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Questions regarding S 2073 (EC)

EC has a stronger dose of hormones than does the contraceptive pill. Does this become unsafe if used frequently?

No, it is not unsafe, even if used multiple times. The most common side effects are nausea and disruption of the menstrual cycle, but there are no dangerous side effects. Studies have also shown that most women do not use it repeatedly.

Is it unsafe for younger (preteen, or teenagers) women, especially after multiple

uses?

It is safe for young women, even if used multiple times. Teens are more likely to experience contraceptive failure and EC is certainly safer than the risks associated with unintended pregnancy.

If so, would it be an amendable option that a pharmacist could deny multiple uses without a prescription? - Could this be a part of the "collaborative agreement"

between pharmacist and physician?

O A better option would be for the pharmacist to refer a patient to a family planning clinic or other provider to find an ongoing form of birth control. A pharmacy may be an easier point of entry for some women who don't have regular health care access. Since there is no medical reason that a woman shouldn't use EC repeatedly, there is no reason for a pharmacist to deny filling it multiple times.

Does the distribution of EC at the pharmacy get reported to a primary doctor and

go in her medical record?

o I'm not sure on this one. I think there is some documentation required about the encounter, but I'm not sure if it gets reported to the woman's primary care physician. EC is taken in a short dose and does not stay in the body long term.

What exactly is meant by "collaborative agreement"?

A collaborative agreement is an agreement between a prescribing physician and a pharmacist outlining the protocols they should use to dispense EC.

When does this "collaborative agreement" take place? Before the patient walks into the pharmacy or does it take place while the patient is at the pharmacy

counter?

The collaborative agreement must be filed at the pharmacy and with the Board of Registration of Pharmacy before a patient comes to the pharmacy counter. A pharmacist must also participate in special training before being able to offer EC to a patient at the counter.

- Does the "collaborative agreement" have any correlation to specific patients and their doctors?
 - o No. The agreement would allow the pharmacist to provide EC to any woman who fit the protocols of the collaborative agreement, not just patients of that particular doctor.
- How often can you buy EC? Under this bill, can you buy one EC pill a day and store them up for personal use?
 - o A woman can buy EC as often as it is needed. Major medical associations actually recommend that women keep a package of EC at home in case of an emergency (like a broken condom) so they can use it right away when it is most effective.
- Is it the survivor's responsibility to go from pharmacy to pharmacy to find a pharmacist willing to distribute EC?
 - O Any woman who needs EC, not just a rape survivor, can access EC from a participating pharmacist. There is no provision in the bill specifying how a woman can find a participating pharmacy, but in other states, websites and hotlines have been set up to provide this info.
- Is it a requirement of the pharmacy to always have a willing pharmacist on duty? Is it a requirement to have posted notice of whether or not there is a willing pharmacist on duty? Can a survivor request written work hours of a willing pharmacist? Is it a requirement of the pharmacy to have *any* willing pharmacist on staff?
 - O This is a completely voluntary program for pharmacists. There is no requirement that any individual pharmacist or pharmacy participate. There is also no requirement that they post a notice. However, it is our hope that pharmacists will want to participate to provide this service to their customers and that they would see it as good for their business.
- Will independent pharmacies be able to use the willingness of a pharmacist to enter into the collaborative agreement as a requirement for employment?
 - o I don't know. I do know that in Washington State where they have had a similar program for several years, that pharmacists are trained in EC provision in pharmacy school and when they enter the job market, they are often interested in working for a pharmacy that will provide this service. It is therefore an incentive for the pharmacy to participate so they get the best graduating students.

AN ACT TO PROVIDE TIMELY ACCESS TO EMERGENCY CONTRACEPTION (EC) – S.2073

What is emergency contraception?

- The Food and Drug Administration has approved emergency contraception (EC) as a contraceptive method for use after rape, contraceptive failure or unprotected sexual intercourse.
- EC is most effective the sooner it is taken, but can be used within five days of unprotected sex.
- EC works much like a regular birth control pill, by inhibiting ovulation and fertilization. It may also inhibit implantation.
- EC is safe and effective. It is <u>not</u> RU-486 (the abortion pill). If a woman takes EC during pregnancy, it will <u>not</u> harm the developing fetus or cause an abortion.

What will the bill do?

- The bill will require hospital emergency rooms to make EC available to rape survivors. Seven other states ensure that rape survivors receive access to EC or information about EC in the ER, including California, Illinois, New Jersey, New Mexico, New York, South Carolina and Washington. None of these states include refusal clauses that allow individuals to opt out of providing information or access to EC.
- The bill will also allow trained pharmacists to dispense EC without a prescription, through a voluntary collaborative agreement with a physician. Seven other states have passed similar legislation: Alaska, California, Hawaii, Maine, New Mexico, New Hampshire and Washington.

Why is the bill necessary?

- Despite EC's proven ability to prevent unintended pregnancy, many hospital emergency rooms do not inform rape survivors about EC or make EC available. A 2004 study by the Massachusetts EC Network and NARAL Pro-Choice Massachusetts found that 12 out of 71 of the state's hospital emergency rooms or approximately one in six do not provide EC to women who have been raped.
- EC has the potential to dramatically reduce the number of abortions. Approximately half of all unplanned pregnancies end in abortion. In Massachusetts, 26,000 abortions were performed in 2001.
- Until the FDA makes EC available over-the-counter, a doctor's prescription is required. However, EC is
 most effective if taken within the first 24 hours. Many women have difficulty getting through to a doctor or
 making an appointment within that time frame particularly on weekends and in rural areas.

Should a woman be able to get EC directly from a pharmacist, without first visiting a doctor?

- EC has no medical contraindications. Possible side effects are mild nausea, mild cramping, headache, dizziness, breast tenderness and temporary menstrual changes.
- Only a pharmacist who has received training approved by the Commissioner of Public Health and has entered a collaborative agreement with a physician will be permitted to dispense EC.

Who has endorsed the bill?

- Massachusetts Medical Society
- Massachusetts Chapter of the American College of Obstetricians and Gynecologists Jane Doe, Inc.,
- The Massachusetts Coalition Against Sexual Assault and Domestic Violence
- Massachusetts Coalition for Choice
- Massachusetts Public Health Association
- Massachusetts Chapter of the American College of Emergency Physicians
- Massachusetts Family Planning Association
- Massachusetts Pharmacy Association
- Northeastern University School of Pharmacy
- Legislative Committee of the Governor's Commission on Sexual Assault and Domestic Violence

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Emergency Contraception

EC Defined

EC can reduce the risk of pregnancy after unprotected intercourse. Emergency contraception pills (EC) — the most common method of EC — contain hormones that reduce the risk of pregnancy if started within 120 hours (five days) of unprotected intercourse. The treatment is more effective the sooner it begins ("FDA Approves ... " 1999; Rodriguez, 2001; Van Look & Stewart, 1998).

Plan B is currently the only product marketed specifically as emergency contraception. Certain oral contraceptives taken in increased doses may also be used as EC

What is the mechanism of EC

- EC should not be confused with mifepristone (RU-486), a medicine used for medication abortion. EC will not induce an abortion in a woman who is already pregnant, nor will they affect the developing pre-embryo or embryo (Van Look & Stewart, 1998).
- EC prevents unintended pregnancies and help prevent the need for abortion. Most often, EC prevents pregnancy by inhibiting ovulation. They also work by altering the tubal transport of sperm or ova to inhibit fertilization.
- According to the Food and Drug Administration (FDA), "Emergency contraceptive pills...act by delaying or inhibiting ovulation, and/or altering tubal transport of sperm and/or ova (thereby inhibiting fertilization), and/or altering the endometrium (thereby inhibiting implantation)" (FDA, 1997). A recent study found that most often, ECPs reduce the risk of pregnancy by inhibiting ovulation (Marions, et al., 2002). A more recent study suggests that progestin-only ECPs work only by preventing ovulation or fertilization, and have no effect on implantation (Croxatto, et al., 2003).

Does EC cause an abortion?

ECPs will not induce an abortion in a woman who is already pregnant, nor will they affect the developing pre-embryo or embryo (Van Look & Stewart, 1998). Emergency contraception prevents pregnancy and helps prevent the need for abortion.

EC has decreased the number of abortions

An estimated 43 percent of the decrease in U.S. abortions between 1994–2000 can be attributed to the availability of emergency contraception (Allan Guttmacher Institute, 2003).

