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Should Providers Give Women Advance Provision of Emergency Contraceptive Pills? A Cost-Effectiveness Analysis

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A B S T R A C T

Purpose: We sought to determine the potential effect and cost-effectiveness of different means of accessing emergency contraceptive pills (ECP) on unintended pregnancy rates in sexually active women.
Methods: We used a computer simulation model to compare the effects of advance provision, on-demand provision, and no use of ECP on unintended pregnancies and costs of care in three hypothetical cohorts of 1 million sexually active women. Data on effectiveness of ECP from the single-use clinical trials, and costs from Medi-Cal, California's Medicaid program were used for the model.
Findings: Advance provision of ECP is projected to avert a greater or the same percentage of unintended pregnancies compared with on-demand provision, with the greatest percentage of pregnancies averted (66%) in low-risk women with advance provision. In the simulation model, the percentage of pregnancies averted decreases as the frequency of unprotected intercourse increases and ECP use decreases. In all scenarios, the cost-savings ratio—the number of dollars saved on averted pregnancy expenditures for each dollar spent on advance ECP—is greater than one.
Conclusion: Advance provision of ECP has the potential to avert unintended pregnancies and reduce medical expenditures. The most likely reason that the advance provision trials fail to demonstrate reductions in pregnancy rates is a result of a combination of small study sizes, the use of ECP in both treatment and control groups, and a failure to take into account a realistic range of rates of unprotected intercourse and imperfect ECP use.

Introduction

Emergency contraceptive pills (ECP)—oral hormonal contraceptives taken after unprotected intercourse—have been demonstrated to be effective in preventing unintended pregnancy (Cheng, Gülmezoglu, Piaggio, Ezcurra, & Van Look, 2008). Levonorgestrel, the hormone in the Plan B ECP, is estimated to reduce the risk of pregnancy by 89% after a single act of unprotected intercourse (World Health Organization [WHO], 1998). The method is also more effective the sooner it is used after unprotected intercourse (Piaggio, von Hertzen, Grimes, & Van Look, 1999). Advance provision, providing ECP for a woman to keep on hand in case she needs it, increases the likelihood that a woman will use it, and use it sooner after an act of unprotected intercourse has occurred (Raymond, Trussell & Polis, 2007). The eight published, randomized, controlled trials of advance provision reviewed by Polis et al. (2007) all found a higher rate of utilization of ECP among women who had them on hand compared with women who were not given advance provisions. In these studies, women were typically randomly assigned to 1) standard access to ECP (call or return to a clinic when ECP is needed), 2) access through a pharmacy, and/or 3) advance provision. Women in any of the groups—advance provision or on demand through clinics or pharmacies may use

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ECP. The two largest studies, which followed women for 1 year with little loss to follow-up, found that women who had been provided ECP in advance were twice as likely to use ECP as women who were given a prescription (Raymond, Stewart, Weaver, Monteith, & Van Der Pol, 2006; Lo, Fan, Ho, & Glasier, 2004).

To date however, none of the randomized trials of advance provision of ECP have shown a reduction in unintended pregnancies (Polis et al., 2007; Raine et al., 2005; Raymond et al., 2007; Walsh & Frezieres, 2006). Based on this information, policy makers and providers may be reluctant to commit limited public health resources to provide advance provisions of ECP to women. Why do the advance provision trials of ECP fail to demonstrate reductions in unintended pregnancy rates when clinical trials of women who take ECP after a single act of unprotected intercourse do? Shedding light on this question may help providers and policy makers to make critical decisions about whether it makes sense to give women an advance supply of ECP.

The discrepancy in findings between the single-use ECP trials and the advance provision trials most likely arises from the fundamental difference in what the two types of trials evaluate. The single-use clinical trials evaluate ECP effectiveness to prevent pregnancy under ideal or perfect-use conditions (i.e., a woman has unprotected intercourse one time and takes ECP). Advance provision trials, on the other hand, assess ECP effectiveness to prevent pregnancy under typical conditions (i.e., a woman has unprotected intercourse any number of times over several months and takes ECP for none, some, or all acts). The results of single-use trials therefore depend only on a few factors, namely, how well the product works and when the product is taken. In contrast, the results of the advance provision trials depend on ECP effectiveness and when it is taken as well as characteristics of the user, including frequency of unprotected intercourse over several months and how often ECP is used. Typical-use effectiveness of contraceptive products that require user compliance is always lower than perfect-use effectiveness.

