, education, and nationality influenced the interviewer-interpreter-participant dynamic and our subsequent interpretation. By holding regular debriefings and discussions, as well as engaging in a reflexive process through formal memoing, we tried to understand and minimize these influences.

Despite these limitations, our findings clearly suggest that the community-based distribution of misoprostol is a highly acceptable strategy from improving access to safe abortion care in Sindh, Pakistan. Given the success of this intervention, and women's overwhelming positive feedback, exploring avenues for expanding the reach of this program in other areas appears warranted. This study provides promising results that could be used to promote similar initiatives in other low resource and /or legally restricted settings.

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Azizah is a 25-year-old woman from a small village in rural Pakistan. She has four children under the age of six. Azizah's living situation is difficult. As is the case for most women living in rural areas, Azizah spends her days working in the fields doing hard physical labour to secure food for herself and her family. Azizah's situation is aggravated by the fact that her husband is mentally unwell. Without access to necessary supports and treatments, his condition had worsened over the past several months, often resulting in violent outbursts towards Azizah and her children.

When Azizah became pregnant for the fifth time she knew that her living conditions were not suitable for raising another child. Already struggling to feed herself and her four children, and with an abusive husband who is not fit to support her family, she made the decision to have an abortion.

After consulting with her mother-in-law, Azizah felt certain about her decision. She had been getting free contraceptive methods from primary health centre in the past, but it was through other women in her village that she heard about misoprostol.

Azizah has no regrets about her decision to have an abortion and feels that it was what needed to be done for the benefit of her family. As she explained: "It was the right decision for me and my family. At that time, we were in very bad condition. No food for kids, and my husband is [mentally ill]. I already work hard for my kids so how can I be responsible for more kids?"

Figure 1: Azizah's story

Amira was 12 years-old when she got pregnant for the first time. She is from a small village in the desert district of Tharparkar. Her and her family travel frequently to work in the fields to earn food or small daily wages.

It was during this time while she and her mother were away doing fieldwork that she became pregnant. Being unmarried at the time, Amira and her mother were very concerned for her safety and feared what would happen if anyone found out. Having heard about misoprostol through other women in the fields, Amira and her mother decided to go to one of the local centres so that she could have an abortion.

Amira's mother pleaded with the lay provider and explained that if they returned home with her daughter still pregnant her husband and sons would beat her, or worse. The lay provider gave Amira the misoprostol tablets, and she aborted successfully without any complications. Most importantly for her and her mother, they were thankful that she was able to have an abortion discreetly.

As Amira stated:

> It is good for privacy. Because here in our community, in our culture, respect is a big thing. If any girl gets pregnant, it means she destroys the respect of her parents. So, it is very bad. And sometimes they kill their daughters, like honour killings. So, [misoprostol] is very private and discreet. So, because of this it is good.

Figure 2. Amira's story

Chapter 6: Discussion

The following chapter will begin by presenting the evaluation of the community-based distribution program through the integration of the results from the articles presented in chapters 3, 4, and 5 of this thesis. I will then outline my positionality and experience as a researcher, the significance and implications of this project, future directions, limitations of the study, and I will end with a concluding statement.

6.1 Program evaluation and integration of results

Over the last several decades, local and global agencies have made considerable advances towards reducing maternal mortality rates. Key players in global health have made concerted efforts targeting four of the five main causes of maternal death. However, action has been slow to respond to unsafe abortion and its role in maternal mortality and morbidity. It has been shown that the highest rates of unsafe abortion occur in developing regions which is then compounded when abortion is legally restricted (8). As global leaders increasingly take notice of this issue, and the discussion continues to broaden, more evidence must be presented and translated into appropriate action.

The aim of this study was to evaluate the community-based distribution of misoprostol in Pakistan as an effective strategy for expanding access to SAC in low resource and legally restricted settings. We employed a multi-methods approach outlined in Chapter 2. Program inputs, outputs, and outcomes are presented through a logic model in Figure 1.

