Abortions in India:
Challenges posed by irrational use of medical abortion pills

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A thesis submitted in partial fulfilment of the requirements for the degree of Master in International Health

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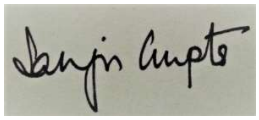
India

Declaration: Where other people's work has been used (either from a printed source, internet or any other source) this has been carefully acknowledged and referenced in accordance with departmental requirements.

The thesis "ABORTIONS IN INDIA: CHALLENGES POSED BY IRRATIONAL USE OF MEDICAL ABORTION PILLS" is my own work.



Signature

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Abstract

Background: Unsafe abortions are the third most important cause of maternal mortality in India. This is despite steps taken by the government and abortions being legal for a broad range of indications since 1971. Several amendments are made in the medical termination of pregnancy act, 1971, including legalisation of medical method of abortion (MMA) to reduce mortality due to unsafe abortions. However, India could not reap full benefits of MMA because of irrational use of medical abortion pills (MAPs) and MMA continues to contribute to unsafe abortions and wide spread complications among abortion seeking women.

Objective: To identify, describe and analyse the gaps in rational use of medical abortion pills in India.

Study Method: Literature review of relevant articles related to medical method of abortion and usage of medical abortion pills.

Results and Discussion: Irrational use of medical abortion pills due to non-availability of MA pills at public health care facilities, unregulated over-the-counter sale of MAPs, low level of knowledge of providers (prescribers and dispensers) and end users (abortion seeking women) made MMA a contributor to unsafe abortions. The private providers were not forthcoming in registering their facilities because of governance issues. Overburdened public facilities and high cost of scarcely available private facilities pushed poor rural women to avail services from unqualified health professionals. As a consequence, MAPs, are being prescribed, dispensed and utilised in irrational ways contributing to complications of medical abortions.

Conclusions and Recommendations: To overcome these gaps there is a need to put emphasis on dissemination of information regarding MMA, ensured availability of MAPs at all public facilities, regularising the sale of MAPs, training of prescribers and dispensers, to amend the MTP Act to include nurses and Indian traditional medicine i.e. Ayurveda, Yoga and Naturopathy, Unani, Sidha and Homeopathy (AYUSH) practitioners as certified medical abortion providers and to augment the capacity of district functionaries to facilitate the process of registering the private facilities for abortions.

Key words: Abortions, Unsafe abortions, Medical abortions, Medical abortion pills, Rational use of medical abortion pills, India.

Word Count: 12,707

List of Abbreviations

ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
AYUSH	Ayurveda, Yoga and Naturopathy, Unani, Sidha, Homeopathy
CAC	Comprehensive Abortion Care
CDSCO	Central Drugs Standard Control Organization
CHC	Community Health Centre
DCA	Drug and Cosmetics Act
DCGI	Drug Controller General of India
DCR	Drug and Cosmetic Rules
DH	District Hospital
EML	Essential Medicines List
FRU	First Referral Unit
GDP	Gross Domestic Product
GNM	General Nurse and Midwife
GOI	Government of India
HMIS	Health Management Information System
HW	Health Worker
IEC	Information, Education and Communication
ISM	Indian System of Medicine
MA	Medical Abortion
MAP	Medical Abortion Pills
MAQARI	Medical Advice, Quality, and Availability in Rural India
MBBS	Bachelor of Medicine and Bachelor of Surgery
MDS	Managing Drug Supply
MMA	Medical Method of Abortion
MMR	Maternal Mortality Ratio
MoHFW	Ministry of Health and Family Welfare
MPW	Multi-Purpose Worker
MSH	Management Sciences for Health
MVA	Manual Vacuum Aspiration
NGO	Non-Governmental Organisation
NHM	National Health Mission
NMEL	National Essential Medicines List
OOP	Out of Pocket
PHC	Primary Health Centre
RMNCH+A	Reproductive, Maternal, Newborn Child and Adolescent Health
SC	Sub Centre
SDH	Sub Divisional Hospital
SRHR	Sexual and Reproductive Health and Rights
TBA	Traditional Birth Attendant
TNMSC	Tamil Nadu Medical Services Corporation

Introduction

About unsafe abortions: Although the maternal mortality rate (MMR) in India declined considerably from 586 in 1990 to 174 in 2015 (WHO,2015), serious efforts will be needed to achieve the Sustainable Development Goal, 3.1 of achieving a level of 70 per 100,000 live births by 2030 (United Nations, 2015). A high proportion of maternal mortality in India is attributable to unsafe abortions although abortions are legal in India for more than four decades. Since 2002, medical method of abortion is also made legal which is much simpler and a non-invasive procedure in comparison with surgical abortions (Iyengar and Iyengar, 2016).

Epidemiology: Despite various steps taken by Government of India, around 10000-12000 women die each year in India due to unsafe abortions (Banerjee, 2007 for Ipas, India).

Strategies adopted at various levels: The Government of India is committed to ensure access to comprehensive abortion care (CAC) for women as part of the Reproductive, Maternal, Newborn Child and Adolescent Health (RMNCH+A) initiative under the National Health Mission (NHM). Government of India (GOI) issued guidelines for comprehensive abortion care (CAC) in 2010, which were last amended in 2014, to reduce MMR. CAC was made an essential component of reproductive health services at all health facilities. CAC guidelines stresses upon easily accessible, quality abortion services of patient's choice. Different levels of health facilities have different cadres of health work force with different kinds of works assigned to them ranging from information and education about availability and legality of abortion services, recognising early signs of pregnancy and confirming it, providing abortions and referring patients to a higher centre in case of complications (National Health Mission, Operational Guidelines, Comprehensive Abortion Care Services).

Relevance and importance of safe abortions: One of the most easily preventable reasons for maternal deaths is unsafe abortions. One such potential lies in medical methods of abortion (MMA). It is a simple method and recommended for termination of early pregnancies. It is even more relevant in India since it can be easily incorporated in primary health care settings.

Self-Perspective

My interest in abortion and its complications generated during 1997, while I was doing post-graduation in Anaesthesiology from a medical college from Rajasthan, India, where I witnessed that almost everyday women were being brought to the operation room with complications of surgical abortions like uterine perforation, infected remains of products of gestation, bowel perforation, septic shock etc. During 1997-2000 dilatation and curettage (D&C) was the commonest method for termination of pregnancy. Though Government of India guidelines stressed upon vacuum aspiration technique but I observed Obstetricians and Gynaecologists struggling everyday with either non-functioning or ill-functioning suction machines and ultimately switching to D&C. Over the years, cases of such grave complications of surgical abortion have significantly decreased after the introduction of medical method of abortion (MMA) but women are still being hospitalised due to complications of self-induced medical abortion like incomplete abortion, excessive vaginal bleeding leading to haemorrhagic shock, failed abortion, septic shock etc. Though medical abortion is reported to have high success rate if provided according to the guidelines, it continues to be one of the causes of maternal morbidity in India. So, I chose to review the literature to identify, describe and analyse the gaps in rational use of medical abortion pills in India.

1. Country Background

Geography: India is the seventh largest country in the world with an area of 3.28 million sq.km. India occupies the greater part of South Asia with China, Pakistan, Sri Lanka, Nepal, Bangladesh, Bhutan, and Myanmar as its neighbours. South of India is surrounded by the Arabian Sea in the West and Bay of Bengal in the East. India is a country with diverse topography consisting of mountains, plateaus, deserts, coasts and plains. The Himalayan range in the north acts as the natural boundary in the north (Indian Geography, 2015).

Demography: India is the second most populous country after China with a population of 1.21 billion as per census 2011. India is one of the most diverse countries in the world with many religions, sects, castes, tribes as well as more than twenty major and two hundred minor linguistic groups. Hinduism is the major religion practiced in India while other religious minorities like Muslims, Christians, Sikhs, Buddhists, etc. also account for a significant proportion of the population (Census India, 2011).

Literacy: India's literacy rate was 74% in 2011. Since independence in 1947, the literacy rate has grown six fold, however, the current literacy rate in India is well below the global average of about 84%. Furthermore, there is gender disparity in literacy in India as female literacy rate is only 65% compared with male literacy rate which stood at about 82% (Census India, 2011).

Government: India is the largest democracy in the world. There are two levels of government at the legislature level – Union government at the Federal level and State governments at the state/provincial level in every state.

Expenditures on Health: Health is a state subject under Constitution of India. National level health policies strive to make healthcare universal in India. The aim is to increase the health allocation to 1.87% of Gross Domestic Product (GDP) from the current levels of about 1% of GDP in the public sector which is very low (Planning Commission, 2010).

Indian Health System: The foundation of the government's healthcare system rests on a three tier structure**.** Health sub-centers in villages act as the first point of contact and take care of essential health needs, including treatment of minor ailments, family planning, nutrition, immunization and diarrheal control. The second tier consists of primary health centers, which serves as a referral unit for sub-centers and provide integrated preventive and curative health care including medical abortions. The third tier is made up of community health centers, typically 30 bed hospitals that serve as a referral unit for primary health centers. In addition, around 8000 hospitals function as the secondary tier for health care for the rural population and as the primary tier for the urban population. Most of these healthcare facilities in the primary and secondary levels are having problems relating to poor infrastructure and lack of medical professionals (Health Management Information System, 2015-16, Rural Health Care System, India).

The private sector in health is highly fragmented**.** At one end are "quacks", private health practitioners with little medical knowledge or formal training. At other end are top rated private hospitals that cater to population segments who can afford to pay for expensive care. Between these two extremes, other private providers range from small private clinics to hospitals (Nandraj et al., 2001).

Extent of unsafe abortions / complications: The lack of awareness and unfocussed monitoring/regulation of medical facilities providing abortions pose a serious challenge to the health-care problem relating to unsafe abortions. Unsafe abortions are contributing majorly to MMR in India. An estimated 8-20% of the maternal deaths are a cause of unsafe abortions which is avoidable and preventable if efforts are made (Duggal and Ramachandran, 2004 and Dahiya et al., 2005).

2. Problem Analysis and Objectives

2.1 Problem Statement

According to WHO (2015), the global maternal mortality ratio (MMR) fell approximately by 43% during 1990 to 2015 i.e. from 385 per 100,000 live births in 1990 to 216 per 100,000 live births in 2015. Annual maternal deaths decreased from about 5,32,000 in 1990 to 3,03,000 in 2015, out of which 66,000 occurred in South Asia. India accounted for approximately 45,000 deaths per year out of 66,000; which was about 15% of global burden of maternal deaths. Although MMR in India declined from 586 in 1990 to 174 in 2015, India could not achieve the desired level of MMR of 140 to achieve the Millennium Development Goal-5 about reducing MMR by three quarters of that of 1990 levels by 2015 (United Nations, 2000). In order to achieve Sustainable Development Goal (SDG)-3.1, India needs to achieve an MMR level of less than 70 per 100,000 live births by 2030 (United Nations, 2015).

According to WHO (1992), maternal mortality is defined as "the death of a woman whilst pregnant or within 42 days of delivery or termination of pregnancy, from any cause related to, or aggravated by pregnancy or its management, but excluding deaths from incidental or accidental causes". Causes of maternal deaths can be classified as either direct or indirect. In the direct causes, haemorrhage was responsible for 27·1%, hypertensive disorders 14·0%, sepsis 10·7%, abortions 7.9% and embolism 3.2% of maternal deaths. The rest of deaths were due to other direct causes (9.6%) while indirect causes accounted for 27·5% deaths (Say et al., 2014). It is estimated that 22 million unsafe abortions took place in 2008 leading to 47,000 deaths and more than 5 million complications arising out of unsafe abortions (WHO, 2008). Maternal deaths on account of unsafe abortions declined from a level of 69,000 in 1990 to 47,000 in 2008. Maximum decline was noticed between 2003 and 2008 probably due to better maternal health services and availability of medical methods of abortion (Ahman and Shah, 2011). However, the proportion of deaths due to unsafe abortions to total maternal mortality remained the same. WHO defines 'unsafe abortion' as "a procedure for terminating an unwanted pregnancy either by persons lacking the necessary skills or in an environment lacking minimal medical standards or both." The skills and medical standards required for medical abortion (drug based method) are different than a surgical abortion (done by vacuum aspiration technique). Skills and medical standards for safe abortion also depend on the period of gestation, (WHO, Fact sheet 2016).

In India, it is difficult to know the number of abortions taking place every year because of prevalent underreporting of abortion cases. A reliable and widely acknowledged study indicated that around 6.7 million abortions happen every year, out of which hardly one million abortions are performed legally and the rest are performed illegally by medical and non-medical practitioners (Johnston, 2002). Levels of unsafe abortion continue to be very high in India, in spite of abortions being legal for a variety of indications, and available in both public and private health sectors. Every year, around 10000-12000 women die due to unsafe abortions and many more suffer from long term morbidity on account of abortion-related complications (Banerjee, 2007 for Ipas, India). According to another study, 8-20% maternal deaths in India are a result of unsafe abortions (Duggal & Ramachandran, 2004 and Dahiya et al., 2005).

The Indian Parliament passed the Medical Termination of Pregnancy (MTP) Act in 1971 (The MTP Act, 1971) to ensure availability of safe abortion services to women seeking abortion care. This law permitted termination of pregnancies of up to 20 weeks' gestation under a broad range of conditions and by a registered medical practitioner (public or private) at a certified (public or private) facility. If the pregnancy is more than twelve weeks, a second doctor's opinion is required.

In 2002-2003, Government of India (GOI) made several amendments to The MTP Act 1971, with an objective to expand safe abortion services to women seeking induced

abortions. These amendments were aimed at decentralising from state level to district level, the process of registration of private facilities providing abortion services and care and included medical method of abortion (MMA) for termination of pregnancy up to seven weeks of gestation using medical abortion pills (MAP) (GOI, MTP amendments 2002 and 2003). Drug controller of India (DCI), approved the use of mifepristone in 2002, misoprostol in 2006 and a combination pack of both drugs in 2008. Medical abortion (MA) has advantages over surgical abortion as it is less painful and involves no surgical or anaesthetic risks (Iyengar and Iyengar, 2016).

For medical abortion, Government of India formulated guidelines (Handbook of MMA, 2016) that clearly indicated that medical abortion can only be prescribed by certified medical practitioners and the provider or centre prescribing medical abortion should have access to a backup health care facility in case of a failed or incomplete abortion or any other emergency.

