Population Effect of Increased Access to Emergency Contraceptive Pills

A Systematic Review

Elizabeth G. Raymond, MD, MPH, James Trussell, PhD, and Chelsea B. Polis

OBJECTIVE: We systematically reviewed data on effects of increased access to emergency contraceptive pills on pregnancy rates and use of the pills.

DATA SOURCES: We searched MEDLINE, POPLINE, EMBASE, and LILACS, and we consulted with experts.

METHODS OF STUDY SELECTION: We included studies that compared the effect of different levels of access to emergency contraceptive pills on pregnancy rates, use of the pills, and other outcomes.

TABULATION, INTEGRATION, AND RESULTS: Of the 717 articles identified, we selected 23 for review. The studies included randomized trials, cohort studies, and evaluations of community interventions. The quality of these studies varied. In all but one study, increased access to emergency contraceptive pills was associated with greater use. However, no study found an effect on pregnancy or abortion rates.

CONCLUSION: Increased access to emergency contraceptive pills enhances use but has not been shown to reduce unintended pregnancy rates. Further research is needed to explain this finding and to define the best ways to use emergency contraception to produce a public health benefit.

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From Family Health International, Research Triangle Park, North Carolina; Office of Population Research, Princeton University, Princeton, New Jersey; and Department of Population, Family and Reproductive Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland.

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Corresponding author: Elizabeth Raymond, MD, MPH, Clinical Research Division, Family Health International, PO Box 13950, Research Triangle Park, NC 27709; e-mail: eraymond@fhi.org.

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Of the 3.1 million annual unintended pregnancies in the United States, most result from situations in which pregnancy risk is immediately evident: a condom breaks, birth control pills are taken inconsistently, or incorrectly, or no contraception is used at all.[1] Increasing women's ability to obtain and use emergency contraceptive pills promptly after such events should improve their chances of averting pregnancy. A modeling exercise published in 1992 suggested that widespread use of emergency contraceptive pills had the potential to cut the number of induced abortions in the United States by at least half.[2]

During the past several years, this potential has been assessed in numerous studies that evaluated various strategies designed to enhance women's access to emergency contraceptive pills. Here we review the findings of these studies, focusing particularly on the strategies' effect on emergency contraceptive pill use and pregnancy rates. This paper will be supplemented by a planned review on this topic for the Cochrane collaboration, which will include statistical meta-analyses that estimate the combined effect of advance provision of emergency contraception on a variety of outcomes among all randomized controlled trials.[3]

SOURCES

In August 2006, we used the following strategies to search MEDLINE, POPLINE, EMBASE, and LILACS databases for studies that presented data comparing the effects of different levels of access to emergency contraceptive pills. The strategies included terms signifying emergency contraception combined (except for the LILACS database) with terms signifying access and had no time restriction.

MEDLINE: search with Ovid as follows: (exp Contraceptives, Postcoital OR postcoital contracept$.mp. OR exp Contraception, Postcoital OR

"emergency contracept$".mp. OR "morning after pill$".mp. OR "day after pill$".mp. OR Yuzpe.mp. OR contracept$, postcoital.mp.) AND ("advance$ provision".mp. OR ("self administ$".mp. NOT "self administ$ question$".mp.) OR home.mp. OR "over the counter".mp. OR "behind the counter".mp. OR exp Health Services Accessibility OR "pharmac$ access".mp. OR exp Community Pharmacy Services OR "pharmac$ provision".mp. OR advance prescri$.mp. OR "expanded access".mp. OR "increase$ access".mp.), Limited to English language. Search with PubMed as follows: (contraceptives, postcoital or postcoital contracept* or emergency contracept* or morning after pill* or day after pill* or Yuzpe or contracept*, postcoital) and (advance* provision or ((self administration or self administered) NOT self administered question*) or home or over the counter or OTC or behind the counter or health services accessibility or pharmac* access or community pharmacy services or pharmac* provision or advance prescri* or expanded access or increase* access)) Limited to English language OR ((contraceptives, postcoital OR contraception, postcoital OR postcoital contracept* OR "emergency contraceptives" OR "emergency contraception" OR "morning after pill" OR "day after pill" OR yuzpe) AND (advance* OR home OR over the counter OR OTC OR behind the counter OR health services accessibility OR community pharmacy services OR access), All languages

