Original Article

Mainstreaming of Emergency Contraception Pill in India: Challenges and Opportunities

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ABSTRACT

Background: Emergency Contraception Pill (ECP) is an essential intervention to prevent unwanted pregnancies. However, its use has remained low due to various barriers including reservations among medical fraternity. **Materials and Methods:** This paper presents findings on barriers to ECP's easy access for potential users from (i) a cross-sectional survey of providers' attitudes, beliefs, and practices and interviews with key opinion leaders, (ii) three consultations organized by Population Council with policymakers and public health experts, and (iii) evidence from scientific literature. **Results:** The major barriers to easy access of ECP include misconceptions and reservations of providers (disapproval of ECP provision by CHWs, opposition to its being an OTC product, and myths, misconceptions, and moral judgments about its users) including influential gynecologists. **Conclusion:** For mainstreaming ECP, the paper recommends educational campaign focusing on gynecologists and CHWs, relaxing restrictive policy on advertisement of ECP, involving press media and strengthening supply chain to ensure its regular supply to ASHA (CHW).

Keywords: Easy access, emergency contraception, family planning, levonorgestrel, provider barriers

Background

Emergency Contraception Pill (ECP) is an effective reproductive health intervention, which could protect millions of women from unwanted pregnancy. In India, ECP was introduced in 2002 by the Ministry of Health and Family Welfare (MoHFW) and was made an over the counter (OTC) drug in 2005. Less than one-third women are aware of ECP and less than one percent have ever used it.[1] The latest data from 8 states covered in the Annual Health Survey shows a continued very low (less than 0.2 percent) use of ECP.[2] Occasionally, media coverage has portrayed ECP use in a negative manner.[3,4] A national newspaper titled, "Morning-after pill: A medical nightmare?" wrote "Often the male partner does not bring the pills and this puts woman at more risk. Youngsters are using emergency pills too often. These pills should be sold only on a doctor's prescription".[3]

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Given the above backdrop, a study was conducted by the Population Council in 2011-12. Some of the key issues addressed in the study included providers' knowledge on mechanism of action and attitudes towards; easy access to ECP and its link to pre-marital sex and promiscuity, repeated use of ECP and as a replacement for regular family planning methods; perceived profile of ECP users, and lack of information and myths about ECP among potential users, particularly in rural areas. In addition to a survey, in depth interviews were conducted with officials of the MoHFW, leading gynecologists, representatives of professional medical associations, and civil society and donor organizations, and the current status of ECP use was analyzed using shop audit data of ECP sale volume collected by AC Neilsen ORG MARG. The findings were presented in a series of three national consultations with 120 key stakeholders mentioned above, including senior managers of pharmaceutical companies.

The present paper summarizes the overall outcome of the consultations supported by some of the key findings

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from the Council study of providers and other published literatures to suggest a way forward for mainstreaming of ECP.

Materials and Methods

This paper is based on findings from

1. The Population Council's study which includes in-depth interviews of key opinion leaders (KOLs),[5,6] whose views could make a substantial difference in policy-making and program implementation;
2. The three consultations mentioned above;
3. The review of literature that was easily accessible to complement the findings, and
4. The presentations made by participants during the consultations.

The first consultation sought to understand policymaker's and health practitioners' attitudes towards ECP, its mechanism of action, concerns in making ECP easily accessible, and similar issues, which could facilitate or create barriers to easy access for women who need it. The findings and concerns raised during the consultation were used in developing tools for the study including guidelines for in depth interviews of the KOLs.

The follow up two consultations organized at Delhi and Mumbai were used to share findings of the study and deliberate its implications for service providers, manufacturers, social marketing firms, and recipients of the services — the woman at large. The Mumbai consultation was particularly important as it included medical associations such as Federation of Obstetric and Gynaecological Societies of India (FOGSI) and Indian Medical Association (IMA), representatives of commercial marketing firms, large NGOs apart from the researchers, and social activists. The key issues discussed in these consultations included:

a. Implications of the providers study on increasing access and use of ECP
b. Mainstream use of ECP in the national family welfare program
c. Strategy that FOGSI could adopt to inform their members and remove their reservations and misconceptions about the product and its users
d. Discuss with key opinion leaders on government restrictive policy on advertisement and manufacturers' support to pharmacists who are the main providers of ECP in urban India.

