

Simplifying medical abortion services in primary care settings in India



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Simplifying medical abortion services in primary care settings in India

THESIS FOR DOCTORAL DEGREE (Ph.D.)

By

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ABSTRACT

Background

Even in countries where abortion is legal, many women suffer mortality and morbidity from unsafe abortion. When faced with an unwanted pregnancy, women encounter many social, geographical, and health system level barriers in accessing safe abortion. Medical methods are far more amenable to be provided in primary care rural settings, however, in practice, women are required to make multiple clinic visits to receive medical abortion services. Two important measures to reduce the number of clinic visits after an early medical abortion, are eliminating the second visit by allowing home use of misoprostol and eliminating the third visit by allowing women to assess the outcome of their abortion on their own. However, most research on home use of misoprostol and on alternatives to routine clinic follow-up visits has been done in high-income countries or in urban areas of developing countries. There is little evidence on efficacy, safety and acceptability of home use of misoprostol and self-assessment approaches from rural areas of low resource settings.

Objectives

The aims of this research were: (a) to assess the efficacy, feasibility, safety and acceptability of self assessment as compared to the routine clinic follow-up after early medical abortion, (b) to assess efficacy, safety and acceptability of home administration of misoprostol as compared to clinic use of misoprostol, and (c) to explore women's experiences and perceptions of home use of misoprostol and of self-assessment of outcome of early medical abortion.

Methods

The study was conducted in southern part of Rajasthan state in India, where 75% population is rural and only about half the women are literate. A randomised controlled, non-inferiority trial was conducted at 6 health centres (3 rural, 3 urban) in 2013-14. Women seeking early medical abortion up to 9 weeks gestation were randomly assigned either to routine clinic follow-up or to self-assessment using a low-sensitivity pregnancy test at home. They were contacted through a home visit or phone call, 10-15 days later, to record the outcome of the abortion. The primary outcome was complete abortion without continuing pregnancy or need for surgical evacuation or additional mifepristone / misoprostol. The non-inferiority margin for the risk difference was 5%. Secondary outcomes included safety, feasibility, interim visits, and acceptability. A secondary analysis of the data was carried out to compare the outcomes among women with home and clinic administration of misoprostol.

In-depth interviews were conducted with 20 women who administered misoprostol at home and assessed their own outcome of abortion using a low-sensitivity pregnancy test, to explore their perceptions and experiences.

Results

In the randomised controlled trial, 731 participants were recruited, of whom 700 were analysed for primary outcome (had a recorded primary outcome and who followed the clinical protocol). Overall rates of complete abortion, incomplete abortion and on-going pregnancy were 94.3%, 4.7% and 1.0%. Comparison of women in the clinic follow-up group and the home assessment groups showed that complete abortion rates and rates of surgical intervention were similar between the two groups, and that home assessment is non-inferior

to clinic follow-up after an early medical abortion. Adverse outcomes were extremely rare in both groups.

Eighteen percent of women made an interim visit. 80% women did the low-sensitivity pregnancy test on their own, without any reminder. Overall, 96% were satisfied with their medical abortion experience and there were no differences between the study groups. Significantly more women in the home-assessment group preferred home-assessment in the future, as compared with women in the clinic follow-up group, who preferred clinic follow-up in the event of a future medical abortion ($p = 0.001$).

Comparison of women using home and clinic misoprostol groups showed that the outcomes related to efficacy, safety and satisfaction rates were comparable between the two groups. Non-compliance with use of misoprostol was higher among women assigned to clinic user than those assigned to home user (3.6% and 0.6% respectively). The time spent on clinic visits and travel was 5 hours extra for clinic users as compared to home users. A significantly greater proportion of home users said that they would opt for misoprostol at home in the event of a future abortion, than the proportion of clinic users that would opt for misoprostol at the clinic, in a similar situation ($p = 0.0002$).

In-depth interviews revealed that almost all women preferred home use of misoprostol, since it allowed them to maintain confidentiality and to avoid difficulties related to childcare, housework and inconvenience of travel. On the day of misoprostol, women were confidently able to manage their abortions, and continue with routine housework. Even though most women were able to understand the outcome of their abortion through symptoms, they found it reassuring to do the pregnancy test to alleviate anxieties about retained products. Majority said they would prefer medical abortion involving a single visit in future.

Conclusion

Our results confirm that self-assessment using low-sensitivity pregnancy test is an effective and safe approach to identify women with on-going pregnancies after an early medical abortion. Further, these studies also confirm that women are capable of administering misoprostol at home, without reduction in efficacy or safety. Women can confidently administer misoprostol at home, can conduct assessment of their abortion outcomes, and find it highly acceptable. Evidence generated by these studies is the only evidence thus far from a low resource rural setting that women with low literacy levels can feasibly assess the outcome of an early medical abortion and can safely use misoprostol at home.

Service delivery guidelines should be revised and offer women a choice between home and clinic use of misoprostol and between self-assessment and clinic follow-up. In health systems, reducing the number of clinic visits would greatly enhance women's access to safe abortion. Greater self-management of medical abortions would require that health systems enable and equip women with necessary information and supplies, and are available to provide backup care.

LIST OF SCIENTIFIC PAPERS

1. **Kirti Iyengar**, Mandira Paul, Sharad D Iyengar, Marie Klingberg-Allvin, Birgitta Essén, Johan Bring, Sunita Soni, Kristina Gemzell-Danielsson.

Self -assessment of the outcome of early medical abortion versus clinic follow-up in India: a randomized, controlled, non-inferiority trial.
Lancet Glob Health 2015; 3: e537-45.

2. **Kirti Iyengar**, Marie Klingberg-Allvin, Sharad D Iyengar, Mandira Paul, Birgitta Essén, Kristina Gemzell Danielsson.

Home use of misoprostol for early medical abortion in a low resource setting: secondary analysis of a randomized controlled trial.
Acta Obstet Gynecol Scand 2015; DOI: 10.1111/aogs.12815

3. Mandira Paul, **Kirti Iyengar**, Birgitta Essén, Kristina Gemzell-Danielsson, Sharad D. Iyengar, Johan Bring, Sunita Soni, Marie Klingberg-Allvin.

Acceptability of Home-Assessment Post Medical Abortion and Medical Abortion in a Low-Resource Setting in Rajasthan, India. Secondary Outcome Analysis of a Non-Inferiority Randomized Controlled Trial.
PLoS One | 2015: 1-14.

4. **Kirti Iyengar**, Marie Klingberg Allvin, Sharad D Iyengar, Kristina Gemzell Danielsson, Birgitta Essén.

“Who wants to go repeatedly to the hospital?”: Perceptions and experiences of simplified medical abortion in Rajasthan, India.
Submitted

LIST OF RELATED PUBLICATIONS

1. Johnston HB, Ganatra B, Nguyen MH, Habib N, Afework MF, Harries J, **Iyengar K**, Moodley J, Lema HY, Constant D, Sen S.

Accuracy of assessment of eligibility for early medical abortion by community health workers in Ethiopia, India and South Africa.

PLoS ONE 11(1): e0146305. doi:10.1371/journal.pone.0146305

2. **Iyengar K**, Iyengar SD, Gemzell-Danielsson K.

Can informal abortion provision in India transition to formal and safe services?

Lancet Glob Health 2016

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3. Gupta P, Iyengar SD, Ganatra B, Johnston HB, **Iyengar K**.

Community perspectives of the role of community health workers in increasing access to medical abortion in India

Submitted

4. **Iyengar K**, Iyengar SD.

Improving access to safe abortion in a primary care setting in rural Rajasthan, India. Reproductive Health.

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Contents

1. Introduction	1
1.1. Unsafe abortion and the law	1
1.2. Availability of medical abortion	2
1.3. Abortion in India	3
1.4. Number of visits required for medical abortion	6
2. Aims of the study	8
3. Methods	
3.1. Thesis overview	9
3.2. Study setting	10
3.3. Study design	11
3.3.1. Randomised controlled trial (paper I, II & III)	11
3.3.2. Qualitative study (paper IV)	15
3.4. Ethical considerations	17
4. Results	
4.1. Background characteristics of participants	18
4.2. Randomised controlled trial (paper I, II & III)	
4.2.1. Comparison of self assessment and clinic follow-up	18
4.2.2. Comparison of home and clinic use of misoprostol	21
4.2.3. Comparison of women making one and three visits for medical abortion	24
4.3. Experiences and perceptions of simplified medical abortion (paper IV)	23
5. Discussion	
5.1. How effective, safe, feasible and acceptable is self- assessment as an alternative to clinic follow-up for women having early medical abortion?	27
5.2. Can women in low resource settings safely administer misoprostol at home for early medical abortion?	30
5.3. What are experiences and perceptions of women regarding home use of misoprostol and self-assessment?	31
5.4. Advantages of self-managed medical abortion	33
5.5. What other measures are needed to simplify medical abortion?	34
5.6. What is needed to allow task shifting to women in health care?	35
5.5. Study strengths and limitations	36
6. Conclusions	40
7. Practice and policy implications	41
8. Implications for research	43
9. Acknowledgements	44
10. References	47

LIST OF ABBREVIATIONS

AHS	Annual Health Survey
DLHS	District Level Household Survey
ES	Evaluable Subjects
FU	Follow-up
hCG	Human Chorionic Gonadotrophin
ITT	Intention to Treat
IU	International Unit
IUD	Intrauterine device
INR	Indian Rupee
LSUP	Low sensitivity pregnancy test
MMR	Maternal Mortality Ratio
MTP	Medical Termination of Pregnancy
NFHS	National Family Health Survey
RCT	Randomised controlled trial
SRS	Sample Registration Survey
TFR	Total Fertility Rate
WHO	World Health Organization

1. INTRODUCTION

Pushpa, 2002

Pushpa, a 24-year old mother of three children (of whom two had survived), lived in a village 60 km away from the district town. She realized that she had missed a period. She went to a private clinic, where a urine pregnancy test was done and it turned out to be positive. Not wishing to continue with the pregnancy, Pushpa consulted some neighbours who advised her to contact a woman belonging to a nomadic tribe, for treatment to abort her pregnancy. A few days after visiting this woman, Pushpa developed high fever, vomiting, abdominal distension, and swelling of hands and feet. When she started fainting repeatedly, she was taken to her parents' house from where she was rushed to the district hospital. The doctor there initiated treatment and recommended that she be shifted to the government Medical College Hospital, 70 km away. The family spent Rs 950 (US\$ 24) at the district hospital. However, instead of taking her to the medical college hospital, the family preferred getting Pushpa admitted to a private hospital nearby, where she received intravenous fluids, oxygen, and a blood transfusion. Pushpa aborted a few hours later. After 10 days of inpatient treatment and an expense of Rs 40,000 (US\$ 1,000), the treating doctor advised the family to shift her to the government Medical College Hospital. Although Pushpa was semi-conscious, her intravenous lines were disconnected and she was discharged. The family transported her to the teaching hospital. She was admitted there, but the doctor informed the family that there was little hope of survival. The family brought Pushpa home where she died after a day.

1.1. Unsafe abortion and the law

Both in countries where abortion is legal and where it is illegal, far too many women continue to suffer mortality and morbidity from unsafe abortion. Unsafe abortion continues to be an important cause of maternal mortality globally, responsible for nearly 8% of maternal deaths (1, 2). The overall rate of unsafe abortion worldwide has remained unchanged between 1995 and 2008 (1, 3). Nearly half of all abortions worldwide are unsafe, with most of them occurring in developing countries, where 56% of all abortions are unsafe, compared with just 6% in developed countries (4). There are wide variations between regions - the proportions of abortions that are unsafe are above 95% in Africa and Latin America, 40% in Asia, 9% in Europe, and 0.5% in North America (4).

One of the biggest barriers to safe abortion has been the restricted legality of abortion. Till the 19th century, there were no laws related to abortions in most countries. The first anti-abortion laws were passed in Britain in 1803, and they became stricter through the century. Other countries too passed laws that outlawed abortions (5). Making abortions illegal however did not prevent its practice -- there were 2 million estimated abortions every year in 1980s in the United States. Women faced with an unwanted pregnancy found ways to terminate it, through safe or unsafe methods. Historically, multiple methods have been used to induce abortions, ranging from highly dangerous sharp objects or liquids inserted in the uterus or vagina, to ineffective options such as oral decoctions and physical methods such as abdominal kneading and the woman jumping up and down (6). Between 1950 and 1985, almost all developed countries liberalised their abortion laws for reasons of human rights and safety. Many developing countries also liberalised their abortion laws, on the grounds on which abortion was permitted (7).

Currently, a quarter of countries (26%) allow abortions only to save women's lives, and an additional 42% allow abortions for at least one other additional reason, such as to preserve a woman's physical or mental health, in cases of rape and incest, because of fetal impairment or for social or economic reasons (8). Most countries with highly restrictive abortion laws are in South America, Sub-Saharan Africa, the Middle East and Asia Pacific. In countries where the abortion is legal on broadly legal grounds, abortion related maternal mortality has declined significantly (9). Within developing countries, more liberal abortion laws are associated with fewer health consequences from unsafe abortion.

However, changing the law is only one step to make all abortions safe. Even within countries in which abortion is permissible on broad legal grounds, it may remain out of reach for many women. Further, legal abortion may not always be safe because of use of less safe and outdated techniques by providers.

1.2. Availability of medical abortion

Women have tried to use medicines and herbs to terminate their pregnancies since recorded history. A wide range of abortion providers, including midwives, homeopaths, and self designated healers have been providing potions and pills that would "bring on the menses" (10). However, medical methods of the past perhaps had doubtful efficacy, and the more effective methods till the 1970s were essentially surgical. During 19th century and the first half of 20th century, a widespread culture of illegal abortion provision was prevalent, with resultant high rates of complications and death. Safe abortions by skilled persons were available only to some persons. Technical advances in the field of abortion occurred only around second half of the 20th century, when abortion started becoming legal in United States. These technological advances included the advent of the vacuum aspirator, cervical anesthesia methods and the Karman cannula (10). These advances meant that abortion could also be provided in the clinics and not only in hospitals. However, these safer methods of surgical abortion provision were not in widespread use in developing countries till about 2 decades ago, where instead, the older method of dilatation and curettage continued to dominate. Reliance on dilatation and curettage meant that abortion could not be provided outside hospitals or large urban clinics.

It was only in 1980s that more effective drugs to terminate pregnancy were discovered and medical abortion developed through clinical trials. Medical abortion was first approved in the late 1980s in China and France (up to 42 days), followed in the early 1990s by the UK and Sweden (up to 63 days and in the second trimester), and is considered to be the most important advance in the reproductive health technology after the discovery of oral contraceptives (11). It was approved in the US in 2000.

