Resources for Emergency Contraceptive Pill Programming

A TOOLKIT

PATH
A catalyst for global health

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PATH
1455 NW Leary Way
Seattle, WA 98107
Tel: (206) 285-3500
Fax: (206) 285-6619
Web: www.path.org

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Emergency Contraceptive Pills (ECPs):

A contraceptive method that can prevent pregnancy after unprotected sex**.**

Resources for Emergency Contraceptive Pill Programming: A Toolkit

Tools to help program managers, policy makers, and donors make ECPs widely available to women in developing countries through large-scale family planning programs.

ECPs are special doses of birth control pills that can be used *after* unprotected intercourse to *prevent* pregnancy. Although ECPs offer a safe and effective contraceptive option, with some notable exceptions the method has yet to be widely integrated into developing-country family planning programs. The purpose of this toolkit is to facilitate the integration of ECPs into developing-country family planning and reproductive health programs. It includes resources for ECP advocacy, assessment, service provision, and evaluation. The planning and implementation tools represent best practices and experience that will help programs move through the steps required to make ECP services routinely available through health service delivery systems. The intent of the toolkit is to share widely an array of materials developed by PATH and by other organizations* as they worked in a variety of settings to incorporate ECPs into family planning services. It is hoped that by bringing together these resources in a format that facilitates their use, the toolkit can reduce duplication of efforts, redundancy, and unnecessary expense.

Although the focus of this toolkit is to facilitate access to ECPs—a method that can be integrated into a wide array of services through a variety of providers—the other emergency contraceptive method, insertion of an intrauterine device (IUD) within seven days after unprotected intercourse, should not be ignored. Because many family planning programs provide IUDs as a regular contraceptive method for ongoing family planning, they are widely available. If emergency contraception is to be comprehensively

*Materials for this toolkit were graciously provided by AltaCare; Association of Reproductive Health Professionals; Deliver Project at John Snow, Inc.; Family Health International (FHI); Family Guidance Association of Ethiopia; International Federation of Gynecologists and Obstetricians; Family Planning Association of Sri Lanka; International Consortium for Emergency Contraception; International Planned Parenthood Federation; Pacific Institute for Women's Health, Population Action International; Population Council; Population Services International; Profamilia Columbia; Reproductive Health Research Unit of the University of Witwatersrand; United Nations Population Fund; United States Agency for International Development; and the World Health Organization.

incorporated into large-scale programs, insertion of IUDs should be one of the emergency contraception options provided to women, along with ECPs. Where possible, advocates of emergency contraception should advocate at all levels—policy, public awareness-raising, and clinical services—for provision of IUDs for emergency contraception.

PATH began development of this ECP programming toolkit by conducting an extensive assessment of country program planners, country representatives of the United States Agency for International Development (USAID) and United Nations Population Fund (UNFPA), and different organizations and individuals who have played an active role in mainstreaming emergency contraception. The assessment results identified the content and resources that developing-country program managers would find most useful in integrating emergency contraception into their family planning programs.

The toolkit is designed to help family planning programs build on the Framework for Introduction that was developed by the International Consortium for Emergency Contraception (ICEC) and move from the concept of ECP introduction to implementation. ICEC developed this introduction framework to guide its efforts to introduce a dedicated ECP—a product specifically packaged and labeled for emergency contraception—in several developing countries. The framework was included in ICEC's information packet *Emergency Contraceptive Pills: A Resource Packet for Health Care Providers and Program Managers* (published in 1998) and also was featured in ICEC's report "Expanding Global Access to Emergency Contraception: A Collaborative Approach to Meeting Women's Needs (2000)."[1] The framework spells out nine steps required to successfully integrate ECPs into large delivery channels: (1) assessing needs, (2) raising support at the national and community levels, (3) addressing product issues, (4) planning for distribution, (5) meeting clients' information needs, (6) training providers, (7) introducing ECP services, (8) monitoring and evaluating services, and (9) disseminating evaluation results. Building on this step-wise approach, ***Resources for Emergency Contraceptive Pill Programming: A Toolkit*** describes in more detail what is involved in carrying out specific steps and provides samples of tools used successfully in an array of countries. Each module of the toolkit focuses on one aspect of the introduction process and provides information and materials that can help advocates and program planners move forward to achieve broad programming of ECPs.

Countries vary as to current awareness and availability of emergency contraception and the status of a dedicated ECP product. Countries also differ in political climate and groups that must be reached with information about ECPs—what they are, how they work, and why it is important for women to have timely access to them. Because of this variability, the toolkit is designed as a foundation upon which users can build according to their needs, adapting information and materials in order to develop the best approach for their particular situation.

Resources for Emergency Contraceptive Pill Programming: A Toolkit is a resource for emergency contraception advocates, decision makers, and program managers—a resource that will help them identify the groups they need to work with and the information they need to provide as they move forward to successful, sustainable, routine provision of ECPs through their family planning programs.

[1] International Consortium for Emergency Contraception. *Expanding Global Access to Emergency Contraception: A Collaborative Approach to Meeting Women's Needs*. October 2000. Accessible through the Consortium's website at http://www.cecinfo.org/html/res-downloadable-mtrls.htm.

Module A

Information for Policy Makers

Objective

To develop a policy environment—both political and social—supporting the introduction and broad programming of emergency contraceptive pills (ECPs).

This module provides information that will help advocates work with key political leaders, government officials, and other stakeholders in the health and family planning community to facilitate provision of an ECP product and related services. The following topics are discussed:

- Political Context
- Resources
- Key Audiences
- Key Messages
- Mexico City Policy and Emergency Contraception
- Domestic Violence, Rape, and Emergency Contraception
- Choosing Effective Channels to Communicate Messages
- Local Data Illustrating Need for Emergency Contraception

Module A: Information for Policy Makers, Module C: Raising Public Awareness, and Module D: Informing Clients, are closely related. Ideally, ECP access will involve all the areas discussed in these three modules—policy, public awareness, and informing clients. Each module provides resources, tools, and techniques that can be adapted according to the target audience and the environment.

Tools Provided at the End of This Module

Statements on ECPs by International Organizations, Agencies, and Major Donors of Contraceptive Commodities:

- American College of Obstetricians and Gynecologists (ACOG) News Release (February 2001).
- International Consortium for Emergency Contraception (ICEC) Evidence-Based Policy Statements (July 2003).
- International Federation of Gynecology and Obstetrics (FIGO) Ethics Committee Report: Guidelines in Emergency Contraception. International Journal of Gynecology & Obstetrics 77:71-175 (2002).
- International Planned Parenthood Federation (IPPF). International Medical Advisory Panel (IMAP) Statement on Emergency Contraception. (October 2003).

Tools continued...

- United Nations Population Fund (UNPFA) Statement on Emergency Contraception (2003).
- United States Agency for International Development (USAID) Statement on Emergency Contraception (2003).
- World Health Organization (WHO) Statement on Emergency Contraception. Fact Sheet No. 244 (June 2000).

Resources for Developing Messages for Policy Makers

- Annotated Bibliography of Core Evidence-Based Research on Emergency Contraception
- Key Facts About Emergency Contraception

Political Context

Government support (whether explicit or implicit) is a prerequisite for successfully integrating ECPs into a large-scale program. The collaboration of government agencies such as the ministry of health and the drug regulatory agency is critical to ensure the availability of an ECP product and appropriate service provision. Although government support is essential, it can be difficult to obtain, due to strong political pressures—and lack of support presents serious barriers. For example, in one country, registration of a dedicated ECP product was delayed over five years because government approval was contingent on the approval of religious leaders. In other countries where abortion is a major political issue, political leaders have been reluctant to become involved with provision of ECPs through government-funded programs. Because navigating such environments can be difficult, it is essential to understand the political currents and how they relate to family planning, before initiating ECP integration.

Resources

The availability of resources to build support in a given environment is another important consideration. Some strategies for influencing policy can be very costly; others, such as holding workshops and meeting with representatives, can be fairly low-cost. In considering the financial, as well as the human, resources that will be involved, the following questions can be useful in helping to determine the direction the strategy should take.

- Is the current political environment favorable toward family planning and reproductive health services?
- What are the social, cultural, or religious attitudes toward family planning?
- What are the reproductive health issues that raise concern among political leaders?
- From what types of leaders is it most critical to gain support?
- What are the potential sources of financial support for providing information to policy makers and stakeholders, and how much effort will be needed to secure that support?
- Are there organizational resources to undertake a large-scale effort to generate ECP support, or should a smaller, more focused campaign be considered?

Harnessing resources available for incorporating ECPs into family planning programs can be a challenge. In some countries, like Mexico, foundation donors were integral to providing substantial funding for the large-scale advocacy campaign undertaken there. In many places, however, this type of funding may be difficult to access, and it is important to be aware of other support available and the mechanisms through which it can be obtained.

There are different types of resources or organizations that may be interested in contributing to efforts to integrate ECPs into public-sector programs. In some settings government may be able to make ECPs part of the country's method mix and integrate ECP information into ongoing client outreach and provider training. Bilateral donors or multilateral donors, particularly those who provide contraceptives or support reproductive health activities, can be a resource. This support is most effectively sought at the country-level mission or country office engaged in health and/or reproductive health work. Private foundations or local donors supportive of reproductive health may have interest in supporting activities related to ECP integration. Include these potential donors early in the planning stages to assess their interest and find out what they can or cannot support.

Key Audiences

When resources requirements and availability are known, the next step is to identify the stakeholders and policy makers whose support is needed. In several countries that have successfully integrated ECPs into large programs, these were individuals from the health care sector including government, international aid agencies, and professional medical groups. Questions that will help identify the target audiences include:

- Who are the key policy makers and stakeholders in the health and family planning community?
- Who contributes to decisions about contraceptive method mix?
- Among these policy makers and stakeholders, which ones are likely or unlikely to support ECP mainstreaming efforts?
- Who are the cultural or religious leaders that might oppose or support increasing access to ECPs?
- What other groups or individuals influence policy related to health and family planning, and which of them could provide support?