Key Findings

Current status of ECP sale from the retail market

Shop audit report by AC Nielsen ORG MARG reveals that sale of ECP in last 5 years has increased almost 4 times, from 4.9 million in 2008 to 16.4 million in 2013, as illustrated in the Figure 1 below.

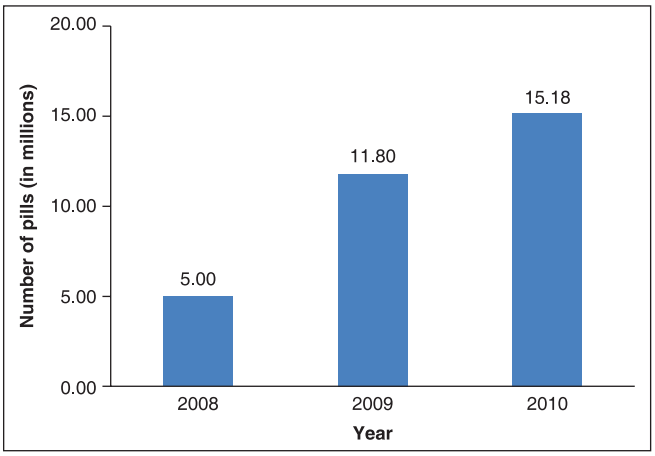

Figure 1: Graph showing the trend in increase for ECP sale in India

Seventy-one percent of total sales are in urban areas, which constitute only 29.8 percent of the national population. The 18 large Metro cities contribute 29 percent of the total sales, while Delhi NCR alone contributes 8.6 percent of total sales, followed by Mumbai and Kolkata. In Chennai, the sale of ECP was negligible as sale of ECP in Tamil Nadu is banned. However, access to ECP is low in smaller towns and in the rural areas. The AC Neilsen ORG MARG data further shows that although there are 42 brands of ECP being sold in the market, only a few brands control the major market share. For example, in 2010, 2 top brands accounted for more than 84 percent of the sale as a result of aggressive promotion and good commission paid to the retailers. Furthermore, the contribution of public health clinics in free distribution of ECP is marginal.[7] The government procures ECPs and provides it free-of-cost from its health facilities, and tries to reach at the door steps in rural areas through the Accredited Social Health Activist (ASHA) since 2011. However, according to the Annual Health Survey in 2010-11, only 0.12 percent of the rural women had ever used ECP.[2] NFHS3 shows that less than 1 percent are aware of ECP.[1] They face barriers such as lack of accessibility or relatively high cost (ranging from Rs. 2 for the government brand to Rs. 100 for the most popular commercial urban brand) of the product.

Mainstreaming of ECP

For the present study, "mainstreaming" has been defined as making ECP readily accessible at an affordable price in the basket of contraceptives for anyone who needs it. At the policy level, ECP is included in the national family welfare program. However, there is a need for better supply, training of providers, and linking it with regular family planning programs. When ECP was introduced, no sustained efforts were made to educate about ECP at any level of providers — doctors, ANMs, and ASHA. Some senior officials of the MoHFW believed

that there is no need to train healthcare providers in ECP, as the leaflet provided with the pill is self-explanatory. To make contraceptives easily accessible in rural India, the MoHFW made ASHA the depot holder of these methods. Initially, this scheme was implemented in 184 backward districts on a pilot basis and expanded to the entire country. Under the scheme, ASHA can charge Re. 1 for a pack of 3 condoms, Re. 1 for 1 month's cycle of OCP, and Rs. 2 for 1 pill of ECP.[8] If the contraceptive supplies are maintained as per requirement, this scheme has potential for making these methods easily accessible to the beneficiaries even in the remote villages. However, success of the scheme is dependent on regular supply of these methods and correct knowledge of ASHAs and their counseling skills. Some of the studies show that contraceptive supply is a serious issue and needs immediate action.[5,7,9] Evaluation of the depot scheme of ASHA reported that 46 percent ASHAs had lack of supply due to challenges in management of the supply chain.[7] A recent study showed that 97 percent ASHAs in Bihar had not been supplied ECP and only 14 percent were aware of the correct use of the method.[10] This indicates that for mainstreaming of ECP, not only do women need to know about the methods but the providers also need to be educated about the correct use of ECP and availability needs to be ensured. The consultations emphasized that counseling of ECP should be linked to counseling of other methods, i.e., every time they counsel for OCPs and condoms, they should inform their clients about ECP as back-up emergency method.