In countries in which abortion is illegal or highly restrictive, medical abortion provides women with a much safer method to terminate their pregnancies compared with unsafe surgical abortion. In countries in which abortion is legal, it provides women a safer, non-invasive and highly acceptable alternative to terminate pregnancy, with greater control over the process (12). The provision of medical abortion does not need a provider skilled in surgical evacuation or anesthesia, and hence it is more amenable to provision in primary care settings.

Mifepristone is registered in about 60 countries, and misoprostol is registered in more than 100 countries (13). It has been estimated that increased use of medical abortion, or misoprostol alone could significantly reduce maternal mortality due to abortion in low resource settings (14, 15). Between 1990 and 2008, the number of deaths due to unsafe abortion declined by one third, from 69,000 to 47,000 (16). The case-fatality rate of unsafe

abortion has also declined globally, likely due to use of safer techniques even by legally unregistered providers, including wider use of medical abortion drugs.

1.3. Abortion in India

In India, abortion was legalized through the Medical Termination of Pregnancy (MTP) Act, 1971, to reduce the maternal mortality linked to abortion complications. The MTP Rules and Regulations, 1975 define criteria and procedures for approval of an abortion facility, consent, record keeping, reporting, etc. (17). The Act allows termination of pregnancy up to 20 gestational weeks. Although it does not allow abortion on request, the Act allows abortions on fairly liberal grounds including grave risk to the physical or mental health of the woman, when pregnancy results from contraceptive failure, rape, fetal impairment, or to save a woman's life. With an aim to increase the number of certified facilities, amendments were made in the Act in 2002 and 2003, that allowed devolution of regulation to district level, and rationalization of requirements for first trimester facilities and medical abortion services (18).

However, despite abortion being legal for over four decades, unsafe abortions continue in India, contributing to about 8% of maternal deaths (19). In their attempt to obtain safe abortion services, women face multiple cultural, financial and geographic barriers (20) (Figure 1.1). Further, even where formal abortion providers are available, some other reasons may deter women from approaching them. For example, service providers might not offer a choice between medical and surgical abortion, might insist on specific contraceptives, might demand husband's consent or follow service delivery protocols that require multiple visits to the clinic (21). Important barriers to safe abortions in India have been outlined below.

1. Uneven distribution of safe abortion facilities: A facility survey by Government of India in 1999 reported that only 4% of primary health centres provided Medical Termination of Pregnancy (MTP) services. Data from a situational analysis study in Rajasthan showed that the distribution of safe abortion facilities was uneven between districts- 83% facilities were concentrated in nine districts with 38% of state population, and 17% facilities were spread over 22 districts with 62% population (22). Even within districts, most abortion facilities are concentrated in urban areas, with almost no abortion facilities in rural areas. Similar results have been reported from other states of India (23).

In rural areas of India, where nearly 70% of India's population resides, seeking safe abortion often means going to a distant clinic, spending the entire day in travel, asking someone to accompany them to the unfamiliar city, making arrangements for childcare and housework, and gathering money. This in turn often attracts the attention of family members and neighbours and hence reduces confidentiality. In a service delivery intervention in rural Rajasthan, a followup of women who were referred to the city for abortion showed that 80% women did not go to the urban facility, and instead either continued with the pregnancy or went to local untrained providers (24).

2. Lack of choice between surgical and medical abortion: Early first trimester medical abortion has been recognised as a safe and effective method for induced abortion (25, 26). It however remains inaccessible for many women in primary care settings. There is increasing evidence that when women have a choice between medical and surgical abortion, women overwhelmingly prefer medical abortion (27-33). One of the reasons for preference of medical abortion could be linked to the fear of surgery in low resource settings (34), possibly a result of higher rates of surgical complications due to poor adherence to standards and poorly skilled staff. Medical abortion was approved in India

in 2002, but is still not widely accessible through its primary care system (35). Further, many facilities don't offer a choice between surgical and medical abortion. A recent survey in Madhya Pradesh has reported that medical abortion services were not routinely available at a majority of public health facilities (36). Hence many women desiring to terminate their pregnancies by pills don't approach formal facilities, fearing that they would have to undergo a surgical procedure.

3. Lack of information on safe abortion facilities: While other health services such as delivery, contraception etc. are often publicised by the health system, there is almost no publicity of safe abortion services. A study in Bihar and Jharkhand, two eastern states of India, showed that 83% women had not been exposed to any information regarding abortion, and of those who had information, only 4% each had received any information through mass media or health providers (37). The study also showed that less than half the women were aware of a safe abortion facility, while majority believed that abortion was illegal. Since all facilities don't offer a choice of medical abortion, women who have heard of and hence desire medical methods may not be aware of which facilities to visit. Although front-line health workers or community health workers are meant to provide information regarding safe abortion, women may be reluctant to approach them because of fear of lack of confidentiality (38).

4. Service delivery protocols:

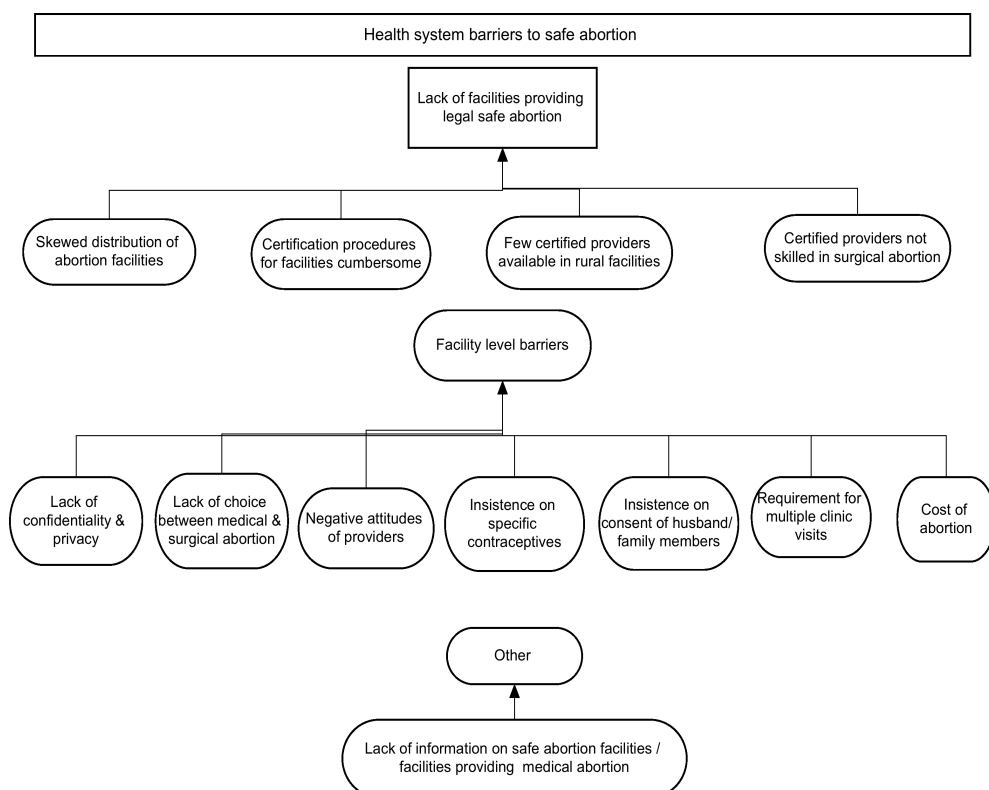
- a. Multiple clinic visits: An important factor influencing access and acceptability of medical abortion among women is the required number of clinical visits (39, 40). Earlier service guidelines required that women make three visits to the clinic for medical abortion (41, 42). Women living in rural areas of low resource settings, find it difficult to make repeated clinic visits. For making multiple visits, women may have to arrange for childcare, housework, and spend money and long hours on travel. Absence for many hours may result in lost wages. Additionally, for repeated absences from home, women need to seek permission from family members and this reduces confidentiality.

In recent years, evidence has emerged that the second clinic visit (for misoprostol) and 3rd clinic visit (for follow-up) after early medical abortion are not necessary (43). Yet, several clinical guidelines for medical abortion require women to make at least 2 or 3 visits for medical abortion (41, 42)

- b. Consent procedures: Several providers insist on procedures that are not required by law, e.g. the Indian law requires only a woman's consent (if she is above 18 years). However, many providers insist that women bring a family member or husband along and take their consent too (22, 23). In a patriarchal society, this poses a barrier to women who may not have informed other family members. Even if the decision to abort is taken after consultation between husband and wife, as it often is, it might not be convenient for a husband to accompany his wife, due to his work routine and high rates of short term out-migration.
- c. Insistence on sterilization or intrauterine device: Many providers, especially those in public health facilities, provide abortion on the condition that women adopt provider controlled contraceptives -- either sterilization or a copper intrauterine device (IUD), along with abortion (44, 45). Women who wish to use other contraceptives are denied abortion services, hence they avoid visiting public health facilities (46). In fact, because sterilization or intrauterine device cannot be provided at the time of medical abortion, this is one of the reasons that some providers prefer to provide only surgical abortion.

- d. Privacy and confidentiality: Many facilities do not make overt arrangements to provide services in a private and confidential manner, or women might be concerned that the matter will not be kept confidential (47).
- e. Cost: The cost of abortion is often high, both at public and private health facilities (48, 49). Although the cost of Mifepristone – Misoprostol pills is low (approx. 0.9 USD), women are often charged anywhere between Rs 2000 to RS 10000 per abortion (30- 150 USD). Given that the estimated average monthly wages for the country is around 215 USD (50), these amounts can prevent women from seeking formal and safe abortion. Many providers may routinely conduct ultrasounds before abortion, and at the time of followup visit, which further increases the cost.

Figure 1.1. Barriers to safe abortion



1.4. Number of visits required for medical abortion

Until recently, most service delivery routines recommended three or four clinic visits for early medical abortion – one for mifepristone administration, second for misoprostol administration, and third for follow-up. In some countries, another visit for consultation is a routine, while the mifepristone is given on the second visit (51), thus a woman desiring medical abortion has to make four visits to the clinic. These requirements can reduce women's access to medical abortion (40).

Home use of misoprostol

Findings from several studies confirm that home use of misoprostol is safe and effective. It is also highly acceptable to women, and when given a choice, women have expressed strong preference for it (52-60). World Health Organization has recommended that allowing women to use misoprostol at home is safe for an early medical abortion with consideration that women understand when and how to use the misoprostol tablets (43). Home use of misoprostol can reduce the need to make a clinic visit lasting several hours for the administration of misoprostol and expulsion of the pregnancy. Therefore, allowing women to use misoprostol at home can potentially increase access to medical abortion (39).

Although in several countries, women are given a choice regarding using misoprostol at home or clinic, in some other countries, clinic administration of misoprostol remains a standard practice (51). Some other service delivery guidelines allow home use of misoprostol only on selected conditions e.g. access to 24-hour emergency services or living within certain distance from the clinic (41, 42, 61).

Irrespective of guidelines, many providers have exaggerated concerns about the side effects of medical abortion (45), and are often reluctant about advising misoprostol for home use to rural women, who often may not own a phone or personal mode of transport (12, 62). Several studies provide evidence regarding safety and acceptability of home use of misoprostol. However, majority of them have been conducted in high-income countries (52, 53, 58, 63), or in the urban hospitals of developing countries (54-57, 59). Very few studies have documented outcomes of home administration of misoprostol among rural women with low education levels.

Studies on women's reasons for choosing home misoprostol or their experiences, largely from high income countries, have shown that women value home use mainly because it provides them more autonomy, privacy and personal integrity. Furthermore, women have a better experience because of comfort of being at home and emotional support from the family (53, 64-67). A review of qualitative studies on women's experiences of home based medical abortion from high income countries has concluded that women appreciate familiar surroundings, privacy and not having to encounter strangers (68).

Follow-up visit after medical abortion

It has been standard practice to call women for a follow-up visit after early medical abortion. The purpose of a follow-up visit after medical abortion is to ensure that pregnancy has successfully terminated, to detect complications and to start contraceptives. However, when faced with post-abortion complications, women often do not wait till routine follow-up visit, (69) and seek care when they have acute symptoms. Further, contraceptives needs to be started as early as possible after mifepristone, and need not wait till a follow-up visit, since the rates of follow-up are low, and women are at risk of another pregnancy. Hence the most important reason for a routine follow-up after medical abortion is to detect on-going pregnancy (70, 71). Most service delivery guidelines

recommend that women return at 2-3 weeks for a follow-up visit (42, 51, 61, 72). Some service delivery guidelines even mention that women who cannot return for a follow-up visit should not be offered medical abortion.

The World Health Organization's technical and policy guidelines recommend that a clinic follow-up visit is not medically necessary after early medical abortion using mifepristone and misoprostol (26). In recent years, studies have explored different ways to substitute a clinic follow-up visit after medical abortion. They have included use of a low-sensitivity urine pregnancy test (LSUP), semi-quantitative urine pregnancy test (SQPT) or a high sensitivity pregnancy test. Most of these methods have also included follow up by a telephone call or through text message or internet-based questionnaire (73-81).

A systematic review has concluded that alternatives to routine in-person follow-up visits after medical abortion are accurate in detecting on-going pregnancies (82). However, women enrolled in most of these studies had educated women as participants, often owning phone or access to internet. There is no evidence to show that women with low educational levels can conduct and interpret their pregnancy test at home. Hence there is a need to assess whether self-assessment of outcome of medical abortion is an effective and feasible approach in low resource settings. Further, for self-assessment to be implemented in the health system, there is a need to understand the experiences and perceptions of women regarding self-assessment.

2. AIMS OF THE STUDY

The overall aim of this thesis is to increase access to safe abortion in low resource settings. Medical abortion is amenable to provision at primary care settings, and is women's preferred method of abortion. However, current service delivery protocols require that women make two or three visits for medical abortion, and this becomes a barrier for women living in low resource settings, with limited autonomy and heavy workloads. Home use of misoprostol, which reduces the need for a visit lasting many hours, is a standard protocol in many settings, while knowledge of its efficacy and safety in low resource settings has been limited. For assessing the outcome of early medical abortion, self-assessment approaches have been found to be accurate and feasible in high resource settings. Investigating the efficacy, safety, acceptability and feasibility of self-assessment in low resource settings is critical to reducing the requirement of a clinic follow-up visit after early medical abortion.

The specific aims of this thesis were:

- To assess whether an approach of home assessment of medical abortion outcome is as effective in detecting ongoing pregnancy as a clinic follow-up visit in a low resource setting
- To investigate women's acceptability of home-assessment after early medical abortion
- To assess the efficacy, safety and acceptability of home administration of misoprostol as compared to clinic use of misoprostol in a low resource setting, and
- To explore women's experiences and perceptions of home use of misoprostol and of self-assessment of the outcome of early medical abortion

3. METHODS

All studies included in this thesis were conducted in a primary care setting of south Rajasthan, India, in partnership with Action Research and Training for Health (ARTH), a non-government organization.