How does EC differ from RU-486 (or medical abortion)

- Medical abortion is the use of medications that can induce abortion. There
 are currently two drugs available in the U.S. for this purpose —
 mifepristone (RU-486) and methotrexate.
- Mifepristone (RU-486) can be taken up to 63 days after the first day of the last menstrual period, and methotrexate can be taken up to 49 days after the first day of the last menstrual period. Both are used in conjunction with misoprostol, which is taken after either mifepristone or methotrexate to complete the abortion (Creinin & Aubény, 1999; Schaff, 2000).
- Mifepristone is more commonly used than methotrexate because it is more effective and more predictable (Grimes and Creinin, 2004; Wiebe, et al., 2002).

What is an abortifacient?

- The Catholic church thinks it is removal, destruction, or interference with the implantation of a fertilized ovum
- From a medical standpoint, an abortifacient is a drug that causes an already implanted embryo to be expelled form the uterus.

How do abortifacient medications work?

- Mifepristone ends pregnancy by blocking the hormones necessary for maintaining a pregnancy (progesterone). In fact it is the opposite of Plan B (a progesterone only pill)
- Methotrexate stops the further development of the pregnancy in the uterus. Misoprostol causes the uterus to contract and empty (Creinin & Aubény, 1999).
- Both these medicines work after a woman becomes pregnant after a fertilized egg attaches to the wall of the uterus. These pills cause the uterus to expel the egg, ending the pregnancy.

How much does EC cost

 In Massachusetts, Plan B is 50\$ without insurance coverage at CVS on 7/3/05, 20\$with insurance coverage

Range of Costs
\$8 – \$50
\$20 - \$50
\$50 – \$70
\$35 – \$150
\$10 – \$20
\$8 - \$240

What is ovulation

The monthly release of a mature egg from an ovary into one of the Fallopian tubes. A woman is most fertile in the days just before and on the day of ovulation.

When does fertilization occur

Ovulation usually occurs about 14 days before a woman's period begins — that's why it is so difficult to predict when it's going to happen. It may occur on day 14 of a regular 28-day menstrual cycle (day one is the first day of bleeding), but most women do not have 28-day cycles. Most young women have irregular cycles (each cycle may be of a different number of days), and women who have regular menstrual cycles may not always ovulate on the same day each month

When does implantation occur

Usually 5-12 days after ovulation, around the time that most women would be getting their next period.

Why aren't pregnancy tests useful when prescribing EC after unprotected intercourse?

Pregnancy tests only detect established pregnancies, which begin when implantation of the pre-embryo is complete. This does not occur until about 10-15 days after vaginal intercourse (Cunningham, F. Gary, et al., 2001).

How effective is emergency contraception at preventing pregnancy? Progestin-only ECPs reduce the risk of pregnancy by 89 percent if started within 72 hours. Only one woman out of 100 will become pregnant after taking progestin-only ECPs.

If a woman takes EC and it does not work, will there be any birth defects?

Studies have been done with women who did not know they were pregnant and kept taking birth control pills. Millions of women worldwide have become pregnant while taking the pill. No studies have found no increased risk for birth defects.

Widespread Use of Contraception Can Reduce the Number of Unplanned Pregnancies

- Ninety-five percent of American women use contraception at some point during their reproductive years. More than 50 percent of contracepting women use prescription methods. Approximately 27 percent use oral contraceptive pills (AGI, 2004a). Oral contraceptive pills (OCPs) and the dedicated product, Plan B, can be used for emergency contraception (EC). Emergency contraception pills (ECPs), when started within 120 hours of unprotected intercourse, greatly reduce a woman's risk of pregnancy. They are more effective the sooner a woman starts taking them.
- The use of ECPs could prevent an estimated 1.7 million unintended pregnancies and 800,000 abortions each year (Ellertson, et al., 2003; "FDA Approves...", 1999; Glasier & Baird, 1998; Rodrigues, et al., 2001; Van Look & Stewart, 1998).

Contraception Refusals by Pharmacists

- OCPs and ECPs work by preventing ovulation and fertilization (Hatcher, et al., 2004; ACOG, 1998). Despite this scientific fact, anti-choice organizations and individuals foment against women's access to safe, effective, and legal contraception by promoting false claims that OCPs and ECPs are abortifacients that they interfere with pregnancy (ALL, 1997). These false claims are reflected in the arguments health care professionals especially pharmacists use to refuse the medications women need.
- Pharmacists serve on the frontlines of the health care system. They are responsible for dispensing prescribed medication, educating patients on health promotion and disease prevention practices, and optimizing patients' "health-related quality of life" (APhA, 2004).
- From 60,000 to 120,000 prescriptions for ECPs are written annually (Kaufman, 2004). However, a 2003 study about the attitudes and knowledge base of Pennsylvania pharmacists, for example, found that 65 percent had negative feelings regarding ECPs, and that 13 percent believed that ECPs are abortifacient (Bennett, et al., 2003).
- Misinformation about the ways in which hormonal contraception works is the primary excuse for this nationwide campaign to refuse women

Contraception Refusals by Hospitals

- Sexual assault survivors face similar obstructions to access to emergency contraception in hospital emergency rooms. An estimated 25,000 unintended pregnancies each year are a result of sexual assault. Approximately 22,000 of these pregnancies could be prevented if all women who were raped were provided with EC (Stewart & Trussell, 2000).
- Women's access to reproductive health care diminishes as an increasing number of non-religiously affiliated hospitals are merging with Catholic hospitals.
- In June of 2000, it was found that 10 of the 20 largest not-for-profit U.S. hospital systems were operated by Catholic entities (Pawelko & Krishnamurthy, 2001).

The History and Meaning of Refusal Clauses

Pharmacists, physicians, and other medical clinicians have professional and ethical responsibilities to their patients. Health-related decisions made between a provider and patient should be based on the personal welfare and health-care needs of the patient — not the morals or beliefs of the caregivers. Unfortunately, this isn't always the case.

In June of 2004, nine Alabama State Health Department nurses quit their jobs rather than distribute EC to patients. In response to their decision, the department's chief of family planning stated that while he respected the nurses' right to their beliefs, he also had "an obligation to provide services to our clients. It's not appropriate...to dictate public policy based on personal beliefs" (Johnson, 2004).

Refuse and Refer

- According to professional organizations, refusal clauses that allow an expression of religious beliefs can be considered acceptable if they provide an adequate plan for referral (APHA, 2003). Health care must not be disrupted or obstructed by either untold delay or barrier. Under the view of these organizations
- Professionals who object to providing a service need to do so consistently and provide forewarning to their employers and clientele.
- All prescription referrals must be directed to a local pharmacist or pharmacy that is within a reasonable distance.
- "Should the alternate means provided by the employer fail to operate...in a timely fashion...then the pharmacist has a duty to the patient to dispense the medication" (APhA, 1998).

Catholic Beliefs:

- Some Catholics state that we need to test whether there is a chance that the woman may have ovulated, and could potentially have had an egg fertilized.
- In such cases, a woman would be denied EC. Implementation of this interpretation may call for a pregnancy test, questioning about the last

menstrual cycle, and hormone testing to try to determine whether ovulation might have occurred (Bucar, 1999).

- This approach is particularly inhumane because the average woman's chance of getting pregnant on any given day ranges from zero percent to 35 percent, depending on the stage of her menstrual cycle (Wilcox, et al., 1995). Under this interpretation, a woman would be denied EC if she happened to be raped during the six days that end on the day of ovulation which is precisely the time of the month she would be most at risk of becoming pregnant.
- Under this interpretation, a woman would be denied EC if she happened to be raped during the six days that end on the day of ovulation which is precisely the time of the month she would be most at risk of becoming pregnant.
- Catholic: *Directives*, basis of policy on Emergency Contraception:

Compassionate and understanding care should be given to a person who is the victim of sexual assault... A female who has been raped should be able to defend herself against a potential conception from the sexual assault. If, after appropriate testing, there is no evidence that conception has occurred already, WHICH DOES NOT EXIST (my edit) she may be treated with medications that would prevent ovulation, sperm capacitation, or fertilization. It is not permissible, however, to initiate or to recommend treatments that have as their purpose or direct effect the removal, destruction, or interference with the implantation of a fertilized ovum (USCCB, 2001)

There is no test for the presence of a fertilized egg that can be given within the time frame that EC requires. Therefore, Catholic providers take differing approaches interpreting the *Directives* (Bucar, 1999). The most conservative interpretation calls for no access to EC, or to information about it.