POPLINE: (emergency contracept* / postcoital contracept* / morning after pill* / morning after contracept* / morning-after pill* / morning-after contracept* / day after pill* / day after contracept* / day-after pill* / day-after contracept* / yuzpe) & (advance* prov* / self administ* / self-administ* / home / over the counter / over-the-counter / behind the counter / advance prescript* / pharmac* access / pharmac* prov* / expand* access / increase* access) All languages

EMBASE: (yuzpe or morning(w)after(w)pill or morning(w)after(w)contracept? or 'postcoitus contraceptive agent' or postcoital contracept? or postcoit-?(w)contracept? or emergencey(w)contracept? or emergency contraception or emergency(w)contracept?) and (over(w)the(w)counter or over the counter or otc or (advance and (access or provision or provid?)) or advance) All languages

LILACS: (emergency AND contracept$) OR Yuzpe OR (morning AND after AND pill$) OR (morning AND after AND contracep$) OR (emergency contraception or emergency contraceptive or emergency contraceptives or postcoital contraceptive or postcoital contraceptives or postcoital contraception or contraceptives, postcoital or anticonceptivos, poscoito or anticoncepcionais, pos-coito or anticoncepcion postcoital or anticoncepcao pos-coito or contraception, postcoital [Words] or morning after pill or (morning and after and (pill or contraceptive or contraception or contraceptives)) or Yuzpe [Words]) All languages

We also examined reference lists from articles identified through the research and spoke with other experts in the field to find additional published or unpublished studies.

STUDY SELECTION

Our searches identified a total of 717 articles. Two authors (E.G.R. and J.T.) independently reviewed all information about these articles provided by the databases. We selected studies of any design that yielded primary data comparing effects of interventions or programs with different levels of access to emergency contraceptive pills. We excluded 694 from this review, including 689 that did not contain any primary data comparing interventions, two that presented the same data or a subset of data published in prior papers,[4,5] and three that evaluated a change in legislation in specific parts of Great Britain,[6–8] because a subsequent study reported on the same issue for the whole country.[9] Thus, 23 articles met our selection criteria. Two or three authors (E.G.R., J.T., and C.P.) then independently abstracted relevant data from the selected studies. We contacted authors of five of the studies to clarify the information presented in their publications.[10–14] We resolved any discrepancies through consensus. We assessed the quality of the design, implementation, and analysis of each study, and when possible we tabulated the data on pregnancies and emergency contraceptive pill use.[15] We did not perform statistical meta-analysis, because study design of our included studies differed substantially.

RESULTS

The 23 included studies were conducted in 10 countries, and all were reported between 1998 and 2006. Ten randomized trials and four cohort studies prospectively allocated women to either an increased access intervention group or a control group and followed up the women individually to ascertain outcomes (Table 1). These 14 studies enrolled a total of 13,564 women. In each of these studies, the intervention included provision of one or more free emergency contraceptive pill packages at enrollment that women could keep at home and use later if needed. The interventions differed in their aggressiveness. In one study, each woman in the intervention group was

Table 1. Description of Studies With Individual Allocation of Participants to Intervention or Control Group

