

## **LONG ABSTRACT**

### **Medical Abortion Drug Dispensing Behavior among Pharmacists in India**

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#### **Abstract:**

In India, abortion is legal under Medical Termination of Pregnancy (MTP) Act since 1971. As per the evidence, around 9% of total maternal deaths are caused by unsafe abortion. Though Medical Abortion (MA) drugs are prescription-only-products, in reality, it is often obtained without doctor's prescription through pharmacists. The pharmacists often have limited knowledge of safe use of drugs that may result in complications. Population Services International's intervention on safe medical abortion aims at educating pharmacists to improve their knowledge and dispensing practices related to MA drug regimen. Using Lot Quality Assurance Sampling method, a simulated client patient survey was conducted on MA drug dispensing behavior among 380 pharmacists in twenty project districts of northern India. The study revealed that 55% of the pharmacists recommended correct dose of MA drug and 45% pharmacists suggested correct route of administering MA drug, while only 25% of the pharmacists asked for doctor's prescription for dispensing MA drug. The findings also revealed that only 42% of the pharmacists behaved correctly on all three key indicators (asked for doctors' prescription, recommended correct dose and route for administration) pertaining to MA drug regimen.

*Key words: MTP Act, Mifepristone, Misoprostol, Safe Abort, MA drug regimen, LQAS*

#### **Background:**

Despite, the rapid economic growth, maternal mortality figures in India remain high. With a national maternal mortality ratio (MMR) of 212 per 100,000 live births (1), maternal health remains a huge challenge for India. According to the government sources, around 9% of total maternal deaths are caused by unsafe abortion (4) but medical experts put the figure at almost 18% (5) higher than the global average of 13% (6). In India, each year approximately 6.7 million abortions occur outside of government-recognized health centers, often in unhygienic conditions or by untrained abortion providers (7). This problem disproportionately affects adolescents, as unsafe abortions account for half of all maternal deaths of women aged 15-19 years (8).

In India, abortion is legal for a broad range of medical and social reasons. Officially, women can access safe abortion services by trained medical personnel in registered facilities and minors need consent from their guardians. In practice, most of women are not able to obtain legal abortions for multiple reasons, including a dearth of information about safe abortion services (10), inconsistent and prohibitive costs; a shortage of trained providers and adequate equipment; lack of confidentiality and informal demands for spousal consent; poor access to facilities, the stigma associated with induced abortion, and lack of knowledge about the legal status of abortion. A study showed that only 9% of Indian women knew that abortion was legal (11, 29). As a result, women often resort to untrained practitioners operating under unsafe conditions and thereby landing into life threatening to chronic reproductive tract morbidity such as infections, chronic disability and infertility.

Induced abortion incidence is extremely difficult to measure in most countries and India is no exception. Abortion procedures, whether performed legally by trained professionals using modern technology or illegally using traditional methods are subject to substantial underreporting. No valid data exist on the incidence of abortion in India. Clinic data are published as government statistics but these reflect only

reported medical termination of pregnancy (MTP) cases conducted in clinics recognized by the government (9).

In India, the Medical termination of Pregnancy Act was first framed in 1971 and went into effect in April of 1972 was amended in 2002. In the year 2003, the government introduced a further amendment to MTP Rules. (25, 26). Medical abortion drugs, namely, mifepristone and misoprostol are both registered in India (13). In April 2002, the Drug Controller of India approved medication abortion provision using mifepristone coupled with misoprostol in gestations of 49 days or less only under the supervision of a gynecologist (27, 28). In 2005, the combination of mifepristone and misoprostol for MA was included on the World Health Organization (WHO) Model List of Essential Medicines for termination of pregnancy where legal and acceptable, up to 63 days (9 weeks) since first day of last menstrual period (LMP) (12, 30 & 31).