Inputs	Activities	Outputs	Outcomes		
			Short-term	Medium-term	Long-term
Funding	Workshops for lay providers on misoprostol and SAC	45 workshops held for lay providers	Increase in women's knowledge on SAC	Reduce recourse to unsafe abortion practices	Improved access to SAC
Training for lay providers	Disseminate accurate SRH and SAC information	377 meetings held with community members about SAC and misoprostol	Increase in women's awareness of misoprostol for SAC	Improved birth spacing	Reduction in maternal mortality
12 lay providers	Counselling for women on misoprostol and abortion	1235 women have received misoprostol to terminate their pregnancies	Reduction in abortion stigma	Increase in women's adoption of safe and healthy abortion methods	Reduction in maternal morbidity
Misoprostol tablets	Misoprostol-only regimen for early abortion	1235 counselling sessions with women receiving misoprostol	Increase in women's motivation to adopt safe abortion methods		Improved self-worth and community standing
Pamphlets		5 radio shows discussing misoprostol and safe abortion			
Centre equipment (desk, chairs etc.)					

Figure 1. Logic model of community-based distribution program

This evaluation highlighted several key findings: 1) misoprostol is a safe and effective means for early abortion; 2) the community-based distribution of misoprostol is a culturally resonant model for safe abortion provision; and 3) community-based distribution of misoprostol is a practical solution for improving access to SAC in low resource and legally restricted areas such as Pakistan.

Through the revision of logbooks and reports from lay providers, our study demonstrated very positive results for the misoprostol-only regimen for early abortion. Out of the 120 cases reported in the logbooks, all of the women successfully terminated without any major complications. As outlined in Chapters 3, 4, and 5, these results are not consistent with the literature, which shows a success rate of 75-90%. However, the high efficacy of misoprostol in the community distribution context has been documented previously (66). We are confident that serious negative outcomes related to misoprostol-only use for early abortion are rare and that when given sufficient time, misoprostol is a highly effective solo abortifacient.

Through the reported experiences of women and lay providers, our study identified several important barriers women face when trying to access abortion care, including lack of infrastructure, mobility, financial burdens, and socio-cultural barriers. By introducing the community-based distribution of misoprostol within their communities, women were able to circumvent these obstacles and access the services they needed. The interview component of the project was also instrumental in highlighting the benefits of a community-based model for distribution and that this mode of intervention was culturally resonant among community members.

These findings are consistent with the pilot project conducted at the Thailand-Burma border and further demonstrate the positive impact of such an intervention. All components of the study were congruent and suggest that the need for expanding the community-based distribution of misoprostol for early abortion is considerable. As the global sexual and reproductive health and

rights (SRHR) community advances, national and international agencies should take these findings into consideration.

6.2 Positionality and experience of the researcher

Two vital components to all qualitative research is the acknowledgment of positionality and reflexive engagement. Positionality is defined in the SAGE Encyclopedia of Action Research as the "stance or positioning of the researcher in relation to the social and political context of the study, the community, the organization, or the participant group". (71) In other words, it is how the researcher relates to every component of the study and what aspects of this impact the different phases of the research process. Reflexivity refers to the active process of reflecting on this positionality. It is the thoughtful consideration of the researcher's own perceptions and biases, and the personal awareness of how these influence the study (72).

As a Caucasian Canadian woman, my positionalities undeniably influenced the various stages of the research. Firs, I do not speak any of the native languages of Pakistan and I am not inherently familiar with Pakistani culture. To address this, I worked very closely with our local partners and they were heavily involved in all phases of the project. In addition, I committed considerable time during my stay in Pakistan to build rapport with the participants and the communities. I met with some of the participants multiple times and participated in community activities. This allowed me to build rapport as well as immerse myself more fully in the culture and customs and ultimately gain a richer perspective. This in combination with my Western background gave me an outsider role and contributed to a unique dimension to the research. Because I was not a member of the community, participants felt confident that they could share their experiences

openly with me. Further, participants also tended to give detailed explanations as to the socio-political context and history of the country and how these impacted them, which may not have been the case if they felt that I would know this information already.

I actively engaged in a reflexive process throughout the entirety of this project. This included taking extensive notes throughout all of the interviews and debriefing with the interpreter regularly after each interaction. In addition to this, I formally memoed at the end of every interview which allowed me to reflect on my positionality and the interviewer-interpreter-participant dynamic and identify reoccurring themes. I believe that these steps allowed me to identify subjectivities and mitigate them.

