Impact of Increased Access to Emergency Contraceptive Pills

A Randomized Controlled Trial

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OBJECTIVE: To assess how a strategy to maximize access to emergency contraceptive pills would affect rates of pregnancy and sexually transmitted infections.

METHODS: Sexually active women, 14–24 years old, were randomly assigned to two methods of access to emergency contraceptive pills: increased access (two packages of pills dispensed in advance with unlimited resupply at no charge) or standard access (pills dispensed when needed at usual charges). Participants were followed for 1 year to assess incidence of pregnancy, gonorrhea, chlamydia, and trichomonas.

See related editorial on page 1060.

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RESULTS: The numbers of women enrolled in the increased and standard access groups were 746 and 744, respectively. More than 93% of participants completed a full year of follow-up. The incidence of pregnancy was similar in both groups (increased access group: 9.9/100 woman years, 95% confidence interval [CI] 7.7–12.6; standard access group: 10.5/100 woman years, 95% CI 8.2–13.2). Aggregate rates of gonorrhea, chlamydia, and trichomonas were also similar in the two groups (increased access group: 6.9/100 woman years, 95% CI 5.1–9.1; standard access group: 7.6/100 woman years, 95% CI 5.7–9.9). The increased access group used emergency contraceptive pills substantially more often and sooner after coitus than the standard access group. No other differences were noted between groups in self-reported measures of sexual behavior and contraceptive use.

CONCLUSION: This intensive strategy to enhance access to emergency contraceptive pills substantially increased use of the method and had no adverse impact on risk of sexually transmitted infections. However, it did not show benefit in decreasing pregnancy rates.

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LEVEL OF EVIDENCE: II-1

Over the past decade, increasing attention has focused on emergency contraceptive pills as an important means to reduce rates of unintended pregnancy and abortion. Because of the potential public health benefit as well as the safety and simplicity of the method, prominent medical and public health organizations have supported efforts to maximize access to it, including a recent application to the United States Food and Drug Administration to allow distribution of emergency contraceptive pills over the counter.[1] Concerns have been raised by activists, providers, and women themselves, however, that easy availability of emergency contraceptive pills could

undermine use of more effective contraceptive methods, particularly condoms. Decreased contraceptive and condom use could raise rates of both pregnancy and sexually transmitted infections. Method substitution has been demonstrated in other situations in which multiple contraceptive options were promoted.[2,3]

We designed this study to investigate these concerns. Our trial compared two approaches for providing emergency contraceptive pills. In the "standard access" approach, we informed women about how to obtain emergency contraceptive pills when needed, at usual charges. The "increased access" approach made taking the pills as effortless as possible: we gave women two packages of emergency contraceptive pills at admission and proactively provided them with free replacements after each package was used or lost. The aim of the trial was to determine how easier access would affect rates of pregnancy and sexually transmitted infection.

PARTICIPANTS AND METHODS

We conducted the trial in Nevada and North Carolina between October 2002 and June 2005. The protocol was approved by the institutional review boards of University of California at San Francisco, which managed the Nevada site, and Family Health International. All participants signed informed consent forms before data collection began. The study was monitored by a Data and Safety Monitoring Board, which reviewed aggregate interim outcome data and data pertaining to trial conduct. We adhered to CONSORT guidelines in the design and reporting of this study.[4]

We recruited sexually active women, aged 14–24 years, who did not desire pregnancy. We excluded women who were using or planned to use longer-term contraceptive methods (sterilization, intrauterine device, or hormone injections, implants, patch, or vaginal ring) and women who had been pregnant within the past 6 weeks or were breastfeeding. At the admission visit, we interviewed each volunteer, and she completed a self-administered computerized questionnaire and submitted urine and self-collected vaginal specimens. We tested the urine for pregnancy and sent the vaginal specimen to the Chlamydia Laboratory at Indiana University for gonorrhea, chlamydia, and trichomonas testing using polymerase chain reaction assays.[5] We then assigned the volunteer to either the increased access group or the standard access group by opening the next in a consecutively numbered set of sealed opaque envelopes containing random assignments. The randomization scheme was stratified by site and used randomly permuted blocks with sizes of 4, 6, and 8 generated by computer at Family Health International before the start of enrollment at each site. We gave participants assigned to the increased access group two free packages of emergency contraceptive pills (Plan B, Barr Pharmaceuticals Inc, Pomona, NY) to take home. If a clinician with prescribing authority was not available at enrollment, we sent packages to the participant as soon as possible by mail. We advised participants in the standard access group how to obtain emergency contraceptive pills from the study site if needed. We counseled participants in both groups to take emergency contraceptive pills as a single dose of 1.5 mg levonorgestrel as soon as possible after unprotected intercourse, but we gave them no other special instructions.