3.1 Thesis overview

The four papers in this thesis are based on two studies – papers, I, II and III were based on one randomised controlled trial, while paper IV was based on a qualitative study. An overview of research methods, designs and data collection methods has been presented in the table below.

Table 3.1. Overview of study methods

Paper	Objectives	Design/ area	Methods	Outcomes
I	To assess whether an approach of home assessment of medical abortion outcome is as effective in detecting on-going pregnancy as a clinic follow-up visit	Randomised controlled non-inferiority trial / 6 health centres in Rajasthan, India	Random allocation of women seeking early medical abortion either to routine clinic follow-up or to home-assessment. Women contacted at 10-15 days.	Primary: 1. Efficacy Secondary: 2. Safety 3. Feasibility 4. Reasons for interim visits
II	To assess the efficacy, safety and acceptability of home administration of misoprostol for early medical abortion	Secondary analysis of randomized controlled trial (mentioned in I above)	Allocation of women seeking early medical abortion either to home or clinic administration of misoprostol. Follow-up contact after 10-15 days.	1. Efficacy 2. Safety 3. Acceptability
III	To investigate women's acceptability of home-assessment of early medical abortion	Secondary outcome analysis of randomized controlled trial (mentioned in I above)	Same as I above	1. Acceptability (future preference of follow-up) 2. Overall satisfaction 3. Expectations 4. Comparison with previous abortion experiences
IV	To explore women's experiences and perceptions of simplified medical abortion	Community based qualitative study / Rajasthan, India	In-depth interviews with 20 women having early medical abortion, who used misoprostol at home and conducted self-assessment	Women's experiences and perceptions with home misoprostol & self-assessment

3.2. Study setting

All studies included in this thesis were conducted in a primary care setting of south Rajasthan, India. Rajasthan state is located in the northwest of India (Figure 3.1), and has a population of about 68 million people, 75% of which is rural (83).

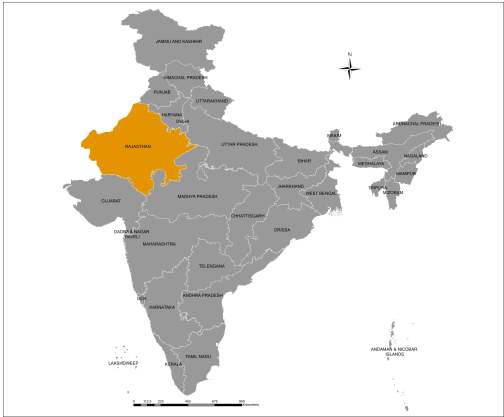


Figure 3.1: India and Rajasthan

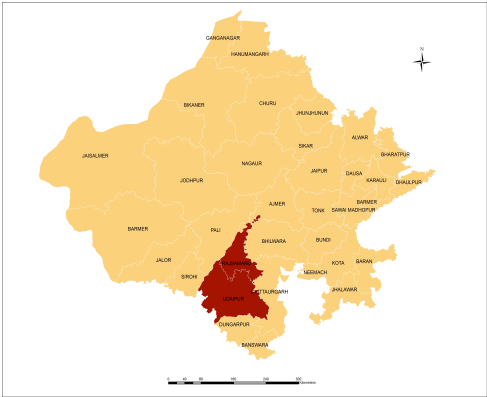


Figure 3.2: Rajasthan and the study districts

Rajasthan is characterized by low levels of female literacy than average, and poor health indicators. Health and demographic indicators for Rajasthan have been shown in table 3.2.

Table 3.2: Demographic and health indicators of Rajasthan and India

	Rajasthan	India	Source
Total population (millions)	68.6 millions	1211 millions	Census, 2011 (84)
Rural (%)	75.1	68.8	Census, 2011(84)
Literacy rate (%)	52.7	65.5	Census, 2011(84)
Maternal mortality ratio	244	167	SRS 2011-13 (85)
Total fertility rate	2.9	2.4	SRS, 2012 (86)
Scheduled caste and tribe	29.6	25.2	Census, 2011 (87)
Sex ratio at birth	875	906	SRS, 2007-9 (84)
Crude birth rate	25.6	21.4	SRS, 2013 (84)

The studies were conducted in two districts in south Rajasthan (Figure 3.2). In these districts, only a minority of rural households owned a phone or motorised transport in 2007-08 (Table 3.3). Only one in six households had access to a toilet facility in 2007-08 (88). The availability of piped water and cooking gas connection was also extremely low in rural areas, which influences women’s workload.

Within these two districts, the studies were conducted in three rural and three urban health centres. Of these, four health centres were operated by a non-profit organisation, Action Research & Training for Health (ARTH), while two urban clinics were managed by private obstetricians. All these clinics provided a range of reproductive and child health services. The abortion services in all clinics were provided by specialists in obstetrics & gynecology. The three rural clinics were located 20 to 50 km from the district headquarters. Around these rural clinics, ARTH operates a field programme in a 68000 population, where health volunteers and social animators carry out certain health interventions.

Table 3.3: Characteristics of study districts

	Udaipur district (89) Total % (rural%)	Rajsamand district (90) Total % (rural%)
Have electricity connection	47.2 (37.2)	74.0 (69.9)
Have access to toilet facility	15.5 (2.5)	16.6 (5.6)
Use piped drinking water	13.7 (3.2)	29.5 (20.1)
Use LPG for cooking	13.9 (2.1)	13.0 (2.8)
Live in a pucca house	22.6 (10.6)	41.9 (34.1)
Own a television	23.1 (11.7)	29.2 (20.2)
Have a mobile phone	26.3 (16.0)	38.5 (32.8)
Have a motorized transport	19.4 (10.6)	20.7 (14.1)

3.3. Study design

3.3.1 Randomised controlled trial (Papers I, II and III)

This study was a randomised controlled, non-inferiority trial, comparing two methods of follow-up after early medical abortion - routine clinic follow-up and home-assessment.

Study participants

A total of 731 women were recruited between 23 April 2013 and 15 May 2014, among women with unwanted pregnancies opting for medical abortion. Inclusion criteria were gestational age up to 9 weeks, residence in an area where follow-up was possible or access to a phone on which they could talk privately, and willing to have a follow-up after two weeks, by either home-visit or phone call. Exclusion criteria were any contraindication to medical abortion, age less than 18 years or haemoglobin value of less than 85 g/dl.

Women with haemoglobin below 85g/dl were excluded from the study because heavy bleeding is a known side effect of medical abortion, and extra care is needed in providing medical abortion to women with moderate or severe anemia (91). However, these women were provided medical abortion service, but with extra follow-up visits. This is in accordance with national guidelines (41), since anemia is a common public health problem in India. The hemoglobin was assessed using Sahli's method, which is a commonly used method and clinical standard in primary care settings in India (92).

Assessment of eligibility and assigning place of misoprostol

All women with unwanted pregnancy were first assessed by doctors, for counselling and eligibility for medical abortion. The doctors assessed eligibility and gestational age based on a clinical checklist and bimanual examination (93). Comparison of bimanual examination with ultrasound for gestational dating has shown it be a reasonably accurate method of gestational dating (93) (94). Furthermore, since most of the primary care facilities in India don't have facilities for ultrasound, provision of safe abortion services is critically dependent on bimanual examination for gestational dating.

For the purpose of assigning the place of misoprostol administration, women were not randomised (Figure 4.1). The decision regarding place of misoprostol use was first made by clinicians based on clinic's standard protocols and consideration to woman's ability to reach a health facility within reasonable time in the event of a symptom requiring care. If clinicians had no concerns, they gave a choice to women regarding home or clinic use of misoprostol.

After receiving mifepristone (oral tablet, 200 mg) (Khushi MT kit, manufactured by PHSI), women in the home misoprostol group were given 4 tablets of misoprostol (200 mcg each) and were given instructions on administering it after two days. They were offered

painkillers (Ibuprofen tablets), and were handed over an instruction sheet in local language (hindi). They were advised to contact the clinic if they had any concerns or adverse symptoms. Clinics' standard procedures determined the route of misoprostol administration- in majority it was sublingual, while for some cases, it was vaginal or oral (for gestations up to 7 weeks).

Women in the clinic misoprostol group were asked to return to the clinic after 2 days, where they were asked to stay for about 4-6 hours after misoprostol administration. However, if women insisted, they were allowed to go back earlier. During the clinic stay, nurse midwives observed the women and recorded important information regarding side effects, number of hours spent in the clinic, abortion outcome, bleeding and any need for pain mediation.

Randomisation and study procedures

Women were randomly assigned to either clinic follow-up or home-assessment after receiving mifepristone (200 mg) orally. Blinding was not possible since instructions regarding place of follow-up had to be given. The two arms were as follows:

Arms	Assigned interventions
No intervention: Controls (Routine follow-up at the clinic 10-14 days after Mifepristone)	
Self-assessment: Intervention	Self-assessment of complete abortion using a low sensitivity urine pregnancy test. Follow-up interview at home or through telephone 2 weeks later by research assistant to evaluate success of procedure.

Women in the clinic follow-up group were asked to return to the clinic 10-14 days later. A travel reimbursement of Rs 200 (=3.3 USD) was offered to women in this group, to ensure better compliance with clinic follow-up, and reduce the loss to follow-up. This was considered necessary since most service providers in the area reported that the proportion of women returning for clinic follow-up visits is less than 50%. In terms of minimum daily wage, this is equivalent to approximately one day of daily wage of an unskilled laborer.

A low sensitivity pregnancy test (with a S-hCG cutoff of 5 IU/ L and 1000 IU/L) was provided to the women in the home assessment group, along with a pictorial instruction sheet (95). They were given detailed instructions on how to do the test 10-14 days later. Specifically, they were instructed to put 2 drops of urine in each of the two pits provided on the pregnancy test card, wait for 10 minutes, and see the number of lines. Due to low literacy levels, women were guided that four lines indicated a positive test (and undesirable result), while one to three lines indicated a negative test (desirable result). They were instructed that for a positive test, they should go back to the clinic, while for a negative test, they need not go back to the clinic unless they had some other concerns or questions.

Follow-up contacts

Women in the home-assessment group were visited at their homes, or were contacted through a phone call (if they had a personal phone), at day 12-15 after mifepristone, for a follow up contact. A few women with lack of privacy at home opted to come to the clinic after doing the test to inform the outcome of their abortion and result of test. Three attempts were made to contact women, up to 30 days after mifepristone. If this succeeded, women were considered complete follow-up and the whole standardized follow-up questionnaire

was administered to record the outcome of abortion, side effects, experiences and acceptability.

Women whose pregnancy tests results were positive or 'not sure', or had symptoms suggestive of complications were advised to go back to the clinic. Those who had not done the test by the time of follow-up contact, were reminded to do the test.

Women in the clinic follow-up group returned to the clinic between day 10-14 and were examined by nurse midwives to assess the outcome of abortion. A low sensitivity pregnancy test was also done for them. Women were offered contraception, if they had not started it till then, and those who opted to start a contraceptive were provided it. Research assistants administered the standardized questionnaire.

The main outcome was complete abortion without continuing pregnancy or the need for surgical intervention or additional mifepristone/misoprostol. Women diagnosed with incomplete abortion, were treated either with surgical intervention (manual vacuum aspiration) or using additional misoprostol in our study. Misoprostol is used as a standard treatment for incomplete abortion (43, 96, 97), hence it was used as an alternative option to treat women who did not want a surgical evacuation. If diagnosed as an ongoing pregnancy, they could be provided MVA or repeat mifepristone and misoprostol.

If successful contact could still not be established with the woman till 30 days after mifepristone, women were contacted through phone calls or visits to as large extent as possible, and this could go beyond 30 days. This was also done for women who did not return to the clinic for further check-up after a positive or 'not sure' LSUP test. However, these contacts were made only to inquire about the abortion outcome and major adverse events (hospitalisation, IV fluids, blood transfusion or surgical intervention).

Additionally, the clinical records retained at the clinics were reviewed for those who came for interim visits. The clinical records are maintained in meticulous manner across the six health centres.

The study is registered with ClinicalTrials.gov number, NCT01827995. One interim analysis was done halfway and safety and efficacy was reviewed by a data and safety monitoring board.

Primary and secondary outcomes

Primary outcome:

- Efficacy: Complete abortion without continuing pregnancy or the need for surgical intervention or additional mifepristone/misoprostol.

Secondary outcomes:

- Safety: Absence of adverse events requiring; hospitalization, blood transfusion, intravenous fluids or intravenous antibiotics
- Feasibility: Ability of women to perform low-sensitivity pregnancy test on their own, to determine their outcome of abortion
- Interim visits: Visits by women between the day of misoprostol administration and scheduled follow-up contact at the clinic or by the research assistant
- Acceptability of home use of misoprostol: satisfaction with the procedure, comparison with previous abortion experience, preference for choosing the same location for misoprostol administration in the event of a future abortion, and advice to sister / friend regarding place of misoprostol.

- Acceptability of the home assessment as compared to clinic follow-up visit: overall satisfaction, women's comparison with previous abortion experiences when applicable, preference for place of follow-up location (for a future abortion, if needed).

