Exploring the Transformative Potential of Medical Abortion for Women[i]

> At present, for the poor mother, there is only one alternative to the necessity of bearing children year after year, regardless of her health, of the welfare of the children she already has, and of the income of the family. This alternative is abortion, which is so common as to be almost universal, especially where there are rigid laws against imparting information for the prevention of conception (Margaret Sanger The Case for Birth Control first published in the *Woman Citizen*, Vol. 8, February 23, **1924**)

I. Medical abortion and its transformative potential for women

To some it may come as a shock that this quote is not from a recent women's health journal but was cited more than seven decades ago when Sanger championed the oral contraceptive pill. Even today the criticality of women's unmet reproductive health needs remains high on the agenda for reproductive health advocates globally. In India, these needs are captured by high fertility rates, high unmet need for family planning, few options for contraception with highest use of terminal methods and high rates of unwanted pregnancy, resulting in abortions. The confluence of such unmet reproductive health needs, gender inequities and supply side constraints in providing quality affordable and accessible services imply that many poor and vulnerable women experience a range of adverse experiences reproductive health morbidity and mortality. It is well known that about approximately 12-15 percent of maternal mortality is attributable to unsafe abortions. From a larger perspective it is evident that the policy environment in India needs to accord greater attention \to expanding options, information, and services for women's reproductive health-innovations and technologies that women need in order to make safe and informed decisions about their reproductive lives.

With few reproductive health options, it is not surprising that a lot of recent attention has been on a reproductive commodity for medical abortion that has the potential to radically alter options and outcomes for safe abortion for women. Medical abortion allows women the option to non surgical abortion within 63 days of gestation. A successful medical abortion process is defined as complete termination of pregnancy without the need for a surgical procedure.

Medical abortion is one of the newer generations of reproductive health drugs that have only recently become available in many countries. While there is ample clinic based evidence available on the efficacy, safety and acceptability of medical abortion, there is limited information on how women make choices while accessing medical abortion and what motivates them to use the pill when other methods of abortion are available as well (Elul et al 2004; Ganatra et al 2005). There is also little information on the role of mid level providers for the provision on medical abortion. As a result medical abortion is surrounded by its own myths of use and misuse that ultimately misrepresent its relevance to policy makers and therefore its introduction in the larger public sector system.

There are about six million abortions annually in the country, of which only one million are legal (Hall 2005). Abortion related morbidity and mortality is also high in the country making medical abortion an alternative for improving the access to safe abortion, as it does not require any extensive infrastructure and is non invasive. As hospitalization is potentially not required, it could provide women greater privacy and control over their decision. In this study we suggest that medical abortion is a public health commodity that can transform women's lives because it can be potentially

empowering and give greater autonomy to women through an expanded set of options, that is less invasive, safe, easy to use and confer greater confidentiality in use. As a non surgical option, it has the potential to be more accessible and de-medicalized in its provision. It reaches out to those who do not want surgery or are afraid of it or those that want a process that is more private; in many cases it might be more affordable than a surgery. It has attributes that contribute to this transformative potential. However the real question if whether this potential is realized in different contexts.

Although medical abortion can be considered as a product that gives women's greater control over and choice in their fertility decision making, there has been policy reticence in India to provide it through the public sector or de-medicalize its access. This is because the evidence thus far had been considered insufficient to allow for these decisions. However in the last few years several studies have provided policy relevant evidence needed for creating greater access for MMA in India. We undertook this study a few years ago to contribute to such evidence through a unique approach to understand what transformations that take place for a health commodity as it goes down its usual supply chain. This was under the premise that MMA is potentially transformative for women although this potential is affected by factors that are not simply located to policy makers but permeate the supply chain of the commodity. Optimally, at every level of its chain, the commodity's value is added, be it by the manufacturer, wholesaler, retailer or provider, so that in the end when it reaches the end user, the woman, it has reached its optimal potential to be transformative for women. If the outcome at the end is that women are still not able making safe and easy choices for themselves and move from unsafe to safer abortions or chose non surgical over other methods if they prefer, then perhaps the value chain for the commodity departed somewhere from its optimal function.

II. Study Setting and Methodology

This study was conducted in the state of Maharashtra where fifty-seven percent of the population lives in rural areas and the fertility rate is 2.23 (NFHS III). Though the literacy rate in the State is 76.88 per cent, the eastern part of the state lags behind western Maharashtra and Mumbai, some districts here have an almost 80 per cent literacy rate. Age at marriage in Maharashtra is relatively low. The median age at marriage for women age 25-49 is 16 years, the same as the all-India average.

The study was located in the urban and rural parts of a district in eastern Maharashtra. The urban block was around a large public hospital and around other facilities that include nursing homes and clinics run by private practitioners providing reproductive health services. Before selecting the study site, an estimate of the use of the medical abortion pills was done with the help of sales figure of two most popular brands of mifepristone. This helped us to know the geographical distribution for the use of the commodity. Thus the rural area was a taluka and an adjoining village where we had some evidence of use of MMA pill**s.**

We used a value chain analysis for the data collection. Defined by Kaplinsky and Morris (2001), the value chain incorporates the full range of activities that take place in order to bring a product or service from conception, through production, to provision of the product to consumers. The value chain approach allows us to determine how the pills' potential to be 'transformative' is affected at

each level of the value chain: policies and programmes (government), production (manufacturers or pharmaceuticals), service providers (formal and informal service providers) and consumers (women).

At the heart of this exploration of transformative potential are the questions: Can we reach out to women and de-medicalize safe abortion? Do women express the lack of empowerment as a barrier in accessing safe abortion services? How far can access be pushed without compromising quality and safety and who will push these boundaries?

Before we started the study we mapped out the key stakeholder along the supply chain of MMA with the assumption that each level of stakeholders has the potential to add value to MMA as it moves down the supply chain. Since our interests were in value addition we did not restrict ourselves to a traditional supply chain but really to identify key agents of transformation. It was also important to us to understand what women users find transforming in their experience of MMA use.

The rationale for this methodology was to create a mapping/ an overview of the perspectives of these key stakeholders and how that impacts on the ground realities. The main domains for the questions were what we conceptually identified as the five key elements of transformation: efficacy and quality, access, information, autonomy and law/regulation.

We identified the key stakeholders for this study based on several questions: Who are the key stakeholders that have the potential to create the momentum/impetus for MMA in the country? Are they facilitators of transformation as defined above? In their roles can they identify barriers to transformation and why do those exist?

We started with the obvious categories of Government Ministry, Public Sector Hospitals, teaching hospitals/ medical colleges, leaders from professional organizations and NGOs as well as drug manufacturers. We also found a newly emerging group of social marketing organizations which are playing an increasingly important role in improving access for women in the community. We spoke to researchers, demographers and activists as well.

We also interviewed the providers from their communities and from the local public and private sector hospitals. Chemists and pharmacists, stockists and wholesalers of the product who were located within the same region were also interviewed.

The in- depth interviews were carried out in person with the exception of a few who were interviewed via telephone and e mail due to constraints of time and other resources. A total of 21 stakeholders were interviewed.

The sample for the study was purposive The study was based on qualitative methods in which experiences of women who had undergone medical abortion in the past two years and the perspectives of abortion service providers were collected through in-depth interviews Data collection was done with the help of field investigators who were graduates in social welfare. The investigators were trained in qualitative data collection methods, the various terminologies associated with medical abortion, contraception and reproduction. The training also focused on the main domains and sub-domains of the study.

We interviewed 120 women seeking reproductive health services from health facilities: public and private hospitals, nursing homes and clinics.

For every interview we first approached women attending these facilities and obtained a very brief obstetric history to assess if they had abortion. We explained the study objectives to those who had an induced abortion in the past two years and sought their participation in the study. Those women, who were willing, were asked to participate in the study with a written informed consent and we fixed a subsequent appointment for a place and time convenient to them.

Some of the women were also identified by snow-ball technique from clients already interviewed
The interviews were conducted with the help of semi-structured Format that obtained information on the demographic profile of the women, their detailed obstetric history and contraceptive use and the details of the latest induced medical abortion. In order to understand the impact of medical abortions pills as a reproductive health technology that would influence women's decision making ability and influence their reproductive lives, women were asked regarding the decision of pregnancy termination, the discussion concerning the decision, the process and experiences of pregnancy termination and their views about medical abortion. They were also asked about the awareness and views of legality of abortion. The interviews lasted for about 50-60 minutes. Women in the rural areas were also identified with the similar technique, through the health care facilities and with the help of key-informants in the community such as a lady health worker, an Anganwadi worker or a nurse. The sample of users sought MMA services from a variety of providers. The Table 1 below shows the distribution of users by type of providers in both urban and rural areas in the study.

