Exploring the Transformative Potential of Medical Abortion for Women in India

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Research Synthesis*

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Reproductive health commodities, such as the medical abortion pill, are ascribed values and given meaning, by stakeholders, as they traverse a pathway from the manufacturer to the woman. These values influence women's access to commodities and ultimately women's realization of their reproductive rights.

Introduction

In India, women's reproductive health is characterized by high fertility rates, a high need for contraception, which is largely not met and limited information and choice around available reproductive technologies, leading to high rates of unwanted pregnancies (Indian National Family Health Survey-3, 2005–2006). A high proportion of unwanted pregnancies lead to abortions. Despite abortion being legal for over three decades, women continue to have limited information on and access to safe abortion (Ganatra and Hirve, 2002; Elul et al, 2004). Unsafe abortion continues to be a significant contributor to maternal mortality in India, accounting for eight percent of all maternal deaths (RGI, 2006). It is, therefore, critical that government health policies and programs focus on expanding options, information and services for safe abortion.

Recently much attention has focused on medical abortion (MA), a method that has the potential to radically transform women's options and outcomes for safe abortion. MA is induced by a combination of pills consisting of Mifepristone followed by Misoprostol within seven to nine weeks of gestation. MA is currently approved in India with Mifepristone (600 mg) followed by Mispristol (400 µg) administered orally within 49 days of gestation. The MA pill (as the combination is known) was approved in India in 2002. The Medical Termination of Pregnancy (MTP) Act (1971)[1] was amended in 2002 to allow for the inclusion of MA as a method of abortion. A subsequent amendment in 2003 allowed for registered providers to dispense MA pills from non-registered facilities as long as emergency medical facilities are available. Currently around 20 brands of MA pills are available in the market and there is a growing demand for the commodity.

This research synthesis is based on a study undertaken by ICRW on 'Guaranteeing Women's Reproductive and Sexual Health and Rights: Exploring the Transformative Potential of Medical Abortion for Women in India'. The findings from the study were disseminated in a meeting held in New Delhi in August 2009. The meeting was attended by a wide set of stakeholders. Key suggestions and recommendations that emerged from the dissemination meeting have also been incorporated in developing this synthesis.

1. The Medical Termination of Pregnancy (MTP) Act was approved in 1972. This Act does not replace or negate the Indian Penal Code, but only allows its provisions to be set aside under a prescribed set of conditions. The MTP Act permits the termination of pregnancy up to 20 weeks, on the following grounds (a) Where the continuance of the pregnancy would involve a risk to the life of the pregnant woman or of grave injury to her physical or mental health; or (b) Where substantial risk exists of the child being born with serious physical or mental abnormality. In the explanation of the Act, the note also indicated that pregnancy due to failure of contraceptive methods could also be aborted as the *"anguish caused by such unwanted pregnancy may be presumed to contribute a grave injury to the mental health of the pregnant woman"*. The termination of pregnancy can be carried out only by registered medical practitioners in registered facilities as defined in the Act. For the termination of a second trimester pregnancy, the opinion of two such qualified registered medical practitioners is needed to confirm that there is a valid reason for the termination.

Because MA is safe, easy to use, cost effective, non-invasive, non-surgical and offers greater confidentiality than other forms of abortion (Coyaji et al, 2002; Mundle et al, 2007), it has the potential to be transformative, that is, to increase women's control over their own reproductive health. However, this transformative potential is limited, because the MA pill is currently only approved for prescription by registered medical practitioners and is also not included in the public sector.

There is limited knowledge about the values attributed to MA and the practices around it as it moves along its supply chain, which is from the manufacturer, to the stockist, the retailer/pharmacist, the provider and finally to the user. We conjecture that such information can provide a roadmap for enhancing the access to MA and realizing its transformative potential. In response to these gaps ICRW undertook a study between 2007–2009, to explore the factors that facilitate or constrain access to MA in India. The premise underlying the study was that MA is potentially transformative for women and the regulatory environment and perspectives of the actors along its supply chain could influence this potential.