Examples of stakeholders in the provision of ECPs include:

Key Audiences	Examples of Organizations
Decision makers and program planners at national and local levels	• Ministry of health – National family planning program – National maternal and child health division • Ministry of justice • Health insurance programs • Representatives from multilateral and bilateral donor agencies
Local leaders	• Community • Local health groups • Women's groups • Religious leaders • Domestic violence support groups • Police and local law officers
Professional groups	• Medical associations and societies • Medical education institutions • Pharmacists associations • Research councils and institutes
Pre-service academic institutions	• Medical schools • Nursing schools • Pharmacy schools
Providers	• Directors of hospitals and clinics • Clinic health workers • Safe abortion service providers • Midwives/traditional birth attendants

ECP forum for stakeholders

In cases where multiple stakeholders are involved, it is important to create mechanisms for communication and collaboration among them. Creating a forum where individuals from these groups can facilitate effective collaboration, avoid duplication, and maintain momentum of advocacy efforts is important. Forums can sort out issues and look at ECP introduction from a variety of perspectives. These forums can serve as a mechanism through which to address issues around emergency contraception, increase the number of people receiving accurate messages about ECPs, and gain the attention of and support from important stakeholders. In several countries this has been a key factor in the successful introduction of ECPs, and this approach should be applied wherever possible when advocating for wide access to ECPs.

Lessons Learned

Holding a National Consensus Forum in India

In cooperation with several organizations, the Consortium on National Consensus for emergency contraception in India held a two-day forum on emergency contraception. The main objectives of the forum were to present updates on the latest advances in emergency contraception, to discuss and debate the strategies for ECP introduction, and to set forth guidelines for introducing emergency contraception in India. Participants included a host of international and national technical experts, policy makers, researchers, pharmaceutical companies, women's advocates, legal experts, nongovernmental organizations, professional bodies, and service providers. The first day of the forum consisted of five sessions during which leading experts addressed the main issues, current data, and findings from other countries where ECPs are already integrated. During the second day, an expert forum was held on six key issues related to ECP introduction in India. A consensus on how to move forward with respect to each of the areas was reached and adopted. The main issues on which a consensus was reached were: selection of a dedicated method for EC in India, preintroduction of media campaigns for public awareness, training curriculum for health care providers, ideal approach to broad-scale introduction and distribution of ECPs, and client information and counseling for safe use. The National Consensus Forum, which occurred in 2002, helped pave the way for introduction of emergency contraception in India. Information on this forum has been compiled in the *The Report & Recommendations of National Consensus of Consortium*, which can be accessed online at http://www.ecindia.org/report.htm.

Including a Range of Interests Helps Garner Support for Emergency Contraception in Zambia

In Zambia, ECP advocates invited a group of individuals representing a wide range of organizations to participate in discussions and meetings on issues related to emergency contraception. Leaders from women's groups, the Catholic Church, the Ministry of Health, and other groups were invited to participate in a discussion about the results of an ECP study conducted by the Population Council. The focused discussions around this study helped highlight evidence about ECPs and simultaneously informed groups on all sides of the issue about emergency contraception. It proved to be a very effective way to build consensus on the issues surrounding the local introduction of ECPs in Zambia. This study is included in the annotated bibliography in the tools section of this module (Skibiak et al. 1999).

Key Messages

Once audiences have been identified, the next step is to determine what information can most effectively inform their decisions and garner their support. In planning key messages and strategies, it is critical to draw from evidence-based and published information about emergency contraception, including why it is a public health issue and the benefits of integrating it into a family planning program. Provision of correct information helps address common misperceptions about ECPs that are often the cause of controversy. Recent research on ECPs has resulted in an excellent body of widely published studies with information on issues such as ECPs mechanism of action, safety, and efficacy—issues that are frequently brought up for discussion. The following section has been designed to provide succinct information on important topics and questions that often arise among policy makers. Links to articles and resources that can be used in developing program-specific messages and information dissemination strategies are provided. Many of the articles and resources listed below are included in the annotated bibliography, which is located in the tools section. The bibliography also contains additional resources that may be useful in developing messages.

ECPs are safe

ECPs are both safe and effective for women to use.[1,2]

Both the United States Food and Drug Administration (FDA) and the World Health Organization (WHO) have stated that ECPs are safe for use.

- Researchers often extrapolate data from safety studies conducted on oral contraceptive pills (OCPs) taken daily over a long period of time for regular contraception to demonstrate that ECPs are safe.[3] Because ECPs are taken for a very short period of time, researchers have concluded in reviews of published data on OCPs and ECPs, that the contraindications for use of daily oral contraception are not applicable to ECPs.[4]
- In the 13-year period following the availability of the dedicated Yuzpe (also known as the estrogen-progestin, or combined) regimen product in Great Britain, the regimen was used over 4 million times. Medical reports showed no clear evidence directly linking adverse events with use of the Yuzpe regimen.[5]
- WHO has stated that there are no contraindications to ECPs due to the small overall hormone dose and short duration of use.[6]
- The only condition restricting use of ECPs is an established pregnancy, defined as beginning with implantation, not because ECPs are harmful, but because they will not work if a woman is already pregnant. Researchers have concluded that ECPs taken inadvertently during pregnancy will not harm a developing fetus. These conclusions are based on studies of oral contraceptive pills, including high-dose formulations, that show oral contraceptives pose no risk of birth defects.[4,7,8,9,10,11,12]
- Because ECPs have been shown to be safe and effective, many countries have simplified access by making them available without prescription or directly from a pharmacist. ECPs are available direct from a pharmacist in Albania, Belgium, Benin, Cameroon, Congo, Denmark, Finland, France, Gabon, Guinea-Bissau, Israel, Ivory Coast, Lithuania, Madagascar, Mali, Mauritius, Namibia, Portugal, Senegal, South Africa, Sri Lanka,

Switzerland, Thailand, Togo, Tunisia, United Kingdom, and parts of United States and Canada. They are available over-the-counter in Norway and Sweden.[13] In 2003 an FDA review panel recommended that progestin-only ECPs be available over-the-counter in the United States.

ECPs are effective

The effectiveness of ECPs varies, depending on the regimen and how soon after sex they are taken.

- There are two major types of ECPs on the market today: the levonorgestrel-only (also known as progestin-only) regimen and the Yuzpe (or combined estrogen and progestin) regimen. The levonorgestrel-only regimen has fewer side effects and is more effective.
- On average, if 100 women have unprotected intercourse during the time of the month when they are most fertile, 8 will become pregnant. If they all took the levonorgestrel-only ECP regimen, 1 would be expected to become pregnant (an 89 percent reduction in pregnancy risk).* If all of those women used the Yuzpe regimen, 2 would be expected to become pregnant (a 75 percent reduction in pregnancy risk).[2*]
- The sooner after unprotected intercourse a woman takes ECPs, the lower her risk of pregnancy. ECPs will be most effective if taken within 24 hours; the effectiveness diminishes with each day, up to 120 hours (5 days).[2,14,15,16]

Mechanism of action of ECPs

- ECPs are effective only before a pregnancy is established (clinically defined as implantation of a fertilized egg in the lining of the uterus).** They cannot work after a fertilized egg has been implanted.[17]
- ECPs' primary mechanism of action is the inhibition or delay of ovulation.[18,19,20,21,22,23,24,25,26]
- Besides inhibiting or delaying ovulation, there is no unequivocal clinical evidence for other mechanisms of action although ECPs may work by:
  - Inhibiting fertilization through thickening of the cervical mucous resulting in trapping of sperm or alterations in the tubal transport of sperm or egg—but no data exist to confirm this possible mechanism of action.[27,28,29]
  - Impairing endometrial receptivity to implantation of a fertilized egg.[21,30,31,32,33,34] However, the evidence showing endometrial effects of ECP treatment is mixed, and it is not clear that the endometrial changes would inhibit implantation.[19,22,35,36]
- Timing plays a key role in how ECPs work. Studies have shown that the specific mechanism of action and effectiveness of ECPs may depend on:
  - Cycle day on which intercourse occurred.
  - Cycle day on which treatment is used.[19,20,22,30,37,38]

*These estimates of reduction in the risk of pregnancy following ECP use are based on studies that evaluated ECP use within a 72-hour time frame.

**Individuals have their own interpretations of when a pregnancy begins. The definition above is provided within a medical/clinical context.

For more information on the mechanism of action of ECPs, refer to the International Consortium for Emergency Contraception's statement on mechanism of action in the tools section of this module.

ECPs can help reduce the number of abortions

Research suggests that access to ECPs can reduce the number of abortions that occur each year.

- It is estimated that in the United States in 2000, 51,000 pregnancies that would have resulted in abortions were prevented by the use of ECPs.[39]
- In a Chinese study, researchers estimated that nearly half (47%) of the abortions in Shanghai could have been prevented if combined-regimen (Yuzpe method) ECPs had been available to women.[40]

Most evidence suggests that advance provision of ECPs does not negatively affect regular, ongoing contraceptive use

- Most research suggests that advance provision of ECPs does not negatively affect regular contraceptive use.[41,42,43,44]
- A Scottish study showed that women did not stop using other more effective contraceptive methods when a back-up method such as ECPs was available in advance.[41]
- Another study showed that women did not abandon regular use of condoms for pregnancy and disease protection, which would have increased their risk of sexually transmitted infection (STI) and HIV. The study concluded that couples may feel more confident about relying on condoms if emergency contraception is available as a backup method.[43]
- A study conducted in Zambia, however, provided some evidence that advance provision of ECPs may have encouraged nonuse of regular family planning methods among users for reasons such as coercion by spouse, curiosity about the method, confidence in ECP effectiveness given its higher dosage compared to regular oral contraceptives, and preference for the convenience of ECPs. Despite this, researchers still concluded that advance provision of ECPs to women is an important option and that issues pertaining to the use of ECPs and other family planning methods can be overcome with provider training and user education.[45]

Medical providers should emphasize continued condom use for clients at risk of STIs, with emergency contraception as a backup.*

Effectiveness of ECPs is increased by advance provision

- Women who received ECPs in advance of need were more likely to use them when needed than those who did not have a supply at home.[41]

*A model for a dual protection approach (an approach that promotes strategies that prevent both unwanted pregnancy and STI/HIV infection) is provided by the National Contraception Policy Guidelines issued by the Republic of South Africa's Department of Health. In discussing barrier methods, these guidelines state, "In the event of condom failure, access to emergency contraception should be promoted more extensively." National Contraception Policy Guidelines Within a Reproductive Health Framework. Republic of South Africa, Department of Health (2001). http://www.doh.gov.za/docs/factsheets/guidelines/contraception/contraception01.pdf. http://www.doh.gov.za/docs/factsheets/guidelines/contraception/contraception02.pdf.