We interviewed 39 providers of medical abortion, individuals who provided abortion services, which could include the formal and informal ones. The formal providers were the ones who are legally allowed to provide medical abortion, allopathic doctors with a degree or diploma in obstetric and gynaecology (MD/DGO) and graduates (MBBS). The informal providers are the ones who are physicians in the Indian System of Medicine namely Ayurveda, Homeopathy, Unani. Nurses were also included as informal providers of medical abortion. Data was collected from both the formal and non-formal providers in the urban and rural areas, from public and private sectors since

Providers of medical abortion from the non-formal sector were a bit hesitant and 4 out of the 22 that were approached refused an interview. The providers, who were willing, were requested to participate in the study after obtaining written informed consent. The background information about the providers was obtained. The interviews were conducted with the help of a semi-structured questionnaire that gained information on the provider's practise of abortion services and their experience in the provision of medical abortion. All the interviews with the clients were conducted in the local language, Marathi and Hindi and the transcripts were translated to English, coded and analysed using AtlasTi Version 5.

Table 1: Distribution of Users by Type of Providers for MMA Services						
Area	Number of Users	Type of Providers that User Sought MMA Services From				
		Specialists(MD /DGO)	MBBS	BHMS/BAMS	Nurse	Pharmacist
Urban	47	27	7	10	-	3
Rural	53	24	10	25	8	6
Total	120	52	17	35	8	9

III. Global History

Clinical testing of mifepristone as a means of inducing medical abortion began in France in 1982. Results from these trials showed that when used as a single agent, mifepristone induced a complete abortion in up to 80% of women up to 49 days' gestation. By adding small doses of a prostaglandin analogue a few days later to stimulate uterine contractions, investigators discovered that they could induce a complete medical abortion in nearly 100 percent of women. In 1988, France became the first country to license the combination of mifepristone and a prostaglandin analogue for abortion during early pregnancy.The former President of the Royal College of Obstetricians and Gynecologists, U.K., Sir Malcom Macnaughton, called it "*an advance in reproductive medicine of the same magnitude as the development of the hormonal contraceptive pill . . .*" The significance of medical abortion for women is captured in this statement by a French Health Minister when he noted that the drug is **"***the moral property of women, not just the property of thee drug company.***"**

Millions of women worldwide have used mifepristone and a prostaglandin analogue to terminate pregnancy with impressive safety and efficacy. The key guidelines for MMA are synopsized in Table 2 below:

Table 2: Guidelines for Use of MMA

- MMA using Mifepristone plus prostaglandin is the most effective method of abortion at gestations of less than 7 weeks.
- It continues to be an appropriate method for women in the 7-9 weeks gestation band.
- Mifepristone in the dose of 200 mg and misoprostol as the choice of prostaglandin is recommended.
- Based on available evidence the following regime appears to be optimal for early MMA up to 63 days of gestation.
- Mifepristone 200 mg orally followed by misoprostol 800 microgm vaginally. This may be self administered by the woman.
- For women at 49-63 days of gestation, if abortion has not occurred 4 hours after the administration of misoprostol, a second dose of misoprostol 400 microgms may be administered orally or vaginally depending on amount of bleeding.

- Ultrasound is not a pre requisite of abortion in all cases. However, access to such services is necessary.
- Any acceptable method of contraception can be initiated immediately after the abortion is completed.

Source: Adapted from the RCOG Guidelines

IV. Context for MMA in India

Historically, in all civilizations, women have carried out abortions for unwanted pregnancies. A study by Coyaji et al (2000) notes that women in developed worlds spend only 10% of their reproductive life wanting to or trying to get pregnant and 90% of their life trying to avoid it.[ii] In India, the unmet need for contraception among women in the reproductive age group is 13.2% (10% urban and 14.6% rural).[iii]

The estimates for the number of abortions taking place in India vary widely. The Shantilal Shah Committee assumed (in 1964) that for every 73 live births, there are 2 stillbirths and 25 abortions -- 15 induced and 10 spontaneous. Many of these are 'illegal' abortions are 'safe' since they are being conducted by qualified doctors in places which are not registered and hence no records are being maintained. Other estimates of 11.2 million abortions (6.7 million induced and 4.5 million spontaneous) , or of three illegal abortions for every one legal abortion in rural area and 4-5 illegal abortions for every abortion in urban area are also based on similar assumptions.[iv, v, vi]

While MMA has been used in over 30 countries around the world and millions of women have used MMA, the potential of this drug has not been fully realized in India. The Drug Controller General of India approved of Mifepristone for use in Medical Abortions in April 2002. The dose approved then was 600mg Mife and 800 mcg Miso for use upto 49 days. India's Medical Termination of Pregnancy (MTP) Act was amended in May 2003 to allow for the use of MMA as a method of abortion. The Act was further expanded to allow the registered provider to dispense it from a non registered facility as long as the doctor and the woman had access to an emergency facility if needed. The market is large and growing substantially. Since its approval by the DCGI in April 2002, there are now 12 different brands being marketed. This is despite the fact that MMA cannot be publically advertised as it is a schedule H drug.

Across the country, the numbers of facilities which are registered and fully equipped for surgical abortion are extremely low in proportion to the population and the distribution is highly skewed. The majority of these facilities are located in urban areas. Further, the less developed but more populous states have fewer abortion facilities than the smaller but more developed states. Maharashtra, with 9.4 per cent of the total population has 21.2 per cent of the total registered abortion facilities in India. Whereas Bihar with 10.3 per cent of the national population has only 1.2 per cent of the approved abortion centres.[vii] A little more than seven out of ten facilities across the country provide only first trimester services.[viii ix]

V. Brief Review of Literature

Abysmal access to safe abortion services in India is reflected in the statistics that frequently get cited in many research studies. Only one sixth of women in India who need abortion are able to access legal services. Often the first point of contact for a rural woman, only three percent of PHCs and 19 percent of CHCs provide MTP services (IIPS 2005). And estimates suggest that there are 12,000 deaths a year on account of unsafe abortion (IPAS 2008).

While abortion has been legal in India for over three decades, the expansion in method choice took a positive turn a few years ago when the government expanded the MTP Act to allow for provision of

MMA. The first clinical trials conducted in India were in 1997 through a multi centre study on the safety, efficacy and acceptability of Medical Abortion using Mifepristone and Misoprostol, as far back as 1997[x]. This study that compared an oral regimen of medical abortion with surgical abortion in India, China and Cuba, concluded that while women were satisfied with either method, more preferred medical abortion. The authors noted that medical abortion can be safe, efficacious, and acceptable in developing countries. Published international studies have been suggesting from as early as 1997 (get ref) that the home use of misprostol is a safe, effective and acceptable variation on the original French regimen. India was a part of the WHO mutli centric study published in 2004[xi] and this study concluded that should a need arise, a majority of women would choose medical abortion again and would prefer to have it at a health facility rather than at home.

A study conducted in Maharashtra to look into the safety, efficacy, and acceptability of mifepristone-misoprostol abortion in the outpatient family planning departments of two urban hospitals and one rural hospital in India[xii] concluded only a significantly small percentage of women did not return for the follow up visit. (4.4% urban women were lost to follow up while only 1.0% rural women were lost to follow-up). While rural women reported fewer side effects at all sites, the vast majority of women were satisfied with their medical abortions. The authors thus recommend that medical abortion can be offered safely, effectively, and acceptably in the outpatient family planning departments of urban and rural hospitals in India.

Recent Indian studies published from 2007 onwards are beginning to show that home use is also effective and acceptable and that this can have the potential to improve access to safe abortion in ways that had proved impossible so far with surgical methods. Studies have shown that home use /use with limited supervision and in resource poor settings have been consistently safe, effective and acceptable to the women.[xiii]

Researchers and programmers are now starting to document the increasing potential for de-medicalizing safe abortion services in India , which has traditionally had an extensive public health care system (even if lacking in terms of infrastructure and human resources). Allopathic doctors trained in ObGyn, the only ones allowed to do MTPs, are scarcely available in rural areas presenting the need to have other safe methods of abortions to overcome these barriers[xiv]. It would appear that MMA is a method that would allow that possibility. Projects in Kenya, Myanmar and Uganda have successfully trained nurse-midwives to provide post-abortion care for incomplete abortion with manual vacuum aspiration, and studies in Ethiopia and India have recommended that providers such as auxiliary nurse-midwives should be trained in abortion service delivery to ensure that they provide safe abortions for low-income women.[xv]

A 2009 review article suggests that a substantial body of evidence demonstrates that mid-level providers, including nurses and midwives specialized in pregnancy-related care for women, are either already competently involved in providing medical abortions or have the requisite skills to expand their scope of practice to include medical abortion with a short course of additional training.[xvi] The authors argue that for first trimester medical abortion the evidence is sufficient for governments to implement, monitor and evaluate programs that allow mid-level clinicians to offer first trimester medical abortion independently.