Access to EC in Catholic Hospitals

- A study of the nation's nearly 600 Catholic hospital emergency rooms found that only 28 percent offered EC to women who had been raped. Even among those Catholic hospitals that did provide EC to sexual assault survivors, the majority mandated some sort of barrier to a woman getting EC, such as requiring a police report or pregnancy test (CFFC, 2002a).
- In Pennsylvania, a study found that in nearly 70 percent of Catholic hospitals, information about EC was at the physician's discretion. In the end, only six percent of Pennsylvania Catholic hospitals offer EC (Clara Bell Duvall Education Fund, 2000).

Only one Catholic hospital in the state of Maryland was found to offer EC consistently to sexual assault survivors (Maryland NARAL Educational Fund, 2002).

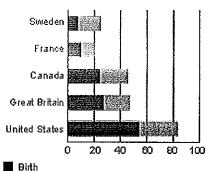
The rates at which EC is withheld from women who have been sexually assaulted are even more disturbing when the reach of the Catholic health care system is considered:

- In June 2000, it was found that 10 of the 20 largest not-for-profit hospital systems in the U.S. were operated by Catholic entities (Pawelko & Krishnamurthy, 2001).
- During the 1990s, there were 159 mergers between Catholic and non-Catholic hospitals, which reduced access to reproductive health services, including EC (CFFC, 2002).
- In the U.S., 13 percent of all hospitals with emergency rooms are Catholic. In many states, 30-40 percent of people who need emergency care visit a Catholic hospital (CFFC, 2002a).
- If a Catholic hospital is a community's only provider, sexual assault survivors are left with very little chance of being taken to a hospital that will provide them with EC.

Teens and EC

- The primary reasons why U.S. teenagers have the highest rates of pregnancy, childbearing and abortion among developed countries is less overall contraceptive use and less use of the pill or other long-acting reversible hormonal methods, which have the highest use-effectiveness rates.
- Once pregnant, women aged 15-17 are more likely to choose abortion than to carry the pregnancy to term in the majority of developed countries. These youngest adolescents are also much more likely to choose an abortion than are 18-19-year-olds.

U.S. teenagers have higher pregnancy rates, birthrates and abortion rates than adolescents in other developed countries.



M Abortion

Rate per 1,000 women aged 15-19

According to a framework that has been used to assess the extent to which five industrialized countries—Canada, France, Sweden, the United Kingdom and the United States—respond to the sexual and reproductive health needs of their youth, one important factor is the accessibility of services and prescription contraceptives. Evidence to date suggests that youth in the United States are much more likely to encounter barriers to access than are their peers in the United Kingdom and other western European countries. (Darroch et al)

Unwanted Pregnancy: Mental Health Consequences

- If safe, legal abortion and contraception were not available, more women would experience unwanted childbearing, and unwanted childbearing affects the entire family.
- Mothers with unwanted births suffer from higher levels of depression and lower levels of happiness than mothers without unwanted births.
- They spank and slap their children more often than other mothers, and spend less leisure time outside the home with their children. Lower-quality mother/child relationships are not limited to the child born as a result of the unwanted pregnancy — all the children in the family suffer (Barber, et al., 1999).

Mental Health and Abortion (Note: I would actually not get into this because the data are not good, and you may enter into a slippery slope abortion debate

- Actually, minimal long term consequences
- 2003 Study. Induced abortion was not associated with changes in the prevalence of subsequent subfertility, spontaneous abortion, or ectopic pregnancy. Previous abortion was a risk factor for placenta previa. Moreover, induced abortion increased the risks for both a subsequent preterm delivery and mood disorders

And Finally, an interesting fact

Compared to pro-choice states, anti-abortion states spend far less money per child on a range of services such as foster care, education, welfare, and the adoption of children who have physical and mental disabilities (Schroedel, 2000).

Massachusetts Emergency Contraception Bill Messages and Q&A

Primary message

I support this bill because making emergency contraception more widely available is one of the most promising ways to reduce the number of abortions. If we are going to get serious about reducing abortion in Massachusetts, we need to get serious about making birth control available when it is needed. It is estimated that greater awareness of and access to emergency contraception could prevent up to half of all abortions.

Supporting Messages

Rape Survivors Deserve Every Opportunity to Avoid Pregnancy

More than 7,000 women are raped each year in Massachusetts, and they deserve every opportunity to avoid pregnancy. Unfortunately, some Massachusetts critical care hospitals still fail to provide emergency contraception to women who have been raped. A 2004 study by NARAL Pro-Choice Massachusetts found that approximately one in six emergency rooms in Massachusetts do not provide emergency contraception to rape survivors.

REPORTED - UNKERONTED

Timely Access is Essential

Timely access is essential because emergency contraception is most effective when taken within 12 to 24 hours. Many women have difficulty getting a prescription from a doctor within that time frame, particularly on weekends and holidays. This bill will give patients access to this backup birth control method when it can be most effective.

Emergency Contraception is Safe and Effective Birth Control

Scientific studies show that emergency contraception is <u>safer than aspirin</u>, which is why it is available without a prescription in 37 countries. It is approved by the FDA as a form of contraception and works in much the same way as a birth control pill. Emergency contraception is not RU-486, the abortion pill, and will <u>not</u> harm an existing pregnancy.

Questions and Answers on the Bill

What will the bill do?

An Act to Provide Timely Access to Emergency Contraception (Senate Bill 2073) will require hospital emergency rooms to make emergency contraception available to rape survivors. The bill will also allow trained pharmacists to dispense emergency contraception without a prescription, through a collaborative agreement with a physician.

Have other states passed similar laws?

Yes, seven states (Alaska, California, Hawaii, Maine, New Mexico, New Hampshire and Washington) have passed laws allowing specially trained pharmacists to dispense emergency contraception without a prescription. In addition, emergency contraception is available without a prescription in more than

Everyone agrees on 1 thing: we must V # of abortion

35 countries, including Albania, Belgium, Denmark, Finland, France, Israel, Norway, Portugal, South Africa, Sweden, and the UK.

Does Governor Romney support this bill?

Governor Romney has not yet indicated his position on the bill, but we are hopeful that he will support it. It's a common-sense prevention measure that could make a real impact on reducing the number of abortions in our state. In addition, when he was running for Governor, he said in Planned Parenthood and NARAL Pro-choice Massachusetts questionnaires that he supported increasing access to emergency contraception. We hope he will live up to that commitment.

Is it safe to provide emergency contraception without a prescription?

Yes, comprehensive data shows that emergency contraception is safe and effective for use without a prescription. It has no potential for overdose or addiction, no harmful effects on an existing pregnancy, no need for medical screening, uniform dosage and no important drug interactions. It is safe for any woman to take, and it will not harm a developing fetus.

Who has endorsed the bill?

- Massachusetts Medical Society
- Massachusetts Chapter of the American College of Obstetricians and Gynecologists
- Jane Doe, Inc., The Massachusetts Coalition Against Sexual Assault and Domestic Violence
- Massachusetts Coalition for Choice
- Massachusetts Public Health Association
- Massachusetts Chapter of the American College of Emergency Physicians
- Massachusetts Family Planning Association
- Massachusetts Pharmacy Association
- Northeastern University School of Pharmacy

Why should all hospitals be forced to dispense emergency contraception to rape survivors if some consider it a form of abortion?

Hospitals are primarily funded with public tax dollars and they serve a broad diversity of non- Catholic patients representing all faiths. As a result, they have a responsibility to provide the standard of care to all patients and not to impose their ideological beliefs on rape survivors. In addition, roughly one third of Catholic critical care hospitals in Massachusetts are already providing emergency contraception to rape survivors, according to a 2004 survey -- so others should be able to do the same.

Questions and Answers on Emergency Contraception

What is Emergency Contraception/the morning after pill?

Emergency contraception is a method of hormonal birth control that can be taken up to five days after rape, contraceptive failure or unprotected sex to reduce the risk of pregnancy. Although emergency contraception has been on the market for seven years, many people have never heard of it and are unaware of its potential to prevent unplanned pregnancies. Many others mistakenly confuse it with the abortion pill, RU-486. It does not work if you are already pregnant and will <u>not</u> harm an existing pregnancy.

Why does you believe it's important to increase access to emergency contraception?

Improving access to emergency contraception is one of the most promising ways of reducing the need for abortion. Experts estimate that wider access to emergency contraception could prevent up to half of all abortions (26,000 abortions are performed annually in Massachusetts).

How does emergency contraception work?

Emergency contraception prevents pregnancy in much the same way as the birth control pill. Studies show it works most often by delaying ovulation. It may also inhibit fertilization and implantation.

When should emergency contraception be used?

Emergency contraception can be taken following a sexual assault, when a condom breaks, or anytime unprotected sex occurs.