Under Indian law, MA drugs are prescription-only-products and abortion services can only be offered by doctors who are certified and who operate within accredited abortion facilities. Despite these restrictions, prescription only drugs are obtained without doctor's prescription from the pharmacies (14). The pharmacists often have limited knowledge of safe and accurate use of the MA drugs (15). This may lead to inappropriate and sometimes dangerous use of abortion medications. Efforts are being made by the various organizations in order to educate pharmacists / counter attendants on correct knowledge and dispensing behavior related to medical abortion drug.

Population Services International (PSI), India, being a social marketing organization, is focusing on increasing the consumers' access to Medical Abortion drug with the brand name as 'Safe Abort' through private clinics and pharmacies. There is a common trend among consumers of self - medication without doctor's prescription (16). One study with pharmacists, conducted by (PSI) in 2010, revealed that 80% of the medical abortion drug are sold to consumers without doctor's prescription.

The pharmacists are most accessible healthcare professionals and in the position to deliver the correct and sufficient information to their clients. Considering the fact and benefiting the consumers (Women in reproductive Age) by providing the correct information through a campaign on medical abortion, the current study was planned to assess the dispensing behaviour related to medical abortion drug among the pharmacists. The pharmacists were assessed on the medical abortion drug regimen, route of administering the drug, possible side effects and warning signs.

### **Objective of the study:**

The objective of the study was to assess the dispensing behavior related to MA drug among pharmacists.

### **Material and Method:**

A cross sectional study was conducted on Medical Abortion Drug Dispensing behaviour among randomly selected pharmacists. LQAS1 (Lot Quality Assurance Sampling) and analysis technique was followed to sampling and analyzing the data. This study was conducted in 20 towns of three states of north

India. A sample of 19 pharmacists was selected from each district. The 20 towns in Uttar Pradesh (UP) were – Lucknow, Gorakhpur, Varanasi, Kanpur, Agra, Bareilly, Barabanki, Firozabad, Mirzapur and Ghaziabad, in Rajasthan–Jaipur, Sriganganagar, Alwar, Jodhpur, Ajmer, Bharatpur, Tonk, Kota and Pali and Delhi.

The sampled pharmacies were visited by trained simulated clients in all 20 towns across all three states. Twelve male simulation clients and twelve male interviewers were trained on the case scenario. The scenario was developed in consultation with the medical experts pertaining to MA drug dispensing behavior. The scenario was enacted by the simulation clients during the visit to pharmacies. The simulation client visited the selected pharmacists, had conversation and made observations. An exit interview was conducted with the simulated client immediately after his visit to the pharmacy by another trained field supervisor using a structured interview schedule.

#### **A case scenario for the simulation client**

*A married man in the age between 25-35 years approaches the pharmacist after his wife is suspecting to be pregnant. His wife has missed her menstrual periods and it has been 10 days since the due date of menstrual periods. They do not wish to have another child soon as they have a son who is 10 months old.*

### **Results:**

The findings of the study have presented and discussed in the next couple of pages.

The findings revealed that of 380 pharmacists only 25 per cent of the pharmacists asked the simulation client for the doctor's prescription before dispensing the MA drug (Fig 1). However, they did not refuse to dispense the drug. In Rajasthan 25% (n=171) pharmacists and in Uttar Pradesh 20% (n=190) of the pharmacists asked for the doctor's prescription (Fig 2).

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1 LQAS is not designed to provide an accurate estimation of the proportion in the community but only classifies the coverage as being above or under a given value. Further, LQAS allows programs to identify areas with levels of coverage that are at or above expectation versus those that are below expectation.

*Whether pharmacists asked about the last menstrual period of the client to confirm the eligibility status of the woman for medical abortion?* The study revealed that overall as well as separately in Rajasthan and Uttar Pradesh, 85% pharmacists asked the simulation client about the menstrual cycle history of the user.