While the government in India has not demedicalilzed access to MMA, in reality its use is more widespread and at various levels of service delivery including over the counter use. A study from Tamil Nadu in fact documents this widespread use as a ‘quiet transformation’ and concludes that MMA now needs to be integrated into the public health system[xvii]. The minimum clinical skills required are taking medical history, performing physical examination, confirming and dating of

pregnancy, counseling patients and managing complication through referrals. All of these can be undertaken at various levels of the public health system with adequate training and protocols. Women on Web is in fact providing these services as telemedicine [xviii] with only online consultation and has outcomes similar to those in outpatient settings.

Evidence from a number of supply side studies points to the high price of the commodity, especially Mifepristone as a major barrier for women. Price of Mifepristone has been high in both developed and developing countries ($7-8 in India for 200 mg, which is one third of a dose). High price of medical abortion is also found to limit public provision of the commodity and therefore reduce access and availability (Hall 2005). Given this evidence it is imperative to understand the supply side mechanics that lead to high prices particularly at the country level.

The Abortion Assessment Project-India, one of the largest studies on abortion ever undertaken in India, drew conclusions that public investment in abortion services nationally was found to be grossly inadequate.[xix] 75% of facilities were found in the private sector in the six states and were overwhelmingly perceived to give better services. The authors recommend that abortion services need to be integrated into primary and community health centers and the use of vacuum aspiration and medical abortion needs to be promoted. Many qualified and 'legal' providers are still using the obsolete and dangerous method of Dilatation and Curettage (D&C). They also suggest that it is time to broaden the base of abortion providers by training paramedics to do first trimester abortions, and re-skilling traditional providers to play alternative roles that support women's access to safe abortion services.

Another study from Rajasthan recommends that models based on MVA and including medical methods be piloted in rural areas of a number of states of the country, to establish the feasibility of delivering first trimester abortion as a primary health service. The authors also note that there is a need to rapidly increase training capacity across the country.[xx] A study from Tamil Nadu which looked at abortion providers and the safety of abortion recommends that government facilities should improve their quality of care, that unqualified providers should be stopped from practicing, and that all providers should be using the safer methods of vacuum aspiration and medical methods to reduce post-abortion complications.[xxi]

VI. Findings

As medical technology, pharmaceuticals, it is said, *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 (Van Der Geest, Anthropology of Pharmaceuticals pp 157)*. Drawing from the work of medical anthropologists, we understand that MMA has the potential to transform use and imbue a new vocabulary to the experience of abortion. This is only possible if some of the intrinsic characteristics of the commodity are realized by the user at the end of the value chain. This we hypothesis can only happen if there are facilitative factors along its value chain that add 'value' to the commodity so that its use can be transformative and optimized to its full potential. The attributes of this transformative use is due to the fact that this commodity embodies safety, ease of use, privacy, non surgical and non anesthetic experience.

We undertook this study in order to understand these facilitative factors or to what extent does the potential to be transformative get realized by all actors of the value chain. From the data five domains of analysis seemed to emerge that together and symbiotically create the potential for transformation. The findings are organized in these five domains: regulatory environment, information, *access,*

quality and efficacy and autonomy in use. Mapping the biographical facts about MMA along these domains we basically try and understand how transformations may and may not happen at each level of the value chain.

1. Fragmented Sources of Information

From our data we found an interesting role of information asymmetry as a key element that affects the value that gets embodied to MMA by different actors. If the information is partial or biased, its full potential to the user cannot be realized as it is not understood by the various actors that transmit knowledge/or services to the next level down. Most of the key stakeholder respondents for this study noted that a lack of awareness at all levels of the supply chain stymies the potential for MMA to be fully and safely utilized. One of the reasons that there is little public knowledge is that it is a schedule H drug and hence cannot be advertised or for that matter sold over the counter without a prescription. However, the free market economy for any commodity taps the informal networks through which information percolates to all levels.

> *Women ask for medical abortion on their own although most are unaware of MA pills. Most women are not concerned whether it is withdrawal bleeding or pregnancy termination, they just want their periods to somehow start. That's why they ask for the pills. They get information from a doctor or other women". [57 years old, Female, Gynaecologist with 23 years practice in urban area]*

> *The only way to promote being a scheduled product is through MR. However, discounts are helping promote these products in a big way. Apart from promotion through medical representatives, doctor's conferences, gifts to doctors are frequently used promotional techniques. Schemes offered by the companies, promotion by the MR and doctors faith in the brand generally determines who captures the market. The major factor affecting the sales of a brand is schemes offered by the company. Most brands are competitively priced however some companies offer better schemes to retailers and doctors. [W1,* Stockist*]*

> ***"****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, 23 years in business, providing MMA for last 2 years in urban area]*

> *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. [Senior Academic/ Demographer]*

Some of the stakeholders who are clinicians informed us that they started using MMA more and more as women started coming in and asking for it, not because they were aware about it at the outset.

> *I started using MMA a year ago. Mostly because women coming to the MTP OPD started asking for it, so we started prescribing it. But even now I would say only 2% of the total abortion patients actually ask for it.* [Senior Faculty Medical College Maharashtra]

While women do have some information and create access by asking for MMA there still is a large untapped potential in the market that is growing through these informal routes of information seeking and sharing.

Almost all providers in the study mentioned that women ask for abortion pills and most (30/38) said that women are aware of the availability of medical abortion pills. Eight providers said that women

come to them and ask whether there is any pill available to start their periods, or for terminating their unwanted pregnancy. These women do not specifically know about MMA pills. According to provider while women may or may not specifically know about the existence of MMA pills, they still try to explore the possibility of using a non-invasive and yet a confidential method to meet their need. The major source of information for these women is their friend circle. Most women have some friend or relative who has had some experience of having used these pills and these persons recommend these pills.

> *"Women ask for MA on their own because they want a painless procedure without intervention, sometimes to hide from the family members and in laws. They are getting their information from word of mouth"[37 year old, Female, Gynaecologist, 8 years practice in rural area]*

One provider said that she does not give any information as most women now know everything even before they come to the doctors.

> *Now a days women have become conscious, they know everything tablets, D and C etc. There is no need to tell". [25 year old, Female, Ayurveda practitioner, 1 year private practice in Urban area]*

The use of oral medications to terminate pregnancy is transformative for these women. It offers them a painless, non-invasive method to terminate the pregnancy without any hospital stay or risks of anesthesia. It provides a choice which not only restores their periods but also does so without the knowledge of the rest of the family members and is thus largely confidential. Five providers stated that chemists themselves are a source of information, as often the husband or partner or the woman herself go to the chemist's shop and ask for pills to start her periods or terminate her pregnancy. Medical personnel, particularly general practitioners, happen to be the source of information according to only a third of the providers.

> *"Medical stores people give them this information. The husbands of woman's bring* ***Epiforte*** *like medicines for them, as they want to get rid of the pregnancy sometimes. They are not bothered whether the drug is for withdrawal bleeding or MA tablets". [57 years old, Female, Gynaecologist with 23 years practice in urban area]*

It is evident that women do try and elicit information directly from a pharmacist although in our data we find that most retailers are reluctant to pass on information to women since it is a prescription drug and they need a referral from a provider.

> *We generally do not suggest any product for abortion. We recommend them to take advice of the doctor if some one wants to know about abortion pills. Women do ask about MA drug of their own. In these cases we recommend them to go to doctor. We tell them that it's a easy method for abortion. We also tell them the side effects of the drug. The specifically highlight side effect like excessive bleeding and weakness.[* P 6: R6, Age: 45, Sex: M, Qualification: DPharma, Area: Urban

The distribution channel is very important in value addition process and is often synonymous with the how information flows. For wholesalers, they would like to sell goods of as many companies as they can handle. For this, both the companies approach wholesalers and even wholesalers' approach companies and offer to distribute their products. Wholesalers maintain adequate inventory and avoid shortages at the market place and manage the second leg of transportation i.e. offer to move goods forward to retailers where buyers can buy the product. This is often how wholesalers get to know about new drugs.

"To become the stockiest, generally companies approach wholesalers (terms stockiest and wholesalers are used interchangeably) however, upcoming stockiest also approach manufacturers. If the company is well established in the market then even established stockiest also approach manufacturers. The approach is generally through local officials of the company". [W1, , Stockist*]*

For a manufacturer or a CFA it is not financially viable to reach as many retailers and nursing homes as a wholesaler can. While approaching the retailer, the wholesalers offer cash discounts in addition to extended credit period in almost every case. A wholesaler with good distribution network in the area is a big asset to the manufacturer. One who has good relationship with the local retailers and nursing homes, caters better and to a larger number of customers (Retailers and Nursing homes). This ensures better accessibility of the product to the end users.

