

Legal, Ethical and Regulatory Aspects of Introducing Emergency Contraception in the Philippines

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Emergency contraception is the use of drugs or devices to prevent pregnancy within a few days after unprotected coitus. A variety of legal and political obstacles may hamper the introduction of emergency contraception into developing countries. Many of these obstacles are rooted in a basic lack of knowledge about the mode of action of emergency methods, the indications for their use and their availability.

The most common methods of emergency contraception, combined oral contraceptives (estrogen-progestin pills) and copper IUDs, are legal for regular contraceptive use in most countries, and are available through public health services, private physicians and pharmacies. More than 20 countries* have licensed existing drugs for emergency contraception; in most developing nations, however, there are no laws specifically governing the use of emergency contraception.

Furthermore, the legal status of other drugs considered safe and effective for emergency contraception—such as certain antiprogestins¹ and androgens—varies markedly by country. These methods must be used within a few days of unprotected intercourse to be effective as emergency contraception. Such compounds must be distinguished from various analgesics, antimalarial drugs, antibiotics and other drugs that women in many developing countries use to induce menstruation or early abortion, none of which have been tested for safety or efficacy for these purposes, or as methods of emergency contraception.

Whether regulatory agencies in a given country will formulate specific policies on emergency contraception depends on a number of factors. In some countries, approval of emergency contraceptives may be dictated largely by the interpretation of abortion laws, despite their use to prevent pregnancy. In others, abortion's legal status may have no connection to the government's willingness to approve emergency methods. In Nigeria, for example,

where abortion is legally prohibited,² the sale of hormonal drugs for emergency contraception is permitted. Such regulatory approval for emergency contraception enables health providers, including pharmacists, to be trained to help women use such methods safely and effectively.

The question of when contraception ends and abortion begins may affect how legislation related to emergency contraception is framed.³ Many countries have no legal definition of abortion or pregnancy. In addition, reproductive health and rights advocates have often sought to separate the concepts of abortion and contraception. However, opponents of contraception and abortion can be expected to incorrectly equate emergency contraception with abortion to create confusion between the two in both the legal and political arenas.

Restrictive abortion laws are likely to have only a limited impact on the actual use of the most common emergency methods (combined pills and the IUD). However, antiabortion laws could increase the likelihood that certain emergency methods will be restricted to controlled distribution points.

In practice, easy access to hormonal methods in many developing countries has enabled women to use these drugs to prevent pregnancy on their own, despite the presence of laws or religious edicts restricting their use. Policies and laws that prohibit or curtail dissemination of health information on emergency methods can also drive women to use them without proper counseling from trained health providers or pharmacists.

Emergency contraception administered immediately after unprotected intercourse would probably be legal in countries with somewhat restrictive abortion laws that use the medical definition of pregnancy—i.e., a pregnancy is not achieved until implantation is completed. (Such countries include Germany, Liberia and New Zealand.) This would be true even in cases when fertilization had most likely occurred, since preventing a fertilized ovum from completing the process of implantation does not constitute an abortion in these countries.

Attempts at preventing implantation are not governed or restricted by abortion

laws in other countries, such as the United Kingdom,⁴ in part because legal proof of criminality would rest on proof of pregnancy; physical trauma from an abortion procedure would also be required for prosecution or conviction of criminality.⁵ In addition, emergency contraception may also be legally acceptable in countries where menstrual regulation (vacuum aspiration) is permitted, such as Bangladesh, or where pregnancy is defined as beginning as late as 35 days after intercourse.

This article describes the complex influences of regulatory laws, religion, politics and ethics on the provision of emergency contraception in one large developing nation—the Philippines, which has no law specifically governing the use of emergency contraception. Although emergency methods are little-known in the country, several factors suggest that they may be well suited to the Philippines.

Philippine Legal Context

In the Philippines, estrogens, progestins and their combinations are included in the National Drug Formulary's Essential Drug List, which specifies routes of administration, pharmaceutical forms and strengths.⁶ These drugs are also included in the reference manual for prescribing pharmaceutical products commonly used by physicians and pharmacies. There is nothing specific to bar a physician from prescribing combined pills in the higher dosages necessary for emergency use. IUD insertion for emergency contraception would probably also be acceptable from a legal standpoint, as long as it could not be established that fertilization had occurred. (Of course, pregnancy is a contraindication for all contraceptives, including emergency methods.)