- Women who have ECPs in advance of need will most likely use them sooner after unprotected intercourse, which increases the effectiveness of this method.[42,46]
- The effectiveness of ECPs decreases significantly the longer a woman waits after intercourse to take them. Advance provision is an important option because it reduces barriers to timely access.[14]

For more information on the timing of ECPs and effectiveness, see the International Consortium for Emergency Contraception's statement on regimen in the tools section of this module.

Access to ECPs does not cause promiscuity among adolescents

The concern is frequently voiced that access to ECPs will cause promiscuity among youth. Two recent studies provided evidence that information about and access to contraceptive methods, including ECPs, does not lead to promiscuity or earlier initiation of sex among adolescents.[47,48]

Repeat use of ECPs does not pose health risks

- Repeat use of ECPs poses no health risks, according to WHO, which has placed repeated ECP use in Category 1 of its medical eligibility guidelines, indicating that there is no restriction for the repeated use of this contraceptive method.[6]
- Experience with ECPs suggests that repeat use within the same cycle is uncommon.[41] Use of levonorgestrel-only ECPs as frequently as four times a month did not reveal negative health risks.[49] While repeat use is not a reason to deny a woman access to ECPs, it is an indication that a woman needs further counseling on routine contraceptive methods, as most other methods are more effective for regular use.[6] Women who have regular intercourse (more than four times per month) are not advised to use ECPs as a regular contraceptive method because they are not as effective as regular contraception.[6]

For more information on repeat use, see the International Consortium for Emergency Contraception's statement on repeat use of emergency contraception in the tools section of this module.

Mexico City Policy and Emergency Contraception

Emergency contraception, like other methods of contraception, is not subject to U.S. government restrictions on development funds that apply to abortion services, counseling and referral, or lobbying. This has been a point of confusion. Foreign governments and nongovernmental organizations that receive U.S. development assistance may provide emergency contraception services, information, and referral. For more information see the Population Action International (PAI) publication, "Emergency Contraception and the Global Gag Rule—An Unofficial Guide," which provides information and clarity about the Mexico City Policy. It can be accessed at the PAI website: http://www.populationaction.org/resources/publications/globalgagrule/GagRule_download.htm.

Domestic Violence, Rape, and Emergency Contraception

Gender-based violence is a significant problem worldwide. It can include physical, sexual, psychological, and economic abuse of women. A review of almost 50 population-based surveys found that between 10 and 50 percent of women report being hit or otherwise physically harmed by an intimate male partner at some point in their lives.[50] This violence can have serious health consequences for women, especially in terms of their reproductive and sexual health. For women who are affected by violence, emergency contraception is particularly important. Women who have been sexually abused are much more likely than nonabused women to use family planning clandestinely; they also are more likely to have had their partner stop them from using family planning and to have had a partner refuse condom use to prevent disease.[50] Rape survivors are also at risk of unintended pregnancy, but because many women in this situation never seek medical care where information about ECPs can be provided, it is important that they be reached through other advocacy avenues. Including those groups and individuals who assist sexual abuse and rape survivors, such as police and local law officers, in advocacy campaigns and trainings is an important aspect of ensuring ECPs reach women who need them.

The Pacific Institute for Women's Health (PIWH), has been working to improve rape and domestic violence survivors' knowledge about and access to ECPs through partnerships with local organizations in Latin America. PIWH found that community-based health care providers participating in a series of workshops conducted in several Latin American countries all had assisted women who had been sexually assaulted or were living with domestic violence, highlighting the severity of the issue in many communities. Following such a workshop, the Organización Lilith de Mujeres Independientes in Mexico worked to train Tijuana Secretary of Health personnel on ECP service provision. PIWH has also worked with organizations in Baja California and Planned Parenthood in San Diego to raise awareness about emergency contraception and advocate for the inclusion of emergency contraception in the family planning norms of the Mexican Ministry of Health. More information on PIWH's work with emergency contraception can be found in Module C: Raising Public Awareness and on PIWH's website: http://www.piwh.org/latinamerica.html.

Choosing Effective Channels to Communicate Messages

Once the key messages have been identified, select the most effective channels for reaching the intended audiences. The following questions can help in considering which communication channels to use.

- What type of information dissemination activities would be most effective in the current environment?
- What are the most important points that need to be made?
- How can these points be made so they have maximum impact on the intended audience?

Local Data Illustrating Need for Emergency Contraception

Specific local data can significantly strengthen the argument for making ECPs widely available in a country. Data on serious health, poverty reduction, and social problems that can be positively affected by decreasing the number of unintended pregnancies and abortions can be powerful tools in advocating policy change to support access to ECPs. Useful data include:

- Adolescent pregnancy rates.
- Unintended pregnancy rates.
- Abortion rates and sequelae.
- Government expenditures on unintended pregnancy and abortion or postabortion care.
- Birth spacing statistics.

Country-specific data for over 220 countries can be found on the Internet at the Population Reference Bureau website, http://www.prb.org, which has links to additional data resources, Measure and PopNet. Another resource is the Global Health Council website, http://globalhealth.org. Useful data for ECP information dissemination can be accessed at http://www.globalhealth.org/news/article/2319.

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Special Note: The information contained in some of these documents may not be updated to reflect 2003 published research regarding timing and dosage (see the ICEC statement on timing and dosage for updated, accurate information on these topics).

- ECPs should be used as soon as possible after unprotected intercourse, but can be used within 120 hours.
- Levonorgestrel-only ECPs can be administered in one, 1.5 mg dose.*

Statements on ECPs by International Organizations, Agencies, and Major Donors of Contraceptive Commodities

ACOG News Release

This statement in support of emergency contraception issued by ACOG can be found online at http://www.acog.org/from_home/publications/press_releases/nr02-28-01-2.cfm.

ICEC Evidence-Based Policy Statements

ICEC has issued a set of five statements with accurate, up-to-date information on improving access, emergency contraception and medical abortion, repeat use, mechanism of action, and timing and dosage. They can also be accessed online at http://www.cecinfo.org/html/res-downloadable-mtrls.htm.

FIGO Ethics Committee Report

This statement provides the guidelines issued by the FIGO Ethics Committee on use, access, and provision of emergency contraception. The statement was originally printed in Guidelines in Emergency Contraception, *International Journal of Gynecology & Obstetrics* 77:171-175 (2002).

IPPF Statement

This document presents information issued by the IPPF International Medical Advisory Panel about provision of emergency contraception in family planning programs worldwide. The statement developed May 2000 and revised in October 2003.

*von Hertzen, H. et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomized trial. *Lancet* 360(9348):1803-1810 (2002).

USAID and UNFPA Statements

Two of the major donors of contraceptives for developing-country family planning programs, UNFPA and USAID, have provided statements supporting the provision of ECPs. Statements of both agencies clarifying the types and levels of support they offer are provided.

WHO Statement on Emergency Contraception

This statement by WHO articulates the safety, efficacy, and ease of emergency contraception use. It was originally printed as WHO Fact Sheet No. 244 (June 2000).

Resources for Developing Messages for Policy Makers

Annotated Bibliography of Core Evidence-Based Research on Emergency Contraception.

This annotated bibliography contains annotations of the articles referenced in Module A: Information for Policy Makers. Exceptions include those articles summarized in either "Statistical Evidence Concerning the Mechanism of Action of the Yuzpe regimen of emergency contraception" or "Mechanism of Action of Hormonal Preparations Used for emergency contraception: A Review of the Literature," both of which are included in this bibliography. Additionally, articles pertaining to studies conducted on oral contraceptives and domestic violence are not included in this bibliography. The annotations provide key data and summaries of studies that will be useful in advocacy and education campaigns.

Key Facts About Emergency Contraception

A fact sheet summarizing key points about emergency contraception . This document can be modified and adapted to emphasize or highlight particular issues, tailoring it to the environment in which advocacy activities take place.

ACOG NEWS RELEASE

Embargoed until February 28, 2001
5:00 PM EST

ACOG Supports Safety and Availability of Over-the-Counter Emergency Contraception

***WASHINGTON, DC** -- The American College of Obstetricians and Gynecologists (ACOG) has issued new and revised documents on the safety and availability of emergency oral contraception (EC). ACOG says the fallback contraceptive method -- a regimen of oral contraceptives that must be taken within 72 hours after unprotected intercourse -- has the potential to reduce by half the 3 million unintended pregnancies occurring each year in the US.*

ACOG supports making EC available to women over the counter in a designated (prepackaged) product, according to its recent **Statement Supporting the Availability of Over-the-Counter Emergency Contraception**. *"The time has come for women to have access to a product that they need," reports ACOG, referring to the ongoing barriers to women's access to the drug. Citing the FDA's declaration that EC is safe and effective in preventing pregnancy, ACOG believes "emergency oral contraception can meet the FDA criteria for over-the-counter availability."*

In **Emergency Oral Contraception**, *a revised Practice Bulletin issued today, ACOG has updated its recommendations to physicians regarding the safety and efficacy of prescription EC. ACOG provides charts on how to combine common prescription oral contraceptives in dosages that provide EC, and has now added information on two EC designated products, Preven and Plan B.*

In another effort to increase women's access to EC, ACOG notes that during routine gynecologic visits, physicians may wish to offer patients an advance prescription for EC, for use in any future emergency. EC should be taken within 72 hours of unprotected intercourse, but may provide the greatest efficacy if taken within 24 hours, says ACOG.