Conceptual Framework

> [Pharmaceuticals] *are not only products of human culture, but producers of it. As vehicles of ideology, facilitators of self-care, and perceived sources of efficacy, they direct people's thoughts and actions and influence their social life. The availability of medicines affects how practitioners and patients deal with sickness.* (Geest et al, 1996, p. 157)

We hypothesized that MA is transformative only if the intrinsic characteristics of the commodity – safe, easy to use, privacy in use, non surgical, non invasive and cost effective – are experienced by women at the end of the supply chain. Yet, these characteristics can be experienced only when facilitative factors – a positive regulatory environment, wider access to information and services and efficient and quality services are available to women while seeking abortion services.

Diagram 1: Transformative Potential along a Value Chain: An Ideal Scenario

Policy makers/ Agenda setters →	*Manufacturers* →	*Stockist/ Retailers* →	*Providers* →	*Women*
Liberalizing law Liberalizing access Providing information Providing access	Access through reduced cost Providing appropriate information Widely distributed Quality of drug	Stocking adequately Providing access and information on safe services	Providing safe abortion services Information Informed decision-making Follow-up and PAC	Safe Easy to use Private Cost effective Non surgical Non invasive

Process of Transformation →

In this study, we used a 'value chain analysis' to examine the value stakeholders ascribe to MA as a commodity along the supply chain.[2] The value chain approach allows us to determine how the MA pill's potential to be transformative is affected at each level of the supply chain, i.e., policies and programs (government/advocacy/research institutions), production (manufacturers or pharmaceutical companies), distribution (retailers/ stockists), service provision (formal and informal) and use (women).

At the heart of this exploration of the transformative potential of MA are the following questions.

- Does MA meet the abortion service needs of women?
- Can access to women needing safe abortion be widened through de-medicalized MA?
- How can access to MA be increased without compromising quality and safety?

Methodology

We interviewed key stakeholders working on MA at the national level. We began by mapping individuals who currently influence policies and programs on MA in India, including representatives of research organizations, public sector hospitals, medical colleges, professional organizations, non-governmental organizations and drug companies. We also identified an emerging group of social marketing organizations that are playing an increasingly important role in improving access to MA for women in the community. We interviewed 13 key stakeholders from these diverse settings who are promoting discourse around MA in India today.

Thereafter we implemented a more detailed analysis in the urban and rural areas of a district in eastern Maharashtra. We purposely chose a district where ICRW had links to a local hospital and its networks from previous projects. The study areas within this district were chosen based on sales trends for the two most popular brands of MA. The urban area was clustered around a large public hospital and the rural area comprised the adjoining villages around the urban hub.

We selected a purposive sample of respondents along the supply chain, including representatives of the pharmaceutical sector (i.e. stockists and retailers), abortion service providers and women who had used MA, to participate in semi-structured, in depth interviews. In all we interviewed eight stockists, 28 retailers/pharmacists, 39 abortion providers and 120 women from the study areas.

Key informants in the community identified the providers of MA, including both approved and non approved providers. Approved providers, gynecologists and MBBS doctors are those who have met the training norms under the MTP Act (registered providers), and are legally allowed to provide medical abortion. The other providers are those with qualifications in recognized Indian Systems of Medicine (ISM) and Homeopathy, pharmacists and nurses.

2. Kaplinsky and Morris (2001) define the 'value chain' as comprising the full range of activities that take place in order to bring a commodity from conception, through production, to provision to consumption.

Table 1: Respondent Categories

Key Stakeholders	13
Stockists	8
Providers	39
Retailers/Pharmacists	28
Women	120

The study team initially asked providers for their help in identifying MA users. After the provider took the women's consent for their participation, the study team approached the selected women for their further informed consent to participate in the study. These women led the study team to more women who had used MA and were known to them. Prior to participation in the study, all respondents gave their written informed consent.

