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Medical Abortion: Some Exploratory Findings from Gujarat

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Abstract

Although legal in India since 1972, abortions can legally be performed only in authorized facilities, which are far fewer in relation to the demand. Partly as a result of this, abortion is frequently performed illegally under unsafe or undesirable conditions. The situation is unlikely to improve in near future until access to safe abortion improves, more and more service providers are trained in advanced but simple surgical procedures such as manual or electric vacuum aspiration (MVA or EVA), infrastructure needed to perform abortion improves, and the community recognizes safe abortion as its right. At the same time, advances in medical science with the advent of medical abortion offer great potential for improving access, safety and an alternative to surgical abortion to the seekers of abortion in India. Anticipating that many women in India will opt for medical abortion because of its advantages over surgical procedure, a preliminary exploration of what it entails is timely.

In this context, the present study based on Gujarat provides interesting insights on medical abortion. Based on interviews with a few chemists, drug industries and the service providers, maladies in the provision of medical abortion that has not yet become widely available or used are identified. These include, inadequate information, awareness, and services that can risk the health and life of the end users. On the basis of our findings we conclude that medical abortion can indeed increase the access to safe abortion. The two major challenges facing medical abortion in the country are cost to the clients and resistance of service providers of surgical abortion. In this context, public awareness and understanding of its safety and efficacy must be created by employing various means, such as media, making information available in the public health facilities and adequate policy measures using the instruments of drug pricing and subsidy.

Key Words : ***Medical Abortion; Drug Supply; Health and Safety; Gujarat; India***

JEL Classifications : ***I 10; I 11; I 12; I 18; K 40***

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1. Introduction

Although legal in India since 1972, abortions can legally be performed only in authorized facilities, which are far fewer in relation to the demand. Partly as a result of this, abortion is frequently performed illegally under unsafe or undesirable conditions. The situation is unlikely to improve in near future until access to safe abortion improves, more and more service providers are trained in advanced but simple surgical procedures such as manual or electric vacuum aspiration (MVA or EVA), infrastructure needed to perform abortion improves and the community recognizes safe abortion as its right. At the same time, advances in medical science with the advent of medical abortion offer great potential for improving access, safety and an alternative to surgical abortion to the seekers of abortion in India.

2. What is Medical Abortion?

A medical abortion is brought about by taking a drug or a combination of drugs orally, intramuscularly and/or vaginally to terminate a pregnancy. It is an alternative to surgical procedure where instruments are used to empty the uterus of products of conception. To induce medical abortion, combinations of Mifepristone along with Misoprostol are used after confirming that a woman is pregnant. The drugs are considered quite effective in the early stage of pregnancy although newer and recent research does indicate that the drugs are effective almost up to the end of the first trimester pregnancy.

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Mifepristone (also known as RU 486) is taken in the form of a pill. It works by blocking the progesterone hormone, which is necessary to sustain pregnancy. When the hormone is blocked, the lining of the uterus breaks down, the cervix softens and bleeding begins (Jones and Henshaw, 2002). Instead of Mifepristone, Methotrexate can be given to a pregnant woman either orally or in the form of an injection. This drug stops the ongoing implantation process that occurs after the fertilisation. Within a few days after taking either Mifepristone or Methotrexate, Misoprostol is administered either orally or vaginally to induce uterine contractions and empty the products of conception. Thus the pregnancy is terminated within a few days (Harvey, et.al., 2002).

Majority of women who take Mifepristone abort within few hours of taking Misoprostol. The most common side effects of medical abortion are caused by Misoprostol, which include in addition to cramps and bleeding, headache, nausea, vomiting, etc. Women are advised to take the medications under the supervision of trained providers, return home and watch for side effects at home. Medical abortion requires a follow-up visit to the provider or clinic to ensure that the abortion is complete.

3. Findings from Previous Studies on Medical Abortion in India

India is one of the first among developing countries to introduce the medical abortion. However, since the approval for its introduction has come just over two years ago, very little community-based empirical research on actual experience of the acceptability of drugs of medical abortion by the women has been conducted. A search for literature indicated that only two organizations have conducted community-based studies on medical abortion so far, namely, KEM Research Centre, Pune and Janani, Patna.

The KEM Research Centre, Pune conducted three studies on medical abortion between 1990 and 1998. These studies focussed on safety, efficacy, acceptability and feasibility in the Indian context mainly to understand the issues before the regimen was accepted and approved by the Drug Controller General of India (Coyaji, 2000). Each study was conducted in a different setting. The first study was carried out at two urban locations as a ‘best-case scenario’, where the

protocols were meticulously followed.[1] The second study was also conducted in urban areas but under liberalized conditions to test the regimen in 'real life setting' by offering medical abortion from existing family planning clinics. The third study was carried out in a rural setting where KEM research centre has a Rural Health Project.

The results showed that 95 to 99 percent of the women in all the studies followed the protocol exactly as they were directed. The women were able to adhere to the protocol of three visits and the pre-requisite of frequent institutional contacts did not affect their choice. Also, in all the three settings medical abortion proved to be effective, acceptable and safe. The side effects reported were within the expected range and could be managed at home. Very few of them found the timing or the place of abortion a problem. The overall conclusion of the study was that medical abortion can be made available in India's rural areas if community is made aware about the regimen, likely discomforts or side effects, etc. by the grass roots level workers and / or functionaries at the government hospitals or primary health centres (PHCs). However, adequate backup facilities, and training of existing staff in screening, monitoring, evaluation of the status of abortion, are very essential before the use of medical abortion is promoted widely.

In 2002-03, Janani, a Bihar based NGO conducted a study of administering Mifepristone - Misoprostol regimen for medical abortion in 210 women with up to 7 weeks of pregnancy, in the outpatient family planning clinic of their urban hospital (Janani, 2004). A three-clinic visit regimen was followed. The protocol followed was almost similar to that used in the 'real-life setting' KEM study conducted in the urban family planning clinics. Women reported minimal side effects such as nausea, vomiting and abdominal pain. The study reported successful termination of pregnancy in 93 percent. Very few (2.5%) women either did not complete the prescribed regimen or did not return for follow up.