How effective is emergency contraception?

Emergency contraception is effective for up to five days, but the sooner it is taken, the more effective it is. When taken within 24 hours, it is more than 95% effective.

Will making emergency contraception more widely available lead many women to use it as their primary form of birth control?

No. There are three main reasons why women are unlikely to use emergency contraception rather than a more traditional form of birth control. First, it is much more expensive than many other birth control methods. Each dose costs between \$18 and \$40, depending on where it is purchased. Second, it is not as effective as condoms or regular birth control pills. Third although emergency contraception is extremely safe, side effects may include nausea and, in some cases, vomiting.

Don't some people consider emergency contraception a form of abortion?

Emergency contraception is regulated by the FDA as a form of birth control. It works in much the same way as a birth control pill, and it cannot harm a fetus growing in the womb. Some religious conservatives are concerned about the possibility that emergency contraception *may* prevent the implantation of a fertilized egg, although there is no definitive medical evidence that it does. They consider preventing implantation to be equivalent to abortion – an extreme position that is not shared by the medical community. They have the same objection to regular birth control pills and IUDs, and also oppose virtually every other form of contraception, including condoms, tubal ligations and vasectomies.

Why isn't prescription-only access enough?

Because emergency contraception is more effective the sooner it is taken, timely access is essential. For women without a primary care physician and women in rural areas, the prescription requirement can be a significant obstacle. In addition, many doctors are not available on holidays and weekends to respond to requests for emergency contraception.

When the FDA refused to grant over-the-counter status for Plan B, they cited concerns about the safety of making it widely available to minors. How do you respond to that?

Planned Parenthood is committed to reducing rates of teen sexual activity, teen pregnancy and disease transmission. We believe that the best way to achieve that is by investing in school-based sex education, which has helped significantly reduce teen pregnancy rates in recent decades. We do not believe that denying teens access to medical treatment is an effective way to reduce rates of sexual activity. Several rigorous scientific studies have shown that minors who have access to emergency contraception are not any more likely to engage in unprotected sex than minors who do not have access. If they do engage in unprotected sex, however, access to emergency contraception can significantly reduce their risk of pregnancy.





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Mechanisms of action of emergency contraception

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Abstract

The use of levonorgestrel (LNG) alone or combined with ethinylestradiol (Yuzpe regimen), for hormonal emergency contraception (HEC) has been approved in several countries whereas in others it is still under debate or has been rejected under the claim that these formulations abort the developmental potential of the embryo. The issue is whether they act by preventing fertilization or by impeding the successful development of the zygote through and beyond implantation. Until now, published work has left this issue largely unresolved, and this paucity of knowledge sustains heated controversies in many settings. A single study indicates that LNG impairs sperm migration in the genital tract of women in ways that could interfere with fertilization. Several studies in women examined the effects of HEC on the outcome of the leading follicle, but lack of precision in the timing of treatment relative to follicular growth, maturation, or rupture confers great variability and inconsistency of results within and between studies. Nonetheless, results indicate that ovulatory dysfunction may account for the prevention of pregnancy in a large proportion of cases. Studies searching for possible alterations of the endometrium at the time implantation would normally take place, found minimal changes of doubtful significance. Recent studies in animals cast serious doubts that LNG prevents pregnancy by interfering with post-fertilization events. Failure to prevent expected pregnancies is close to 25% in women, and this is likely to be accounted for entirely by treatment given too late to prevent fertilization. The exact mode of action of HEC remains undetermined.

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Keywords: Emergency contraception; Yuzpe regimen; Levonogestrel; Steroids; Rat; Cebus monkey

1. Introduction

Current hormonal emergency contraception (HEC) pills contain 0.75 mg levonorgestrel (LNG) or 0.5 mg LNG plus 0.1 mg ethinylestradiol (Yuzpe regimen) and two doses must be taken 12 h apart. When taken within 72 h after intercourse, these pills are believed to prevent about 75% of the pregnancies that would have otherwise occurred [1–3]. The mode of action of HEC has become the subject of heated debate in several countries. The main question is whether or not HEC prevents pregnancy by interfering with post-fertilization events. This issue is of importance for many people who believe that a new human life begins at the time fertilization is completed; thus, interference with post-fertilization events would lead to loss of human life.

Research efforts to discover exactly how HEC prevents pregnancy, and why it fails more often than regular contraceptive pills, have been only partially successful.

1.1. The window for HEC

The fertile days of the menstrual cycle are the days in which an act of sexual intercourse can give rise to pregnancy. These are the 5 days that precede ovulation and the day of ovulation [4]. Thus, spermatozoa have to wait one to 5 days in the female genital tract before encountering the ovum in most cases. This interval provides an opportunity to interfere with the migration and function of spermatozoa and/or with the process of ovulation. EC pills may prevent the encounter of spermatozoa with the ovum; and, even if the two gametes do come in contact, fertilization may not proceed to completion.

The efficiency of fertilization in human beings is very low in comparison with most mammals. Under ideal circumstances, when intercourse takes place during the most fertile days, the chance that fertilization will take place does not exceed 50% [5] and it is plausible that even minor alterations in the preceding processes will greatly decrease this probability. It has been shown that HEC pills do interfere with pre-fertilization events [6]. When the pills are taken too late to prevent fertilization there are two possible outcomes: (a) that HEC will not be effective and the method fails; (b) that

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HEC prevents pregnancy, in which case it acts after fertilization. When a woman uses HEC, she does not know whether she takes the pills before or after ovulation, before or after fertilization. For ethical and logistic reasons, it has not been possible to segregate groups of women who take EC after fertilization so as to assess its effect on the establishment of pregnancy. Hence, there is no direct evidence, either for or against, the hypothesis that EC pills prevent pregnancy by interference with post-fertilization events.

1.2. Effects on the migration and function of spermatozoa

Administration of 400 µg LNG 3-10 h after sexual intercourse affected sperm migration between 3 and 9 h after treatment. It reduced the number of spermatozoa recovered from the uterine cavity, increased the pH of the uterine fluid (which immobilized spermatozoa), and increased the viscosity of cervical mucus (which impeded further passage of sperm cells into the uterine cavity) [7]. Although the investigators used only 57% of the current LNG dosage, these results are highly relevant to the actions of LNG used as an emergency contraceptive. There are no similar studies for the Yuzpe regimen.

The few data available indicate that, as in other mammals, sperm migration in women occurs in two phases [8]. In the first phase which takes place few minutes after insemination, some spermatozoa, aided by propulsive contractions of the genital tract, reach the fallopian tube. In the second phase, spermatozoa that have been stored in the crypts of the uterine cervix migrate in successive cohorts towards the fallopian tube, over several days. Only those from the second phase have the ability to fertilize. As spermatozoa reach the fallopian tube, many proceed to the peritoneal cavity, Non-capacitated spermatozoa attach to the tubal epithelium for a few hours until they become capacitated, whereupon they acquire hyperactivated motility and resume their journey. Once capacitated, spermatozoa do not remain viable for long; thus, to maintain a fertile population of spermatozoa continuously within the tube until the time of ovulation, it is essential that fresh cohorts keep migrating from the cervical reservoir. If ovulation occurs after a woman has taken LNG, interference with the sustained phase of sperm migration could well reduce or eliminate the probability of fertilization.

1.3. Effects on the ovulatory process

Current understanding of the ovulatory process indicates that, when a normal gonadotropin surge acts on a mature follicle, it triggers a series of coordinated local responses that eventually lead to the extrusion of a fertilizable oocyte and the formation of a fully functional corpus luteum. These responses encompass resumption and completion of the first meiotic division; expansion of the cumulus oophorus and its detachment from the follicle wall, activation of a collagenolytic cascade, luteinization of granulosa and the-cal cells, angiogenic invasion of the granulosa, and follicle

Table 1
Proportion of women who did not ovulate or presented ovulatory dysfunction within the 5-day period following administration of Placebo or Yuzpe regimen

Follicular diameter at treatment (mm)	Placebo	Yuzpe regimen*
12-14	5/18	9/9
15-17	1/20	9/9
≥18	1/20	1/5
All	7/58 (12%)	19/23 (83%)

Data taken from [17].

rupture and voiding. Only the gonadotropin surge, follicular rupture, and functional luteinization (as indicated by progesterone measurements) can be assessed in clinical studies without use of invasive methods. The coordinated development of these responses requires a normal gonadotropin surge and proper evolution of the ensuing signaling cascades inside the follicle; and when this fails, the result can be ovulatory dysfunction [9–14] and compromised fertilization [15,16].