"Generally the orders are booked by the wholesaler's sales representative. Most retailers buy the product from the wholesaler's counters and Medical Representatives also book order. There are under cutters also who purchases goods from wholesalers and sale it to retailers. Retailers get about 45 to 60 days credit period from wholesalers. In case of cash payment they get about 2 to 3 % cash discount". [W2, , Stockist*]*

Products can bring the transformation not only when they are accessible but also there is awareness about the product. Wholesalers and retailers do not stock all the brands manufactured by different manufacturers. The brands which are prescribed mostly by the doctors are the one which are stocked by most retailers. At times even offering incentives for stocking a brand is given by the manufacturer as part of investment program. The way the market gets segmented between manufacturers interestingly feeds into the brand loyalty by wholesalers and retailers.

"Company launched this product and we are getting prescriptions. We stock brands of Cipla and Sun Pharmaceuticals. Near by doctors prescribe these brands that is the reason we stock it. I do not have any brand loyalty. Doctors in the vicinity prescribe these brands maximum that's the reason we stock them more."[Retailer, 22 year old business].

"We decided to keep these drugs because of demand for these drugs. We do not keep these drugs on our own. Clients do not come to us directly they come through doctors so we keep those drugs which doctors prescribe to clients." [Retailer, 25 year old business].

2. Perseverance towards Quality and Efficacy

Almost all providers who we interviewed as providers of abortion services (36 out of 38) took women's consent before providing them MMA. Of these more than two thirds said that they took written consent while nine took oral consent. The providers noted that they explained everything about the procedure, its pros and cons to the women and did insist on consent. Interestingly most of their narratives suggest consent as a way to safeguard themselves and ensuring women are aware of the risk rather than explain the choices and why MMA might be a preferred method. It is one process through which actual information is exchanged with women and from the data it seems it mostly pertains to the risks and side effects rather than benefits and informed choice. Some providers also mentioned that consent was sought because they thought it was legally mandated.

"Consent is the same. I use same format for MA & SA. I take the consent from the woman as well as her relative. I am not aware how lawful it is to take consent in MA patients, but I take written consent. I take consent of woman because in essential for her to confirm that she

knows the pros and cons of these methods".[39 year old, Female, Gynaecologist, 12 year private practice in Urban area]

"I have a prescribed format (in Hindi) for MA; I directly give the patient to read it. I explain to them the chances of incomplete abortion and failure. It is necessary to explain everything to the patient. No risk should be with me" [35 year old, Female, Gynaecologist, 7 year private practice in Urban area]

"Written consent is very essential now-a-days as the PNDT law is there. Female infanticide is a big issue. In such a scenario taking consent is vital. Sometimes patient also has a dual mindset. She might change her mind after taking tablets" [42 year old, Female, MBBS, 15 year private practice in Rural area]

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Another aspect of quality and efficacy is what might be the consistency in protocols and regimens that providers use for MMA . We found a range of practices with little consistency across the board.

Women were told about the various methods available, protocols, effectiveness, side effects and cost. Twenty three providers mentioned that they explained the protocol as well as side effects of both the methods surgical as well as medical. One third of the providers also explained the need for surgical evacuation in case of incomplete abortion by medical method. The providers implied that this information was necessary for the women to make informed choice about the method they would opt for. A much smaller section of providers' told the women about the follow up and the cost. The quality of the information provided also reveals the method bias as well as the provider hierarchy as the purveyor of knowledge.

"I explain to the women, that both options are available, SA as well as MA. If you opt for MA, you should be ready for incomplete abortion, chances of failure, and excessive bleeding in next menses. In case of incomplete abortion, you will have to go for SA. In that case you will have to bear the extra charges of SA. Then the choice is up to you. Both are available at my clinic, cost of both already mentioned. SA is more effective & side effects are more with MA". [57 year old, Female, Gynaecologist, 23 year private practice in Urban area]

"We tell her that if she is ready to come for follow up for at least 3 visits, she will be given MA tablets. She is explained about the side effects like fever, bleeding, diarrhea, fatigue. And we tell her that if she has excessive bleeding, then SA has to be done. And then contraception advice like CU-T and OC pills is given. [43 year old, Female, Gynaecologist, 17 years service in Government set up in Rural area]

"I tell women that this is a sort of surgical abortion. Only the thing is that it is being done with tablets. With 1st tablet, the seed in your uterus will be dead and with the tablet on Day 3, the products will be expelled. I insist that the protocol be followed completely and she should report as soon as there are complications. Complications like heavy bleeding can happen in anyone. She cannot go out of station; this procedure is 99% successful. Now 1% failure is there even with Cu-t, oral pills, tubectomy." [45 year old, Female, Gynaecologist, 18 year private practice in Rural area]

Five out of the 39 providers mentioned that they ask the women to continue the pregnancy as far as possible and then opt for some contraceptive. This was true particularly for those who are primiparas or those who come in later gestation group.

"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 undergo SA 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, Gynaecologist, 8 years in private practice in Urban area]

At the first glance some of these providers may come across as deterrents to the use of MMA. However, providers voiced their dilemma about how much to tell a prospective client. While experience has shown that explanations about side effects can be counter productive and can lead to lower acceptance or use as in case of intra-uterine contraceptive devices, not explaining or forewarning the client is contrary to creating informed choice. Responses from interviews of providers indicate that the information provided can be genuinely based on the providers own experience but can also reflect the vested interest of the provider. In both cases it may counter the transformative potential of the method. Nonetheless, what is remarkable is that despite all this information about side effects and complications women do opt for MMA. This indicates the intense need as well as a desire for a non surgical product.

One of the conditions around provision of MMA is that the woman needs to come back for at least one follow up appointment to ensure that the process has been completed, there are no complications and also for post abortion contraception. Of the 36 providers who provided MA services majority i.e. 34 talked about need for follow up. Two providers mentioned that they did not advise follow up. While one of them did not believe in it, the other said that she herself goes for home visit and follows up. Overall the communication around follow up varied by providers.

"We don't call the patient for follow up on any specific day she can come anytime after she bleeds. Patients come for follow up at any time by their convenience". [37 year old, Female, Ayurveda practitioner, 12 year private practice in Urban area]

"I do not think there is any need for follow up because I am like a family doctor. I come to know from discussion with patients. I visit SA patients of my area. I go to give them B12 injection etc. at that time I come to know about the status of other patients also". [40 year old, Female, Ayurveda practitioner, 15 year private practice both in Urban and Semi-urban area]

"Follow up is necessary. This is because the women have no knowledge about the amount of normal bleeding after MTP. So all this can be looked after only if the women comes back for follow up. Almost all women come for follow up and IFA and Calcium supplementation. If a woman doesn't come it is because the bleeding stops and she thinks there is no need to go back". [28 year old, Female, Ayurveda practitioner, 2 year private practice in Rural area]

The follow up schedule recommended by the providers had some variation. Providers talked about the 3rd, 7th and 15th day, after the first period and anytime during emergency.

"After giving MA I call the woman for follow up on 7th day only in doubtful cases where the completeness of abortion needs to be confirmed". [33 year old, Female, Gynaecologist, 4 year private practice in Urban area]

"I ask the patient to come on 3rd, 5th and 15th day. On day 5, a per speculum examination is done to confirm the amount of bleeding…. On day 15, I do USG in doubtful cases". [35 year old, Female, Gynaecologist, 7 year private practice in Urban area]

Fifteen of the providers said that more than three fourths of their patients come back for follow up. The others mentioned that a much smaller proportion complied with the follow up advice. According to them, once the abortion is complete and they start their periods, they do not think it necessary to go for follow up.

"About 60 to 70% patients come back for follow-up at least on day 3. If periods start, they think, there is no need to come. After 4-5 months sometimes they again come with another pregnancy asking for the same tablets they had been given previously for abortion". [43 year old, Female, Gynaecologist, 17 year government service in Rural area]

"All patients come back for follow up. In my entire practice only once or twice it has happened that patient didn't come back for 2nd visit due to some personal problem" [36 year old, Male, Gynaecologist, 8 year private practice in Urban area]

In terms of the method efficacy, about a third of the providers recommended medical method of abortion (14) and an equal proportion mentioned that they tell women about both (12). Some of them said that though they do inform the woman about both the methods, the method that is used depends on the eligibility of the woman for that. Surgical method was listed as a preferred method for abortion by just three of the providers and another three mentioned that they do not provide the service at all. There were seven providers who said that they had neither any specific preferences nor did they let women decide the method. They decided case by case about which method to use.
Those who preferred medical method over surgical gave clear reasons for this preference.

"I don't do SA so I suggest MA. Truly speaking both are equally effective but side effects of invasive procedure like perforation, bleeding, infection are seen in surgical abortion." [37 year old, Female, Gynaecologist, 8 year private practice in Rural area]

"I prefer MA mostly if the patient is suitable for MA, because my surgical risk decreases, hospital load decreases and its safe and effective." [30 year old, Female, Gynaecologist, 3 year private practice in Urban area]

There were some providers who understood the advantages of the method and how it matched the need from a client's perspectives. These providers were quick to add value to the transformative nature of this commodity and promoted it in their practice.