Study	Population	Interventions*	Primary Outcomes
Randomized trials			
Ellertson 2001[13]	411 condom users in India	Three courses of emergency contraceptive pills (Yuzpe regimen) free on enrollment compared with information only	Unprotected sex
Hazari 2001[11]	200 condom users in India	One course of emergency contraceptive pills (Yuzpe regimen) free on enrollment with unlimited free replacements as requested compared with information only	Emergency contraceptive pill use
Jackson 2003[14]	370 postpartum women in California	One course of emergency contraceptive pills (Yuzpe regimen) free on enrollment with unlimited free replacements as requested compared with routine contraception counseling	Use of emergency contraceptive pills and other contraceptives, unprotected sex, knowledge
Gold 2004[10]	301 adolescents aged 15–20 y in Pennsylvania	One course of emergency contraceptive pills (Yuzpe or levonorgestrel regimen) free on enrollment with up to 2 free replacements upon request compared with information only	Unprotected sex, use of emergency contraceptive pills, use of other contraceptives
Lo 2004[21]	1,030 family planning clients aged 18–45 y in China	3 courses of emergency contraceptive pills (levonorgestrel regimen) on enrollment with up to 6 replacements as requested compared with information only	Use of emergency contraceptive pills and other contraceptives
Belzer 2005[12]	160 parous adolescents aged 13–20 y in California	1 course of emergency contraceptive pills (levonorgestrel regimen) free on enrollment with one free replacement upon request compared with information only	Use of emergency contraceptive pills and other contraceptives, unprotected sex
Hu 2005[20]	2,000 postpartum women in China	3 courses of emergency contraceptive pills (mifepristone) free on enrollment compared with information only. Emergency contraceptive pills (levonorgestrel regimen) available over the counter in community	Abortion
Raine 2005[19]	2,117 family planning clients aged 15–24 y in California	1) 3 courses of emergency contraceptive pills (levonorgestrel regimen) on enrollment compared with 2) unlimited prescription for free emergency contraceptive pills compared with information only	Pregnancy, sexually transmitted infections
Raymond 2006[16]	1,490 family planning clients aged 14–24 y in North Carolina and Nevada	Two courses of emergency contraceptive pills (levonorgestrel regimen) on enrollment with free replacements as each course was used compared with standard access at usual cost	Pregnancy, sexually transmitted infections
Walsh 2006[18]	2,868 family planning clients in California	One course of emergency contraceptive pills (levonorgestrel regimen) free on enrollment compared with information only	Use of emergency contraceptive pills, use of other contraceptives, pregnancy, attitudes
Cohort studies			
Glasier 1998[24]	1,083 emergency contraception and abortion clients aged 16–44 y in Scotland	One course of emergency contraceptive pills (Yuzpe regimen) free on enrollment with unlimited free replacements upon request compared with information only. Allocation by birth date	Pregnancy, use of emergency contraceptive pills and other contraceptives
Skibiak 1999[23]	900 new acceptors of oral contraceptive pills or condoms in Zambia	1) 1 package of emergency contraceptive pills (Yuzpe) on enrollment compared with 2) prescription for 1 free package of emergency contraceptive pills compared with information only. Alternate allocation	Emergency contraceptive pill use, condom use
Lovvorn 2000[22]	211 spermicide users aged 18–44 y in Ghana	1 course of emergency contraceptive pills (Yuzpe regimen) free on enrollment with free replacements as requested compared with information only. Allocation by site	Unprotected sex, emergency contraceptive pill use
Raine 2000[17]	263 family planning clients aged 16–24 y in California	One course of emergency contraceptive pills (Yuzpe regimen) free on enrollment compared with information only. Alternate allocation	Use of emergency contraceptive pills and other contraceptives, unprotected sex, knowledge

* Yuzpe regimen was two doses of 100 mcg ethinyl estradiol plus 0.5 mg levonorgestrel taken 12 hours apart; levonorgestrel regimen was two doses 0.75 mg levonorgestrel taken either together or 12 hours apart; mifepristone regimen was 10 mg mifepristone.

given two packages of emergency contraceptive pills at enrollment, and thereafter the study team made proactive efforts to promptly replace each package used or lost.[16] However, in other studies, the interventions were weaker: two studies dispensed only one package of emergency contraceptive pills and allowed no refills,[17,18] and the rest either provided multiple packages at enrollment, allowed women to obtain additional packages at the study site, or both. In most studies, women in the control groups were advised about how to obtain emergency contraceptive pills outside the study at the time of need; however, one study did not provide even this information routinely.[14] The control participants' access to emergency contraceptive pills varied. In some studies, women had to see a clinician to obtain the pills, whereas in two of the largest studies, emergency contraceptive pills were available over the counter or behind the counter.[19,20] In addition, control participants had to pay for the emergency contraceptive pills in some settings,[16,20] but in at least one study, most control women could obtain the medication for free.[19] Charges in other studies were not clearly reported. Thus, the difference in access between the intervention and control groups was less in some studies than in others.