Findings

The findings are organized by the following domains of analysis which are considered facilitative factors – **regulatory and policy environment, information, autonomy in use, access and quality and efficacy** – which when fully enabled, will lead to realizing the transformative potential of MA for women. While specific actors along the supply chain of MA have particular influence on one or several of these domains as articulated in the above framework, the study team looked at the perspectives of all the respondents along the supply chain to ascertain whether a specific domain is more facilitative towards the transformative potential of MA. The impact the findings might have on the realization of the transformative potential of MA is reported at the end of each Section in a highlighted box.

1. Regulatory and Policy Environment

The MTP Act (1971) defines abortion as a medical procedure to be performed only by MBBS doctors with requisite training or by ObGyns. Recent amendments to the Act in 2002 and 2003 have facilitated the inclusion of MA and its provision by registered gynecologists and MBBS doctors. The findings from this study showed many areas of dissonance within the legal and regulatory framework.

Revising the law: Almost all the key stakeholders felt that the Act was either obsolete or needed revisions to respond to the present needs of women. Some respondents specified that the Act needed

> *The MTP Act should be done away with. No other medical procedure has an Act of Parliament so why this one?* (Senior Clinical Researcher)
>
> *The law should be amended to allow MA to be used up to nine weeks and certainly for use in the second trimester. Most doctors are using it in the second trimester anyway. Non-MBBS doctors should also be allowed to prescribe MA after training. Also, if qualified nurses with midwifery training and three years of training can conduct deliveries then why not do MA or even MVA?* (Representative of the Federation of Obstetric and Gynaecological Societies of India)

to be revised so that providers besides gynecologists and trained MBBS doctors are also allowed to perform abortions.

Liberalizing access: However, not all respondents felt that liberalizing access to MA was necessarily good. Amongst providers, retailers and stockists, there was a bias against liberal access to MA services for unmarried women or repeat users. Several respondents across categories of stockists, retailers and providers expressed their biases against liberal access to unmarried women, because it would lead them to 'misuse' the commodity.

Limited knowledge regarding the law: Knowledge regarding the law was found to be variable among providers. More than half the providers said that they were not aware of the detailed legal and medical guidelines for the MTP Act. Only 10 of the 39 providers correctly identified the guidelines of the MTP Act. Women were found to have limited knowledge about the law on abortion. While the majority (80 out of 120) responded that they had no knowledge regarding legality, five said they had some knowledge and a further 15 women reported that they knew about the laws on abortion. An overwhelming 80 of 120 women respondents expressed that abortion was permissible only up to two to three months' gestation. Interestingly women reported greater awareness about the Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act (2003)[3] and wrongly assumed that it was abortion that was illegal, rather than determining the sex of the fetus. Stakeholders expressed concerns that there is a challenge in expanding access to safe abortion because of the association of easier access to abortion with sex selection.

Is the transformative potential realized? *There is limited knowledge among most users and some providers regarding the legality of abortion. There is also confusion about abortions being legal due to the regulations around sex selection, which is illegal. While the current regulatory environment does not impede provision of MA in the public sector, it is not available in the public sector. There is need to revise the law so that provision of MA can go beyond gynecologists and MBBS doctors. The impact on transformative potential is that as a result of all these factors much of the use of MA exists outside of regulated spaces.*

2. Information Asymmetry

Information is the key to the provision and access of reproductive health commodities. The findings from this study indicate that lack of information affects access and ultimately the transformative potential of MA. While appropriate information is not made available in the public domain, evidence shows that women get information through other means such as through direct transaction with the retailer/pharmacists or from their friends who have used the commodity. Providers and retailers demonstrate that their social attitudes could constrain or facilitate access to information for women.

3 The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act and Rules 1994 (as amended up to 2002) (the PCPNDT Act) mandates that sex selection by any person, by any means, before or after conception, is prohibited.

Lack of information across the supply chain: Most of the key stakeholders reported that a lack of awareness at all levels of the supply chain stymies the potential for MA to be fully and safely utilized.

