THE USE OF EMERGENCY CONTRACEPTIVE PILLS IN INDIA: A SYSTEMATIC REVIEW

PRAYAS HEALTH GROUP

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Ritu Parchure I Nikisha Mehta I Shrinivas Darak

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Authors

Ritu Parchure, Nikisha Mehta, Shrinivas Darak

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Prayas Health Group
Amrita Clinic, Athawale Corner Building
Karve Road, Deccan Gymkhana
Pune 411004, India
www.prayaspune.org/health
email- health@prayaspune.org

About Prayas Health Group

Prayas (Initiatives in Health, Energy, Learning and Parenthood) is a non-governmental, non-profit organization based in Pune, India. Prayas Health Group is committed to generate evidence based discourse on emerging issues on sexual and reproductive health and rights (SRHR). We also strive towards improving access to health care for these issues. PHG is actively involved in socio-behavioural and epidemiological research, awareness building, programmatic interventions and provision of clinical and counselling services especially to persons living with HIV.

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Key Points

- Emergency contraceptive pills (ECPs) are available in the country for a long time now. Several concerns have been raised about its misuse/overuse. This systematic review seeks to understand the patterns of use of ECPs and clarify some uncertainties surrounding the issue.

- Majority of the literature from India is cross-sectional in nature. The proportion of EC pill users ranges widely (0 to 84%). Poor methodological quality of these studies raises questions about the validity, reliability, and generalizability of the findings. The use is mostly understood in the context of marriage leaving out vulnerable populations like adolescent girls, unmarried women, and female sex workers.

- Repeat use of ECPs remains unexplored with patchy information and varied definitions. Although inadequate, the evidence does not support concerns about misuse of ECPs.

- Moralistic attitudes among healthcare providers, gender inequality pose significant barriers to the access of ECPs. Easy access in the form of advance provision of ECPs improves its uptake. More importantly, easy access does not increase unsafe sexual behaviors or irrational use among women.

- There is little information on adverse health effects of repeat use of ECPs as well as its contribution to preventing morbidity and mortality related to unintended pregnancies. A better understanding of positive as well as negative health impacts of ECPs is important in shaping the discourse in right direction.

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Introduction

Unplanned pregnancies are a major public health concern all over the world. It is estimated that of the 210 million pregnancies that occur each year, 80 million are unplanned.[1] Almost 214 million women of reproductive age in developing countries who want to avoid pregnancy, are not using a modern contraceptive method.[2] With an estimated 48.1 million pregnancies in India in 2015, 33% pregnancies ended in induced abortions.[3] The national family health survey (NFHS-4) report indicates that almost 13% of currently married women have an unmet need for family planning.[4] The need varies across subgroups; the unmet need is higher among adolescents, migrants, slum dwellers, and postpartum women.[5]

India's family planning program offers a wide range of modern contraceptive options. ECPs were officially introduced under the Family Welfare Programme in 2002-03.[6] EC refers to methods of contraception that can be used to prevent pregnancy after sexual intercourse (post-coital). ECPs and copper-bearing intrauterine devices (Cu-IUD) are the two forms of EC available. The copper-bearing IUDs prevent fertilization by causing a chemical change in the sperm and egg before they meet. The Levonorgestrel (LNG) only pill, which is the most commonly used ECP, prevents fertilization by thickening the cervical mucus and inhibiting ovulation. Cu-IUD, when used as an emergency contraceptive method, should be inserted within 5 days of unprotected intercourse.

ECPs are recommended for use within 5 days (120 hours) of sexual intercourse but are more effective if used sooner. The terms 'morning after pill' and 'after sex pill' are often used to describe it, however, it causes confusion regarding the time and purpose of the approach, and is best avoided. Emergency contraception can be used in the following situations - unprotected intercourse, concerns about possible contraceptive failure, incorrect use of contraceptives, and sexual assault without contraception. These pills are not recommended as regular contraceptive methods and are meant for occasional use only (*please refer to Appendix 1 for more information on ECPs).*

ECPs are now a part of the Essential Drug List (EDL) for primary healthcare and have been included in Accredited Social Health Activist's (ASHA), Auxiliary Nurse Midwife's (ANM) and Lady Health Visitor's (LHV) kits to address unwanted pregnancies. In 2005, ECPs became available as an over the counter (OTC) drug, when pharmacies were allowed to sell the product without prescription.[7] Despite easy availability, the level of awareness of this method of contraception remains limited. In

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[1] Department of Reproductive Health and Research, World Health Organisation (2012) Unsafe abortion incidence mortality. Retrieved from: http://apps.who.int/iris/bitstream/handle/10665/75173/WHO_RHR_12.01_eng.pdf?sequence=1

[2] Guttmacher Institute (2017) Adding it up: Investing in contraception and maternal and newborn health. Retrieved from: https://www.guttmacher.org/fact-sheet/adding-it-up-contraception-mnh-2017#seenote

[3] Singh, S., Shekhar, C., Acharya, R., Moore, A., Stillman, M., Pradhan, M., Frost, J., Sahoo, H., Alagarajan, M., Hussain, R., Sundaram, A., Vlassoff, M., Kalyanwala, S., Browne, A., (2018) The incidence of abortion and unintended pregnancy in India, 2015. *The Lancet Global Health,* 6(1), PE111-E120

[4] International Institute of Population Sciences (IIPS), & ICF 2017 (2015-16) National Family Health Survey (NFHS-4), India, Mumbai: IIPS. Retrieved from: http://rchiips.org/NFHS/NFHS-4Reports/India.pdf

[5] World Health Organisation (2019) Sexual and reproductive health: unmet need for family planning. Retrieved from: https://www.who.int/reproductivehealth/topics/family_planning/unmet_need_fp/en/

[6] Anonymous, (n.d.) National Family Welfare Programme. Retrieved from: http://pbhealth.gov.in/pdf/FW.pdf

[7] Dixit, A., Khan, M., &Bhatnagar, I., (2015) Mainstreaming of emergency contraception pill in India: challenges and opportunities. *Indian Journal of Community Medicine,* 40(1), 49-55

2015-16, around 85% women were aware of oral contraceptive pills (OCPs) and only 38% women had knowledge of ECPs.[8] The level of awareness was lower in unmarried women compared to married ones, and rural women compared to urban. Anecdotal evidence shows that there has been a rise in the sale of ECPs in the last decade. Most healthcare providers appear to have concerns over the misuse/overuse of ECPs and its adverse effects on women's health. However, the available evidence including the NFHS-4 report and other scientific studies report that the proportion of use of ECPs is quite low. According to the NFHS-4 report, only 0.4% had ever used ECPs and only 0.2% had used ECPs in the past 12 months.[9] Also, there is very little evidence on the adverse effects of ECP use in India.