We asked each participant to return to the clinic at 6 and 12 months after admission. Data collection procedures at follow-up visits were similar to those at admission. We reviewed available medical charts for relevant interim events. If a participant could not complete a visit in person, we mailed a pregnancy test kit and vaginal swab to her. We asked her to perform the pregnancy test herself and to report results by telephone along with other data and to mail the vaginal specimen directly to the study laboratory. At approximately 2, 4, 8, and 10 months after admission, we sent each participant by mail or e-mail a short survey about contraception use in the last 2 weeks. We did not tell participants in advance about the planned timing of these surveys.

We asked participants in both groups to notify the study site every time they used emergency contraceptive pills. We provided those in the increased access group with a replacement package for each package used or lost. At each follow-up visit, we questioned each increased access participant about the number of unused packages in her possession, and we gave additional packages to those who had fewer than two. The goal was to ensure that each increased access participant had two unused packages available at all times.

After randomization, we provided no unsolicited counseling about contraception unless a participant requested emergency contraceptive pills both four or more times total and more than once in any single month. However, we did not deny emergency contraceptive pills to such women. We notified participants who had positive pregnancy or sexually transmitted infection tests and referred them for care.

The target enrollment was 1,490 women. We selected this number to allow at least an 80% chance of showing with 95% confidence that the relative risk (RR)

of infection, comparing the increased access approach with the standard access approach, was no more than 1.8. In our calculation, we assumed that the risk in the increased access group would be 6%, the increased access approach did not change that risk, and at most, 20% of the anticipated follow-up person-time would be missing. This sample size also provided at least 83% power to reject the null hypothesis of no difference in pregnancy rates between groups at the .05 significance level if the true RR were at least 1.6 and the pregnancy rates in both groups were at least 10%. Note that the null hypothesis for the sexually transmitted infection outcome was that the increased access approach would result in a higher infection rate than the standard access approach (with a true RR of at least 1.8), whereas for the pregnancy outcome the null hypothesis was that the risk is the same in the two groups.

Primary analyses included all enrolled participants. We analyzed each participant in the group to which she was assigned. For pregnancy analyses, we estimated the date of fertilization of each pregnancy using last menstrual period and ultrasound results, if available, and we excluded women pregnant at admission. Women not known to have become pregnant contributed time to the analysis through the later of 10 days before the last negative pregnancy test or 5 days after the last menstrual period. We tested the null hypothesis of no difference in pregnancy rates between the two treatment groups through 365 days after admission using a log-rank test, stratified by clinic. We defined incident sexually transmitted infections as gonorrhea, chlamydia, or trichomonas detected by the study laboratory or by a confirmed positive test performed elsewhere. For sexually transmitted infection analyses, we considered time in study to start at the earlier of the date of the first negative study test or, if the first study test showed a positive result for any of the three sexually transmitted infections, the date of single-dose treatment recommended by the Centers for Disease Control and Prevention. We assigned each subsequent infection to an interval between the date that the participant was last known to be uninfected and the date of the sexually transmitted infection diagnosis. We used a parametric Weibull proportional hazards model, which accounts for interval-censored data, to obtain an estimate of the RR of sexually transmitted infection along with a 95% upper confidence bound.[6] We used proportional hazards models in secondary analyses of both primary outcomes to adjust for potentially important baseline covariates. We analyzed dates and times of coitus and emergency contraceptive pill use as reported by participants, except that we excluded all emergency contraceptive pill uses recorded as more than 2 days before or more than 7 days after sex (n=10) from analyses. We compared the median number of emergency contraceptive pill uses per participant and median delay between sex and emergency contraceptive pill use between treatment groups using median regression,[7] implemented via the QUANTREG procedure in SAS 9.1 (SAS Institute Inc, Cary, NC). We considered $P<.05$ to be statistically significant throughout the analysis.