In April 2002, the Drug Controller General of India (DCI) approved the regimen of Mifepristone and Misoprostol to end pregnancy of up to 49 days (or 7 weeks) gestation. In a letter to Pharmacy Industry, DCI stated that the drugs should be used only under supervision of expert gynaecologists. In response to liberalisation, three Indian pharmaceutical companies have begun marketing the

[1] The first study was a part of a three-country study; the other two countries being China and Cuba and aimed also to assess the popularity of medical abortion compared to the standard surgical procedure.

drugs to gynaecologists nationwide. There is therefore a need to explore and examine the acceptability and availability of medical abortion by Indian women before it becomes widely available. Research is needed to understand what marketing strategies are followed by the distributors of the drugs, and what challenges does the Indian medical community face as it strives to make medical abortion accessible to women. In the process it is equally important to understand how all the stakeholders handle the new technology.

4. The Gujarat Study

In response to the issues that need some empirical evidence, Foundation for Research in Health Systems (FRHS) and Gujarat Institute of Development Research (GIDR), both in Ahmedabad, undertook a small exploratory qualitative study in the Ahmedabad urban area with the support of Ipas, New Delhi. The focus of the study was to (1) interview a few chemists to understand the marketing strategies that are followed by the drug industry and (2) the perspective of the service providers in making medical abortion available to their clients.

5. Findings and Observations

5.1 Chemists

Structured interviews were conducted with chemists to understand whether drugs for medical abortion were available with them, and their knowledge about the usage.[2] Using the snowballing technique, 13 chemists were interviewed who belonged to all categories - small, mid-sized and large – so delineated on the basis of the number of persons attending the counter at the drug stores. The small chemist generally had only one person at a time at the counter; the mid-sized chemist had 2-3 persons attending the counter and the large chemist had more than 3 persons attending the drug counter. Seven of the 13 chemists had mid-sized operation, four were large drug stores and two were small. While, location of medical stores, their vicinity to clinics and hospitals, and socio-economic status of the people living in the neighbourhood were kept in mind, the chemists interviewed were geographically spread throughout the city of

[2] Free-flowing discussion with the chemists while they attend their medical stores was not possible. Even interviews were interrupted several times while clients coming to buy drugs. Visiting them at home or elsewhere was not considered feasible or even desirable.

Ahmedabad. It was believed that this would help understand the variations in availability, usage pattern and experiences of the chemists.

The pharmaceutical companies provide the drugs for medical abortion directly to the gynaecologists as well to the chemists to stock, although getting information related to the availability of drugs with chemists was a sensitive issue. In spite of assuring the respondent chemists that following the ethical code of conduct, their names, addresses or any other information identifying them would not be shared with anyone and kept strictly confidential, after granting the interview, they were not willing to provide information on all questions put to them. For example, some of them were not very willing to disclose information about the stock of drugs that they maintained or about selling them to their clients directly because of the fear that they might get into some trouble with the law enforcement agencies.

5.2 Availability of Drugs

Discussions with the chemists provided us with the list of drugs available for inducing abortion, shown in Table 1 along with their cost in the market.

Table 1: Abortifacients Available with Chemists

#	Drugs and Pharmaceutical Company	Dosage	MRP Rs.
Mifepristone Tablets			
1	Mifegest (Zydus Alidac Ltd.)	1	325.50
2	Mifeprine (Sun Pharma)	1	325.50
3	MT Pill (Cipla Ltd.)*	3	930.00
4	Mifyron (German Remedies)	1	325.00
Misoprostol Tablets			
1	Cytolog 100 (Zydus Alicac Ltd.)	4	31.00
2	Cytolog 200 (Zydus Alidac Ltd.)	4	60.00
3	Zitotec 200 (Sun Pharma)	2	30.50
4	Misoprost 100 (Cipla Ltd.)	4	31.00
5	Misoprost 200 (Cipla Ltd.)	4	60.00
6	Misogon	4	60.00

* The Cipla tablets are sold in a pack of three tablets.

Apart from the abortion pills, some drugs meant for regularizing menstrual cycle were also used for abortion. These were available from chemists supplying both Ayurvedic and Allopathic medicines and were reportedly accompanied with a heavy dose of Quinine. According to the chemists the success rate of these in terminating pregnancy was quite low with a likelihood of serious side effects. The

names, recommended dosage and cost of some of such Allopathic and Ayurvedic medicines that are available in the market of Ahmedabad is given below in Table 2.

Table 2: Drugs Used for Regularizing Menstrual Cycle and for Abortion

#	Tablet and Pharmaceutical Company	Type	Dosage	MRP for the recommended dosage in Rs.
1	EP Forte (EN PA Forte) (Subina Pharmaceuticals, Indore, MP)	Ayurvedic	3	14.00
2	CVK Forte	Ayurvedic	6	30.00
3	Reglum	Ayurvedic	10	50.00
4	Gynaforte	Ayurvedic	3	50.00
5	CVP Forte (Sterling Lab, Hosur, TN)	Ayurvedic	10	110.00
6	Gynec Forte (Ankit Pharmaceuticals, Ahmedabad, Gujarat)	Ayurvedic	10	50.00
7	Gynolate Forte	Ayurvedic	NA	NA
8	CV Forte (Ankit Pharmaceuticals, Ahmedabad, Gujarat)	Ayurvedic	6	15.00
9	Dyenaforte	Ayurvedic	10	50.00
10	NK Capsule	Ayurvedic	2	15.00
11	Emppea (Rekvina Pharmaceuticals)	Allopathic	10	45.00
12	Duibogen (Unichem Laboratories Ltd.)	Allopathic	10	47.00
13	Megestone (Wyeth Health Care)	Allopathic	10	38.00

NA : Not Available

Some variations were noted in the cost of the medicines, although the variations were not very large. The costs of most of the drugs are shown in Tables 1 and 2, which are based on either what the chemists reported to us, or what we noted when the medicines were shown to us by the chemists.