"Earlier I used to advise SA to patients. Now since 3-4years I tell them about MA tablets. I found that this method was very convenient for women and I started promoting these tablets". [47 year old, Female, ANM, working in Rural area for 24 years]

"Although I keep the pros and cons of both MA & SA in front of patients, I prefer to advise MA since I have USG machine. Both are available at my clinic, both are cost effective, both are equally effective". [39 year old, Gynaecologist, 12 year private practice in Urban area]

There were others who though they recognized the advantages of the medical methods were little more cautious in outright promotion of the method. They promoted the method after exercising due caution.

"I think both are good. I offer both options to women, unless she has previous LSCS, asthma, fibroid or she has crossed the gestational age". [35 year old, Female, Gynaecologist, 7 year private practice in Urban area]

Bias toward surgical methods was noted in some providers who were also academics at medical colleges:

*We are surgeons and over 95% of the cases we do are surgical abortions. This is our mindset. It is something we do well and we are assured of completion of the procedure. MMA needs supervision and follow up. If the woman does not come back what do we do?…Who will teach surgical abortion to future gynecologists? In a teaching hospital we need to keep that also in mind. [*Senior Faculty Medical College]

Table 3: Provider's Preference for Abortion Method		
	Type of Method	**Number of Providers (n=39)**
	Not applicable/ No response	3
	No specific method	7
	Surgical abortion	3
	Medical abortion	14
	Both	12

Lastly, currently MMA is a prescription based drugs but it is well acknowledged that over the counter sales do occur. This may have implications for quality if women do not have adequate information and knowledge of side effects and how to manage complications. A recent paper reports on a survey of 209 chemists, in the Indian states of Bihar and Jharkhand in 2004.[xxii] It found that only 34% of the interviewed chemists stocked mifepristone and misoprostol, sales volumes were low and there was more demand for cheaper, often ineffective preparations for abortion. Men were more likely to buy abortifacient drugs than women therefore the context of giving information directly to women not arise.

We do regular prescription surveys at random with a fixed no. of prescriptions from doctors. If 20,000 anti-ulcer prescriptions are taken and Pantoprezol has 2000 then we estimate a 1:12 ratio of actual sales. If we see a 2 lakh sale of Miso and estimate backwards with a 1:12 ration, we should see at least 15,000 prescriptions. The reality is 28 prescriptions!! We suspect that either the doctors stock it themselves, there are OTC sales or use by quacks and general practitioners.[P10: Senior Pharmaceutical Company Rep]

Most providers were against the OTC availability of the pills and nine out of thirty nine mentioned that there should be serious penalty against pharmacists who provide these OTC.

"OTC sale of these drugs should be prohibited. The pharmacists are not even qualified sometime, he doesn't know anything – they even give Didofenac tablet blankly to any patient." [28 year old, Female, Ayurveda practitioner, 2 year private practice in Rural area]

3. Expanding Method Choice

Women's own preference for a method is a key element of enabling their access. Interestingly, due to information asymmetries, there may be a disconnect with what providers think is an appropriate

method and what women might prefer or there might be a disconnect between what the women think about the method and its actual attributes. Women who prefer MMA because it is a non-invasive methods of abortion may be suggested surgical methods based on their gestation age. Interestingly we find that the window of flexibility for a MMA seems to vary by providers in our study from less than 15 days to less than 45 days. By the MTP Act the current time frame is less than 49 days and by WHO standards MMA can be used safely for anywhere less than 63 days of pregnancy. Intermittent in providers narrative is their own bias for a method depending on what they think a woman can understand and how effectively she can make a choice for herself. These quotes aptly capture how medical providers often shape and influence the choices women make in different ways.

> *"If the patient is <45 days, we suggest her medical abortion only, women can't think so much about which procedure she must use, its upto us that what choice we give then. Even patients with 3 months pregnancy ask for MA. They want a painless procedure without anaesthesia and hospital stay". [37 year old, Female, Gynaecologist, 3 and a half year private practice in Rural area]*

> *"Patient does not tell what she wants, you have to explain her pros and cons of both. Duration of pregnancy decides what method has to be chosen. If she is <15 days overdue then MA is preferred. Both methods cost the same. In surgical she has to face anesthesia, admission & operative treatment". [48 year old, Female, Gynaecologist, 16 year private practice in Urban area]*

While providers have a clear influence and sometimes power over women's choice of method, both women and providers identify common elements of why MMA may be considered transformative such as privacy, non surgical or natural method.

> *"Now the number of surgical abortion has decreased due to increased awareness of medical abortion. Previously the number of second trimester surgical abortions was more. Now patients approach by 1st trimester and prefer medical abortion as there is no hospital stay, they can go home, it is economical non-invasive, and they do not want to tell in the family. [52 year old, Female, Gynaecologist, 26 year private practice in Urban area]*

Of the 36 providers who provided abortion services, only 16, all gynecologists, discussed surgical and medical abortion caseload in their practice. Seven said that the caseload of medical abortion was almost double that of surgical abortion in their practice. Three noted that the caseload of surgical abortion was more, and an equal number said that the caseload depended upon the client profile, the trimester of pregnancy, their financial situation and their own preference. Overall, with the introduction of MMA in the market and the awareness about the pills there is a shift in the demand and preference for MMA. Providers and women alike noted that a substitution towards non-invasive methods. Women's preference for surgical method is mostly because it is a one time process while with MMA there is the requirement of multiple visits to the provider.

> *"The proportion of Medical vs Surgical in my practice is 70:30. Medical is mostly used by women when they want privacy, have fear of anesthesia / surgery or when they are working women. Also it's less costly. Women use surgical abortion when they want faster completion of procedure & want a one-day procedure". [33 year old, Female, Gynaecologist, 4 year private practice in Urban area]*

> *"The exact proportion cannot be commented upon but the number of surgical abortion definitely more in my practice. The reason is most of the times the woman has crossed 8 weeks of gestation. Another reason for choosing surgical vs medical abortion is that the woman wants a one-time procedure". [32 year old, Female, Gynaecologist, 5 year private practice in Urban area]*

Most of the key stakeholders expressed their opinion that for true transformation of access to safe abortions for women in India, it must be made available in the public sector.

> *The government must move this forward. Health is a state matter ...Given the quality of care and infrastructure at public health facilities, MMA can be given much better than surgical methods. The policy environment is currently very supportive, both at state and central level. FOGSI is trying to get MMA on the schedule of drugs since it has been included by WHO in the list of essential drugs. At the government level, the policy makers are favorable in principle but the logistics are a barrier with issues of obtaining drugs, inventory, preventing pilferage etc* {Senior FOGSI Representative]

> *Yes, I would recommend it to be available in PHCs. These are captive govt employees and the govt is competent enough to get them trained. Backup with M/VA is needed in 5% of the cases. With proper training and patient selection and using it only upto 7-8 weeks the success rate is so high that only 5-10% may need some form of intervention. What happens in villages when women have spontaneous abortions? Those numbers are much larger in fact. PHCs are the key to increase access to women in India. It has to be through govt service if it is to reach all.* [Medical Doctor, Clinical Researcher MMA- Dr Coyaji]

Still others expressed reservations over training of public sector providers in subcenters, foreseeing a pattern where untrained people would continue to give prescribe this drug resulting in complications which would be coming to the qualified doctors and hospitals.

> *It should be a part of the government programme. Why is it not? In our country, we should insist on women coming to the facility to take the drug not on home use. I am not at all convinced about the availability of this drug at the Subcentre level. I think the private providers including those from ISM but not the quacks, can be allowed to prescribe the drug. No huge training is required for using the drug in their practice".* [Senior Researcher, Women's RHR/Demographer]

> *" I get patients for evacuation and with prolonged bleeding on an average 2 per month who have been given wrong doses of MA by a GP. They take these at home because of their faith in the GPs and the price at which these are given". [39 year old, Female, Gynaecologist, 12 year private practice in Urban area]*

4. Diversifying Points of Access

From the findings it seems that women may choose to go to a pharmacists or a provider or a specialist depending on where she got the information, at what stage did she have the information and what her constraints are in seeking specialist help. From the 120 narratives in this study, these diversified points of access seem to work for women but in terms of what is quality provision of care and whether these are all acceptable points of service delivery, there are several questions that remain about what level of services can a MMA be dispensed at, can women use MMA at home and with what kind of back up services.

More than half the women (n=64) themselves decided about the type of provider, in another 25 cases both husband and wife made the decision about the provider type and in 16 cases the husband decided about the provider. In rest of the women (n=15), the type of provider was decided based on the suggestion of a relative or friend. Decisions were either due to convenience, familiarity or through referrals.