6.3 Significance and implications

This study presents valuable insights regarding the barriers women face when accessing abortion care in Pakistan and how the community-based distribution of misoprostol is an important tactic for overcoming those challenges. Although there is growing evidence supporting the use of a misoprostol-only regimen for early abortion, there are only a modest number of studies highlighting its effectiveness in low resource and legally restricted settings. As evidence about the effectiveness of misoprostol for early abortion increases, more discussions presenting actionable strategies and modes of implementation are needed. This study merges evidence supporting the use of misoprostol with the evidence supporting a community-based distribution model as a harm-reduction strategy.

This project has been instrumental in improving program operations and ultimately broadening its reach in other communities. By providing local partners with tools for M&E they have improved their monitoring and evaluation practices which is essential for receiving funding and continuing their operations. In addition, through this project we facilitated the connection between local partners and other agencies and organizations such as the Women's Empowerment Department, local hospitals, and the Sindh Education Foundation, which could be valuable allies. This study strengthens current evidence supporting the distribution of misoprostol at the community level as an important strategy for improving SAC in low resource and legally restricted settings.

6.4 Future directions

As a valuable step in the process of action research, I intend on disseminating my findings from this study through multiple streams including peer-reviewed journals, academic conferences, and final reports and briefings provided to the local partners. Along with endeavours made while in the field, I plan on continuing efforts to support local partners in expanding the reach of their program by increasing awareness of their activities and strengthening their advocacy efforts.

An actionable strategy for change would be to share findings from this study with actors and agencies in the global SRHR community to increase engagement. This would also be beneficial for local partners by increasing buy-in among global stakeholders. Moving forward, SRHR actors should explore the mobilization of misoprostol in their harm reduction strategies.

This study will contribute to the literature and knowledge generated will inform NGOs and policymakers on possibilities for change to reduce harm from unsafe abortion in Pakistan. Future studies should assess the impact of similar programs in other regions experiencing varying barriers to access. Further research will help gain a better understanding of the larger scope of the issue of unsafe abortion and the development of targeted programing.

6.5 Limitations

All interpretations of these findings must take into account several potential limitations. First, the legal restrictions on abortion in Pakistan and potential security threats did influence how we carried out the project. For instance, lay providers could only collect limited information from the women in order to minimize potential risks to safety. Consequently, our evaluation did not include detailed case reports or any comprehensive patient histories. Second, women who participated in our study likely have higher levels of mobility and support from their families compared to other women in the community. In fact, all of the women that we spoke to had a supportive husband and/or mother-in-law when deciding to terminate their pregnancy. Women in a more restrictive environment may be living different experiences. Third, given the limited resources within this setting women self-reported their treatment outcomes and clinical confirmation did not take place. This is characteristic of outcome measures for community-based distribution programs but means that our results need to be viewed with caution. Fourth, Pakistan is a diverse country both culturally and linguistically and has over 70 spoken languages (73). We attempted to overcome language barriers with interpreters, however, not all terms could be translated verbatim for every language/dialect spoken. Another limitation to take into consideration is the positionality of the research team. Our educational levels, spoken languages, and nationalities inevitably influenced the execution of the study. However, we regularly

engaged in a reflexive process through formal memoing and discussions among team members. We believe that this allowed us to better understand the influence of our positionality and strengthen the credibility and trustworthiness of this study.

Finally, as is true for all qualitative research, our study is not generalizable or representative. This study simply serves as an exploration of participants' experiences, perceptions, and opinions. Despite these limitations, the congruence in our findings gives us confidence that our findings are credible, trustworthy, and transferable.

6.6 Conclusions

Recent data indicates that every year nearly 56 million abortions occur worldwide; roughly 25 million of these in unsafe conditions (8). Unsafe abortion occurs overwhelmingly in the Global South (8). In fact, 93% of countries with highly restrictive abortion laws are in developing regions (8). The evidence clearly shows that limiting women's ability to access abortion care by imposing restrictive laws and policies does not prevent them from terminating their pregnancies. In fact, these hurdles simply lead more women to resort to unsafe and clandestine methods. Expanding legal grounds and reformulating current policies can take many years of societal reform and continuous political will. However, identifying targeted and innovative ways to address unsafe abortion in low resource and legally restricted areas is crucial. Given the success of this project, we believe that the community-based distribution of misoprostol is an effective strategy for improving access to SAC in Pakistan. Future endeavours should aim to implement or strengthen programs in similarly low resource and restrictive settings.