In addition, it is unlikely that women's access to the pill and IUD could be reduced. Since 1973, pills, IUDs and other fertility regulation methods have become generally available through the Philippine family planning program in public and private

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*These countries include Bulgaria, the Czech Republic, Ecuador, Finland, Hong Kong, Hungary, Jamaica, Kenya, Malaysia, the Netherlands, Nigeria, Pakistan, Poland, Russia, Singapore, Slovakia, Thailand, the United Kingdom, Uruguay and Vietnam.

hospitals, clinics and pharmacies. The fact that these methods are so accessible to women and represent the standard option in the public and private sectors suggests that it would be difficult to prevent their use for emergency contraception.

However, some legislators who oppose “artificial” family planning on religious grounds have made repeated attempts, through bills and resolutions submitted in the Philippine congress, to classify all oral contraceptives and IUDs as abortifacients. Thus, methods used for emergency contraception are clearly vulnerable to the same legal challenges as regular contraceptives.

Given this background, it may be useful to examine the Philippine experience with the use of oral contraceptives containing estrogen and progestin to induce menses. Many Filipino women have the mistaken belief that such drugs can act as abortifacients: A number of studies have shown that Filipino women sometimes devise their own remedies for protection from unwanted pregnancy through the widespread use of very high doses of combined oral contraceptives.⁷ These studies also revealed that women and health providers distinguish between contraception, induction of delayed menstruation (before pregnancy status is determined) and abortion, although the same drugs in varying amounts may be used with varying degrees of efficacy for these different purposes.

In 1992, a survey was conducted of the availability of, use of and regulations imposed on combined pills in the city of Davao and its surrounding areas, in the southern Philippines.⁸ The survey was conducted about one year after the Philippine government passed the Generic Drugs Act, which requires that oral contraceptives containing estrogen and progestin be prescribed only by a doctor. The prescription must indicate the generic name of the active ingredients and the specific chemical form (and brand name, if desired), the dosage, the delivery mode or system and the appropriate dose frequency.

To collect the data in this survey, two women (one dressed poorly, the other well-dressed) posed as clients in need of a substance to induce menstruation (locally known as *pamparegla*) and sought assistance from pharmacies and doctors in the Davao area. Even though the Generic Drugs Act restricts prescription responsibility to doctors, the women easily obtained a variety of combined pills (Gestex, Duphaston, Femenal, Promolut N and Proseckon) from pharmacies—and even

from sales clerks—by requesting *pamparegla*. No questions were asked or prescriptions required.

The most popular remedy prescribed for treating delayed menstruation (especially in areas outside the city limits) was an oral contraceptive brand containing mestranol and norethindrone (Gestex, manufactured by the drug company Medichem). This drug is also indicated for treatment of secondary amenorrhea of short duration; doctors prescribe it and other formulations upon request.

These pills are often referred to as “pregnancy test pills” because of the notion—among both women and doctors—that if such pills do not successfully bring on menstruation, then a woman must be pregnant.

Thus, Philippine women use pills such as Gestex to induce menses, deliberately taking twice the prescribed dosage or more. The two women investigators were never informed by pharmacists or doctors about the compound’s contraindications or its possible effects on a developing fetus. Some of these drugs are relatively inexpensive. (Gestex, for example, costs US \$1.00–\$1.50 per tablet.) Other mestranol-norethindrone combinations are far costlier, however, with one (marketed as Proseckon) costing US \$4.50–\$7.80 per tablet. Some pharmacy clerks, especially those working in poorer areas, also prescribed herbal potions and remedies for delayed menstruation.

Anecdotal evidence suggests that prostitutes take other drugs, such as Fansidar (an antimalarial drug) and Methergine (used to control uterine bleeding), which are rumored to be effective for inducing menses. An over-the-counter remedy for stomachaches (Esencia Maravillosa), whose active ingredient is unknown, is also said to be commonly used by low-income women because it is cheap and easy to obtain.