One of the reasons for little public knowledge is that it is a Schedule H drug, which means that it cannot be sold over the counter (OTC) without a prescription. Pharmaceutical representatives also do not advertise the MA pill as they do the Emergency Contraceptive pill (EC is an over the counter drug in India and also on the Government Schedule of Drugs). Two providers talked about the fact that even providers lacked information about MA. They reported that some providers prescribed MA, without actual knowledge of the commodity, because it was demanded by women. Only nine providers out of 39 correctly reported the approved gestational age limit for prescription of MA pills. While women may or may not specifically know about the existence of MA pills, the findings show that they try to explore the possibility of using a non invasive and a confidential method to meet their needs.

Information pathways: Women learn about MA from diverse sources such as providers, nurses, their friends and retailers. About two thirds of the women in the study got to know about MA from their medical providers. Corroborating this, ten out of 39 providers reported that women often sought information from them. Eight of these ten providers said that women come and ask them whether there is any pill available for starting their periods or for terminating their unwanted pregnancy. These women did not specifically know about MA. Providers noted that a major source of information for women is a friend or relative who has used these pills. Secondly, five providers stated that a woman or her partner seek information/ pills directly from chemists to terminate a pregnancy. Providers too learn about MA through varied sources that include medical training, which is restricted to registered providers. Other providers learn about MA from their colleagues, professional associations, and medical representatives.

> *We are seeing a 40 percent increase in sales since we started. This is seen not only because there is increase in awareness among women, but also among gynecologists.* (Senior Pharmaceutical Representative)
>
> *The major barrier in my opinion is unawareness at every level, women users, chemists and providers. Women or their partners go to chemists tell them about the unwanted pregnancy and ask for some pill to terminate it. More than half these women / their partners do not come with any doctor's prescriptions. The chemists based on the knowledge garnered from MR's of various pharma companies dispense drugs OTC. They know that there is literature in every tablet package, but they don't read it. They either expect the woman to figure out the dosage and regimen herself or tell them what the MRs have told them.* (Senior Demographer)

Differential information provision: Most retailers have the potential to influence information flow to women. The retailers reported that they were reluctant to pass

on information to women since it is a prescription drug and they need a referral from a provider. Several retailers were against facilitating access to women who were unmarried. These findings, however, must be interpreted with care as available evidence suggests that OTC sales are high and it is quite likely that retailers are a source of information for women.

> *In order to improve the access of MA drugs in India, a lot of awareness should be created. Proper information should be given to needy as well as to married people. Many times married are not using these drugs, may be they are not aware about these drugs and unmarried are using these drugs, unmarried are aware about it through word of mouth.* (Retailer)

Is the transformative potential realized? *The distribution channel of any commodity is very important in the value addition process and is often synonymous with the way information flows. In this study we find that information flows arbitrarily to providers and women. While MA is not advertised and there are no specific government channels providing information about it, women access information about it from other sources such as providers, retailers or friends. Providers too access information from other providers and medical representatives, but only the registered providers get formal training. Moreover retailers do pass on information to women although they may have their own biases against unmarried women accessing MA. These factors of restricted settings and restricted flow of information have meant that the full transformative potential of MA is yet to be realized in India.*

3. Increasing Autonomy and Expanding Method Choice

It is evident from the data that women are prepared to undergo some form of abortion, safe or unsafe, when faced with compelling need of an unwanted pregnancy. With the introduction of MA and an increased awareness about this method, there seems to be a shift in the demand and preference for MA. The key to the transformative potential of MA lies in the fact that as a method it holds potential to truly empower women by offering them a safe and effective choice where none is available or offering them expanded choices through a method that confers ease of use and confidentiality. The findings clearly indicate that women demonstrate a preference for this method.

Ease in use: For about a third of the women, MA offered a transformative potential even before they underwent abortion. They had chosen this as the method of abortion on their own for various reasons, the most important being easy availability, affordability and privacy. They could have the tablets at home, rather than stay at a hospital. All the 120 MA users talked about a sense of relief in using this method due to its attributes, despite the pain and anxiety during the decision making process about the abortion. A majority of providers confirm that given a choice, women prefer to opt for MA because of its attributes of confidentiality, it is non surgical and does not require hospital stay.