Contrary to the guidelines, self-administration of these drugs by pregnant women of India is a common practice. Women take abortion pills on their own without prescription from registered medical practitioners and many are admitted to hospitals with complications of abortions like incomplete abortions, failed abortions, sepsis, haemorrhagic shocks, ruptured ectopic etc. (Armo et al., 2015 and Nivedita and Shanthini, 2015). They take medicines for termination of pregnancy from sources such as local chemists, nurses or any other unauthorised and illegal provider, which often leads to complications (Godara and Kaushal, 2013).

A WHO Conference held in Nairobi in 1985 defined rational use of medicine as: "Rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, and at lowest cost to them and their community". Any deviation from the above cited principles about rational use of drugs would be considered as irrational use of medicines (WHO Policy Perspectives on Medicines, 2002). It has been estimated that 50% of all medicines are prescribed, dispensed or sold irrationally which leads to medication errors, improper treatment regimens, dosage schedules and also self-medication (WHO Policy Perspectives on Medicines, 2002). Thus, self-medication of medical abortion pills, selling of MAPs by pharmacists without prescription from a registered medical practitioner and provision of medical abortion by unauthorised and illegal providers leads to irrational use of MAPs leading to unsafe medical abortions (MDS-3, 2012).

This study is intended to find out the causes of irrational uses of medical abortion pills by looking into the lacunae at the health system level, at the provider's level and at the end user's level. As about 70% of Indian population lives in rural areas, the main focus of this study will be the rural women of India.

2.2 Justification

Though MMR in India has declined from 586 in 1990 to 174 in 2015, it continues to be unacceptably high. In India, about 8-20% maternal deaths are due to complications of unsafe abortions amongst other causes of maternal mortality; which are completely avoidable (Duggal and Ramachandran, 2004 and Dahiya et al., 2005). To provide and expand safe abortion services to women seeking induced abortions, GOI, legalised medical method of abortion for termination of pregnancies up to seven weeks of gestation using medical abortion pills (The MTP Act 1971, amendment 2002 and 2003). Medical abortion using mifepristone followed by misoprostol is a safe and effective method of termination of early pregnancy (Ngo T.D. et al., 2011 and Raymond et al., 2012). When provided rationally, medical abortion has a success rate of approximately 95 per cent (Kahn et al., 2000). Thus, medical abortion can be a safe alternative to surgical abortion in resource poor settings.

Medical abortion is now widely available everywhere and its practices and governance mechanism will have significant impact on the provision of safe/unsafe abortions. In

countries where abortion is legal, medical abortion pills have the potential of improving abortion services where skilled providers are in scarcity and surgical equipment is not available at most facilities (Åhman and Shah, 2002). But several recent studies from India indicated that women were admitted in the hospitals due to complications of medical abortions arising due to irrational use of medical abortion pills (Armo et al., 2015 Nivedita and Shanthini, 2015 and Sharma, Gupta and Sharma, 2015).

Given the scenario that medical abortion pills are now being viewed as safe alternative to surgical abortions, this paper analyses the reasons for wide incidence of complications arising out of irrational usage of medical abortion pills in India. Moreover, there are not many structured studies focused on analysis of causes of irrational use of medical abortion pills. As this paper is intended to identify, analyse and describe the factors responsible for irrational use of medical abortion pills, its results may act as a reference point for further research in this area.

2.3 Objectives

The general objective of this literature review is to identify, describe and analyse the gaps in rational use of medical abortion pills in India in order to suggest measures to improve rational use of medical abortion pills in India.

Specific Objectives

1. To describe government laws and policies with reference to medical abortions in India.
2. To identify, describe and analyse the gaps in rational use of medical abortion pills in India at various levels viz.
   a) at health system level,
   b) at provider level,
   c) at end users level
3. To give recommendations to stakeholders to improve rational use of medical abortion pills in India.

3. Methodology

3.1 Study Design

This study is a review of literature to find and analyse the reasons for complications arising out of usage of medical abortion pills. An extensive study was undertaken, covering laws and policies related to abortions particularly medical abortions and on factors responsible for irrational use of medical abortion drugs. A search on articles available online using PubMed, Google Scholar, Google, VU library was made. Combination of key words "Abortions", "Unsafe abortions", "Medical Abortions", "Misoprostol", "Mifepristone", "Rational use of medicines" and "India" was used as mentioned in Table-1, to search only the relevant articles and to limit the number of articles. Only the English Literature has been referenced as the relevant information about India and the subject is available in English and also because English is the only international language known to me. By examining the references of shortlisted articles, other relevant papers were identified and included in the study. I also searched relevant reports and articles published by well-known international and national organizations like WHO, Management Sciences for Health, Ipas, International Institute for Population Sciences, Population Council, etc. For laws, regulations and guidelines, I referred various government documents from organisations such as the Ministry of Health and Family Welfare of the Government of India, Comptroller and Auditor General of India, the Registrar General of India, the Census Commission of India, and Central Drugs Standard Control Organisation of India, etc. As medical abortion was introduced in India in 2002 only, limited information was available on this subject in relation with the experience in India. Therefore, some relevant articles from other developing countries were also referenced. Articles published between year 2000 to 2017 are included and some old but relevant information is also included which was published before year 2000.

Chapter	***Keywords Used***	***Search Engine and Website used***
Country Profile	'Geography' AND 'India' 'Demography' AND 'India' 'Health System' AND 'India' Census India, 2011 Health expenditure in India	Google, Registrar General of India, MoHFW
Problem Statement	'MMR' AND 'India' 'Abortions' AND 'India' 'Unsafe Abortions' AND 'India' 'Medical Abortions' AND 'India' 'Misoprostol' OR Mifepristone AND 'India' 'Medical Abortion Pills' AND 'India' 'Irrational Use of Medicines' AND 'India'	PubMed, Google, Google Scholar, VU library, MoHFW, WHO
Methodology	'Conceptual Framework' AND 'Unsafe Abortions' 'Conceptual Framework' AND 'Irrational Use of Medicines'	Google, Google Scholar, PubMed, VU library
Study Findings	MTP Act of India 'Performance Audit of Hospitals' AND 'India' 'Drug Control' AND 'India' Pharmacy Act of India 'Over the Counter Drugs' AND 'India' 'Health System' AND 'Abortions' AND 'India' 'Providers' AND 'Medical Abortions' AND 'India' 'Women seeking Abortions' AND 'India' and the rest same as in problem statement	PubMed, Google, Google Scholar, VU library, WHO MoHFW, Comptroller and Auditor General of India, Pharmacy Council of India, Central Drugs Standard Control Organisation.

Table 1: Keywords and search engines used for different chapters

It needs to be mentioned here that in India, a number of hormonal, herbal and traditional abortion pills are also available over the counter apart from mifepristone and misoprostol, however, the term medical abortion pills (MAPs) in this paper is restricted to refer to the usage of mifepristone and misoprostol only. Here, the term medical abortion (MA) or medical method of abortion (MMA) will mean a method of abortion using mifepristone and misoprostol to terminate pregnancies up to seven weeks of gestation.

3.2 Limitations of study

India is a large country with 29 states and 6 union territories. States are divided by geography, climate and languages but unified by social and cultural values. As far as abortions are concerned some states are better studied than others. Though every effort has been made to include information from all over India, few states certainly has been left due to scarce availability of relevant literature. So, there is a possibility that this study might not be able to capture certain issues pertaining to irrational use of MAPs which are unique to a particular area or state.

In addition, abortion is a social stigma in Indian society, so there is dearth of both quantitative as well as qualitative information regarding abortions. Due to stigmatisation of abortions there is hardly any literature available for issues related to pregnancy due to sexual violence and pregnancy out of wedlock. Moreover, MMA is legalised since 2002 only, so the information regarding irrational use of medical abortion pills is available only in few small scale studies. Thus, it is possible that there are remaining issues related to irrational use of MAPs, other than those highlighted in this literature review.

3.3 Conceptual framework

If the use of medicines is not according to the definition of rational use of drugs (WHO, 1985), it is considered as irrational use of medicines. According to Management Sciences for Health (MDS-3, 2012), irrational use of medicines may be due to lack of knowledge, skills and independent information about drugs, non-availability of medicines, over-burdened health professionals, or inappropriate promotion and incentives from selling unsuitable medicines. This results into increased adverse drug reactions, poor patient outcome, increased out of pocket expenditure and higher morbidity and mortality. In turn, this results into patient's loss of confidence in health systems. Overall, all the factors viz. health system, prescriber, dispenser, patient and community; contribute towards irrational use of medicines.

First, to identify and analyse the causes of irrational use of medical abortion pills, the framework given by Mao et al. (2015) in their systematic review on irrational use of medicines in China and Vietnam; was studied for possible adoption and for analysing the reasons for irrational use of medicines.

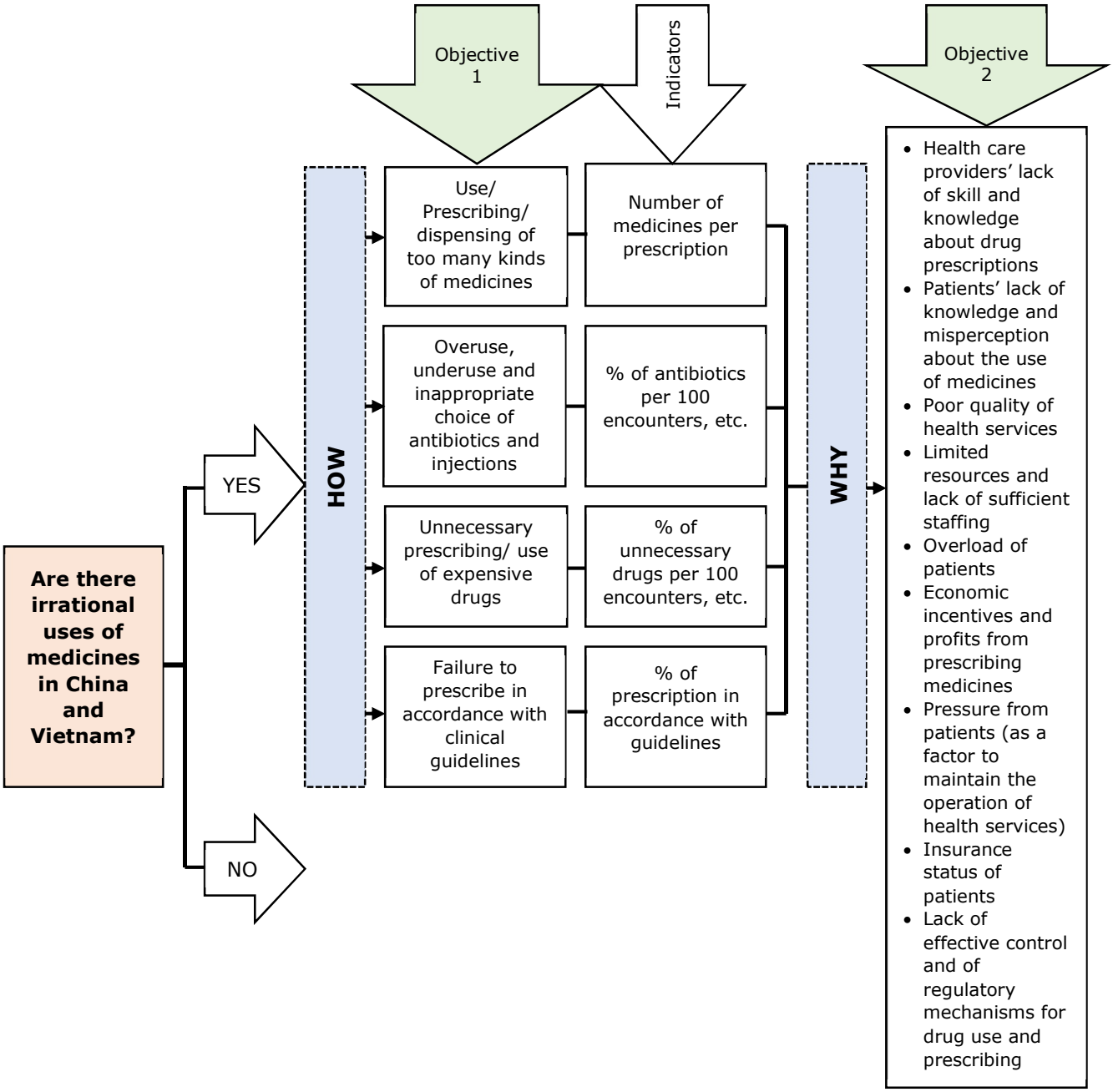

Figure 1: Conceptual Framework for the use of rational medicines, Mao et al. (2015, pg.4/16)

This framework uses quantitative indicators to statistically quantify the irrational use of medicines. These quantitative indicators were developed by WHO (How to investigate drug use in health facilities, drug use indicators, 1993). In addition, qualitative indicators are used to know the reasons of irrational use of drugs. After careful consideration, it was concluded that quantitative indicators' evaluation might not be possible in this study on account of a strong likelihood of non-availability of associated data. Moreover, the primary focus of this study was on qualitative factors in finding out the causes for irrational use of medical abortion pills.

During the course of this study, another well acknowledged framework from MDS-3: Managing Access to Medicines and Health Technologies, chapter 27 pg. 27.10: Managing

for rational medicine use, by Management Sciences for Health (MDS-3, 2012) was referred. This framework gives insights for exploring the factors underlying irrational use of medicines at various levels of health system and also guides in formulating strategies for rational use of medicines. This framework was preferred for this study over the frame work given by Mao et al. (2015) as framework by MDS-3 (2012) broadly divided the factors influencing irrational use of drugs under three headings viz. system, providers and end users. This division allowed freedom to incorporate qualitative indicators specified by Mao et al and factors other than these indicators, which could be encountered during the course of writing this paper. As the main objective of this paper was to identify, analyse and describe the gaps in rational use of medical abortion pills, the focus was only on the factors responsible for irrational use of medical abortions pills at health system level, at provider's level, and at end user's level.