According to a community-based study in Davao conducted among urban poor women, nearly 71% said they had ever tried to induce menstruation.⁹ Most had used high doses of combined pills; others had tried prostaglandins such as misoprostol, an antiulcer drug that is used in some countries with mifepristone in medical abortion, as well as analgesics and bitter herbal concoctions.

Our examination of the medical records of women attending a clinic in Metro

Manila in 1994 confirmed this practice of taking combined pills to induce menstruation (in the belief or hope that the amenorrhea was not caused by pregnancy) or an abortion (when a pregnancy was strongly suspected or confirmed). Among

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the 237 women who wanted to induce menstruation or terminate their pregnancy, 40% had already attempted to do so. (Sixty percent had done nothing.) Among the 40%, 12% said they had tried combined pills (and this proportion was probably larger, since some women reported having injected or ingested an unknown compound); 9% had resorted to abdominal massage or acupressure and 7% had taken misoprostol. The remaining 11% had taken a variety of other drugs (including analgesics and antibiotics) or herbal medicines. Most of these women (75%) had used more than one of these methods to induce bleeding.

These studies suggest that both women and health providers in the Philippines would welcome having the option of emergency contraception. They also indicate that there would likely be little compliance with any law restricting emergency contraception in case of potential claims that it is an abortifacient.

Barriers to Emergency Methods

Although emergency methods may be well suited to the Philippines, their introduction will doubtless encounter a number of obstacles, including those related to the country’s laws, the influence of foreign agencies, medical barriers, a wide range of ethical issues and the Philippine political situation.

Regulatory Obstacles

The Philippine government’s reaction to the widespread use of misoprostol to induce menstruation and abortion may illustrate how regulations could restrict emergency contraceptives. In June 1994, newspapers reported that the Bureau of Food and Drugs had confirmed the drug’s abortion-inducing effect.¹⁰ The secretary of health then directed the bureau to con-

duct a survey among obstetricians, gynecologists, drugstores and hospitals to determine whether misoprostol, which was approved only for the treatment and prevention of gastritis induced by anti-inflammatory drugs, was being misused as an abortifacient.

Although the results of the survey were never released, the sale and dispensing of misoprostol has since been limited to tertiary hospital pharmacies and big drug-store chains. These outlets are now required to keep a special log for prescriptions, listing the name and address of each patient,

“Since many Filipino women are already using hormonal compounds to induce menstruation, teaching them how to properly use emergency contraceptive pills would not be difficult.”

the quantity dispensed and the name of the dispensing physician. The manufacturer, Searle, also agreed to regulate the distribution and sale of the drug.

Any effort to legally designate oral contraceptives as abortifacients might use a regulation similar to the one governing misoprostol. Access to other hormones used in emergency contraception is already limited in many cases. For example, under the Generic Drugs Act, ethinyl estradiol tablets are included in the list of products requiring strict precaution in prescription, sale and use. Diethylstilbestrol, another high-dose estrogen that can be used for emergency contraception, is registered under the “complementary list” in the National Drug Formulary, which lists alternate drugs that can be used when those classified in the core or main list are ineffective or inappropriate. Danazol is included in the core list of essential drugs, while other androgens are in the complementary list.¹¹

Impact of U.S. Policies

Since the Philippines, and developing countries in general, are usually not equipped to test and approve drugs, they must rely on assessments made in developed countries. About 75% of contraceptive research and development funds come from the United States, which is the main donor of contraceptives to developing countries and which will not supply drugs unapproved by the U.S. Food and Drug Administration.¹²

Thus, U.S. approval of a specifically in-

dicated method of emergency contraception might be expected to pave the way for possible approval in other countries. On the other hand, some products may be suitable for one population but not for others, given the cultural, social and even biological variations in populations. Support for locally-based research on specific issues related to emergency contraception would probably be helpful to local regulatory processes.

The U.S. Food and Drug Administration has no explicit policy regarding specific labeling for use of oral contraceptives

or copper IUDs in emergency contraception; thus, these methods are exported to developing countries without a listing of the additional indication for emergency use. In the Philippines, the indication for any product is the one approved by the Bureau of Foods and Drugs. How-

ever, no provision in the Generic Drugs Act prevents use of a drug beyond the label’s stated indication—as the use of combined pills in the Philippines for purposes other than their approved indication attests.