The key finding was that of the 13 chemists interviewed, 11 were found to be stocking Mifepristone and Misoprostol. Two chemists reported that they stored only pills meant for regularizing menstrual periods, but they opined that these tablets were commonly used for abortion as well. Interestingly, eight of the 11 chemists who stocked the drugs reported that they stocked these drugs on their own, (and not at the request of any of the neighbouring gynaecologists) because of a demand from their regular customers who approach them directly or because the gynaecologists in the vicinity prescribe them to the clients. The remaining three of the 11 chemists indicated that the gynaecologists in the neighbourhood of their medical shops requested them to stock the drugs so that

their patients could easily buy them from the drug store and the provider would not have to recover the cost of the drugs from women and handle payment related issues.[3]

Eight of the 13 chemists revealed that they were approached by the pharmaceutical companies directly for stocking Mifepristone and Misoprostol, while four who stocked the tablets reported that they were asked to stock them by the stockists who normally supplied them various other drugs. One chemist indicated that in spite of being approached by a stockist to keep the tablets, he declined to stock because of his perception that there was very little demand for such drugs in his area. The high cost and very low turnover were the reasons for him not to stock them.

A number of factors determined which brand name drugs to stock. The sales incentives and schemes offered by the pharmaceutical companies was one factor. Another factor determining stocking of certain brand names was the commission offered. On certain products, the retailers received commission up to 20 percent. However, chemists were reluctant to stock drugs of little known companies even when they offered good commission because of the fear that the customers might not either be prescribed these drugs or might not prefer them. However, they would willingly stock them if the company directly approached them. This was not surprising because of the competition between the retail chemists.[4]

5.3 Drug Supply Channel

It was evident after talking to the chemists that most of them do stock both Mifepristone and Misoprostol by their brand names. Therefore, it was important to understand the supply channel or how the drugs reach the retail chemist shops. In order to satisfy ourselves about the links in the supply channel, we also

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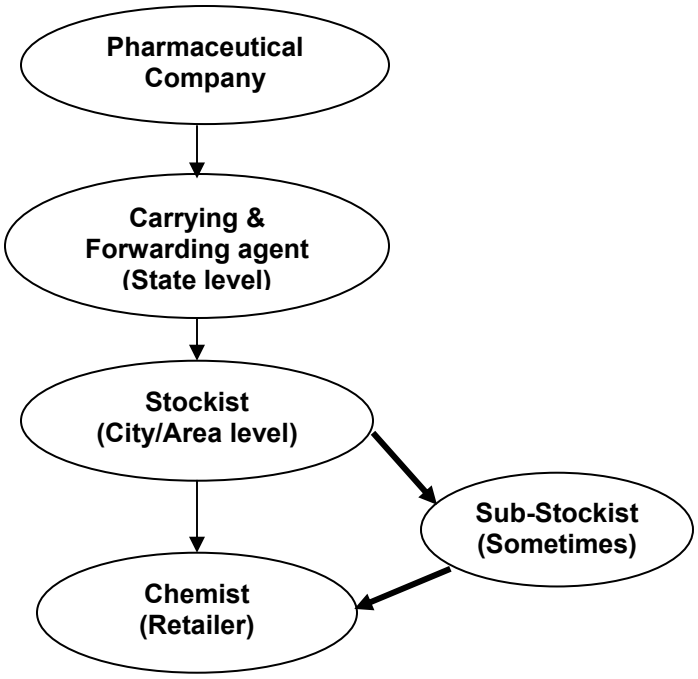
[3] The issue was whether and what discount the drug companies offer to the gynaecologists and what proportion of that they pass on to their clients.

[4] The number of drug stores in the city of Ahmedabad is so large and the competition is so intense that the chemists are willing to stock almost any drug and provide it to their customers even without prescription.

interviewed one person involved in the distribution channel. The supply channel generally followed for all pharmaceutical products is shown in Figure 1.

Figure 1: Distribution Channel of Pharmaceutical Products



The pharmaceutical company appoints a Carrying & Forwarding Agent (C & F agent who is also known as a Consignee) for each state or union territory except for the parent state, where their manufacturing units are located. The C & F Agent is given a commission of 3-4 percent for storing these medicines at his warehouse. His role is largely limited to only storing medicines but this arrangement saves the pharmaceutical company 4 percent central excise tax. After the stocks reach the warehouse of C & F Agent, the products are sent to the stockists as per the orders placed by the stockists. The stockist gets a commission of about 8-10 percent on the medicines, depending on the policy of each company. In a city there could be several stockists and they do not necessarily cater to any defined geographical area. They supply medicines to different retail chemists anywhere in the city, depending on their relationship with the chemists.

Occasionally there are also sub-stockists who procure goods from the main stockists and then pass them to the retailers. A sub-stockist generally earns

commission of about 5-6 percent. The retail chemist is the last link in the entire distribution network and earns 7-10 percent commission on the Maximum Retail Price (MRP) printed on the drugs that is charged to the customer. However, additionally, the pharmaceutical companies do offer special discounts on certain products, some free drugs depending on the quantum of the order to the stockists and retailers to promote their products. The incentives and commission vary between products and companies.

It is clearly indicated on the websites of the pharmaceutical companies manufacturing drugs for medical abortion that they are to be administered only in a clinic, medical office, or hospital, by or under the supervision of a gynaecologist, who is able to assess the gestational age of the embryo and diagnose ectopic pregnancy.[5] Further, the gynaecologist must check the medical history of the patient to avoid complications. Women should be informed about the complications or side effects of the drug and about the measures to be taken in case of side effects of medical abortion.

5.4 Demand for Abortion Drugs

Eight of the 13 chemists indicated that on an average anywhere between one and four customers come asking for the abortion pills in a month. The remaining 5 indicated that they sold the drugs to more than 8 customers in a month. The location of the medical shop in terms of nearness to practicing gynaecologists and the socio-economic status of people living in the area were the main factors determining the demand for the product.