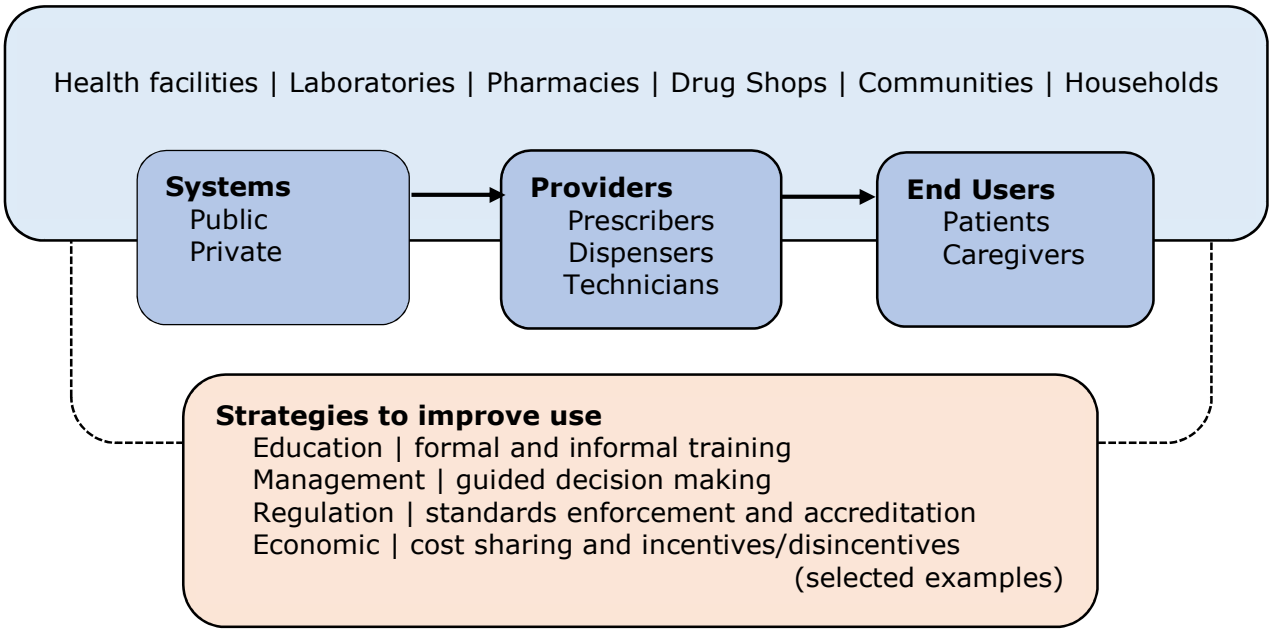

Figure 2: Conceptual Framework for improving medicine use

Source: MDS-3 - Managing for rational medicine use, chapter 27, Pg.27.10, Management Sciences for Health 2012.
(Available from https://www.msh.org/sites/msh.org/files/mds3-jan2014.pdf)

4. Study Findings

4.1 Laws and Policies

As per WHO (2015), Maternal Mortality Ratio in India is 174 per 100,000 live births. Unsafe abortions contribute around 8-20% of all maternal deaths in India (Duggal & Ramachandran, 2004 and Dahiya et al., 2005). Each and every death and complications of unsafe abortions can be prevented through provision of sexuality education, family planning, safe abortion services as per national laws and post abortion care to all in an acceptable, accessible and affordable way (WHO, 2012). The relationship between restrictive abortion laws and higher mortality and morbidity due to abortions is well established (Johnson et al., 2017). However, it is not only restrictive abortion laws but also associated policy issues which act as a barrier to women and girls to access safe abortion services. This includes provision of abortions by obstetricians and gynaecologists only, insistence on third party consent, undue regulations in certification of facilities, unnecessary medical tests and long waiting hours (WHO, 2012).

As this paper is about irrational use of medical abortion pills in India leading to unsafe abortions, the Indian laws and policies related to abortions and medicines are analysed. Furthermore, the focus being on medical abortion, laws and policies for medical abortions up to 7 weeks of gestation (The MTP Act 1971, Amendments 2002 and 2003), are analysed in this chapter.

4.1.1 Legislative provisions on Medical Abortions

The Medical Termination of Pregnancy (MTP) Act was passed by the Indian Parliament in 1971 to regulate and provide access to safe and legalised abortion services to women with unintended pregnancy (The MTP Act, 1971). The MTP Act of 1971 stipulates that only registered allopathic doctors can provide abortion services in order to save a woman's life or for preserving her physical or mental health. Also, the law permits abortions in cases of valid economic or social causes, reasons such as rape, incest, foetal impairment, pregnancy due to failure of contraception, etc. Consent for abortion, either from the woman's husband or relatives, is not required as per this legislation. However, a guardian's consent is needed if the woman seeking abortion is younger than eighteen or mentally disabled. The act allows termination of pregnancy up to 20 weeks' gestation; however, if the pregnancy is more than twelve weeks, the opinion of a second doctor is required. All the government facilities (Primary Health Centres and above levels) are allowed to perform abortions but private facilities need certification/registration from the government to perform abortions. The MTP Rules framed under MTP Act defines criteria and procedures to certify/register a private facility, for consent when required, for record keeping and to maintain confidentiality.

Further amendments have been made in the MTP Act, 1971 by Government of India (GOI) in 2002-2003 to provide and expand safe abortion services to women seeking induced abortion (The MTP Act 1971, amendments 2002 and 2003). For the purpose of this paper, emphasis is on two amendments, first amendment related to devolution of the powers to district levels (District Level Committees, DLC) from state level for evaluation and registration of private facilities for abortion, and second amendment about inclusion of medical abortion as a legal method of abortion in the MTP Act.

4.1.1.1 District Level Committees

All public facilities from Primary Health Centres (PHCs) level and above; are certified by default to provide abortion services if they have a certified provider and necessary equipment are available. However, private facilities need to be registered by a District Level Committee (DLC). Under the MTP rules 2003, evaluation and registration of private facilities for abortion is decentralised from State level to DLCs. There is one DLC for each district which is headed by the Chief Medical Officer (CMO) of the district. DLCs are comprised of three to five members including the CMO. One of the members should be

either a gynaecologist, surgeon, or an anaesthetist, and other members should be from non-government organisations and local self-governments of the district. One of the members of the committee should be a woman. Tenure of the committee is for two calendar years. The CMO, after receiving an application from the owner of a facility to be registered, verifies or inspects the place to satisfy that abortions can be done under safe and hygienic conditions and recommends approval to the committee. The inspection of the place should take place within two months of receiving the application and the certificate should be issued within two months of inspection. If any deficiency is found, it should issue the certificate within two months of rectification of deficiency. It is the responsibility of the CMO to inspect the facility from time to time to ensure continued safe and hygienic conditions for conduct of MTPs. DLC can cancel the registration of a facility if irregularities are found at a facility. For a facility to get registered, it should have a gynaecological labour table, sterilization equipment, resuscitation equipment, essential drugs, back up facilities in case of complications and facilities for transportation if there is an emergency.

Though decentralization of the process of registration of facilities was intended to better organise the services in accordance with the local needs, it was observed that DLCs imposed additional conditions on providers for registration. In Maharashtra state, DLCs made it mandatory to have a blood bank within five km radius of the facility. Similarly, in Delhi and Haryana states, it was made compulsory to submit the floor plan and plan of parking facility with the application for registration (Hirve, 2004). It was noticed in states of Bihar and Jharkhand that not even a single private facility was certified in the year 2010 (Paramita, 2011a & 2011b). In the state of Jharkhand, 54% of districts did not even constitute any District Committee for registration (Paramita, 2011b). As per Audit report of the Comptroller and Auditor General of India for the state of Uttar Pradesh, DLCs in 14 out of 20 sample districts were found invalid in 2014-15 as respective tenures of the committees had expired and DLCs were not renewed during 2010-15. It was also observed that DLC meetings were never held regularly in these 20 districts, defeating the very objective of the constitution of the committees. As per Directorate, Family Welfare of Uttar Pradesh state, approximately 75 per cent MTPs were being conducted at private clinics, most of which were unregistered. Despite operation of a large number of unauthorised MTP clinics, the CMOs neither conducted inspections nor enforced provisions of the MTP Act with regard to taking any action against the unregistered/unauthorised private clinics carrying out MTPs in unsafe and unhygienic conditions (Audit report of the Comptroller and Auditor General of India in respect of the state of Uttar Pradesh, 2014-15).

4.1.1.2 Medical Method of Abortions

Another amendment in the MTP Act, 1971 was about inclusion of medical method of abortion (MMA) for termination of pregnancies up to seven weeks of gestation using medical abortion pills (MAP). Drug controller of India (DCI) approved the use of mifepristone in 2002, misoprostol in 2006 and a combination pack of both drugs in 2008 (one tablet of 200 mg mifepristone and four tablets of misoprostol of 200 mcg each). Medical abortion (MA) has advantages over surgical abortion as it is less painful and involves no surgical or anaesthetic risks. Above all, medical abortions can be done even at home in a secure and confidential environment (Sri and Ravindran, 2015).

For medical abortions, Government of India formulated guidelines (under provisions of MTP Act, 1971 and amendments of 2002 and 2003) that clearly indicate that medical abortions can only be prescribed by certified medical practitioners and that the centre prescribing medical abortion need not have onsite capability of providing abortion, provided it has access to a certified health care facility to deal with failed or incomplete abortion or any such emergency. Females asking for medical abortion should have thorough pre-abortion counselling regarding procedures, such as when to administer the drugs, likely duration of bleeding/pain, chances of failure and requirements for surgical intervention if necessary. Women should be instructed about a follow up visit on 14th day to confirm complete abortion and should be counselled for post abortion contraception methods. Patients should be examined to confirm duration and location of pregnancy

(whether it is intra uterine or extra uterine), if an ultrasonography (USG) machine is available, to rule out any contra-indications for medical abortion, and basic laboratory (Haemoglobin, urine complete and ABO Rh) workup should be done. Currently, the MTP Act approves medical abortions up to seven weeks of amenorrhea i.e. up to 49 days of pregnancy. Also, it is mandatory for providers to fill four forms: Form-I for certified provider's opinion, Form-II for monthly reporting (to be sent to district authorities), Form-III is admission register for case records and Form C for consent of the patient or consent of custodian in case of minor or mentally ill patients (Handbook on medical method of abortion, Government of India Guidelines, 2016).

After legalisation of MMA, it was assumed that safe abortion services would be available at all government facilities from PHCs level and above, at least for early pregnancy abortions. In two separate studies from Maharashtra and Rajasthan it was found that almost all PHCs and many CHCs were not providing MA at all. Moreover, no information, education and communication (IEC) material was available about safe abortion services at government facilities particularly at PHCs. Even if some IEC material was available, most of it was about Pre Conception and Pre Natal Sex Determination Act (PCPNDT Act) and most of the women in the study area were aware about the illegality of pre-natal sex determination (Jejeebhoy et al., 2011a and Jejeebhoy et al., 2011b). Similarly, Bajwa et al. (2011), in their study in Punjab found that women in the study area did not know that a medical abortion facility was available in the government facility of the area.

Powell-Jackson et al. (2015), in their study about three urban and three rural districts of Madhya Pradesh state found that MAPs were available at almost all the towns in urban areas but availability in rural areas was less. Though mifepristone, misoprostol and combination packs were available in the market, but combination packs are widely available with almost 15 brands in the market. Median price for combination pills was Rupees 350 per pack and lowest price was Rupees 150 per pack.

Reymond et al. (2013), found the regimen of mifepristone (200 mg) and misoprostol (400 mcg) highly effective for women up to 49 days of gestation with less than 5% of women requiring a surgical method for completion of abortion. Only 1.1% of women were hospitalised for serious complications out of 45,000 women included in the study. But failure rate of this regimen was high (>25%) if used in women with nine or more weeks of gestation.

WHO's "Clinical practice handbook for Safe Abortion" (2014) recommends home use of misoprostol for MMA for pregnancy up to seven weeks only. This will improve the comfort, confidentiality and the acceptability of said services without affecting the safety of due process. But guidelines for MMA by Ministry of Health & Family Welfare, Government of India (2016) mandates three visits to the abortion facility: on day 1 for administration of mifepristone 200mg orally, on day 3 for administration of 400 mcg misoprostol orally and on day 14 for ensuring completion of abortion process. Iyengar et al. (2015), in a randomised control non inferiority trial in three rural and three urban clinics of Rajasthan state found that women were more satisfied by using misoprostol at home and can use a low sensitivity urine pregnancy test successfully to access completion of process and can better diagnose the complications arising out of use of medical abortion if provided with information in the form of pictures. Though in this study women were less educated in comparison to other studies done in Vietnam and Europe, results of home assessment of completion of abortion process by using same low sensitivity urine pregnancy tests were comparable (Ngoc, et al., 2014 and Oppegaard et al., 2015). Similarly, Reymond et al. (2013) did not find any increase in complications when women administered misoprostol at home in a scenario where most women preferred this option of home use of misoprostol.

4.1.2 Legislative provisions on Drugs

In India, manufacturing, distribution, sale and import of drugs and cosmetics are regulated by Drug and Cosmetics Act (DCA), 1940 and Drug and cosmetics Rules (DCR), 1945. The

Central Drugs Standard Control Organization (CDSCO) is a central regulatory body attached with the Director General of Health services in the Union Ministry of Health and Family Welfare (MoHFW). CDSCO is responsible for approval of newer drugs, for giving approvals for clinical trials, registration and quality control of imported drugs and for regulation and amendments of Acts and Rules. CDSCO also coordinate functioning of state drug councils and advise these on issues related to uniform administration of Act and Rules i.e. DCA,1940 and DCR,1945 in the country.

State drug councils are responsible for licensing, inspection and regulation of drug manufacturing units and sales outlets at the state level. The councils have powers to take legal action on defaulters as per Act and Rules. State drug councils operate through state drug inspectors. An inspector can inspect any premises where drugs are compounded or dispensed. Inspectors have the authority to check if a pharmacy unit and persons operating it are registered or not, can investigate any written complaint registered against a pharmacy unit (DCA,1940; DCR,1945).

Profession and practice of pharmacy is regulated by Pharmacy Act, 1948. The central pharmacy council regulates the pharmacy education standards and maintains a central pharmacy register which has names of all the pharmacists registered from each state. State pharmacy council maintains a state register containing "(a) full name and residential address of the registered person; (b) the date of his first admission to the register; (c) his qualifications for registration; (d) his professional address, and if he is employed by any person, the name of such person". In India, any person who is more than eighteen years old is eligible to have his/her name entered in the register if he fulfils one of the following educational qualification/experience parameters:

(a)	holds a degree or diploma in pharmacy or pharmaceutical chemistry or a chemist and druggist diploma, or a prescribed qualification granted by an authority outside India
(b)	holds a degree of an Indian University other than a degree in pharmacy or pharmaceutical chemistry, and has been engaged in the compounding of drugs for a total period of not less than three years
(c)	has passed an examination recognised as adequate by the State Government for compounders or dispensers
(d)	has been engaged in the compounding of drugs in a hospital or dispensary for a total period of not less than five years
Source: Pharmacy Act, 1948	

Table 2: Eligibility parameters for a person to register as a pharmacist in India

Also, the law states that only a registered pharmacist shall compound, prepare, mix, or dispense any medicine on the prescription of a medical practitioner.