RESULTS

Between October 2002 and May 2004, 1,490 women enrolled in the study (Table 1). We did not keep records of women who were excluded or refused to participate. All participants met all admission criteria. The median age was 20 years. Many more participants intended to use hormonal contraceptives after admission than had been using these or other highly effective methods in the month before admission. Participants reported a median of four coital acts in the prior 14 days, including a median of two without condoms. Six percent had had an sexually transmitted infection in the past year, 39% had had more than one sexual partner in the previous 6 months, more than 25% were in a sexual relationship of less than 1 month duration, and 30% had partners who were probably or definitely not monogamous. The only notable difference between groups was that a higher proportion in the increased access group had a sexually transmitted infection at baseline. Participants in Nevada were slightly younger than those in North Carolina and were more likely to be Hispanic, white, and using nonhormonal methods of contraception.

Implementation of the intended protocol was successful in both groups throughout the study, with few exceptions. All increased access group participants were given or sent at least two free study emergency contraceptive pill packages within 8 days after admission to the study. Only 146 increased access participants (20%) experienced any time without emergency contraceptive pills after having used all previously dispensed packages; the mean total delay until resupply among all women was 7.2 days, less than 2% of the full expected year of follow-up. No increased access participants paid for study emergency contraceptive pill packages. One standard access participant was mistakenly given two study emer-

Table 1. Baseline Characteristics of Enrolled Participants

	Increased Access Group (n=746)		Standard Access Group (n=744)	
	n	%	n	%
Location				
Nevada	450	60	450	60
North Carolina	296	40	294	40
Age (y)				
14–15	35	5	34	5
16–17	178	24	161	22
18–20	267	36	266	36
21–24	266	36	283	38
Hispanic	115	15	82	11
Race				
White only	510	68	535	72
Any nonwhite	165	22	152	20
Refused to answer	71	10	57	8
Previous pregnancies				
0	587	79	554	75
1	112	15	128	17
2 or more	47	6	62	8
Previously had unwanted pregnancy	128	17	164	22
Contraceptive methods used in month before admission				
Oral contraceptive pills	362	49	353	47
Condoms	489	66	499	67
Condoms only	189	25	179	24
Any highly effective method*	365	49	357	48
Withdrawal	209	28	217	29
Emergency contraceptive pills	37	5	31	4
Any method	721	97	726	98
Contraceptive methods planned for year after admission				
Male condoms	499	67	512	69
Oral contraceptive pills	602	81	627	84
Withdrawal	157	21	140	19
Emergency contraceptive pills	91	12	93	13
Sexual activity in past 14 days				
Sex at least once	712	95	704	95
Sex at least once without condom	491	66	484	65
Sex at least once without contraceptive	193	26	179	24
Ever previously used emergency contraceptive pills	238	32	222	30
First sex with main partner occurred within past month	192	26	206	28
Since first sex act with main partner, he probably or definitely had sex with other woman	225	30	224	30
Had STI in past year	47	6	41	6
Positive STI laboratory test at baseline				
Chlamydia	49	7	24	3
Gonorrhea	11	1	12	2
Trichomonas	2	Less than 1	5	1
Any of these	61	8	40	5
None of these	685	92	702	94
No result	0		2	Less than 1

STI, sexually transmitted infection.
* Includes hormonal methods other than emergency contraceptive pills, intrauterine devices, and male sterilization.

gency contraceptive pill packages, which were both retrieved from her one week later.