# # #

The American College of Obstetricians and Gynecologists is the national medical organization representing nearly 40,000 physicians who provide health care for women.

International Consortium for Emergency Contraception

Policy Statement (July 2003)

Improving Access to Emergency Contraception

Prompt, easy and affordable access to emergency contraception within 120 hours of unprotected sex can reduce the rate of unwanted pregnancies and abortions.[1] [1] Despite endorsement of emergency contraception by major health organizations such as the World Health Organization, and greater availability of dedicated Emergency Contraceptive Pills (ECPs), access remains limited for most women throughout the world.

Why do Women Need Improved Access to Emergency Contraception?

- Studies have shown that the earlier an emergency contraception regimen is taken, the more effective it is at preventing unwanted pregnancies.[1] If access is easy and without a prescription, women can begin to use the regimen without consulting a physician and may begin to use ECPs earlier.[2]
- In Scotland, women who were provided advance supplies of ECPs were nearly twice as likely to use them as those who sought emergency contraception from a physician. Women with advance supplies of ECPs also experienced lower rates of pregnancy than those who did not have easy access.[3] Another study showed that women provided with ECPs in advance were no more likely than those without advance provision to engage in unprotected intercourse.[4]
- In the United States, increased access to emergency contraception was instrumental in averting 51,000 abortions in 2000 and accounted for an estimated 43% decline in abortions between 1994 and 2000.[5]
- The World Health Organization has called emergency contraception safe and effective and has called for greater access to ECPs as well as inclusion of the method in country health programs.

Where is Emergency Contraception Available?

- Several brands of dedicated ECPs are now marketed in the United States, Europe and other countries. Health advocates and private ECPs manufacturers are actively working to achieve broader registration and over-the-counter status for ECPs in both developed and developing countries. At this writing, ECPs are registered in a total of 97 countries worldwide.[6] Twenty-seven countries in Europe and Africa, and two states in the U.S. offer ECPs directly through pharmacies.[7]

What Are Some of the Barriers to Improving Access to Emergency Contraception?

- In many countries, **lack of government policy** about the method leaves providers unclear about its legal status and insufficiently informed to recommend it to women when needed. Clear policy to promote provision of emergency contraception ensures that it is available in situations such as when contraception has failed as well as among vulnerable groups such as young women and rape survivors.
- Some policy makers and providers are **misinformed** about how ECPs work and believe that they may be an abortifacient. ECPs, like other hormonal contraceptives act in a variety of ways by inhibiting ovulation and preventing sperm and egg from uniting.[8] While the exact mechanism of action is not fully understood, it is not likely that ECPs prevent implantation of a fertilized egg.[9] Once implantation of the egg has begun, ECPs are ineffective and will not interfere with an established pregnancy or harm a developing embryo.[10-11]

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- Most **women are unaware of the existence of emergency contraception**, thus resulting in little demand for the product. Women must be sufficiently aware of the method before it is needed in order to initiate use within the required time frame. Improvements in awareness may come through health care providers, public service communication campaigns as well as through the availability of dedicated ECPs in pharmaceutical outlets.
- **Unclear service delivery protocols** may impede women's access to emergency contraception by requiring unnecessary medical screening to receive the product. While counseling may be desirable when recommending emergency contraception, it is not indispensable to its correct use[12].
- **Prescription requirements** may result in women needlessly delaying use of ECPs beyond the recommended time frame for its use. Past studies have shown that women understand labeling on emergency contraception[13] and have used it safely and effectively suggesting that involvement of a medical provider is not essential. The established safety record of ECPs and the public health benefits from improved access at the point of sale justify a change in its regulatory status.[14]

Recommendation

Improved access to emergency contraception has the potential to avert unwanted pregnancies and abortions worldwide. To achieve this pubic health benefit, policy makers should include the method in medical and legal protocols, providers should inform women about emergency contraception and women should have the ability
to obtain the method without a medical prescription.

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Association of Reproductive Health Professionals • British Pregnancy Advisory Service • Catholics for a Free Choice • Center for Reproductive Law & Policy • Center for Research on Women and Gender, University of Illinois • CEPAM • Concept Foundation • CONRAD Program/EXT International • Engender Health • Family Care International • Family Health International • Institute for Reproductive Health • International Planned Parenthood Federation • International Planned Parenthood Federation/Western Hemisphere Region • Ipas • JSI • Management Sciences for Health • Marie Stopes International • Meridian Development Foundation • Pacific Institute for Women's Health • PATH (Partnership for Appropriate Technology in Health) • Pathfinder International • Population Action International • Population Council • Population Services International • ProSalud Inter-Americana • Reproductive Health Initiative of the American Medical Women's Association • Sahl Pregnancy Advisory Service • Sri Lanka Family Planning Association • Ukrainian Family Planning Association • WHO, Special Programme of Research, Development and Research Training in Human Reproduction

Address Correspondence to:
Consortium Coordinator
c/o Meridian Development Foundation
1350 14th Street NW, Suite 350
Washington, DC 20037
Tel: (202) 466-8511 Fax: (202) 466-3079
www.cecinfo.org

International Consortium for Emergency Contraception

Policy Statement (July 2003)

Emergency Contraception and Medical Abortion

Emergency contraceptive pills (ECPs) are a safe and effective means of preventing pregnancy after unprotected sexual intercourse[1,2] The use of ECPs cannot terminate or interfere with an established pregnancy and will not harm a developing embryo.[3,4] ECPs work very differently than medical abortion (abortion pills); however, confusion between emergency contraception and medical abortion agents can present a barrier to broader access to emergency contraception.

What is the difference between emergency contraception and medical abortion?

ECPs are a back up contraceptive method used to prevent a pregnancy after unprotected sex or contraceptive failure. Medical abortion is a non-surgical option for terminating an established pregnancy at an early stage.

ECP regimens consist of the same hormones used in many brands of oral contraceptives (levonorgestrel only or combined estrogen and progestin) in a modified dose that is taken within five days (120 hours) of unprotected intercourse. ECPs are effective only *before* a pregnancy is established, defined as implantation of a fertilized egg in the lining of a woman's uterus. ECPs, like other hormonal contraceptives act in a variety of ways by inhibiting ovulation and preventing sperm and egg from uniting.[5] While the exact mechanism of action is not fully understood, it is not likely that ECPs prevent implantation of a fertilized egg.[6] Once implantation of the egg has begun, ECPs are ineffective and will not interfere with an established pregnancy or harm a developing embryo.[7,8]

Drugs used to provide medical abortion (mifepristone and misoprostol) are distinct from emergency contraceptive pills in that they are used to terminate an existing pregnancy up to 7 weeks after implantation. Existing medical abortion agents work in one of two ways: they either block the hormones required to sustain an existing pregnancy or they stimulate uterine contractions to disrupt the pregnancy.

Why is this distinction important?

Confusion about the two methods can lead to barriers to ECPs access. While medical abortion regimens are administered under a health care provider's supervision, use of ECPs does not require prior medical screening. Women can determine their need for ECPs and self-administer them safely.[9] There are no contraindications to use of ECPs, dosage of the most common levonorgestrel-only ECP products is uniform, and ECPs have no known important interactions with other medications and will not cause birth defects if pregnancy is not prevented. Increasingly ECPs are sold over the counter through pharmacies. Twenty-seven countries in Europe and Africa offer ECPs directly via pharmacists, and a petition is pending before the U.S. Food and Drug Administration to make EC available over-the-counter without a prescription in the U.S.

How is broader access to ECPs important to women's reproductive rights and health?

ECPs are the only available means of preventing a pregnancy after unprotected intercourse that a woman can self-administer. As such, ECPs have important potential impact for preventing unintended pregnancies and abortion worldwide. In the United States, increased access to emergency contraception has been estimated to have prevented 51,000 abortions in 2000 and accounted for an estimated 43% decline in abortions between 1994 and 2000.[10]

For more information, visit www.cecinfo.org

Recommendation

ECPs are a safe and effective back up means of preventing unintended pregnancy. No medical or legal barriers should exist to limit their use. Policy makers, medical professionals and other health advocates should continue to highlight the safety of ECPs and to promote their universal availability, timely access and affordability to women and couples worldwide, with the understanding that ECPs are not a replacement for, but rather are an adjunct to regular contraceptive practice.

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Association of Reproductive Health Professionals • British Pregnancy Advisory Service • Católicas por a Free Choice • Center for Reproductive Law & Policy • Center for Research on Women and Gender, University of Illinois • CEPAM • Concept Foundation • CONRAD Program EKT International • EngenderHealth • Family Care International • Family Health International • Institute for Reproductive Health • International Planned Parenthood Federation • International Planned Parenthood Federation/Western Hemisphere Region • Ipas • JSI • Management Sciences for Health • Marie Stopes International • Meridian Development Foundation • Pacific Institute for Women's Health • PATH (Partnership for Appropriate Technology in Health) • PathFinder International • Population Action International • Population Council • Population Services International • ProSalud Inter Americana • Reproductive Health Initiative of the American Medical Women's Association • Stalo Pregnancy Advisory Service • Sri Lanka Family Planning Association • Ukrainian Family Planning Association • WHO, Special Programme of Research, Development and Research Training in Human Reproduction

Address Correspondence to:

Consortium Coordinator

c/o Meridian Development Foundation

1250 24th Street NW, Suite 300

Washington, DC 20037

Tel: (202) 466-0511 Fax: (202) 466-3079

www.cecinfo.org

International Consortium for Emergency Contraception

Policy Statement (July 2003)

How Do Emergency Contraceptive Pills Work to Prevent Pregnancy?

Mechanism of Action

Like all hormonal contraceptives, emergency contraceptive pills may work in a variety of ways. The precise mechanism of action of ECPs in a particular case cannot be determined and depends on the time in a woman's menstrual cycle when intercourse occurred and when ECPs were taken.[1]

Emergency contraceptive pills:

- **Inhibit or delay an egg from being released from the ovary when taken before ovulation**
- **May prevent sperm and egg from uniting**
- **May stop a fertilized egg from attaching to the uterus**

- Several studies have provided direct evidence that both combined estrogen and progestin regimens and progestin-only ECPs act by preventing or delaying ovulation, perhaps by inhibiting follicular development and maturation or the release of the ovum itself.[3-6] Some researchers have proposed that this may be the principal or only mechanism of action.