The chemists believed that women wishing to end pregnancy initially tried local home remedies. When these did not work, they approached chemists. Some chemists believed in and advocated to their regular clients who sought their help to first try drinking a concoction of ground black pepper boiled with tea to end the pregnancy, before taking any drugs. They felt that home remedies were safer and had no side effects.

All the 13 Chemists indicated that women do ask for branded medicines to induce abortion or medicines to regulate menstrual cycle. Initially, the chemists refused to admit that they provided abortion pills to any client without a

[5] www.cipla.com / Our Products - Therapeutic Index - Abortifacient - MTPILL

prescription from a medical doctor. However, on probing, many of them agreed that they do provide such medicines to their 'regular or known' customers. The following Table 3 indicates the perceptions of the chemists about the percentage of clients approaching them with or without prescription for medical abortion drugs.

Table 3: Perceptions of Chemists about Clients Seeking Drugs

Prescription	**No of Chemists Reporting**	**Percentage**
All clients come with prescription	3	23
Most clients (75 % or more) come with prescription	3	23
About 50 per cent come with prescription	3	23
Some of them (25 % or less) come with prescription	3	23
Never come with prescription	1	8
Total	**13**	**100**

This does not mean that the clients who come without prescription are denied the drugs. The information provided by the chemists is inclusive of those customers who come to buy Ayurvedic formulas for which no prescription is required. Five of the 13 chemists reported that some of the customers who came to them without doctors' prescription knew the names of the abortion medicines and asked for them by either their brand names or by the generic names. The remaining 8 chemists indicated that the customers who came without prescription sought their help to suggest what medication to take for terminating pregnancy. However, two of these chemists denied that they ever recommended any pills on their own as it could create problem for them and 5 chemists reported that in such a situation they gave only Ayurvedic medicines to the clients since they are not supposed to have any or few side effects. In all, four chemists disclosed that they do recommend abortion drugs to their customers when their advice is sought and if they have the drugs in stock, they also sell them to the customers.

5.5 Information Given to Clients

To further understand the role of chemists in providing and recommending abortifacients, we asked them a few questions about the specific information they gave to customers at the time of selling the drugs. The range and content of the information that the chemists provide to the customers is shown in Table 4. When the chemists were asked whether they advised their customers to consult

a doctor before starting the medicines meant for abortion, 4 of the 13 said they do not whereas the rest indicated that they do advice their clients to consult a doctor. On probing, we learnt that these chemists had little knowledge or understanding of when to take which of the drugs. This ignorance is reflected in the response to another question whether while selling the drugs, they inform the customers about when abortion would occur or after which drug they take, would it occur.

Table 4: Information Provided to the Clients by the Chemists About Any Abortion Drugs (Allopathic or Ayurvedic)

	Yes	No
❖ Do you advice customer to consult a doctor before starting to take the medicine?	4 (31%)	9 (69%)
❖ Do you tell the customer about the time frame by which the abortion will be completed?	4 (31%)	9 (69%)
❖ Do you tell the customer about the possible side effects?	2(15%)	11 (85%)
❖ Do you tell the customer what to do in situations when they have side effects?	2 (15%)	11 (85%)

If the clients asked them what measures should they take in the event of abortion not occurring even after taking the drugs sold to them, only four of them offered suggestions such as consulting a doctor or going in for surgical abortion. One chemist, however, indicated that he recommended two tablets of Cytolog 200 or Zitotec 200 to his clients for completion of abortion.

Only two chemists reported that they informed the clients about the possibility of side effects or what they should do in the event of heavy bleeding, severe abdominal pain, etc. Clearly, while selling the drugs directly without prescription, which they are not supposed to do, the chemists did not see it their responsibility to inform the clients about the likely side effects of the drugs. They assumed that either the clients were aware or had been informed by the doctors whom they consult.

None of the chemists gave any pamphlet or write-up on the drugs to the customers. The larger pack that they get from the pharmaceutical companies do contain some literature in the package but it appears that neither do the chemists read to understand the dosage, likely side effects of the drugs, etc. nor do they pass on the literature to the buyers. They indicated that if the buyer asks for the

drugs by the brand name or comes with a prescription, then she would presumably know how to use the drug.

5.6 Knowledge of Abortion Pills

On probing, we learnt that these chemists had little knowledge or understanding of when to take which of the drugs and could not provide much information to the clients.

The chemists' perception about the dosage required for completion of abortion varied a great deal. The knowledge among chemists was also quite limited with regard to the combination of drugs for abortion. Only two chemists could correctly tell that a combination of Mifepristone and Misoprostol is required for safe and complete abortion. The rest sold them either based on what the clients asked for or dispensed as per the prescription if the clients produced a prescription. The chemists were generally unaware about the recommended gestation period up to which medical abortion drugs should be provided or are perceived to work effectively. Except for one chemist, others were not even aware that tablets like Pill 72 and Ecce2 are emergency contraceptives and should be taken within 48-72 hours of unprotected sexual intercourse.

If the client asked them about the possible side effects the drugs might have, only two of the 13 had any knowledge of the likely side effects. The rest were quite vague or ignorant.

5.7 Efficacy of Abortion Drugs

We also tried to understand from the chemists whether their clients reported to them about the successful abortion or the side effects after taking the medications. Interestingly, one chemist reported that he always knew what happened to his client after taking the drugs. On the other hand, seven chemists indicated that sometimes they would know from some of the customers whether the tablets were successful in terminating the pregnancy but their contact with many clients was not such as to know the outcome or be informed about it. Five chemists did not ever know about the outcome. They were not even interested in knowing once the drugs were sold. Overall, the perception of the chemists was that the clients would on their own return for further advice if the pregnancy did not terminate.

