

**MENSTRUAL REGULATION AS AN ABORTION METHOD :  
A SOCIO-MEDICAL AND LEGAL EVALUATION TO EXPLORE ITS PROMOTION IN INDIA**

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**ABSTRACT**

The present paper explores the applicability of menstrual regulation (MR) as an abortion method in the Indian context. While doing so, MR method is evaluated socio-medically and legally. Effort has also been made to evaluate its feasibility in terms of resources and acceptability to providers and users in India. Evaluation is based on a review of literature on various aspects of MR of the last 25 years.

This exercise of socio-medical, legal and feasibility evaluation of MR builds a strong case for its promotion to bring down abortion related morbidity and mortality, to enhance the opportunities for potential users to avail of contraceptive services, to reduce the psychological burden of guilt borne by the women for undergoing an abortion, to reduce the intensity of emotional trauma that they experience for having had an abortion.

Finally, the paper also discusses the constraints in promoting MR in India and strategies to overcome them. Against this backdrop, the paper emphasises the critical role of the Information-Education-Communication (IEC) component and the need to incorporate it officially in the MR promotion policy.

**INTRODUCTION**

Contribution of abortion related mortality to maternal mortality in rural India is as high as 11.8% (GOI, 1990). The proportion of illegal abortion to legal abortion is 11:1. There exist a large number of non-registered abortion care centres. According to our survey conducted during 1997 in Pune and Ratnagiri districts of Maharashtra, proportion of registered to non-registered abortion care centres is about 1 : 4. Of the total 20,000 Primary Health Centres (PHC) only 7,121 provide abortion care to women (PSS, 1994). The private health care sector plays an important role in providing abortion care as it is true with general health care service. The distribution of abortion care centres is skewed across the states and within states, too. Physical accessibility is poor because of the unequal distribution of the abortion care centres even in a small geographical area. A considerable number of medical professionals are involved in abortion practice who may not necessarily meet the training requirements stipulated in the MTP Act. The experiences from all over India indicate that a considerable number of non-allopaths are involved in abortion practice. Over the years many of them have acquired the skills and competence for abortion procedures and yet they are constantly under the threat for they don't meet MTP Act requirements. Besides, paramedics, too are involved in abortion practice.

As a result, women face problems getting a safe and legal abortion done. The problem of access to abortion care is multifaceted. It needs to be dealt with at number of fronts. If the MTP Act has not been able to combat the problem of abortion mortality and morbidity, the various concerned constituencies need to review the situation afresh.

Against this backdrop, considering new methods or techniques of abortion, related procedures and issues is one among many, that is dealt with in this communication.

The developments of surgical and medical methods for early uterine evacuation in early 70s and early 80s respectively are important in this light. Early uterine evacuation is most commonly referred to as Menstrual Regulation(MR). It is the treatment of the delayed menstrual period up to 14 days, to assure a non-pregnant state and a normal menstrual cycle the next time.

Medical advances as regards MR have been of interest to various concerned constituencies for different reasons. It does so to the medical community and especially the abortion providers because of the simplicity of the technique; simple and inexpensive instruments; minimum requirement of infrastructural facilities,

emergency services and back-up etc.; at least comparable rates of risks, complications and failure to the prevalent abortion procedures. It interests to the demographers and population control lobby because the advantages that are mentioned above enable its wider spread even in interiors where there is no sophisticated health care set-up possible for lack of resources - finances, personnel, infrastructure etc. It appeals to women clients mainly because of non-medical advantages such as, it is less expensive, it is an office procedure; less traumatic - physically as well as emotionally. For government, it is a cheaper and probably more feasible option for fertility control. MR has an advantage in the countries where abortion is legally banned because it could be conducted without a confirmatory pregnancy test. MR is also used for some other clinical purposes, such as, for uterine biopsy, to treat incomplete abortions, to regularise the menses. Experiences with MR of these various constituencies from all over the world over the last two decades seem to be encouraging. However, there are certain issues and concerns that require to be debated before we arrive at any recommendation either in its favour or against.

As regards India, there seems to be a gap between research based experiences and practical experiences of medical professionals. Experiences differ from region to region. The MR trials as part of the international multi-centred studies have evaluated MR positively. One finds references (Chhabra and Nuna, 1994) made to North India, especially Bihar where MR is being practiced as an abortion method. The experiences of organisation like Family Planning Association of India (FPAI) are also encouraging. However, information obtained through interviews of medical professionals in Maharashtra as part of our study clearly indicate that they are not satisfied with efficacy of MR. It is hardly practiced in Maharashtra. This requires us to examine the factors responsible for these regional differences in MR practice. Its direct and indirect benefits need to be weighed afresh against the reservations that are being expressed by the medical professionals. If the reservations are about the problems such as lack of quality instruments or lack of required training or women's ignorance about MR, they perhaps could be taken care of by formulating, planning and implementing an appropriate strategy.

This paper explores applicability of MR to Indian situation. Broadly speaking applicability of any medical procedures or techniques depends much on whether it is acceptable to both, the medical professionals and to the users. Medical professionals' acceptance depends on factors, such as, availability of instruments and/or drugs required for the procedure; finances involved in it; infrastructural requirements (which means capital investment for providers); training needs and availability of such facilities; safety of the procedure in terms of risks, failure rate, complications, advantages over the other prevalent methods etc. Users' acceptance depends much upon safety of the procedure, cost involved, the extent of the invasive nature of the procedure, advantages over the other prevalent methods, the extent of in-admission or hospitalisation etc. A few of these factors are of common concern to both, providers and users.

In addition to this the paper also discusses the legal status of MR, its implications for women, providers and in turn for women's reproductive morbidity and mortality. Such an exercise of evaluating the method will help us to be in better position to advocate its promotion or otherwise.

The paper is divided in two parts. Broadly speaking, Part I deals with its socio-medical aspect and Part II deals with its legal aspect.

## **PART I : SOCIO - MEDICAL EVALUATION OF MR**

### **WHAT IS MR?**

Menstrual regulation is defined as any procedure which disrupts the intrauterine environment so that embryonic implantation either cannot occur or cannot be maintained (Brenner & Edelman, 1977). The technique is also known as menstrual aspiration, menstrual extraction, interception, and uterine aspiration. (Goldthorp, 1977). It can be performed using drugs, physical agents, and surgical techniques. Of the drugs investigated, it appears that prostaglandins (PGs) are the most practicable. Unfortunately, vomiting and diarrhoea are frequent unpleasant side effects of PG administration (Brenner and Edelman, 1977; Cameron & Baird, 1988). Till 1970 the only useful abortion method has been vacuum aspiration (VA). Number of countries all over the world conducted trials of PG method. However, the combinations of prostaglandins and its analogues with RU-486 have been working wonders not only for very early menstrual evacuation but also for first and second trimester abortions. The surgical method of MR using flexible cannula and hand

vacuum syringe are being used in various parts of the world, including developed and developing countries, with competing success rates to that of prevalent methods of abortion.

- **Menstrual regulation is a treatment for delayed menstruation either because of clinical indications or conception.**
- **Menstrual regulation can be done by surgical and medical methods.**
- **Its success rates are comparable to the prevalent methods of abortion.**
- **It is being practiced all over the world.**

## MR BY SURGICAL MEANS

**History and Background of MR by surgical means :** Vacuum aspiration is used to conduct MR surgically. Battelle Northwest laboratories conducted a workshop in December 1971 to discuss techniques of termination of pregnancy. Karman introduced his vacuum aspiration 50 ml syringe and flexible plastic cannula. He had been using it for 'menstrual extraction' in the preceding years. In June 1973, this syringe was modified by the Battelle Population Study Centre with the addition of a pinch valve to allow for evacuation of the syringe prior to use. The Karman syringe is used today in this modified form. In 1972, the International Fertility Research Program (IFRP) started conducting clinical trials in 21 countries at 61 clinics all over the world and introduced the term 'menstrual regulation (MR)' (Laufe, 1977). It was at the conference organised by the University of Hawaii School of Public Health and Battelle Population Study Centre in 1973 in Honolulu, Hawaii that MR got its international recognition. Investigators from more than 50 countries narrated their experiences of MR performed on 3500 cases (Laufe, 1979).