Several research groups, using diverse experimental designs, have explored the possibility that HEC pills alter the ovulatory process in women. All of them found instances in which none of the measured indices were abnormal as well as others in which either the luteinizing hormone peak was partially or totally suppressed or postponed, or luteinization failed partially or totally. The results seem to depend on the timing of HEC administration relative to the ovarian cycle (see [6] for review). When the Yuzpe method was administered in the follicular phase, there was good correlation between follicular development at the time of treatment (leading follicle 12-14, 15-17, or \geq 18 mm in diameter) and inhibition of follicular rupture. Ovulation was prevented in 80. 50, and 0% of the cases, respectively, and ovulatory dysfunction was present in another 25% of the treated cycles [17]. It is therefore plausible that lack of ovulation and ovulatory dysfunction account for the contraceptive effect in all cases who take the Yuzpe regimen when the leading follicle is 12-17 mm at the time of treatment (Table 1).

Depending on how close to the luteinizing hormone peak the treatment is given, LNG inhibits or postpones the gonadotropin surge or follicular rupture, or interferes with the formation or function of the corpus luteum, or has no effect on them [18–20]. Clearly, HEC pills given during the follicular phase have the capacity to interfere with the ovulatory process, suppressing the LH peak, follicular rupture, or luteinization.

1.4. Effects on the endometrium

The only post-fertilization mechanism that has been investigated in women—an alteration in endometrial receptivity that could interfere with implantation—is an indirect

^{*} Excluding uncertain cases.

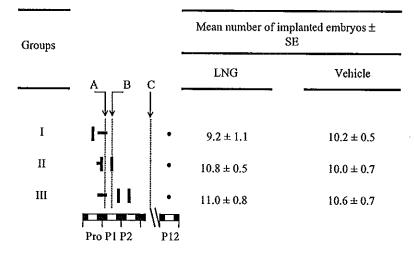


Fig. 1. Effects of levonorgestrel (LNG) or vehicle upon implantation in the rat. (|), timing of each injection of LNG or vehicle; (-), period of pairing resulting in mating; A-C, approximate times of ovulation, fertilization, and implantation (P5), respectively; (•), autopsy. The time scale indicates days of the estrous cycle (Pro, proestrus; Est, estrus) and days of pregnancy (P1-P12). None of the differences was statistically significant. Data taken from [27].

one. Endometrial biopsies have been obtained at about the time implantation would occur in a fertile cycle, in women after taking HEC and during their control cycles. Cycles in which the ovulatory process was believed to be abnormal or suppressed were excluded since endometrial development would reflect abnormal ovarian function rather than a direct effect of HEC. Some studies have found alterations in endometrial morphology or in the expression of certain progesterone-dependent molecules [21–23]. Whether or not such changes have any impact on endometrial receptivity is open to question. Other workers have found either negligible alterations or none [19,20,24,25]; and in the case of LNG, full publications in refereed journals do not support the hypothesis that it alters endometrial receptivity or impedes implantation.

From a physiological and pharmacological point of view, the administration of synthetic progestins such as LNG is highly unlikely to reduce endometrial receptivity. Progestins, whether natural or synthetic, are so called because of their ability to sustain pregnancy in ovariectomized animals. The 25% failure rate of HEC and the fact that it works best when used soon after sexual intercourse [26] are further reasons for doubting that this method impedes pregnancy by interference with post-fertilization events.

1.5. New studies in the rat and Cebus monkey

Since animal experimentation allows segregating groups treated before or after critical events, such as fertilization, in order to pinpoint the specific stages of the reproductive process which are interfered by the treatment, we undertook such studies. The effects of acute treatment with LNG upon ovulation, fertilization, and implantation were assessed in the rat [27]. LNG inhibited ovulation totally or partially depending on the timing of treatment and/or total dose admin-

Table 2

Effect of levonorgestrel or placebo given in the follicular phase or post-coitum upon ovulation and pregnancy, in Cebus monkeys

Time of treatment	Outcome measurement	Number of events/ number of cycles	
		Placebo	LNG
Follicular phase	Ovulation	6/6	8/12
Post-coitum	Pregnancy	13/24	13/24

Data from Ortiz et al., unpublished observations.

istered, whereas it had no effect on fertilization or implantation, when it was administered shortly before or after mating, or before implantation (Fig. 1). Thus, acute post-coital administration of LNG at doses several fold higher than those used for HEC in women, which are able to inhibit ovulation, had no post-fertilization effect that impairs fertility in the rat.

Studies conducted in the Cebus monkey tested the effect of acute treatment with LNG upon ovulation in non-mated cycles and upon pregnancy rate in mated cycles in comparison with a placebo in a crossover-randomized design (Ortiz et al., unpublished observations). Here again, LNG 750 µg given twice in the follicular phase inhibited ovulation when it was not impending at the time of treatment, whereas it had no effect on the pregnancy rate when it was administered after mating (Table 2). From these observations it was concluded that acute administration of LNG post-coitum, at doses which inhibit ovulation, has no post-fertilization effect that impairs fertility in the Cebus monkey.

2. Conclusion

The studies conducted so far have not fully characterized the mechanisms of action of EC pills. The information analyzed provides evidence for pre-fertilization effects and offers no evidence that EC pills prevent pregnancy by interfering with development or implantation of fertilized eggs.

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OBSTETRICS AND GYNECOLOGY/ORIGINAL RESEARCH

Availability of Emergency Contraception: A Survey of Hospital Emergency Department Staff

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Study objective: I investigate accessibility of emergency contraception pills at hospital emergency departments and survey staff at Catholic and non-Catholic hospitals across the United States. More specifically, I sought to report the likelihood that a woman calling a hospital and seeking emergency contraception could access the medication; (2) If emergency contraception is not provided, whether hospital staff would provide a referral to another facility; and (3) the outcome of the referral process.

Methods: Using a "mystery client" approach, I telephoned staff at all 597 Catholic hospitals in the United States and at 17% of non-Catholic hospitals (n=615). I used this interviewing method to reflect the experience of a laywoman calling to inquire about the availability of emergency contraception.

Résults: I found that staff at 42% of non-Catholic hospitals and 55% of Catholic hospitals said that they do not dispense emergency contraception, even in cases of sexual assault. Overall, more respondents at Catholic hospitals (23%) reported that they provide emergency contraception only to victims of sexual assault compared with staff at non-Catholic hospitals (17%). Among staff who said that their hospital does not provide emergency contraception under any circumstances, only about half gave callers a valid referral, and most referrals were ineffective.

Conclusion: To improve women's access to emergency contraception, hospitals can (1) use collaborative drug-therapy agreements to enable hospital pharmacles to dispense emergency contraception without a prescription, (2) develop and communicate written policies that support provision of emergency contraception, and (3) encourage health care providers who observe religious or ethical guidelines to provide effective referrals for women seeking emergency contraception. [Ann. Emerg Med. 2005;

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INTRODUCTION

Hormonal emergency contraception is a safe and effective method to prevent pregnancy after unprotected intercourse, contraceptive failure, or sexual assault. 1,2 Emergency contraception is a higher dose of combined estrogen and progestin, or progestin-only, oral contraceptive pills. Hormonal emergency contraception regimens have been used in the United States for more than 2 decades, but low levels of knowledge and misinformation among women and providers^{3,4} have restricted its access and limited its use. Three million unintended pregnancies occur annually in this country, half of which end in abortion.5 Furthermore, 5% of sexual assault victims of reproductive age become pregnant as a result of their attack.⁶ Emergency contraception can reduce the risk of pregnancy by at least 75%, depending on the regimen used and timing of treatment^{2,7}; therefore many of the unintended pregnancies and abortions that occur each year could potentially be averted with greater access and use.

As of this writing, emergency contraception is not yet available over the counter in the United States; therefore, women wanting to avoid pregnancy after unprotected intercourse, contraceptive method failure, or sexual assault may need to obtain emergency contraception from a hospital emergency department (ED). Although some women may obtain emergency contraception from their primary care provider, EDs are a key point of access for victims of sexual assault who seek examination and treatment. Additionally, nearly one fifth of women (17%) do not have a regular health care provider,8 and more than 11 million women of reproductive age do not have health insurance.9 Women may also rely on hospital EDs during nights and weekends when clinics and physician's offices are typically closed. Because emergency contraception pills are indicated for treatment within 72 hours of unprotected intercourse, and some research indicates it is more effective when taken within 24 hours,² timely access to emergency contraception is essential.