Therefore, it is likely that the sample size required to demonstrate that advance provision of ECP is effective in reducing pregnancy rates under typical conditions with repeated acts of unprotected intercourse and varying levels of ECP use is significantly larger than that required to demonstrate reductions in pregnancy rates after a single act of unprotected intercourse or perfect-use conditions. Most studies of advance provision were relatively small because they were powered to detect large reductions in pregnancy rates or differences in intermediate outcomes such as ECP use or sexually transmitted infection rates (Glasier & Baird, 1998; Jackson, Schwarz, Freedman, & Darney, 2003; Raine et al., 2005; Raymond et al., 2006). In addition, women in the control groups in the advance provision trials had some access to ECP (i.e., through clinics or pharmacies), thereby diluting the observable effect of advance provision of ECP on pregnancy rates.

What is not clear is under what circumstances advance provision of ECP is effective in reducing unintended pregnancy rates. Unfortunately, it is unlikely that there will be future advance provision trials large enough to detect small differences in pregnancy rates between treatment and control groups under typical use patterns and widespread availability of ECP. A cost-effectiveness analysis can be utilized to quantify the probability that an intervention is cost-effective given the available data on ECP effectiveness and costs (Griffin, Claxton & Sculpher, 2008). We combined effectiveness data from the single-use clinical trials of ECP and costs from Medi-Cal, California's Medicaid program, and Family PACT, California's Medicaid 1115 Waiver Program, into a simulation model to estimate the effect and cost effectiveness of different means of accessing ECP on unintended pregnancy rates in sexually active women who are at risk of having unprotected intercourse. We assess under what circumstances advance provision of ECP could have an observable effect on pregnancy rates and potential cost savings of advance provision of ECP compared with on-demand access (through clinics or pharmacies) from the perspective of a public payer of medical care.

Methods

Model Overview

We developed a computer simulation model of pregnancies among sexually active women using STATA version 8.2 (STAT Corp, College Station, TX). Probabilities of unprotected intercourse, ECP use, and conception were used to simulate the number of expected pregnancies in a hypothetical cohort of three groups of 1 million women: 1) women who have ECP on hand to use if needed after an episode of unprotected intercourse (advance provision); 2) women who must seek ECP from a clinic or pharmacy after an episode of unprotected intercourse (on demand); and 3) women who do not have access to ECP and do not use ECP (no ECP). Costs for pharmacy dispensing, clinical visits, ECP, and pregnancy were assigned. Pregnancy rates and medical expenditures were linked to the probability of having unprotected intercourse and taking ECP after an episode of unprotected intercourse. Because rates of unprotected intercourse vary dramatically based on personal circumstances, we modeled pregnancy rates under three different preset probabilities of unprotected intercourse (once per week, once per month, and once per year) over the course of 1 year (13 consecutive menstrual cycles). Our model assumes that the frequency of unprotected intercourse does not vary as a function of ECP access based on data from prior clinical trials demonstrating no evidence of increase in risk taking among women receiving advance provision of ECP (Raine, Harper, Leon, & Darney, 2000; Raine et al., 2005).

In our simulation, we modeled conception as a Markov process, a type of analysis often used to determine the probability of an event (e.g., pregnancy) that is random but influenced by other variables (e.g., unprotected intercourse and ECP use) as well as by its own previous value (e.g., the probability of having already conceived). Women who have not already become pregnant have a preset probability of having an act of unprotected intercourse in a given month and, depending on ECP use, experiencing an unintended pregnancy. The simulation model produces the number of pregnancies, the number of women who experience at least one pregnancy over the course of the year, and the quantity of ECP dispensed in advance and on demand. The model assumes that in a random 50% of unintended pregnancies, the woman carries the pregnancy to term and in the remainder, the woman is assumed to have a spontaneous or induced abortion with return to risk of unprotected intercourse and pregnancy after 3 months (Henshaw, 1998). In this model, women can experience more than one unintended pregnancy over the course of a year.