**The technique & procedure of MR by VA :** The principles of surgical instrumentation for menstrual regulation are identical to those for first-trimester abortion done by using vacuum aspiration. It mainly involves (a) physical examination of the woman and menstrual history taking, (b) preparing the woman for the procedure, (c) paracervical block, if required, (d) vacuum aspiration (e) pre and post procedure counselling.

The necessity of anaesthesia for menstrual regulation has been debated. Some feel it is not required except 'verbal' anaesthesia (Laufe, 1977), that is the patient should be informed about the steps of the procedure and informed about the probable discomforts and complications. Those who prefer paracervical block do so for the associated risk is so low that the benefits should outweigh these risks. (Soderstrom, 1979). Pain intolerance can lead to an increased incidence of retained products of conception (Vander & Piotrow, 1974 as cited in Soderstrom, 1979). However, there seems to be consensus that general anaesthesia (GA) is not at all required for MR. On the contrary, higher rates of complication related to anaesthesia occur when general anaesthesia is routinely used (Brenner and Edelman, 1977).

Efficacy of the procedure depends on sounding the uterus to confirm the criteria of menstrual regulation. An increased incidence of missed evacuation when the aspiration cannulae were too small for the gestational age was demonstrated (Stim, 1974 cited in Soderstrom, 1979). Application technique of the cervical tenaculum is an important factor. Efficacy of paracervical block depends upon proper anaesthetic placement, deposition of an adequate amount of fluid and sufficient 'set time'.

- **MR by surgical method is a simple and safe method.**
- **Vacuum aspiration is the technique used for conducting MR.**
- **Plastic flexible cannula and hand-pumped syringe are the equipment used for MR.**
- **It does not require anaesthesia.**

**The safest period for MR by surgical method/VA:** MR can be done any time within 14 days of missing the period. However, the best time to perform MR is after 35 days and before 45 days from the first day of the last menstrual period (LMP). Before 35 days, about 50% or more cases are found after MR not to have been pregnant. This involves unnecessary risks and trouble to a large number of patients and an extreme burden upon the medical personnel; besides, the failure rate of MR is also higher during this period (Edelman and Brenner, 1977). According to Goldthorp (1977) the appropriate time is between 10-18 days after missing a period. He mentions that MR conducted earlier than this may lead to continuation of

pregnancy despite the woman menstruating or there is a decidua but the blastocyst is so small that it could be easily missed out. After 18 days the pregnancy is growing quite rapidly, and after 22 days becomes more uncomfortable to deal with - the amount to be removed is copious, and doubts exist about the completeness of the procedure. Aspiration undertaken between 42nd to 49th day from LMP gives the best results in terms of pregnancy rate and reduced complications (Rajan, 1979).

• **The safest period for MR is between 42nd to 49th day from LMP**

**Equipment and its maintenance :** Acceptance to any new medical technique depends upon the nature of equipment. In that, availability and cost of equipment, mode and cost of its maintenance, its durability, its operational comforts to the practitioner and client are the most important. These factors determine the extent of spread and popularity of the technique.

Equipment needs for menstrual regulation are the ones basic to the first-trimester abortion. But they are less complicated and less extensive (Soderstrom, 1979). Majority of the advocates of the method have highlighted advantages of equipment for its low price, easy maintenance, durability of syringe as well as cannulae despite their disposable nature. Vacuum source could be non-electrical. This, therefore, could be easily adopted in rural areas where electric supply may be a problem.

Cervical dilatation is rarely necessary, simple equipment can be used (Edelman & Brenner, 1974 cited in Brenner & Edelman, 1977). The minimum equipment needed is a vaginal speculum to expose the cervix, a non-traumatic tenaculum to stabilise the cervix, a sterilising box for the metal equipment and Karman cannula & plastic syringe, that is modified Karman syringe. Instead of Karman cannula and syringe other types could also be used.

Prevacuumed syringes, like the modified Karman syringe which has pinch valve, are beneficial because no manual efforts are required for evacuation and uterus does not get pressurised. Also, better shearing action is produced by the cannula, resulting in a shorter operating time and less blood loss while prevacuumed equipment are used (Branch & Bridgman, 1973). There is no pump to produce noise and patient stress.

Sterilisation of the syringe and cannulae is simple. It is not necessary to sterilise the syringe since the material is only drawn into it and at no time does it touch the woman. It could be reused after washing with cold water. The cannulae are required to be only cold sterilised since they are of plastic. It is found to be feasible according to a study conducted by Spence and others (1978). It also ascertains the appropriate solutions and time intervals for this sterilisation process. The organisms studied were *Neisseria gonorrhoea*, *Escherichia coli*, Lancefield group B, - hemolytic streptococci and *Bacteroides fragilis*. The solutions tried were sterile normal saline, 10% formalin, Cidex and 70% ethanol, 95% ethanol, Prepodyne, tincture of iodine (2% iodine by weight in 70% alcohol). The cannulae were soaked in the different antiseptic solutions for 1, 5, 10 and 20 minutes. It was found that Cidex, 95% ethanol and 2% tincture of iodine are capable of clearing cannulae all of organisms when they were soaked for 20 minutes. Except 2% tincture of iodine clearing of organisms was possible even after soaking cannulae for 10 minutes only. The organisms employed in this study are the most commonly encountered pathogenic organisms in the female reproductive tract. Generally natural defense mechanism keeps her from becoming infected. Inoculation of these organisms into a freshly curetted uterine cavity might result into adverse effects. If these abortion cannulae are sterile, the number of post abortion infections would decrease. A Calcutta based study reports cold sterilisation in liquid germicide containing chloroxynel 4.8 per cent in solution of cetrimide and chlorhexidine and were re-used (Dawn and Mullick, 1975)

The durability of the cannula and the syringe depends much upon how carefully the instructions of manufacturers are followed. They generally include the brands of solutions and disinfectants to be used for sterilization and length of time for soaking. (Fortney et al, 1980). This study examined as to what extent the instruments durability could be enhanced by good care maintenance of the equipment. Properly maintained Karman syringe is capable of performing at least 40 operations and some syringes have been used many hundreds of times. The cannula can be used 10 times or more provided they are properly sterilized. If the cannula tip begins to crack it should be rejected.

The opinions about convenience and advantages of flexible cannula in MR are divided. The need was felt to examine efficacy of this cannula against that of the rigid cannula. A multi-centric study was conducted by World Health Organization (WHO) Task Force in seven centres of which three were in India<sup>1</sup> (1984). It was found that the frequency of continued pregnancy, postabortal bleeding requiring secondary curettage, delayed complication were higher in the one-holed rigid cannula group than those with one and two holed flexible and two holed rigid cannula groups. This study says that if a rigid cannula is to be used, it should be a two-holed cannula patterned after the commercial models.

Many emphasized the advantages of MR to developing country on account of inexpensive and easy-to-operate equipment in addition to other advantages. (Fortney et al 1980; WHO, 1984).