To resolve these contradictions about usage and address the concerns about its health impact, we synthesized the exiting evidence on ECP use in India.

[8] International Institute of Population Sciences (IIPS), & ICF 2017 (2015-16) National Family Health Survey (NFHS-4), India, Mumbai: IIPS. Retrieved from: http://rchiips.org/NFHS/NFHS-4Reports/India.pdf

[9] International Institute of Population Sciences (IIPS), & ICF 2017 (2015-16) National Family Health Survey (NFHS-4), India, Mumbai: IIPS. Retrieved from: http://rchiips.org/NFHS/NFHS-4Reports/India.pdf

Methods

Objective

This systematic review aimed to understand the patterns of use of ECPs in India (ever use and repeat use) and the factors associated with its use.

Types of studies

The review is confined to all primary studies assessing the use and repeat use, and the side effects associated with ECPs. It excludes meta-analysis, systematic reviews and overviews. It excludes studies confined to (i) regular contraceptive methods or; (ii) assessment of only awareness/knowledge/attitudes towards ECPs; and; (iii) the effectiveness of ECPs. Articles published only in the English language were included. Studies restricted to India were included.

Studies conducted on, both women and men were considered, however, the male population was excluded while calculating proportions of use of ECPs. The emergency contraceptive pills included in the review were all doses of oral LNG. Studies using any other form of emergency contraceptive were excluded. Studies comparing the efficacy or adverse effects of different forms of ECPs were excluded.

Search methods

The search attempted to identify all relevant articles in the English language. For the review, we searched PubMed, Popline and Google Scholar databases. For identification of studies included in or considered for this review, detailed search strategies with relevant search terms were developed for each database. The search strategy for PubMed was developed first and revised appropriately for Popline and Google Scholar to take into account syntax rules and controlled vocabulary. The PubMed search strategy combined subject terms, free text terms, and appropriate Mesh terms. Details of search strategies and data extraction are presented in Appendix 2. All references cited in the included articles were checked for additional studies. The search was undertaken in the month of July 2018.

Methodological Quality

Quality assessment was carried out after data extraction. Most of the studies included in this review were cross-sectional studies. The Newcastle Ottawa Scale adapted for cross-sectional studies was used to assess quality.

Findings & Analyses

This section elaborates on the findings of the review and its interpretations.

Selection of studies

The electronic database search yielded 284 articles. Articles cited as references in the included studies were checked and 11 relevant articles from those references were included in this review. Thirty-one duplicates were identified and removed. Title and abstract screening was carried out for 264 articles of which 222 were considered to be ineligible. Full articles were obtained for the remaining 42 studies. From the full articles, nine studies were ineligible. The PRISMA chart below illustrates our screening process.

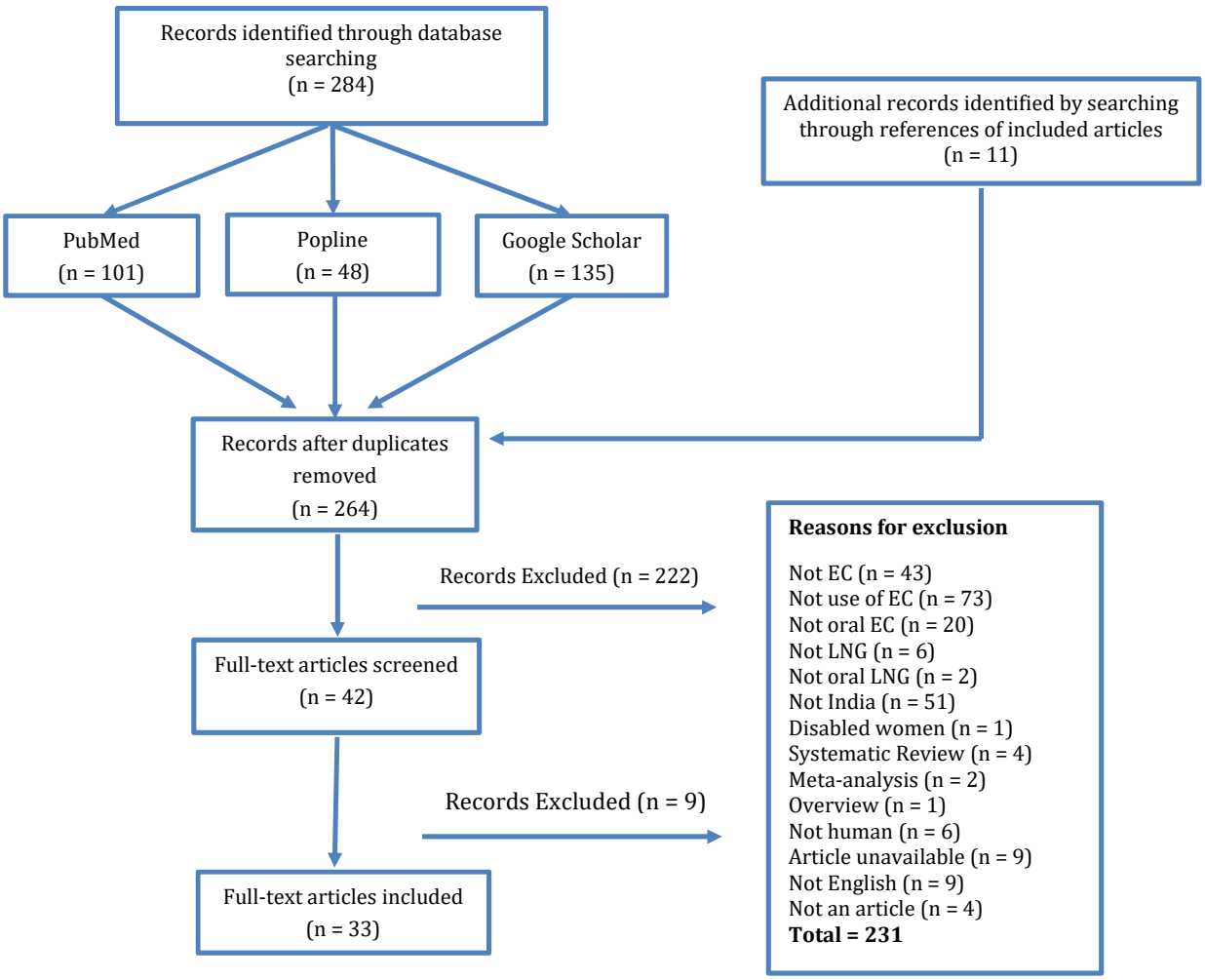

Figure1. PRISMA chart illustrating the screening process

Study characteristics

Of the 33 included studies, 30 were conducted among women[10] and provided quantitative information on use or repeat use of ECPs, one was a case study on adverse effects of using levonorgestrel (LNG) as an EC; one study assessed medical practices and attitudes of gynaecologists; and one assessed the practices of pharmacists. Of the 30 studies done among women, 27 were cross-sectional studies. Two prospective cohort studies assessed the impact of advance provision of ECPs and one was a prospective observational study which assessed the use of contraceptives in relation to the choice of formulation.