In order to understand the perceptions of the chemists about the success rate of the medicines, we asked them to indicate as to how many customers out of ten are able to successfully terminate pregnancy after taking the drugs. Three of the 13 were reasonably sure that the abortion medicines were very effective in most of the cases but five of them did not know to what extent the medicines really worked.[6] The rest felt that the medicines were probably effective in 50 to 80 percent of the cases. The limited feedback that the chemists receive from the clients is probably the reason why they were not sure about the efficacy of the medicines that they dispense. Their job is to sell the drugs and responsibility towards their clients is hardly a consideration unless complaints are reported.

The chemists felt that the future of medical abortifacients was good as an alternative to surgical abortion, which is more expensive if sought in private clinics. Additionally, the difficulty in maintaining secrecy also would deter some women from opting for surgical abortion. Oral tablets have a distinct advantage because women can take them without anyone knowing. However, these drugs are not very cheap and therefore some of the chemists felt that a cost of more than 300 rupees may act as a deterrent to some poor clients.

6. Providers

During the course of another study on the availability and accessibility of abortion services in urban slums of Ahmedabad city, both the service providers and women did mention medical abortion as a method to terminate pregnancy (Barua, 2004). To understand the viewpoint of the service providers on medical abortion in depth, 11 service providers were contacted, but 10 were interviewed and one refused to be interviewed. They were purposively selected using the snowballing technique. The study was initiated by contacting two providers whose names were mentioned as service providers of medical abortion in the earlier study. They in turn gave names and contact addresses of other providers known to them who were approached for interview. The usual ethical considerations guided the interview.

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[6] The question was not asked specifically about each of the abortion drugs that the chemists sell. Since they sell allopathic as well as Ayurvedic tablets, it is not clear when they reported that drugs worked successfully, the reference was to any drug or to Mifepristone or Misoprostol only.

Unlike the chemists who were administered structured questionnaire, the interviews with the service providers were free flowing using an interview guide. Their long comments or explanations on certain issues were noted down and some of these verbatim responses are used in describing their perceptions, understanding and knowledge.

6.1 Profile of Providers

Of the 10 providers who were interviewed, one worked in the public hospital and the remaining 9 were private practitioners working either in urban or peri-urban or rural areas in the vicinity of Ahmedabad city (Table 5). Except for the gynaecologist working in the government tertiary care hospital and two private practitioners; the remaining seven did not have a legally recognized facility to provide Medical Termination of Pregnancy (MTP). However, they did perform abortions and the caseload ranged from 1 to 10 per week. Three of the service providers were male; the rest were women. They all were young in early and mid-thirties and were qualified gynaecologists with obstetric and gynaecology practice and except for two, others were practicing for more than five years. None of them had received any special training even for conducting surgical abortion.

Table 5: Characteristics of Service Facilities in the Sample

	Government Provider	**Private gynaecolo-gists: Urban**	**Private gyna-ecologist: Semi-urban**	**Private gynaecolo-gists: Rural**
Number	**1**	**5**	**1**	**3**
Services Provided	Ob/Gy OPD and Indoor	Ob/Gy OPD and Indoor	Ob/Gy OPD and Indoor	Ob/Gy OPD and Indoor
Recognised for MTP	Yes (1)	Yes (1)	Yes (1)	No
MTP Caseload per week	>10	1-10	1-5	5-10

6.2 Sources of Information

The service providers had come to know about medical abortion drugs and regimens mainly from the medical representatives of pharmaceutical companies. Medical representatives are generally the major source of information on the new products that the pharmaceutical companies wish to introduce in the market and

promote. Some of the pharmaceuticals even arrange workshops that are attended by the gynaecologists. As one provider said:

> "*I came to know about the drugs at a workshop in Nadiad. The workshop was arranged by CIPLA pharmaceuticals*".

Six of them also mentioned that the topic being current and controversial featured often in the Obstetric and Gynaecology journals. Five of them said that they learnt about medical abortion from the conferences arranged by the Federation of Obstetric and Gynaecological Societies of India (FOGSI), various local chapters of their associations and from the literature made available by the pharmaceutical companies producing the medical abortion drugs.

Only the provider from the government tertiary hospital reported awareness about the drugs for medical abortion being available at the local drug stores. All others indicated that they were not aware that the local chemists stocked and sold the drugs or were categorical about the drugs not being available with the chemists. According to them, the drugs are supplied directly by the pharmaceutical companies to the gynaecologists. To quote one,

> "*As far as I know none of the chemists in my neighbourhood sell these. They are not supposed to sell these as the prescription of these tablets is under strict legal stipulations. They are not over the counter drugs to be available freely. They need gynaecologist's prescription. Otherwise, there will be rampant misuse. The consequences will be disastrous, there will be manifold increase in complications and maternal mortality.*"

Except for the one rural practitioner, all the other had correct knowledge that the medical abortion tablets have been approved by the Drug Controller of India in the last one or two years only. The rural practitioner who had been using the tablets for more than two years believed that they have been legal for a long time.

6.3 Supply and Cost of Drugs

Most of the service providers indicated that they received the supply of drugs directly from the medical representatives of pharmaceutical companies.[7] Only one practitioner said that she received free samples from the pharmaceutical companies. The provider working in the government tertiary hospital indicated that her clients purchased them from the chemists.[8]

The service providers used the drugs of three pharmaceutical companies - Zydus Adilac, Sun Pharma and Cipla. The rural provider who had been administering the medical abortion tablets for more than two years said that earlier she used to get Chinese drugs, but ever since the drugs manufactured in India are available, she has switched to Indian products. At the same time, she felt that the Chinese drugs were of better quality and more efficacious but were more costly.

The provider's choice of drugs of a particular pharmaceutical company depended on a range of factors. If the supplier of a product of a particular company was a close relative of the provider and who ensured regular supply of the drugs of that company, those drugs were preferred and obtained. Since there was very little variation in the price of the drugs of different companies, the cost per se was not a real consideration. However, when the commission that medical representatives provided to the providers varied, the providers choice of the drugs was influenced by that.