Studies from states of Bihar and Jharkhand regarding availability of MAPs in 2005 indicated that pharmacists offered ayurvedic medicines (Indian traditional medicines) when asked for medicines for abortions or delayed periods. Only 35-50% pharmacies were stocking MAPs. About 95% pharmacists admitted that sales representatives from pharmaceutical companies and doctor's prescriptions were their primary source of drug information (Ganatra et al., 2005). Mishra et al. (2016), when they interviewed 110 workers, working in pharmacies located largely in urban areas of Delhi, found that amongst 110 workers, 75 workers i.e. only 68% were having bachelor's degree in pharmacy but all were dispensing medicines independently.

4.2 Health System

According to WHO, for a robust health system, it is mandatory to have a well-functioning and interconnected six building blocks of health system viz. adequate and well-performing health work force, equitable access to quality and cost effective essential medicines, efficient health financing system to protect people from financial catastrophe or

impoverishment due to need to pay for using health care facilities, accountable leadership and governance and equitable service delivery (WHO, Health System Framework).

Similarly, rational use of medicines is impossible without the availability of sufficient number of competent staff and adequate finances for essential medicines (WHO, 2002 core components). Untrained staff leads to irrational prescribing while unavailability of essential medicines promotes use of non-essential medicines. Because of unavailability of essential medicines, patients lose confidence in the public health system and providers morale become low due to community pressure (Prinja et al., 2015).

This section deals with the structure of health system in India and the situation regarding availability of essential medicines in India.

4.2.1 Structure of health system in India

India is the second largest populous country of world with 68.9% population residing in rural areas (Census, 2011). To provide primary health care to all, Indian health system has developed as a three tier system comprising of Sub Centres (SC), Primary Health Centres (PHC) and Community Health Centres (CHC). Details of these has been shown in figure 3 (HMIS, 2015-16, Rural Health Care System in India, pg-4) below:

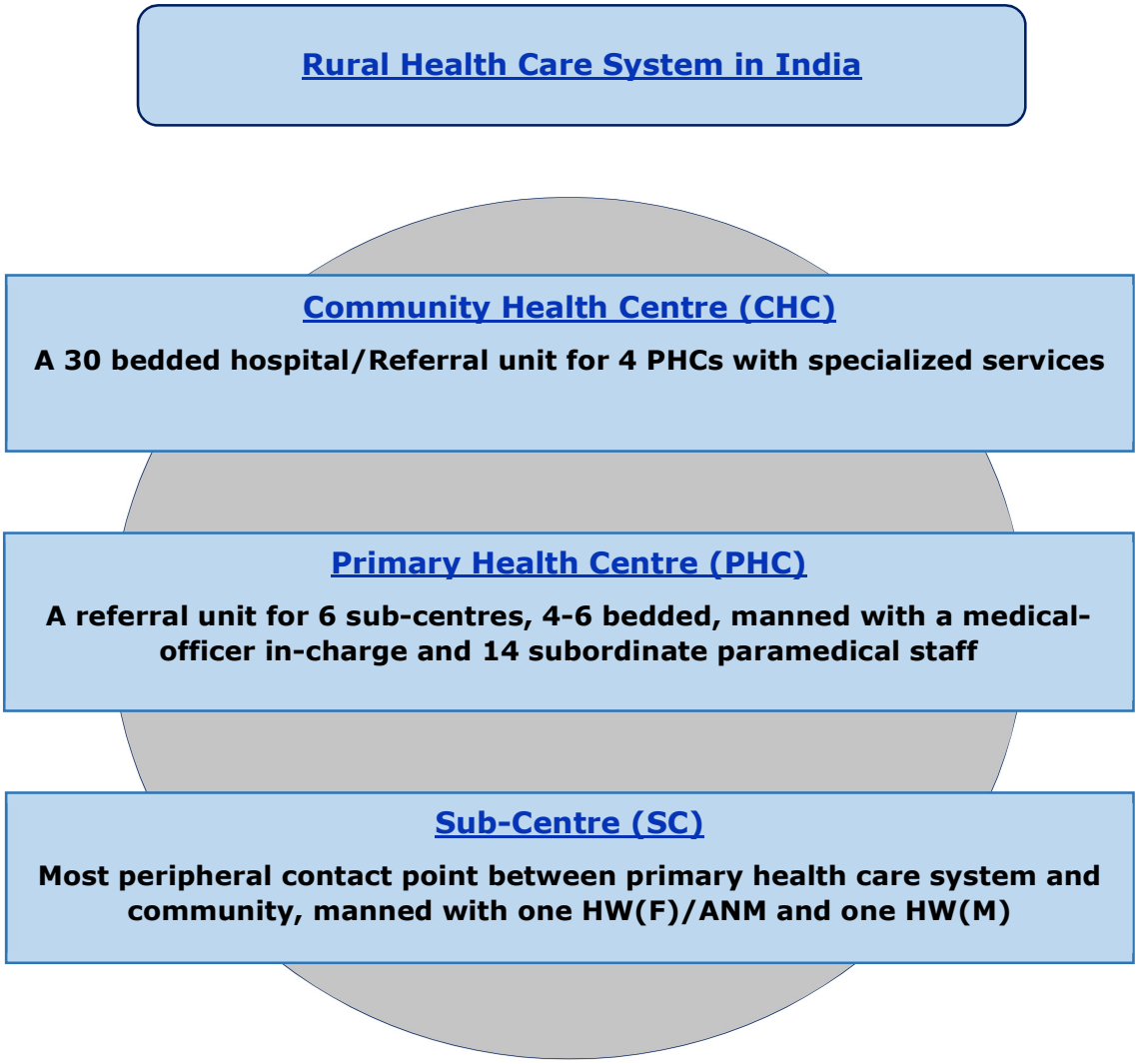

Figure 3: Three tier rural health system in India
Available from: https://nrhm-mis.nic.in/ [Accessed16 June 2017]

For secondary care, there are sub-divisional hospitals and district hospitals. Hospitals attached to medical colleges and super-speciality hospitals in public sector provide the tertiary care.

As per the Health Management information system (HMIS) of India, 5.8% of Sub Centres are without a female health worker (FHW) or an Auxiliary Nurse Midwife (ANM). In the next level of primary care, 8.1% PHCs are without any doctor, 38% PHCs are without a Laboratory Technician and 18.7% PHCs are without pharmacists. In addition, there is a shortfall of 76.7% Gynaecologists and Obstetricians and overall 81% shortfall of specialists in CHCs.

In India, community level workers like auxiliary nurse midwives (ANMs), Accredited Social Health Activists (ASHAs), Traditional Birth Attendants (TBAs) and friends/family are first source of information for rural women with unintended pregnancy. ANMs, ASHAs, TBAs, local pharmacists all are providing abortion services (Iyengar et al., 2005). Apart from these, persons trained in Indian system of medicines (ISM) like Ayurveda, Yoga and Naturopathy, Unani medicines, Siddha and Homeopathy (AYUSH) are legally recognised to provide health care services in India. Presently there are 10,279 trained AYUSH practitioners who are posted at various health facilities in India (HMIS, GOI). AYUSH practitioners also provide services at their private clinics in both urban and rural areas. At many PHCs, they are posted as medical officers in-charge and are supposed to look after maternal and reproductive services like taking deliveries, providing contraceptives including insertion of Intra Uterine Devices but are not authorised to provide any kind of abortion services (Jejeebhoy et al., 2012). PHCs and CHCs are certified places for Medical termination of Pregnancy (MTP) but they often fail to provide the abortion services to poor rural women of India due to scarce resources (Mundle et al., 2007, Paramita et al., 2011a and Paramita et al., 2011b). Some facilities do not have a certified provider, some do not have necessary equipment and drugs and some lack both (Iyengar et al., 2005). As per the India Facility Survey (2005), 94% PHCs and 69% CHCs did not provide any abortion services, which was alarming. Some selected Rural Health Statistics (2012) of Primary Health Centres and Community Health Centres regarding availability of medical personnel is given below:

Characteristic	%
Primary Health Centres	
Lady Medical Officer on staff	24
Open 24 Hours	53
Offers referral services for complicated pregnancy/delivery	55
Meets Indian Public Health Standards	15
Community Health Centres	
Obstetrician-gynecologist on staff	25
Delivery services offered 24 hours	90
Has operating theatre	65
Designated as FRU	52
FRU with functioning blood storage facility	9
Meets Indian Public Health Standards	15
Source: https://www.guttmacher.org/sites/default/files/report_pdf/abortion-india-lit-review.pdf	

Table 3: Facilities available at Primary Health Centres and Community Health Centres in India (Stillman et al., 2014, pg. 25)

Service providers in the private sector are many a times unqualified persons but can be super-specialists as well, and the private facilities also vary in scope and size from an informal outpatient clinic to a hospital having latest technology (Nandraj et al., 2001). As far as abortions are concerned, a study from Rajasthan found that only 0.67 certified private facilities are available on an average for 100,000 population and these small number of private facilities are clustered around few districts only. The study also

mentioned that 83% of facilities were clustered in nine districts out of 31 districts and the other 22 districts had only 17% of the facilities. Amongst 22 districts, 5 districts did not have any certified facility and 6 districts had only one facility each. Iyengar et al. also noticed that the number of abortions provided per month was significantly low at PHCs and CHCs level as compared to district and sub divisional government hospitals and private facilities (Iyengar et al., 2005).

In 2005, public spending on health in India was 0.9% of GDP which was extremely low as compared with other countries. During 2004-2005, India's total expenditure on health was 5.2% of Gross Domestic product (GDP). Out of this expenditure, more than 82% was from private spending. Under private spending category, employers paid 9%, health insurance covered 5-10% and the rest about 82% was out of pocket (OOP) expenditure of the patients. Due to this heavy OOP expenditure, around 40% of total admitted patients had to take loans or sell assets for their treatment (Planning commission, 2005). Total health expenditure remained at 0.93% of GDP in 2007–08 and it increased to about 1.04% during 2011–12. Though Government of India plans to increase public health spending in the 12th five-year plan to 1.87% of the GDP, it needs to increase even more over the next decade (Planning Commission, 2010).

4.2.2 Essential Medicines in India

According to WHO, "Essential medicines are those that satisfy the priority health care needs of the population". Essential medicines should be selected on the basis of burden of disease in the country, of proven efficacy, safety and cost effective. Good quality essential medicines should be available all the time, in adequate amounts, in the appropriate dosage and at an affordable price to all. In India, health is the responsibility of each state. Many states have developed their own Essential Medicine Lists (EMLs) depending upon disease prevalence and their budget. The National Essential Medicines List (NEML) is a model list and should be adapted according to the general health status, incidence of diseases, economic and social status and other logistic requirements for procuring medicines within the state. Though both mifepristone and misoprostol are included in EML but these remain unavailable in most public health care facilities (Iyengar and Iyengar, 2016).

In India, access to medicines for people is either through private retail shops or pharmacies or through government owned pharmacies functioning at various levels like PHCs, CHCs, District Hospitals and other tertiary level hospitals or medical colleges. Some prescribers also dispense medicines, and in that case patient can directly get the medicines from prescriber on payment. For universal health coverage, availability of essential medicines in public facilities is crucial. According to WHO (2004), 68% of people in India have no access or limited access to essential medicines. Non-availability of essential medicines leads to increased out-of-pocket (OOP) expenditure on medicines, which in turn push around 2.2% population to below poverty line every year (Oberoi and Oberoi, 2014). Overall availability of essential medicines in the states of Punjab and Haryana in public sector health facilities and hospitals was 45.2% and 51.1% respectively which is well below the WHO standards of 80% (Singh et al., 2013 and NHM, Haryana, 2012).

According to Planning commission's 12th five-year plan document, only 80% of patients in India have access to any kind of medical facility and the remaining 20% of patients are deprived of any kind of health facility as being out of his/her reach. Amongst the patients who have access to medical facilities, only 20-25% avail public health facilities which is expected to increase to 40% if patients get free and quality medicines all the time in Public Health Facilities (Planning commission, 2010). In Tamil Nadu, after the establishment of Tamil Nadu Medical Services Corporation (TNMSC), an autonomous corporation in Public Sector, the proportion of patients visiting public health facilities increased to 40% as free medicines to all patients availing public health services were made available by TNMSC.

4.3 Medical Service Providers

4.3.1 Prescribers

India spends four to five percent of its gross domestic product on health care, most of which represents private out-of-pocket expenditures (Planning Commission, 2010). These statistics are indicative of high level of reliance and use of private health care facilities in India. According to MAQARI Team (2011), though the doctors in government facilities are educationally qualified, most patients seek medical services from the private facilities. The doctors at the private facilities have very wide ranging qualification status from a self-styled quack with no formal training to a super specialist (MAQARI Team, 2011). The following table reflects the position of availability of private providers and public doctors to an average person within a village in a sample selection of villages of different states of India and the skewed position of availability of public doctors vis-à-vis private providers:

Availability of Healthcare Providers within a Village to an Average Person					
State	***No. of providers by provider type***				
	Private Providers	Public Doctors	Public Other	Total	Ratio of Public Doctors to Private Providers
Andhra Pradesh	2.10	0.22	2.67	5.05	1:9
Assam	1.59	0.12	2.03	3.94	1:14
Bihar	5.51	0.13	0.21	6.21	1:42
Chhattisgarh	6.94	0.39	5.85	13.44	1:18
Gujarat	1.19	0.25	3.49	4.97	1:5
Haryana	5.60	0.51	3.63	9.95	1:11
Himachal Pradesh	1.45	0.28	0.98	2.72	1:5
Jharkhand	3.03	0.06	0.58	3.76	1:5
Karnataka	1.22	0.29	1.22	2.75	1:4
Kerala	1.78	1.55	0.43	3.97	1:1
Madhya Pradesh	2.87	0.24	3.83	7.14	1:12
Maharashtra	1.60	0.15	2.41	4.19	1:10
Orissa	2.00	0.23	2.91	5.20	1:9
Punjab	4.01	0.46	0.37	4.95	1:9
Rajasthan	2.82	0.55	4.00	7.44	1:5
Tamil Nadu	0.97	0.11	1.66	2.76	1:9
Uttar Pradesh	4.07	0.37	1.73	6.31	1:11
Uttaranchal	1.88	0.19	3.51	5.61	1:10
West Bengal	9.24	0.25	1.39	10.93	1:37
India	**3.21**	**0.34**	**2.31**	**5.97**	**1:10**
Note: "Private Providers" include all private practitioners and a wide range of qualifications and practice. The second category includes public doctors who are formally recognized by the government and generally possess an MBBS degree. The final category, "Public Other" comprises of all public paramedical staff (GNMs, ANMs, MPWs, etc.)					
Source: MAQARI Team, (2011, pg.4), Mapping medical providers in rural India: four key trends. Available from http://www.cprindia.org/research/reports/mapping-medical-providers-rural-india-four-key-trends [Accessed 25 June 2017].					