Thirty-three articles were eligible for this review and were published between 2001 and 2017. Table 1 and 2 illustrate details on the methods and findings of each study.

The studies were conducted across India. The state-wise distribution of the studies is as follows - Karnataka (n=5), Maharashtra (n=4), Delhi (n=4), New Delhi (n=2), Uttar Pradesh (n=3), Sikkim (n=2), Haryana (n=2), West Bengal (n=2), Uttarakhand (n=1), Madhya Pradesh (n=1), Puducherry (n=1), Jammu & Kashmir (n=1), Chhattisgarh (n=1) and Chandigarh (n=1). Fourteen studies did not report the area where the study was conducted. Thirty studies provided information on the use or reuse of ECPs (27 cross-sectional, one prospective observational, two prospective cohorts). Of these, 10 studies were conducted in urban areas, four in rural areas and two were conducted in both rural and urban areas.

The sample size of the 30 studies that provided information on the use or reuse of ECPs, ranged from 131 to 1474. Of these studies, 16 studies were conducted in health care facilities (11 in hospitals, three in family planning clinics, one in a government health centre, one in a public health centre), seven in community settings, and four in colleges. Of the four, one had medical college students, one had engineering college students, one had students pursuing post-graduation and one had professionals as respondents. Three studies did not report the study site and of all the studies only 7 gave a detailed description of sampling methods. Although some studies had reported that participants were randomly selected/assigned, methods used for randomization of individuals was not explicitly explained. All studies conducted in healthcare facilities (hospitals, family planning clinics, government health centre, and public health centre) used purposive sampling to recruit individuals.

Characteristics of the study population

Nine studies were conducted on married women only, nine on both married and currently single (never been married, separated, divorced, widows), and one study was conducted on all unmarried women. Eleven studies did not report the marital status of the participants. Eighteen studies included participants below 20 years of age and only one study was conducted among female sex workers. While 27 studies reported the literacy level of participants, only 10 studies reported their socioeconomic status. Fourteen articles reported the use of other regular methods of contraception (like natural methods, condoms, intrauterine device, oral contraceptive pills, female sterilization) and 11 studies reported the side effects associated with the use of ECPs.

[10] With the exception that two studies - Mandal 2012& Arora 2005were conducted on both men and women

Proportion of women using ECPs

Of the 27 cross-sectional studies that have reported the use of ECPs, the data reported in two articles (Arora *et al.* &Mishra *et al.*) are misleading/confusing. In the remaining 25 studies, the proportion of ECP use ranges from 0 to 84%. However, these proportions must be interpreted with caution as the denominators used for calculating these proportions vary across studies. Of the cross-sectional studies, 15 studies considered the total study population for calculating proportions of ECP use, six studies considered only a subset of the study population, that is, women who had knowledge of ECPs, one study considered women who had sexual exposure in the last one year, one study considered women who were using either a permanent or temporary method of contraception, one considered sexually active participants only and one did not give an explanation.

Two prospective cohort studies included in this review assessed the use of ECPs among women who were offered counselling and advance provision of ECPs. Both were randomized control trials and it was observed that having advance supplies of ECPs did not increase their chances of having unprotected sex. However, if they did have unprotected sex, those with advanced supplies were more likely to use them. Despite improved accessibility, ECPs did not substitute the ongoing regular methods of contraception.

Only 10 studies provided data on ECP use by socio-demographic factors. However, the data was not sufficient for subgroup analysis. Of all the cross-sectional studies, six articles reported ECP use by area (urban/rural), two studies reported use by socioeconomic status, and only one each reported ECP use by literacy level and marital status. It is known that women's contraceptive practices change with socio-demographic characteristics like age, marital status and parity, however, the studies don't take much cognizance of these factors. Most of the studies that recruited sample from family planning clinics included women seeking abortion services. The likelihood of these women using ECPs is clearly different from women seeking regular contraceptive services. Unfortunately, none of the studies explore these differences.

A multi-country analysis of the use of ECPs shows lesser proportions, than the studies included in this report. The proportion of sexually experienced women who had ever used ECPs ranged from less than 0.1% in Chad to 12% in Colombia.[11] This proportion is a mere 0.4% according to the Indian national family health survey.[12] The proportions observed in the included studies, however, must be interpreted with caution as most studies used purposive sampling, had much smaller sample sizes and numerous methodological limitations.

Repeat Use of ECPs

Only eight studies reported data on repeat use. The two prospective studies reported it as the number of times individuals used ECPs during the one year follow-up period. Among the rest, three reported repeat use as the number of times individuals ever used ECPs, two reported the number of times individuals used ECPs in the last one year and one reported as the number of times individuals

[11] Palermo, T., Bleck, J., & Westley, E., (2014) Knowledge and use of emergency contraception: a multicountry analysis. *International Perspectives on Sexual and Reproductive Health,* 40(2), 79-93

[12] International Institute of Population Sciences (IIPS), & ICF 2017 (2015-16) National Family Health Survey (NFHS-4), India, Mumbai: IIPS. Retrieved from: http://rchiips.org/NFHS/NFHS-4Reports/India.pdf

used ECPs in a year. None of the authors provide information on repeat use of ECPs in the same menstrual cycle. Almost all these studies, except one, have recruited samples from a family planning clinic, raising concerns about the representativeness of the sample.

Of the five cross-sectional studies, the proportion of repeat use of ECPs ranged from 12% to 69%. Among the two prospective cohort studies, the study by Rocca *et al.* reported that around 46% women used ECPs two or more times whereas, the other study by Ellertson *et al.* reported no repeat use among women. In both the studies, women were offered an advance provision of ECPs. Although the proportions of repeat users appear to be high, it is worthwhile to note that this repeat use is spread over one year or more. This means that frequent use of ECPs in the same menstrual cycle is very low. Although limited, the evidence clearly shows that there is no irrational use/overuse/misuse of ECPs, a concern commonly raised by health care providers.

Some of these studies have used the term *'regular user'* to describe a repeat user. Guha *et al.* referred to individuals who have used ECPs more than once in their life as regular users. Purohit *et al.* referred to individuals who use ECPs in non-emergency situations as regular users, however, the author does not mention what is considered as a non-emergency situation.