In terms of duration of medical abortion drug, fifty five percent of the pharmacists provided this information to the simulation client. In Uttar Pradesh 45% and Rajasthan 65% of the pharmacists provided the correct information on the duration of dose. Delhi was also found as the low performing area with the average coverage of 45%. **‘Correct doses: One pill (Mifepristone) on 1st day and 4 pills (Misoprostol) on 3rd day’**

The study also revealed that only 45 per cent of the pharmacists provided the information and suggested the correct route of administering MA drug. Majority of the pharmacists either did not discuss the route of administration of drug or suggested the incorrect route of administering drug. Separately, in Rajasthan as well as Uttar Pradesh 55% of pharmacists suggested the correct route of administering the drug (Fig 3). **“Correct route of administration: Oral (Mifepristone) + Sublingual / Vaginal / Buccal (Misoprostol)”**.

The findings also showed that 50% of the pharmacists (n=380) provided the information with the possible side effects of the medical abortion drug. In Rajasthan 60% and UP 45% of the pharmacists informed the simulation client about the side effects of use of MA drug. Only 45% of the pharmacists in Delhi provided the information to the simulation client about the associated side effects with MA drug (Fig 4).

As shown in Fig 5, the further analysis of the data showed that only 42% of the pharmacists counseled correctly on all there indicators as mentioned under level 3<sup>2</sup>.

### **Discussion:**

The findings of the study show that the dispensing of the medical abortion drug without doctor’s prescription is a common practice across the project. Despite of being the prescription only drug, MA drug is being sold without doctor’s prescription. Similar types of findings were reported in many parts of the world (19, 20 & 21). Of 380 pharmacists only 25% of asked the clients for doctor’s prescription at the time of dispensing MA drug. The findings of the study suggest that there is a need of special

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<sup>2</sup> To understand, whether the pharmacists are performing the correct practice on all the key indicators like asked for doctor’s prescription, when and how the MA drug to be taken. The indicators were recorded separately at the time of exit interview.. The level 1, 2 3 indicators were computed for analysis purpose as given below:

Level 1 - Advised to go to the doctor **OR** Recommended Allopathic drug (Mifepristone + Misoprotol) in separate / combination packs

Level 2 - Advised to go to the doctor **OR** Recommended Allopathic drug (Mifepristone + Misoprotol) in separate / combination packs **AND** Asked to take one pill on 1st day and 2 pills/4 pills on either 2nd day or 3rd day

Level 3 - Advised to go to the doctor **OR** Recommended Allopathic drug (Mifepristone + Misoprotol) in separate / combination packs **AND** Asked to take one pill on 1st day and 2pills/4pills on either 2nd day or 3rd day **AND** Route: Oral + Sublingual/ Vaginal/ Buccal

attention on delivering the information to pharmacists on the importance of doctor's prescription before dispensing MA drug (19).

The medical abortion drug is a prescription only drug. The current study shows that majority (75 %) of the pharmacists were observed selling the drug without doctor's prescription. In order to minimize the complications and the side effects of the MA drugs, the pharmacists must confirm whether the patient is eligible for the abortion through MA drug by asking the menstrual history of patient. The findings of the study revealed that 85% pharmacists asked the simulated client about the last menstrual period (LMP) of the consumer.

Once, it is confirmed by the pharmacist that the patient is eligible for the medical abortion; s/he must provide the correct information to the patients about MA drug regimen, route of administering the drug and the associated side effects with MA drug. In terms of duration of medical abortion drug, fifty five percent of the pharmacists provided this information to the simulated client. However in Uttar Pradesh and Delhi each, only 45% pharmacists were found providing the correct information. The study further revealed that only 45% of the pharmacists provided the correct information about route of administering MA drug. Majority of the pharmacists either did not discuss the route of administration of drug or suggested the incorrect route of administering drug. It is utmost important that the pharmacists counsel the patient on MA drug regimen i.e., dose of drug and route of administration.