Knowledge of ECP and ambiguity regarding mechanism of action

The Population Council study in 2011 showed that majority of the providers including gynecologists believed that ECP works by preventing implantation (96%), which was indicated in the 20th edition of Contraceptive Technology.[11] However, subsequent studies documented that there is no scientific evidence that ECP interferes in implantation of fertilized egg. It was well established by 2012 that its primary mechanism of action is by inhibiting ovulation.[12-14] A meta-analysis of 444 articles confirmed that ECP does not interfere with fertilized egg and does not prevent implantation.[15] However, during the consultations both in Delhi and Mumbai, most of the doctors were not aware of this and were still of the view that ECP works by preventing implantation.

ECP is a safe and effective method with no contraindications. However, according to the providers' study, doctors have misconceptions about contraindications and side effects. Many incorrectly believe that ECP should not be used by women in pregnancy, breastfeeding, and various other illnesses.[5,6] Some doctors also expressed the fear that repeat use of ECP could lead to ectopic pregnancy. However, many studies including a systematic review of 136 studies ruled out any increased risk of ectopic pregnancy due to mifepristone and levonorgestrel emergency contraception.[16] ECPs, like other contraceptives, reduce the chance of ectopic pregnancy.[17,18] Such misconceptions about ectopic pregnancy among professionals need to be addressed.

While most doctors in the consultation felt that ECP could not induce abortion, the Council's study showed that 10 percent of the doctors believed that ECP could be used as an abortion pill. This misbelief and a confusion between OCP, ECP, and abortion pills was also reported by ASHAs and ANMs.[7] The consultation unanimously agreed on the need to educate the providers as well as the users on this aspect and eradicate the misbelief that ECP could also be used as abortion pills.

During consultations many senior gynecologists, including three of the past and current Presidents of FOGSI felt that the recent research findings were not reaching doctors and gynecologists, and hence, they continue to believe that the main mechanism of ECP is preventing implantation. There was a general consensus that medical associations such as FOGSI and IMA could play a critical role in disseminating new research and findings on ECP through their national, state, and regional conferences and through their newsletters and articles in their journals.

Attitudes of Providers on

In the providers' study, in-depth interviews of KOLs and during the two consultations, questions were asked regarding the attitude of the doctors on different aspects of ECP use. The responses are briefly summarized below:

Provision of ECP

Gynecologists have strong influence on policymaking and uptake among beneficiaries and hence have major role in mainstreaming of ECP. The reservations amongst gynecologists is a barrier to access of ECP for those who need it.[6,19-21] Research findings show that gynecologists opposed ECP provision as a prophylactic (51 percent), as an OTC product (64 percent), by ASHA (52 percent), and without an age restriction (83 percent). A senior gynecologist at the consultation meeting said, "*even though our attitudes have changed in the past 10 years on the use and provision of ECP, we still do not want to inform a young girl about ECP. She is just informed that she needs to be careful and seek help if unprotected sex or gynecological problems occur*".

Perception about ECP users

According to Council's study, gynecologists believed that women who use ECP have premarital sex, have multiple sexual partners, have STIs, have risky sexual

behavior, and could substitute ECP for other family planning methods. Gynecologists' interviews by national media also support these findings.[3,4,22] These attitudes also influence provision of ECP services by gynecologists and general medical practitioners. For example, during the ECP study, the ECP supplied by the government was lying in large number in a corner but not given to beneficiaries because of the lady doctor in-charge of the clinic had instructed the Social Worker who dispensed contraceptives to "*….not give ECP to any one unless I prescribe it*".

Most doctors said that married women and women who have infrequent or unprotected sex can use ECP but fewer agreed to its use by unmarried adolescents. It is important to note that the available evidence does not show any linkages between ECP use and sexual behavior.[23-27] Another study showed that use of ECP does not increase risky sexual behaviors or decrease use of other contraceptive methods.[28-30]

ECPs role in reducing abortion

During the consultations, it emerged that there is no consensus on the role of ECP in reducing abortion. While a few felt that the number of young girls seeking abortion in their clinic has decreased, others did not support this observation. For example a senior gynecologist, during in-depth interview, said "*…the number of young girls who used to come for abortion has declined. In my own clinic 2-3 unmarried young girls used to come every month. Now it is rare. So perhaps ECP does reduce unnecessary abortions.*" However, the quantitative study did not report any such impact of ECP. Evidence also reported no public health effect of ECP.[31,32] The consultations strongly recommended that the role of ECP in abortion should not be debated and women must have access to safe and hygienic abortion services as their right.