Adverse effects associated with the use of ECPs

Nine studies reported adverse effects associated with the use or reuse of ECPs. Of the cross-sectional studies, six studies reported that the most common adverse effect was nausea, vomiting, and menstrual problems. In one study, no adverse effects were observed.

Reasons behind the use or non-use

Some studies also reported reasons for use or non-use of ECPs. Six articles reported reasons for using ECPs and the most frequently reported reason was unprotected intercourse followed by condom slippage/tear. Five studies reported reasons for not using ECPs and the most frequently reported reason was religious/cultural beliefs followed by fear of side effects and inadequate knowledge (in terms of not knowing where one can get it or dosage and timing of use). The religious and cultural beliefs could be associated with the fact that a majority of the women think of an ECP as an abortifacient and in most cultures aborting a foetus is considered a taboo.

Table 1: Details of cross-sectional studies reporting use/repeat use of ECPs

Sr No	Author (year)	State/Region	Study site and sample size [j]	Marital status of women	Proportion of ECP users	Proportion of repeat users [i]
1	Ahmad 2016[a]	Delhi	Hospital (n=190)	Not reported	36.3%	69.5%
2	Arora 2005[a,g]	New Delhi	Family Planning Clinic (n=37)	All married	0	-
3	Arora 2013[c]	Delhi	College (n=110)	Both married and unmarried	12.7%	In the last 1 year: Twice - 28.5% Thrice or more - 21.4%
4	Awasthi 2013[b]	Uttarakhand	Community (n=406)	Not reported	6.9%	-
5	Dahiya 2012[a]	Haryana	Hospital (n=55)	Majority married	72.7%	-
6	Fernandes 2014[b]	Karnataka	Public Health Centre (n=350)	All married	2%	-
7	Gupta 2012[a]	Jammu & Kashmir	Community (n=60)	Not reported	13.3%	-
8	Kaushal 2014[b]	Madhya Pradesh	Hospital (n=1042)	Majority married	7.7%	-
9	Kose 2012[a]	Maharashtra	Hospital (n=164)	All married	4.8%	-
10	Kotwal 2017[b]	Not reported	Hospital (n=500)	Not reported	12%	-
11	Kumar 2015[b]	Haryana	Not reported (n=540)	Not reported	20%	-
12	Lafort 2017[b]	Karnataka	Not reported (n=455)	Only 54% married	2.4%	-
13	Makade 2012[b]	Maharashtra	Community (n=342)	All married	0	-
14	Mandal 2012[d]	West Bengal	College (n=42)	Only 13.8% married	26.2%	27.3%
15	Mittal 2007[a]	New Delhi	Hospital (n=4)	Not reported	0	-

16	Mishra 2017[b,g]	Uttar Pradesh	Hospital (n=385)	Majority married	73%	-
17	Nivedita 2014[f]	Puducherry	College (n=105)	Only 35% married	22.7%	-
18	Puri 2009[b]	Chandigarh	Community (n=1448)	All married	1.4%	-
19	Purohit 2013[e]	Not reported	Community (n=19)	All unmarried	83.9%	66.9%
20	Rahman 2013[a]	Sikkim	Hospital (n=598)	Only 38.7% married	15.1%	-
21	Rahaman 2010[c]	Sikkim	Hospital (n=112)	Only 55% married	12%	-
22	Raikar 2015[b]	Karnataka	Community (n=286)	All married	3%	-
23	Relwani 2012[a]	Maharashtra	College (n=139)	Not reported	5.8%	-
24	Singh 2014[b]	Chhattisgarh	Hospital (n=300)	All married	19.3%	12.1% used it more than once in a year
25	Srivastava 2005[b]	Uttar Pradesh	Not reported (n=281)	Majority married	0	-
26	Umashankar 2013[a]	Karnataka	Family Planning Clinic (n=3)	Not reported	0	-
27	Verma 2015[b]	Delhi	Community (n=410)	All married	9%	-
28	Guha 2017[h]	West Bengal	Hospital (n=367)	Not reported	17.4%	Twice - 5.7% More than twice - 7.6%

'n' refers to the population used to calculate proportion of use of ECPs

a - Proportions of ECP use calculated using the total study population as the denominator

b - Proportions of ECP use calculated using the number of women who had knowledge of ECPs the denominator

c - Author has not given an explanation for the denominator used when calculating proportions of ECP use

d - Proportions of ECP use calculated using the number of women who were sexually active in the last one year

e - Proportions of ECP use calculated using the number of women who were sexually active

f - Proportions of ECP use calculated using the number of women who used either a temporary or permanent method of contraception

g - The data provided on ECP use is misleading/confusing/inconsistent

h - Although it was a prospective observational study, no details were provided on follow up. The history of use and repeat use of ECP was assessed using a one-time interview.

I - calculated among women who had used ECPs)

J – Sample size considered for calculating proportion of use of ECPs

Table 2: Details of other studies exploring various dimensions of ECP use

Author (year)	State/Region and study site	Study design	Sample size	Aim/Objective	Findings
Ellertson 2001	Maharashtra Family Planning clinic	Prospective cohort	Arm 1 (Information only) – n=198 Arm 2 (Information and supplies) – n=213	To determine whether multiple courses of emergency contraceptive therapy supplied in advance of need would tempt women using barrier methods to take risks with their more effective ongoing contraceptive methods	Women given advance supplies reported unprotected intercourse at rates nearly identical to those among women given only information (0.012 versus 0.016 acts per month). Among those who did have unprotected intercourse, however, supply recipients were nearly twice as likely (79% versus 44%) to have taken emergency contraception. No women used emergency contraception more than once during the study. All women found knowing about emergency contraception useful, and all those receiving only information wished they had received supplies as well.
Rocca 2013	Karnataka Government Health Centre	Prospective cohort	EC counselling and supplies were offered to 322 women.	To assess the acceptability and use of LNG ECs in young married women who were offered EC counselling and advance provision in a clinical research setting. In addition, factors associated with EC use were examined.	A total of 228 (70.8%) EC study participants consented to EC counselling and 123 (38.2%) requested advance provisions of ECPs after counselling. Overall, 37 women used ECPs during the follow-up period (14.1% of women in the study and 33.0% of women who took advance provisions). Most used the method once (54.1%); 24.3% used it twice; 18.9% used it thrice, and 1 woman used it 6 times. Majority of the women who used EC pills sought husband's permission.
Khan 2014	Uttar Pradesh (Agra, Aligarh, Lucknow)	Mixed methods study	A survey among 63 gynaecologists and 20 general practitioners/other specialists In-depth interviews	The study explores the perceptions and attitudes of medical doctors in India about ECPs and how those might contribute to medical barriers and reduced access	Doctors had strong reservations against OTC provision of ECPs by pharmacists and community health workers (CHWs) and negative attitudes toward ECP users. About 75% thought that ECP users have multiple sex partners while 53% thought that women using ECPs were more likely to have sexual encounters early/at a young age. About 78% of the doctors felt that it should not be used