The type of providers varied in urban and rural settings, whether they were the formal or informal type and from public or private sector. Whether urban or rural, abortion services for women were mostly sought or available from the private sector. In fact, most women in the rural areas preferred the private doctors for abortion services. There were a few cases of direct purchase from a local pharmacist.

> *I had wrapper of previous tablets and knew the tablets were effective so I didn't even think of consulting a doctor.* (27-year old married, rural woman) --
>
> *I knew that the tablets are available in pharmacy because one of my relatives got results from these tablets. So we decided to take the tablets from pharmacy.* (25-year old married, rural woman)
>
> *First I went to the nurse who was known to me. I went to her to do urine test but the nurse herself told me that there are tablets available for abortion. Therefore, I did not go anywhere else and decided to have the abortion from the nurse* (32-year old married, rural woman)

Though more than half the women had their abortion from a specialist in the urban areas, in rural areas non specialists, particularly non-allopathic practitioners played a significant role in the provision of abortion services. Indeed, about two third of the providers of medical abortion in rural areas were the non-allopathic practitioners and more than half of the women sought abortion from the non-formal providers in the rural areas (Table 4 below),

Table 4: Users of MMA by Type of Provider

Site	Type of facility		Type of Provider n (%)				
	Private	Public	Specialist	MBBS	Non-Allopath	Nurse	Pharmacist
Urban	29/43	14/43	27 (57.4)	7(14.8)	9(19.1)		4(2.13)
Rural	50/58	8/58	19(26.0.0	15(20.5)	24 (32.8)	10 (13.7)	5 (6.85)

Women preferred to go to a doctor, particularly the one who was near to their homes, known to them perhaps as a family physician or one who had previously provided some health service. The choice of provider was mainly based on economic reasons, women choosing a provider or facility that would cost less and would be affordable.

> *Because I knew that abortion, services were available there that too at less cost than private hospital. I thought it would be better to go for abortion at that hospital because it would be reasonable, and there are good doctors at Govt hospitals also and it would be easier to go for follow up. If I have to go to a private hospital it would be costly, they take 50/- to touch the patient, and the medicines cost extra. First of all it's necessary to think of money.* (34-year old married, rural woman).

The next important factor for the choice of provider was the convenience of the doctor being near to their homes. This is an important aspect of abortion with MMA pills, which is possible in a facility that may not be equipped with an operation room but be a dispensing centre for drugs. This entirely has changed and broadened the scope of providers that women may access for abortion services.

> *For the abortion, I directly went to the doctor (BAMS, Private). I chose this provider for abortion because it was convenient, near-by and needed less money*. (31-year old married, rural woman)

> *I went to the doctor (MBBS ,Private) since she was known to me, she provided good services, explained everything and was also near to my home. In case of any difficulty, it would be convenient to go for follow-up visit* (31-year old married, urban woman) *The reason was that once when my health was not good, I had gone to the same doctor(BAMS, Private). I thought that I should not have much trouble in having an abortion, it should be done at home with the help of medicines. If asked to come again for the visit, then it would be convenient* (24-year old married, rural woman)

Confidentiality, an element of why this commodity may be transformative for women, was also another important factor that influenced women's choice of the provider

> *Finally as per advice of my elder sister, I decided to use tablets, purchased them from pharmacy because expenses were very less as compared to hospital's expenses. I did not have to be admitted in the hospital and could maintain secrecy, only my husband and sister knew about it.* (22-year old married, rural woman)

Interestingly while there is home use of tablets, very few providers were in favor of home use of MA pills compared to those against. And those who endorsed home use were both specialists and non allopathic donors. They did make it conditional that the woman be carefully screened, understand the dosage and complies with the regimen as well as follow up, there is no risk.

> *"Home use is applicable to women who are ready for consultation and strict follow up and therefore comply with home use…Women comply with the home use of MA drugs because it is the question of their health". [40 year old, Female, Ayurveda practitioner, 15 year private practice in Urban and Semi-urban area]*

> *"Women do comply with home use. If patient is reliable and stays nearby, both tablets can be given at home. Initially the drug was new no data was available so I was afraid of giving it for home use. Now through conferences and paper presentations, I have knowledge and hence confidence. If patient stays too far, I ask her to stay at her relative's place, ask her to see if the sac is expelled and ask her not to work and take rest at home. I do USG so I have no tension of incomplete abortion". [48 year old, Female, Gynaecologist, 16 year private practice in Urban area]*

Those against home use of MMA expressed their reservations about women's ability to comply with the regimen, the possibility 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 drugs by their GPs without any proper instructions.

> *"We don't recommend home use because we don't come to know about the abortion status in that case". [37 year old, Female,Ayurveda practitioner, 12 year private practice in Urban area]*

> *"About one in five women come as case with complications. Women who are administered medicines at home need follow up as they often confuse the doses of Miso. Instead of stat they take one in morning and one in evening". [40 year old, Female, Ayurveda practitioner,16 year private practice in Rural area]*

> *"There are many patients who came to my clinic with increase bleeding and shock. They have been given MA at wrong gestational age." [37 year old, Female, Gynaecologist, 3 and a half year private practice in Rural area]*

5. Demedicalizing Access

While the findings show that women are already using MMA through a diversified provide base, some that are within the purview of the law and others that are not, including over the counter from pharmacists. We asked ourselves whether demedicalizing access would enable the transformative potential of MMA if in reality it was already being used in that manner. While the key stakeholders we interviewed were convinced of the huge potential for MMA in India and also spoke very positively of the ease of use and cost benefits as being positive attributes, there was polarization on this issue. One of the overwhelming reasons stated towards demedicalized access was the limited coverage of abortion services if we rely only on specialists.

> *Non MBBS doctors should also be allowed to prescribe MMA after training. Also, if qualified nurses with midwifery training and 3 years of training can conduct deliveries then why not do MMA or even MVA? There are only 22.000 members of FOGSI and we have a country of over 1 billion population.* [Abortion Provider; Senior FOGSI Representative, Mumbai]

The skepticism came from equally sanctimonious medical settings were senior medical faculty raised questions about safety and quality in the absence of back up services.

> *I am not convinced that there is a trade off with the current scenario of unsafe invasive methods of abortion. Where are the systems to train all these new providers? Who will monitor, supervise? Who will look after those 5% who have complications? It may be better to send a qualified doctor to the periphery on a regular basis and do the abortions. If we cannot stop the unqualified users, at least let us not make them legal!* [Senior Medical College Faculty, Mumbai]

Those who were not so sure, did however note that offering MMA in the public sector was a step forward to improve access for the women who have no access to other facilities. Those who did accept that midlevel providers need to be brought into the loop here in order to meaningfully have an intervention which improves access, suggested that appropriate training should be mandatory, again in order to ensure safety and quality issues for the women.

Most stakeholders shared their discomfort on the issue of over the counter use but suggested that demedicalizing access would actually help address the direct purchase from pharmacists. And some suggested a more pragmatic view of taking pharmacists into the fold of referrals.

> *It should be made available as far down the health system as possible. Self use is not safe. The Pharmacist probably can give the pill but should be a qualified person with appropriate training and knowledge about Mife- Miso and linkages for emergency. Also this is possible only for early abortion and obviously the later terminations need a clinic based care. This is better than no option. But women are doing self medication anyway at present. We can try to see if some pharmacist can work as referral centers. Maybe sell pregnancy kits and refer them to doctors i.e. when women come directly for MMA sell her a pregnancy test kit and refer to doctor for the abortion. [*Senior Researcher with subject expertise].

> *I am not very comfortable with Pharmacists being the providers. Women can calculate their LMP and gestational age but a pelvic examination is important and if you get drugs OTC, who will do this? I don't agree that we should legitimize it just because it is happening anyway. If pharma companies make it available OTC and there are so many spurious drugs, do you expect the doctors to regulate this {Senior Researcher Medical Faulty]*

It was universally accepted though that over the counter sales (OTC) are happening. While we cannot endorse this, perhaps we need to work with it and at least ensure that women who do get this OTC do get the necessary information and if possible a referral to a doctor. In fact even the potential entry of a dedicated combi-pack allows a interface being between the chemists and the women where there is a potential for ensuring the right dose 'even women self medicate (which no one wants to endorse, as explained, for safety and quality reasons) but pragmatically all accept as a growing reality (MSI study 2009)

Thus pharmacists and retailers are seen as an important constituency to engage with, even before we can start assimilating non allopathic doctors and nurses. Some stakeholders are even willing to go down the line as far as the woman herself. They project this as an ideal situation, since the presence of other safety systems are not a reality currently nor are likely to be in the near future, where a woman can buy this at a grocers or even buy in advance and keep and be able to use it safely effectively and also have access to emergency care and post abortion contraception / care as and when needed.