> *I chose this method of abortion myself as the pharmacy was nearby, the expense was less, there was no need to stay in hospital, similarly, for this work the expense was going to be less as compared to Doctor's hospital.* (23-year old Married, Rural Woman)

***Decision making*:** Almost all women responded that while the decision to undergo an abortion should be made jointly with the spouse, the woman herself should decide on the method of abortion. Her decision would be based on the advice of the doctor and there could be no role for the husband or any other family member. The fact that the MA pill can be used in privacy is a key element in enabling access for women with specific unmet needs, such as those who need confidentiality for fear of coercion from their in-laws or those who faced violence from their spouses.

The decision about the provider and method were well thought out. Women preferred to go to a doctor near to them, known to them and who provided services that were affordable.

Disconnect between provider and user preferences: Due to information asymmetries, there may be a disconnect between what providers think is an appropriate method and what women might prefer. Women who prefer MA may be suggested surgical abortion by the provider, based on the gestation period. Interestingly out of 39 providers in the study, only 12 offered a choice of methods to women. Providers also did not completely know about the clinical criteria, which would exclude a woman from using any particular method. Seven out of 39 providers noted that cost plays a role in what method they offer and provide to women. Providers' narratives are punctuated by their own bias for a method depending on what they think a woman can understand about the method, how well she can make a choice, and their own preference for financial reasons.

Expanded choice affected by concerns around 'misuse'? While women continue to have unmet needs, gatekeepers at various levels try and regulate access in the guise of a concern for 'misuse'. The fears of misuse include use by unmarried women, incorrect or incomplete regimen and lack of follow up. Different respondents interpreted the term 'misuse' differently and key stakeholders expressed that the fear of misuse undermines the real potential of MA for enabling choices for women.

> *I do not understand the argument about "misuse" and that it makes abortion too easy. What does misuse mean? I think the problem is that there is too little accurate information. More control is not the answer. You cannot control this technology. Women need this and they will get it. We need to make sure that they have the right information, adequate access and trained providers. The more we restrict it the more it will go into illegal routes of provision* (Senior Policy Advisor)

Is the transformative potential realized?: *While autonomy and empowerment are long term and intangible goals, women's articulation of why they prefer MA clearly indicates higher autonomy and easier decision making for themselves. While providers have a clear influence and sometimes power over women's choice of method, both women and providers identify common elements of why MA may be considered transformative such as privacy, or the fact that it is non surgical and non invasive. The need for safe abortions coupled with the availability of this potentially liberating commodity open up the possibility of greatly escalating the use of this commodity, while respondents along the supply chain express concerns around misuse as well.*

4. Access: Diversifying Provision and De-medicalization

Parameters of De-medicalization

- *Product*: standard dose, combi-pack or "kit"
- *Providers*: alternate or mid-level providers
- *Users*: (partial) self medication – home use
- *Protocols*: standard dose, more convenient route of administration (buccal, sub-lingual)
- *Information*: easy to comprehend, readily available
- *Cost*: inexpensive
- *Regulation*: not restrictive

Source: Dr Sharad Iyengar, Presentation at ICRW Dissemination Meeting, August 2009

The findings demonstrate that women are using MA through a diversified provider base, both within and outside the purview of the law. A critical question is whether de-medicalizing access would enhance the transformative potential of MA, as there is sufficient evidence to suggest that women access the method from various sources. While most of the key stakeholders were convinced of the huge potential for MA in India and argued for de-medicalization and provision at all levels of the public health system, some retailers and providers expressed reservations about de-medicalization.

Where and from whom? The findings indicate that women may choose to go to a retailer/ pharmacist, an unregistered provider or a registered provider to access MA, depending on the source of information, stage at which they received information and constraints faced in seeking the help of a registered provider. Whether urban or rural, abortion services were mostly sought or available from the private sector. There were a few cases of direct purchase from a local pharmacist.