Nonetheless, cost of medical abortion to the seekers was quite high if the service providers followed the recommended protocol including the use of ultra-sound. The total estimated cost of drugs of medical abortion alone is upward of Rs. 1200 and added to it would be the consulting charges of the provider and the charges for three Ultra Sound Graphics (USG). Thus, the total cost to the client works out quite steep and is a potential deterrent to many. In fact, seven out of 10 service

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[7] None of the providers indicated that they received the medical abortion drugs from the stockists. Apparently, the chemist shops contact the stockists for various drugs and obtain the abortion drugs as well from the stockists.

[8] The public sector or government hospital does not stock the medical abortion drugs and therefore the clients of the gynaecologist to whom she prescribed them, had to buy them from the market.

providers believed that if a woman were to seek surgical abortion in a government facility, the total cost would be lower than that of medical abortion.

Interestingly, three of the 10 service providers had devised ways of keeping the cost of medical abortion on par with surgical abortion either by doing away with at least one each of ultrasound examination, and clinic visit or getting the drugs at a discount and passing on some of it to their clients.

6.4 Method Choice

Generally speaking, the providers left the choice to select medical abortion vis-à-vis surgical option to the client. However, while offering the choice to the clients or recommending the method, the providers were guided by factors such as cost, and ability to follow the instructions.

According to one provider:

> "*I use pills in selective cases - for those who are educated, can afford the cost, and will comply with the follow up regime*".

Except for one provider others indicated that they left it to the women to choose the abortion method. They informed their clients about various methods but did not insist on use of any specific one. At the same time, three of the service providers opined that cafeteria approach in selecting abortion method is impractical because not all methods are suitable to everyone. As one provider explained the process that she follows:

> "*I strongly believe in cafeteria approach. But I equally strongly believe that not all methods are suitable to everyone. So, I do tell the woman and her partner about all the abortion methods, their advantages and disadvantages, cost, and side effects using slide shows, educational material and couple counselling. Then I ask them about their choice. After discussing whether the selected method is suitable for the acceptor, I guide the couple and most accept my advice. I also find out whether the couple plans to have any more children in future and the duration of the pregnancy. Only if I am convinced that the woman is suitable for medical abortion, do I prescribe the tablets.*

Service providers also claimed that they prescribed medical abortion largely because that was the client's preference. They believe that the reasons guiding the preference for medical abortion were that it is an effective, non-invasive technique not requiring any anaesthesia or hospital stay.

One of the service providers indicated that religious beliefs of the clients also determined the choice of the method to a certain extent. According to her, most of her clients are Jains, who do not prefer surgical abortion. Since medical abortion is their preferred choice, it is the predominant method in her centre.

Eight of the 10 service providers claimed that some women come to them after having tried some other methods to end pregnancy, such as some Ayurvedic preparations or morning-after pills either on their own or that might be prescribed by their general practitioners.

6.5 Regimen and Protocol

Almost all the service providers were aware about the protocol to be followed while administering the medical abortion drugs. The legal concern has prompted the service providers to adhere to the strict protocol which involved first confirming the gestational age by clinical examination and ultrasound and ruling out ectopic pregnancy. Only after that the provider administers the Mifepristone tablet in the clinic and sends the woman home with Misoprostol tablets with the advice to take them 48 hours later. The clients are also advised to visit the clinic or the provider for the first follow up after 7 days and second follow up after about two weeks. One of the service providers indicated that she preferred to give the Mifepristone tablets on a Friday to be followed by Misoprostol on a Sunday, because it is easier for the client to get in touch with her on a holiday if the client develops any problem or heavy bleeding after taking Misoprostol.

However, such rigorous protocol was not followed by either the practitioner working in the government hospital or by one of the three providers working in rural area. Both felt that since majority of their patients belonged to lower income group, they avoided increasing the total cost of the procedure by not fully adhering to the protocol and used USG sparingly.

The rural practitioner who used the drugs even in the second trimester said that though she was aware of the recommended gestational age, the protocol she followed was based on her own field experience. As she articulated:

> **"***I give the tablets up to 12-13 weeks of pregnancy after confirmation of intra-uterine pregnancy by USG. The books do talk about 49 days only, but I have excellent results up to 10 weeks. I use it at 10 weeks and later for termination of foetal malformation cases. I give one Mifepristone orally and insert one Misoprostol vaginally in my clinic after an USG. I send the woman with two tablets of Misoprostol to take after 48 hours at 3 hours interval. I have used this protocol extensively and there is no need for D & E*".

6.6 Counselling and Management of Side Effects

Before actual prescription of the method almost all the service providers reported that they counsel their clients. The service providers mentioned that counselling for medical abortion tends to take much more time compared to that for surgical abortion. The clients need to be told about surgical abortion both as an option to medical abortion and as a possible back-up procedure for a failed medical abortion. When the clients lack knowledge about the recent developments, and tend not to be actively involved, the counselling takes time. With experience, the time required decreases since the service providers stress on select points only. But most of this counselling is oral. According to one practitioner:

> "*I have some material given to me by the pharmaceutical company but I don't use it. Their material does not have Misoprostol mentioned and if my prescription is different from what the material says, I will get into legal trouble. Therefore I believe in oral counselling rather than giving any material*".

Only one out of 10 service providers had prepared written IEC material in local language for her clients and advised them and their families to go through the material before actually taking the drugs.

At the same time, the service providers do take consent of their clients before prescribing the tablets. They justified the need for consent by indicating that medical abortion is after all a termination of pregnancy and therefore falls under the legal purview of MTP Act. As one provider put it:

> "*All the legal formalities apply to it as much as they apply to surgical abortion. In fact, even the prescribing doctor and facility should withstand the same scrutiny as is the case with surgical abortion."*

The service providers generally informed their clients about the possible side effects of the drugs. This was perceived as very essential to mentally prepare the clients for the process where the timing of abortion varied somewhat between individuals. In that sense, medical abortion is very different from the surgical abortion, where once the doctor carries out the procedure, the abortion is complete. One provider gave the following instructions to her clients:

> "*The four main instructions I have for the women are: (1) the variable time interval between taking of the drug and the actual onset of bleeding, (2) the consequent need to be careful and to stay at home, (3) the possible side effects they should know about, and (4) the need for follow up in case of any side effects persisting for unduly long period*".