- **MR equipment are easy to operate with.**
- **They are inexpensive, durable and easy to maintain.**
- **It does not require electric supply because vacuum source is only manual.**
- **The risks are less because they are flexible.**
- **Anaesthetic equipment are not required because only paracervical block is sufficient, if required any.**
- **Equipment of Indian manufacturer are available in the market.**

**Infrastructure and backup :** A full fledged operation theater is not required for MR. Instead, it could be performed in the general practitioner's clinic chamber. All that is needed is a well-lit, clean room. It can be performed in primary health centres, too in Indian context (Chaudhuri, 1996). However, it is desirable to have a good referral within easy reach and back up in case of post MR complications and rarely occurring emergencies respectively. Some others suggest 24-hour emergency services to reduce the risks (Brenner & Edelman, 1977). Some of the stronger aspirators, such as, Battelle automatic negative pressure bottle, a Battelle hand-pumped aspirator or an electric suction apparatus are advised to be kept in clinics and centres to back up MR by suction evacuation in cases where MR fails because of an inadvertent attempt to evacuate an uterus of larger size. (Chaudhuri, 1996).

The immediate complications that have been recorded in various studies till today are uterine perforation, cervical laceration, reaction to local anaesthesia (Wong & Schulman, 1974); Heamorrhage, injury to cervix, injury to uterus (WHO, 1984). They are as low as less than 0.8 per cent in various situation. Excessive bleeding, syncopal attack, nausea and giddiness and bradycardia were recorded in Indian based study (Vasistha et al, 1976). It stated that none of the complications mentioned warranted hospitalisation or any treatment except observation for short time. It is to be noted that the percentage of such complications is very low.

- **MR is a office procedure. It doesn't require sophisticated infrastructure.**
- **It is desirable to have good back-up and referral medical care.**
- **None of the immediate complications warrant hospitalisation.**

**Hospitalisation :** In most instances, patients will be able to leave the chamber or hospital after 15-30 minutes. Prophylactic antibiotics e.g. Tetracycline 250 mg 6 hrly for 4 days may be given. It takes about 10 minutes counting that from swabbing the vulva to the completion (Goldthorp, 1977). It takes only 1 to 2 minutes for the actual procedure (Goldthorp, 1977; Rajan & Kaimal, 1977).

Saving valuable ward beds and operating time are the advantage of MR being only a day-procedure requiring no hospitalisation at all. This has direct bearing on health care resources which are often short of the needs. This is an indirect benefit of the procedure (Goldthorp, 1977).

- **MR takes only about 2 minutes for the actual procedure.**
- **Woman can be on her own after about 25-30 min. because she is not subjected to general anaesthesia.**

<sup>1</sup> Seth G S Medical Collge, KEM Hospital, Bombay, India; Postgraduate Institute of Medical Education and Research, Chandigarh, Inida and All India Institute of Medical Sciences, New Delhi.

- **MR doesn't require hospitalisation**

**Information to be gathered from the woman before taking her up for MR :** Careful history taking is essential, especially about menstrual regularity, sexual activity, timing of intercourse, contraception, possibility of failure, sources of anxiety and tensions that may cause amenorrhoea, and if pregnant, why the patient does not wish it to continue (Brenner & Edelman, 1977; Goldthorp, 1977; Hodgson, 1977). This has special relevance for it helps reducing the number of unnecessary procedures without really conducting expensive and time consuming pregnancy tests.

- **Information on menstrual regularity, sexual activity, timing of intercourse, contraception, possibility of failure, sources of anxiety and tensions that may cause amenorrhoea should be obtained from the woman.**
- **This is critical to reduce unwanted procedures.**

**Pre and post procedure counselling & mandatory follow-up :** Pre and post MR counseling is of critical importance for various reasons which implies safety measures and benefits to woman. As it is true with any other medical intervention, it is necessary that the woman is told about the risks and possible complications that she may face as result of MR. This should be followed by all those who perform such a procedure as part of medical ethics and code of conduct that is expected to be followed by the procedure performer. The failure instances of the procedure, such as, continuing pregnancy and ectopic pregnancy should be conveyed to woman. The follow-up visits, therefore, are important. Any of the above mentioned consequence of the MR procedure could be attended to if woman sticks to the follow-up plans as mentioned by the provider. It is suggested that the woman should have 2-4 weeks follow-up examination to ensure that the pregnancy is interrupted, no complications have occurred and contraception is being used correctly (Brenner & Edelman, 1977). The counseling helps woman understand the significance of the follow-up visits.

A common concern expressed by many of the MR researchers is about the danger that women may take recourse to MR repeatedly given its advantageous characteristics, such as, it is quick, cheap, less invasive. If not avoided, is quite clearly an abuse of MR as contraception. The counseling by the provider on post-MR use of contraception against this backdrop, therefore, becomes mandatory.

- **Woman should be informed about the risks and complications that are associated with MR.**
- **Contraceptive counseling is of critical importance so as to avoid repeat MR.**
- **Minimum one follow-up visit should be made mandatory to confirm non-pregnancy status.**

**Who could perform MR?** The studies from all over the world indicate that a wide range of medical and paramedical professionals can effectively and safely provide MR services. The experiences of paramedics MR providers from various points of views and the issues therein are dealt with at length in one of the accompanying discussion papers.

- **Gynaecologists, Physicians, nurses and paramedics can perform MR equally safely and effectively.**

**Risks & Complications:** The same complications can occur as with an aspiration abortion performed a few weeks later, after pregnancy is confirmed. However, because only flexible instruments are used, there is less risk of perforating the uterus, and problems that might result from dilating the cervix are avoided. There is slightly more chance that the practitioner may miss aborting the pregnancy, if there is one, since the fetal tissue is so minimal. One drawback is that woman may indeed not be pregnant, that is, unnecessary MR procedures will be conducted.

One can say two types of risks are associated with MR. One, continuation of pregnancy and two, complications. Various complications mentioned by researchers include cervical laceration, hypotention, pelvic infection, prolonged bleeding (>5 days) not requiring curettage and prolonged bleeding requiring

curettage. According to Brenner and Edelman (1977) MR is associated with low risks of continuing pregnancy (<1.0%) and other complications (2.4%) when compared to abortion later in pregnancy.

Selection of cases is the most important thing to reduce the failure rate, complications and unnecessary procedures. Complication rates are said to be higher in nulliparas than in multiparas, when 6 mm rather than 5 mm cannula is used, when general anaesthesia is routinely used rather than paracervical block or local anaesthesia is used, after 6 weeks' amenorrhoea. Failure rates are higher when the vacuum pump is used than the syringe, with 4 mm cannula than 5 or 6 mm cannulae.

It is more a matter of balancing the medical (avoiding MRs for non-pregnant women) and social factors (avoiding repeat visits for MR services that women may have to make if repeat pregnancy tests are insisted upon).

In the earlier phases of MR practice, many of the medical professionals felt the need to develop specific and sensitive pregnancy tests so that unnecessary MR procedures could be avoided (Chez, Callari and Branch, 1974; Wong & Schulman, 1974; Hodgson, 1977). Today, such sensitive pregnancy tests are available. Eliza and B-gravidex or Latex method are sensitive even within 6 to 10 days after missing the menses.<sup>2</sup>

- **MR is associated with low risks of continuing pregnancy (<1.0%) and other complications (2.4%) when compared to abortion later in pregnancy.**
- **Selection of cases is the most important thing to reduce the failure rate, complications and unnecessary procedures.**
- **Development of sensitive pregnancy tests will help reduce the quantum of unnecessary MR procedures.**

**Acceptability of the method :** With all the advantages of the method it builds a strong case for its acceptance from point of view of the both, woman clients and providers. Since pregnancy is terminated before the major developments of embryology are completed women find it easier to accept it emotionally.

- **Acceptance of MR is high among both, service providers and women users.**

**Advantages :** MR by aspiration is advantages for wide range of reasons. Since a syringe rather than a motorised pump is used to create a vacuum, electricity is not needed. No dilation is needed to insert a small flexible plastic cannula into the uterus, local anaesthetic is rarely used because there is no dilation. The procedure takes a few minutes. Also, tests for Rh blood type are usually not part of preemptive abortions and Rh-negative women are not usually offered Rhogam. It is also said that menstrual regulation avoids interference with routine gynaecological work and permits an operator to widen his criteria for accepting patients for termination (Goldthorp, 1977).