Table 4: Proportion of private providers vis-à-vis public doctors

According to MTP Act, apart from post graduate degree or diploma holders in field of Obstetrics and Gynaecology or MBBS doctors with six-month residency in Obstetrics and Gynaecology, all other doctors need to undergo a two week MTP training from a designated training centre to become a certified abortion provider (The MTP ACT, 1971). A private practitioner would only be enrolled for MTP training if he/she would be working in a facility

registered for providing abortions and a private facility would only be registered if a certified provider would be working there. Moreover, private practitioner's application for MTP training should be approved by the CMO and zonal director before getting a place as trainee (Iyengar et al., 2005). Iyengar et al. in their research in Rajasthan state also pointed out that there are only 8 training centres in Rajasthan including 6 medical colleges and on an average only 5 trainees were being trained per year per institution. Amongst all doctors who were trained in these institutions till 2005, 86% were working in government facilities. According to a study including about 2000 medical students from Maharashtra, it was found that very few students got any practical training in providing abortion services in the fifth year of medical college and 25% of these students thought abortions are morally wrong (Hogmark et al., 2013).

In a study from Maharashtra and Bihar, it was noticed that more than half of trained providers were working in their own clinics, one quarter in public facilities and remaining were attached with private facilities like trusts, corporate hospitals or clinics owned by NGOs. They also reported that only two thirds of certified providers, provide MA and there is low level of awareness amongst certified providers about permitted duration of gestation for MA, correct dose of MAPs and time interval for follow up visits. Moreover, some providers hesitate to provide medical abortion to uneducated rural women thinking that they would not be able to follow the instructions given to them. However, most of the providers believe that MA is a safe, effective, easily available and a cheaper option for early pregnancy abortion than surgical abortion. But some providers were not inclined for MMA as they thought there are more chances of incomplete abortion with MA than surgical abortion and some think that already anaemic rural women would not be able to withstand heavy bleeding for 6-8 days. Private providers also prefer surgical abortion over MA as it is more profitable to them (Acharya and Kalyanwala, 2012).

In a study by Consortium for Safe Abortions in Rajasthan, it was found that at least one medical officer is posted at most of the PHCs but less than 5% of them are certified to provide abortions (Jejeebhoy et al., 2011b). Paramita et al. in their study in Bihar and Jharkhand (2011a and 2011b) reported that sometimes certified public providers do not provide services due to their ignorance about registration of the facility for abortion services. Providers were not aware that public facilities like PHCs and above do not require such registration. Though the MTP Act of India does not mandate for consent of the spouse or family member of women with age 18 years and above, 86% of facilities asked for spousal consent and denied to provide abortion services to women who came alone (Iyengar et al., 2005).

Indian Census 2011 revealed that child sex ratio further declined to 918 girls from 927 girls per 1000 boys in 2001. This led authorities to impose stricter regulations on abortion providers and on chemists for stocking and dispensing MAPs; in order to curb the sex selective abortions. As a consequence of this, many providers stopped providing abortions and more than 50% chemists stopped stocking MAPs to avoid complex documentation and legal hassles attached to abortions and MAPs (Stillman et al., 2014).

In the initial years of introduction of medical method of abortion (MMA) in the state of Rajasthan, providers did not provide the abortion services to women coming alone due to provider's inexperience in the MMA but later when they realised that this has become a barrier for women they stopped asking for companion. Moreover, initially when there were not enough evidences of safety of home administration of misoprostol, providers called women for three visits for MMA, but as they became experienced and confident in MMA and with increased evidences on safety of home administration of misoprostol, they started to give the choice to women to choose between clinic or home administration of misoprostol. Given this option, 38% women chose to administer misoprostol at home. It was also noted that after the introduction of MMA, more and more females opted for MMA over Manual Vacuum Aspiration (MVA), because of MMA being non-invasive. In this study majority of abortion seeking women were married and less than 25% were using any kind of modern contraceptives (Iyengar and Iyengar, 2016).

In a countrywide study in 2004, it was found that uncertified providers at all levels range from ANMs, ASHAs, trained or untrained paramedics and AYUSH practitioners, who are providing abortion services which often lead to complications (Duggal and Ramachandran, 2004). Similarly, Varkey et al., 2000 in a study from Vellore district of Tamil Nadu state found that unqualified female health care providers like ANM were working in their villages as doctors and were providing abortion services in their 'Nursing Homes'. During in-depth interviews, they admitted that they had provided abortions up to seven months of pregnancy and in cases of complications, they referred the case immediately to either qualified private practitioners or to government hospitals. To prevent infection, they were boiling the instruments and were giving 2-3 antibiotics intravenously prior to the abortion procedure.

In contrast to this study, Jejeebhoy et al. (2012) conducted a study in Bihar and Jharkhand states on allopathic physicians, nurses and ayurvedic physicians (10 each), none of which had any previous experience with medical abortions but were trained to provide MA; and thereafter these providers provided MA over a period of two years (2008-2010) to 1225 women (around 400 each) who were pregnant up to eight weeks of gestation. On review of outcomes, they did not find any gross difference in results when medical abortion services were provided by these trained nurses, ayurvedic practitioners and allopathic physicians. Similar evidence from rural Rajasthan is available where maternal and new born services at two PHCs were successfully provided between year 2000 to 2008, by trained nurse midwives and complicated cases were referred to higher centres with immediate effect (Iyenger and Iyenger, 2009).

Cost of the treatment also plays a major decisive role in choosing provider of abortion services. Many factors influence the financial charges of abortion in India like age of gestation, marital status of woman, age of women, cause of abortion seeking, socio-economic status of women, location of the facility, certification of provider and facility and method of abortion. Generally, young and unmarried women are charged more than old and married women. The same provider can charge more from a well off client than from a poor client. In the state of Rajasthan, cost for first trimester abortion ranged from Rupees 195 to 457 in government facilities and this ranged from Rupees 540 to 724 in private facilities (Iyengar et al., 2005), which does not include the indirect cost of transport and loss of daily wages. In a study from urban Maharashtra, a surgical abortion cost around Rupees 1000 to 1200 while cost for a medical abortion is around Rupees 500 (Acharya and Kalyanwala, 2012).

4.3.2 Dispensers

In a study on drug dispensing practices of private pharmacies in the state of Tamil Nadu, it was observed that 55.8% of medicines were dispensed without a prescription from a doctor and amongst that, 26.9% were dispensed on request of clients themselves and 28.9% were dispensed on suggestions/recommendations of the pharmacist. Furthermore, out of over-the-counter dispensed medicines, 61.2% medicines were prescription only medicines (Basak and Sathyanarayana, 2010). Tariq et al. (2013) in their study to know the drug dispensing behaviour of pharmacists in 20 districts of three states viz. Delhi, Uttar Pradesh and Rajasthan; found that 75% of pharmacists did not ask for prescription of doctors when a fake client asked for MAPs. Though the remaining 25% asked for doctor's prescription but eventually delivered the medicines even if the prescription was not available. 85% of pharmacists did enquire about menstrual history of beneficiary. Only 45% of pharmacists knew the correct dosage and route of administration of drugs in Delhi and Uttar Pradesh in comparison to Rajasthan where 65% had the correct knowledge. In all three states, only 50% of dispensers gave correct information regarding side effects of MA drugs. Mishra et al. (2016), found that about 95–98% of clients were male when they interviewed 110 workers working in pharmacies located largely in urban areas of Delhi. About 20% of pharmacists told that abortion is immoral and it should not be liberalised. More than 92% think that medical abortion is 100% safe and remaining said around 2% of clients come with complaints about failure of abortion or complications. None of them

were aware of serious complications of medical abortion pills like sepsis, shock, ruptured ectopic, ruptured uterus etc. Ganatra et al., (2005) in their study in Bihar and Jharkhand, reported that almost all the pharmacists told that 50% of customers for abortion pills were males who wanted these pills for their wives. Both men and women were hesitant in asking for abortion pills, so they generally came at odd hours to avoid encountering people at pharmacies.

Following data also indicates poor statistics when it comes to good practices; even when pharmacists may have good knowledge about the abortion process and services. This study was carried out in Madhya Pradesh state by Powell-Jackson et al. (2015, pg. 9/14):

	% of Practice of Pharmacist	***% of Knowledge of Pharmacist***
Asked timing of last menstrual period	38.5	67.3
Asked to see prescription	13.8	35.3
Offered any advice on usage and directions of use	62.5	73.5
Offered any advice on warning signs of complications	4.7	26.2
Offered any advice on where to seek medical attention	1.5	25.1
Correctly advised heavy bleeding is a warning sign to seek care	49.5	90.9
Correctly advised on weeks pregnant MA can be used	21.5	34.9
Correctly advised on how many and when to take MA pills	35.3	68.0
Correctly advised on where to seek care from if needed	28.4	96.7
Source: Powell-Jackson, T., Acharya, R., Filippi, V., Ronsmans, C., (2015) Delivering Medical Abortion at Scale: A Study of the Retail Market for Medical Abortion in Madhya Pradesh, India. PLoS ONE 10(3): e0120637. DOI: https://doi.org/10.1371/journal.pone.0120637.		

Table 5: Statistics about the practices and knowledge of pharmacists in Madhya Pradesh

4.4 End Users

India endorsed the idea of International Conference on Population and Development (ICPD), Cairo 1994 and Beijing Plan of Action (1995) for Sexual and Reproductive Health and Rights (SRHR) i.e. "Right of all couples or individuals to decide freely and responsibly the number, spacing and timing of their children, right to information to do so, right to highest standard of reproductive health, right to make decision concerning reproduction; free of discrimination, coercion and violence". According to this, women in India have the right to quality family planning services and counselling that respects reproductive needs of couples and individuals, right to have safe motherhood and prevention from unsafe abortions and management of consequences of unsafe abortions and prevention and management of other reproductive health disorders including HIV/AIDS. SRHR also emphasises to empower adolescents by providing them sexual and reproductive education and information in the most comprehensible way (Park and Park, pg. 454). Within the ambit of national laws, the norms, applicable standards clinical practices on abortions, providers should ensure (i) health and the human rights of females, (ii) informed and voluntary decision-making without the need for relative's consent, (iii) privacy and confidentiality. Amongst the 1.2 billion people of India, 328 million are women of reproductive age group (15-49 years). According to national family health survey 2015-2016, 68.4% women of reproductive age group (15-49 years) are literate (81.4% in urban areas and 61.5% in rural areas), however, only 35.7% studied up to grade 10 or more

(51.5% urban and 27.3% rural). Total fertility rate is 1.8 in urban and 2.4 in rural women whereas 2.2 is the national average. Only 47.8% married women of 15-49 years of age are using any modern method of family planning (51.3% urban and 46% rural). The proportion for unmet need for family planning amongst currently married women of 15 to 49 years of age is 12.9 % (12.1% urban and 13.2% rural). Spacing between two births and limiting the family size are the two main reasons given by women who are seeking abortions (Ganatra et al., 2005, Hirve, 2004 and Varkey, et al., 2000).

For women with unintended pregnancy, provider attitude, provider skills, gender of provider, distance of facility, infrastructure of facility, privacy and confidentiality of service, cost of abortion and availability of post abortion counselling are the main factors which either enable or restrict women for seeking abortion (Stillman et al., 2014). Following is the data of experience of women regarding quality of care they received from abortion providers in Maharashtra and Rajasthan as revealed by a study conducted by Population council, India, (Jejeebhoy et al., 2011a, pg.21 & Jejeebhoy et al., 2011b, pg.21).

Quality of care measure	Percentage of positive responses	
	Maharashtra	Rajasthan
Provider offered sufficient privacy	85	87
Provider required husband's consent for abortion	95	87
Provider forced the women to accept contraception as a condition of abortion	7	18
Very satisfied with provider	27	49
Source: https://www.popcouncil.org/uploads/pdfs/2011RH_IndiaSafeAbortionMaharashtra.pdf, https://www.popcouncil.org/uploads/pdfs/2011RH_IndiaSafeAbortionRajasthan.pdf		

Table 6: Perception of women in Maharashtra and Rajasthan states about Provider's Services

In the above mentioned studies, considerations for choosing a provider were different for married women and unmarried women. Cleanliness of facility, speed and quality of services, behaviour of staff and most importantly - if husband's consent was required, were considerations for married women; while privacy and confidentiality were most important for unmarried women. Also availability of female provider was an important factor for both (Jejeebhoy et al., 2011a & 2011b and Sri and Ravindran, 2015). Women preferred bigger and costlier private facilities over government facilities because they considered private facilities were better equipped, cleaner and had well behaved staff than government facilities (Ramachander and Pelto, 2004).

Abortion seeking behaviour also depend upon their knowledge regarding MTP law. Majority of young, unmarried, abortion seeking females from Bihar and Jharkhand believed that abortion is legal for married women only and few had the knowledge about the legal age of gestation for abortion services (Kalyanwala et al., 2012). In rural areas of Rajasthan, women believed that consent of husband is mandatory to get abortion services. Similarly, women have misconceptions regarding legality of providers, some believe that any health worker can provide abortion and some think that abortion is totally illegal. Many women either try to self-induce abortion or seek care from illegal providers due to lack of knowledge about safe abortion methods and providers (Elul, 2011). Nivedita and Shantini (2015) in a small scale retrospective observational study on women admitted in a medical college hospital of Puducherry found that over a period of one year, 128 women were admitted in hospital, with a complication of abortion and out of 128, 40 women took abortion pills without any consultation with a certified medical practitioner. Out of these 40 women, 34 women were admitted for excessive bleeding per vaginum, three for severe

abdominal pain, one for fever and two for not expelling products of conception. Moreover, 75% of women took pills after 7 weeks of gestation and 42.5% of women had some associated medical or surgical contraindication of medical abortion.

According to Sri and Ravindran (2012), different groups of women have different opinions regarding MMA. Most thought that it is a good method and give women a safe option for abortion. Some groups were against home administration of misoprostol. Reasons given were: they did not know how to administer, nobody would allow them to lie on bed, everybody at home would come to know that she is having an abortion or what would happen if some complications would occur? In another study by same authors in 2015, most women preferred administration of misoprostol at clinic. Reasons given were lack of washroom at home, lack of family support for the process and opportunity to get some rest at the clinic while undergoing the abortion process.