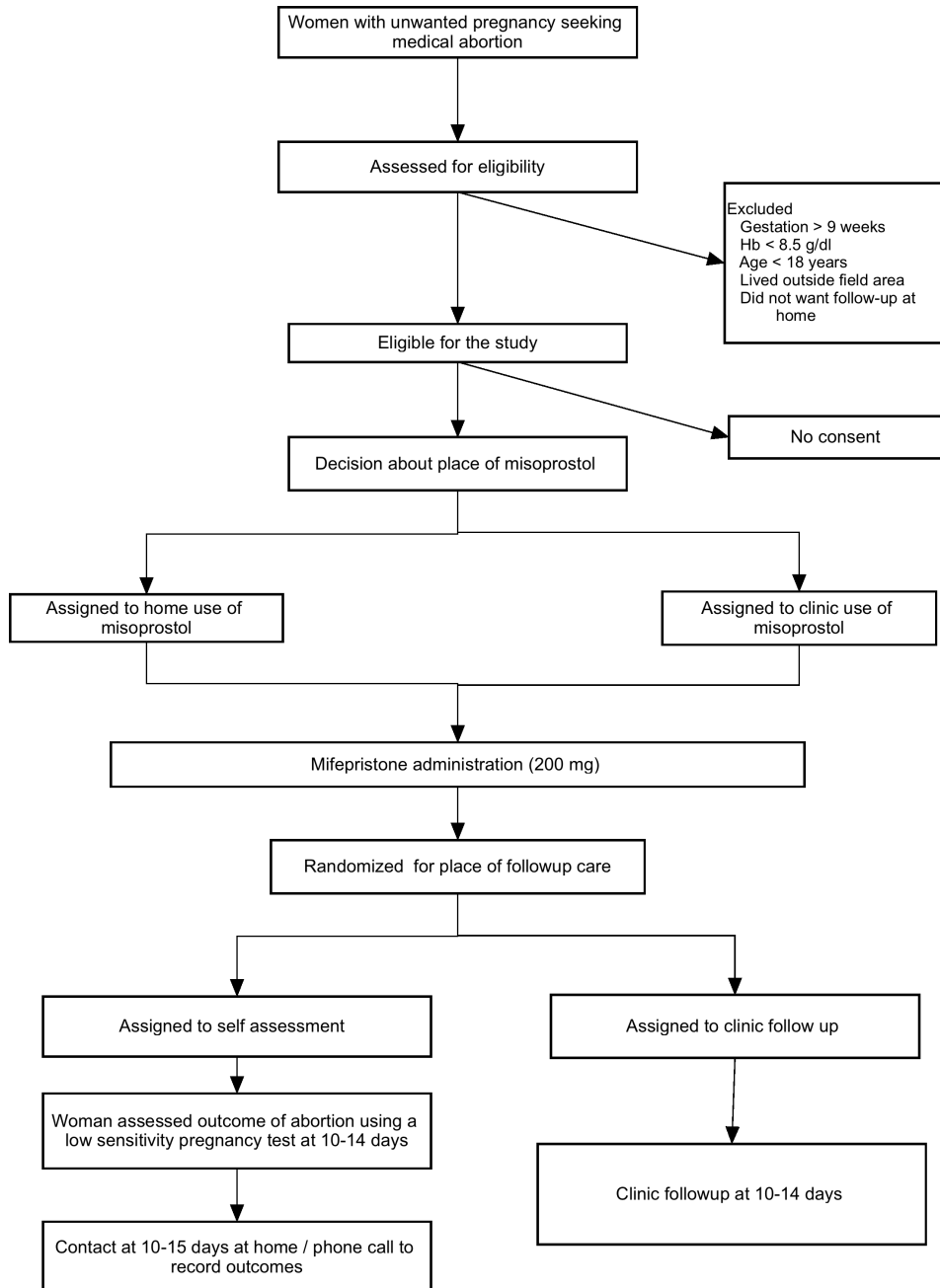


Figure 3.3: Study flow

Statistical methods and analysis

For testing if the approach of self (home) assessment of outcome of abortion was non-inferior to the clinic follow-up, a non-inferiority margin of 5% points was set up as an absolute difference between groups in the rate of unsuccessful abortions. The rate of complete abortion with mifepristone and misoprostol reported in practice is 95%, (71), hence, we aimed to prove that rate of complete abortion is at most 5% lower in the home-assessment group as compared to the clinic follow-up group. To establish non-inferiority of the intervention, a sample size of 596 women was calculated to be sufficient (with a two sided 95% CI and 80% power). To allow for 20% women to be lost to follow-up, it was planned to recruit 716 women.

For analysis and interpretation, we identified two study populations: intention to treat (ITT) population and evaluable subjects (ES) population. ITT population included all randomly assigned women as per the random list, irrespective of actual allocation. Evaluable subjects (ES) population included women as actually allocated to the study groups, who followed the clinical protocol (who took both mifepristone & misoprostol), and had a reported primary outcome (through scheduled follow-up contacts / later contacts / records of interim visits). Our analysis and interpretation of the primary outcome is based on the evaluable subjects population.

Information on primary outcome was missing for 18 women in ITT population, hence two sensitivity analyses were done where the missing values were imputed: in one analysis, it was assumed that all women with missing values had successful abortions and in another, all women with missing values were assumed to have unsuccessful abortions.

For the purpose of comparisons related to acceptability outcomes (paper II & III), women having a scheduled contact in the randomised controlled trial were included.

The focus of paper II was the place of misoprostol administration – it compared women with home and clinic administration of misoprostol. This was a secondary analysis of the randomized controlled trial (RCT) covered in study I (95).

SPSS (version 22) and in R (version 3.0.3) were used for calculations. To present categorical variables, descriptive statistics were used and compared using Chi-2. Continuous data was presented as mean (SD) and compared using t-test. P-values below 0.05 were considered statistically significant. Multivariate logistic regression analysis was used to compare selected outcomes. Odds ratios (OR) for the acceptability variables were derived using logistic regression with different explanatory variables. Where OR were significant, adjusted odds ratios (AOR) were derived with multivariate logistic regression.

3.3.2. Qualitative study (paper IV)

A sample of women who were assigned to use misoprostol at home and to carry out self-assessment of the outcomes of their abortion was selected for in-depth interviews. To ensure diversity of respondents, women from both rural and urban areas, belonging to different caste (socio-economic) groups, and literacy levels were purposively selected. Four to 6 weeks after mifepristone, women were approached by a research assistant to ask whether they were willing to participate in an interview. Although we tried to interview a diverse group of women, it also depended on whether they appeared to be expressive, and were

willing to participate in an interview. We also included women who had unsuccessful abortions. An in-depth interview guide was developed in Hindi, pilot tested and then finalized.

To ensure better rigor, sensitivity and probing, all the interviews were personally conducted by the first author, who has many years of experience of working on sexual & reproductive health issues in this context, high level of sensitivity on the issues being researched, and fluency of local dialect as well as english. A local female field worker or research assistant, with experience of working in this area assisted to take notes and to record the interviews.

Initial interviews were with rural women, and the first few interviews were conducted in women's villages – in their homes or farms. However, at points, there were interruptions from family and neighbors, which could compromise confidentiality, or led to discontinuation of interviews. Hence, majority of subsequent interviews were held at the health centres, so that participants could give responses freely, and were not concerned about others listening on them. A few interviews with urban women were conducted at their homes, who lived in nuclear families and had better privacy at homes. In health centre too, we ensured a private place and not the outpatient room. Each interview lasted between 45- 60 minutes.

An iterative process was used during the study, the data was reviewed frequently after every 2-3 interviews, and additional new questions were added if a new finding emerged in earlier interviews. The results were discussed frequently with the research team to modify sampling strategy. After completing interviews with twenty women, we perceived that there was not much new incremental information, hence it was decided to not continue with further interviews (98). Interviews were conducted between August 2013 to March 2014. Data from two incomplete interviews was not used.

All interviews were transcribed verbatim into the local language (Mewari and Hindi dialect). After multiple readings of transcripts, a list of codes was developed, and the patterns of commonalities and differences in the data were identified. A final report was prepared in English that included translation of important findings and illustrative quotes.

3.4. Ethical considerations

Women participating in both the studies consented to participate in the studies. For the randomised controlled trial, the consent was sought in two stages- those who said they were unwilling to have a female research assistant make a home visit or phone call to their houses were excluded in first stage (at the time of assessment of eligibility). Further, eligible women were again explained the study and asked if they were willing to participate in the study. Written informed consent was sought from all women in the local language. For participants who could not read and write, all information from the participant information sheet was read out to them in the presence of a witness and a thumb impression was taken if they consented to participant. For participants of the qualitative study, written consent was also sought for tape recording.

The most important ethical consideration was confidentiality. Strict attention was paid to confidentiality during home visits and phone calls during follow-up contacts for the RCT. All forms for data entry had codes, and the data was anonymised during analysis and transfer.

To ensure confidentiality at the time of in-depth interviews, especially when done in women's houses, at least one woman who had not had a recent abortion, was also approached in the same village / hamlet, in order to camouflage the visit. If a family member or neighbor came to the house during the interviews, the topic of conversation was changed by the interviewer. If it appeared difficult to continue with the interview, it was discontinued.

For any side effects or unsuccessful abortions, study participants were provided free treatment. For those who needed referral, free transport and referral was arranged, and the cost of treatment at referral hospital were borne by the project.

Institutional Ethics Committee of Action Research & Training for Health (ARTH), Udaipur approved both the studies. Additionally, the Regional Ethics Committee of Karolinska Institute reviewed the trial.

4. RESULTS

4.1 Study I: Randomised controlled trial

The results of this study can be categorised into: “Background characteristics of participants”, “Comparison of self-assessment and clinic follow-up”, “Comparison of home and clinic use of misoprostol”, and “Comparison of women making one and three visits for medical abortion”.

4.1.1. Background characteristics of participants

Seven hundred and thirty one women participated in the trial. The mean age was 27 years. Nearly three fourths (73%) of women lived resided in a rural area, and 55% were illiterate (Figure 4.1). More than half belonged to ‘scheduled caste or tribe’, communities that tend to be socio-economically more disadvantaged. All except 5% had given birth in the past, and one third had undergone a prior induced abortion.

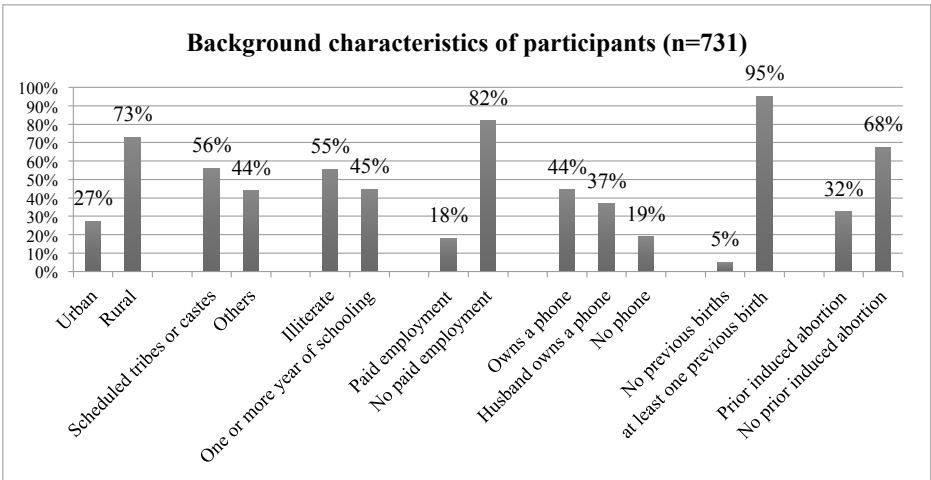


Figure 4.1: Background socio-demographic characteristics

4.1.2. Comparison of self-assessment and clinic follow-up (paper I & III)

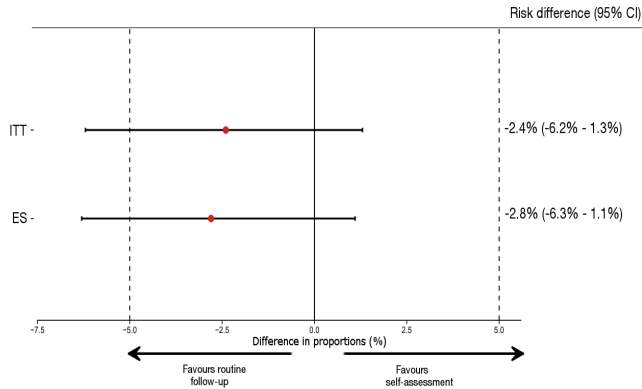
Eighteen women were lost to follow-up and 13 women did not use misoprostol, hence our evaluable subjects population (for analysis of primary outcome) was 700 women. Scheduled follow-up was done for 623 women- 274 (78%) women in the clinic follow-up group and 349 (92%) women in the home assessment group. Outcomes on efficacy and safety between the two groups were compared for all women in ES population, while feasibility and acceptability outcomes were analysed for 623 women.

4.1.2.1. Efficacy of self-assessment

For evaluable subjects (ES) population, overall rates of complete abortion, incomplete abortion and on-going pregnancy were 94.3%, 4.7% and 1.0%, respectively. The complete

abortion rates were 93% in the clinic follow-up group and 95% in the home-assessment group. The risk difference for complete abortion rate between the clinic follow-up group and home-assessment group have been depicted in Figure 4.2, and was within the non-inferiority margin (5%) for both ITT and ES analyses (95). The rates of surgical intervention or additional mifepristone/ misoprostol were not statistically significant between the two groups.

Figure 4.2. Risk difference between groups for the primary outcome
ITT= intention to treat, ES= Evaluable subjects



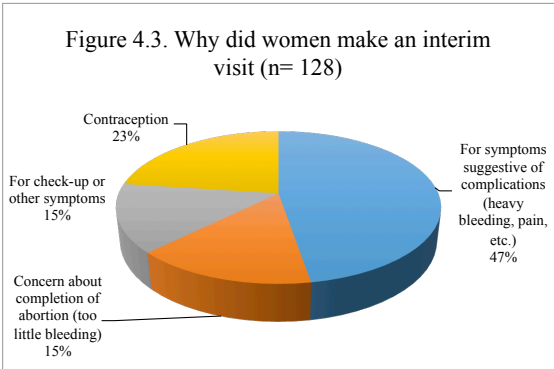
On-going pregnancies were detected in 7 women in the ES population (5 and 2 in clinic follow-up group and home assessment group respectively). More than half of the on-going pregnancies (4 out of 7) and incomplete abortions (21 out of 33) were detected through interim visits, rather than through scheduled visits. Of these 7 ongoing pregnancies, one woman continued with her pregnancy, while 6 women obtained an abortion (5 had a surgical termination and one had repeat mifepristone & misoprostol). Of 33 women with incomplete abortions, 26 underwent surgical intervention, while 7 were treated through additional misoprostol.

4.1.2.2. Safety of self-assessment

The rates of adverse events were 0.3% in both the groups- one woman in each group suffered haemorrhage requiring blood transfusion or intravenous fluids. Of 623 women who had a scheduled follow-up, 95 (15%) women reported other side effects (heavy bleeding, severe abdominal pain, fever, or feeling unwell).

4.1.2.3. Interim visits and their reasons

18% of all women sought care through interim visits, made between the day of misoprostol use and scheduled contact. The most important reasons for making an



unscheduled visit included symptoms suggestive of complications and desire to start contraception (Figure 4.3). Interestingly, almost 15% of interim visits occurred because women were concerned about having too little bleeding or lack of expulsion.

4.1.2.4. Feasibility of self-assessment

Eighty percent women in the home-assessment group had conducted their low sensitivity pregnancy test on their own, 19% did it after being reminded, while 2 women did not do it at all. All except 2 % of those who did the LSUP test without reminders said that it was easy to use (95).

Of those who conducted their pregnancy test, 5% (15 women) had a positive test or were unsure of their result, while 95% had a negative test result. All those with a positive or 'unsure' result (n= 15) were instructed to return to the clinic. However, only 11 of them went to the clinic, and of them, one was diagnosed to have an on-going pregnancy, while 3 had incomplete abortions. Follow-up of the six women (included 2 who had not done their test at all, and 4 who had not followed up at the clinic after a positive or 'not sure' test result), showed that all had complete abortions. Among the 272 women with a negative test, 25 (9%) women had some symptoms or concerns at the time of contact at home or phone-call, for which research assistants referred them to the clinic. Only 10 of them complied and returned, and of these, one had an incomplete abortion.