**Advantages :**

- **Medical - less risky, safe, easy, less invasive, no anaesthesia required.**
- **Socio-cultural and psychological - women experience less trauma and emotional setbacks because it is not an "abortion", per se.**
- **Legal - Access to abortion care has been possible in countries with restrictive abortion laws because of semantics.**
- **Indirect advantages, such as, saving hospital beds have positive implications for health care system as a whole.**

**Prerequisites for woman to be in position to make use of MR and for providers to offer such service :**

MR is simple and safe provided that the woman is referred shortly after missing a period, as the critical period is 35-45 days after the first day of LMP. The woman should approach the practitioner within this critical period and also should be undergoing such an aspiration. This is attendant on woman's knowledge about MR, especially the importance of 'critical period' and her LMP, as accurately as possible. Also, that women should be in position to decide upon approaching the MR services within 6 weeks after LMP. This depends much upon socio-familial factors, viz. : woman's status in the family, her role in decision making.

<sup>2</sup> Personal communication with pathologists and gynaecologists.

Positive attitude among the medical professionals towards method becomes mandatory for making woman's access to MR possible. It is important that the MR service providers do not waste time arranging a pregnancy test since it leads to losing the advantages of MR.

The IEC plays an important role in achieving this goal - bringing about awareness and positive attitude towards the technique among the users and providers.

- **Women should know about MR and its critical period.**
- **Providers should also have positive attitude towards the method.**

### **MR (by surgical method) PRACTICE : EXPERIENCES IN INDIA**

Experiences in India as regards MR practice that are presented here are drawn from hospital based research studies and our own field experiences during last three years. The research studies are the ones conducted and reported by gynaecologists. Our field experiences are based on interactions with medical professionals providing abortion care. Some estimates of MR procedures based on sale of total MR instruments also throw light on the extent of MR practice in India. However, we did not come across any comprehensive research on MR practice in India.

#### **Clinical Research Studies :**

- In India, the practice and clinical research on MR is by and large conducted by the India Fertility Research Programme. A Calcutta based study (n = 1455) in which majority of them were conducted in MR clinics set up in the poor communities was conducted and reported by Dawn & Mullick (1975). It studied safety, complications and failure rates. It reported favourable results. The other two Bombay based Indian studies (Kanitkar, et al, 1974; Khandwala & Pai, 1974) also support these results. Researchers at that early stage had expressed the need for MR program development for its wider dissemination. In that, the low cost, requiring no extra facilities and mandatory post-MR contraception were emphasised.
- A study (n = 220) conducted at the Postgraduate Institute of Medical Education and Research, Chandigarh to determine efficacy of the procedure, its safety and complication reports that it has many advantages over the suction abortion. It highlighted no requirement of cervical dilation reducing the danger of tearing and lacerating the endocervix, minimised blood loss. However, it reported 25.5% of unnecessary procedures. (Vasishta, et al, 1976).
- A study (n = 250) was conducted at Department of Gyneacology and Obstetrics, Medical College Hospital, Kerla, to examine efficacy of MR for women with 33 to 63 days of amenorrhoea, that is much beyond the conventional limit for conducting MR. In spite of longer length of gestation, no anaesthesia was administered. Larger size cannulae were used for longer length of gestation. 'Earlier an abortion performed, lower is the complication rate' was one of the major findings in confirmation with the earlier findings. The failure rate among the women with 33 to 49 days of amenorrhoea was 0.83% while women with 50 to 63 days of amenorrhoea it was 1.61%. The comparisons made with first trimester abortions done by suction curettage indicated that MR is comparable. MR was found to be superior in terms of less post-procedure complications. Ease with which contraception could be made appealing post procedure to women was emphasised (Rajan and Kaimal, 1977).
- While narrating personal experience with this method (n = 1000) Rajan (1979) points out that unnecessary procedure that are performed is the major drawback of the method. The best results in terms of pregnancy rate and reduced complications are obtained between 42 to 49 days from LMP. The need for more reliable pregnancy diagnosis, such as, radio-receptor assay, was expressed to avoid unnecessary procedures.
- A study (n = 1000) conducted at MR clinic at Armed Forces Medical College Hospital, Pune refers MR as a post-coital contraception method. It highlights high acceptability rate and opportune time for accepting contraception, especially intra-uterine devices (Suchadeva et al, 1979).

#### **Field Experiences :**



- MR is being practiced at the family planning clinics run by Family Planning Associations. However, the length of gestation exceeds than what is generally accepted for MR procedures to be conducted. MR procedures are recorded as MTPs. Thus, it is more in terms of the technique of evacuation which are similar to that used for MR. This reduces unnecessary procedures to a great extent while loses indirect socio-cultural advantages that are highlighted by proponents of MR all over the world. Their experiences about the technique of evacuation using flexible cannula are positive.
- One of the medical professionals from Ratnagiri area reported that MR is widely practiced in Uttar Pradesh and other parts of north India. She reported medical professionals' satisfaction with the method.
- Providers from our survey mentioned following reasons as deterrents to practice MR. The most frequently mentioned was 'high failure rates of MR'. One provider mentioned that the MR equipment is an expensive affair and cumbersome methods of maintenance. However, the methods of sterilisation described by him were found to be incorrect. This reduces durability of the equipment increasing cost per procedure. One provider mentioned of his uncomferts with the technique and lack of confidence for its use. A few in this connection mentioned that they don't want to try with new techniques because it affects their reputation and quantum of practice. To one's surprise many of the abortion provides still practice D&C for this reason alone while vacuum aspiration has been proved to be a superior method.

Providers' impressions of MR failure rates that we have gathered during our field survey go quite against the research findings from the world over including developing countries and India itself. It is necessary that the reasons behind this gap are tapped methodically and scientifically. The diffidence about the procedure could easily be attributed to lack of training facilities to upgrade skills. The prevalent medical education system doesn't have such an arrangement of continuing education. Such lacunae in the medical education system needs to be acknowledged and attended to.

MR does not constitute part of government programmes. However, a few of the medical professionals in public health care service have been practicing MR and hold good opinion about the method according to our field experiences.

The magnitude of MR procedures that take place in India could be drawn from the sale of MR kits. They are manufactured in India. About 50-70,000 MR kits a year are sold by one of the manufactures. Each kit is estimated to be used for 25-30 procedures. Another major manufacturer seems to have admitted a sale of less than 1000 kits a year, comparatively a smaller number. (Chhabra and Nuna, 1994).

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| <ul style="list-style-type: none"> <li>• <b>Clinical research based experiences in India as regards MR are encouraging.</b></li> <li>• <b>There are regional differences with regard MR practice within India.</b></li> <li>• <b>The reasons behind these need to be explored.</b></li> </ul> |
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### MR BY SURGICAL METHOD : THE INTERNATIONAL EXPERIENCE

MR is being practiced extensively in Western and European countries. In many countries where abortion laws are restrictive, menstrual aspiration is distinguished from abortion and permitted - for example Bangladesh, Indonesia, Fiji. Taiwan, Sri Lanka, Korea, Japan are some more to mention who went for MR in early 70s on a large scale.

The government's initiatives and efforts in promoting MR in these countries are worth taking note of. MR is included in the government health care programs in Bangladesh and Indonesia. Liberalisation of abortion laws came in the First Five Year plan because the government felt concerned for the population growth. However, it allows abortion only if woman's life is at stake. The pressures of religion don't permit any further liberalisation of the abortion law. The efforts of national family planning programme since 1975 have led to the increased practice of MR (Tofayel et al, 1983). The Bangladesh experiences are unique in that the government and Medical Colleges are committed to developing a nationwide MR training and service capacity to achieve these reductions in the absence of legalisation ( Bhuiyan & Burkhart, 1982).