			with 19 key opinion leaders		more than once in one menstrual cycle and not be used as a regular method of contraception.
Mishra 2013	Delhi	Cross-sectional	65 pharmacies	To evaluate the knowledge and over-the-counter services provided y the pharmacists in an urban city of India	Number of packs sold in a month per pharmacy varied from 2 to 500 packs/month. Only 18% clients were referred by doctors. One-third of the clients were adolescents. Almost 67% pharmacists had adequate knowledge of EC. None of the pharmacists inquired if: (i) there were one or multiple acts of unprotected intercourse or, (ii) any regular contraceptive method was being used. None explored the reasons for use of ECPs. Only 3.3% asked about the last menstrual period or the time elapsed since the last unprotected sexual encounter. The dosage schedule was explained to the clients by 91.7% pharmacists. Only half of them explained that the client may experience side effects. None of the pharmacists advised their clients for a sexually transmitted disease screening, and 35% counseled the clients regarding regular contraception.
Ghosh 2009	Not reported	Case study	Hospital	To highlight ectopic pregnancy as a potential adverse effect of using LNG as an emergency contraceptive	In spite of prompt use (within 12 h of intercourse) in the correct phase of cycle (preovulatory) in a woman with no pre-existing risk factors for ectopic gestation, LNG failure resulted in an ectopic pregnancy.

Perceptions of healthcare providers

There were two studies among healthcare professionals. One study (Khan, 2014) was conducted among gynaecologists in Uttar Pradesh to assess their knowledge, attitudes, and practices regarding ECPs and the other (Mishra, 2013) on practicing pharmacists in Delhi to evaluate their knowledge and over-the-counter sale of ECPs. In their study, Khan *et al.* found that gynaecologists play an unfavourable, self-identified role of moral policing where negative judgments are made about ECP users. About 75% of the respondents thought that ECP users have multiple sex partners while 53% thought that women using ECPs were more likely to have early sexual encounters/sexual encounters at a young age. While only 21% of the doctors believed that young unmarried women use ECPs, over three-quarters of them considered marriage an important criterion for appropriate use of ECPs.

In the study by Khan *et al.* a gynecologist with a private practice said that:

"I do feel that the easy availability of ECPs has increased the sexual contacts among young girls. There is a lot of misuse of ECPs by the current generation."

Some respondents also felt that with ECPs being easily available at pharmacies as an OTC drug there is a constant fear of women misusing the drug. They felt that there should be a minimum-age restriction for buying ECPs.

"I personally feel that it should not be sold as an OTC drug. Though it reduced unwanted pregnancy, misuse is increasing. I feel that publicity of ECPs and its availability as an OTC product is not good. Women come to us only when complications arise due to repeat use; [they] never come for counselling or advice before use. The main reason for such misuse is the lack of knowledge and awareness among the public regarding its appropriate use."

There were also concerns about women using ECPs on several occasions, which actually made it a regular contraceptive for these women; however, findings from two studies in our review contradict these concerns. In their study (Rocca, 2013 & Ellertson, 2001), they found that advance provision of ECPs improves an individual's uptake of pills but does not lead to unsafe sexual practices or misuse of pills.

There was a substantial confusion about the definition of repeat use of ECPs and its possible adverse effects. About 78% of the doctors felt that it should not be used more than once in one menstrual cycle and not be used as a regular method of contraception. Their perceptions of adverse effects varied from irregular bleeding patterns including excessive menstrual bleeding (85%), to nausea (20%) and weakness (12%). About 24% thought it leads to ectopic pregnancies and infertility. As a result of the use of ECPs, 40% of the doctors have seen an increase in patients with menstrual problems. Most of them think that there is little or no evidence suggesting a change in abortion-seeking behaviours of young or unmarried women as a result of ECPs. However, 3 gynaecologists felt that there has been a decrease in the frequency of young girls seeking an abortion.

"... the number of young girls who used to come to me for abortion has declined. In my own clinic 2-3 young girls used to come every month. Now it is rare."

This data should be carefully interpreted as the gynecologists have based the above finding solely on their own private practice.

In their study, Mishra *et al.* found that only 18% of their clients who bought ECPs were referred by doctors. The number of packs sold by pharmacies per month ranged from 2 to 500 with a mean of 62 a month. Of the 60 pharmacists, 38 claimed that individuals bought ECPs once a month, 62% claimed that a majority of their customers repeated use in the same month. Only 2 pharmacists claimed that the same clients bought ECPs as high as even 30 times a month. Around two-thirds of the pharmacists had adequate knowledge of ECPs. About one-third of the clients at pharmacies were adolescents, and of all the customers that approached the pharmacy for ECPs, 53% were males and 47% females. Most pharmacists felt that it was easier to communicate with males than females, as communicating with the latter was a little embarrassing. Interactions with the customers were difficult because of lack of time & knowledge and because they didn't want to lose the customers. Despite this, most pharmacists reported that they provided information on dosage and side effects.

There is a large discrepancy in the data reported by the NFHS-4 survey, this review and data from studies on pharmacists and gynecologists. While only 0.4% women (Urban - 0.6% & Rural - 0.3%) ever used ECPs in the NFHS-4 survey, our review shows that the proportion of use of ECPs ranges from 0 to 84%. One study conducted on doctors, to assess the perception of doctors towards the use of ECPs, showed that there is rampant use of ECPs. However, this data must be interpreted with caution as the studies included in our review are smaller, low-quality studies and the NFHS-4 is a much larger high-quality survey. Also, the perceptions of gynaecologists are mainly based on their own private practices.

The role of gender norms in ECP use

This review also explored the decision-making paradigm of family planning and emergency contraceptive use. While ECPs are relatively easily available contraceptives for women, a myriad of factors come to play in depriving women the right to control their own bodies and pregnancies. In India, gender norms, power relations, and socio-cultural values and beliefs limit opportunities for women.[13,14] A woman's 'value' within and outside her family is merely reduced to her ability to reproduce. We came across similar findings in our study, where the man appears to be the decision maker.

A study by Makade *et al.* reported:

"…. in 41.45% cases decision about family planning was taken mutually by the husband and wife; in 30.77% cases taken independently by the husband, in 26.07% cases by the wife and in 1.71% cases by in-laws."