But U.S. Food and Drug Administration approval, or the lack of it, can clearly affect use, as when the agency previously withheld approval for depot medroxyprogesterone acetate, which was subsequently banned in the Philippines. On the other hand, if the U.S. Food and Drug Administration were to list emergency contraception as an indication for some family planning methods, conservative forces in the Philippines might respond by encouraging the stricter regulation of or even an outright ban on these contraceptives.

Medical Obstacles

Prescribing practices that hinder access to contraceptives or that erect medical barriers to family planning use need to be further examined. Many current family planning prescribing policies and practices, including eligibility criteria for use, are based on findings from studies conducted in the 1970s on older methods or reflect local experiences and beliefs. The current lack of knowledge about emergency contraception is not likely to be remedied unless information and training programs impart current data about correct use. Health providers need to be educated so they can enable women to use hormonal emergency methods safely and correctly

in the privacy of their home, without the need for further intervention from health professionals.

Ethical Issues

Ethical issues related to the use of emergency contraception are particularly thorny. In a country with restrictive abortion laws, what is the obligation of medical professionals when women seek their help after unprotected intercourse? Is it ethical to withhold the benefits of a technology that is less dangerous than either carrying a pregnancy to term or undergoing a clandestine abortion? How can a health provider be guided by the ethical principle of beneficence? Do the goals of medical intervention include not only the promotion of health and the prevention of disease or untimely death, but also the relief of symptoms, pain and suffering? Will the use of emergency contraception help to achieve these goals?

Two central ethical issues related to the provision of any family planning method are informed consent and an assessment of the risk-benefit ratios of different methods. It is the obligation of health professionals to provide adequate information in terms that the client understands; health providers must ensure that these risks and benefits are adequately communicated to women seeking emergency contraception.¹³

• *Testing and safety.* The short- and long-term safety of contraceptive methods, especially when these are provided to poor women in developing countries, have too often been neglected by regulatory bodies and health service personnel. In the case of emergency contraception, where existing methods are used for a different yet important purpose, would women suffer discomfort, side effects or any other consequences because of the larger doses or changes in the mode of administration? Will the treatment be less or more dangerous than the condition it seeks to prevent (i.e. pregnancy), given that many potential users suffer from iron deficiency anemia, goiter, hypertension, kidney and heart disease, and other ailments?

The further testing of emergency methods, even in countries where health standards are generally low, could indeed be ethical. To date, nearly two dozen studies have specifically found copper IUDs to be safe for emergency contraception¹⁴ and no long-term complications have been reported for the emergency use of oral contraceptives.¹⁵ Moreover, combined oral contraceptives and IUDs have been extensively studied for regular contraceptive use, and numerous studies have found them to be

safe for appropriately screened women.

•*Cost.* An estimated 120 million women in developing countries do not practice family planning, even though they do not want to become pregnant.¹⁶ There are no estimates, however, of the number of women who might seek methods to prevent pregnancy after unprotected coitus if emergency contraception were available and accessible.

In the Philippines, many women do not seek medical care until their health problems, including those associated with pregnancy, childbirth and abortion, become serious. One reason for delaying care is its cost—in terms of transportation fees, payment for medical consultation and treatment, and missed time from housework or paid work. Since emergency contraception is used by women who are highly motivated to prevent a pregnancy, cost is unlikely to be a big consideration, especially if medical methods represent a more effective alternative to folk remedies. Once emergency methods are available, women would no longer have to spend money on popular but ineffective and dangerous remedies and methods, and the emotional costs associated with using illicit or dangerous methods would also be reduced.

•*Infringement on women's reproductive rights.* Filipino women's right to reproductive self-determination, including the rights to health care and the benefits of scientific progress, are protected by the International Covenant on Economic, Social and Cultural Rights.¹⁷ As a matter of human rights, therefore, women exposed to unprotected intercourse should have access to emergency contraception.