The likelihood of doing a pregnancy test ion their own without reminder was lower for women who had suffered a side effect (p=0.002), lived in a rural area (p=0.007), belonged to a scheduled tribe or caste (p= 0.003), or were illiterate (p= 0.06) (Figure 4.4).

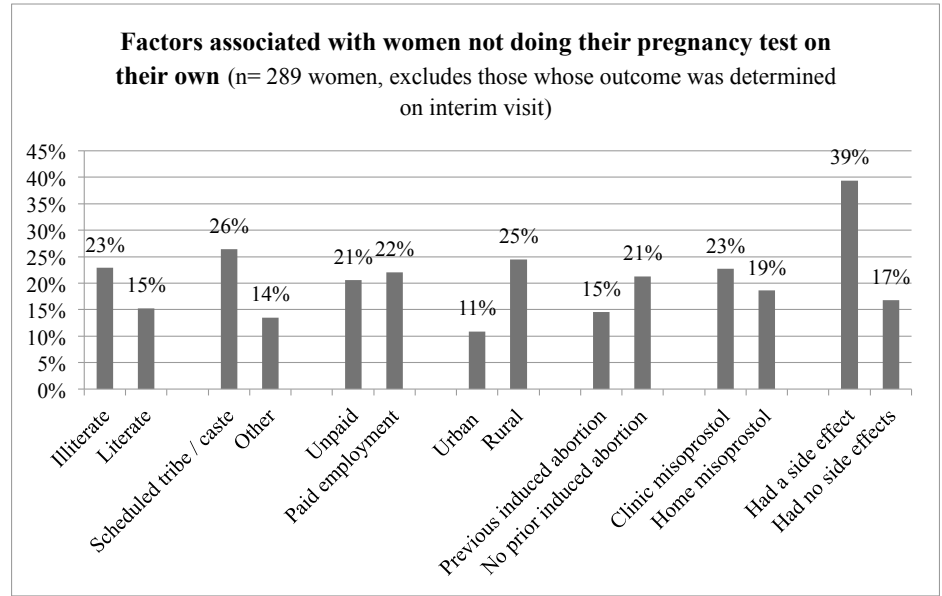


Figure 4.4: Factors associated with likelihood of women not doing low-sensitivity pregnancy test on their own

A total of 25% women in the self-assessment group made a visit to the clinic. Of these, 19.5% women made an interim visit for a symptom, or concern, or for initiating contraception. A minority of women (5.5%) in the self-assessment group made a visit after the scheduled contact, on which they reported a positive or doubtful pregnancy test, or a symptom, for which they were advised by the research assistants to visit the clinic.

In our study, for detection of ongoing pregnancies, the LSUP test showed sensitivity of 100% (95% CI- 19.7-100), specificity of 94.5% (95% CI- 92.1-96.2), negative predictive value of 100% (95% CI- 99.0-100), and positive predictive value 6.7% (95% CI- 1.2- 23.5).

4.1.2.5. Acceptability of self-assessment

Ninety-six percent women with scheduled follow-up were satisfied with their medical abortion experience. Rates of satisfaction were not different between the women with clinic follow-up and those conducting self-assessment (99).

The acceptability of home assessment was high. Greater proportions of women in the self-assessment group (82%) said they would prefer self-assessment in future, as compared with women in the clinic follow-up group, of who 70% said they would prefer clinic follow-up in the future ($p=0.001$). Overall, a majority of women with experience of previous induced abortion found the current experience better or same as before.

Higher levels of dissatisfaction were found among women having an unsuccessful abortion, those experiencing side-effects during misoprostol administration and those having to make an unscheduled visit to the clinic (99).

4.1.3. Comparison of home and clinic use of misoprostol

A secondary analysis of participants of the randomised controlled trial was done to compare women using misoprostol at home and in the clinic. Compared to home users, clinic users were more likely to have higher gestational age, greater number of children and live in a rural area (100). This could indicate greater provider willingness to allow home use of misoprostol for women with lower gestational ages, lower parity and those living in urban areas.

4.1.3.1. Compliance of use of misoprostol

Significantly greater proportion of women assigned to clinic use (14 women, 3.6%) did not misoprostol, as compared to those assigned to home use (2 women, 0.6%) who did not comply with use of misoprostol ($p=0.006$).

4.1.3.2. Abortion outcomes with home and clinic use of misoprostol

Data for abortion outcomes was available for 700 women who used misoprostol, and for 13 women who did not use misoprostol. The rates of ongoing pregnancy, incomplete abortion and surgical intervention were not significantly different among the women with clinic and home administration of misoprostol (Table 4.1) (100). Among the 13 women who did not use misoprostol, almost 30% had unsuccessful abortions.

Table 4.1: Outcome of medical abortion among clinic and home users of misoprostol

Outcomes among women who completed the protocol (mifepristone+ misoprostol)	Home use of misoprostol* (n=327)	Clinic use of misoprostol* (n= 373)	Total (n= 700)
• Complete abortion	308 (94.2%)	352 (94.4%)	660 (94.3%)
• On-going pregnancy	3 (0.9%)	4 (1.1%)	7 (1.0%)
• Incomplete abortion§	16 (4.9%)	17 (4.6%)	33 (4.7%)
Additional intervention			
• Surgical intervention	16 (4.9%)	15 (4.0%)	31 (4.4%)
• Additional mifepristone / misoprostol**	3 (0.9%)	5 (1.3%)	8 (1.1%)
Outcomes among those who did not use misoprostol	(n=2)	(n=11)	(n=13)
• Complete abortion	2 (100%)	7 (63.6%)	9 (69.2%)
• On-going pregnancy	0	3 (27.3%)	3 (23.1%)
• Incomplete abortion	0	1 (9.1%)	1 (7.7%)

* Based on actual place of misoprostol use

§ Incomplete abortions were defined as diagnosis of retained products of conception with need for surgical intervention or additional misoprostol.

** 'Additional misoprostol' was defined as use of misoprostol for treatment of incomplete abortion at least 2-3 days after the regular dose of misoprostol.

4.1.3.3. Time spent by women and side effects

On an average, clinic users of misoprostol spent a total of five extra hours (mean time spent on travel and clinic visit was 9 hours) as compared to home users (mean time spent on travel and clinic visit was 4 hours). Rural women spent higher time on travel than urban women.

One woman in each group developed haemorrhage (requiring intravenous fluids or blood transfusion). At two weeks, higher proportion of home users reported a side effect (18.6%), as compared to clinic users (12.6%). Even then, fewer women in home misoprostol group made an interim visits to the clinic as compared to clinic misoprostol group (16.2% and 21.9% respectively).

4.1.3.4. Misoprostol administration in the clinic

Four percent of women coming to the clinic for misoprostol reported that they had already expelled the products, and 17% reported that they had started bleeding before using misoprostol. The average duration of clinic stay was 5.2 hours for the rural women and 1.6 hours for urban women. More than two thirds women had expelled their products the time they left the clinic.

4.1.3.5. Misoprostol administration at home

Nearly three fourths of women had a companion present with them at the time of administration of misoprostol, commonly husbands, or family members from her own or the husband's family (Table 4.2). However, except for 3.8% women for whom no one was aware that she was taking misoprostol, in all other cases, some family member was aware of this. Overall, only 32% of them reported experiencing a side effect of misoprostol administration at home, of which the most common was severe abdominal pain reported by 11% women.

Table 4.2: Awareness of family members and side effects on day of home-use of misoprostol

Characteristics	Number (n= 290)	%
Who was present when she took home misoprostol		
○ Husband	140	48.3%
○ In laws	64	22.1%
○ Maternal relatives	20	6.9%
○ No one	75	25.9%
Whether someone knew she was taking pills for abortion		
Yes, some people knew	279	96.2%
No one knew	11	3.8%
Side effects of misoprostol at home		
None	197	67.9%
One of the side effects	93	32.1%
○ Severe pain in abdomen	32	11.0%
○ Vomiting	17	5.9%
○ Heavy bleeding	26	9.0%
○ Fever	22	7.6%
○ Nausea	12	4.1%
○ Giddiness	6	2.1%
○ Weakness	3	1.0%
○ Shivering	1	0.3%
○ Others (diarrhea, anxiety, acidity, headache etc.)	4	1.4%

4.1.3.5. Acceptability of home use of misoprostol

96% women in both groups (home misoprostol and clinic misoprostol) were satisfied (Table 4.3). Those with a previous abortion experience were asked to compare their current experience with earlier one-- majority (85% home users and 88% clinic users) reported it to be similar, or better than the previous one (100).

Women were asked about the preferred place to use misoprostol in the event of a future abortion. Among home users, 10% said that they would prefer to use misoprostol in the clinic in future, whereas among the clinic users, 20% said they would prefer to use misoprostol at home for a future abortion. Desire to change the location of misoprostol was considered to be indicative of dissatisfaction, hence there was higher satisfaction among home users than clinic users ($p= 0.0002$).

Table 4.3: Satisfaction and acceptability of home misoprostol and clinic misoprostol (100)

	Home use of misoprostol (n= 290)	Clinic use of misoprostol (n= 331)	P value
Satisfaction level			
Satisfactory /good	276 (95.2%)	320 (96.7%)	p= 0.341
Not satisfactory /bad	14 (4.8%)	11 (3.3%)	
Comparison of this abortion with previous abortion if any	(n= 101)	(n=118)	P= 0.692
Better than before	52 (51.0%)	67 (56.8%)	
Same as before	34 (33.3%)	37 (30.5%)	
Worse than before	15 (14.7%)	14 (11.9%)	
Preference for place of misoprostol (if another abortion is required)	(n=288)	(n=329)	
Home	236 (81.9%)	67 (20.4%)	P= 0.0002
Clinic	28 (9.7%)	224 (68.1%)	
Either	24 (8.3%)	38 (11.6%)	
Advice to sister/ friend regarding place of misoprostol	(n=288)	(n=329)	
Home	181 (62.8%)	50 (15.2%)	P=0.92
Clinic	43 (14.9%)	234 (71.1%)	
Either	64 (22.2%)	45 (13.7%)	

4.1.4. Comparison of women making one and three visits for medical abortion

In the study, 183 women were assigned make three clinic visits related to medical abortion (visit for mifepristone, followed by clinic use of misoprostol and clinic follow-up), whereas 172 were assigned to make only one visit (visit for mifepristone, followed by home misoprostol and self-assessment for outcome of abortion). Comparison of outcomes among women with one and three visits for medical abortion revealed that there were no significant differences in the rates of complete abortion, adverse events, side effects or interim visits (Table 4.4) (100). However, women making three clinic visits were far more likely to dissatisfied with the current place of misoprostol use than those making only one clinic visit.

Table 4.4: Comparison of women with one visit (home misoprostol & home assessment) & three visits (clinic misoprostol & clinic follow-up) for a medical abortion

	Group making one clinic visit	Group making three clinic visits	P value
Outcome of abortion	(n= 163)	(n= 172)	
• Complete abortion	155 (95.1%)	160 (93.0%)	P= 0.42
• Incomplete abortion or ongoing pregnancy	8 (4.9%)	12 (7.0%)	
Adverse events	0	0	
Interim visits	27 (16.6%)	32 (18.6%)	P= 0.62
Side effects and acceptability	(n= 156)	(n= 140)	
• Side effects reported on follow-up visit	26 (16.7%)	19 (13.6%)	P= 0.459
• Abortion experience worse compared to expectation	7 (4.5%)	4 (2.9%)	P= 0.466
• Dissatisfaction with place of misoprostol*	12 (7.7%)	30 (21.4%)	P= 0.001

* Wants to use a different place of misoprostol for next abortion, if required.

4.2. Study II: Experiences and perceptions of simplified medical abortion (paper IV)

In-depth interviews with 20 respondents revealed interesting findings about women's views on home use of misoprostol and self-assessment. All respondents were married with one of more children. Two thirds were rural, half belonged to socio-economically disadvantaged scheduled tribes or castes, and about two thirds lived in joint families. Eleven women did not have any mode of transport, while nine had a vehicle (mostly 2-wheeler) available at their homes. Two of these women had required surgical interventions for incomplete abortions.

Deciding to use misoprostol at home

Women preferred to use misoprostol at home for many reasons, most importantly because clinic use was associated with inconvenience to travel to the clinic, and for going to the clinic, they would have to complete housework and make arrangements for childcare. Some women opted for home use because it provided them greater privacy, or that they liked the comfort of family being around: *"Because .. the family stays near you and ... you remain comfortable at home. In the clinic, lots of patients come and go, so there is no privacy.. At home, we have privacy, we can sleep and sit as we wish, and can do other work side by side.. "*.(P19: urban, educated)

Some women linked repeated and long absences from home for a clinic visit to lack of confidentiality: *"I said why to go to the clinic daily. My in-laws will say that she is not staying at home. If I go to the hospital again and again, they will ask. That's why I thought why to go there again"* (P 5: rural, illiterate, mother of two).

Most women had no concerns at all about administering misoprostol at home, which was largely linked to prior experience with a medical abortion, or because they felt they could reach the clinic quickly if they needed to: *"Someone should be there. I was a bit afraid, but my husband was home. He said that if anything happens, we will take you to a hospital in jeep"* (P6 : rural, literate woman).

Taking misoprostol at home and managing the abortion

All women took misoprostol in the morning hours, after which they started having abdominal pain, followed by bleeding and expulsion of products, which was an important event in the process. *"(After I took the pills), the bleeding started after half an hour. I had no other problem – no nausea, no abdomen pain, no giddiness. ... The day (I took pills), it was a little more bleeding. Pieces fell at 12 O' clock - pieces were just little. I was there in my farm, when the piece fell."* (P11: rural, illiterate).

On the day of misoprostol, most women did their household work as usual or with some help. Those whose responsibility included working outside home, reduced their outdoor work: *"My husband was at the construction site, I was at home and did all work, looked after the children. But I did not go to construction site that day."* (P13: rural, illiterate).

For majority of women, only the husband was aware that his wife had taken pills for abortion. Most husbands provided some support to their wives on the day that their wives took misoprostol. This is evident by the following statements: *"My husband was there at home, there was no one else. He was aware. When I had lot of nausea, he gave me a blanket."* (P1: rural, illiterate); and *"My husband did all work in morning like cooking, preparing tiffin for children and cleaning the house. He had gone for work, but he told me to call him if I developed any problem, so that he could take me for the check up."* (P17: urban, educated).

Some women had to make an extra visit to the clinic, either because symptoms such as severe nausea, or prolonged bleeding, or for not seeing the expulsion. Some others made a phone call to the clinic for their concerns.

Assessing the completion of abortion

Majority of them figured out about completion of abortion through initiation of symptoms such as bleeding and seeing the expelled product or alleviation of pregnancy symptoms: *'I knew because (after taking four tablets), the bleeding started. When my pieces fell down, then I came to know that nothing is there.* (P12: rural, illiterate). *"When anyone gets pregnant, then appetite is lost, you do not feel hungry, feel irritable, there is nausea. After taking the tablets, I was not feeling anything. I was eating timely, and there was no nausea.... . so it means that abortion was complete.."* (P15: rural, educated).