Deciding when and how many children to have is a fundamental human right that should be upheld in all regions no matter the context. The benefits of expanding safe abortion services reverberate at every level of the social order. For each individual woman and girl, being able to safely access an abortion has a direct impact on her health and well-being, which then extends to her family and community. At a societal level, expanding the reach of such programs and continuing the progress towards universal access to comprehensive SRH services can affect the global discourse surrounding unsafe abortion and abortion services, ultimately creating long-lasting substantial change.

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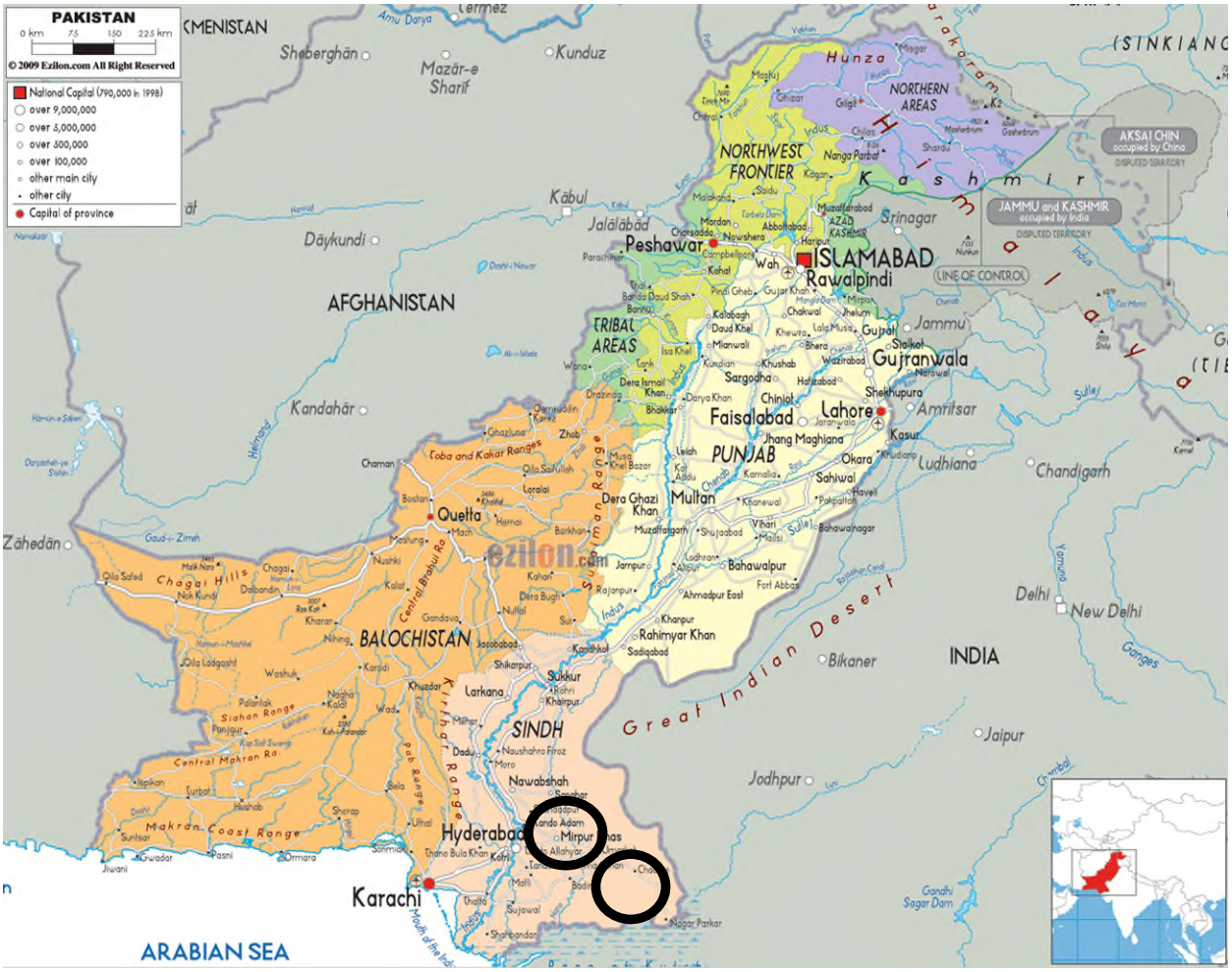
Appendix A: Map of Pakistan with marked study sites



Appendix B: University of Ottawa Ethics Approval Letter

[Insert University of Ottawa Ethics Approval Letter]