•*Rape.* In countries with restrictive abortion laws and where reproductive health services may be perceived as related to abortion, it may be helpful to focus initial legal efforts at making emergency contraception available to women who have been raped. In one Philippine national survey, the 1993 Safe Motherhood Survey, about 3% of women who had ever been pregnant reported having been raped.¹⁸

•*Religious arguments.* There are considerable religious constraints to the potential use of emergency contraception in predominantly Catholic countries such as the Philippines, where the Church vigorously opposes the use of "artificial" family planning methods. Despite this official stance, however, a 1992 survey conducted by the Philippine Legislators' Committee on Population and Development showed that many Filipinos appeared unaware of the Church's opposition to tubal

ligation; 46% asserted that the Church allows it with conditions and another 18% said that the Church had no policy about sterilization.¹⁹ According to a report on the survey, many Filipinos simply separate their views on family planning from what their religion teaches; intensity of religious belief does not seem to have an effect on family planning attitudes.

Another survey, conducted by the University of the Philippines Population Institute, showed that many Filipinos do not accept Roman Catholic teachings on family planning.²⁰ Practically all (98%) of the 400 couples interviewed said that they were in favor of the government's population policies, and more than three-fourths claimed that they would not be swayed by the pronouncements of the Church on family planning.

Nonetheless, even if many Filipino women do not necessarily follow the Church's teachings on contraceptive use, the Church exerts a powerful influence on government policies that affect legal access to family planning methods. Since the pill and IUD are legally available, their use as postcoital methods cannot be prevented. However, the Church is likely to continue, and even escalate, its campaign to ban these methods. Tactics include erroneously asserting that methods of emergency contraception are abortifacients and claiming that their use (and the use of any contraceptive) is intrinsically evil. Pressure will most likely continue to be exerted on the Department of Health, the President, legislators (particularly those supported by the Church) and Catholic parishioners (through pastoral letters).

•*Cultural acceptability.* Another important consideration is the cultural acceptability of emergency contraception to both users and providers. One reason for the relatively low prevalence of modern contraceptive use in the Philippines—25% among married women aged 15–49²¹—is a fear of rumored side effects, so emergency one-time use may be more culturally acceptable than regular, sustained use.

Filipino language also reflects a cultural predisposition that might incline women to use emergency contraception, since the vocabulary of pregnancy implies that life has not yet been created at the time of conception. For example, a woman is not considered pregnant (*buntis*) in the first few weeks after a missed period. Instead, she is "conceiving" (*naglililihi*), or in the process of becoming pregnant, which takes a month or more after a missed period. Many Filipino women do not believe that they are pregnant until they experience quickening.

Since many Filipino women are already using hormonal compounds to induce menstruation, teaching them how to properly use emergency contraceptive pills would not be difficult. The larger, more complex problem would be devising ways to teach Filipino women to practice family planning regularly (and to adopt measures to prevent sexually transmitted diseases) so they would not need to rely on emergency methods.

Conclusions

The drafting of the 1987 Philippine Constitution, which involved an unsuccessful campaign to amend the Bill of Rights to grant full rights to the unborn, awakened the need to promote women's health and reproductive rights. Since then, advocates, including governmental and nongovernmental organizations, academia and the media have worked together in many projects and programs to advance women's reproductive health and rights. However, the professional medical and legal associations have not been as active. The challenge for the broad health community is to work effectively to enable women to have more control over their reproduction and exercise their full rights.

Filipino women would probably welcome any safe product or method that would allow them to avert an unwanted pregnancy within the first few days after unprotected intercourse. Women have discovered on their own that estrogen-progestin drugs induce menstruation. Expanding providers' knowledge about emergency methods and then motivating them to apply this knowledge could contribute to safer and more effective pregnancy prevention among women exposed to unprotected intercourse.

Although legal restrictions on both family planning and abortion will certainly influence the availability of emergency contraception, this method may prove compatible with cultural norms in the Philippines, and women and providers may welcome its introduction. Moreover, women who are highly motivated to prevent pregnancy will circumvent restrictions placed on its use, regardless of the political and religious climate. The best strategy, therefore, would be to include women in decisions regarding the use of emergency contraception.

Given the controversial nature of family planning in national Philippine politics, it is essential that accurate information about emergency contraception be disseminated to women's advocates, health providers and policymakers con-

nected to the issue. A better understanding of the methods among these groups may increase the ability of women and their families to manage fertility, promote health and determine quality of life.

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