> *Over the next 2 years the combipack should happen. Over the next 5 years the proportion of MMA within 1st TM abortions should be > than 30% (Estimate that reflects the probable proportion of women who will be eligible for MMA in 1st TM and then should all get MMA instead of surgical). MMA will continue to be a private sector led service but will also be available in the public sector at least in some states.Almost all studies are provider based and there are no studies about self use since it is so difficult to trace these women. But we believe*

that if a combined product is made available it will increase the effectiveness of the self use.[Service Delivery NGO Representative]

Broadly speaking, the stakeholders are supportive of the expanding access and are attempting facilitation of access at every level, whether it is training, public sector provision or advocacy for amending the MTP Act. Many express caution at expanding the base of providers without mechanisms / systems in place that can ensure training, supervision and monitoring. Others feel that we should not be overcautious and create further hurdles to the de- medicalization process.

There is another aspect of liberalizing access which is to extend the gestation time under which MMA can be used under the MTP Act of India. The real thorny issue is one of regulating sex selective abortion under the PCPNDT Act. Stakeholders suggested the need to take this issue head on since MMA is currently permissible for use upto 63 days by the WHO.

It should be available at least upto 63 days. Even 9-13 weeks is now shown to be feasible, effective and acceptable. Make sure it is in the procurement list of all PHCs and states. More information should be available about its dose, side effects etc. The 7 weeks limit really is a barrier. Most women do come late and there is no real medical contraindication. Providers need to develop more confidence but economic barriers (for the providers – they get less money) will remain.{Senior Researcher Subject Expert]

Second trimester abortions are threatened buy the sex selection issue and the perception by policy makers that all 2nd trimester abortions are only for that reason. It is important for civil society and professional bodies such as FOGSI to ensure that the government is well informed about facts and scientific progress in opening up MMA for greater use in the country.[FOGSI representative]

6. Autonomy

This might be the most important component to explore in order to understand the transformative potential of MMA. Would women be able to make easier decisions, more informed choices, free of coercion and would their experience of abortion be easier? The reasons women had abortions were because they already had the number of desired children, the previous child was too young and they could not manage to take care of another child, or they faced financial difficulties and could not afford the pregnancy at that time. Other reasons for abortion were health problems or a husband who was violent or fear of a girl child again. It is evident from the data that women will undergo some form of abortion, safe or unsafe when they are faced with these circumstances. However all the 120 MMA users talk about a sense of relief with this method due to its attributes despite the anxiety of going through abortion.

For about a third of the women the MMA offered a transformative potential even before they underwent abortion. They had decided 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 stay at a hospital. Some women thought that a method of abortion, which did not require surgery, would be more simple and safe considering their own health and presence of a previously scarred uterus due to cesarean section.

My health was not good and I had a previous caesarean during 2nd delivery, I was very weak. During my 4th pregnancy, my condition was very bad and my husband feared whether I would survive or not. This was the reason why my husband declined surgical and advised to do medical abortion(28-year old rural , married woman)

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)

I decided myself to use this method. I could look after my daughter, as the procedure was possible at home itself. Similarly, I had nobody to help me at home; I was doing all the work even when I had the bleeding. I did not take any rest. There was no need to be admitted in the hospital. (24-year old married, rural woman) 02_MVN]

The choice between surgical and medical method of abortion was accessible for 53 of the 120 women who had medical abortion. The type of provider for 74 women was a non-specialist, where in fact there is no choice other than a medical method or use of medicines.

I would have gone to a dai or done some household remedy, and if its not done with this then I would have done whatever the doctor would have told, as I would have no other option. (26-year old married, rural woman)

On the other hand not all providers are ready to accept that women can make their own choice on what method of abortion they prefer. Some of them struggle with the notion of women's informed choice and suggest that the choice should best be with the provider.

The method of MTP which a woman needs is a doctor's decision. I decide whether M.A. or S.A. is suitable for the patient. Sometimes I even advise the patient to continue the pregnancy. SA has lesser side effects, it is a better option with M.A. [42 year old, Female, Gynaecologist, 21 year private practice in Rural area]

*A*ll women users considered medical abortion as a safe method, which should be done at an early gestation, under supervision of the doctor and preferably in the hospital.

Medical abortion is a safe abortion practice. There is confidentiality in this method. No body comes to know about it. Neither the children nor the people outside come to know about this method. A doctor should do it within 2 months. [Case 57]

Abortion will be successful with any method but a method with no trouble at all is medical method. The abortion done by medical method is safe. Medical abortion within three months on the advice of the doctor in the hospital is a safe method.[Case 53]

One third of the women chose to have a medical abortion based on the suggestion of the doctor or relative or a nurse. Some women thought that a method of abortion, which did not require surgery, would be more simple and safe considering their own health and presence of a previously scarred uterus due to cesarean section.

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)

Almost all women responded that an abortion should be done under the supervision and on advice of a doctor and in a hospital setting. More than two thirds of the women considered that there is a definite role of husband and other family members in the decision for abortion. Women said that it was

necessary for the husband to give his consent for the abortion, rationalized that the husband was the care taker and the one who would provide financial help, he contributes to the baby and should be included for the consent procedure. One third of the women felt that there was no need to take consent of the husband, the woman herself can take the decision since she is the one who has to undergo all the trouble.

Almost all women responded while the decision should be joint with the spouse, the method of abortion should be decided by the woman herself on the advice of the doctor and there could be no role of the husband or any other family member.

> *The decision of abortion should be taken by both but the method should be chosen by the woman only since she has to tolerate the pain. The husband is not going to share the pain.[*Case 33_]

The key stakeholders for this study all noted the relative disempowerment faced by women in India especially in relation to lack of any meaningful choice in terms of contraception use. Women needed products closer to them while there are gatekeepers at all levels who worry about the fear of 'misuse'. The term misuse was interpreted differently by the respondents and in all cases it undermines the real potential of MMA for enabling choice to 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 Researcher Subject Expert]*

> *Those who are reluctant to see it in the public sector raise issues of misuse but that is possible with so many other drugs so why single out MMA? That is because there are moral issues involved in their perspective. Often unfortunately, there is collusion between women's groups and the govt policy makers and they all behave as though women do not know what is best for them. Women are not supposed to have 'agency'. 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. The barrier is in the failure to understand MMA technology by the public sector. At least first trimester use should be open in the public sector. Why do they always link it to second trimester and this to the issue of sex selection? This is the principle barrier. The idea of 'misuse' is a myth. Those who seek treatment in the public sector are only those who have no other option so in fact these are the very ones who are being left out due to their vulnerability and not likely to 'misuse'.*

From a rights-based perspective we realize that while we are talking about enhancing choice in reality women are in a situation where abortions are sought because of little choice, often a substitute of unmet need for contraception. A stakeholder noted this as he makes a larger point about the lack of male involvement in family planning and the lackadaisical role of the state in promoting this.

> *Most women in India get pregnant not because they have a choice. They cannot accept or refuse anything of their own choice. If the husband refuses to use condoms and does not allow them to use a method what do they do? These women are disempowered, and this is the only option they have. So while women using MTP as the method of FP is not acceptable, it is often unavoidable. No matter what we feel about it, this gives a way out to the woman who suffers the consequences of an unwanted pregnancy. Lack of male involvement in FP is THE reason for this state of affairs. {Senior Researcher Medical Faculty Mumbai]*

While autonomy and empowerment are the long terms of goals the articulation of women's reproductive rights at all levels of the value chain is almost absent. We found it difficult to track the transformative potential for MMA with respect to women's autonomy or freedom to be ultimate decision makers for their own lives. Perhaps the reason is precisely because of the many interlocking domains of analysis that affect women's autonomy including issues around access, concerns about safety and efficacy, information and lastly the domain of law and regulations.

7. Regulation and Policy

The MTP Act considers abortion as a medical procedure and only performed by allopathic doctors.[xxiii] The recent amendments have facilitated the use of MMA within the purview of the Act. The findings from our study showed many areas of dissonance with this legal framework, which can impact the transformative potential of MMA in India.

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. One of the key stakeholders interviewed noted that the law is almost redundant and why there needs to be Act of Parliament what that does not hold true for any other medical procedure. Certainly abortion is not 'any' medical procedure but one that evokes strong sentiments amongst all levels of the value chain of MMA. Almost all the stakeholders we interviewed felt that the Act was obsolete and needed to be replaced with something more in keeping with the needs of women today.

> *The way to reduce illegal abortions is of course to have more legal and safe abortions available. What is illegal anyway? The Act is superfluous and illegal is just a technicality. [Senior researcher; Medical Faculty]*

There were some stakeholders who had reservations with doing away the MTP Act since it still offers some protection to women against potentially unsafe practices. However the real conflict is between what is regarded as 'legal' and what may be considered as 'safe'.