The US Food and Drug Administration, the American Medical Association, and the American College of

Editor's Capsule Summary

What is already known on this topic

Rinergency contraception is unavailable over the counter in the United States. Thus, any woman who needs to obtain emergency contraception must contact a health care provider.

What question this study addressed

Investigators, posing as a woman in need of emergency contraception, called all Catholic hospital emergency departments (EDs) and 17% of other EDs to determine whether there is a difference in accessibility of emergency contraception between the 2 ED types.

What this study adds to our knowledge

Only about half of EDs provide emergency contraception, even in cases of sexual assault. Catholic hospitals were less likely than other EDs to provide emergency contraception.

How this might change clinical practice

In general, EDs are insufficiently responsive to requests for emergency contraception. Emergency physicians need to review their hospital's policies and ensure that access to emergency contraception is available for patients who request it.

Obstetricians and Gynecologists advocate the use of emergency contraception for any woman who has experienced unprotected intercourse. 1,10,11 The American Medical Association's guidelines on sexual assault advise physicians to counsel patients about emergency contraception and to provide treatment if the victim requests the product. 12 In response to the need for expanded access to emergency contraception, policymakers in 6 states have passed legislation requiring hospitals EDs to provide emergency contraception-related services to sexual assault victims. 13 Several states, however, exempt hospitals from providing family planning services based on religious and moral reasons. 14 Catholic hospitals in particular operate under written guidelines that can be strictly interpreted to deny women access to emergency contraception, even sexual assault victims. Given that 15% of all ED visits occurred at Catholic hospitals in 2000, a substantial number of women, Catholic and non-Catholic, are affected by such policies.15

To assess the accessibility of emergency contraception in hospital EDs, I conducted 2 surveys, one among all Catholic hospitals in the United States and the other among a US sample of non-Catholic hospitals. Specifically, I sought to report the likelihood that a female client calling to inquire about emergency contraception would have access to either the pills or a prescription; if emergency contraception was unavailable, whether hospital staff would provide a referral to another facility; and the outcome of the referral process. I also wanted to assess whether availability of emergency contraception and

referral patterns differed between non-Catholic and Catholic facilities.

MATERIALS AND METHODS Study Design

In August 2002, I surveyed all 597 US Catholic hospital EDs. The list of hospitals was compiled from 2 diocesan hospital lists generated by the Catholic Health Association. In June 2003, I surveyed a sample of non-Catholic hospital EDs. For the second study, the American Hospital Association generated a list of all 3,600 non-Catholic hospitals in the country reporting at least 1 ED visit. We purchased a sample of 1,000 hospitals selected by the American Hospital Association to include at least 1 hospital from every state and a mix of control types (hospital "control type" is defined by the American Hospital Association as the type of organization responsible for establishing policy about overall operation of the hospital, eg, not-for-profit, state, county).

Because of budget constraints, I aimed to survey staff at about 20% of non-Catholic hospitals in each state in the United States. The state-level sampling fractions ranged from 11% of hospitals in Pennsylvania to 96% in South Dakota. To equalize sampling fractions among states, I reduced the sample in the 36 states in which the initial sample represented more than 20% of hospitals in that state. For states in which the sampling fraction was initially less than 20% or where removing 1 hospital would significantly reduce the sampling fraction below 20%, no effort was made to adjust the sample. To eliminate hospitals, I divided the sample of hospitals in a particular state by the number of hospitals that would be eliminated and removed every nth hospital. For example, if 30% (n=15) of Colorado's 50 hospitals were included in the initial sample, and I wanted to survey only about 20% of the state's hospital universe (n=10), then I eliminated every third hospital (15/5=3) from the alphabetized list. The outcome was a national sample of 663 hospitals representing 18% (range of 22% to 11% by state) of all non-Catholic hospitals. I excluded 35 hospitals because they treated only specific populations (eg, children, cardiac patients, psychiatric cases). Another 13 hospitals were excluded after 3 failed contact attempts (ie, the point at which I assumed a layperson would consider the facility to be closed, giving a response rate of 98% [615/628]). The final analysis included responses from staff at 615 non-Catholic hospitals and 597 Catholic hospitals.

Data Collection and Processing

The interviewing method in the Catholic and non-Catholic hospital studies was identical; the instrument was modified for the non-Catholic hospital survey to include a response option for offering emergency contraception by telephone prescription. Trained female interviewers followed a written script and recorded responses on precoded forms. Interviewers made up to 3 attempts to contact each hospital.

The surveys were conducted during weekend hours to simulate the experience of a woman who had unprotected

Table 1. Availability of emergency contraception and provision of referrals at Catholic and non-Catholic hospital EDs.

Availability and Referrals	Non-Catholic (n=3,425), No. (%) [95% Cl]*	Catholics (n=597) No. (%)
Circumstance		
EC unavailable, regardless of circumstance	1447 (42.2) [41-44]	328 (54,9)
EC available with restrictions	1278 (37.3) [36-39]	172 (28.8)
EC available at woman's request without restrictions	595 (17.4) [16~19]	30 (5.1)
No response/do not know/unclear	105 (3.1) [3-4]	67 (11,2)
Referrals to another facility (among those who said EC unavailable)	, ,,	• • •
Valid referral given	757 (52.3) [50-55]	154 (47.0)
Referral refused or invalid	690 (47.7) [45–50]	174 (53.0)
Total	(100.0)	(100.0)
EC, Emergency contraception. *Weighted n.		

intercourse on a Thursday evening and was seeking emergency contraception (either pills or a prescription) outside of regular clinic hours. The studies used a "mystery client" approach whereby female interviewers anonymously spoke with staff fielding calls in the emergency department and began by asking "Do you give out emergency contraception?" If the hospital staff indicated that they do not disperse emergency contraception under any circumstances, the caller asked specifically about the provision of emergency contraception for sexual assault victims and the need for a pregnancy test. If emergency contraception was not available even in this case, the caller requested the name and telephone number of another facility where she could obtain emergency contraception. Callers then pursued referrals until they reached a dead end (ie, were not offered emergency contraception or a prescription or a referral to another facility) or were told they could obtain emergency contraception. We used this interviewing methodology to reflect the experience of a laywoman calling a hospital seeking emergency contraception. The institutional review board considered this study exempt under National Institutes of Health criteria.

Primary Data Analysis

This analysis included responses from staff in a sample of 615 non-Catholic hospitals chosen at the state level. To account for states in which the sampling fraction was less than 20%, I applied weights to adjust for differential selection probabilities. For example, in states with 17% of hospitals in the sample, the weighting fraction was 1/x, where x represents the proportion of hospitals included in the sample; thus, the weighting factor was 6.0. The weighting factor (ranging from 4.5 when 22% of hospitals in the state were represented to 8.8 when 11% of hospitals in the state were represented) was applied to responses at the hospital level. The weighted n in the final analysis was 3,425 non-Catholic hospitals.

To check for potential selection bias in the non-Catholic hospital data, we compared the distribution of hospitals in the sample against the distribution of hospitals in the United States by control type. The distributions were similar, with the

exception of non-governmental "other not-for-profit" hospitals (ie, non-church operated), which were undersampled by 12%. A comparison of "other not-for-profit" hospitals to all other hospital types combined showed that staff at "other not-for-profit" hospitals more frequently reported that emergency contraception was available on request than staff at other types of hospitals (20% versus 16%). Because "other not-for-profit" hospitals were undersampled, the overall proportion of hospitals reporting that emergency contraception was available on request would have been slightly higher if "other not-for-profit" hospitals had been proportionally represented.

The weighted survey responses were summarized by calculating proportions and 95% confidence intervals (CIs) with standard errors adjusted for sampling design. (See Appendix E1 [available online at http://www.mosby.com/AnnEmergMed] for the SEM calculation.) We did not calculate CIs for Catholic hospital results because we conducted a census of Catholic hospitals. Because sampling weights were applied to the data, we used weighted point estimates and a weighted n in the SEM calculation. We used SPSS version 11.5 statistical software (SPSS, Inc., Chicago, IL) to estimate the population proportions.

RESULTS

Table 1 shows hospital staff responses to the inquiry of emergency contraception provision. In general, hospital staff reported limited access to emergency contraception. Forty-two percent (95% CI 41% to 44%) of respondents at non-Catholic hospitals said that emergency contraception is not available, regardless of a woman's circumstance, compared with 55% of respondents at Catholic facilities. Staff working at non-Catholic hospitals were more likely to report that emergency contraception is available on request than staff at Catholic facilities (17%; 95% CI 16% to 19%, versus 5%). Two percent of respondents at non-Catholic hospitals offered a telephone emergency contraception prescription to a local pharmacy (data not shown; telephone prescription was not recorded for the Catholic hospital survey).