The model depicts the percent reduction in pregnancies as a function of treatment strategy: advance provision or on-demand through clinics or pharmacies compared with no access to ECP. The cost savings per dollar spent on ECP is the product of the number of averted pregnancies and the medical cost of an unintended pregnancy divided by the expenditures on ECP.

Values over one indicate cost savings. The probability of pregnancy does not differ by whether a woman in the on-demand arm receives ECP from pharmacies or clinics; however, the cost and therefore cost-effectiveness of mode of delivery does differ. We calculate the sample size needed to demonstrate that the difference in pregnancy rates we observe in the simulation is statistically significant using a two-sided 95% confidence interval test of proportions with a power of .90. This number gives us an idea of the sample size that would be needed for a randomized, controlled trial to demonstrate a reduction in pregnancy rates when comparing women who have on-demand access to ECP, advance provision of ECP, and no access to ECP.

Data

Probability of taking ECP

We project pregnancy and cost outcomes for each preset rate of unprotected intercourse under two scenarios: 1) Women have an advance provision of ECP and take it after every episode of unprotected intercourse and 2) women have an advance provision of ECP and take it after 50% of episodes of unprotected intercourse. We assume that women in the on-demand group who must seek ECP through clinics or pharmacies after an episode of unprotected intercourse are 50% less likely than women in the advance provision group to use ECP (e.g., take it after 50% and 25% of episodes; Jackson et al., 2003; Raine et al., 2005). Women in the advance provision group are assumed to have been given one pack of ECP in advance. After the pack of ECP is used, women need to return to the clinic or pharmacy for additional ECP supplies; therefore, for any subsequent episodes of unprotected intercourse, ECP taking occurs with the probability and cost of provision of the on-demand group.

Probability of conception

We used available data on conception rates, mean time to use of ECP, and ECP effectiveness after an episode of unprotected intercourse to derive estimates of probability of conception if ECP is taken (Table 1). The probability of conception per act of intercourse is greater than 0 starting 3 days after the first day of menses and peaking at 0.086 on day 13, with an average of 0.03 per act of intercourse randomly occurring on any day of the cycle. We therefore assume that each act of unprotected intercourse without ECP use has a 0.03 probability of conception (Wilcox, Dunson, Weinberg, Trussell, & Baird, 2001). ECP's effectiveness in preventing conception declines as a function of time elapsed between the act of unprotected intercourse and administration. Each 12 hours of delay in starting ECP treatment was found to reduce efficacy by about 50% in an analysis of levonorgestrel and Yuzpe regimens (Piaggio et al., 1999). In the absence of data on time to ECP administration when obtained on-demand from clinics, we used data from pharmacy access studies and assumed the mean time to administration for women in the advance provision group would be 29 hours, which would reduce the risk of conception to 0.0057; administration in the on-demand provision group would be 36 hours, reducing the risk of conception to 0.0069 (Foster et al., 2006; Piaggio et al., 1999). We assume the same reduction in the probability of conception whether EC is obtained through a pharmacy or clinic after an act of unprotected sex (Table 1).

Costs

Medical costs of providing ECP come from Medi-Cal, California's Medicaid program, and Family PACT, California's Medicaid 1115 Waiver Program, which provides family planning services to low-income, uninsured women otherwise ineligible for Medicaid services. The cost of advance provision includes the product cost plus the increased cost of an office visit to add EC to the counseling topics. This cost figure comes from a comparison of counseling and office visit costs when EC is dispensed compared with visits when it was not. The total cost for women who received EC in advance includes the cost of on-demand provision once the advance supply is used up. The cost of on-demand provision in clinics includes the product cost plus the cost of office visits and counseling for encounters in which ECP were dispensed. Cost of on-demand provision in pharmacies is the cost of dispensing the product. Costs of unintended pregnancy by pregnancy outcome are estimated using the costs of medical services associated with each pregnancy outcome in Medi-Cal. We use the cost of providing medical services for abortion, miscarriage, prenatal care, and delivery in 2005 (Table 1; Amaral et al., 2007).