The two groups contributed equal amounts of data. In the increased access and standard access groups, respectively, 709 (95%) and 703 (94%) had a final contact at 365 days after admission or later. In each group, 94% had known pregnancy status at 355 days after admission, and 93% had known sexually transmitted infection status at 365 days after admission (Fig. 1). Approximately 93% and 95% of the total

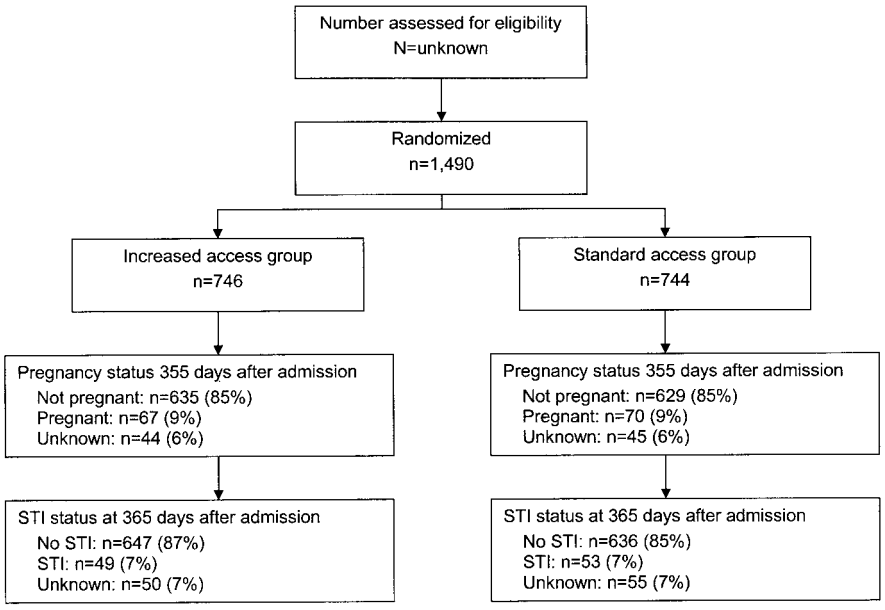

Fig. 1. Flow of participants through the study.
Raymond. Access to Emergency Contraceptive Pills. Obstet Gynecol 2006.

possible person-time was ascertained for the pregnancy and sexually transmitted infection analyses, respectively, which was substantially higher than planned for in the power calculations.

Over the entire study, 3,552 study emergency contraceptive pill packages were dispensed to the increased access group; the median number dispensed was four, and the maximum was 33. Most of the packages dispensed were either used by the participant or retained by her at the end of follow-up (Table 2). Less than 1% of the emergency contraceptive pills used by the increased access group were obtained outside the study. Women in the increased access group used emergency contraceptive pills substantially more often than women in the standard access group (Table 3). The median numbers of emergency contraceptive pill uses per participant in the two groups, respectively, were 2 and 0 ($P<.01$). In the standard access and increased access groups, respectively, 103 and 128 emergency contraceptive pill uses occurred within 1 day after admission. These immediate uses constituted 28% of total use in the standard access group, a much higher proportion than in the increased access group (6%). Emergency contraceptive pill users in the increased access group used the emergency contraceptive pills significantly sooner after sex (Table 2): the median delay was 12 hours in the increased access group and 36 hours in the standard access group ($P<.01$). Emergency contraceptive pill use patterns were similar at the two study sites. Participants in the standard access group reported having paid for 80% of the emergency contraceptive pills they used; the median charge was $15 in Nevada and $40 in North Carolina (overall range $1 to $60).

The incidence of pregnancy was similar in the two groups (Table 4) (hazard ratio 0.95, 95% confidence interval 0.68–1.33, log-rank $P=.78$). No interaction was observed between treatment group and study site. Adjustment for potentially important baseline covariates (previous pregnancy, black race, Hispanic ethnicity, marital status, and use of highly effective birth control methods in the month before enrollment) did not change this finding. However, the adjusted analysis suggested that women who had previously been pregnant were significantly more likely to have a study pregnancy and that women who used a highly effective birth control method before enrollment were significantly less likely to become pregnant. Also, pregnancies were much less common in North Carolina than in Nevada (6.8% and 11.3% of women contributing data, respectively). In the increased access and standard access groups, respectively, five and four participants had two pregnancies in the year after admission (the first pregnancy of one standard access participant was determined to have been fertilized before admission), and one woman in the increased access group had three pregnancies.