Pharmacists attitudes

Pharmacists are the main providers of ECP in urban areas and have a major role in mainstreaming ECP. In the consultation, most of the participants including manufacturers felt that it is difficult to use the pharmacists to provide information on ECP to their clients. Generally, the shops are crowded and women and men who come for purchase of ECP may not like to discuss it with the pharmacist nor the pharmacists have time to explain it to them. The Council study in which 199 pharmacists were also interviewed revealed that many of the pharmacists also have reserved attitudes towards the users and felt that use of ECP will lead to premarital sex and promiscuity (74 percent and 46 percent, respectively), as one of the pharmacist said, "*Almost all who come to this shop are unmarried girls and boys*".[33] They were also in favor of an age restriction to use ECP (76 percent). Curiously, for them their personal attitude did not interfere in stocking and selling ECP as it was their business. In Delhi during qualitative interviews of pharmacists, 24 out of 28 pharmacists' qualitative interviews said that they receive 50 to 70 percent of commission from medical representatives to sell their brand. A pharmacist said that "*The medical representative told me that there is a big margin in ECP and motivated me to keep ECP*", and another reported that "*Money is the motivator.*" Attitudes of different providers from the Council study, presented and discussed in the consultation, are reported in Table 1 below.

ECP replacing use of other contraceptive method

Discussion on possibility of ECP replacing or reducing regular family planning use, had a mixed reaction in the consultations as well as in the study of the providers. However, in general, majority felt that in absence of evidence it is difficult to believe that women are switching over from regular method to ECP. It was argued that given the cost of ECP, its use as a regular method could be a strong deterrent. In contrast some studies indicate that instead of reducing the use of regular family method, ECP could play bridging role, as many women after using ECP switch over to regular method or to an effective modern method. For example, a Bangladesh study showed that after using ECP, 96 percent of women who were earlier using a method went back to their previous method.[30] Of the 16 percent of women who were not using any method, 68 percent adopted contraception after using ECP. A similar study in India, showed that use of regular methods (condoms, OCP, CuT, and sterilization) increased from 13 percent to 70 percent after ECP use.[34]

Repeated use

The discussion on repeated use of ECP revealed that most of the experts as well as respondents in the Council study lacked clarity whether ECP could be used repeatedly within the same menstrual cycle. During the consultation and KOLs in-depth interviews, senior gynecologists said that they were getting increasing number of cases with menstrual disturbance. The consensus was that repeat use would be harmful as it could disrupt a woman's menstrual cycle and may not protect against unwanted pregnancy.

Table 1: Attitude of various providers towards ECP (percentage)

Attitude	Doctors (*n* = 83)	Paramedics (*n* = 33)	Pharmacists (*n* = 199)
Disapproved ECP as OTC drug	67	61	34
Favored minimum-age restriction	84	94	74
ECP will promote promiscuity	45	59	46
ECP may be used as regular contraceptive	39	30	31
Approved prophylactic provision of ECP	48	58	58
Disapproved ECP provision by CHWs	53	36	19

Source: Khan *et al*., 2012

However, a representative from the ICEC endorsed WHOs statement that *"Repeated use poses no known health risks"*.[35] A senior gynecologist also added that *"there is no contraindication to repeated ECP use, and women should not be denied repeat access to ECPs if needed"* (Association of Reproductive Health Professionals) and "…, *in particular when pregnancies are unintended and women do not have access to safe abortion services. Women should use ECPs as often as needed*" (International Consortium for Medical Abortion).[36] At the end of deliberation, most recommended that ECP could be used only in an emergency, as recommended by the government, or if it's necessary, not more than 2-3 times in the same menstrual cycle.[37]

Advertisement for demand generation

At the time of introduction of ECP, aggressive advertisements by some manufacturers attracted negative attention and led to nationwide ban on advertising. A Chennai-based lawyer who represented parent's associations in the high court pleading for banning its sale in Tamil Nadu said, *"such an advertisement takes away responsibility from the act of sexual intercourse; and the branding (of this pill) is also not so subtle insinuation that pre-marital sex is alright"*.[38]

All representatives of different manufacturing firms felt that in absence of permission for advertisement, promotion of ECP in smaller towns and urban areas is a big challenge, and many firms may discontinue manufacturing it. A senior government official, informed that a decision had been taken to allow advertisements, provided a committee formed by the MoHFW approves the content. Given the long procedure of government approval on advertising, it is discouraging to manufacturers and they may not seek such permission.