More than one third (37%; 95% CI 36% to 39%) of respondents at non-Catholic hospitals and 29% of respondents at Catholic hospitals indicated that emergency contraception is available at their facility; however, various restrictions applied. Among staff at non-Catholic hospitals reporting that access to emergency contraception is restricted, 45% indicated that emergency contraception is available only for victims of sexual assault (with or without other requirements such as taking a pregnancy test, filing a police report, or both), 44% reported that the decision to provide emergency contraception is made at the discretion of the physician on duty, and 11% reported that a woman would be required to take a pregnancy test to obtain emergency contraception. In comparison, 79% of staff at Catholic facilities where emergency contraception is reportedly restricted said that the method is provided only to victims of sexual assault (with or without other restrictions), 19% indicated that the dispensing decision is made by the physician on duty, and 2% reported that a pregnancy test is required. Eleven percent of staff in Catholic hospitals were unwilling or unable to respond to the question about the availability of emergency contraception compared with 3% (95% CI 2% to 4%) of staff at non-Catholic hospitals. Staff at Catholic hospitals were consistently more likely to report restricted access to emergency contraception across geographic regions (see Table E1, available online at http://www.mosby.com/ AnnEmergMed).

Among all hospital staff working in states with legislation governing provision of emergency contraception for victims of sexual assault, 40% responded that emergency contraception is not available under any circumstances compared with 34% and 21% who reported that emergency contraception is available on a restricted basis and on request, respectively (data not shown). This trend is consistent among staff employed in states with no such legislation, with 45% reporting no availability of emergency contraception, whereas 36% and 15% reported limited and unrestricted access, respectively.

Among staff who reported that their facility does not provide emergency contraception for any reason, 52% (95% CI 50% to 55%) of those working in non-Catholic hospitals and 47% working in Catholic facilities gave callers a valid referral (ie, an actual name and telephone number of another facility where emergency contraception might be available). When specifically asked if the referral facility provides emergency contraception, 84% and 80% of staff at non-Catholic and Catholic hospitals, respectively, did not know the answer to this question (data not shown). The majority of staff surveyed at non-Catholic hospitals (70%; 95% CI 60% to 80%) and at Catholic hospitals (77%) that did provide referrals directed callers to another hospital (data not shown). Fourteen percent of respondents at non-Catholic hospitals and 7% of respondents at Catholic hospitals directed callers to clinics (eg, Planned Parenthood), whereas 16% of respondents at non-Catholic and Catholic facilities provided callers with valid referrals to a rape crisis hotline or another facility such as the local Department of Health. When callers pursued referrals, 80% (95% CI 77% to 83%) of those

Table 2. Outcome of referrals for emergency contraception at Catholic and non-Catholic hospital EDs.

Outcome	Non-Catholic (n=757), No. (%) [95% CI]*	Catholics (n=149), No. (%)
Dead end	603 (79.7) [77-83]	96 (64.5)
Led directly to EC	154 (17.3) [15-20]	44 (29.5)
Led eventually to EC	23 (3.0) [1-5]	9 (6.0)
Total	(100.0)	(100.0)
EC, Emergency contracept *Weighted n.	ion.	

given by staff at non-Catholic hospitals were ineffective compared with 65% given by staff at Catholic hospitals. Ineffective referrals were considered those leading to wrong numbers, clinics that were closed on weekends, and facilities that did not provide emergency contraception (Table 2). Nearly twice as many referrals from staff working in Catholic hospitals (30%) led directly to emergency contraception compared with referrals from staff at non-Catholic hospitals (17%; 95% CI 15% to 20%).

Hospital staff frequently made informal comments when responding to the survey questions. Many respondents provided helpful information, yet a number of comments made during the interview indicated that the respondent was misinformed about emergency contraception. For example, several respondents erroneously reported that emergency contraception is not available in the United States or in their particular state. A number of respondents confused emergency contraception with the abortion pill mifepristone. A handful of staff at non-Catholic hospitals mentioned that their facility does not perform sexual assault examinations and would therefore not provide emergency contraception.

LIMITATIONS

The current study has several limitations. First, the non-Catholic hospital sample was not randomly selected. The estimated proportion of emergency contraception availability on request would have been slightly higher if "other not-for-profit" hospitals had been proportionally represented; this difference may have introduced a small negative bias. Second, the proportion of non-Catholic hospitals in the sample varied by state; therefore, we applied weights adjusting for differential selection probabilities. However, the differences between the unweighted and weighted results were small and not significant in any of the analyses. Third, because the geographic distribution of Catholic hospitals differs from that of the non-Catholic hospitals, the observed variation could be a combination of differences by hospital type and potential regional differences. Fourth, staff responses might have differed if we spoke specifically with a physician or other medical staff person. Staff triaging telephone calls may not be fully aware of ED policy about provision of emergency contraception. In addition, a woman requesting emergency contraception in person may

receive a different response than a woman inquiring by telephone about access to the method. Finally, the 2 surveys were conducted at different points, and any changes in hospital policies may have artificially increased or decreased the differences between the 2 hospital groups.

DISCUSSION

The use of emergency contraception to prevent unintended pregnancy has been endorsed by leading medical authorities, yet our data show that availability of emergency contraception appears to be poor in hospital EDs across the country, regardless of affiliation with the Catholic Church. Staff at a considerable number of hospitals indicated that their facility would not provide emergency contraception for any reason. In states with legislation governing provision of emergency contraception for victims of sexual assault, our data suggest that the mandates may have had some impact on staff's knowledge about the availability of emergency contraception. Comments made by hospital staff, however, suggest that many may be unaware of emergency contraception or misinformed about the method, thus contributing to the apparent limited availability of emergency contraception.

Most respondents at Catholic hospitals who reported that emergency contraception is available at their facility indicated that access to emergency contraception is limited to sexual assault victims (with or without other restrictions), that the treatment decision would be made by the physician on duty, or that a pregnancy test or pelvic examination is required. Although staff at non-Catholic hospitals also reported such limitations, they were more likely to report that emergency contraception could be obtained simply by request. Reports of more restricted access to emergency contraception among Catholic hospital staff was consistent across geographic regions, suggesting that differences between Catholic and non-Catholic hospitals are not a result of the distribution of Catholic hospitals but rather of other potential factors, such as observance of the Ethical and Religious Directives for Catholic Health Care Services. 16 A number of surveys have shown that Catholic hospitals in the United States are likely to have policies prohibiting physicians from prescribing emergency contraception, even to victims of sexual assault. 17-15

Because emergency contraception is safe and effective and there are no absolute contraindications to using the method, any woman requesting emergency contraception should be eligible to receive it. A recent study conducted by Kesharvaz et al²⁰ found that ED practitioners were less willing to prescribe emergency contraception for women after unprotected consensual sex than after sexual assault (73% versus 88%). Because a physician's willingness to provide emergency contraception may vary by a woman's circumstance, I believe that this decision should not be made solely at the discretion of an individual physician, as was commonly reported in our study, but rather in accordance with guidelines set forth by leading medical authorities.

To promote availability of emergency contraception in a hospital setting and to reduce the need for contact with a health care provider, an urban medical center in Minneapolis established a program simulating nonprescription access to emergency contraception under a collaborative agreement between a physician and the pharmacy department. The study results showed an increased use of nonprescription emergency contraception during the study period, demonstrating how regulations that require contacting a health care provider to obtain a prescription are a barrier to the use of the method. Hospitals operating in states with collaborative drug-therapy agreements and not already providing emergency contraception through pharmacies should consider taking advantage of such opportunities for the benefit of patients, as well as to reduce the time commitment of ED clinicians. However, such arrangements would not completely absolve hospitals from the responsibility of providing emergency contraception for victims of sexual assault and for women who choose not to use such programs.

Several states have legislation mandating provision of emergency contraception to sexual assault victims if they request the method. Our finding that a large proportion of hospital staff working in these states reported that emergency contraception is unavailable suggests that mandates may not have had an impact on availability of emergency contraception in these states. It is also possible that policies were not yet implemented at the survey or that staff were not informed of a policy change about provision of emergency contraception.