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| <ul style="list-style-type: none"> <li>• <b>MR experiences from all over the world are positive and encouraging.</b></li> </ul> |
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## **MR BY MEDICAL METHOD : ADMINISTRATION OF RU-486 FOLLOWED BY PROSTAGLANDIN**

Vacuum Aspiration used for the first trimester abortion though is safe and highly effective, complications related to both gestational age and surgical and anaesthetic techniques can't be eliminated totally. Consequently, and with the desire of many women to avoid operative treatment (Rosen et al, 1979) recently there has been much interest in the development of medical agents to interrupt the unwanted pregnancy at an early stage, 'menstrual induction'.

The two major drugs that have been tried for menstrual regulation are prostaglandin (its various analogues) and Ru-486 either alone or in combination. The trials conducted all over the world indicate that prostaglandin or RU-486 alone are less effective and have more severe side effects such as, nausea, headache, diarrhoea, pyrexia, vomiting and uterine cramps in case of prostaglandin alone and heavy bleeding requiring hospital admission for blood transfusion and curettage in case of RU 486 alone. Failure rates are unacceptably higher than when their combination is used. The recent studies indicate that regimen of combination of these drugs works better in terms of its efficacy. The following discussion therefore restricts only to this combination/sequential regimen skipping the review of intermediate stage of trials with either of these two drugs alone<sup>3</sup>. Some of the issues are also raised here regarding its applicability in India.

**History and background of RU-486 :** RU-486 is the antiprogestine abortion pill. It provides a medical alternative to instrumental or surgical intervention for early first trimester pregnancy. In 1982 Philibert and colleagues at Roussel-Uclaf, the French firm, reported the synthesis of RU 38486, "an antiglucocorticoid with a new mechanism of antihormone activity." The uterine RU-486 (mifepristone) was discovered by a French biochemist, Dr E E Baulieu working in Roussel-Uclaf. Since 1988 the drug has been registered for inducing abortion in four countries, namely France, China, UK and Sweden. It has been used on over 100,000 women for abortion (Baird, 1993 in Chaudhuri, 1996). In France alone the mifepristone and prostaglandin combination is used by over 1000 women a week, and about 45, 000 treatments have been registered by May 1990 (Aubeny, 1990 in Guille, 1990). WHO is now sponsoring clinical trials in various countries. It includes Sweden, the Netherlands, Hungary, Great Britain, Italy, Chile, Hong Kong, Singapore and India. It has stimulated political controversy in some Western countries particularly the US. As of today, it is not being manufactured in India. Importing from outside is an expensive affair.

It is widely used in France since 1988, the country of manufacture. Its acceptability among the users and providers is very high. It has also been registered for clinical use in UK and China. In all three countries the drug is licensed for use in MTP with the recommendation that it be administered in conjunction with a uterotonic prostaglandin analogue injected or used as a vaginal pessary. The trials for combination of these drugs for early and first trimester abortions are being conducted in number of countries.

**How does it function?** When pregnancy proceeds human chorionic gonadotrophin almost immediately is detectable, and this prevents regression of the corpus luteum. Continued secretion of progesterone from the ovary - and reception at the endometrium - are essential for the maintenance of early pregnancy. By blocking the normal action of progesterone in the uterus RU-486 can prevent implantation of a fertilised egg in the uterus or can bring on menses even if implantation already has taken place. This is done by a reversible inhibition of the action of progesterone on its own receptors. This reversibility allows endocrine functions to return quickly to normal after discontinuation of treatment. However, target cells which depend upon a continuity of progesterone action will be irreversibly disrupted by receptor blockade. The effects of mifepristone vary with the phase of menstrual cycle. This antiprogestrone drug is most effective when used within nine weeks (63 days or 2 months and a week) of the last menstrual period (LMP) and when followed forty-eight hours after ingestion by a dose of prostaglandin, either by suppository, by injection or orally. The prostaglandin increases uterine contractions and enhances the effectiveness of RU-486.

In early pregnancy, the decidua, which has high levels of progesterone receptors, is the primary target of for antiprogestrone action. The response to RU486 administration is rapid. The rate of increase in human

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<sup>3</sup> The issues that are common to both medical and surgical methods of MR have dealtwith in the discussion paper no 1 on MR.

chorionic gonadotropin (hCG) production which characterizes this stage of pregnancy, slows and once the embryo is detached, levels of hCG decrease sharply. Consequently, the maintenance of ovarian function is withdrawn, resulting in an irreversible luteolytic effect, with corresponding reductions in levels of plasma progesterone and estrogen. The antiprogestone also increases the contractility of the myometrium, probably via endogenous production of prostaglandins. The cervix becomes softened and dilated to facilitate evacuation of the lining of the uterus and eventually the embryo. This may either be a direct effect of RU 486 or an indirect effect owing to increased prostaglandin activity.

**Dosage :** In 1991 a major breakthrough was made by the discovery of a Pge1 analogue (misoprostol) which is inexpensive and effective orally, needing no refrigeration. Various studies have already shown that 600 mg of RU-486 followed 36-48 hr. later by 400 meg (0.4 mg) of misoprostol or 0.25mg sulprostone by injection or single vaginal pessary of 1 mg of gemeprost produced complete abortion in about 95% women (Baulieu, 1989; Guille, 1990; Aubeny and Baulieu, 1991; ICMR, 1994 cited in Chaudhuri, 1996)

**Efficacy of the drug :** With increasing length of pregnancy, the failure rate due to post-RU 486 incomplete expulsion increases more rapidly than the failure associated with unaltered pregnancies. Therefore, a limiting 'post-RU486' mechanism was postulated, implicating an insufficient increase of endogenous prostaglandin (Baulieu, 1989). The best results with RU-486 **alone** are obtained with a single administration of 600 mg to patients with less than 41 days of amenorrhea (Baulieu, 1989). In that the success rate was about 83%. However, the failure rate of 17% percent is unacceptably high. The combination of RU486 and prostaglandin variants (gemeprost, sulprostone, meteneprost) increases the efficacy ranging between 95% to 99% (Ulmann & Dubois, 1989). According to OBOS RU-486 plus prostaglandin is successful 96 per cent of the time when used within nine weeks of a woman's last menstrual period. In case of failure of the treatment, a suction abortion or D & C is necessary. (OBOS, 1994). The method is as effective as surgical termination of pregnancy within 7-8 weeks. The rate of efficacy is approximately the same as that of vacuum aspiration and therefore has been considered as an alternative to vacuum aspiration and D & C (Ulmann & Dubois, 1989).

**Equipment, infrastructure:** Since the drug is administered orally there are no separate equipment required.

**Backup :** The bleeding after RU-486 and PG regimen usually starts 1-3 days after taking RU-486 and lasts for about 10-12 days (very rarely upto 12 days). The amount of bleeding (average 80 ml) is similar to that observed following VA. However, for heavy bleeding D& C is urgently needed in 1% of women. Incomplete abortion has the potential for infection, D & C should be performed if bleeding lasts longer than 2 weeks or is heavy. This method should be used where medical supervision is available in cases of need, although the need might occur rarely.

**Contraindications :** There are no absolute contraindications of RU-486. The relative contraindications include cardio-vascular risk factors, adrenal insufficiency and allergy or epilepsy.

**Safety :** So far, RU-486 plus prostaglandin appears relatively safe in the **short term**.

**Risks :** It avoids the risk of cervical and intrauterine injuries following surgical method and the risk of infection is much less than with abortions performed unsafely and illegally.

If a pregnancy should continue after administering RU-486 plus prostaglandin, the effects on the growing fetus are unknown. RU-486 being a steroid might cause birth defects. However, several known cases where a woman took RU-486, did not subsequently take the prostaglandin and went on to have a baby that appeared normal in all respects.

**Long-term effects** of RU-486 plus prostaglandin are **unknown** at this time.

**Acceptability is very high.** Among women with experiences of both the medical and surgical methods of abortion, 77-100% favour the medical approach (WHO, 1994).