Most of the 14 individually allocated studies had low power to detect even moderate differences in pregnancy rates between groups. Only four were designed with pregnancy as a planned primary outcome. In some of the studies, the study population was not at high risk for unintended pregnancy or abortion, as demonstrated by low rates in the control groups or nonintervention settings.[20,21] Outcome ascertainment approaches also varied. Pregnancies were detected by participant report, supplemented in some studies by chart review and scheduled or indicated pregnancy testing. In four studies, pregnancies were not reported for the intervention and control groups. Data on emergency contraceptive pill use were obtained exclusively by participant report and was thus not verifiable. Planned follow-up duration ranged from 3 to 12 months. The proportion of enrolled women who did not complete the planned follow-up was very high (more than 30%) in at least four of the studies (Table 2).

An additional nine studies included in our review did not assign individual participants to intervention or control groups (Table 3). Rather, these studies compared population-level statistics in settings where the intervention was implemented to corresponding statistics in other times or settings. Interventions included legislation allowing distribution of emergency contraceptive pills over the counter or behind the counter from a pharmacist, provision of an advance supply of emergency contraceptive pills, implementation of a telephone prescription service, and introduction of a dedicated product by a pharmaceutical company. In the reports of these studies, information on factors other than the intervention that might have influenced the findings was limited or nonexistent. Some reports provided no evidence about the penetration of the intervention in the study community, so the proportion and characteristics of the population actually exposed was therefore unclear. These studies also suffered from other weaknesses akin to those noted for the studies using individual allocation, including populations at low risk for pregnancy, relatively easy emergency contraceptive pill access in the control settings, and possibly incomplete reporting of outcomes.

The specific emergency contraceptive pill regimens used in the 23 studies included the Yuzpe regimen (two doses of 100 mcg ethinyl estradiol plus 0.5 mg levonorgestrel taken 12 hours apart), the levonorgestrel-only regimen (two doses 0.75 mg levonorgestrel taken either together or 12 hours apart), and the mifepristone regimen (10 mg mifepristone).

None of the included studies found clinically or statistically significant differences between intervention and control groups in pregnancy or abortion rates (Tables 2 and 3). Of those that provided data on emergency contraceptive pill use, all but one[9] showed that a substantially higher proportion of women in the intervention group than in the control group used emergency contraceptive pills. Several studies suggested that the intervention also increased promptness of use of emergency contraceptive pills,[7,10,16,22,23,25] although one large trial did not confirm this effect.[20]

CONCLUSION

A substantial body of research is now available on the effects of improved access to emergency contraceptive pills. These data demonstrate convincingly that greater access increases use. However, to date, no study has shown that increased access to this method reduces unintended pregnancy or abortion rates on a population level. The specific interventions varied among the studies, and the quality of some of the studies was poor. Nevertheless, the consistency of their primary findings is hard to ignore.

Further research is clearly needed to inform funding agencies, family planning program managers, policy makers, and women in making decisions about spending limited resources on emergency contracep-

Table 2. Results of Studies With Individual Allocation of Participants to Intervention or Control Group