Some women did the test only because it was given to them, although they had known that had aborted even without doing the test. Some of them felt that the test was not of any use: *"No, it is not necessary, since I already knew that my work (abortion) was complete. If you are not sure that something is left inside, then you can do the test "* (P18: urban, educated).

On the other hand, many women had concerns about retained products, and they found it reassuring to do the test, even though they had symptoms suggestive of abortion: *"Need (to*

do the test) is there. If the test was not done, then we remain in doubt... if a lump remains inside, then a problem can arise inside the body" (P22: urban, educated)

Most women were confidently able to conduct the test and interpret the results. Some of the statements were: *"The clinic staff gave me the pregnancy test and asked me to do it after 15 days. (They told me that), like in this photo, if there are 4 lines,... your 'work' is not done... , and if there are one or two lines, it means the abortion is complete" (P15: rural, educated).* Most women did their test on their own, without a need to ask anyone: *"I did not ask anyone. Whatever they taught me, I did. I looked (at the pictures)... and understood "* (P2: Rural illiterate).

Most of them also reported that the pictorial instruction sheet was useful to interpret the pregnancy test: *" I did the test after reading (the papers) only. I kept reading from this and continued to do the test."* (P22: urban, educated). Some women did not see the pictorial instruction sheet, either because they were illiterate or they had understood the instructions given, hence did not see a need to refer to instruction sheet: *" Papers were given to me. I have not opened (the papers) them. I am illiterate. I don't understand, what to do by opening. They are kept as it is" (P13: rural, illiterate).*

Views on medical abortion with a single visit

When asked to speculate how they feel about the possibility of an abortion involving single visit in the event of a future abortion, majority said that they would prefer to have an abortion involving single visit. The most important reason for this was that it saves them an additional visit to the clinic, which is inconvenient and they have to seek permission to go to the clinic: *"It's good to visit once only, because during 3 visits if anyone has work at home or if someone's mother-in-law does not allow her to go outside, husband can also say what's the need of going again and again, you should go only once," (P17: urban, educated).*

One woman even mentioned that she doesn't see much added benefit in clinic: *"... as there one has to go (to the clinic) by bus. What else can be done there, if taken at home, then it's good" (P5: rural, illiterate woman).* One woman compared her experience with previous abortion when she had gone for a follow-up visit: *"Who wants to repeatedly visit the hospital? It's ok to come once only. Last time, I had gone to the clinic for follow-up, this time it is better."* (P22: urban, educated).

To summarise, results of qualitative study indicate that home use of misoprostol is appealing to women because they find it difficult to leave home for many hours, and because they want to avoid a stay in the clinic lasting for several hours. Further, women can manage their abortions at home reasonably well, balancing housework and childcare, often keeping it a secret from family members. They are able to recognize symptoms that need further care from a clinic, and visit the clinic when needed. Women also find it appealing to carry out self-assessment of outcomes of abortion, since they have concerns about retained products, it helps them to avoid a clinic visit, and they are able to carry out the assessment on their own.

5. DISCUSSION

In countries such as India where access to safe abortion access is limited despite abortion being legal, several actions at different levels would be needed to make safe abortion accessible to women. First, for improving access to safe abortion in primary care settings, and to reduce the gap of availability between rural and urban areas, medical abortion needs to be made the main method. Women have shown strong preference to medical abortion as compared to surgical abortion (29, 31), and it is far more amenable to provision in rural primary care settings than surgical abortion. While the most important skill required to perform a surgical abortion is uterine evacuation, the most important skill required for providing medical abortion is assessment of gestational age. Eligibility for medical abortion can be assessed by ruling out contraindications using a simple checklist (101), along with bimanual examination for and gestational dating.

The focus of this thesis was on simplification of service delivery guidelines for medical abortion by reducing the number of clinic visits for women living in low resource settings. The results of studies included in this thesis suggest that home assessment of outcome of abortion using a low-sensitivity pregnancy test is an effective alternative to clinic follow-up after early medical abortion, and that women can safely and effectively use misoprostol at home, and that they find it highly acceptable.

5.1. How effective, safe, feasible and acceptable is self-assessment as an alternative to clinic follow-up for women having early medical abortion in low resource settings?

Our findings suggest that self-assessment is non-inferior to clinic follow-up after early medical abortion. It also showed that women living in low resource settings can feasibly conduct and interpret a low sensitivity pregnancy test to assess the outcome of their abortion.

In recent years, some studies have evaluated self-assessment after early medical abortion, many of them conducted in high-income countries. Two randomised controlled trials that compared self assessment with clinic followup had important contextual differences. The trial in Vietnam recruited only educated women, owning a phone, used a semi-quantitative pregnancy test and followed-up all women with a phone call (79). In another trial in 3 European countries, the phone was used to follow-up women, and ultrasound was used to assess their gestational age (76). Our study was conducted in a rural primary care setting, in which more than half the participants could not read or write, and only about 42% had their own phone. Further, the method of contact was largely through home visit.

In our study, the numbers of on-going pregnancies detected in the self -assessment group was lower than the clinic follow-up group. However, only 1.9% women in the home assessment group were lost to follow-up, hence we believe that we have not missed any on-going pregnancies, and that this difference was by chance.

Our study showed a very low rate of adverse events of medical abortion. Previous studies have also reported low rates of adverse events (between 0.11% and 0.16%) after early medical abortion. For example a recent systematic review has reported four women requiring blood transfusion and one woman with suspected infection requiring hospitalization among 4522 participants from 9 studies, indicating 0.11% serious adverse

events (60). Similarly, a study of 233805 medical abortions in Planned Parenthood clinics showed that significant adverse events (defined as hospital admission, blood transfusion, emergency department treatment, infection requiring intravenous antibiotics administration or hospitalization, and death) occurred in 0.16% patients (70).

Comparison with other alternatives

The other alternatives considered and tried by others to assess the outcome of abortion are: relying on symptoms alone, doing a low-sensitivity pregnancy test, doing a high-sensitivity pregnancy test, or a semi-quantitative pregnancy test. Research has shown that only 68% of ongoing pregnancies can be detected if women assess the outcome of their medical abortion by depending on symptoms alone, without any additional method to detect HCG (82, 102). The important symptoms reported by women with failed abortions were less vaginal bleeding, continuation of symptoms of pregnancy, and lack of expulsion. Hence an objective method of detecting continuing pregnancies is still needed.

A high-sensitivity pregnancy test turns negative only at 3-4 weeks after medical abortion, and can be done at around one month. Relying on it would delay the detection of on-going pregnancies and women in rural areas would not be able to easily obtain a safe abortion service.

We decided to use a Duo-test with two cut-offs (1000 IU/L and 5 IU/L) for this study, because it is a simple test with two columns (75, 76), and women with lower educational levels were more likely to be able to interpret it. When we started the study, a simpler test with only one column for 1000 IU/L was not available, hence we had to use a test with two columns for 5 IU/L and 1000 IU/L. In some other studies, semi-quantitative pregnancy test (SQPT) with five columns has been used (74, 79), however, we did not consider using SQPT for this study, since it did not offer any advantage for the purpose of our study, and it would have been difficult to explain to the women with low literacy.

Some studies have used telephonic follow-up with a symptom checklist along with self-assessment using a low or high sensitivity pregnancy test (74, 75, 78-80). However in our setting, majority of women currently do not have their own phones and hence, phone follow-up or reminders would not be feasible. Because of confidentiality concerns, home-visit by a health worker would not be feasible. Therefore, in areas similar to our settings, giving women an option of self-assessment to be done by themselves, without any method of phone or home based contact would be most appropriate.

Feasibility and acceptability of self-assessment

The majority of women did the low-sensitivity pregnancy test on their own (80%) in our study. Almost all interpreted it correctly and found it easy to do. It was encouraging to know that even rural and illiterate women were also able to do their LSUP test. Due to the study design, which required that all women in the self-assessment group were informed that a home visit or a phone call will be made to contact them, a few women might have misunderstood that they are meant to wait for this visit before doing the pregnancy test. Whether a higher proportion of women conduct the test without being reminded needs to be tested in a non-research setting.

In our study, 25% women in the self-assessment group made a clinic visit- of these 19.5% were interim visits, while 5.5% were in response to the result of pregnancy test, or a symptom reported on follow-up contact. We feel that women may visit a clinic for various concerns and that self-assessment is not meant to completely eliminate the need for clinic

visits, but to substantially reduce them. It is significant that seventy five percent of women in this group did not make any clinic visits, and still knew their abortion outcomes. The rates of additional consultations reported in our study were similar to other studies. In another study that assessed the feasibility of telephonic follow-up after medical abortion, 32% women made a clinic visit (80), while a study from 3 countries from Europe reported that 19% women in the self-assessment group and 20% in the clinic follow-up group made an additional telephonic consultation, while 7% and 9% women in the two groups, respectively made an additional clinic visit (76). We expect that with greater ownership of phone and skills to use phone, more women will be able to make telephonic consultations for their concerns than coming to the clinic personally.

High acceptability of early medical abortion with self -assessment was shown in our study. Other studies with a self-assessment and telephonic follow-up have also reported high rates of satisfaction (103). In our study, most important determinants of satisfaction were success of abortion, having to make an interim visit, experience of side effects, and travel time. In a study in Brazil, three determinants of user satisfaction with primary health care were identified to be important- getting an appointment (encountering problems to be seen at the health facility is negatively associated), getting better (positively associated), and the type of district (rural women express higher satisfaction than their urban counter-parts) (104). A review of determinants of women's satisfaction with maternal health care reported that important determinants of satisfaction included: (a) structural elements (e.g. physical environment, cleanliness, human resources, medicines and supplies); (b) processes (e.g. provider behavior, privacy, promptness and competency); (c) Outcome (maternal and newborn outcome); and (d) access, cost and socio-economic status (105). In our study, the elements related to access and processes did not have much variation, however, similar to above studies, the most important determinant was found to be outcome of abortion (success, and side effects).

Similar to our results, previous studies on acceptability of medical abortion have also reported that satisfaction was determined by completion of abortion and side effects experienced (57, 58). Interestingly, we did not find a significant difference in satisfaction between rural and urban women. This could be related to overall a low number of dissatisfied women in our study.

Availability of low sensitivity pregnancy tests

While the demand for high sensitivity pregnancy tests, used to detect pregnancy has been high over past few decades, the same has not been the case for LSUP tests since their main use would be for follow-up after abortion. While high sensitivity pregnancy tests are available at very low costs (e.g. equivalent to 0.1 USD in India), the low sensitivity pregnancy tests are generally not available outside Europe or the US, and are very expensive. We feel that development and production of LSUP tests has been slow since they are still not a part of routine abortion care, and their wider availability might be linked to service providers' fear of losing control over the abortion process, and its associated income. However, if low sensitivity pregnancy tests become part of standard service delivery guidelines, are produced at large scale, and promoted through social marketing, their costs could become affordable.

Self-assessment and contraception

Since women would have fewer contacts with the health facility, self-assessment could potentially lead to lower rates of contraceptive use after abortion. However, women need to be provided contraceptive counselling before abortion, and should be provided one if they chose to start a method, and the contraceptive can be safely provided on the day of

mifepristone. Except intrauterine devices, most contraceptives can be initiated on the day of mifepristone. A recent study comparing self-assessment with clinic follow-up has shown that there was no difference in the proportion of women using contraception at 1 month after abortion (76).

5.2. Can women in low resource setting safely administer misoprostol at home for early medical abortion?

Comparison of women using misoprostol at home and clinic in our study showed that the rates of complete abortions and surgical evacuation were similar. In our study, greater proportion of home users expressed preference for using misoprostol at home again for a future abortion, than clinic users who said they would prefer clinic use in the future. Other studies have also reported that home and clinic use were comparable in terms of efficacy and safety (54-56, 59, 106). Similar to our results, home use of misoprostol was associated with higher acceptability, both from developed (58, 63), and developing countries (55, 56).

Many previous studies which have assessed home use of misoprostol, have been from developed countries (52, 58). Even when carried out in developing countries, they have largely been done in urban areas or tertiary hospitals (54-57, 59), and included women with some years of education, and those living within a short travel time from the clinic. By contrast, we studied home use of misoprostol among largely rural women, staying far from the clinic, and having to spend long hours on travel because of lack of transport.

In our study, more women in the clinic misoprostol group, did not comply with the use of misoprostol, than those in the home misoprostol group, and this non-compliance was linked to more unsuccessful abortions in the clinic group. It is likely that some of these women could not return because of house work, childcare or travel difficulties, or perhaps because their bleeding had already started. In our study, as well as other studies, 17-20% women started bleeding after taking mifepristone (59, 107). Greater non compliance among clinic users as compared to home users was also reported in another study (56), indicating that providing women the option of home use allows them greater adherence to use misoprostol, and therefore successful abortions.

One woman in each group suffered haemorrhage (requiring blood transfusion or IV fluids), and it could not have been prevented by clinic use of misoprostol, since it occurred more than 24 hours after using misoprostol. These findings are similar other studies that have found that acute haemorrhage mostly occurs after more than 4 hours after using misoprostol (70, 108), and mostly not prevented through clinic use of misoprostol.

Nearly 15% women reported one of the side effects (excessive bleeding, severe abdominal pain, feeling sick or fever) at the time of follow-up contact at 2 weeks, while 32% reported that they had experienced one of the side effects on the day of using misoprostol at home. Of these, 11% reported experiencing severe abdominal pain. All women assigned for home use of misoprostol were provided pain killers to be taken home, however, we did not record information on what proportion of women actually consumed pain killers. Other studies have described much higher prevalence of side effects (usually above 50%) reported by women (53, 56). We feel that a lower prevalence of side effects recorded in our study could be related to differences in the perception of symptoms, especially pain, and the tolerance for side effects between rural than urban women. Furthermore, 95% women in our study had given birth to at least one child, and this could have influenced their experience of pain. Other studies have observed that parous women have less likelihood of experiencing strong pain than nulliparous women (53, 63). A study from Pakistan on use of self medication

(including pain killers) has shown that rural and illiterate persons are less likely to consume medication for pain (109). The perception and tolerance of pain, and use of pain medication for medical abortion need to be studied in future studies.

Service providers and program managers are sometimes reluctant to allow home use of misoprostol for women living in rural areas, mainly because of concerns related to complications such as acute heavy bleeding. The other reason could be concern about the loss of control over the final outcome, which has been reported in a study in Bangladesh (110). Abortion providers from different settings often do not have accurate and evidence based information regarding medical abortion (12), hence provider training on management of medical abortion would be necessary.