Results

Table 2 shows projected pregnancies and pregnancy expenditures for the 1 million women in each of three hypothetical

Table 1
Parameter and Cost Estimates

Parameter	Estimate	Source
Probability of conception if a woman has unprotected sex and does not take ECP	0.03	Wilcox et al. (2001)
Probability of conception if a woman has unprotected sex and takes an advance supply of ECP	0.0057*	Based on WHO (1998) and Piaggio et al. (1999)
Probability of conception if a woman has unprotected sex and gets ECP from a clinic	0.0069†	Based on Foster et al. (2006) and Piaggio et al. (1999)

Costs	Expended	Cost per episode	Source
Cost of dispensing ECP in advance	All women regardless of use	$26	2005 Medi-Cal, Family PACT claims data
Cost of dispensing ECP for immediate use at a clinic	Only when used	$48	2005 Medi-Cal, Family PACT claims data
Cost of dispensing ECP for immediate use at pharmacy	Only when used	$30	2005 Medi-Cal, Family PACT claims data
Cost of medical services for an unintended pregnancy ending in miscarriage, ectopic pregnancy or abortion	50% of pregnancies	$389	Amaral et al. (2007)
Cost of medical services for an unintended pregnancy through delivery	50% of pregnancies	$5,709	Amaral et al. (2007)

* The reduction in the probability of conception with ECP advance provision is estimated based on the average time to use ECP for women who have it on hand and the efficacy of ECP from time of unprotected intercourse to administration.

† The reduction in the probability of conception with ECP on demand is estimated based on the average time to use ECP for women who seek ECP from pharmacies after intercourse and the efficacy of ECP from time of unprotected intercourse to administration.

Table 2
Projections of Pregnancies and Cost Savings of ECP Provision for 1 Million Women With no ECP, Advance Provision, and On-Demand Provision, by Frequency of Intercourse and Level of ECP Use

Provision of EC	Pregnancies (*n*)	Reduction in Pregnancy Rate Compared With No ECP (%)	Percentage of Women Experiencing ≥1 Pregnancy (%)	Costs-Savings Ratio[‡]		Required Sample in Each Arm to Test Difference in Pregnancies	
				Pharmacy Dispensed On Demand ($)	Clinic Dispensed On Demand ($)	Advance Compared With No ECP	Advance Compared With On Demand
High use of emergency contraception[*]							
Once per year							
No ECP	30,103		2.8				
Advance	10,218	−66	0.9	1.92	1.75	1,201	4,556
On demand	18,515	−38	1.7	2.39	1.50		
Once per month							
No ECP	345,784		30.6				
Advance	211,353	−39	19.0	2.12	1.39	306	35,230
On demand	221,931	−36	20.0	2.08	1.30		
Once per week							
No ECP	982,930		76.8				
Advance	687,310	−30	57.6	1.60	1.01	133	320,926
On demand	692,816	−30	58.0	1.61	1.00		
Low use of emergency contraception[†]							
Once per year							
No ECP	30,103		2.8				
Advance	18,787	−38	1.7	1.28	1.24	4,370	16,030
On demand	24,191	−20	2.2	2.49	1.56		
Once per month							
No ECP	345,784		30.6				
Advance	274,281	−21	24.5	2.17	1.50	1,158	36,650
On demand	286,372	−17	25.6	2.04	1.28		
Once per week							
No ECP	982,930		76.8				
Advance	838,892	−15	68.0	1.65	1.07	562	182,488
On demand	846,863	−14	68.5	1.64	1.03		

[*] Women with advance provision take ECP after all episodes of unprotected intercourse, women with on-demand access take ECP after half of episodes.
[†] Women with advance provision take ECP after half of episodes of unprotected intercourse, women with on-demand access take ECP after one quarter of episodes.
[‡] Pharmacy and clinic dispensing for advance provision refers to where women sought additional supplies once their clinic-dispensed advance supply had been used.