- Statistical evidence suggests that ECPs could not be as effective as data indicate if they only worked by interfering with ovulation.[7]

- No direct clinical data exist regarding mechanisms other than the inhibition, alteration, or delay of ovulation.[8]

- Researchers have found that ECP regimens containing levonorgestrel may interfere with sperm transport or penetration. ECPs may prevent sperm from reaching the egg by thickening the cervical mucus resulting in the trapping of sperm. Alterations in the tubal transport of sperm, egg, or zygote may also occur.[3,9]

- Some studies have shown changes in histologic and biochemical features of the endometrium after treatment with combined ECPs, suggesting that they may act by impairing endometrial receptivity to implantation of a fertilized egg.[3,9,10] However, other studies have shown no such effects with both the combined and levonorgestrel-only regimens,[3,5,9,11,12] and it is not clear that the observed changes would be sufficient to prevent implantation.

- Another potential mechanism of action that may occur at the level of the ovary is interference with corpus luteum sufficiency and responsiveness.[5] The corpus luteum is responsible for producing estrogen and progesterone, which prepare the endometrium for implantation.

- Even if emergency contraceptive pills altered endometrial receptivity, other steps preceding implantation may be altered enough to prevent a pregnancy at an earlier stage.[13]

- ECPs are ineffective once implantation has begun. Data from studies of high dose oral contraceptives indicate that ECP regimens cannot interfere with an established pregnancy.[6,17]

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Why is the Mechanism of Action of ECPs Significant?

- The mechanism of action of emergency contraceptive pills is important for some users, healthcare providers, policy makers and manufacturers because of sensitive ethical and legal debates.[5]
- Exploring the mechanism of action of emergency contraceptive pills is central to understanding the difference between emergency contraception and early medical abortion. The two have occasionally been confused. ECPs are effective only in the first few days following intercourse before pregnancy begins, while medical abortion is an option for women in the early stage of pregnancy. At least five days elapse between unprotected intercourse and the establishment of a pregnancy, defined as implantation of a fertilized egg in the lining of a woman's uterus. ECPs work prior to implantation to prevent pregnancy by delaying or preventing ovulation, or possibly by blocking fertilization or altering endometrial receptivity; they cannot interrupt an established pregnancy or harm a developing embryo.[17]

Recommendation

For women to make an informed choice about using emergency contraceptive pills, they must know that ECPs may prevent pregnancy through various mechanisms of action that will not interfere with an established pregnancy.

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Address Correspondence to:

Consortium Coordinator
c/o Meridian Development Foundation
1350 24th Street NW, Suite 350
Washington, DC 20037
Tel: (202) 466-0511 Fax: (202) 466-0379
www.cecinfo.org

International Consortium for Emergency Contraception

Policy Statement (July 2003)

Repeated Use of Emergency Contraception: The Facts

Repeat use of emergency contraception or over reliance on the method is a concern sometimes mentioned by health providers, policy makers and the public.[1-5] The facts are that emergency contraception is safe, even when used more than once in a cycle. In addition, studies have found that repeat use of more than a few times in a one year period is uncommon, even when women have easy access to the method.

How often do women use ECPs more than a few times a year?

Studies investigating how often women use ECPs have found that using it more than four times in one year is uncommon. A study of general practice patients in the UK found that less than one percent of ECP users requested ECPs more than three times in a year.[6] Another study among family planning clinic attendees in the UK found that 23% had used the method more than twice in a year, but only 6% had used it more than four times.

Does increasing the availability of ECPs lead women to adopt more risky sexual behavior, to abandon ongoing contraceptive methods, or to repeatedly use ECPs?

Studies around the world indicate that advance provision of ECPs does not lead women to abandon ongoing contraception, to have unprotected sex more frequently, or to repeatedly use ECPs.[9-10] In fact, the studies show that women with easier access to ECPs are more likely to use it when needed, potentially reducing unintended pregnancy.

Are ECPs safe when used repeatedly?

The World Health Organization guidelines on ECP service delivery state, "Although frequent use of emergency contraceptive pills is not recommended, repeat use poses no health risks and [health risks] should never be cited as a reason for denying women access to treatment."[11]

There are no medical contraindications to ECPs when used occasionally, for example, once a month or less. If use exceeds this amount, the contraindications to regular combined or progestin-only oral contraceptives *might* apply.[12] There is no direct data on this issue, however, and extrapolating from long-term oral contraceptive use might not be appropriate because ECP use involves much shorter exposure to hormones. A woman would have to use combined ECPs approximately 3 times in a month in order to be exposed to the same amount of estrogen as a long-term low-dose combined pill user. Such a frequency of use is rare. Even for women with contraindications to estrogen, taking ECPs is likely safer than carrying an unwanted pregnancy to term. In such cases, women should be offered progestin-only ECPs as often as needed.

ECPs cause more side effects than other hormonal methods, although these are not serious and last only a short time. The most common side effects are menstrual irregularities and nausea.[13] In a study of repeat postcoital use of 0.75 mg of levonorgestrel (half the dosage used in the levonorgestrel-only ECP regimen), 70% of the participants reported menstrual irregularities. A high proportion of the women in this study dropped out early because of the side effects. This may indicate that the side effects themselves would deter repeat use of ECPs.[14]

How effective are ECPs when used repeatedly?

Biologically, there is no reason to suspect that the effectiveness of ECPs would decrease with repeat use; however this issue has not been studied. It is important to note that the cumulative failure rate of ECPs over a number of uses is higher than the failure rate for one use because of the simple statistical fact that the probabilities of the individual events are compounded.

Recommendation

Medical and behavioral research conducted to date does not provide any basis for limiting the number of times that women use ECPs, in a year or in a month. In every single case, ECPs are safer than pregnancy, in particular when pregnancies are unintended and women do not have access to safe abortion services. Women should use ECPs as often as needed. However, counseling should include the following messages: ECPs are less effective at preventing pregnancy than other non-emergency hormonal contraceptive methods; women choosing to take ECPs should start the method as early as possible after unprotected sex, since ECPs are more effective the earlier they are initiated; [15] ECPs don't protect against STIs and that barrier methods should be used if the woman is at risk. Finally, repeat ECP use may indicate that a woman requires further counseling on other contraceptive options.[12-13]

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Address Correspondence to:

Consortium Coordinator
c/o Meridian Development Foundation
1250 24th Street NW, Suite 350
Washington, DC 20037
Tel: (202) 466-0511 Fax: (202) 466-3079
www.cecinfo.org

International Consortium for Emergency Contraception

Policy Statement (July 2003) ***Regimen Update***

Dosage and Timing

Recent studies have provided new information concerning the regimen for levonorgestrel–only emergency contraceptive pills (ECPs). Study results indicate that a single dose of 1.5 mg of levonorgestrel can substitute for two 0.75 mg doses 12 hours apart. New research also indicates that ECPs can prevent pregnancy up to five days (120 hours) after unprotected intercourse (both levonorgestrel and Yuzpe regimens).

- **A single dose of 1.5 mg (levonorgestrel-only ECP)**

A World Health Organization (WHO) multi-center randomized trial in ten developed and developing countries found a single 1.5 mg dose of levonorgestrel to be as effective in reducing the risk of pregnancy as two 0.75 mg doses taken 12 hours apart. Side effects did not differ between the two regimens. [1] A Nigerian study corroborated this finding that a single 1.5 mg dose of levonorgestrel is both effective and safe. [2] This single dose approach simplifies the use of levonorgestrel for emergency contraception.

- **ECPs should be taken as soon as possible, but can be used up to 5 days (120 hours) after unprotected intercourse**

Levonorgestrel-only emergency contraception is effective in preventing a high proportion of pregnancies up to five days (120 hours) after unprotected intercourse according to the findings of a WHO multicenter randomized trial. [1] The combined estrogen and progestin (Yuzpe) regimen also reduces the risk of pregnancy for up to five days according to data from a Canadian study. [3] However, results from the WHO study showed a significant trend towards a lower efficacy the longer the delay between treatment and unprotected intercourse, and earlier WHO trials have indicated that pregnancy risk increases over time with delay of treatment. [1, 4] These results underscore the importance of providing ECPs to women who seek treatment beyond 72 hours. To maximize the effectiveness of the method, however, women should be encouraged to take ECPs as soon as possible after unprotected intercourse. ECPs are not effective after implantation.

Recommendation

While product labeling and information provided by ECP manufacturers is not likely to change in the immediate future, providers are encouraged to update their ECP protocols to reflect this new information. Based on evidence to date, providers should advise women to take a single 1.5 mg dose of the levonorgestrel-only ECP regimen. Providers should continue to promote ECP treatment as soon as possible following unprotected intercourse, but provide ECPs up to 120 hours after unprotected sex, as needed.

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Address Correspondence to:

Consortium Coordinator

c/o Meridian Development Foundation

1250 24th Street NW, Suite 350

Washington, DC 20037

Tel: (202) 466-3511 Fax: (202) 466-3079

www.prdn.b.org

Guidelines Issued by the FIGO Ethics Committee

Background

1. The Committee recognizes that basic human rights to health include the freedom to control sexual and reproductive health. Individuals also have the right to enjoy the benefits of new scientific knowledge in sexual and reproductive health.
2. The Committee noted its prior statement[1] that "Failure to advocate policies that will improve women's health care and advance women's rights broadly will deleteriously influence the health care of individual patients cared for by the Ob/Gyn."
3. In unprotected intercourse, emergency contraception is highly effective in diminishing the number of unwanted pregnancies without the need of an abortion.[2, 3] Early evidence suggests that abortion rates among teenagers drop following access to information and use of emergency contraception.