Comparison of time spent by clinic and home users in our study showed that on average, four hours of extra time was spent by the clinic users. By using misoprostol at home, women are able to avoid this visit, lasting for many hours. Allowing women to use misoprostol at home, is even more crucial for rural women, who often have less autonomy and suffer greater disruption of routine.

5.3. What are women's experiences and perceptions regarding home use of misoprostol and self-assessment?

Qualitative exploration of women's perceptions and experiences showed that women prefer to use misoprostol at home and assess the outcome of abortion on their own, and that they can confidently do it. Quantitative studies from India and Nepal have shown that 90% and 88% women opted for home use of misoprostol, when given a choice (54, 57).

In our study, women preferred home use of misoprostol for many reasons – one important reason was concerns about completing housework and arranging for child-care. Women also wanted to avoid clinic visit because of travel difficulties, which was expected since public transport is poorly available, and only around 20% households owned motorised transport in Rajasthan in 2007-08, this being much lower for rural families (88). Women also apprehended that repeated visits to clinic might lead to inquiries by marital family members about her whereabouts, which would be difficult to answer since the majority had not informed anyone other than husbands about the unwanted pregnancy.

Studies from high-resource settings have reported that women preferred home administration of misoprostol because it provided them greater privacy, and comfort to remain at home. Further, they perceived a greater sense of personal integrity and autonomy (53, 64-66). In addition to the above, women also received better emotional support from the family (67). A review on women's experiences showed that women value the familiar surroundings and not having to encounter strangers (68). In a study from Mozambique, women mentioned that they preferred to expel their products at home also because home environment provided them cleaner bathrooms and clothes (111). In our study, lack of confidentiality related to making clinic visits and problems in managing housework and childcare appeared to be more important reasons.

Most women in our study had kept their abortion a secret from family members other than husbands, who in turn provided them support during home use of misoprostol. Other studies too, have reported that women undergo abortions at home, often in secret with others around but unaware of the situation (65, 68, 111). The role of husbands in decision making about abortions and in procuring the drugs, often from chemists has been reported in other studies too (112), (113). Data from abortion clinics has shown that almost all men desired to be involved in counseling as well as stay with their wives or partners during the

abortion process (114). Hence it appears that involving men in information and counseling would be a useful strategy if women seeking abortion desire so, and they are accompanied by their husbands or partners.

Ability to manage abortions at home

Despite lacking personal transport and a phone, women preferred to manage their abortions at home in this study, and most had no concerns about it. Several women mentioned that they had been given detailed instructions about the method of doing the low-sensitivity pregnancy test, and that this had helped. Many women also mentioned that pictorial instruction sheet acted as reminder (115), and enabled them to do the test. Thus, it appears that women's ability to confidently manage their abortions at home was linked to their own ability, assurance by husbands, and also because they were enabled and equipped to do it using simple tools. The low-sensitivity pregnancy test was simple to use and was explained well in simple language, along with a pictorial sheet.

Need for a method to confirm completion of abortion

There were several women in our study who were reasonably sure even without doing the low-sensitivity pregnancy test that they had completed their abortions, by relying on disappearance of pregnancy symptoms and expulsion of products. Another study that compared women's perception of expulsion with ultrasound findings after medical abortion concluded that women's perceptions in determining expulsion of gestational sac are fairly accurate (116). Despite this, many women had the over-riding concern related to retained products of conception after abortion, and low-sensitivity pregnancy test provided confirmation of completion of abortion, and helped to alleviate anxieties.

Educated urban women were able to understand the instruction sheets much better than illiterate women. We found that even illiterate women valued having the pictorial instruction sheet, largely for its value for pictures of doing the pregnancy test and contact numbers of clinics. However, the pictures related to danger signs were not understood consistently, which is similar to the findings of another study in India that reported that comprehension of pictures by non-literate populations is different as compared to educated persons (117). Although some studies have raised reservations about the value of an instruction sheet or a checklist for simplified follow-up (74, 79), our results suggest that women find it useful to refer to a pictorial instruction sheet, both for the method of doing the test as well as for other information such as contact details of clinics.

Although no data is available on proportion of women buying medical abortion from the chemists, there has been rapid increase in sales of medical abortion pills in India, much higher than reported abortions (113), and there are concerns regarding its indiscriminate use (118). Hence it is likely that women who procure it from chemists, take both tablets at home without any contact with formal health system. Since pharmacists lack accurate knowledge on dosage and side effects (119), it would be crucial that the health system offers women a simplified medical abortion with single clinic visit, so that women receive proper care and counseling instead of an uncontrolled home abortion.

5.4. Advantages of self-managed medical abortion

Introducing a system of home use of misoprostol and self-assessment would confer several advantages on women and the health system (Figure 5.1).

First and foremost, since women in low-resource settings suffer low autonomy, limited financial resources, and lack of personal transport facilities, the requirement for multiple clinic visits is indeed burdensome. Long absences from home and travel to a distant clinic, results in disruption of housework and childcare. To make a clinic visit, women have to seek permission from senior family members and find a person to accompany them to the clinic. This raises suspicion not only on part of family members, but also among neighbors. Hence being 'seen' continuing with their routine work itself is a measure of confidentiality. Allowing women to use misoprostol at home and to assess their outcome of abortion, is even more crucial for rural women, who generally have lower autonomy and longer absences from home.

Second, introduction of self-assessment in the health systems could result in cost savings for women (including travel and consultation costs related to a clinic visit), as well as for health system (provider time). In our study, 75% of the women in home assessment group did not have to make a clinic visit.

Third, since significant proportions of women seeking medical abortion don't turn up for a clinic follow-up visit (31, 69), and those who don't follow-up are at risk of undetected on-going pregnancy, self-assessment allows a greater proportion of women to determine their abortion outcome.

Fourth, evidence suggests that unnecessary ultrasounds and surgical interventions are done when women go for a follow-up visit, self-assessment is likely to prevent these unnecessary procedures (120). Hence, providing women a home based method to confirm the outcome of abortion is likely to reduce the rate of unnecessary surgical interventions, and will also alleviate their anxieties about completion.

Fifth, home misoprostol and self-assessment provides women a greater measure of control over their own lives. While program managers might be more willing to allow fewer clinic visits for medical abortion to urban educated women, our study shows that this is as or more critical for rural women, and that women living far from clinics themselves perceive the value of fewer visits.

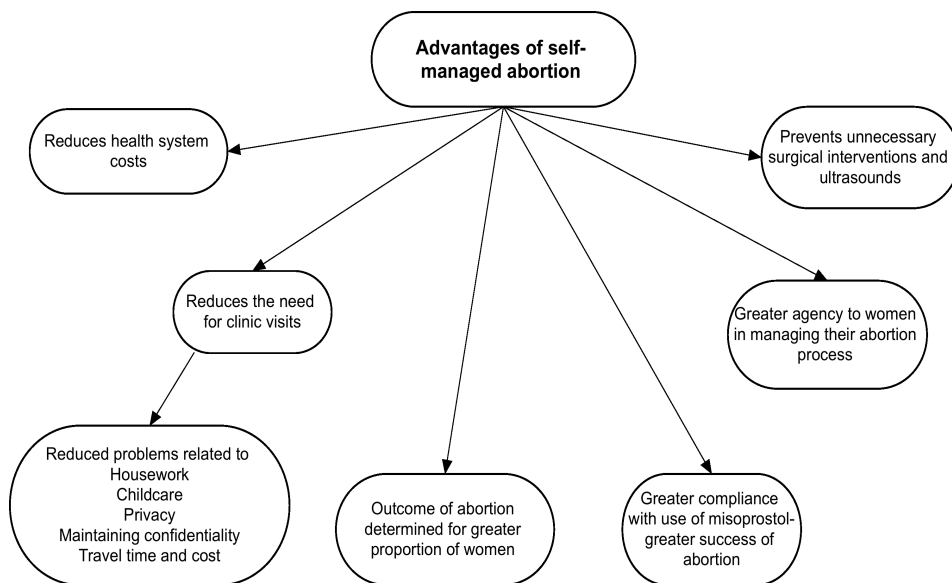


Figure 5.1: Advantages of self- managed abortion (home use of misoprostol and self assessment) to women

5.5. What other measures are needed to simplify medical abortion?

Reducing the number of clinic visits is one important step to simplify medical abortion, however, other measures are also needed to simplify medical abortion. These include procedures for eligibility assessment, and assessing the completion of abortion and other complications (40). In our study, gestational dating was based on bimanual examination, and not based on ultrasound assessment. In two studies that compared bimanual examination with ultrasound for gestational dating, results showed high accuracy of bimanual examination (93) (94). However, minor errors in gestational dating are not likely to result in complications because medical abortion is considered to be safe and effective even in gestations between 63-70 days (121). In most of the primary care facilities in low resource settings, ultrasound is not available. Hence reliance on ultrasound-based methods would act as a barrier to provision of medical abortion services in such settings.

Ectopic pregnancy is a known contraindication to medical abortion, and standard guidelines recommend that the ectopic pregnancies should be ruled out at the time of initial clinical examination. A review of 59 studies reporting on ectopic pregnancies after medical abortion reported that ectopic pregnancy was diagnosed very infrequently, occurring in only 10 of 44,789 (0.02%) women (122). The review concluded that various screening methods that providers use to exclude patients with ectopic pregnancies are successful, and that there is no evidence to suggest that medical abortion leads to unusual complications for women with ectopic pregnancies. Further, the service delivery guidelines by WHO and by government of India do not mandate ultrasound for assessment of eligibility, hence this represents a standard procedure (41, 43). This implies that for eligibility assessment, providers use combination of a checklist (based on symptoms and physical examination) to rule out contraindications, and bimanual examination for gestational dating. Any women with suspected ectopic pregnancies would need to be referred to a higher centre for

investigations. Similarly, for women choosing to come to the clinic for follow-up, providers need to avoid doing routine ultrasounds, unless clinically indicated.

5.6. What is needed to allow task shifting to women in abortion care?

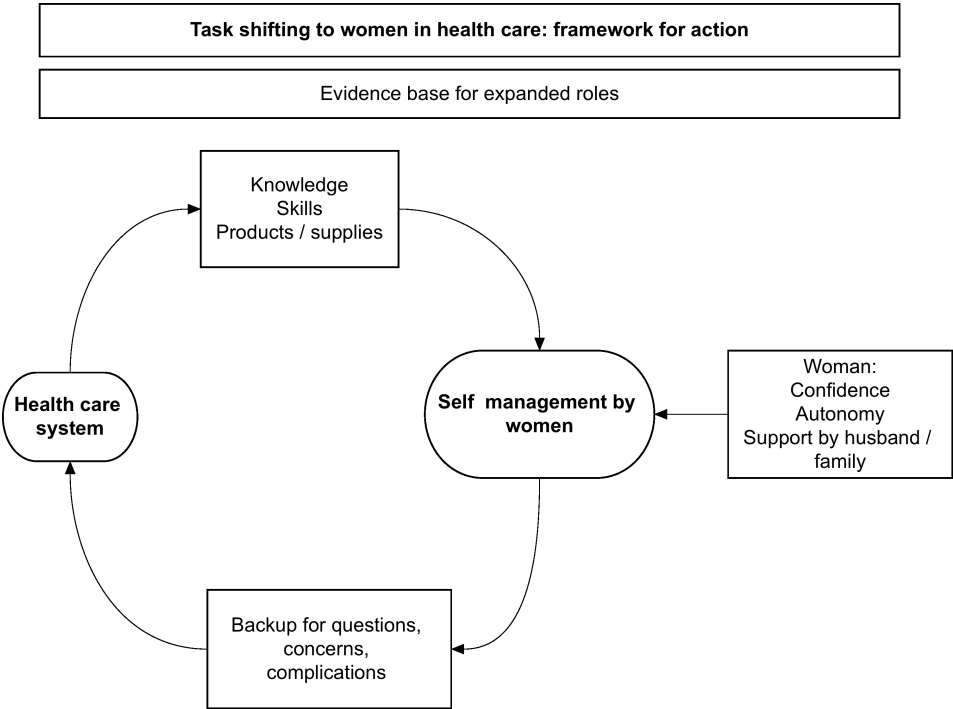
Bringing care closer to home has been identified as an important strategy in improving access and reducing the cost of abortion, while continuing to focus on clinical quality and safety (123, 124). Task sharing and shifting strategies have focused on shifting tasks to different levels of health care providers. However, in recent years, it has become possible to transfer some diagnostic, monitoring, and caring tasks, which were traditionally carried out by health providers, to patients or clients themselves. Task shifting to patients themselves has several advantages- (a) it reduces dependence of clients / patients on providers, and hence empowers them, (b) possibly improves the quality of care by improving the timeliness of the procedure, (c) reduces the healthcare costs for both patients and the health system (125), and (d) saves the time and effort by family members to accompany patients for clinic visits. A strategy of greater self-management in health care has been tested to improve the treatment of patients with chronic diseases, including diabetes, cancer and HIV (126-129).

The studies included in this thesis have been based on shifting tasks related to medical abortion to women themselves. Effectiveness of an approach of self-management depends on providing clients sufficient information, skills and necessary supplies to be able to perform the task, as well as providing backup support when needed (Figure 5.2). To manage an abortion themselves, women need to have confidence in their abilities, and (in some cases) support by husband or family. For example, assurance by husbands that they were willing to transport her to the clinic if needed, was helpful to provide women the confidence to use misoprostol at home.

It implies that for a simplified medical abortion, all necessary supplies should be provided to women, along with detailed information on how to use them, and the health system should be available for backup support for those who have questions, concerns, danger symptoms or positive results on pregnancy test.

In the coming years, it would be crucial to simplify medical abortion provided through the formal health care system. When formal abortion services are not available, women have resorted to abortion using pills procured through informal providers or chemists (130). Simplification of protocols for medical abortion would enable its provision through safe and formal health care system, which would lead to reduction in mortality and morbidity related to informal and unsafe abortions.

Figure 5.2: Task shifting to women for health care: Framework for action



5.6. Study strengths and limitations

The studies covered in this thesis attempt to bridge the information gap on women’s ability to manage their medical abortions in the context of a low resource developing country setting. The strengths of the studies were the following:

1. Randomised controlled trial design: The strength of this thesis was the RCT design. To evaluate the interventions, RCTs are considered to produce high level of evidence. In this study, rigorous methodology was followed at all stages, including randomisation, sampling, explanation of the intervention, follow-up contacts, data management and analysis. The proportion of clients missing for the purpose of abortion outcome were only 2.5%, thus a high rate of follow-up was achieved for the primary outcome.
2. Selection bias was at a minimum. Women residing in a wide geographic area spread over about 75 km area were included. Further, women were not excluded on the basis of their educational status or phone ownership. Some studies include only women who have been educated up to a certain level or own a phone (79), while in our study about half the women were illiterate and only about 40% owned a phone of their own.
3. Triangulation through combination of quantitative and qualitative methods: While quantitative methods have been used in many studies to assess acceptability and preferences of women related to self-assessment and home use of misoprostol, our study also used

qualitative methods, which allowed a deeper understanding of women's perceptions and ability to manage an abortion at home. Further, since most studies on women's perceptions on home use of misoprostol are from high-income countries (64, 66, 67, 131), this study provides valuable evidence from a low resource setting in the context of low literacy and limited communication facilities.