Another study by Rocca *et al.* reported that of the 94 participants who opted out of ECP counselling, where the most common reason for opting out was concerns about husband's disapproval. The study also reported that among women who consented to participate:

"Most women spoke to their husbands prior to EC use (26 [70.3%]) or asked their husbands for permission (25 [67.6%])."

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[13] Sen, G., &Ostlin, P. (2008) Gender inequity in health: why it exists and how we can change it. *Global Public Health,* 3(1), 1-12

[14] Hawkes, S., &Buse, K., (2013) Gender and global health: evidence, policy and inconvenient truths. *The Lancet,* 381, 1783-87

In the studies mentioned above, in-laws were consulted 10.8% of the times in one study and 1.71% of the times in the other. This indicates the power relations that are deeply ingrained in our society where the power to make decisions still lies in the hands of men alone and the in-laws. An equal number of men and women buying ECPs from pharmacies is a more hopeful finding from a study in Delhi, however, the other studies also show that that's not the case all over India. Moralistic attitudes from healthcare providers are deeply problematic and can severely reduce access of ECPs to vulnerable populations of the country like young girls.

In a study by Khan *et al.* gynecologists reported:

"With the influence of western culture and values, young people view casual sex as a normal activity, making the pill a powerful tool in a woman's hands."

Quality of included studies

The Newcastle Ottawa Scale adapted for cross-sectional studies was used to assess the methodological quality of cross-sectional studies that provided information on the use or repeat use of ECPs. Of the 25 cross-sectional studies[15], only six studies have satisfactory quality. The remaining 19 studies are of poor quality and overall the scores ranged from one to six.

It must be noted that we came across three articles with inconsistent data reported on ECP use. Due to these reporting errors, it was difficult for us to estimate the proportions of ECP use and interpret the findings of the study.

Similarly, Mishra *et al.* in their article report that *"The majority of females, 73% (281)* ***felt*** *that they used EC before."* It is very difficult for us as reviewers to interpret if the women actually used ECPs or not.

Another article (Singh *et al.*) reported *"58 of 300 i.e. 19.6% had ever used ECPs"* in the narrative of the article, however, a table in the paper shows 58 i.e. 19.3% respondents used ECPs.

We came across some studies in which authors had reported that participants were randomly selected/assigned, however, methods used for randomization was not explained. It is essential for authors to give a detailed explanation of how the randomization of participants was done to improve transparency and both methodological and reporting quality of papers.

[15]Considering the misleading information provided in Arora *et al.* & Mishra *et al.,* it was anyway considered poor quality

Summary of review findings

The available literature on the use of ECPs focuses mainly on the proportion of ECP use and most of them are cross-sectional studies. The studies are of low methodological quality and raise questions about the validity, reliability, and generalisability of the findings. Misuse of ECPs which has been a major public health concern for healthcare providers and policymakers remains inadequately explored.

1. In this review, the proportion of ECP use among women ranges widely:
    a. The proportion of women who 'ever used ECPs' ranges widely, from 0 to 84%. These high proportions are likely to be result of small sample sizes and purposive sampling used in most of the studies. Majority of studies were conducted in health care settings. The findings therefore are not representative and need to be interpreted cautiously.
    b. The evidence shows that easy access to ECPs does not increase unsafe sexual behaviours.
    c. The studies fail to provide data on the use of ECPs by socio-demographic factors (age, area of residence, marital status, socioeconomic status, literacy levels). There is a limited representation of vulnerable populations like unmarried/single women and female sex workers.
2. Little information available on repeat use of ECPs:
    a. Only eight studies provide information on repeat use of ECPs. Most authors have described repeat use of ECPs in a span of one year. The proportion of women who used ECPs more than once ranged from 12% to 69%. The sample size considered for assessing repeat use in this review was very small and recruited from health care facilities, thus questioning its generalizability. The studies also did not report on repeat use in the same menstrual cycle. The evidence is inadequate to draw any conclusions. However, it also does not support possibility of rampant misuse.
    b. Repeat use of ECPs may be indicative of an unmet need of regular contraception. The knowledge about profile of repeat users can help programs design better out-reach strategies. However, none of the studies in this review attempted to identify socio-demographic factors associated with repeat use.
3. Moralistic attitudes of healthcare providers, gender norms and power relations around reproductive health decisions impede women's access to ECPs:
    a. In a married context, men have the power to make decisions about pregnancy. The same is also reflected in the attitudes of healthcare providers.
    b. Prevailing moralistic attitudes among healthcare providers limit access to ECPs.

Implications for future research

1. Repeat use of ECPs remains inadequately explored. there is a need for a more accurate definition of repeat use of ECPs that is well correlated with possible adverse events. Longitudinal studies that provide information on repeat use in one menstrual cycle are more likely to provide a better understanding about the burden of adverse effects.
2. There is a need to explore socio-demographic factors associated with the use and repeat use of ECPs (in terms of who are the repeat users and reasons for repeat use). The evidence generated can then be used by existing family programmes to refine program strategies.
3. It is necessary for authors to be careful when reporting the use of ECPs. Using parameters like 'ever used ECPs' provides data that is indefinite. A more helpful/meaningful parameter would be - use of ECPs in the last 12 months. Using a time frame helps address problems like recall bias and provides a better understanding of the use or repeat use of ECPs. Also, information on sexual behaviours of participants (whether they were sexually active in the last 12 months, number of times they have had sexual encounters in the last month and so on) would provide a better understanding of met or unmet need for contraception.
4. This review found a lot of articles where authors had reported that the participants were randomly selected/assigned but failed to explain the methods used. It is essential for authors to give a detailed explanation of how the randomization of participants was done to improve transparency and both methodological and reporting quality of papers.
5. The cost-benefit ratio of any intervention is an important piece of information for policymakers. The existing evidence hardly provides any information on the public health impact of EC pill use on unwanted pregnancy and abortion rates.

Implications for Family Planning programs

1 In a marital setting, the husband appears to play a critical role by making decisions about pregnancies and ECP use, thus making it equally important to counsel men/husbands/partners. At the same time, it must be remembered that ECPs are an important female-controlled contraceptive method and there is a need to enable women to control their own pregnancies. A multi-sectoral approach where family programs include or collaborate with life skills training programs that empower women to make their own decisions, will go a long way in bringing about the necessary changes. Also, simpler measures such as advance provisions can further facilitate access to emergency contraception.

2 Currently, ECPs are available at all public healthcare facilities and program outreach services; however, the private health sector remains the dominant provider of ECPs. As reported by the NFHS-4, the most common source of ECPs was pharmacies followed by private doctors and the public health sector. The ASHA/ANM/AWW as a source, contribute only around 3%. Facilitating access of ECPs through the public health sector is crucial and needs urgent attention. The attitudes of society at large and healthcare providers, in particular, play a pivotal role. In the current situation, it would be difficult for a woman to walk up to a pharmacy or a doctor for ECPs. Accessing ECPs becomes even more difficult for vulnerable populations like unmarried or single women. Sensitizing public and private healthcare providers is crucial. Their heightened concerns about misuse/excessive use, possibly coming from the deep-rooted gender in-sensitive patriarchal norms of sexual behaviours, need to be addressed.