Table 2: Distribution of Users by Type of Providers for MA Services

Area	*Number of Users*	*Type of Providers for MA Services*				
		Specialist (MD/DGO)	*MBBS*	*BHMS/ BAMS*	*Nurse*	*Retailer/ Pharmacist*
Urban	47	27	7	10	–	3
Rural	73	24	10	25	8	6
Total	120	51	17	35	8	9

Diversifying provision: Most providers were against self use through OTC availability of the pills and nine out of 39 felt that serious penalties must be levied against pharmacists who provide MA pills over the counter. Yet findings from key stakeholder and provider interviews indicate widespread acknowledgement of OTC sales. Key stakeholders felt that while this cannot be endorsed, steps also must be taken to ensure that women get correct and appropriate information on its use from retailers, who should also provide a referral to a doctor when such sales occur.

> *We do regular prescription surveys at random with a fixed number of prescriptions from doctors... If we see a 2 lakh sale of miso [prostol] and estimate backwards, we should see at least 15,000 prescriptions. The reality is 28 prescriptions!* (Senior Pharmaceutical Company Representative)

Most of the key stakeholders expressed that for true transformation in access to safe abortions for women in India, MA must be made available in the public sector. Several stakeholders noted that while there was no legal or regulatory impediment for the public sector provision of MA, it was still not available in the public health sector. The stakeholders were supportive of expanding access through enhanced training, public sector provision and advocacy for amending the MTP Act.

> *Yes, I would recommend it to be available in PHCs. These are captive government employees and the government is competent enough to get them trained. Backup with MVA is needed in [only] 5% of the cases...What happens in villages when women have spontaneous abortions? Those numbers are much larger in fact. PHCs are the key to increasing access for women in India.* (Senior Clinical Researcher)

Most stakeholders expressed caution at expanding the base of providers without mechanisms/systems in place that can ensure training, supervision and monitoring. A few felt that over cautiousness would create further hurdles to the de-medicalization process. Perspectives on de-medicalization varied with those in favor pointing out that the current coverage of abortion services is limited, and those against pointing out that de-medicalizing access might create potential problems around safety and quality in the absence of back up services. Fears were also expressed about the impact de-medicalization might have on sex selective abortion, and further if such fears might provide an argument for limiting MA use to under 49 days, when evidence shows that its use up to 63 days is safe. One stakeholder noted that retailers/pharmacists are an important constituency to engage with, even before assimilating non allopathic doctors and nurses in the abortion provision.

> *Non MBBS doctors should also be allowed to prescribe MA after training. Also, if qualified nurses with midwifery training and 3 years of training can conduct deliveries then why not do MA or even MVA? There are only 22,000 members of FOGSI and we have a country of over 1 billion population.* (Senior Pharmaceutical Company Representative)

***Concerns around home use*:** Only a few providers were in favor of home use and this included both gynecologists and non allopathic doctors. These respondents felt home

use had to be conditional, so that the woman is carefully screened, understands the dosage and complies with the regimen and goes for a follow up. Some gynecologists expressed their reservations against home use of MA, and expressed fears about women's ability to comply with the regimen and the possibility of a higher rate of failure and complications. Some of them mentioned coming across women with complications because of home use of MA. These women, according to the providers, had been given MA pills by their general practitioners without any proper instructions.

The entry of a dedicated combination pack for medical abortion (that has Mifepristone and Misopristol in the same pre-packed foil) would allow an interface between retailers and women users with the potential for educating women about the correct regimen, even if they self medicate.

Is the transformative potential realized? *The patterns of MA use are quite de-medicalized and not restricted to legal providers alone. Since the law currently does not permit anyone other than a gynecologist or a trained MBBS doctor to perform MTPs, its relevance to the actual context of use needs to be reconsidered. It is evident that the transformative potential for women is conditional on improving access to MA beyond the settings where it is currently mandated to where it is needed, without compromising on quality and therefore ensuring proper mechanisms for training, supervision and monitoring.*

5. Quality and Efficacy

Currently MA is a prescription based drug, but it is well acknowledged that OTC sales do occur. This may have implications for quality of care if women do not have adequate information and knowledge of the side effects and how to manage complications. Providers too need to have complete knowledge of consent procedure, correct protocol, side effects and follow up for ensuring quality and efficacy. Providers also need to understand the advantages of the method and how it matches the need from a woman's perspective.