In a study from Tamil Nadu state by Sri and Ravindran (2015), with a lens of Sexual and Reproductive Health and Rights (SRHR), it was found that even if a woman can get access to a safe abortion service, often the pregnancy is the result of lack of power to negotiate the sex and contraception. Though most of them were engaged in household work, taking care of their children and extended families and some were working outside home, yet they were financially dependent on husbands as their work was not paid because these works were considered as part of their duties post marriage. Even if they earned, they did not have control over money earned by them. Poverty, lack of family/husband support to take care of children, domestic violence, spacing between two births, limiting family size were the reasons given by women for seeking abortions. Some women came against the wishes of their husband, while others came with the consent of the husband, but were forced by the husband for abortion. Moreover, availability of female doctor and female nursing staff at the facility, cleanliness and confidentiality were main factors for choosing a particular facility. Most of the women gave preference to medical abortion over surgical abortion because of MA being cheaper, non-invasive, less painful and confidential and did not interfere much in their routine work.

Similarly, in another study from south of India, it was found that 29% of women took the decision to terminate the pregnancy without telling their husband and in 11% of cases the decision was taken by either husband or mother-in-law and women were forced to get their pregnancy terminated. The other 60% of women terminated pregnancy with the consent of husband. In this study, only 6.6% women went to certified providers, 65% went to uncertified providers and rest went to ANM, self-claiming women doctors, male indigenous practitioners or pharmacists. Poor accessibility, lack of privacy and long hospital stay, unwelcoming attitude of providers and coercion to accept temporary or permanent method of contraception were some of the reasons given by women for not going to government hospitals (Varkey et al., 2000).

Apart from poor knowledge about legality and availability of safe abortion services, abortion is a social stigma in Indian society. Uneducated rural women, unmarried women and women with pregnancy out of wedlock are most affected by the stigma attached to abortions. This stigmatisation push woman to either self-induce abortion or avail services of unsafe providers (Banerjee et al., 2012). To keep their pregnancy secret, these women seek help from local chemists, village health workers or traditional health practitioners. They think these providers can maintain confidentiality better than in case of formal providers. Higher cost of formal abortion providers is another reason to seek services from uncertified providers (Sri and Ravindran, 2012).

5. Discussion

Globally, unsafe abortions are the third most important cause of maternal mortality. As per WHO global estimates (2008), unsafe abortions are cause of 13% of maternal deaths. The relationship between restrictive abortion laws and unsafe abortions is well established. In India, despite liberal abortion laws in action since 1971, unsafe abortions are responsible for 10000-12000 maternal deaths every year. There are many other issues as well, which act as a barrier for women and girls to access safe abortion services apart from gaps in implementation of abortion laws.

Government of India introduced medical method of abortions (MMA) in 2002 to combat deaths and complications arising out of surgical abortions. Though the introduction of MMA led to significant decline in the deaths and serious complications, yet challenges have emerged due to irrational use of medical abortion pills (MAPs) like complications arising due to self-administration of MAPs, irrational dispensing by providers and pharmacists etc. As discussed in the conceptual framework, it is not only the inefficient health system, but also lack of prescribers' knowledge and experience, flaws in dispensing practices and knowledge gaps of dispensers and beliefs and experiences of end users; which all contribute to irrational use of medical abortion pills (MDS-3, 2012).

This chapter analyses the causes of irrational use of medical abortion pills at the health system level, providers level and at end users level along with laws and policies pertaining to abortions and medicines.

5.1 Laws and policies for abortions and medicines

While the Government of India is committed to reduce the incidence of unsafe abortions and made policy changes like decentralising the regulation of registration of health centres giving abortion services and making the medical method of abortion legal since 2002, there are gaps to overcome even after 15 years of making these changes.

5.1.1 District Level Committees

DLCs at the district level were entrusted with the function of registering private medical facilities for abortions. However, in many districts, DLCs were not even formed and in significant number of districts, DLCs were not reconstituted after their term was over. No provisions under the law were made to address this situation and to regulate the DLCs in cases of non-performance. Moreover, some DLCs imposed their own restrictions for approving a facility for abortions, which made the registration process difficult rather than making it easier. These restrictions discouraged private providers to get their facilities registered. Since abortions at unregistered facilities are considered illegal, as a result, abortions and their complications happening at these facilities largely remain unreported.

Chief Medical Officers and DLCs did not inspect the registered facilities regularly. So, the facilities, once registered, might not be cautious anymore for maintenance of hygiene, availability of necessary equipment and record keeping. This again might have contributed to unsafe abortions and under reporting of abortions. It was quite apparent that the DLCs were not having the capacity to act independently and regulate the functioning of private medical centres providing abortion services. This was counter-productive and inability on part of DLCs was responsible for incidences of unregistered facilities, which in turn led to an increase in the burden of unsafe abortions.

For a private practitioner to get enrolled for training in abortion related services, he/she must be working in a registered facility and for registration of a facility there should be a certified medical practitioner working there. Therefore, it is difficult for a private practitioner to get registered for training or to get his/her facility registered for abortion. This situation is leading to lack of training amongst private abortion providers. This lack of training of private providers led to their low level of knowledge regarding MMA so they

either do not provide MA safely or prescribe MAPs irrationally, adding to unsafe abortions and their complications.

5.1.2 Pharmacy Act

Although the complications that may arise out of MMA are far too less when compared with surgical abortions, there is high incidence of hospitalisations due to prolonged bleeding, incomplete or failed abortion etc. which was attributable to irrational use of medical abortion pills (Nivedita and Shantini, 2015).

As per Pharmacy Act 1948, any person who is not a qualified pharmacist but who has been engaged in compounding and dispensing of drugs for more than five years; is eligible to apply for registration as a pharmacist. The pharmacists who are not trained in pharmacy are more likely to engage in furthering irrational dispensing of drugs (MDS-3, 2012).

In India, people without a degree in pharmacy are dispensing medicines independently. Prescription medicines are being dispensed without a prescription. Literature review clearly indicates that pharmacists did not ask for doctor's prescription for Medical Abortion Pills (MAPs) and provided MAP over the counter. As pharmacists are not aware that MA can lead to life threatening complications like sepsis, haemorrhagic shock, ruptured ectopic, rupture uterus, etc. they were not hesitant to dispense MAPs over the counter without prescription. Moreover, as abortion is a social taboo in India, pharmacists are not comfortable talking about it so they dispense MAPs to the customers without giving adequate information to them about correct dosage, side effects, and serious complications of MAPs, even if they had knowledge about it.

Over the counter availability of abortion pills led to self-medication, which in combination with poor quality of advice regarding dosage and side effects of MAPs, might culminate into incomplete abortions or other serious complications of MMA.

5.2 Health System

5.2.1 Human Resource

Public health services are the main service providers for Indian rural population but they are often not equipped with necessary resources to provide abortion services. As per India facility survey (2005), only 6% of PHCs and about 31% of CHCs provide abortion services. This is in contrast with the fact that 92% of the PHCs are having at least one qualified medical doctor. The medical doctors posted at these PHCs are not authorised to give MMA as they are neither trained nor certified to provide MMA. Moreover, there are scarce private facilities in the rural areas. In this situation of non-availability of certified providers both at public and private facilities, abortion seeking rural women of India have no option other than turning towards unqualified local health care providers, which in turn lead to increase in maternal mortality and morbidity due to unsafe abortions. Also, number of abortions provided per month was significantly low at PHC and CHC levels as compared to district and sub divisional level government hospitals. Thus, doctors at SDH and DH were over-burdened.

Medical abortion is a simple procedure but only certified practitioners can provide it legally in India. In Rajasthan, at least one doctor was posted at each PHC but only five percent of these were certified to perform MAs. Abortions provided by untrained providers like TBAs, ANMs, ASHAs, Paramedics, and AYUSH practitioners led to complications. Interestingly, doctors trained in Indian system of medicine (AYUSH) are posted at various health facilities but they are neither trained nor authorised to provide MMA. However, no gross differences were observed in abortion outcomes between abortions provided by trained nurses, AYUSH practitioners and abortions provided by doctors after providing training for MMA to these.

It is evident that the training statistics about medical abortions are very discouraging and a large proportion of PHCs and CHCs either do not have the qualified staff or the facilities

for giving medical abortion services. This may also be because of unwillingness at various levels to reach out to the rural population. As a consequence, pregnant women (especially from rural areas) seek care from unqualified health professionals due to unavailability of trained staff leading to complications owing to unsafe abortions.

5.2.2 Essential Medicines

For universal health coverage, availability of essential medicines in public facilities is crucial. According to WHO (2004), 68% of people in India have no access or limited access to essential medicines. Though both mifepristone and misoprostol are included in EML, these remain unavailable in most primary care facilities (Iyengar and Iyengar, 2016). Non availability of essential medicines leads to far higher direct and indirect costs than the actual costs of medicines themselves. Patients buy these medicines from private pharmacies when medicines are not available in public facilities. This leads to not only extra expenditure but also necessity to return to the prescribing government facility again for administration of drugs; which makes it unduly cumbersome for women to avail MA at public facilities. Such circumstances push women to go directly to the pharmacists for MAPs and self-administration of MA which lead to complications of MA due to irrational use of medical abortion pills.

Thus, non-availability of essential medicines not only increases the out of pocket expenditure on medicines but also leads to irrational prescription of drugs and patient's loss of faith in the public health system.

5.3 Medical Service Providers

Although, abortion is legalised in India since 1971 for a broad range of indications, there continues to be low level of knowledge about legality of abortions in India. The low level of awareness about MTP Act amongst abortion providers was also evident as some were not even aware that government facilities did not require registration and many providers were asking for consent of husband or relatives even when this was not required. Moreover, some providers in public facilities pressurise women to accept either long acting contraceptives or to go for permanent sterilisation (Powell- Jackson et al., 2015). This deter women to seek abortion care from public facilities as they fear about confidentiality. Sometimes, women come even alone to medical facilities in order to keep their pregnancy a secret from their family but they fear otherwise if relative's consent is insisted at the medical facility. Moreover, women do not have any control over their reproductive rights, so they do not feel empowered to use contraceptives with-out their husband's consent. All these factors discourage women in taking services from public facilities.

Even certified providers have low level of knowledge about MMA. Most of them do not know about correct doses of MAPs, permitted duration of gestation for medical abortions, time intervals for follow up visits etc. Medical abortion has a high success rate if provided under supervision of trained professionals whether by doctors or trained paramedics, but it can lead to high incidence of incomplete abortions and other complications if provided by inadequately trained providers. Because of inadequate knowledge about MMA, doctors prescribe incorrect doses or provide MA beyond seven weeks and women return with either incomplete abortion or failed abortion.

AYUSH doctors trained in Indian system of medicine were not supposed to provide MA as per the MTP Act. Though there was no dearth of AYUSH doctors at the PHCs, they were neither trained nor were legally eligible to give MA in spite of the fact that MA is a simple procedure and trained personnel can give MA safely. Thus, potential of these providers to be utilised as certified providers remains unrealised and women continued to face non-availability of MMA at PHCs.

5.4 End Users

Abortion, like other sexuality issues is considered a taboo in the Indian society. Women, especially from rural areas, are generally confined to house and are not supposed to go

out alone. They neither have power to take their own decisions nor have any control over money. As discussed above, most of the PHCs and CHCs are not providing abortion services and social situation of women do not allow them to travel alone to DH or SDH. Under such circumstances, women with an unintended pregnancy are not left with any other alternative but to go to unqualified local health providers. Even if they reach a hospital which provides safe abortion services, these hospitals are overcrowded and providers are overburdened with work. There is very little time to interact with doctors and very often doctors do not have a welcoming attitude towards them. Thus, women do not feel empowered to discuss issues related to pregnancy in such circumstances.

At times, public providers ask for husband's or relative's consent and enforce them to take up post abortion contraceptives, thus not respecting their sexual and reproductive health rights. These situations turn women to seek care from local health care providers because it is easier for women to approach them, there are less chances of stigmatization if someone from the village see them there, as they often go there to seek care for other ailments and women feel comfortable to discuss their problems with such providers who come from the same society they are living in.

Abortion services available to unmarried women and pregnancy as a result of sexual violence, rape etc. need to be emphasized as pregnancy out of wedlock is a social stigma in India. They may be subjected to social discrimination if someone from society spots them at an abortion facility. As most of the unmarried women think that abortion is legal only for married women, they are afraid of going to public facilities. Private providers take advantage of this ignorance and exploit them by asking more money than usual. Such circumstances push these females either to go for self-induced abortions or seek help from local chemists, or traditional health providers which result into irrational use of medical abortion pills.

6. Conclusion

To improve accessibility and availability of safe abortion services to the grass-root levels and to curb morbidity and mortality due to complications of unsafe surgical abortions, amendments were made (2002-03) by Government of India in the MTP Act 1971 with focus on devolving the powers/functions of registering private medical facilities for abortions to district levels and legalisation of MMA. However, India could not reap full benefits of MMA notwithstanding its reported high success rate. There are gaps in implementation of policies and at the same time there are social, cultural and systemic issues which resulted in irrational use of MAPs contributing to unsafe abortions and wide spread complications among abortion seeking women using medical method of abortion.

The government could not effectively monitor the functioning of DLCs. DLCs in many states did not discharge its duties in certifying and registering the private clinics which could have provided legal abortions. Though the amendments in the MTP Act of 1971 were intended to make the process of registration to be non-restrictive, the outcomes were different. The private providers were not forthcoming in registering their facilities because of governance issues. As a result, it led to illegal abortions in the private facilities which were not registered; and these abortion cases largely remained unreported.

There is need for dissemination of IEC material and infographics about medical abortions, preferably in vernacular local languages, to the providers and end users. In absence of awareness, there are perceptive issues leading to irrational over-the-counter distribution of MAPs without prescriptions. The women are not approaching the public providers in absence of legal awareness and doubts about confidentiality and requirement of consent, etc.

Non-availability of MA pills at public facilities and unregulated over-the-counter sale of MAPs; made MMA an unsafe option for termination of unwanted pregnancy at the hands of untrained providers. Pressure from the demand side encouraged irrational use of MAPs by pharmacists, end users and unqualified health professionals. Superimposed by inadequate knowledge of certified providers, dispensers and end users, medical abortion pills were not being prescribed, dispensed and utilised in rational ways. This resulted in enhanced risks/complications of MMA like incomplete abortions, failed abortions, heavy vaginal bleeding and sometimes women admitted with septic shock, haemorrhagic shock, ruptured ectopic etc.