3 In the current discourse, ECP use is mostly understood in the context of marriage. However, more efforts are needed at the program level to ensure that they are easily accessible to everyone irrespective of marital status.

Abbreviations

ASHA - Accredited social health activists

ANM - Auxiliary nurse midwives

Cu-IUD - Copper-bearing intrauterine device

ECP - Emergency Contraceptive Pill

EC - Emergency contraception

EDL - Essential Drug List

IUD - Intrauterine device

LHV - Lady health visitor

LNG - Levonorgestrel

MoHFW - Ministry of Health and Family Welfare

NFHS - National Family Health Survey

OTC - Over the counter

STD - Sexually transmitted disease

Appendix 1. About Emergency Contraceptive Pills

History

A few decades ago, rumoured folk methods for contraception like postcoital douching with coca-cola or water, consuming raw papaya and vaginal sponges were a woman's only alternative. The roots of emergency contraception date back to the 1920s when veterinarians administered estrogen to dogs and horses that mated when their owner had not wanted them to. Clinical use of postcoital estrogen in humans was first documented in the mid-1960s, when physicians in the Netherlands gave high doses of estrogen to prevent pregnancy of a 13-year-old girl who had been raped.[16] These preparations soon became standard and women took either conjugated estrogens, non-steroidal estrogendiethylstilbestrol or steroidal estrogenethinylestradiol. As effective as it was in preventing implantation, it was associated with harmful adverse effects.[17]

In the early 1970s, a Canadian physician Albert Yuzpe and his colleagues began further research on a combination of estrogen-progestin standards. This combination came to be known as the 'Yuzpe regimen' (100μg ethinylestradiol and .5 mg levonorgestrel) and it had replaced the traditional estrogen because it had lesser side effects as compared to the previously used standards.[18]Groundbreaking research of the late 1970s led to the development of copper-releasing IUDs, the main non-hormonal method available today. A number of studies conducted at the same time suggested that Levonorgestrel (LNG) alone might prove useful as an emergency contraceptive pill. WHO conducted the first study comparing the effectiveness of LNG with the Yuzpe regimen and found that if consumed within 48 hours of unprotected coitus LNG was equally effective and had lesser adverse effects.[19] It formed the groundwork for making levonorgestrel the drug of choice.

ECPs were traditionally designed as a rescue/backup measure for women who have had unprotected intercourse or in case of failure of regular contraceptive methods.[20] The availability of ECPs over the counter has raised many concerns about repeated use, however, there exists no consensus for what comprises repeat use or the threshold at which repeat use becomes unsafe. Individual studies conducted earlier found LNG unsuitable for use as a regular contraceptive method postcoitus.[21,22] Halpern et al. (2014) in their review, however, highlighted the need for more rigorous research on the efficacy and side effects of repeat use of the drug.[23]

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[16] Morris, J.M., Wagenen, G. (1973) Interception: the use of Postovulatory Estrogen to Prevent Implantation. *American Journal of Obstetrics and Gynaecology,* 115, 101-6

[17] Ellertson, C., (1996) History and efficacy of emergency contraception: beyond coca-cola. *Perspectives on Sexual and Reproductive Health: a journal of peer-reviewed research,* 28(20)

[18] Consortium for Emergency Contraception in India (n.d.) *Guide Book for Healthcare Providers: Training Manual.* Retrieved from: https://www.aiims.edu/aiims/events/Gynaewebsite/ec_site/manual.htm

[19] Ho, P.C., Kwan, M.S., (1993) A Prospective Randomised Comparison of Levonorgestrel with the Yuzpe Regimen in Postcoital Contraception. *Human Reproduction,* 8, 389-92

[20] Rome, E.S., &Issac, V. (2017) Sometimes you do get a Second Chance: Emergency Contraception for Adolescents. *PediatrClin N Am,* 64, 371-80

[21] United Nations Development Programme. (2000) Efficacy and Side Effects of Immediate PostcoitalLevonorgestrel Used Repeatedly for Contraception. *Contraception,* 61, 303-08

[22] Chin-Quee, D., L'Engle, K., Otterness, C., Mercer, S., Chen, M., & FHI 360. (2014) Repeat Use of Emergency Contraceptive Pills in Urban Kenya and Nigeria. *International Perspectives on Sexual and Reproductive Health: A Journal of Peer-Reviewed Research,* 40(3), 127-28

[23] Halpern, V., Raymond, E.G., Lopez, L.M. (2014) Repeated Use of Pre- and PostCoital Hormonal Contraception for Prevention of Pregnancy. *Cochrane Database of Systematic Reviews,* 9, CD007595. DOI: 10.1002/14651858.CD007595.pub3.

Types & Mechanism of Action

The methods available for emergency contraception have evolved over the years. Its use has increased rapidly in countries where products are available OTC. The most common and widely used method of emergency contraception is LNG (1.5 mg). The table below shows the different types of emergency contraceptive methods used today:

Types	**Mechanism of Action[24,25]**
Yuzpe Regimen	It works by inhibiting implantation of a fertilized egg.
Levonorgestrel-only	It prevents fertilization by thickening the cervical mucus and inhibits ovulation if given when the ovarian follicle measures around 12-17 mm in diameter. However, once luteinizing hormone starts surging it ceases to have an effect on ovulation.[26]
Ulipristal Acetate (UPA)	It is a progesterone receptor modulator and inhibits or delays ovulation. It remains effective even if it is taken after the luteinizing hormone surge, however, it has no effect on ovulation once luteinizing hormone has reached its peak.
Mifepristone	It is a selective progesterone receptor modulator and affects the endometrium. It can both, inhibit implantation and act as an abortifacient.
Cu-IUD	If inserted after fertilization, it can inhibit implantation. If inserted before fertilization, it prevents the oocyte from being fertilized.

Efficacy

In a study, WHO (1998) compared the efficacy of LNG (2 doses of 0.75 mg given 12 hours apart) with Yuzpe regimen.[27]

Treatment	**Efficacy (%)**	**95% CI**	**Number of participants**
Levonorgestrel	86	74-93	976
Yuzpe regimen	58	41-72	979

[24] Shen, J., Che, Y., Showell, E., Shen, K., & Cheng, L. (2017). Interventions for emergency contraception. *Cochrane Database of Systematic Reviews*, 8, CD001324. DOI: 10.1002/14651858.CD001324.pub5.