Recommendations

1. Early access to hormonal emergency contraception improves the success rate and therefore decreases health risks. Therefore, at a public policy level, the medical profession should advocate that emergency contraception be easily available and accessible at all times to all women.
2. Emergency contraception is not medically appropriate as an ongoing contraceptive method. Physicians have the obligation to assure accurate information is available regarding emergency contraception, as well as discuss future strategies for individuals to avoid the need for emergency contraception.
3. Access to emergency contraception should be an essential component of immediate care for women who suffer rape and are exposed to pregnancy. Adolescents because of their special vulnerability in society form another group for whom emergency contraception should be made easily available.

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[1] The Role of the Ob/Gyn as Advocates for Women's Health page 6 Recommendations on Ethical Issues in Obstetrics and Gynecology by The FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health, August 2000.

[2] Definition of pregnancy: "Natural human reproduction is a process which involves the production of male and female gametes and their union at fertilization. Pregnancy is that part of the process that commences with the implantation of the conceptus in a woman, and ends with either the birth of an infant or an abortion." (The FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health, August 2000). Published in the International Journal of Gynecology and Obstetrics, March 1999 volume 64/3:317.

[3] "Induced abortion may be defined as the termination of pregnancy using drugs or surgical intervention after implantation and before the conceptus has become independently viable" (WHO definition of a birth: 22 weeks menstrual age or more.) (The FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health, August 2000). Published in the International Journal of Gynecology and Obstetrics, March 1999 volume 64/3:318.

This material originally printed in the *International Journal of Gynecology and Obstetrics* 77:171-175 (2002). Reprinted with permission from the International Federation of Gynecology and Obstetrics (FIGO) Ethics Committee. Note: Committee documents do not represent FIGO's official position; rather they represent the views of a group of independent experts.

International Planned Parenthood Federation Statement on Emergency Contraception

Introduction

Despite the availability of highly effective methods of contraception, many pregnancies are unplanned and unwanted. Such pregnancies can result in abortion and carry an excess risk of morbidity and mortality. The risk of pregnancy with one unprotected act of sexual intercourse can be as high as one in three, depending on the cycle day of exposure in relation to ovulation. For the woman exposed to unprotected sexual intercourse, e.g., lack of contraceptive use, condom breakage, missed pills, or sexual assault, emergency contraception can be used to prevent an unwanted pregnancy.

Since the mid-1960s, the post-coital use of certain orally administered steroid hormones has been shown to be effective in preventing pregnancy. In addition, intrauterine devices (IUD) and the anti-progestogen mifepristone are also highly effective for emergency contraception.

Hormonal Methods

Two commonly available oral regimens have proved to be safe and effective for emergency contraception.

Levonogestrel-only regimen

The most convenient regimen is a single dose consisting of 1.5 mg levonorgestrel taken as soon as possible after unprotected intercourse; alternatively, one dose of 0.75 mg levonorgestrel can be taken as soon as possible after unprotected intercourse followed by the same dose taken 12 hours later.

Levonorgestrel pills are more effective the sooner they are taken after unprotected intercourse. They are most effective if taken within 3 days (72 hours). However, there is still some effect up to 5 days after unprotected intercourse.

Where pills containing 0.75 mg levonorgestrel are not available, 0.03 mg levonorgestrel pills which are used for regular contraception offer a possible alternative. Twenty-five of these mini pills should be taken initially, and a further twenty-five 12 hours later. There is anecdotal evidence to support this regimen, but no clinical studies have evaluated its efficacy.

Combined estrogen-progestin regimen

This regimen consists of two 50 µg ethinyl estradiol/0.25 mg levonorgestrel pills, or four 30 µg ethinyl estradiol/0.15 mg levonorgestrel pills, taken as soon as possible within 72 hours after unprotected intercourse, followed by a second similar dose 12 hours later. This method shows little efficacy after 72 hours from unprotected intercourse.

Choice of method

The levonogestrel-only regimen should be the first choice where available because it is more effective and is less likely to cause nausea than the combined regimen. However, the combined regimen should remain an option where the levonorgestrel-only regime is less accessible and more costly, as in many countries.

Mechanism of action

Hormonal emergency contraception achieves its contraceptive effect by several mechanisms depending on the time in a woman's cycle it is taken. It can inhibit or delay ovulation and may also interfere with ovum and sperm transport and fertilization. Studies differ on whether hormonal emergency contraception can cause changes in the endometrium that would be sufficient to interfere with implantation. There is no evidence that hormonal emergency contraception dislodges the embryo after implantation has occurred. Hormonal emergency contraception does not cause an abortion".

Efficacy

Various studies have shown that the levonorgestrel-only regimen reduces the risk of pregnancy by 60%-93% or more after a single act of intercourse, and the combined regimen reduces it by 56%-89%. In direct comparisons, the levonorgestrel regimen has been shown to be substantially more effective than the combined regimen. ECPs are not as effective as consistent and correct use of most modern contraceptive methods.

Eligibility criteria

No known contraindications exist to the use of hormonal emergency contraception. Although this method is not indicated for a woman with a known or suspected pregnancy, it will not affect the course of her pregnancy, or harm the foetus. There is no need for a physical examination or pregnancy test before it is provided.

Side-effects

Nausea and vomiting are common among women using the combined regimen and considerably less common among women using the levonorgestrel-only regimen. When the combined regimen is used, anti-emetic pre treatment may be considered; with the levonorgestrel-only regimen this is unnecessary.

If vomiting occurs within one hour after taking a dose, it is common practice to repeat the dose. However, there is no evidence that this improves efficacy; indeed, vomiting can be an indication that the hormone has been absorbed. In case of vomiting, further pills may be administered vaginally. Although there are no clinical data supporting the efficacy of this practice, contraceptive steroid hormones are known to be readily absorbed from the vagina.

Other side-effects with hormonal EC include abdominal pain, fatigue, headache, dizziness, and breast tenderness. After the use of hormonal emergency contraception, menses usually occur at the regular time, but may be either earlier or later. Some women may experience irregular bleeding or spotting after taking ECPs.

Drug interactions

Women should be advised that the effectiveness of ECP may be reduced if they are taking drugs which reduce the efficacy of regular oral contraceptives (including but not limited to rifampicin, griseofulvin, barbiturates). At the current time there is insufficient information on drug interactions to make any specific recommendations on increased ECP dosing schedules.

Frequency of use

Hormonal emergency contraception should not be used for routine pregnancy prevention since the cumulative pregnancy rate for frequent use of ECP is higher than that with regular contraception. However, if unprotected intercourse occurs in a cycle where the emergency contraception has already been used it can be repeated. Women should understand that emergency contraception pills may not protect them from the possibility of pregnancy from episodes of unprotected intercourse more than 5 days before the ECPs are taken or from intercourse after the pills are taken.

In cycles where unprotected intercourse has occurred more than once, hormonal emergency contraception can be used. However, efficacy will be influenced by the time interval since the first act of unprotected intercourse. If the woman is already pregnant because of earlier intercourse, emergency contraception will not be effective.

Mifepristone

A single dose of mifepristone 10 mg taken within 5 days of unprotected intercourse is highly effective for emergency contraception. It has a low incidence of side-effects. However, 9 -18% of women experience a delay of menses of more than 5 days. Women should be counselled appropriately. A major constraint from the use of mifepristone is its limited availability.

Copper-releasing IUDs

The copper-releasing IUD is also highly effective for emergency contraception. It can reduce the chance of pregnancy by more than 99% when inserted within 5 days of unprotected intercourse. This method may be particularly useful when the client is considering its use for long-term contraception and/or when the hormonal regimens are less effective because more than 72 hours have elapsed. When using an IUD for emergency contraception, the eligibility criteria are the same as those for regular use of these devices.

Essential information for users

Information on emergency contraception should be available to all women who may need the method. Whether contained in product pamphlets or offered by a service provider, it should include guidance on the following:

- Correct use
- Possible side-effects and their management

- Risk of pregnancy (detection and management of possible failure of the ECPs to prevent pregnancy)
- Changes in the menstrual pattern
- Preferences for regular contraception
- STI risk

Risk of pregnancy

If menstruation is delayed by more than one week from the expected time or if it is much lighter than normal, emergency contraception may have failed and the woman should consider the possibility that she may be pregnant. In the event of a pregnancy, she should be counselled on the available options and her decision should be respected and supported. If she chooses to continue with the pregnancy, she should be reassured that there is no evidence that hormonal emergency contraception affects the foetus. The use of hormonal emergency contraception has no impact on future fertility.

Regular contraception

After use of emergency contraception, women should employ another method of contraception (e.g. condoms) if she continues to have sexual intercourse. If oral contraception is chosen, it can be started the day after the ECP regimen is completed). Women who began regular use of hormonal contraception immediately after emergency contraception should be advised to expect withdrawal bleeding three weeks after starting the pills. Women choosing a long-acting hormonal contraceptive should start the method after the onset of the first menstrual period or after pregnancy has been excluded. Women opting for the IUD for emergency contraception should be advised that the IUD will provide ongoing protection from pregnancy from the time of insertion: follow-up should be arranged after the expected date of menstruation to ensure that pregnancy has been prevented and for counselling on regular contraception. Women who choose to continue using the IUD for long-term contraception should subsequently receive the same services as any other IUD user. If a woman chooses to have the IUD removed, she should be advised to come back during menstruation for removal and initiation of another contraceptive method.

Sexually transmitted infections (STIs)

Emergency contraception does not protect against sexually transmitted infections. Women who have had unprotected intercourse should be advised about the possibility of STIs. Those who may have been exposed to STIs should be offered testing or presumptive treatment that cures the commonly occurring STIs and be counselled appropriately. For women who may have been exposed to HIV, post exposure prophylaxis with ARVs should be offered where available and with appropriate counselling and follow-up.

Advocacy and Access

IPPF member associations have an important role to play in increasing awareness of emergency contraception and advocating for its easy access in local communities. Member associations should undertake activities in the following areas:

Increasing the availability of emergency contraception:

Member associations providing services should include emergency contraception in their method mix and integrate emergency contraception into their national programmes. Associations can play a lead role in ensuring the existence of a dedicated EC product in their countries and campaigning for its over-the-counter status.

Advocacy and dissemination

Member associations should disseminate information on emergency contraception and how to obtain it, by means, including mass media, training of service providers, and sexual and reproductive health education programmes. Information geared specifically to the needs of young people is particularly important.