It was found that abortion was being provided only in 6% of the PHCs. Doctors posted at the PHCs were not trained for MA. This led to increased burden on district hospitals for MAs. Overburdened public facilities and high cost of scarcely available private facilities further pushed poor rural women to avail services from unqualified health professionals. As a consequence, women suffered from morbidity of MMA.

To overcome these gaps, there is a need to put emphasis on dissemination of information regarding MMA, ensured availability of MAPs at all public facilities, regularising the sale of MAPs, training of prescribers and dispensers, to amend the MTP Act to include nurses and AYUSH practitioners as certified medical abortion providers and to augment the capacity of DLCs so that these bodies play a positive role in certifying and registering the private facilities. These measures if implemented will reduce the extent of irrational use of medical abortion pills and therefore, will contribute in reducing the complications of unsafe medical abortions.

7. Recommendations

Based on the findings of this study, following recommendations are made for possible adoption so that the current gaps can be filled in and rational use of medical abortion pills can be ensured:

- **Dissemination of information regarding availability of MMA:** Women in India, especially in rural areas, have low levels of awareness regarding availability of MA at public facilities. The Ministry of Health and Family Welfare should proactively ensure that Information, Education and Communication (IEC) material about MA, preferably in local language, is available at all levels of health system. IEC material should also be available as infographics in pictorial form. This will not only educate women about MMA but also make it easier for village health workers to spread information about safety dimensions and availability of MMA.
- **Training of Providers:** There is acute shortage of certified providers both at public and private levels. The medical undergraduate academic curriculum offered by different medical colleges in India should be reviewed by the Medical Council of India and emphasis should be given by medical colleges on training on MMA to medical students during their final year clinical training and during internship associated with undergraduate courses so that every student who pass out from medical college should be capable of providing MMA without the specific need for extra trainings and certifications. It will improve the availability of MA at PHCs and above levels. This will also help in curbing the prevalence of irrational prescribing and dispensing of MAPs.
- **Amendment in The MTP Act to include trained nurses and AYUSH practitioners as certified providers:** The Government of India should consider amending the MTP Act in order to utilise the potential of nurses and AYUSH practitioners (Indian medicine system practitioners). These practitioners can be regarded as certified providers after providing them training for MA and certifying them to provide MMA. Such experiments have proved successful both in India and in other countries. As many of the nurses and AYUSH practitioners posted at PHCs come from local society, this will help in facilitating the removal of social and cultural barriers faced by rural women. This will also have a significant positive impact on rational prescribing of MAPs.
- **Regulation of sale of Medical Abortion Pills:** The sale of medical abortion pills which are prescription drugs should be regulated. At the same time, any regulation measure should not hamper availability of medical abortions. Regulated sale will check the irrational dispensing of MAPs and improve the reporting on medical abortions.
- **Monitoring of District Level Committees:** Functioning of DLCs should be monitored and their capacities augmented so as to increase the number of registered private facilities for safe abortion services. DLCs should function to facilitate the registration of private facilities instead of being restrictive.
- **Research:** Very few small scale studies have been conducted on MMA so far. State wide and nationwide studies are needed to assess the real impact/outcome of legalisation and introduction of MMA. Such studies would assist in objectively determining the gaps in policy and implementation so that timely corrective actions and rectifications are possible.

8. References

Acharya, R. and Kalyanwala, S. (2012) Knowledge, attitudes, and practices of certified providers of medical abortion: Evidence from Bihar and Maharashtra, India. *International Journal of Gynecology and Obstetrics,* 118, 40–46. Available from: http://onlinelibrary.wiley.com/doi/10.1016/j.ijgo.2012.05.009/full [Accessed 22 February 2017]

Åhman, E. and Shah, I. (2002) Unsafe abortion: worldwide estimates for 2000. *Reproductive Health Matters,* **10** (19): 13-17. Doi: https://doi.org/10.1016/S0968-8080(02)00012-5 [Accessed 22 February 2017]

Åhman, E. and Shah, I. (2011) New estimates and trends regarding unsafe abortion mortality. *International Journal of Gynecology and Obstetrics*, **115** (2), 121–126. Available from: http://www.sciencedirect.com.vu-nl.idm.oclc.org [Accessed 22 February 2017] Doi: https://doi.org/10.1016/j.ijgo.2011.05.027

Armo, M., Babbar, K., and Viswas, S. (2015) Self-medication for Medical Abortion in Rural Scenario: Why to choose Unsafe Way? *International Journal of Scientific Study,* **3** (6). Available from: http://www.ijss-sn.com/uploads/2/0/1/5/20153321/ijss_sep_oa26.pdf [Accessed 23 February 17]

Banerjee, S. (2007) Increasing access to safe abortion services in Uttarakhand: Identifying medical termination of pregnancy (MTP) training centres. New Delhi: *Ipas India.* Available from: http://www.ipas.org/en/Resources/Ipas%20Publications/Increasing-access-to-safe-abortion-services-in-Uttarakhand.aspx [Accessed 6 May 2017]

Banerjee, S.K., Andersen, K.L. and Warvadekar, J. (2012) Pathways and consequences of unsafe abortion: A comparison among women with complications after induced and spontaneous abortions in Madhya Pradesh, India. *International Journal of Gynecology and Obstetrics,* **118** (2), 113–120. Available From: https://www.researchgate.net/profile/Sushanta_Banerjee2/publication/232713519_Pathways_and_consequences_of_unsafe_abortion_A_comparison_among_women_with_complications_after_induced_and_spontaneous_abortions_in_Madhya_Pradesh_India/links/0a85e53733c9ab3783000000.pdf [Accessed 19 September 2016]

Basak, S.C. and Sathyanarayana, D. (2010) Evaluating medicines dispensing patterns at private community pharmacies in Tamil Nadu, India. *Southern Medical Review,* **3** (2), 27-31 Available from: http://apps.who.int/medicinedocs/documents/s17529en/s17529en.pdf [Accessed 7 June 2017]

Beijing, Declaration and Platform for Action (1995) The Fourth World Conference on Women, Beijing, 4-15 September, 1995. Available from: http://www.un.org/womenwatch/daw/beijing/pdf/BDPfA%20E.pdf [Accessed 24 July 2017]

Census, India (2011) Available from: http://www.census2011.co.in/p/glance.php [Accessed 13 June 2017]

Comptroller and Auditor General of India (2015) Performance audit on empowerment of women, Government of Uttar Pradesh, Report No. 3 of 2016. Available from: http://www.cag.gov.in/sites/default/files/audit_report_files/Uttar_Pradesh_Performance_Audit_on_Empowerment_of_Women__Report_3_2016.pdf [Accessed 16 June 2017]

Dahiya, K., Madan, S., Hooda, R., Sangwan, K., and Khosla, A.H. (2005) Evaluation of the efficacy of mifepristone/misoprostol and methotrexate/misoprostol for medical abortion. *Indian Journal of Medical Sciences,* **59**, 301-306. Available from:

https://tspace.library.utoronto.ca/bitstream/1807/7611/1/ms05046.pdf [Accessed 6 May 2017]

Duggal, R. and Ramachandran, V. (2004) The Abortion Assessment Project-India: Key Findings and Recommendations. *Reproductive Health Matters*, **12** (24), 122-129. Available from: http://www.tandfonline.com/doi/pdf/10.1016/S0968-8080%2804%2924009-5?needAccess=true [Accessed 23 March 2017]

Elul, B. (2011) Determinants of induced abortion: an analysis of individual, household and contextual factors in Rajasthan, India. *Journal of biosocial science*, 43,1–17. Doi: https://doi.org/10.1017/S0021932010000490 [Accessed 23 March 2017]

The United States Department of Food and Drug Administration. Available from: https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/over-the-counterdrugs/default.htm [Accessed 30 July 2017]

Ganatra, B., Manning, V. and Pallipamulla, S.P. (2005) Availability of medical abortion pills and the role of chemists: a study from Bihar and Jharkhand, India. *Reproductive Health Matters*, ***13*** (26), 65-74. Doi:10.1016/S0968-8080(05)26215-8 [Accessed 17 March 2017]

Godara, S. and Kaushal, J. (2013) Practice of self-medication of mifepristone-misoprostol drug combination for medical abortion. *International Journal of Basic & Clinical Pharmacology,* **3** (3),572-573. Available from: http://www.ejmanager.com/fulltextpdf.php?mno=154568 [Accessed 17 June 2017]

Government of India (2016) Ministry of Health and Family Welfare (Department of Health), The Drugs and Cosmetic Act and Rules 1945 (amendment, December, 2016). Available from: http://www.cdsco.nic.in/writereaddata/2016Drugs%20and%20Cosmetics%20Act%201940%20&%20Rules%201945.pdf [Accessed 16 June2017]

Handbook on Medical Methods of Abortion to Expand Access to New Technologies for Safe Abortion (2016). Ministry of Health & Family Welfare, New Delhi, India. Available from: http://nhm.gov.in/images/pdf/programmes/maternal-health/guidelines/MMA_Handbook.pdf [Accessed 30 May 2017]

Health Management Information System (2015-16) Rural Health Statistics of India. Ministry of Health and Family Welfare, Government of India. Available from: https://nrhm-mis.nic.in/Pages/RHS2016.aspx?RootFolder=%2FRURAL%20HEALTH%20STATISTICS%2F%28A%29RHS%20-%202016&FolderCTID=0x01200057278FD1EC909F429B03E86C7A7C3F31&View=%7b3EF44ABD-FC77-4A1F-9195-D34FCD06C7BA%7d [Accessed 16 June 2017]

Hirve, S. (2004) Abortion policy in India: lacunae and future challenges. Abortion Assessment Project, India. Available from: http://www.cehat.org/go/uploads/AapIndia/hirve.pdf [Accessed 11 June 17]

Hogmark, S. et al. (2013) Medical students' knowledge, attitudes and perceptions towards contraceptive use and counselling: a cross sectional survey in Maharashtra, India. *British Medical Journal,***3,** 003739. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863118/ [Accessed 26 June 2017]

India Facility Survey (2005) (Under Reproductive and Child Health Project) Phase II, New Delhi: Ministry of Health and Family Welfare, International Institute of Population Sciences and Macro International, New Delhi, India. Available from: http://rchiips.org/pdf/rch2/National_Facility_Report_RCH-II.pdf [Accessed 7 July 2017]

Indian Geography (2015) Facts and Information about Geography of India. Available from: http://www.factsninfo.com/2015/06/indian-geography-facts-and-information.html [Accessed 22 June 2017]

International Conference on Population and Development (1994) Cairo, 5-13 September 1994. Programme of action, United Nations Population Fund 2004. Available from: http://www.unfpa.org/sites/default/files/event-pdf/PoA_en.pdf [Accessed 24 July 2017]

Iyengar, K. et al. (2015) Self-assessment of the outcome of early medical abortion versus clinic follow-up in India: a randomised, controlled, non-inferiority trial. *Lancet Global Health*, **3**, 537–45. Available from: http://www.thelancet.com/pdfs/journals/langlo/PIIS2214-109X(15)00150-3.pdf [Accessed 5 July 2016]

Iyengar, K. and Iyengar, S.D. (2009) Emergency obstetric care and referral: experience of two midwife-led health centres in rural Rajasthan, India. *Reproductive Health Matters,***17** (33), 9-20. Doi: http://dx.doi.org/10.1016/S0968-8080(09)33459-X [Accessed 22 June 2017]

Iyengar, K. and Iyengar, S.D. (2016) Improving access to safe abortion in a rural primary care setting in India: experience of a service delivery intervention. *Reproductive Health Matters*, **13**, 54. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4863363/ [Accessed 22 June 2017]

Iyengar, S.D., Iyengar, K. and Suhalka, V. (2005) Situation analysis of abortion services in Rajasthan. *Action Research & Training for Health (ARTH), Udaipur, India*. Available from: http://arth.in/wp-content/uploads/2012/03/situation-analysis-of-abortion.pdf [Accessed 25 June 2017]

Jejeebhoy, S. J., Francis Zavier, A.J., Acharya, R. and Kalyanwala, S. (2011a) Increasing access to safe abortion in rural Maharashtra: Outcomes of a Comprehensive Abortion Care model. New Delhi: *Population Council*. Available from: https://www.popcouncil.org/uploads/pdfs/2011RH_IndiaSafeAbortionMaharashtra.pdf [Accessed 26 June 2017]

Jejeebhoy, S. J., Francis Zavier, A.J., Acharya, R. and Kalyanwala, S. (2011b) Increasing access to safe abortion in rural Rajasthan: Outcomes of a Comprehensive Abortion Care model. New Delhi: *Population Council*. Available from: https://www.popcouncil.org/uploads/pdfs/2011RH_IndiaSafeAbortionRajasthan.pdf [Accessed 26 June 2017]

Jejeebhoy, S.J. et al. (2012) Feasibility of expanding the medication abortion provider base in India to include ayurvedic physicians and nurses. *International Perspectives on Sexual and Reproductive Health*, **38** (3), 133–142. Available from: https://www.guttmacher.org/sites/default/files/article_files/3813312.pdf [Accessed 25 June 2017]

Johnson, Jr. et al. (2017) A global database of abortion laws, policies, health standards and guidelines. Bulletin, *World Health Organization*, **95,** 542–544. Doi: http://dx.doi.org/10.2471/BLT.17.197442 [Accessed 7 July 2017]

Johnston, H. B. (2002) Abortion practice in India: a review of literature. *Working Paper, Abortion Assessment Project. 1st ed. Mumbai: Centre for Enquiry into Health and Allied Themes (CEHAT).* Available from: https://www.researchgate.net/publication/237293562_Abortion_practice_in_India_A_review_of_literature [Accessed 23 March 2017]

Kahn, J.G. et al. (2000) The efficacy of medical abortion: a meta-analysis. *Contraception,***61**, 29–40. Available from: http://www.revho.fr/professionnels/bibliographie/sources_doctrinales/anglais/generalites/meta_kahn.pdf [Accessed 27 April 2017]

Kalyanwala, S., Jejeebhoy, S.J., Francis Zavier, A.J. & Kumar, R. (2012) Experiences of unmarried young abortion-seekers in Bihar and Jharkhand, India. *Culture, Health &Sexuality*, **14** (3), 241-255. Doi: http://dx.doi.org/10.1080/13691058.2011.619280 [Accessed 22 June 2017]

Mao, W., Vu, H., Xie, Z., Chen, W. and Tang, S. (2015) Systematic Review on Irrational Use of Medicines in China and Vietnam*. PLoS ONE,* **10** (3), 0117710. Doi: https://doi.org/10.1371/journal.pone.0117710 [Accessed 11 May 2017]