Our data provide significant evidence that, in the target population, the risk of the combined sexually transmitted infection outcome using the increased access approach is not substantially

Table 2. Study Package Disposition and Delay in Use of Emergency Contraceptive Pills

	Increased Access Group		Standard Access Group	
	n	%	n	%
Disposition of study packages dispensed				
Used	2,045	58	0	0
Retained at end of follow-up	1,012	28	0	0
Gave away	95	3	0	0
Lost	297	8	0	0
Returned to study/destroyed/unknown	103	3	2	100
Total study packages dispensed	3,552		2	
Delay between coitus and use of any ECPs (h)*				
1–24	1,365	66	130	36
25–48	324	16	121	33
49–72	132	6	66	18
73 or more	54	3	31	8
Missing	182	9	18	5
Total ECP uses	2,057		366	

ECP, emergency contraceptive pill.
* Includes uses of study packages and ECPs obtained elsewhere. Midpoint was imputed for ECP uses with dates but without times for coitus and/or ECP use.

Table 3. Frequency of Emergency Contraceptive Pill Use

Emergency Contraceptive Pill Uses Per Participant*	Increased Access Group (n=746)		Standard Access Group (n=744)	
	n	%	n	%
0	219	29	508	68
1	146	20	155	21
2	91	12	52	7
3	68	9	19	3
4	56	8	5	1
5 or more	166	22	5	1

* Includes uses of study packages and emergency contraceptive pills obtained elsewhere.

higher than the risk with the standard access approach. In fact, the observed risk was lower in the increased access group (hazard ratio 0.91, 90% confidence interval 0.66–1.26). Adjustment for site, youth, black race, positive sexually transmitted infection test at admission, sexually transmitted infection in the year preceding enrollment, and multiple partners in the 6 months preceding enrollment did not substantially affect this conclusion. Women with a sexually transmitted infection at admission, black women, and women with multiple partners in the previous year had a significantly higher risk of infection than women without those characteristics. Study site and age were not significantly related to sexually transmitted infection risk. No effect of treatment group on sexually transmitted infection rates was noted in subgroups defined by age category or study site. No significant differences between groups were observed in rates of any of the three sexually transmitted infections individually.

Participants' coital activity and use of contraception, as reported 5–7 and 12–14 months after enrollment, did not differ significantly by group (Table 5), except for use of emergency contraceptive pills, which was much more common in the increased access group ($P<.01$, χ^2). Behaviors reported at these two follow-up visits changed little compared with behaviors reported at enrollment: the proportion of women having sex decreased slightly, as did the proportion of sexually active women who used no contraception.

In the increased access and standard access groups, 246 (33%) and 280 (38%) of women, respectively, admitted at least once to having had unprotected sex without having used emergency contraception afterward. In both groups, the most common reasons cited for failure to use the emergency contraceptive pills were inconvenience and failure to appreciate risk of pregnancy. Participants in the increased access group used emergency contraceptive pills in 17 of the 74 total menstrual cycles (23%) in which pregnancy occurred; the corresponding figure for the standard access group was 2 of 74 cycles (3%). No serious adverse events related to the study occurred during the trial.

DISCUSSION

In our study, a strategy designed to enhance women's ability to take emergency contraceptive pills when needed led to substantially increased emergency contraceptive pill use and greater promptness of use after unprotected coitus. This strategy had no effect on coital and contraceptive use patterns or on incidence of sexually transmitted infections. However, it did not have any apparent benefit in reducing pregnancy rates.

Recently published research on other programs to increase access to emergency contraceptive pills, including distribution in advance of need, direct provision by pharmacists, and over-the-counter marketing, has yielded findings consistent with ours.[8–14] Although the evidence of absence of harm is reassur-

Table 4. Pregnancies and Infections Within the Year Following Admission

	Increased Access Group (n=746)	Standard Access Group (n=744)
Pregnancy		
Number pregnant (ever)	67	70
Number contributing any data	724	717
Person-years contributed	674	669
Incidence per 100 person-years (95% CI)	9.9 (7.7–12.6)	10.5 (8.2–13.2)
Sexually transmitted infection		
Number with any infection (combined outcome) (ever)	49	53
Chlamydia	38	29
Gonorrhea	10	17
Trichomonas	7	9
Number contributing any data	725	714
Person-years contributed	712.3	700.4
Incidence of combined outcome per 100 person-years (95% CI)	6.9 (5.1–9.1)	7.6 (5.7–9.9)
Number with positive test on more than one date	5	4

CI, confidence interval.