Increasing access to supplies and services

Emergency contraception should be widely available in clinical and non clinical settings, such as community-based services, social marketing programmes, and the commercial sector. Member associations can work to increase access through the advance provision of emergency contraception to individual women.

Overcoming obstacles

Member associations should initiate locally relevant efforts aimed at removing the multiple social, cultural and religious barriers to emergency contraception.

Statement developed by the International Medical Advisory Panel (IMAP), May 2000 and revised in October 2003 IMAP reserves the right to amend this Statement in the light of further developments in this field.

INTERNATIONAL PLANNED PARENTHOOD FEDERATION
REGENT'S COLLEGE, INNER CIRCLE, REGENT'S PARK, LONDON, NW1 4NS, UK
TELEPHONE: +44 (0)20 7487 7839 FAX +44 (0)20 7487 7981
E-MAIL ADDRESS: medtech@ippf.org IPPF WEBSITE: www.ippf.org

United Nations Population Fund (UNFPA)

Statement on Emergency Contraception

The United Nations Population Fund (UNFPA) endorses the view that the aim of family planning programs must be to enable couples and individuals to decide freely and responsibly the number and spacing of their children and to have the information and means to do so and to ensure informed choices and make available a full range of safe and effective methods (ICPD para 7.12). In response to government requests, UNFPA can provide supplies for those methods including progestin-only dedicated emergency contraceptive pills. UNFPA is committed to reducing the incidence of abortion and it does not promote or support abortion in any country. UNFPA supports emergency contraception as a means for expanding contraceptive choice and reducing abortion. In line with accepted definitions of medical science, the World Health Organization states, "Emergency contraceptive pills do not interrupt pregnancy and thus are no form of abortion." By making emergency contraception more widely available, reproductive health care providers of family planning can help reduce unplanned pregnancies, many of which result in unsafe abortion and take a large toll on women's health. Emergency contraception also is an essential part of treatment for women who are victims of sexual assault. UNFPA shares the view that EC should be promptly available as a back-up for unprotected intercourse. With its major role in the prevention of both unintended pregnancies and recourse to abortion, EC is a valuable addition to reproductive health programs. UNFPA collaborates with national authorities to improve access to EC as part of high-quality care for reproductive health.

United States Agency for International Development (USAID)

Statement on Emergency Contraception

USAID is committed to providing a full range of contraceptive options. Providing information about ECPs has become a medical norm. In fact, the American College of Obstetricians and Gynecologists (ACOG) now recommends that women be informed of ECPs as standard good medical practice. The USFDA action further reinforces this norm.[1] Accordingly, USAID supplies information about the use of ECPs in a variety of its technical and training materials, and supports sharing information with family planning clients about this contraceptive option. Another role for USAID-supported programs is to collect data on the need, use, and potential impact of ECPs in participating countries; to conduct operations research on how the provision of ECPs can be integrated within family planning and other reproductive health programs and which groups would benefit most from having ECPs available; and biomedical research on the mechanism of action, use, and effectiveness of ECPs. Although USAID-supplied oral contraceptive pills are among the FDA-approved formulations that can be used for emergency contraception, USAID does not currently fund separate packaging of pills for this purpose nor has USAID purchased any of the two USFDA-approved dedicated ECP products. USAID is able to help interested Missions seek out other sources of donor support for the provision of a dedicated EC product.

[1] The USFDA published a formal notice on February 25, 1997, in the *Federal Register* stating that any one of six different [and now many more] common brands of combined oral contraceptive pills, all containing norgestrel or levonorgestrel and ethinyl estradiol, are safe and effective for use as emergency contraception up to 3 days after unprotected sex.

World Health Organization Emergency Contraception Statement

Emergency Contraception

Emergency contraception refers to contraceptive methods that can be used by women in the first few days following unprotected intercourse to prevent an unwanted pregnancy. Emergency contraceptive methods are effective and safe for the majority of women who may need them, as well as being simple to use.

Who may need emergency contraception?

Any woman of reproductive age may need emergency contraception at some point to avoid an unwanted pregnancy. It is meant to be used in situations such as:

- after voluntary sexual intercourse that took place with no contraceptive protection;
- after incorrect or inconsistent use of regular contraceptive methods or when there has been an accidental failure of other contraceptive methods such as:
- condom breakage or slippage;
- miscalculation of the infertile period when using periodic abstinence or failure to abstain from sexual intercourse during the fertile days;
- expulsion of an intrauterine device (IUD);
- failed coitus interruptus, when ejaculation has occurred in the vagina or on the external genitalia;
- failure to take oral contraceptives for more than 3 days;
- being late for a contraceptive injection;
- when a woman has been a victim of sexual assault and has had no contraceptive protection.

Methods of emergency contraception

The most common methods of emergency contraception are:

- high doses of combined oral contraceptives (COCs) containing ethynyl estradiol and levonorgestrel (Yuzpe regimen).
- high doses of progestogen-only pill containing levonorgestrel.

Mode of action

Emergency contraception pills (ECPs) are thought to prevent ovulation, fertilization, and/or implantation. ECPs are not effective once the process of implantation has begun, and will not cause abortion.

Efficacy

After a single act of unprotected sexual intercourse, the Yuzpe regimen fails in about 2 percent of women who use it correctly (the chances of pregnancy are approximately four times greater when no emergency contraceptive is used). The progestogen-only regimen is equally effective.

Eligibility criteria

The World Health Organization (WHO) has drawn up medical eligibility criteria for the use of emergency contraception pills based on the relative health risks and benefits of the method for women with given conditions.

The sole contraindication for the use of emergency contraception pills is pregnancy. Emergency contraception pills should not be given to a woman who has a confirmed pregnancy primarily because they will not be effect. Experts believe there is no harm to a pregnant woman or fetus if emergency contraceptive pills are inadvertently used during early pregnancy. Emergency contraceptive pills are for emergency use only and not recommended for routine use because of the higher possibility of failure compared to regular contraceptives and the increase in side effects such as nausea and vomitting. However, their repeated use poses no known health risks.

Further reading

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Annotated Bibliography of Core Evidence-Based Research on Emergency Contraception

Special Note:

This annotated bibliography contains annotations of most of the articles referenced in Module A: Information for Policy Makers. Exceptions include those articles summarized in either *Statistical Evidence Concerning the Mechanism of Action of the Yuzpe Regimen of Emergency Contraception* (Trussell and Raymond) or *Mechanism of Action of Hormonal Preparations Used for Emergency Contraception: A Review of the Literature* (Crozatto, Ortiz, and Muller), both of which are included in this bibliography. Additionally, articles pertaining to studies conducted on oral contraceptives and domestic violence are not included in this bibliography.

Aiken, A.M., Sackey, N., and Gold, M.A. That was then, this is now…changes in young women's knowledge, attitudes, and perceived barriers to using emergency contraception. *Journal of Pediatric and Adolescent Gynecology* 16(3):177-178 (2003).

This abstract describes a study presented at the North American Society of Pediatric and Adolescent Gynecology's annual conference on May 16, 2003, in Philadelphia, Pennsylvania. The purpose of the study was to compare the knowledge, attitudes, and perceived barriers to ECP use between two samples of young women, one from 1996 and the other from 2002. One hundred young women were recruited in 2002 from the same adolescent clinic as the 1996 sample. Seventy-seven percent were African American and 80 percent of the participants had been sexually active. Participants watched a 4 ½ minute video and received a review of emergency contraception. They were then interviewed using a semistructured questionnaire, nearly identical to the one used in 1996, about sexual and contraceptive history as well as knowledge of and experience with ECPs. Results showed that a greater percentage of the 2002 participants (74 percent) had knowledge of ECPs than participants in the 1996 study (51 percent). Thirteen percent of the 2002 group had used ECPs compared to only 3 percent in the 1996 group. Of those who had heard of ECPs, 96 percent of those in 2002 knew where to get it compared to 81 percent of the 1996 group, and 53 percent in 2002 vs. 21 percent in 1996 knew the correct time limits for use. The authors concluded that young women attending this urban clinic had an increased level of knowledge and awareness of and positive attitudes toward ECPs. Interventions focused on improving knowledge on the correct use, timing, side effects, costs, and barriers to ECPs among adolescents can further increase their use of this method.

Blanchard, K. et al. Evaluation of an emergency contraception advance provision service. *Contraception* 67(5):343-348 (2003).

This paper presents the results of a questionnaire and telephone survey to evaluate an ECP advance provision service in the United Kingdom. Women requesting ECPs were asked to fill out a questionnaire, and those who provided telephone contact information were called for more detailed information. Over a three-month period, 485 women who requested ECPs

were given questionnaires. Two hundred and fifty-nine women returned the questionnaire (53 percent response rate). Of those women who returned the questionnaire, 54 were followed up for further interviews and 31 were interviewed. Women were supportive of advance provision and indicated that it would not change their regular contraceptive use. They supported wider dissemination of information and services, especially for younger women. Several women thought that potential "abuse" or health risks of ECPs warranted strict control, while others were supportive of ECPs. The authors concluded that women and providers need accurate information about ECPs, advance provision is important especially in countries where ECPs are not yet available from pharmacists, and uptake of advance provision might be improved by subsidizing the cost of the method.

Bracken, M.B. Oral Contraception and congenital malformations in offspring: a review and meta-analysis of the prospective studies. *Obstetrics and Gynecology* 76(3 Pt 2):552-557 (1990).

This meta-analysis was conducted on prospective epidemiologic studies on oral contraceptive pills (OCPs) and congenital malformations to determine the overall relative risk of an association between congenital malformations and regular oral contraceptives. The analysis found very strong evidence against the hypothesis that exposure to OCPs in pregnancy is related to a risk of malformations in stillborn babies or live newborns. Given that much of the safety data on ECPs is extrapolated from studies conducted on regular OCPs, this study has been cited in several papers on ECP safety, highlighting the implausibility that inadvertent use during pregnancy might have an effect on a developing fetus.