MAQARI (Team2011) Mapping medical providers in rural India. *Centre for Policy Research*; New Delhi. Available from: http://www.cprindia.org/research/reports/mapping-medical-providers-rural-india-four-key-trends [Accessed 25 June 2017]

MDS-3: Managing Access to Medicines and other Health Technologies (2012) *Managing for rational medicine use*, chapter 27, *Management Sciences for Health*. Available from: http://apps.who.int/medicinedocs/documents/s19577en/s19577en.pdf [Accessed 11 May 2017]

Mishra, A., Yadav, A., Malik, S., Purwar, R. and Kumari, S. (2016) Over the counter sale of drugs for medical abortion- Knowledge, Attitude, and Practices of pharmacists of Delhi, India. *International Journal of Pharmacological Research,***6** (3). Available from: http://ssjournals.com.md-in-1.webhostbox.net/index.php/ijpr/article/view/2999/2244 [Accessed 23 February 17]

Mundle, S., Elul, B., Anand, A., Kalyanwala, S. and Ughade, S. (2007) Increasing access to safe abortion services in rural India: experiences with medical abortion in a primary health centre. *Contraception,* **76,** 66 –70. Doi: 10.1016/j.contraception.2007.03.010 [Accessed 17 January 2017]

Nandraj, S., Muraleedharan, V.R., Baru, R.V., Qadeer, I. and Priya, R. (2001) Private health sector in India, Review and Annotated Bibliography. Available from: http://www.cehat.org/go/uploads/Rphsi/phsi.pdf [Accessed 7 July 2017]

National Family Health Survey-4 (2016) Ministry of Health and Family Welfare, Government of India. Available from: http://rchiips.org/NFHS/pdf/NFHS4/India.pdf [Accessed 7 July 2017]

National Health Mission (2014) Operational Guidelines, Comprehensive Abortion Care Services. Ministry of Health and Family Welfare, New Delhi. Available from: http://nhm.gov.in/images/pdf/programmes/maternal-health/guidelines/CAC_Operational_guidelines.pdf [Accessed 19 July 2017]

National Health Mission, Haryana (2012) Medicine Procurement & Management Policy, Haryana. Available from: http://www.nrhmharyana.gov.in/files/drugpolicyfinal.pdf [Accessed 22 June 2017]

Ngo T. D., Park M. H., Shakur H., & Free, C. (2011) Comparative effectiveness, safety and acceptability of medical abortion at home and in a clinic: a systematic review. *Bulletin of the World Health Organization*, ***89*** (5), 360–370. Doi: http://doi.org/10.2471/BLT.10.084046 [Accessed 22 June 2017]

Nivedita, K. and Shanthini, F. (2015) Is it safe to provide abortion pills over the counter? a study on outcome following self-medication with abortion pills. *Journal of Clinical and Diagnostic Research,* ***9***(1), *QC01–QC04*. Doi: http://doi.org/10.7860/JCDR/2015/11626.5388 [Accessed 4 July 2016]

Ngoc, N.T. et al. (2014) Acceptability and feasibility of phone follow-up after early medical abortion in Vietnam: A randomized controlled trial. *The American College of Obstetricians and Gynecologists,* **123** (1), 85-90. Available from:

http://ovidsp.tx.ovid.com.vu-nl.idm.oclc.org/sp-3.26.1a/ovidweb.cgi?WebLinkFrameset=1&S=HFCNFPCCFODDAHHNNCGKPGMCJPPEAA00&returnUrl=ovidweb.cgi%3f%26Full%2bText%3dL%257cS.sh.22.23%257c0%257c00006250-201401000-00014%26S%3dHFCNFPCCFODDAHHNNCGKPGMCJPPEAA00&directlink=http%3a%2f%2fovidsp.tx.ovid.com%2fovftpdfs%2fFPDDNCMCPGHNFO00%2ffs047%2fovft%2flive%2fgv031%2f00006250%2f00006250-201401000-00014.pdf&filename=Acceptability+and+Feasibility+of+Phone+Follow-up+After+Early+Medical+Abortion+in+Vietnam%3a+A+Randomized+Controlled+Trial.&pdf_key=FPDDNCMCPGHNFO00&pdf_index=/fs047/ovft/live/gv031/00006250/00006250-201401000-00014 [Accessed 9 July 2017]

Oberoi, S.S. and Oberoi, A. (2014) Pharmacoeconomics guidelines: The need of hour for India. *International Journal of Pharmaceutical Investigation*, **4** (3),109-11. Available from: http://www.jpionline.org/text.asp?2014/4/3/109/138338 [Accessed 21 June 2017]

Oppegaard, K.S. et al. (2015) Clinical follow-up compared with self-assessment of outcome after medical abortion: a multicentre, non-inferiority, randomised, controlled trial. *Lancet* ,**385**: 698–704. Doi : https://doi.org/10.1016/S0140-6736(14)61054-0 [Accessed 26 June 2017]

Paramita, A., Banerjee, S.K., Jha, T.K., Aggarwal, A. and Sinha, D. (2011a) Situation Analysis of MTP services in Bihar. New Delhi, Ipas India. Available from: https://www.researchgate.net/publication/260595734_Situation_Analysis_of_MTP_Services_in_Bihar [Accessed 11 June 2017]

Paramita, A., Banerjee, S.K., Jha, T.K., Aggarwal, A. and Sinha, D. (2011b) Situation Analysis of MTP services in Jharkhand. New Delhi, Ipas India. Available from: http://www.ipas.org/en/Resources/Ipas%20Publications/Situation-analysis-of-MTP-services-Jharkhan9d.aspx [Accessed 11 June 2017]

Park, K. (2011) *Park's Text Book of Preventive and Social Medicine* (21st Edition) Jabalpur: Banarsidas Bhanot Publishers.

Planning Commission (2010) Report of the Working Group on Drugs & Food Regulation for the 12th Five Year Plan, Government of India. Available from: http://planningcommission.gov.in/aboutus/committee/wrkgrp12/health/WG_4drugs.pdf [Accessed 21 June 2017]

Powell-Jackson, T., Acharya, R., Filippi, V. and Ronsmans, C. (2015) Delivering Medical Abortion at Scale: A Study of the Retail Market for Medical Abortion in Madhya Pradesh, India. *PLoS ONE,***10** (3), e0120637. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4379109/pdf/pone.0120637.pdf [Accessed 4 January 2017]

Prinja, S., Bahuguna, P., Tripathy, J.P. and Kumar, R. (2015) Availability of medicines in public sector health facilities of two North Indian States. *BMC Pharmacology and Toxicology,***16**, 43. Available from: http://apps.who.int/medicinedocs/documents/s22216en/s22216en.pdf [Accessed 7 June 2017]

Ramachandar, L. and Pelto, P. J. (2004) Abortion Providers and Safety of Abortion: A Community-Based Study in a Rural District of Tamil Nadu, India. *Reproductive Health Matters*, **12** (24), 138-146. Available from: http://www.tandfonline.com/doi/full/10.1016/S0968-8080%2804%2924015-0 [Accessed 7 July 2017]

Raymond, E. G., Shannon, C., Weaver, M. A. and Winikoff, B. (2013) First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review.

Contraception, **87**, 26–37. Available from: http://www.contraceptionjournal.org/article/S0010-7824(12)00643-9/fulltext [Accessed 27 June 2017]

Sarda, R. R., Ladkat, N.B., Khodade, R.B., Chaudhari, P.M. and Kasture, P.V. (2012) The Indian pharmaceutical industry: Evolution of regulatory system and present scenario. *International Research Journal of Pharmacy,* **3** (6). Available from: http://www.irjponline.com/admin/php/uploads/1164_pdf.pdf [Accessed 27 June 2017]

Say L. et al. (2014) Global causes of maternal death: a WHO systematic analysis. *The Lancet, Global Health,***2** (6) e323–e333. Available from: http://www.thelancet.com/journals/langlo/article/PIIS2214-109X(14)70227-X/fulltext [Accessed 30 April 2017]

Sharma, R., Gupta, M. and Sharma, S. (2015) Over the counter sale of abortion pills - time to act now. *International Journal of Reproduction, Contraception, Obstetrics and Gynecology, **4** (4), 1053-1056.* Available from: http://www.ijrcog.org/index.php/ijrcog/article/view/2058/1785 [Read Only Access] [Accessed 7 June 2017] Doi: http://dx.doi.org/10.18203/2320-1770.ijrcog20150425

Singh, P.V., Tatambhotla, A., Kalvakuntla, R. and Chauksi, M. (2013) Understanding public drug procurement in India: a comparative qualitative study of five Indian states. *British Medical Journal*, **3,** e001987. Available from: http://apps.who.int/medicinedocs/documents/s20032en/s20032en.pdf [Accessed 7 June 2017] Doi:10.1136/bmjopen-2012-001987

Sri, B.S. and Ravindran, T.K.S. (2012) Medical abortion: Understanding perspectives of rural and marginalized women from rural South India. *International Journal of Gynecology and Obstetrics,* **118**, 33–39. Available from: http://onlinelibrary.wiley.com/doi/10.1016/j.ijgo.2012.05.008/epdf [accessed 7 June 2017] Doi:10.1016/j.ijgo.2012.05.008

Sri, B.S. and Ravindran, T.K.S. (2015) Safe, accessible medical abortion in rural Tamil Nadu clinic, India, but what about sexual and reproductive rights? *Reproductive Health Matters,***44**, 134-143. Available from: http://www.sciencedirect.com.vu-nl.idm.oclc.org [Accessed 3 July 2017] Doi: https://doi.org/10.1016/S0968-8080(14)43789-3

Stillman, M., Frost, J.J., Singh, S., Moore, A.M. and Kalyanwala, S. (2014) Abortion in India: A Literature Review. *Guttmacher Institute*, *New York*. Available from: https://www.guttmacher.org/sites/default/files/report_pdf/abortion-india-lit-review.pdf [Accessed 20 February 17]

Tamil Nadu Medical Service Corporation. Drug Procurement Policy. Available from: http://www.tnmsc.com/tnmsc/new/html/Procurement%20&%20Tender.php. [Accessed 17 June 2017]

Tariq, M., Chaudhury, N. and Kapoor, A. (2013) Medical Abortion Drug Dispensing Behaviour among Pharmacists in India Available from: http://iussp.org/sites/default/files/event_call_for_papers/Long%20Abstract_MA%20_IUSSP_2013.pdf [Accessed 23 February 17]

The Medical Termination of Pregnancy Act (1971) Government of India. The Medical Termination of Pregnancy Act, No. 34, 1971, Ministry of Health and Family welfare, New Delhi. Available from: http://mohfw.nic.in/index1.php?lang=1&level=4&sublinkid=3615&lid=2598 [Accessed 24 April 2017]

The Medical Termination of Pregnancy Act,1971 (Amendment,2002) Government of India. Ministry of Health and Family welfare, New Delhi. Available from: http://www.mohfw.nic.in/index1.php?lang=1&level=4&sublinkid=3614&lid=2599 [Accessed 24 April 2017]

The Medical Termination of Pregnancy Rules 1975 (Amendment, 2003) Government of India. Ministry of Health and Family welfare, New Delhi. Available from: http://pbhealth.gov.in/Manuals/notify/5.pdf [Accessed 24 April 2017]

The Pharmacy Act (1948). Available from: http://www.ipapharma.org/pdf/Pharmacy_act_1948.pdf [Accessed 16 June 2017]

United Nations General Assembly (2000) United Nations Millennium Declaration. A/RES/55/2. New York. Available from: http://www.un.org/millennium/declaration/ares552e.htm [Accessed 23 March 2017]

United Nations (2015) Transforming our world: the 2030 Agenda for sustainable Development. Available from: (https://sustainabledevelopment.un.org/post2015/transformingourworld [Accessed 4 June 2017]

Varkey, P., Balakrishna, P.P., Prasad, J.H., Abraham, S. and Joseph, A. (2000) Reality of unsafe abortion in a rural community in South India. *Reproductive Health Matters*, **8** (16). Available from: http://www.sciencedirect.com.vu-nl.idm.oclc.org/science/article/pii/S0968808000901903 [Accessed 24 July 2017]

Visaria, L., Barua, A., & Mistry, R. (2008) Medical Abortion in India: Role of Chemists and Providers. *Economic and Political Weekly, **43*** (36), 35-40. Available from: http://www.jstor.org/stable/40277925 [Read Only Access] [Accessed 14 June 2017]

WHO (1985) The rational use of drugs: A review of the major issues. Report of the conference of experts, November 22-29, Nairobi, Kenya. Available from http://apps.who.int/medicinedocs/documents/s17054e/s17054e.pdf [Accessed 21 May 2017]

WHO (1992) International Classification of Diseases and Related Health Problems, ICD-10, World Health Organization, Geneva. Available from: http://www.who.int/classifications/icd/en/ [Accessed 5 May 2017]

WHO (2002) Policy Perspectives on Medicines, Promoting rational use of medicines: core components. Available from: http://apps.who.int/medicinedocs/pdf/h3011e/h3011e.pdf [Accessed 20 May 2017]

WHO (2004) The World Medicines Situation. Geneva: World Health Organization,2004. Available from: http://apps.who.int/medicinedocs/pdf/s6160e/s6160e.pdf [Accessed 22 June 2017]

WHO (2008) Unsafe abortion: global and regional estimates of the incidence of unsafe abortion and associated mortality in 2008. 6th edition. Available from: http://apps.who.int/iris/bitstream/10665/44529/1/9789241501118_eng.pdf [Accessed 5 May 2017]

WHO (2012) Safe abortion: technical and policy guidance for health systems- 2nd edition. Geneva, Switzerland, World Health Organization. Available from: http://apps.who.int/iris/bitstream/10665/70914/1/9789241548434_eng.pdf?ua=1 [Accessed 11 June 17]

WHO (2014) Clinical practice handbook for Safe Abortions. Available from: http://apps.who.int/iris/bitstream/10665/97415/1/9789241548717_eng.pdf?ua=1 [Accessed 2 July 2017]

WHO (2015) Trends in maternal mortality: 1990 to 2015: Estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. Available from: http://apps.who.int/iris/bitstream/10665/194254/1/9789241565141_eng.pdf?ua=1 [Accessed 4 May 2017]

WHO (2016) Preventing unsafe abortions [Fact sheet]. Available from: http://www.who.int/mediacentre/factsheets/fs388/en/ [Accessed 6 May 2017]

WHO, Essential Medicines. Available from: http://www.who.int/medicines/services/essmedicines_def/en/[Accessed 16 June 2017]

WHO, Health system Framework. Available from: http://www.wpro.who.int/health_services/health_systems_framework/en/ [Accessed 9 July 2017]