Consent: Almost all providers of abortion services (36 out of 38) took the women's consent before providing them MA. Of these, more than two thirds said that they took written consent. The providers noted that they explained everything about the procedure, its pros and cons to the women and insisted on consent. Interestingly, most of their narratives suggest consent as a means to safeguard themselves by ensuring women are aware of the risks rather than to expand choice. Some providers also mentioned that they sought consent as it was legally mandated. Based on data from women, the consent of the husband was asked for in nearly two thirds of the cases (35/120), the women's consent was taken in another one third (38/120) whereas for more than one third (47/120) there was no mention of any consent procedure.

Counseling: There was little consistency in the information given to women about methods available, protocols, effectiveness, side effects, follow up and cost. Almost all providers gave some information about the side effects although the quality of information was varied. One third of the providers explained to women about the need

for surgical evacuation in case of incomplete abortion by the medical method. The providers implied that this information was necessary for the women to make an informed choice. A much smaller section of providers told women about follow up and costs. This was confirmed in the narratives from the women as well. The quality of the information provided also reveals the method bias as well as the provider hierarchy as the purveyor of knowledge. Providers voiced their dilemma about how much information to give about methods and their side effects to a prospective client.

> *I explain everything. I tell her about the chances of incomplete abortion and surgical evacuation and also about the necessity of follow up visits. Also, that with Mifepristone there may be continuation of pregnancy and in such cases she may have to undergo surgical abortion as there is a risk of congenital anomaly in the fetus. If 2nd gravida comes to me, I generally counsel her not to abort and continue pregnancy. I also discourage abortions in primigravidas. I tell her that there will be chances of infertility in future.* (36 year old, Male, Gynecologist)

Variations in protocols: There were varied screening criteria, protocols, drug combinations, dosage and routes of administration, follow up procedures and post abortion contraception. The data does not show any standard protocols that are being followed, indicating a lack of knowledge of the guidelines for MA among the range of providers, including the legal providers.

Women reported that the number of tablets that they used ranged from four tablets (64/120), three (44/120) to two tablets (31/120). A couple of women received 10 tablets for the abortion and five women reported the administration of injections along with oral drugs. The route of administration of the drugs was oral and vaginal; many times the women did self insertion of the tablets at home.

> *On day 1 we give Mife – 200mg 1 or 2 tablets orally. After 48 hours we give 4 tablets of Miso – 2 orally and 2 PV or only 1 PV depending upon dilatation. If not complete after 48 hours, sometimes we repeat 2 tablets of Mife 12 hourly. Also we titrate the dose of Miso. If she doesn't abort with one tablet of Miso, we give 2 tablets and if she is overweight, we give 3 tablets of Miso stat.* (ISM Practitioner, 15 years Rural Practice)

A majority of the providers (34/36) who provided MA services talked about the need for follow up. The follow up schedule recommended by the providers had some variations. They reported that women were asked to come back on the 3rd, 7th and 15th day after the first period and in any emergency situation. Less than half the providers said that most of their patients come for follow up. The others mentioned that once the abortion was complete and women started their periods, they did not think it necessary to go for follow up.

Efficacy: Women who used MA found it efficacious, 98 out of 120 women reported that they did not face any problem using MA. On an average the duration of bleeding was five to six days. Retailers confirmed that the main information that clients are interested in is the efficacy of MA in terminating the pregnancy. They want assured results and certainty of outcomes. Providers across the board noted that MA is a safe and effective

method and some noted that the method used depends on the eligibility of women for the method.