[25] ESHRE CapriWorkshop Group, Baird, D.T., Cameron, S., Evers, J.L.H., Gemzell-Danielsson, K., Glasier, A., Moreau, C., Trussell, J., von Hertzen P.G. Crosignani, H., La Vecchia, C., Volpe, A. (2015) Emergency Contraception. Widely Available and Effective but Disappointing as a Public Health Intervention: a review. *Human Reproduction*, 30(4): 751-60

[26] Gemzell-Danielsson, K., &Marions, L. (2004) Mechanism of Action of Mifepristone and Levonorgestrel When Used for Emergency Contraception. *Human Reproductive Update,* 10(4), 341-48

[27] World Health Organisation Methods for Fertility Regulation, (1998) Randomised Controlled Trial of Levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet*, 352, 428-33

Another study, von Hertzen et al. (2002) compared the efficacy of Levonorgestrel with Mifepristone and found that LNG had an efficacy rate of 80% (95% CI 71.2-85.6).[28]

Adverse Effects

In a review, Shen et al. (2017) compare the effectiveness and safety of the aforementioned methods of EC. Mid-dose mifepristone (25 - 50 mg) was found to be most effective followed by low-dose mifepristone (<25 mg). Ulipristal Acetate and mifepristone was found to be more effective than LNG. Yuzpe regimen was the least effective. While nausea and vomiting were the main side effects associated with EC, participants also complained of spotting or bleeding after treatment, early menses and late menses. Some studies also reported headache, dizziness, fatigue and abdominal pain within 24 hours of treatment.[29]

Any Side Effect **Anticipated Absolute Effects (95% CI)**		**Relative Effect (95% CI)**	**Number of participants**
Levonorgestrel	**Yuzpe regimen**	RR 0.80 (0.75-0.86)	1955 (1 RCT)
545 per 1000	681 per 1000		
Mid-dose mifepristone (25-50 mg)	**Levonorgestrel (1.5 mg)**	RR 0.55 (0.40-0.74)	4352 (18 RCTs)
111 per 1000	202 per 1000		
Low-dose mifepristone (<25 mg)	**Levonorgestrel (1.5 mg)**	RR 0.26 (0.17-0.38)	609 (3 RCTs)
89 per 1000	342 per 1000		
Mifepristone (all doses)	**Yuzpe regimen**		
610 per 1000	735 per 1000	RR 0.83 (0.77-0.88)	1693 (2 RCTs)
Ulipristal Acetate (all doses)	**Levonorgestrel**		

[28] Von Hertzen, H., Piaggio, G., Peregoudov, A., Ding, J., Chen, J., Song, S., Bartfai, G., Ng, E., Gemzell-Danielsson, K., Oyunbileg, A., et al. for the WHO Research Group on Postovulatory Methods of Fertility Regulation. Low dose Mifepristone and two regimens of Levonorgestrel for Emergency Contraception: A WHO multicentre randomised trial, *Lancet*, 360, 1803-1810

[29] Shen, J., Che, Y., Showell, E., Shen, K., & Cheng, L. (2017). Interventions for emergency contraception. *Cochrane Database of Systematic Reviews*, 8, CD001324. DOI: 10.1002/14651858.CD001324.pub5.

Lack of evidence			
Low-dose mifepristone	**Mid-dose mifepristone**	RR 1.31 (1.01-1.70)	2464 (11 RCTs)
88 per 1000	115 per 1000		
Copper Intrauterine device	**Mifepristone (all doses)**	RR 0.06 (0.00-0.99)	285 (1 RCT)
5 per 1000	84 per 1000		

Appendix 2. Search strategy

Search terms

Intervention of Interest	Emergency contraceptive, emergency contraception, postcoital contraceptive, postcoital contraception, emergency contraceptive agents, postcoital contraceptive agent, female emergency contraception, female emergency contraceptive agent, emergency pill, e-pill, morning after pill, levonorgestrel
Outcome of interest	Use, utilisation, utilization, repeat use, repeated use, reuse, behavior, behaviour, practice, therapeutic use, contraceptive usage, contraceptive practice, contraceptive behaviour,
Outcome of interest	Adverse effects, negative effects, complications, side effects, contraceptive agents side effects
Population	India, indians

Search strategy

Database	**PubMed**
Strategy	#1 AND #2 AND #3 AND #4 OR #1 AND #2 AND #4 OR #5 AND #4
#1	“Emergency contraception” OR “emergency contraceptive” OR "postcoital contraception" OR "postcoital contraceptive" OR "emergency pill" OR "morning after pill" OR "e-pill" OR "emergency contraceptive agent" OR "postcoital contraceptive agent" OR "levonorgestrel"
#2	"use" OR "utilisation" OR "utilization" OR "repeat use" OR "repeated use" OR "reuse" OR "behavior" OR "behaviour"
#3	"side effects" OR "adverse effects" OR "complications" OR "negative effects"
#4	"India" OR "Indians"
#5	“Levonorgestrel/adverse effects"[Mesh] OR "Levonorgestrel/therapeutic use"[Mesh] OR "Contraception, Postcoital/adverse effects"[Mesh] OR "Contraception, Postcoital/therapeutic use"[Mesh] OR "Contraception, Postcoital/utilization"[Mesh] OR "emergency contraception" OR "Contraception, Postcoital/adverse effects"[Mesh] OR "Contraception, Postcoital/therapeutic use"[Mesh] OR "Contraception, Postcoital/utilization"[Mesh]

Database	**Popline**
Strategy	#1 AND #2 AND #3 AND #4 AND #5
#1	"emergency contraceptive" OR "emergency contraception" OR "female emergency contraception" OR "female emergency contraceptive agents" OR "postcoital contraceptive" OR "postcoital contraception" OR "emergency contraceptive agents" OR "postcoital contraceptive agents" OR "emergency pill" OR "e\-pill" OR "morning after pill" OR "levonorgestrel"
#2	"contraceptive usage" OR "contraceptive practice" OR "contraceptive behaviour" OR "use" OR "utilisation" OR "utilization" OR "repeat use" OR "repeated use" OR "reuse" OR "behavior" OR "behaviour" OR "practice" OR "therapeutic use"
#3	"adverse effect" OR "negative effect" OR "complication" OR "side effects" OR "contraceptive agents side effects"
#4	"India" OR "Indians"
#5	Filter - English

Database	**Google scholar**
#1	"emergency contraceptive use" OR "emergency contraceptive practice" OR "emergency contraceptive reuse" OR "emergency contraceptive repeat use" OR "postcoital contraceptive use" OR "emergency pill use" OR "levonorgestrel utilization" AND "India"