Some key stakeholders are of the opinion that the Ministry of Health and Family Welfare or even the Ministry for Women and Children may have different priorities. They noted that often the State project implementation plans (PIP) may not even budget for commodities related to safe abortion services. The RCH plan mentions increasing access to safe abortion but there is no mechanism to support that and no one leading that effort.

> *Currently even FP is not a priority it seems. Where are the advertisements for FP that we used to have earlier? Abortion does not seem to be on the radar of the policymakers—they have other things to worry about!*

Several stakeholders including a senior Pharma representative noted the lack of a positive regulatory environment to support provision of MMA in the public sector

> *There was no data when we started. So we did epidemiology studies and looked at NFHS data, FOGSI studies etc. We thought if even 10% of the current abortion patients move to this method, what are the numbers? Sales data and prescription data can be available only after you are in the market. Once 2-3 brands are in the market, we can get the sales data and other data and make projections about the demand. We are seeing a 40% growth in sales every year since we started! We did many doctors meetings in the early days. This increase in sales is not only because of increase in awareness amongst women but also in gynecologists. There are attempts to introduce it in the government programme but there is not much progress. There is no active blockage as such. I think it requires lot of lobbying. The regulators at the*

government level often do not understand the core issues of health. They are basically administrators. [Senior Pharma Representative; Personal Interview 12 Jan 2009]

An interesting revelation was that there is a very small cohort of donors which support work towards safe abortion. Most persons interviewed had very little expectations from domestic donor base and some even said it was a 'lost cause' due to their constituency and board members composition. It seems that there are only 5 bilateral donors that fund abortion programs. Domestic donors belonging to prominent industrial houses of the country do not touch abortion issues due to religious or other personal beliefs. Those we interviewed did not seem to have considered the need for preparing a strategy to work for changing this.

As the role of the private sector in health care is expanding there is concern that the policy environment for abortion should be proactively promoting safe abortion access through different models of health care. A stakeholder notes this point as they stated:

There is a worry that as these domestic 'big names' get into the corporate health care they do not undermine access to abortion. They are in a position to create private sector health care networks which do not provide abortions and that is very worrying. Tata Memorial at Jamshedpur for example does not do abortions but they refer women to Janani, a service delivery NGO. This may not work for all women and the Public Private Partnership deals should look at this issue to ensure that this does not happen.[senior researchers and Policy Influencer]

At the level of the provider, twenty of the thirty eight providers said that they were not aware of the detailed legal and medical guidelines for medical termination in general and medical abortion in specific. One gynecologist noted that she is aware of the FOGSI guidelines about abortion and wanted to know whether those are the ones which apply to MMA. About 10 providers correctly indentified that the guidelines specified that the provider should be an allopath qualified to provide these services and should be either operating out of a recognized or approved facility or should at least have access to an approved facility as backup. Only nine providers mentioned the gestational age requirement for prescription of medical abortion pills. The overall gestation age mentioned ranged from 21 to 49 days after the LMP.

"MA can be safely done up to maximum 21 days overdue. Consent should be taken like routine consent. This is just to make the patient realize that it is a procedure like surgery, not very safe. Clinic need not be recognized provided it has a back up facilities" [45 year old, Female, Gynaecologist, 18 year private practice in Rural area]

Women's choice for abortion does not get reflected anywhere in the discourse around regulations and laws. Women in fact had limited knowledge about the laws on abortion. Women were universally of the opinion that abortion should be done as early as possible, both as a legal necessity and as a moral concern. They believed that an abortion is legal only upto three months. Most of the women thought that it was legal for a married woman to have an abortion, many also thought that unmarried girls and widows could legally have an abortion. Those women who thought that it was illegal for an unmarried or widow to have an abortion, were of the opinion that it would be socially necessary for them and hence justified in doing it. Women felt that an abortion would be needed in case a woman does not want a child at a particular time, has all the number of children they have or in case of socially distressful situations

According to my knowledge, abortion can be done only up to one and a half months when a married woman does not want the child because at that time the pregnancy is only water and its not very difficult. Unmarried girls should definitely should have an abortion or else how can they lead their future life without a husband, what can she do with a baby.[Case 47]

Abortion should be done upto 1.5-2 months when the previous child is small or the financial condition is not good. In such situations, married women can have an abortion. Unmarried girls should not behave in such a way that they need an abortion. Widows need to do an abortion.[Case 113_]

As opposed to the laws of abortion, almost all women knew about sex determination laws and were aware that it is a punishable crime. Many women also voiced their concern over its growing use and the change in the sex ratio. A couple of women did justify sex determination defending it on the basis of need and demand of the family to have a son.

Everybody has a wish to have a male child. Just as a man wants a son so does the woman too. After all it is going on despite the laws. Instead, there should be a legal option to go for sex detection once or twice, punishment should be there if detection has been done more than twice. Today, two children are sufficient, therefore, if, anybody had first female, one should be allowed for sex detection.[P 6: KH Case39_Jyoti.txt - 6:43 (141:148)]

Sex determination of fetus is a crime. But that crime has to be done in hope of getting a male child. Because my in-laws had only one son (my husband) and he had no siblings. So they in laws felt that they should have at least one grand son. My husband had a desire to have a son. Due to this I had to do abortion twice, that too surgical.[P12: KH Case45_Sunita.txt - 12:47 (117:121)]

Neither is the law particular open about women's rights nor interestingly are women aware of their own rights. It is an interesting conundrum in the policy space that creates the possibility for misinformation and misinterpretations. Interestingly the pharmaceutical companies that have created the MMA as a potentially transformative commodity appear as progressive engineers of women's reproductive rights, while profit is biggest driver of this innovation.

It is lucrative…. My company X has been in female health care for a very long time now. …. We have been working with hormones for long. 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. Secondly 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 Pharma Representative; Personal Interview 12 Jan 2009]

VII. Conclusion

The findings from this study suggest that whichever perspective and domain of analysis you look at, the basic tension between MMA's transformative potential and its translation into reality is the lack of full and expanded access and information about the commodity. It also seems that this might be the appropriate time to take on these discussions to catalyze the expansion of the MMA provision both in the public sector and to lower levels of providers to truly enhance access to safe abortions for women in India.

If we go this route of opening up access, the MTP Act will need to also have provisions that require the Government to ensure training and monitoring mechanisms, to ensure that this expanded provider base functions with safety and quality. Awareness about the MTP Act needs to improve within the community, especially in view of the high level of knowledge people seem to have about the PCPND Act, which often creates a misunderstanding that all abortions are illegal.

There is a sense that this is a technology whose time has come and women are increasingly likely to demand as well as obtain access by their own means. It also brings up to the thorny issue of 'misuse'. This is a value laden term and elicited a varied response across all groups we interviewed. There was an active set of arguments for liberalized access to MMA although those who did advocate for this were all careful to maintain that they were not endorsing OTC use or self medication, but were cognizant of the reality and accepting its existence while seeing it as a part of the 'big picture' in terms of enabling access.

Many felt that having MMA available in the public sector was now long overdue, considering that the drug had been approved in 2002 and the MTP Act amended to incorporate it. Despite their reservations about the capacity of the public sector to provide quality care, it is obvious to them that for the transformation of access to safe abortion services for all the women in the country, this is where it needs to be freely available.

It is interesting to see that pharmaceutical companies and social marketing companies have moved into the driver's seat and it is matter of contemplation whether profit driven industries can somehow move the 'empowerment' agenda without meaning to, or even really wanting to. Some stakeholders felt that if our government is committed to international covenants such as the CEDAW and ICPD, as well as to our own national policies and programs such as the National Rural Health Mission with its emphasis on safe motherhood etc, then we can no longer avoid putting MMA in the public sector with provisions made to prevent 'misuse'. However there were also compelling statistics provided by the manufacturers which point to large gaps in the data and also perhaps in the accountability mechanisms at all levels. The real question however is whether these checks and balances if implemented strictly will have a practical impact on the safety issues faced by women and whether this will in fact act to reduce access.

At the heart of this study are these questions: Can we reach out to women and de-medicalize safe abortion and is this the same as empowerment? How far can access be pushed without compromising quality and safety and who will push these boundaries? What do women find empowering? Do they express the lack of empowerment as a barrier in accessing safe abortion services?

While the debates are not resolved easily, the findings from this study suggest that one of the key avenues for expanding access is putting this drug on the schedule of public health sector services. However, some stakeholders were skeptical about the capacity of the public sector to ensure safety and quality of care. Weighing in need with access though, most stakeholders felt that the probability of requirement of such backup facilities is very low and that expanding access is critical. The main message that filters down through the study findings is that MMA has to be made available through the public sector if not in other demedicalized settings if a serious impact is expected on the safe abortion services.

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[xxiii] 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 as defined in the Act. For the termination of a second trimester pregnancy, the opinion of two such qualified iregistered medical practitioners is needed to confirm that there is a valid reason for the termination.