### **Conclusion:**

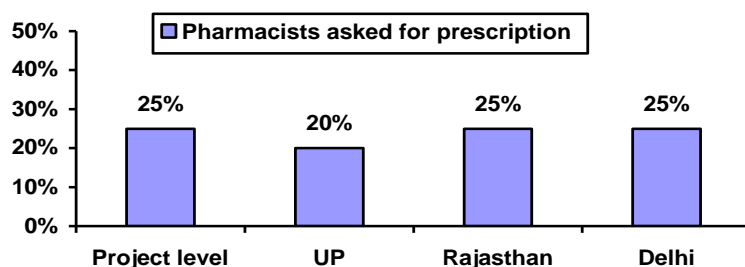
As discussed, the result of the study highlighted that only around 40 per cent of the pharmacists provided the prerequisite information to the client while dispensing the drug. Therefore, it is recommended that there is need of intensive training for further improvement on dispensing behavior related to MA drug among the pharmacists. MA drug regimen, side effects and warning signs associated with the drug.

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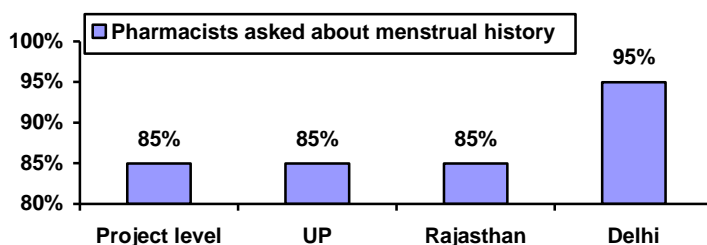
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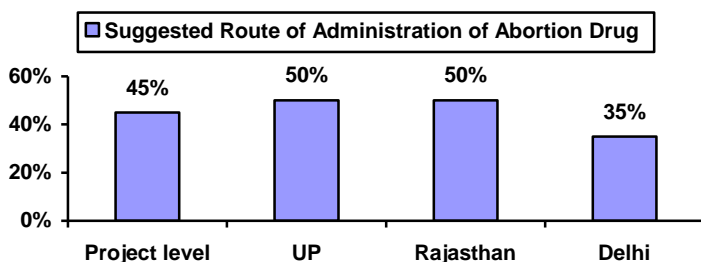
## Annexure



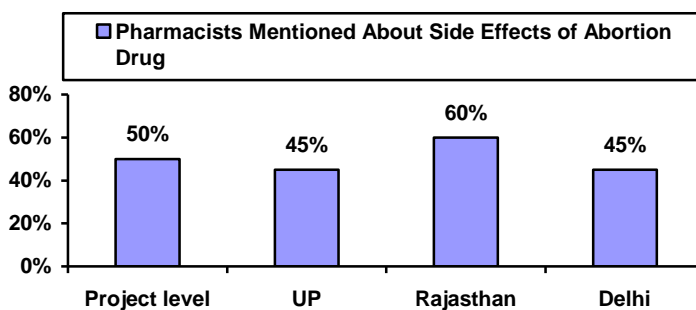
*Fig 2: Whether pharmacists asked for doctor's Prescription*



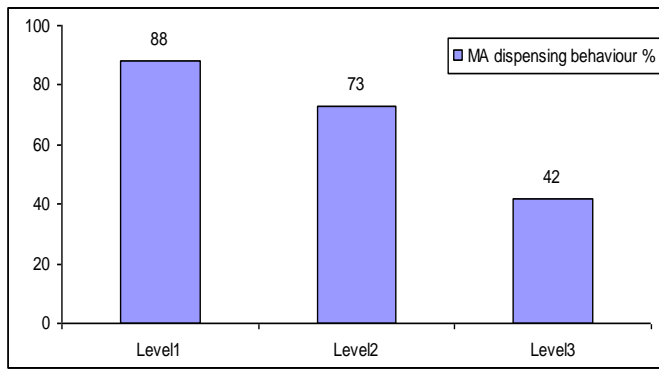
*Fig 3: Whether Pharmacists asked about menstrual history*



*Fig 4: Whether Pharmacists suggested the route of administrating the drug*



*Fig 5: Whether Pharmacists counselled about side effects of the drug*



*Fig 5: Over all dispensing behaviour about the key indicators*