Women's health activists and representatives of Feminists Women's Health Centre too have favourable response to this early abortion method. Women overwhelmingly preferred this method to the surgical method.

It is an alternative to women with a strong aversion to inserting any instruments into their uterus.

**Who could administer the drugs?** This is considered to be a self-administering drug in Western and European countries. Studies undertaken to evaluate the possibility of self-treatment at home state that the efficacy and safety of the treatment seem good enough to allow self-treatment at home. However, in Indian context it may need to be done under medical supervision. It should be noted that it requires supervision, back-up and referral.

**Where could it take place?** It is considered to be an office procedure which can be administered in a doctor's office as well as in a clinical setting.

### INDIAN EXPERIENCE

Reporting of the study (Hingorani, 1989) conducted to examine safety and efficacy of sequential use of mifepristone and prostaglandin at All India Institute of Medical Sciences, India concluded that it is highly safe, simple and effective non-surgical method for termination of early pregnancy. The regimen consisted of twice a day dose of 25 mg of RU486 for 4 days and another group for 3 days. All women received an intramuscular injection of the prostaglandin derivative sulprostone, 0.25 mg, on the last day of RU 486 treatment. In Group I, all women had a complete abortion with a success rate of 100%. In Group II it was 95%. The side effects are reported to be extremely mild and did not require any medication. They were primarily nausea, dizziness, and uterine cramps, symptoms commonly experienced during the process of a spontaneous abortion. None of them developed any evidence of pelvic inflammatory diseases, nor did they require antibiotics.

India participated in the multi-centric study supported by Population Council between Oct 1991 to Aug 1993 (Winikoff et al 1997). The other two countries were Cuba and China. It is supposed to be the first large comparative efficacy trial of the two methods and the first to assess the acceptability and efficacy of the mifepristone-misoprostol medical abortion regimen in developing countries. The treatment regimens was as follows - The women who chose the medical method of abortion received 600 mg of mifepristone orally during the admission visit. Woman remained in the clinic for 30 minutes for observation and blood pressure checks. She was asked to return 48 hours later for misoprostol during which she received 400 mg of it orally and was observed for 4 hours. Rh negative patients received anti Rh (D) immune globulin. A final visit for checkup and exit interview was scheduled 14 days later. In India 250 women participated in this research. The failure rate was 5.2%. Specific symptoms and side effects, including cramping, nausea, and vomiting, were far more frequent among the medical than the surgical abortion patients. Serious side-effects were rare. The only serious complication was excessive bleeding which often is the reason for surgical intervention. Acceptability to patients was as high as 95.2% in India. However, those who had failures were unsatisfied.

### APPLICABILITY AND FEASIBILITY OF RU-486 IN INDIAN CONTEXT

According to women's health activists clinical trails involving women of different racial, cultural, socio-economic backgrounds are also essential to demonstrate safety and efficacy for women of different backgrounds and with different health problems, such as malnutrition.

The major constraint seems to be the need for women to approach the providers before 7-9 weeks of LMP. Secondly, women have to make at least two visits to the provider. The second visit for intake of prostaglandin has to be either on the third day or on the fourth day after RU-486 has been administered. This strict time schedule perhaps defeats the purpose of choosing this method in Indian situations, especially in rural areas.

The other constraint is the high cost of the drug as of today.

### **Restrictions that are used for distribution of RU-486 :**

It is interesting to note the nature of restrictions that are used for distribution of RU486 in France. According to Aubeny (1990) it must be given in registered clinics under medical control. There is a tightly regulated protocol in France :

- it can be given only to French nationals or people with a minimum of three months' residence in France;
- a week's delay is necessary for reflection;
- there must be adequate social support;
- specified contraindications must be observed;
- official forms must be signed and countersigned;
- mifepristone 600 mg should be given no later than the 49th day of amenorrhoea and prostaglandin given 48 hours later with surveillance in the clinic for three to four hours;
- and there must be a follow up visit after five to nine days;
- women must sign an agreement to accept surgical abortion in the event of failure - for fear of teratogenesis, though this has not established in humans

Besides, the other concerns expressed by researchers regarding RU486 and prostaglandins are intended to check the morbidity arising from careless distribution and/or administration of the drug. It is said that the sequential use of RU486 and prostaglandin constitutes a medical alternative for early pregnancy termination, provided that (1) it is prescribed in authorised centre, (2) the woman can have permanent access to medical facilities and (3) vacuum aspiration or D&C is performed in cases of incomplete pregnancy termination 8-12 days after RU486 intake, as the outcome of a pregnancy after exposure to RU486 is unknown in humans.

In absence of these facilities a safe alternative perhaps may turn into an hazardous one posing more threat to women's health than that exists to date.

### **MR AND CONTRACEPTION**

Prevention of unwanted pregnancy is the best way to attend the magnitude of abortion mortality and morbidity. It has been consistently pointed out that use of abortion as contraception is an hazardous choice. On the same line, using MR as an family planning measure is an abuse of the method (Brenner and Edelman, 1977). The procedure may have to be repeated twice a year for women in thirties and three times a year for those in twenties if no other contraception is used (Potter, 1972 in Chaudhuri, 1996). MR should be used as a back-up method of contraception.

Acceptance of contraception after MR is much higher than before MR. IUDs particularly copper devices, are introduced with advantages at the time of MR (Rajan, 1979; Brenner and Edelman, 1977). Sterilisation can be done safely at the same sitting if required. (Chaudhuri, 1996). Insertion of IUDs or sterilisation immediately after MR are not contra-indicated.

Many of the proponents of MR by surgical method (Rajan, 1979; Suchadeva et al, 1979; Laufe, 1979; Bhatia et al, 1980; Bhuiyan & Burkhart, 1982) have been focusing the relationship between MR and contraception. According to them the episode MR could be potentially used for advocating contraception. Pregnancy scare and invasive procedures that are required to be used for unwanted pregnancy could indeed be the basis of good contraceptive practice. This potential for prevention of pregnancy so closely linked with this simple method of menstrual regulation has often been highlighted for its contribution towards better fertility control results. This is an added advantage. However, the efforts and appropriate strategising for wider use for contraceptives to prevent even the need of MR remains the top priority not only for betterment of women but also in the interest of nation.

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| <ul style="list-style-type: none"><li>• <b>MR provides opportunity for advocating contraception.</b></li><li>• <b>Women are better prepared for accepting contraception after undergoing MR.</b></li><li>• <b>Insertion of IUD and sterilisation immediately after MR procedure are not contra-indicated.</b></li></ul> |
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## Part II : LEGAL EVALUATION OF MR<sup>4</sup>

### LEGAL STATUS OF MR<sup>5</sup>

It is important to understand the legal status of menstrual regulation in relation to the legal history and current legal status of abortion in India. A brief background of the MTP Act in India with regard to the criminal status of abortion in earlier period will provide us the context of this discussion.

**Criminal status of abortion and the MTP Act :** Abortion was criminalised according to the Indian Penal Code of 1860. Indian Penal Code of 1860 follows the Scottish tradition. It applies widely in Commonwealth Asia. This includes India, Bangladesh, Malaysia (Peninsular, Sabha, Sarawak), Singapore and Sri Lanka. Its Section 312 provides that, “Whoever voluntarily causes a woman with child to miscarry shall ... be punished ...”. The two Commonwealth traditions regarding penal legislation - British and Scottish - differ on an issue of abortion. The English tradition of abortion law is formulated within the Offences Against the Person Act 1861. Its Section 58 provides that : “whosoever, with intent to procure the miscarriage of any woman, whether she be or be not with child, shall unlawfully administer to her ... any poison or other noxious thing, or shall unlawfully use any instrument or other means whatsoever with the like intent, shall be guilty of felony ...”. According to the Scottish tradition based Commonwealth abortion law, an abortion offense is committed only when the woman acted upon was in fact pregnant. According to British Law acting with the intention to procure an abortion whether a woman is pregnant or not was made a crime for which the mother as well as the abortionist could be punished except where it had to be induced in order to save the life of the mother.