4. Validity and reliability of qualitative study: There is no consensus on methods to assess the quality of qualitative research(132-134). In our study, we used the strategies suggested by Morse et al to ensure reliability and validity of the research, which emphasize that strategies to implement rigor should be implemented during the research process, instead of evaluating the quality of research after completion of a study (132). These strategies include *investigator responsiveness* (sensitivity, flexibility and skill of investigator that allow ability to synthesize, listening to data, modifying future sampling strategy, etc.); ensuring *methodological coherence*; sampling sufficiency; *dynamic relationship* between design and implementation (iterative nature of research); and *thinking theoretically* (deliberation between micro-perspective and macro understanding as a outcome of research process).

To ensure investigator responsiveness, the interviews were personally conducted by the first author, who could synthesize the data while doing the interviews, probe when needed, and change strategies for data collection, if required. We used the method of in-depth interviews to answer our research questions because of sensitive nature of the topic. To ensure methodological coherence, the questionnaires were pilot tested and improved before the actual conduct of the study. To elicit honest responses from the participants, we paid attention to privacy and confidentiality, so that participants could give responses freely, without being concerned about others listening on them.

To ensure sampling sufficiency, we interviewed a diverse group of women, and continued data collection till we felt that the incremental new information was very little in subsequent interviews. Furthermore, we also included women who had unsuccessful abortions. To ensure dynamic relationship between design and implementation, we used an iterative process, by reviewing the data frequently, and adding additional new questions where a new finding emerged in earlier interviews. The results were discussed frequently with the research team to modify strategy.

There were several other measures that improved rigor during the process of research. The partner organization ARTH had been working in the area for over one and a half decades, providing clinic and community based health services. Further, at the time of interview, the interviewer did not reveal her identity as a doctor, so that the respondents could relate to her as a researcher and not provider. In our data, there was almost no loss in translation, since the main researcher who collected and analysed the data, is fluent with local dialect (Mewari), local language (Hindi) as well as with English.

5. External validity and applicability: Study participants included women representing low and middle income populations of India and other similar countries, in terms of their socioeconomic and demographic characteristics. For example, 70% of India's population is rural (87), while 72% of participants in our study resided in rural areas. Since poor access to safe abortion and the problem to unsafe abortion is the greatest in low resource settings, the applicability and relevance of these findings is high.

Further, the health centres where the research was based, represent primary care facilities, and not the tertiary care hospitals. For abortion access to expand, it would be crucial to provide services in rural and urban primary care clinics, similar to those included in this study.

Limitations

1. In the randomised controlled trial, the participants and research staff could not be blinded to the allocation. This was because of the nature of the intervention, which included explanation about use of low-sensitivity pregnancy test and its interpretation, hence it was important to inform the participants and research staff about the allocation group.
2. The relatively high adherence to clinic follow-up in randomised controlled trial seen in our study was partly due to the study design. In real clinical situation, the clinic follow-up rates after early abortion are likely to be lower, while in our study, 78% women in the clinic follow-up group returned. This is likely to be due to greater efforts by the research team to counsel them and offer of travel reimbursement.
5. One limitation of the study was that outcomes related to satisfaction and acceptability could not be assessed among women who could not have a scheduled follow-up contact. The rates of scheduled follow-up were 93% and 78% in the home assessment and the clinic follow-up groups respectively. Hence we cannot rule out the possibility that satisfaction rates were different among 22% women in the clinic followup group who did not followup. However, other studies have also reported high rates of satisfaction with self-assessment similar to our study(135, 136).
6. In our study, fifteen women who were in the clinic follow-up group as per the randomisation list, were incorrectly allocated to the home-assessment group, and two women who were in the home assessment group as per the randomization list, were incorrectly allocated to the clinic follow-up group (95). Thus the numbers as per the randomization list were 366 and 365, respectively in the clinic FU group and home assessment groups, while actual allocation in two groups was 353 and 378, respectively. This perhaps occurred due to oversight on part of one research assistant. However, we see this as a minor error that can occur in large trials like this, and since data does not show that the misallocated women were different from the study population at large, we believe that this is by accident and does not affect the outcome of the study.
7. Furthermore, the place of followup was different between women in the self-assessment group and those in the clinic follow-up group, and this could have influenced the responses, especially those related to satisfaction. However, the rates of dissatisfaction were low in both groups. Furthermore, research assistants reported that when women who had come for scheduled follow-up visits to the clinic, were subsequently contacted for outcomes, majority said that they didn't come since they didn't have any trouble. Hence it appears that interviewing them in the clinic didn't make much difference to women's responses.
8. We were unable to conduct any followup of women after the initial follow-up at 2 weeks (extending upto 30 days if needed). For example, a followup contact at 6 or 12 months for outcomes such as their attitudes, contraceptive use or repeat pregnancies would have been useful. However, we were unable to make this contact because of concerns related to confidentiality especially in rural areas.
9. For the purpose of comparison of home users of misoprostol and clinic users, the groups were not randomly allocated. There were some differences in the socio-demographic characteristics of the two groups. Those in the home misoprostol group were more likely to be urban, with lower gestations. Even then, 50% of home users were illiterate, 68% were rural, and more than half did not have their personal phone.

10. While all women in home misoprostol group were offered painkillers, some women did not take them home. Furthermore, we did not record data on use of pain medications by women on the day of misoprostol, hence we do not have information on proportion of women who actually used painkillers.
11. One limitation of the qualitative study was that some rural women were not very expressive, and gave brief responses. We have encountered similar experience with earlier studies in this area, where rural women, especially those with low levels of education are not too expressive. We attribute this to many years of illiteracy and upbringing in a society wherein the act of women expressing opinions or “criticizing the establishment” is viewed in terms of local culture and etiquette as being inappropriate.
12. Since the qualitative data is defined by the specific context in which it occurs, transferability of these results is limited. The findings of these studies would be of interest for other low resource settings, where the managers and providers are concerned about ability of rural women to manage their abortions.

6. CONCLUSIONS

1. Evidence generated by the randomised controlled trial showed that self-assessment using a low-sensitivity pregnancy test is non-inferior to clinic follow-up to identify women with on-going pregnancy after early medical abortion. Self-assessment of abortion outcome is a safe, acceptable and feasible option, even for women with low literacy living in rural areas of developing countries.
2. Comparison of home and clinic administration of misoprostol showed that women in low resource settings are capable of administering misoprostol at home for early medical abortion, without reduction in efficacy or safety.
3. In-depth exploration of women's perceptions and experiences showed that women living in low resource settings can confidently use misoprostol at home, with avoidance of disruption of their routines and greater confidentiality. Women were able to conduct self-assessment, it helped to alleviate their anxiety, and provided them reassurance of completion.
4. Simplified medical abortion involving a single clinic visit is highly acceptable to women living in Rajasthan, India. An abortion with fewer clinic visits would have tremendous appeal for women, and would provide them greater control over their lives.
5. Service delivery guidelines on medical abortion should consider replacing a clinic follow-up visit with self-assessment using an appropriate pregnancy test and locally appropriate instruction sheet. Further, providers should not place restrictions on giving choice to women regarding place of misoprostol, based on distance of their residence and travel time from the clinic. Women seeking early medical abortion should routinely be allowed to choose between home and clinic use of misoprostol.
6. Within health systems, reducing the need for multiple clinic visits for medical abortion would greatly enhance women's access to safe abortion services, and contribute to reduction in unsafe abortions. However, health systems need to take steps to enable and equip women to manage their own medical abortions after a single clinic visit, and to be readily available for backup care when needed.

7. PRACTICE AND POLICY IMPLICATIONS

The findings of studies included in this thesis suggest that health systems could introduce simplified medical abortion, with reduced number of visits as well as other measures required for early medical abortion. A simplified medical abortion routine involving home use of misoprostol and self-assessment would require that at the time of visit for mifepristone, women are enabled and equipped with tools to manage their abortions at home (Figure 7.1). This would mean that over and above the other tasks (e.g. routine counseling, including counseling about contraceptives, and eligibility assessment), the health system is equipped to do the following:

- (a) Choice: On the day of mifepristone, women are counseled to choose the place of misoprostol and place of follow-up.
- (b) Supplies: Those choosing home use of misoprostol and self-assessment would need to be provided with misoprostol tablets and analgesics, appropriate low-sensitivity pregnancy test and containers for collecting urine on the day of mifepristone. Woman who opt for a contraceptive that can be safely provided on the day of mifepristone, are provided with that method.
- (c) Information: All women would need to be provided detailed instructions on how to use misoprostol, when to take analgesics, and when to seek care during home administration of misoprostol. Since women may not comply to use misoprostol if their bleeding starts after taking mifepristone, all women should be informed of this possibility and to use misoprostol even if some bleeding starts.

Further, irrespective of place of misoprostol use and the system of follow-up, all women should be informed about danger symptoms, and where to seek care in such situations. On the day of mifepristone, they should also be routinely informed about other danger symptoms and symptoms suggestive of continuing pregnancy.

Women should also be given clear instructions on how to conduct and interpret low-sensitivity pregnancy test, and about contraceptives. All women may also be given local language instruction material regarding home use of misoprostol and self-assessment.

- (d) Backup support: The health system should also be available to respond in case women have questions, concerns, side effects or complications and to provide contraceptives. Since the mobile phone availability is rapidly increasing in India, some women could make use of telephonic consultations in case of questions.

Providing women the choice of using misoprostol at home and conducting self-assessment would mean that providers spend a few minutes extra to give information on how to use misoprostol, when to seek care, and how to conduct self-assessment. However, the task of giving instructions on the day of Mifepristone can be carried out by existing midlevel providers or non-medical staff of health facilities, but it would save health system costs related to staff time and bed occupancy during clinic administration of misoprostol, as well as the rates of unnecessary surgical interventions which are often dependent on individual provider practices (120, 137).

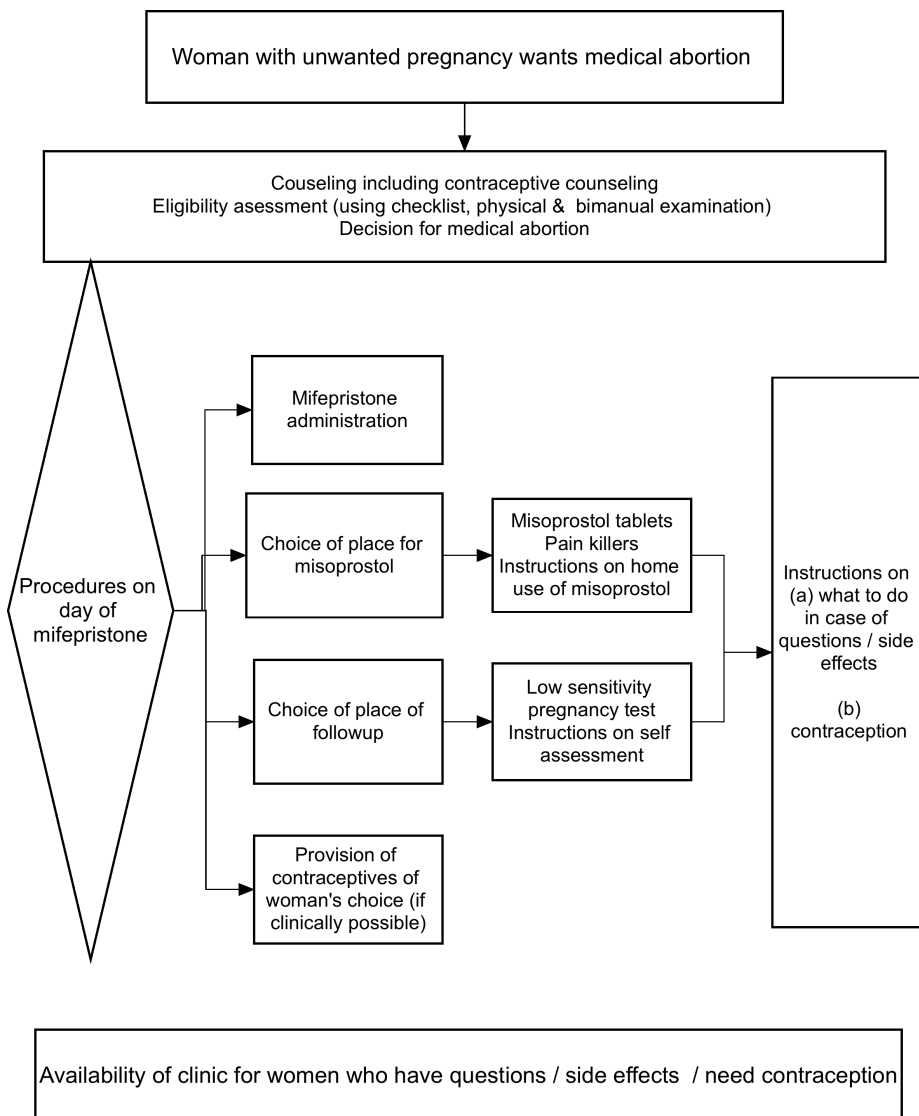


Figure 7.1: Service delivery implications for a simplified medical abortion

8. IMPLICATIONS FOR RESEARCH

The results of these studies substantiate that simplification of early medical abortion is safe, effective and acceptable option in low resource settings. However, our work as well as earlier experiences supporting simplified medical abortion have been tested in research settings so far. There are no documented experiences of implementation of these approaches in the health system.

For policy makers to successfully implement an approach involving simplified medical abortion in large health systems, they will need information on various operational components required for this approach. Intervention research is needed to answer specific questions such as the following:

1. What inputs are required for implementation of simplified medical abortion, e.g. staff time, equipment, supplies, clinical records forms, staff training, training materials? How do the roles of clinic staff change with an approach involving home use of misoprostol and home assessment?
2. What is the user comprehension of different types of self-administered low-sensitivity hCG test kits, and which type of test might be most preferred by users in low resource settings? Which type of low sensitivity pregnancy kit is the most cost effective in a large health system?
3. To what extent any telephonic contact is feasible for women in different settings (in terms of owning a phone, preference of women to make or receive calls or messages, number of calls, staff time required)
4. What are the cost implications of the intervention, for women and for the health system?
5. What is the impact of the intervention on the proportion of women opting for medical v/s surgical abortion, what proportion of women choose a medical abortion involving a single visit versus two or three visits?
6. What is the effect of a simplified medical abortion routine on the number of unscheduled visits, surgical intervention, detection of unsuccessful abortions and contraceptive use?

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