cohorts with varying modes of ECP provision by rate of unprotected intercourse and probability of taking ECP. In all scenarios, advance provision is projected to avert the same or greater percentage of unintended pregnancies as on-demand provision. The greatest percentage of pregnancies is averted (66%) in women with advance provision who have unprotected intercourse infrequently (once per year) and have high use of ECP (after every episode of unprotected sex); a 38% reduction is projected for women in the same scenario who have on-demand provision of ECP. In the simulation model, the percentage of pregnancies averted decreases as the frequency of unprotected intercourse increases and ECP use decreases. In the highest risk group, women who have unprotected intercourse every week and have low ECP use, both advance provision and on-demand provision are projected to avert a small percentage of unintended pregnancies (15% and 14%, respectively); however, the number of pregnancies averted (144,038 and 136,067 pregnancies per 1 million women, respectively) is greater than the number averted in the lower risk group with advance provision (19,885 per 1 million women) because the overall number of pregnancies in the highest risk group is greater.

In all scenarios the cost-savings ratio, the number of dollars saved on averted pregnancy expenditures for each dollar spent on ECP, is greater than one. The cost-savings ratios ranged from 2.49 to 1.00, with the highest savings rendered in low-risk women with on-demand pharmacy access and moderate-risk women with advance provision. In the highest risk group, both advance provision and on-demand provision of ECP through clinics are essentially cost neutral to avert a large number of pregnancies. Advance provision through clinics is more cost effective than on-demand clinic provision for all scenarios except for low-risk women who have unprotected intercourse infrequently (once per year) with low ECP use (after half of episodes of unprotected intercourse) where the cost-savings ratio was 1.56 for on-demand through clinics compared with 1.24 for advance provision. Pharmacy dispensing is more cost-effective than clinic dispensing. Only among low-risk women is on-demand provision of ECP through pharmacies substantially more cost effective than advance provision.

The required size of a study designed to test differences in pregnancy rates between advance provision and no ECP access is low, ranging from 133 to 4,370 in each arm. However the required sample size of a study designed to test differences in pregnancy rates between advance provision and on-demand provision is much higher, ranging from 4,556 to 320,926 in each arm depending on frequency of intercourse and EC use. If women take ECP after one half of episodes of unprotected intercourse and have unprotected intercourse once a month or once a week, one would need sample sizes of 36,650 and 182,488, respectively, in each arm to observe a significant difference in the proportion of women experiencing at least one pregnancy at 1 year.

Discussion

The effect of ECP on unintended pregnancy rates and the cost effectiveness of ECP provision varies significantly depending on the rate of unprotected intercourse and whether women use ECP after all or some acts of unprotected intercourse. This simulation model indicates that advance provision is always projected to avert a greater number of pregnancies than on-demand provision. In all scenarios, provision of emergency contraception, either in advance or on-demand, is cost-effective—expenditures on provision of ECP are lower than the cost of unintended pregnancies they avert. Although provision of ECP in advance involves paying for ECP whether it is used or not, cost savings occur because a woman is more likely to use it if she has it on hand than if she must seek it after an act of unprotected intercourse. Given that ECP have a higher monthly cost and are less effective than other contraceptive methods, use of combined hormonal or long-acting contraceptive methods (intrauterine contraceptives, implants, and tubal ligation) would yield greater savings and fewer unintended pregnancies than ECP use alone. Although providers and policy makers should clearly undertake efforts to increase the use of effective hormonal contraceptive methods to decrease the rates of unprotected intercourse and unintended pregnancy, expending resources on advance provision of ECP should be viewed as a cost-effective means to avert unintended pregnancies. Even among regular users of hormonal contraceptives, gaps in coverage and missed pills present occasions for use of ECPs as a backup contraceptive method (Nelson, Westhoff, & Schnare, 2008).

The failure of recent advance provision trials of ECP to show a reduction in pregnancy rates has called into question the effectiveness of the method (Raymond, Taylor, Trussell, & Steiner, 2004; Trussell & Raymond, 2006). However, our model suggests that these trials have not had sufficient power to detect differences in pregnancy rates. Even the meta-analysis, which combined data from eight randomized, controlled trials of advance provision of ECP representing 6,389 women, was smaller than the 16,030 women we project are needed in each arm to detect differences in pregnancy rates between the two arms when women have unprotected sex once a year and use ECP after half of episodes and the control groups has on-demand access to ECP (Polis et al., 2007).