High cost of many popular brands of ECP makes ECP less affordable to the poorer section of population. Lack of advertisement makes manufacturing companies dependent upon pharmacists to stock and promote demand for their product. To attract pharmacies to stock their product, manufacturers are forced to pay unusually high commission to the pharmacists thereby persuading them to keep the price high. If advertisement is allowed and people are aware of all available brands, clients could demand a brand of their choice, thus forcing pharmacists to stock more than one brand and making ECP cheaper is economically viable. Similar concerns were expressed at the consultations by social marketing firms who sell ECP at a marginal profit. This limits them in expanding to smaller towns and rural areas, where there is lack of awareness and little demand. This makes ECP a non-attractive product for pharmacists, who do not want to block their money and shelf space on a slow moving product.

Way forward

Based on the study, consultations and the model for change, which emerged from these discussions, Table 2

Table 2: Addressing barriers to improve access to ECP

Barriers	Activities	Outcome (process variables)	Outcome	Impact
Negative Attitude of Doctors: Reservations of Ob/Gyns on ECP use and misperceptions about ECP/ECP users leading to negative environment and continued biases against ECP	Involve medical associations (IMA, FOGSI) to address the reservations	Support by well informedmedical fraternity will create conducive environment	Improved access to and better social environment for ECP	Increased adoption of modern FP methods due to bridging effect Reduced unwanted pregnancy
Lack of knowledge and misconception about ECP among ASHA and other providers	Include ECP in current training of ASHA on ECPand trainers Include ECP in teaching/ training of all levels of providers	Correct knowledge of providers about ECP will help reduce reserved attitude towards ECPand its users		
Media: Restrictive policy on advertisement of ECP and poor demand generation activity Negative Coverage: Press and magazinesuse medical barrier and create negative image of ECP	Relax advertisement policy and provide guidelines to avoid negative image Educational campaign for all with focus on young population for correct use of ECP			
Press and magazinesuse medical barrier and create negative image of ECP	Educate and involve media. Scientific discussion should replace the moral policing Women's rights issue for choice should be highlighted and advocated	Increase in awareness and knowledge will help De-stigmatization of ECP users Link ECP use as back-up support with other spacing methods Women's rights issue addressed through proper program	Improvement in correct use of ECP	
Supply Chain Management: Difficult procurement procedure and lack of supply/stock out	Advocacy with MoHFW to strengthen procurement and supply chain. It could be outsourced	Increase access, zero stock out and informed choice	Increased demand, sale and use, leading to reduced price and increased affordability	

recommends a framework for consideration of all stakeholders for mainstreaming of ECP in the national family welfare program.

Conclusion

The Population Council study and the consultations brought to light several critical issues to be addressed for mainstreaming ECP. Several barriers including lack of correct knowledge about ECP, and myths and misconceptions related to its effectiveness and contraindications were identified among providers including senior gynecologists. Most of the providers demonstrated reservations about easy access and use of ECP. Among doctors, strong tendency of medicalization of ECP was observed and reflected in opposing continuation of ECP as OTC drug or making it available through CHWs such as ASHA. Disapproving attitude of providers and perceived reservations about the users could be serious barriers to expanding access to ECP. While manufacturers and social marketing firms could contribute in mainstreaming ECP, their profit motives limits their activities to large urban areas, and to relatively better-educated audiences who can afford to pay high cost of ECP. Restrictive policy by government on advertisement further dampens ability of manufacturers and social marketing firms to expand to smaller towns and rural areas. The poor and rural segment of the population are left to the public health system, where demand generation, supply chain and providers reservations are major barriers. The study findings followed by consultations helped identify various ways through which these barriers could be addressed and help in contributing in mainstreaming of ECP.

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