Study	Duration of Follow-up	Pregnancies*		Ever Use of Emergency Contraceptive Pills*		Dropped Out Early†
		Intervention	Control	Intervention	Control	
Randomized trials						
Ellertson 2001[13]	Up to 1 y	0/194 (0)	0/172 (0)	11/185 (6)	4/157 (3)	60
Hazari 2001[11]	3 mo	2/99 (2)	4/99 (5)	32/99 (32)	29/100 (29)	0.5
Jackson 2003[14]	1 y	11/152 (7)	16/163 (10)	17	4	31
Gold 2004[10]	6 mo	13/122 (11)	18/142 (13)	26/119 (22)	20/135 (15)	26
Lo 2004[21]	1 y	7/499 (1)	9/487 (2)	149/499 (30)	63/487 (13)	4
Belzer 2005[12]	1 y (6 mo data shown here)	4/57 (7)	10/54 (19)	15/36 (42)	2/41 (5)	31
Hu 2005[20]	1 y	38/974 (4)	32/974 (3)	183/974 (19)	90/974 (9)	17
Raine 2005[19]	6 mo	1) 66/826 (8) 2) 58/814 (7)	27/310 (9)	1) 309/826 (37) 2) 197/814 (24)	65/310 (21)	8
Raymond 2006[16]	1 y	67/724 (9)	70/717 (10)	527/746 (71)	236/744 (32)	6
Walsh 2006[18]	3–9 mo	31/573 (5)	21/517 (4)	108/573 (19)	60/517 (12)	62
Cohort studies						
Glasier 1998[24]	1 y	28/549 (5)	33/522 (6)	180/379 (47)	87/326 (27)	1
Skibiak 1999[23]	3 mo	N/A	N/A	1) Approx 126/300 (42) 2) approx 39/300 (13)	approx 39/300 (13)	1
Lovvorn 2000[22]	8 wk	N/A	N/A	54/103 (52)	20/97 (21)	14
Raine 2000[17]	4 mo	N/A	N/A	22/111 (20)	7/102 (7)	19

N/A, interpretable data were not available; approx, approximately.
Data are n/N (%) or %.
* Denominators reflect those used in the published analyses if available, or the number providing outcome data.
† Did not complete the full intended duration of follow-up for reasons other than pregnancy.

Table 3. Description and Results of Studies Without Individual Allocation

Study	Design	Setting and Intervention*	Findings
Wells 1998[26]	Trends over time	Washington: Program initiated to allow trained pharmacists to distribute emergency contraceptive pills without physician prescription	Emergency contraceptive pill sales by participating pharmacies increased dramatically after initiation of the project.
Tydén 2002[27]	Trends over time	Sweden: Legislation passed allowing sale of emergency contraceptive pills over the counter	Increased availability of emergency contraceptive pills was coincident with rise in number of abortions.
Glasier 2004[25]	Demonstration project	Lothian county, Scotland: 5 packages of emergency contraceptive pills (Yuzpe regimen) provided to 17,831 women	Abortion rates in Lothian during intervention period were approx 23/1,000 women, not different from rates in Lothian in years before intervention or from concurrent rates in comparison counties.
Mawhinney 2004[28]	Trends over time	Northern Ireland: Legislation passed allowing distribution of emergency contraceptive pills (levonorgestrel regimen) by trained pharmacists without prescription to women age 16 and older	Fewer emergency contraceptive pill requests overall were recorded at an emergency department in year after legislation passed than in prior year, but teenagers made more requests.
Raymond 2004[29]	Trends over time	North Carolina: Toll-free statewide telephone prescription service for emergency contraceptive pills established by Planned Parenthood affiliates	Yearly number of emergency contraceptive pill packages distributed by Planned Parenthood clinics was twice as high in 3 y after program initiated than in year prior
Marston 2005[9]	Trends over time	England: Legislation passed allowing distribution of emergency contraceptive pills (levonorgestrel regimen) by trained pharmacists without prescription to women age 16 and older	Within the 2 y after legislation passed, the proportion of women in national survey who obtained emergency contraceptive pills was similar to that in the in year before, but more of the emergency contraceptive pills were dispensed by pharmacists.
Soon 2005[30]	Trends over time	British Columbia, Canada: Legislation passed allowing distribution of emergency contraceptive pills (levonorgestrel regimen) by trained pharmacists without prescription	Number and proportion of women using emergency contraceptive pills was higher in 2 y after legislation than in 5 y prior.
Moreau 2006[31]	Trends over time	France: Dedicated product introduced; legislation passed allowing distribution of emergency contraceptive pills (levonorgestrel regimen) by pharmacists without prescription; public funding increased	After interventions were instituted, emergency contraceptive pill use increased, and most emergency contraceptive pills dispensed were provided by pharmacists.
Larsson 2006[32]	Trends over time	Sweden: Legislation passed allowing sale of emergency contraceptive pills over the counter	Abortion clients in two clinics were more likely to have used emergency contraceptive pills 2 y after deregulation than in year before deregulation.