Table 5. Contraception Use Reported at 5–7 Months and 12–14 Months After Admission

	5–7 Months				12–14 Months			
	IA Group		SA Group		IA Group		SA Group	
	n	%	n	%	n	%	n	%
Contraception use in past month								
Provided data	624		630		569		572	
Oral contraceptive pills	360	58	377	60	310	54	327	57
Condoms	329	53	337	53	285	50	271	47
Condoms only	89	14	85	13	84	15	81	14
Any highly effective method*	378	61	395	63	330	58	351	61
Withdrawal	179	29	180	29	146	26	143	25
Emergency contraceptive pills	104	17	19	3	57	10	17	3
Any method	598	96	593	94	518	91	532	93
Sexual activity in past 14 days								
Provided data	627		632		568		572	
Sex at least once	551	88	536	85	459	81	479	84
Sex at least once without condom	405	65	383	61	323	57	350	61
Sex at least once without contraceptive	113	18	94	15	87	15	100	17

IA, increased access; SA, standard access.
* Includes hormonal methods other than emergency contraceptive pills, intrauterine devices, and male sterilization.

ing, the failure to demonstrate a population-level contraceptive effect has been disappointing. One leading explanation has been that the ability of earlier studies to detect a benefit was limited by acknowledged flaws in study design and execution, such as low power, low baseline risk for pregnancy, adequate emergency contraception access in the comparison group, short follow-up, and crossovers between groups. Also, the interventions tested in many of the previous studies may have been intrinsically ineffectual: only one or two emergency contraceptive pill packages were provided, or participants were required to make special efforts to obtain replacements. Our trial largely avoided all of these weaknesses. In particular, the difference in amount of emergency contraceptive use between the groups in our study was substantial, greater than in previous studies. Thus, other explanations for the failure of increased emergency contraceptive use to translate into lower pregnancy rates must be considered.

One possibility is that emergency contraceptive pills are simply not highly efficacious. Published estimates suggest that after a single act of intercourse, the levonorgestrel regimen reduces pregnancy risk by 60–94%.[15] However, the method used to derive these estimates is questionable because it did not take into account factors other than emergency contraceptive pill use that might have

accounted for differences in pregnancy rates between women who did and those who did not use emergency contraceptive pills. More convincing evidence of efficacy comes from studies showing that emergency contraceptive pill treatment can increase the chance of anovulation and other physiologic events incompatible with pregnancy.[16] Furthermore, two randomized trials showed that the levonorgestrel regimen is significantly more efficacious than an older regimen. Therefore even if the older regimen is no better than placebo, the levonorgestrel regimen logically must have some efficacy.[17] But robust data on the specific level of efficacy are unavailable.

A second hypothesis is that any contraceptive benefit of the increased emergency contraceptive pill use may be counteracted by increased risk taking. However, like prior researchers,[8–14,18] we found no gross differences between groups in reported coital behavior or use of regular contraception other than emergency contraceptive pills. Admittedly, these data are self-reported and impossible to verify, as are the data on emergency contraceptive pill use. However, consistent with one prior study,[12] we also observed no difference in rates of sexually transmitted infections between groups, which is objective evidence of a lack of a clinically meaningful effect on condom use.

A third hypothesis is clearly supported by our data. More than one third of women in both study groups admitted to having had unprotected sex at least once without using emergency contraceptive pills afterward. This number is probably an underestimate because of poor recall, denial, and desire to please the researchers. Furthermore, as has been previously reported,[8,10,11] most participants who became pregnant did not use emergency contraceptive pills in the menstrual cycle in which the pregnancy occurred. At least 146 increased access participants experienced some time in the study (7.2 days, on average) during which they did not have unused emergency contraceptive pills in their possession. Clearly, despite increased access, many risky coital acts remained "uncovered" by emergency contraception.

Our proactive intervention to keep increased access participants stocked with emergency contraceptive pills was expensive in terms of both labor and commodities. For this reason, it would probably not be feasible for widespread, long-term use outside a study. If emergency contraceptive pills are to achieve a measurable direct population-level impact on pregnancy rates, strategies to target high-risk women and high-risk coital acts may be needed. We plan to examine our data in more detail to evaluate possible explanations for our negative findings, which we hope will help to inform the development of such strategies.

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