Health care facilities refusing to dispense emergency contraception on ethical or moral grounds have an obligation to provide a referral to another facility, yet in our study only half of hospital staff who said emergency contraception was unavailable followed this protocol. Even when hospital staff did provide a valid referral, it rarely led to a facility where a woman could have obtained emergency contraception. Despite Catholic hospitals' unwillingness to make emergency contraception available for most women, a strong majority of American Catholic women (76%) prefer to have a community hospital that offers emergency contraception for sexual assault victims, and more than half (57%) of these women want a hospital that provides it generally for pregnancy prevention.²²

The findings from this study illustrate the barriers that women face when trying to access emergency contraception from hospital EDs, particularly outside of regular business hours. Because emergency contraception is labeled for treatment within 72 hours of unprotected intercourse, hospitals that impose restrictions or do not provide emergency contraception under any circumstance could delay access to emergency contraception.

In summary, women's access to emergency contraception at hospital EDs appears to be poor. Hospital administrators should consider evaluating current emergency contraception practice guidelines to ensure that they are complying with the medical standards of care. Until emergency contraception pills are available over the counter in the United States, there are several ways to increase women's access to the method. First, hospitals can use existing collaborative agreements to enable pharmacists to dispense emergency contraception pills without a prescription. Second, hospitals can develop and communicate written

policies that support counseling on and provision of emergency contraception to any woman who wants to avoid an unintended pregnancy, which includes training all ED staff (especially those answering the telephone) about the availability, use, and benefits of emergency contraception. For example, it is important to distinguish emergency contraception from RU-486 (ie, mifepristone) to correct the misperception that emergency contraception induces an abortion. 23-25 Hospitals should also encourage emergency contraception provision through advance and telephone prescriptions. Finally, health care providers who follow religious or ethical guidelines that prohibit provision of emergency contraception should counsel their patients about all available options and provide valid and effective referrals. Implementing these recommendations would improve women's access to an important reproductive health product in the United States.

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Harrison

Editor's Capsule Summary What is already known on this topic: Emergency contraception is unavailable over the counter in the United States. Thus, any woman who needs to obtain emergency contraception must contact a health care provider. What question this study addressed: Investigators, posing as a woman in need of emergency contraception, called all Catholic hospital emergency departments (EDs) and 17% of other EDs to determine whether there is a difference in accessibility of emergency contraception between the 2 ED types. What this study adds to our knowledge: Only about half of EDs provide emergency contraception, even in cases of sexual assault. Catholic hospitals were less likely than other EDs to provide emergency contraception. How this might change clinical practice: In general, EDs are insufficiently responsive to requests for emergency contraception. Emergency physicians need to review their hospital's policies and ensure that access to emergency contraception is available for patients who request it.

Volume **BB**, NO. **B** : Month 2005



TO: Massachusetts Advocates of Reproductive Rights & Health

FROM: Catholics for a Free Choice

DATE: March 2005

RE: Addendum to CFFC's Massachusetts State Report

Catholic Health Care State Reports: Massachusetts is one in a series of state reports produced by Catholics for a Free Choice (CFFC). This publication, along with reports on Wisconsin, New York, Illinois, Michigan, California and Texas, chronicle state-specific challenges when non-religious hospitals merge with Catholic-owned entities. The report also covers reproductive health at Massachusetts' Catholic universities, as well as important information that prochoice advocates need to know about the Massachusetts Conference of Catholic Bishops.

Each of these state reports chronicle the history and developments of Catholic health care and how it affects you: the consumer, the taxpayer, the reproductive health advocate and foremost, the patient. Knowledge is power. When it comes to your health, accurate information about your health care providers is especially vital.

Since the original publication of Catholic Health Care State Reports: Massachusetts in November 2003, quite a bit has changed for the church, the viability of prochoice legislation in Massachusetts and the health care infrastructure itself. Please note the following developments since the publication of the Massachusetts state report.

- The General Election of 2004 brought significant changes to Beacon Hill. Besides a prochoice majority in the General Court, Massachusetts has new prochoice leadership in the House; this represents a significant change from the era of "Speaker-for-Life" Tom Finneran and unprecedented opportunity for prochoice legislation.
- There are now fewer clinics in Massachusetts where women can go to obtain an abortion. The WomenCare clinics, which served Southeastern Massachusetts, Cape Cod, Brookline and the North Shore, closed abruptly, leaving some patients without a referral or follow up care. Remaining clinics include: Boston Medical Center; FourWomen in Attleboro; Planned Parenthood health centers in Boston, Worcester and Springfield; and Women's Health Services in Chestnut Hill.
- Long time lobbyist Gerry D'Avolio, Executive Director of the Massachusetts' Catholic Conference, announced his retirement at the end of 2004. He has yet to be replaced.
- An effort to consolidate parishes by the Archdiocese of Boston has decreased the amount of active churches in the state from the 713 listed in the report. The Archdiocese of Boston has plans to close a total of 80 parishes this year. Currently, there are 621 active parishes across the state, although this number is expected to fluctuate.

Gay marriage is now legal in Massachusetts. (The pending decision is mentioned in the Report.) This has certainly mobilized the Catholic church in Massachusetts, as have recent legislative hearings on stem cell research.

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Ray Flynn, the former Boston Democratic mayor and former ambassador to the Vatican under President Clinton, has reemerged on the Massachusetts political landscape as a leading critic of the Democratic Party with an organization entitled Catholic Citizenship, which claims to educate Catholics on the political process in order for them to be to be faithful to the Magisterium.

Catholics for a Free Choice is committed to working with our advocacy partners in states across the nation to ensure a future where the reproductive rights and health of women are always advanced and protected. If you are interested in more information about CFFC's Catholic health care research and activities, please contact the Public Policy department at (202) 986-6093, or email us at cffc@catholicsforchoice.org.

EMERGENCY CONTRACEPTION:An update

Eve Rittenberg, M.D. Internist, Southern Jamaica Plain Health Center, Brigham and Women's Hospital

U.S. Pregnancies: Unintended vs. Intended

Unintended 49%:
Unintended 49%:
Unintended births 22.5%
Elective abortions 26.5%

3 million unintended pregnancies a year in the U.S.

lenshaw SK. Fam Plann Perspect. 1996;30:24-29.

What difference could EC make?

Increased use of EC could reduce the number of unintended pregnancies in the US by 1.7 million and the number of abortions by 800,000

In 2000: estimated 51,000 abortions prevented by EC (43% of total decline between 1994 -2000)

Alan Guttmacher Institute; Princeton University, Office of Population Research

EC: What is it?

Intervention used <u>after</u> unprotected intercourse to <u>prevent</u> pregnancy

- •Must be started within 72 120 hours of unprotected intercourse
- •It is NOT an abortifacient
- •Also called: The Morning After Pill

Mechanism of Action

Prevent pregnancy from starting: do not interrupt an established pregnancy

- · Inhibit or delay ovulation
- · Decrease corpus luteum function
- · Interfere with transport of sperm & egg
- Change endometrium to prevent implantation

Glasier A. Emergency Postcoital Contraception. NEJM 1997; 1058-1064.

Medical Contraindications

- None
- · NOT indicated if already pregnant
- WHO guidelines do NOT restrict EC for:
 - cardiovascular disease, hypertension, migraines, liver disease, smoking, thromboembolic disease
 - however, progestin-only regimen available
- No serious adverse effects even with repeat use

United Nations Task Force on Post-Ovulatory Methods for Fertility Regulation. Contraception 2000;61:303-308

Side Effects

- Nausea/Vomiting
- · Altered Next Menses
- · Abdominal Pain/Cramping
- · Breast Tenderness
- Dizziness
- · Fatigue
- Headache
- · NO evidence of teratogenicity

Effects on behavior

 Making emergency contraception available ahead of time does NOT increase unprotected sex or decrease use of regular contraception

Glasier A, Baird D. N Engl J Med. 1998;339:1-4.

Jackson RA, Schwartz EB, Freedman L, Darney P. Obstetrics Gynecol. 2003;102:8-16.

Gold MA, Wolford JE, Smith KA, Parker AM. J Pediatr Adoleso Gynecol. 2004



American College of Obstetricians and Gynecologists

- "...emergency contraception should be offered to women who have had unprotected sexual intercourse within 72 hours..."
- "...during a routine gynecologic visit, physicians may offer patients an advance prescription for emergency contraception."
- · supports an OTC product

ACOG Practice Bulletin, Number 25, March 2001



American Medical Association

- "physicians and other health care professionals should be encouraged to play a more active role in providing emergency contraception,... by discussing it as part of routine contraceptive counseling..."
- "...enhance efforts to expand access to emergency contraception..."

AMA policy H-75.985

Summary

- EC is used <u>after</u> unprotected intercourse to <u>prevent</u> pregnancy
- · No absolute contraindications
- · Only minor side effects
- · Very effective
- Potential large impact in reducing unintended pregnancies and abortions
- TIME IS CRUCIAL