Though majority (8 out of 10) of the service providers indicated that less than one fourth of their patients complained of any side effects; three of them said that they exercised caution by prescribing pain killers, haemostatic agents and antibiotic tablets to their clients in anticipation of some pain or discomfort. As one provider emphatically stated:

> "*I have never come across a single woman with side effects in my extensive practice. I ensure through prescription of painkillers, haemostatic agents and Oral Pills that none occur. I use these as preventive measures since I do not want to be bothered by women in the middle of the night. It is not convenient for them either*".

Table 6: Side Effects of Medical Abortion

	Government Provider	Private gynaecolo-gists: Urban	Private gyna-ecologist: Semi-urban	Private gynaecolo-gists: Rural
Number	**1**	**5**	**1**	**3**
Side effects				
Bleeding problems	1	5	0	0
Incomplete abortion	1	4	1	1
Pain in abdomen	0	2	1	1
Rupture Uterus	1	2	0	0
Nausea, Vomiting	0	0	1	1
Infection	1	3	0	1

Note: *Many service providers reported multiple side effects of medical abortion.*

Those who did not prescribe the painkillers and similar medicines, believed that pre-prescription counselling and informing the woman about likely excess bleeding or some abdominal discomfort or pain and further counselling her after she reports side effects or problems, is enough to reassure the woman. They emphasized that counselling and pro-active side effect management are enough in most cases. There is no need for drugs to manage problems that are neither serious nor long lasting. If clients come complaining about heavy bleeding, one provider practicing in rural areas gave them estrogen tablets and even a cycle of oral contraceptive pills, essentially to pacify them. However, according to her, she did this after ensuring that there were no serious complications.

> "*In my rural practice, 15 to 20 percent of clients come with heavy bleeding and abdominal pain. I check them by doing an USG. If no problem is detected, I just reassure them and give Orral G - a high estrogen tablet - if bleeding is heavy. Further, I give them a cycle of Oral pills after confirming through USG that there are no residual products of conception in the uterus".*

6.7. Efficacy

All the service providers rated the efficacy of the drug regimen, if properly adhered to, above 90 percent. Overall, except for one practitioner, all others felt that the regimen of medical abortion was highly effective and failure rate was very low. Only in about 5 percent of cases, abortion was not complete and required surgical intervention, which rarely posed any problem.

> "*I have prescribed medical abortion to 500-600 women till date. However, in only 2 women it failed where I had to resort to Dilatation and Evacuation. Doing D & E in these cases was very easy as the cervix was soft and dilated"*.

Except the provider from government tertiary hospital and one private practitioner practicing in rural area, the remaining eight service providers were of the opinion that the drugs are effective in the very early stages of pregnancy i.e. up to 49-63 days (7 to 9 weeks) after the last menstrual period. The other two not only mentioned that the drugs can be used to terminate pregnancy of longer duration but also indicated that since Misoprostol has been used for inducing labour in the second trimester even before the advent of medical abortion, it can be used to terminating pregnancy of more than 63 days of duration.

6.8 *Advantages of Medical Abortion*

All of the service providers felt that medical abortion is beneficial to both the service providers themselves and to the clients. The benefits to the service providers are more in terms of the technique being non-invasive and therefore much less fraught with risk. The service providers also do not have to worry about autoclaving of the instruments. Further, when surgical procedure is carried out in a facility, anaesthesia has to be arranged and beds have to be provided for the clients to rest for a few hours. Both of these require staff and maintenance of facility. In medical abortion these requirements are completely bypassed and therefore associated risks to patients and costs to the service providers are minimised. The absence of need for hospital admission is advantageous not only to the service providers but also to the clients.

> *"Medical abortion is non-invasive and therefore requires less time. Same earning with less time investment for doctors!*"

Another benefit of medical abortion that involves taking Misoprostol tablets at home is that the demand on their clinic time is significantly reduced. This has a net effect on the reduction of cost of abortion also. Some of the service providers also claimed that since the clients have to make a few visits to the clinic, a stronger bond or relationship between them and their clients is created.

Table 7: Advantages of Medical Abortion to the Women According to Service Providers

Number	Government Provider	Private gynaecologists: Urban	Private gynaecologist: Semi-urban	Private gynaecologists: Rural
	1	**5**	**1**	**3**
Reasons for use				
Women prefer	1	3	1	2
Non-invasive	0	1	0	2
No anaesthesia	0	0	0	3
No hospital stay	0	2	0	1
No infection risk	0	1	0	0
Confidential	0	1	0	0
Effective	1	2	0	0

Note: *Many service providers reported multiple reasons for the choice.*

At the same time, some service providers felt that despite counselling given to the clients about bleeding, some of them panic by the ill-timed bleeding and get in touch with them even at any odd hours. This they perceived as a major disadvantage of the method.

According to some service providers, from the perspective of women, the main advantage of medical abortion is that it is patient friendly and the woman does not have to be admitted to the hospital. Also, women can use the method without informing the family, if they need to do so. (The need for secrecy and confidentiality is especially desired when pregnancy has occurred out of wedlock.) At the same time, whether medical abortion should be kept as a secret from the family members was debated by some of the service providers, who believed that some family members should be informed in the interest of the women themselves. As described by one provider:

> *"Occurrence of side effects is always a possibility, which can complicate matters if the woman has taken the tablets without anyone's knowledge in the family. Also, promoting secrecy from family can become counter-productive particularly if the woman develops serious side effects. I therefore insist that the person in the family who resists the woman using a particular method should meet me. I spend time explaining everything because I believe in transparent practice and feel that in the long run it is beneficial to the clients"*.