It is possible that the discrepancy between the single-use trials and the advance provision trials is due to an overestimation of ECP effectiveness in the single-use clinical trials. The estimate of the effectiveness of ECP in the WHO single-use clinical trial was derived by comparing the number of observed pregnancies in the trial with the expected numbers of pregnancies by timing of coitus in relation to predicted ovulation in women trying to conceive (WHO, 1998; Wilcox, Weinberg & Baird, 1995). If some women in the WHO trial were not truly at risk of pregnancy either because of menstrual cycle length variability or misperceptions about method failure, then the trials may have overestimated the expected pregnancy rate. Using an inflated expected pregnancy rate would lead to an overestimate of the effectiveness of ECP. If ECP is not as effective as estimated in the single-use trials, then the number of pregnancies averted and cost effectiveness of ECP projected in this simulation would be lower whether it is provided in advance or on demand. It is unlikely that anyone will perform a true randomized, controlled trial of ECP with placebo to determine the precise magnitude of the effectiveness of ECP because of ethical considerations given that the evidence to date suggests that ECP reduces the risk of pregnancy. Our model, however, suggests that the most likely reason that the advance provision trials fail to demonstrate an effect on unintended pregnancy rates is a result of a combination of small study sizes, the use of ECP in both treatment and control groups, and a failure to take into account a realistic range of rates of unprotected intercourse and imperfect ECP use.

There are several factors that affect the projected number of pregnancies averted and costs that should be noted. This study looks at the savings from pregnancies averted in 1 year. To the extent that women keep their ECP supplies for longer than a year,

this study will underestimate the cost savings associated with advance provision. In this study, we modeled the provision of only one pack of ECP in advance. For low-risk women, one pack seems to be a cost-effective strategy because few low-risk women need more than one pack. In a randomized, controlled trial that included predominately high-risk participants, only 11% of women in the advance provision arm (who received three packs of ECPs) used ECPS more than once (Raine et al., 2005). Providing more than one pack of ECPs in advance would likely have little impact on ECP use and pregnancies averted and hence diminish the cost-effectiveness of advance provision. We also assume that unprotected acts of intercourse occur randomly throughout the menstrual cycle. However, if women are more likely to use ECP for acts that occur in the week before ovulation, the cost savings associated with ECP use for advance provision and on demand would be higher than we project. We only model acts of intercourse when no contraceptive method was used. If women use ECPs in situations where the likelihood of conception is probably lower than with no contraception but for which no data exist (i.e., missing pills) then the cost effectiveness would also be lower. Our model attempts to reflect information from the most likely scenarios of EC use—after completely unprotected intercourse.

This study uses 2005 medical cost data from California's Medicaid program, which may be lower than private health plan costs. However, any payer with proportionately higher costs of both ECP and pregnancy will find that advance provision of ECP reduces total medical costs. We have also only considered the medical costs of an unintended pregnancy for up to 2 years after a birth. Social, welfare, and private costs are likely much higher (Amaral et al., 2007; Foster, Arons, Lauren, Biggs, & Brindis, 2008). Introduction of generic emergency contraceptive products may reduce the cost of the drug, increasing cost-savings from advance provision (Kalish, 2009).

The use of a computer-based simulation model allows us to set the levels of typically unobservable behavior, such as the frequency of unprotected intercourse and ECP use to predict unintended pregnancy rates. The model demonstrates the large fluctuations in results from changes in a series of random events—having unprotected intercourse, taking ECP, and becoming pregnant. It is difficult to conduct a trial of sufficient size and magnitude needed to account for the range of behaviors that occur in reality. Despite the important limitations to this analysis mentioned, use of a simulation model allows us to capture some of the complexity of predicting unintended pregnancy rates and demonstrates that advance provision of ECP has the potential to avert unintended pregnancies and the potential to save medical expenditures.

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