India (MTP Act implemented in 1972) has enacted advance laws expressing the indications upon which pregnancy may be medically terminated. These advance laws do not repeal (withdrawing officially) the Acts prohibiting abortion, but simply provide additional exemptions. Persons not thereby exempted are liable to be convicted unless they can establish a legal defense to a charge of illegal abortion.

The Basic crimes have two elements namely a wrongful act and a wrongful intention. Either of these in isolation or in themselves are not criminal. The wrongful act is criminal if and only if it is guided by the wrongful intention. The wrongful act of abortion under English law consists in administering any poison or other means, upon a woman when possessing an illegal intention of committing abortion. The wrongful act of abortion under the Indian Penal code is the same, but has the additional element that the woman must be with child, meaning that she must actually be pregnant.

The English 1861 legislation thus, relieved the prosecutor of the burden of proving the fact of pregnancy. In jurisdiction following the Indian Penal Code, however, a prosecutor alleging illegal abortion must prove not only an intention to abort a woman other than on bona fide grounds of preservation of life or health but also that she was actually pregnant.

- **The act of an abortion was accorded the status of crime by Indian Penal Code, 1860.**
- **The MTP Act, 1972 does not repeal the Acts prohibiting abortion, but provides additional exemptions.**
- **The Basic crimes have two elements - a wrongful act and a wrongful intention. Either of them in isolation are not criminal.**
- **The wrongful act of abortion under the Indian Penal Code requires that the woman must actually be pregnant.**
- **This often poses difficulty for the prosecutor alleging illegal abortion.**

<sup>4</sup> The discourse is based on work of Rebecca Cook, P P Bhiwandiwalla , Malcom Potts, Dickens Bernanrd, Victor Tunkel, Luke Lee and M Paxman.

<sup>5</sup> The issue of legal status of MR was mostly discussed with reference its surgical method. However, as far as the length of gestation is concerned, the discourse is applicable to medical methods, too. Also, the fact that there is no ambiguity as regards abortifacient qualities of drugs being used for MR by medical method, such a discourse may not take place.

**Legal status of MR :** We, with this legal background of abortion, have examined as to where could MR be placed. Menstrual therapy is a generic term describing medical and surgical procedures performed on the uterus for diagnostic and therapeutic indications. This includes, menstrual aspirations, and the use of drugs, such as prostaglandin, as well as the more traditional dilation and curettage. Menstrual aspiration may be employed to remove products of conception in incomplete, inevitable or septic abortion, whether of spontaneous or induced origin. D & C may be clinically indicated for heavy bleeding, amenorrhoea or any other menstrual irregularities. Diagnostic biopsy may be indicated upon clinical grounds, such as apparent infertility, dysfunctional bleeding and suspected uterine cancer.

Treatment of a incomplete abortion is a common medical procedure and involves the operator in no liability under abortion laws, since the operator does not initiate the miscarriage, nor participate in any criminal scheme. The operator simply responds to a clinical situation in a clinically appropriate way. Abortion laws are meant to limit the initiation of abortion and not to affect conscientious treatment of endangered women.

Uterine evacuation initiated for purposes of abortion in a woman known to be pregnant must conform to the abortion law of the jurisdiction. In most circumstances of Commonwealth Asia, pregnancy cannot be medically confirmed until at least 6 weeks' gestation. Thus, menstrual therapy undertaken as a means of abortion in a case of proven pregnancy must conform to local abortion law, menstrual therapy undertaken for another purpose need not conform to such law.

Against this background then, in Indian context, a doctor proposing to undertake menstrual therapy of a woman not proven to be pregnant need not strive to conform to the requirements on approval of the place where the procedure is to be done, or for instance, its regulations on the practitioner's experience in Gynaecology and obstetrics or training in performance of the procedure as mentioned in the MTP Act.

All menstrual therapies need not be abortions. Yet, it would be bad law and worse ethics to believe that abortion can be undertaken under the guise of menstrual regulation in Penal Code jurisdiction because of the evidentiary difficulties prosecutors may face in bringing criminal charges. Those employing menstrual therapies must show good faith. Scientific evidence may indicate that a significant proportion of instances of menstrual delay may be due to pregnancy. However, both doctors and prosecutors must concentrate on an individual rather than group or epidemiological statistics.

It appears that the legal status of menstrual therapies, described above, depends primarily upon whether the delay in pregnancy is on account of clinical indications or because of conception. There does not seem to be any ambiguity as regards its legal status, at least theoretically, about menstrual therapies taken recourse to if conception is confirmed. If so, both the provider and the client are expected to conform to prevalent abortion laws and not otherwise. However, debates about the legal status of menstrual therapies arose mainly as a result of complex relationship among the three forces. They are, restrictive abortion laws, obsessive concerns for population growth & its own dynamics and thirdly unavailability of pregnancy tests in very early phases. The other factor which featured in these debates was 'high maternal mortality and morbidity'. As we are aware, the abortion laws and the extent of their liberal nature varies from state to state. The countries which allow abortions only if mother's life is at stake also give vent to a large scale practice of illegal and clandestine abortion increasing the mortality and morbidity rates. In such situations then it was found easier to circumvent the restrictive abortion laws rather than amend them (a rather difficult task for various socio-cultural and religion forces are at work) in a seemingly legitimate way under the pretext that there are no reliable and affordable pregnancy tests available upto 6-7 weeks of gestation so as to decide MR is being conducted to evacuate conception or to treat clinical indication.

The merits of this circumvention or evasion of restrictive laws lie in the concerns for maternal and abortion mortality and morbidity. However medical ethics seem to have been jeopardised for it is a medical intervention without sufficient diagnostics. Maternal mortality and morbidity is central to the entire debate on legal status of MR. The population control forces at work can't go without mention. It will be too naive to underestimate or ignore them. Not doing required diagnostics results into unnecessary procedures. The concerns regarding this are consistently raised and have remained unresolved even after more than two decades of popularity and practice of MR. Over the time, in the haste for bringing down population growth rates, the issue of 'unnecessary procedures and its implications for women's health' has become rather blurred and of secondary importance. Such an approach may be justified, not without reservations, in

countries with restrictive abortion laws provided conscious efforts are taken to reduce unnecessary procedures. In such circumstances merits of keeping MR outside the purview of abortion law seems to be two fold. One, it serves the public health goals by attending the problem of abortion mortality and morbidity. Two, it also meets population control goals of state. However, in absence of strict vigilance & monitoring such strategies may fall prey to coercive population control policies of the state defeating the purpose of such serious compromises.

- **The dilemma about the legal status of MR is necessarily on account of the conflict between its semantics and usage.**
- **MR undertaken as means of abortion in a case of proven pregnancy must conform to local abortion law.**
- **The merits of use of MR to circumvent restrictive abortion laws lie in the concerns for maternal and abortion mortality and morbidity.**

**The MTP Act and MR :** In India, the implication of the entire discussion on legal status of MR will be quite different. This is because India practices a liberal abortion law unlike many of those countries where benefits of doubts about conception in early phases are used to practice MR to evade restrictive abortion laws so as to facilitate women's access to abortion care. This fundamental difference between these two situations requires a critical look at the position 'keeping MR outside the purview of the abortion law (MTP Act) is meritorious'. The various aspects that need to be examined are, is it really required to adopt the same position on legal status of MR in India with liberal MTP Act? What are the pros and cons of either of the position that one may justify in Indian context ? If in case we differ on the position about legal status of MR, how could it be reconciled with those at the international level ? On the contrary, if we don't differ on this, how do we reconcile with our appreciation for the legal provision for abortion care in general and in India specifically ? This is a conflicting situation at more than one fronts. It is possible that we may not have clear answers to these dilemmas. However, striving to find them is of critical importance.