6.9 Securing Practice and Need for Training

There have been no concerted efforts on the part of the health system to make medical abortion popular. At the same time, since the service providers cannot advertise through any media that they provide the services, they rely on satisfied customers and word of mouth for making it known in the community that they provide medical abortion. Sometimes, women come on their own seeking medical abortion after learning about the method from their relatives or friends who might have used the method or know about it. Also, the service providers inform about medical abortion as an alternative method to women who come to them requesting induced abortion through any of the usually known methods. In fact, six out of 10 service providers believed that it is their responsibility to make the clients aware of various options, regardless of their own preference for a particular method.

All the service providers explicitly mentioned that the medical abortion drugs should not be available with the chemists who supply most of the drug to their clients over the counter. Nine of them also indicated that only a qualified gynaecologist who understands the pharmacology of the drug formulation, can anticipate and manage problems if and when they arise, should provide medical abortion. Further, since they have the requisite skills and emergency backup facilities in their clinics, they can manage complications. Some even expressed a fear that easy availability of the drugs with the chemists or general practitioners would "*increase immorality in the community. Illicit relationships and illegal pregnancies would be on the rise".* Although not specifically articulated, there could be an underlying fear that over the counter availability of the drugs might adversely affect their practice.

The gynaecologists were aware of the need for training because of the rapid advances in medical technology. Many of them had obtained their medical education some years ago when medical abortion was not even heard of and therefore felt the need for training. They also felt the need for being regularly informed and updated about the new research and products coming in the market and research carried out on them in other countries.

At the same time, the service providers did not feel that limited space, staffing and training to be significant barriers to medical abortion as the method did not

require technical skill. When asked about the kind of training they received and its usefulness, seven out 10 service providers reported that direct experience of dealing with patients was their training, which was the most effective method of learning. Information about the rapid advances in the product was viewed as important but for communicating with the clients or dealing with them, they did not need any training.

6.10 MTP Act and Medical Abortion

The service providers were asked whether the rules and conditions stated in the MTP Act should be applicable to medical abortion as well. Interestingly, seven out of 10 service providers felt that since medical abortion results in termination of pregnancy, all the rules of MTP Act should apply to it as well. The method used for termination of pregnancy is not important, according to them, it is the risk associated with expulsion of the product of conception that is addressed in the MTP Act. The three who were a little uncertain felt that since medical abortion does not require any surgical intervention or hospital stay, it should be covered by some modified rules. Some expressed a feeling that since the MTP Act is designed to make abortion safe for all, medical abortion, which does not involve the risk to woman due to the administration of anaesthesia or due to surgical intervention, is the safest of all abortion techniques and should be promoted as a safe method. [9]

6.11 Promotion of Medical Abortion

The service providers were in favour of promoting medical abortion through IEC targeted at both the clients and themselves. The providers need technical information about the dosage, likely side effects and their management. Advocacy is also necessary to inform the service providers about the efficacy of the method. The clients need to be motivated to choose the method best suited to them from various alternatives.

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[9] In reality the rules of MTP apply to medical abortion as well, except that since medical abortion does not require woman to be an indoor patient, the requirement of registering of the facility has been done away with provided the norms of the back up care are adhered to.

The service providers further felt that since the pharmaceutical companies manufacturing the drugs sell them directly through medical representatives, they should take the responsibility of giving technical data about their products as well. They also expressed a fear that if the drugs become available over the counter from the chemists, there is a possibility of misuse of the drugs.

7. Challenges and Implications of Findings for Future Research and Policy

Medical abortion is emerging as a new alternative for terminating early pregnancy and has proved to be safe and effective method. However, the medical fraternity does not yet appear to be fully convinced about its advantages. In a country like India, where the consequences of unwanted pregnancy and efforts to terminate it and absence of knowledge of and means for safe abortion are grave, medical methods offer a window of opportunity to advance the cause of women's health.

A critical discrepancy noted during this study was that while almost all service providers believed that the pharmaceutical companies directly sold the drugs to them, the chemists on assurance of anonymity mentioned that the pharmaceutical companies through their stockists directly provided the drugs to them. Further, while the service providers claimed that they insisted that the clients take the Mifepristone in their clinic, the chemists indicated that women go to them with or without prescriptions to purchase the drugs. It implies that at least some doctors do write prescription, quite likely to avoid the hassle of charging the patients for the drugs in addition to their own consulting fee and other procedures. It was not possible to find out whether these women were asked to come back with the drugs to the clinics. However, the issue of chemists making drugs available to customers without prescription even when doctor's prescription is mandated requires stricter enforcement and vigilance. This is to be viewed particularly in the context of termination of pregnancy being within the purview of the MTP Act in India. The MTP Act was drafted when medical abortion was not available and the stringent stipulations made with surgical methods in view, appear unwarranted given the facility and provider requirements for medical abortion. In light of the safety of medical methods of abortion and the likely increase in the demand for abortion services the Act needs to be re-visited.

The chief advantage of medical abortion is that it can increase the access to safe abortion. In this context, public awareness and understanding of its safety and efficacy must be created by employing various means, such as media, making information available in the public health facilities. At the same time, the students of medicine should be informed about the current research in medical abortion and also trained to provide the services. In the process the pool of trained personnel would increase contributing to improving access.

The two major challenges facing medical abortion in the country are cost to the clients and resistance of service providers of surgical abortion. Those in favour of wide spread use of medical abortion counter these two challenges by alluding to the hidden costs of surgical abortion such as staff training, operating room time, and hospital stay. They believe that inclusion of the drug in government programmes and thus offering it at a subsidized rate would be cost effective. Opposition from service providers can be overcome through strong leadership from the medical establishment and by undertaking empirical research programme. The proponents of medical abortion also feel that its increasing availability through public sources and large-scale acceptance will create market conditions, which will encourage service providers to rethink about their resistance. The likely opposition from Women's groups in India is not expected to be strong, since the method is woman controlled, designed for one-time use (not long acting), indicated for unwanted pregnancy, and difficult to impose on women against their will.

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