approx, approximately.
* Yuzpe regimen was two doses of 100 mcg ethinyl estradiol plus 0.5 mg levonorgestrel taken 12 hours apart; levonorgestrel regimen was two doses 0.75 mg levonorgestrel taken either together or 12 hours apart.

tive pills. One obvious question is prompted by the observation in many studies that poor access to the pills is not the only impediment to their use: even when women have emergency contraceptive pills available, they often fail to take them after the most risky coital acts. For example, four trials reported the proportion of pregnant women who took emergency contraceptive pills in the menstrual cycles in which pregnancy occurred–ie, who may have tried to prevent the pregnancy by taking the pills.[16,20,21,24] In each trial, this proportion was less than 30% in both intervention and control groups. Qualitative studies have found that commonly reported reasons for nonuse of emergency contraceptive pills include failure to

recognize the risk of pregnancy, neglect of perceived risk, stigma, and misperceptions about the method.[33–35] Certainly, emergency contraceptive pills cannot reduce the risk of pregnancy unless they are actually used. Therefore, development and evaluation of strategies to overcome these barriers and maximize emergency contraceptive pill use seem imperative.

In addition, more precise estimates of the efficacy of emergency contraceptive pills are desirable. A recent analysis has confirmed that the levonorgestrel regimen, which is the form of emergency contraceptive pills most commonly used worldwide, is significantly more efficacious after a single coital act than no treatment. Specifically, this analysis suggested that we can be 95% confident that it reduces pregnancy risk by more than 23%.[36] But just how much more remains poorly defined; the published efficacy figures calculated from currently available data on this regimen—on average, approximately 80%[37,38]—may overstate actual efficacy, possibly quite substantially.[36,39] Clearly, if the method is only weakly efficacious, it is unlikely to produce a major reduction in unintended pregnancy rates no matter how often women use it. The best way to obtain reliable efficacy data would be by conducting a placebo-controlled randomized trial. Such a trial would need to be large to provide precise results, and would therefore be expensive. Furthermore, because it is already clear that emergency contraceptive pills are more effective than placebo, ethical issues and recruitment methods would need careful consideration.

Some have speculated that easier access to emergency contraceptive pills might promote risk taking, thereby offsetting the reduction in pregnancy risk when emergency contraceptive pills are actually used. However, the comparative trials have found almost no evidence of differences between intervention or control groups on either unprotected sex or compliance with primary contraceptive use.[13,14,16,18–22,24] In addition, the three studies that collected data on sexually transmitted infections, an indicator of sex unprotected by condoms, also found no effect of the intervention.[10,16,19] Additional research on this topic therefore does not seem a high priority.

Because emergency contraception can safely reduce the risk of unintended pregnancy for individual women who use it, improved awareness of and access to the medication is certainly appropriate and desirable. Thus, the recent United States Food and Drug Administration decision to allow adults to purchase emergency contraceptive pills behind the counter is a welcome step for our country. However, previous expectations that improved access could produce a direct, substantial impact on a population level may have been overly optimistic. Ultimately, emergency contraception may contribute its greatest public health benefit indirectly, by providing an opportunity to encourage women who may be in a particularly receptive frame of mind to adopt a more effective contraceptive method or to use their current method more correctly and consistently. Numerous studies have found that women who use emergency contraceptive pills are subsequently likely to adopt more effective contraception,[14,21,22,24,25] but rigorous research on this possibility remains to be conducted.

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