In India, we probably can afford not to keep MR outside the legal provisions. By doing this, we will mostly loose on the socio-cultural advantages of MR when left outside the purview of the abortion law. However, we will be saving on 'conducting unnecessary procedures' to a great extent. Also, all the advantages of legal abortion provision will remain, for instance, accountability of providers to the client. Public health issues will be attended to effectively with cheaper, less expensive, safe, less imposing and less invasive method of MR. The advantages to women will be doubled because for she gets a legal procedure done at much reduced length of gestation thereby running lesser risks. What is then required at this juncture is designing the strategies to maintain the socio-cultural, psychological and emotional advantages of MR. While so doing, it is important not to compromise medical ethics and women's autonomy & rights.

Some have suggested to leave the legal status of MR ambiguous. However, it doesn't seem to have an edge over making it unambiguous.

The rest of the dilemmas need deliberations upon so as to get closer to resolve them. The various constituencies, such as, advocates & legal health experts, health researchers, medical professionals will together be able to resolve these dilemmas more satisfactorily.

- **It appears advisable not to keep MR outside the Act when used for conducting an abortion, given the less-restrictive nature of the MTP Act.**

## MR AND POPULATION CONTROL

Abortion acts were liberalised in many countries from 1950s onwards. The concern for growing population in all over the world has been one of the reasons for this liberalisation, though often not explicitly. The overemphasis on population reduction and abortion acts guided by population control motivations can explain a range of problems for women's access to abortion care despite its liberalisation.



We have in this paper seen the advantages of MR at various levels. MR, after getting an international recognition, has been promoted by proponents of population control in countries including those with restrictive abortion laws. This was because MR could be practiced easily to circumvent these abortion acts. Population control projects have exported this technique to many developing countries because it is easy to train laypersons to do it and since it does not require a motorised suction pump or much equipment. The intentions behind promoting MR appears to be again misplaced as it happened with liberalisation of abortion laws. It is more for benefits of the society at large or the state than offering choices to women for her to gain control over life.

Woman' movement is advocating safe and legal abortion facilities and abortion to be recognised as woman's right. Legalisation of abortion in almost all parts of the world is without repealing the earlier legal codes which criminalised abortion. The major contribution of the abortion laws has been to decriminalise the act of abortion under specified (bona fide/stipulated) circumstances. By doing this some kind of accountability mechanism has been built for both, women undergoing abortion and the providers conducting abortion. If so, the position that MR should be kept outside the MTP Act needs to be articulated to avoid paradoxes that may arise.

- **MR as an abortion method must be looked at not as a population control means but a way to provide women safer fertility control choices.**

### **CRITICAL ROLE OF IEC COMPONENT BOTH FOR WOMEN CLIENTS AND PROVIDERS**

We have earlier discussed the prerequisites that the user and provider of MR services should comply with for optimisation of MR practice. General practitioners should be convinced of the usefulness of the method keeping in mind its advantages vis-à-vis the current methods of abortion. Women should be aware of such an early uterine evacuation method. Creating awareness, imparting knowledge about and cultivating positive attitude towards MR could be achieved through IEC. Literature on various aspects of MR has hardly made reference to as to how this new method was communicated to its prospective clients during the initial stages of promotion of MR. However, developing systematic IEC strategies will certainly have an impact on its informed acceptability.

**IEC strategy :** The content and means of communication will have to be carefully worked out while designing IEC strategies for creating MR awareness among women and providers. Broadly speaking, IEC material for provider should highlight the technique, efficacy of the procedure and advantages over the prevalent methods along with its limitations. The research experiences in different set-ups and varied geographical areas will help developing opinion about MR. The IEC material for women should highlight its advantages over the other methods and abortions conducted with longer gestation period. The common items for IEC material for provider and women should highlight the importance of the critical period for women to approach the provider and avoiding delays in conducting procedures by the providers. Safety, efficacy along with its 'office procedure' nature should be central while deciding upon the content of IEC material for both, provider and women user.

The policy makers is the third constituency that may need IEC aid to bring about policy level changes. The IEC material for policy makers, in addition to the above information, should highlight economics behind adopting such innovations. In this particular context the inexpensive equipment required for the procedure, its durability, its easy maintenance, non requirement of electric supply, non requirement of anaesthesia, its feasibility in rural areas, role of paramedics and the quantum of probable off-load of physicians and gynaecologists, saving of hospital beds because its a office procedure nature, potential scope for widening the base of abortion care because of induction of paramedics etc. could constitute IEC package. The issue of public health and woman's rights needs to be highlighted.

**Means/Modes of IEC :** Opinion formation among the medical professionals is possible by conducting seminars and discussions on the method. The IMA, FOGSI, Nursing Associations can play an important role in this regard.

Besides, various formats, such as, book-let, posters, slide-show, audio and video cassettes etc. of print, audio and visual media could be utilised choosing the most appropriate for a particular constituency. Health researchers, activists and health advocates can play an important role in developing IEC material and designing IEC strategies.

Nitty-gritties could be better worked out situationally.

- **IEC should highlight safety and efficacy of MR and the critical period of gestation.**
- **IMA, FOGSI, Nursing Associations, health researchers and activists will be important in this regard.**

### **POLICY IMPLICATIONS**

It will be advisable to incorporate MR in public health care programme to reap fruits of its advantages. This, however, requires to examine its policy level implications. The following will have to be taken into account while so doing :

- Training centres/set ups for MR : Adoption of a new medical procedure or technique means training needs. The expertise, the training resources, training centres, financial arrangements are implied in this. Designing the training modules, deciding upon its content and strategies need to be discussed over.
- Equipment needs : Adoption of this new technique also means the availability of the equipment required for the procedure, that is, flexible cannulae and Karman-type syringe. As of today, MR equipment are being manufactured in India. The quality control and cost will be important factors for wider use of the method.
- Accommodating paramedics in MR practice : The advantages of MR in terms of paramedics getting into its practice entail specific requirements, mainly in terms of training.
- Budgetary allocation for MR : All the above mentioned needs in reality means revision of present budgetary allocation and/or a new budget head.
- IEC strategy should constitute part of the MR promotion programme.
- MR should constitute the comprehensive health care package for women.
- Need to formulate workable monitoring and evaluation system to guard against misuse of MR.

### **ISSUES OF CONCERN FOR DISCUSSION**

The various issues that have been raised in the paper need continuing discussion among the concerned constituencies before any decision is arrived at. They could be summarised as follows:

- Whether the MTP Act should made reference to MR explicitly? What will be its implications?
- How do we control 'unnecessary MR procedures' so as to enhance efficacy of MR ?
- Could it be incorporated in the regular medical and para-medical education itself ?
- How could it be integrated in the comprehensive health care for women in the public health care system ?
- What and who will constitute the monitoring and evaluation system ?

#### **Some other related issues are :**

- The studies conducted to understand socio-cultural aspects of abortion have revealed that decision making process are lengthy ones and appears to be unavoidable. In such situation what will be the extent to which IEC could change this pattern? How beneficial will it be to promote MR if women continue to approach abortion care facilities later than stipulated for MR ?
- To what extent will promotion of MR will attend to the issue of maternal and abortion mortality and morbidity ?
- How appropriate will it be to depend upon the prevalent mal-functioning public health care delivery system for providing MR services ?

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### **Acknowledgments**

**The Consultants :** Dr Anant Phadke, Dr Amar Jesani, Mani Mistry &  
**The REAP team members :** Mugdha Lele, Hema Pisal & Madhuri Sumant.

*Paper presented for The State Level Consultation on Issues Related to safe and Legal Abortion, Pune June 7, 1998*