Cost: The average cost of MA varied from Rs.320 to Rs.1200. The range depended on the type of provider, the setting and use of additional services like Ultrasonography (USG). Providers also note that costs varied according to the economic condition of the woman, gestational age and interestingly also the marital status. Stakeholders note that cost is a barrier for women and they seek affordable alternatives, whether these include Miso only or using non allopathic drugs. Women confirm that they do explore cheaper options, such as seeking MA directly from retailers or seeking services from the public sector.

> *MA will continue to be a private sector led service but will also be available in the public sector at least in some states. There is a lot of market economics at work with a lot of profit for all concerned and women are willing to pay for it. It will continue to be so since women are traditionally used to paying for the services of delivery and abortion! ... No, I do not see it going down much in the near future since if the margins become too low, the retailers will not stock it.* (Expert, Independent Consultant)

Is the transformative potential realized? *Providers' practices that affect quality are very varied. Despite the variation, we find little evidence that it affects efficacy in use of MA. Women do not report complications and find the method acceptable, safe and effective. However, cost is an issue and can affect the transformative potential of MA as it often pushes cheaper services in to the unregulated sector.*

Conclusions and Recommendations

Women have unmet needs for abortion, have clear expectations of privacy, ease of use, costs and proximity from any method for abortion and do explore methods to meet their needs. Clearly MA pills have the potential to meet women's expectations and needs. From the findings of the study, we demonstrate that there are factors throughout the supply chain that facilitate / deter meeting women's needs and expectations for more autonomy in making reproductive health choices and thus affect the transformative potential of the MA pills. The recommendations that arise from the study are suggested below.

Promoting awareness: Awareness about the MTP Act as well as safe methods of abortion needs to improve within the community, especially in view of the high level of knowledge people seem to have about the PCPNDT Act, which often creates a misunderstanding that all abortions are illegal. Appropriate information must be disseminated by the government and social marketing organizations at all levels – providers, retailers and consumers – to ensure proper access to MA. Information should be provided as package inserts to ensure that women (and providers) are equipped with accurate facts, which can in turn promote independent decision making. The pharmaceutical sector has a major role to play in creating awareness.

Expanding access: There is a sense that the MA pill is a commodity whose time has come and women are increasingly likely to demand as well as obtain access by their own means. There is a huge scope for MA provision in the public sector and at different provider levels to truly enhance access to safe abortions for women in India. Given the government's commitment to international covenants such as the CEDAW and ICPD, as well as to national policies and programs such as the National Rural Health Mission (NRHM) with its emphasis on safe motherhood, there should be a greater urgency to introduce MA in the public sector with provisions to prevent misuse.

> *Often unfortunately, women's groups and the government policy makers ... behave as though women do not know what is best for them.... Women clearly do not go for abortion mindlessly. They may be repeat aborters, but that is an indication of their disempowerment and the fact that they are unable to negotiate contraception use.* (Senior Policy Advocate/Researcher)

Ensuring quality: Expanding access to MA will need to be matched with efforts to safeguard quality. This might entail amendments to the MTP Act and/ or government resources to allow for enhanced training and monitoring mechanisms. A more effective and a wider base of training and information are essential to ensure that an expanded provider base functions with safety, efficacy and quality. It is important to move safe abortions with MA from unregulated to regulated spaces and ensure that regulated de-medicalization can facilitate MA's transformative potential by making abortions safer for women. Therefore any effort to de-medicalize access to MA must take such factors into consideration.

Promoting women's reproductive rights: It is interesting to see that pharmaceutical companies and social marketing companies have moved into the driver's seat for promoting women's reproductive rights to safe abortions. It is worth considering if profit driven industries can somehow move the 'empowerment' agenda for women. Therefore, it is essential that the government programs have a strong role both in the provision and promotion of MA as a safe method of abortion for women.

> *It is lucrative.... My company has been in female health care for a very long time now ... We felt it was a good opportunity and there was also the concern that the country is burdened with the issue of inadequate FP and therefore unwanted pregnancies. There are limited abortion services available. We felt that this is a good product which has the potential to transform the way the condition is treated and how people handle their lives.* (Senior Pharmaceutical Company Representative)

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