Chaohua, L. et al. Investigation on knowledge of and attitude to emergency contraception among induced-abortion women. *Reproduction and Contraception* (English edition) 9(2):94-102 (1998).

This paper describes a study conducted in Shanghai, China, to assess women's knowledge, attitudes, and acceptance of emergency contraception in order to inform strategies to improve service provision. The study enrolled 606 women presenting for medical abortion at MCH clinics in Shanghai. A face-to-face, questionnaire-based interview was administered. Results indicated that 29 percent of the women presenting for abortion were aware of emergency contraception, and of those 97 percent (168) were aware of the emergency contraceptive pill. Seven of who knew about emergency contraception knew of the IUD. Of those who knew about emergency contraception, 25 percent did not think it was available in China. Only 25 women who knew about the ECP knew the correct timing, while 5 of the 7 who knew about the IUD knew its correct timing. The proportion of women willing to use emergency contraception was 86 percent in general and 91 percent among those who had known about emergency contraception prior to the study. Of those willing to use emergency contraception, 83 percent preferred the pill. The low knowledge of emergency contraception availability among those women who knew about emergency contraception shows the need for education and awareness around this method in China.

Croxatto, H.B. et al. Effects of the Yuzpe regimen, given during the follicular phase, on ovarian function. *Contraception* 65(2):121-128 (2002).

This paper discusses the results of a study undertaken to assess the extent to which the Yuzpe regimen, or half of the normal dose of that regimen, prevents ovulation when given during the follicular phase. Sixty women were enrolled in the study. All women received both a placebo and drug during the study, but in randomized order. The women were divided into six groups which differed by dosage and size of the leading follicle at treatment time (12

to 14, 15 to 17, or 18 to 20 mm). Results showed that ovulation did not occur during the ensuing five days in 65 percent of the participants nor in 40 percent of the participants who received the full and half dose, respectively, at follicle size 12-17 mm. In 18 percent of those participants who received a placebo, no ovulation occurred during the critical period. At follicle size 18 to 20 mm, ovulation was not prevented by treatment. In most of the treated cycles, sex steroid and plasma gonadotropin levels were significantly depressed during the critical period, even when follicular rupture occurred. The authors concluded that the Yuzpe regimen is effective in suppressing or postponing ovulation to the point exceeding the fertile life of spermatozoa. The lack of ovulation that occurs as well as the disruption of the ovulatory process with this method during the critical period is the likely cause of its contraceptive effect. Data did not warrant recommendation of the use of half a dose of the Yuzpe regimen.

Croxatto, H.B., Devoto, L., Durand, M., et al. Mechanism of action of hormonal preparations used for emergency contraception: a review of the literature. *Contraception* 63(3):111-121 (2001).

A comprehensive review of the literature on the mechanism of action for hormonal contraception is presented to describe how ECPs act to prevent pregnancy and to identify gaps in the literature. One hundred and two studies are included in this analysis. Information contained in this article includes a discussion of the current modes of use, efficacy, and side effects of the Yuzpe regimen, levonorgestrel, and mifepristone; the effects of postcoital administration of steroids upon fertility in nonprimate animals; studies in nonhuman primates; and clinical studies focusing on the effects of the Yuzpe regimen administered before and after the luteinizing hormone surge, progesterone-regulated endometrial proteins, and an appraisal of the possible mechanisms of action for the levonorgestrel-only method and mifepristone. The results of this analysis are further summarized in "Emergency contraception pills: how do they work?" *IPPF Medical Bulletin* 36(6) (December 2002).

Croxatto, H.B., Oritz, M.E., Muller, A.L. Mechanisms of action of emergency contraception. *Steroids.* 68(10-13):1095-8 (2003).

This article highlights two key animal studies and discusses results of several other studies undertaken to determine exactly how emergency contraceptive pills work to prevent pregnancy. In one study looking at the rat, the effects of acute treatment with levonorgestrel upon ovulation, fertilization, and implantation were evaluated. Results showed that LNG partially or totally inhibited ovulation depending on both the dosage and time of treatment. It did not, however, have an effect on fertilization or implantation when given shortly before or after mating or before implantation. Researchers concluded that no postfertilization effects were present in the rat. Results of this study, "Postcoital treatment with levonorgestrel does not disrupt postfertilization events in the rat," were published in *Contraception* in 2003. A similar study on Cebus monkeys (currently in press) was conducted to test the effect of acute LNG treatment on ovulation in nonmated cycles and on the pregnancy rate in mated cycles. LNG given twice in the follicular phase inhibited ovulation but had no effect on the pregnancy rate when given after mating. Researchers concluded that acute postcoital LNG treatment had no postfertilizaiton effects in the Cebus monkeys.

Durand, M. et al. On the mechanisms of action of short-term levonorgestrel administration in emergency contraception. *Contraception* 64(4):227-234 (2001).

A study to understand better the effects of short-term administration of levonorgestrel on

the pituitary-ovarian axis, corpus luteum function, and endometrium at different stages of the ovarian cycle was undertaken in 45 healthy, surgically sterilized women with regular menstrual cycles over two cycles. During the second menstrual cycle (treatment cycle), two doses of 0.75 mg levonorgestrel were given 12 hours apart. Women received the treatment in four groups during different phases of their menstrual cycles: Group A during the follicular phase (day 10), Group B during the periovulatory phase (luteinizing hormone [LH] surge), Group C during the postovulatory phase (48 hours after urinary LH detection), and Group D during the late follicular phase (just prior to LH surge). During both the control and treated cycles, urinary LH assays performed by each woman at home were used as the benchmarks for transvaginal ultrasounds and serum LH assays to begin. The ultrasounds and serum assays were used to determine ovulation. During the complete luteal phase, serum estradiol and progesterone were measured. Each woman also underwent an endometrial biopsy nine days after LH detection during both the control and treated cycles in order to find indications of hormone action after LH surge. Results of the study suggest that interference of levonorgestrel on the LH preovulatory surge is strongly dependent on the stage of follicular development. Anovulation observed in Group A is a result of disrupting the development and/or hormone activity of the follicle only in the preovulatory stage. Levonorgestrel did not affect the corpus luteum function or endometrium when given during the peri- and postovulatory stages.

Ellertson, C. et al. Emergency contraception: randomized comparison of advance provision and information only. *Obstetrics and Gynecology* 98(4):570-575 (2001).

This article reports the results of a study undertaken in India to determine whether several courses of ECPs provided in advance to women would tempt women using barrier methods to take more risks with their effective ongoing contraceptives. Most of the women enrolled in the study were condom users. Four hundred and eleven women who used barrier contraceptives were randomly assigned to one of two groups: those to receive information and three courses of ECPs in case of need and those to receive only information (which included where they could go to obtain ECPs if needed). Results indicated that women in both groups reported nearly identical rates of unprotected intercourse. Among women who reported unprotected intercourse, those with advance provision were almost twice as likely to use ECPs as those who received information only. No woman used ECPs more than once. Ninety-eight percent of women with advance supplies said having ECPs did not make them take more chances with condoms.

Ellertson, C., Evans, M., Ferden, S., et al. Extending the time limit for starting the Yuzpe regimen of emergency contraception to 120 hours. *Obstetrics and Gynecology* 101(6):1168-1171 (2003).

Current protocols call for initiation of emergency contraception within 72 hours of unprotected intercourse. This study questioned whether initiation of ECPs after 72 hours could have any benefits. Investigators conducted a prospective observational study to determine the effectiveness of the Yuzpe regimen when started between 72 and 120 hours after unprotected intercourse. They examined effectiveness rates for 111 women who used the regimen between 72 and 120 hours and 675 women who used the same regimen but within 72 hours. Results indicate that the failure rates differed by 2 to 4 percent between the groups, with the standard regimen having a greater effectiveness as compared to the regimen that was initiated after 72 hours. The authors note that their study lacked power due to the small sample size, but refer to the 72-hour cutoff as “unnecessarily restrictive.” They argue

that the regimen can substantially reduce the risk of pregnancy even after 4 to 5 days of unprotected intercourse.

Glasier, A. Emergency postcoital contraception. *New England Journal of Medicine* 337(15):1058-1064 (1997).

In this review article, Glasier defines ECPs' mechanism of action, the indications for ECPs, and the various forms of ECPs. Glasier also describes the controversy and misconception that ECPs are an abortifacient. The author explains that "the balance of evidence suggests that the most widely used hormonal emergency contraceptive [at the time], estrogen plus progestin, works mainly by inhibiting or delaying ovulation." Glasier emphasizes that ECPs interfere with ovulation and not fertilization and it states that implantation is not achieved until at least seven days after ovulation; ECPs taken within 72 hours [or up to five days] therefore cannot be considered an interruption of pregnancy. Glasier also notes that availability and access to ECPs are critical to achieving maximum effectiveness. Because the ECP regimen must start within 72 hours of unprotected intercourse, a woman has to know about the methods before the need for it arises. Recommendations are made for increased knowledge about how ECPs work, particularly its timing after unprotected intercourse, and improved accessibility.

Glasier, A. Safety of emergency contraception. *Journal of American Medical Women's Association* 53(5 Suppl 2):219-221 (1998).

This paper describes the safety records of combined oral contraceptives (ethinyl estradiol and levonorgestrel), levonorgestrel only, mifepristone, and the IUD when used as emergency contraception. The author determines that based on available information, all four methods have considerable data confirming their safety. The case is made that emergency contraception is often over-medicalized, (i.e., requiring a gynecologic exam or prescription from physician) and that consideration should be given to making ECPs available without a prescription wherever possible.

Glasier, A. and Baird, D. The effects of self-administering emergency contraception. *New England Journal of Medicine* 339(1):1-4 (1998).

The authors compared the use of ECPs in 553 women who were provided with a replaceable supply of hormonal ECPs to be taken at home (the treatment group), and 530 women who could obtain ECPs through a doctor (the control group). The study found that women in the treatment group were no more likely to use emergency contraception repeatedly than women in the control group, and that nearly all women used emergency contraception correctly. The authors concluded that making emergency contraception more easily attainable may reduce the rate of unwanted pregnancies and does not pose any risks or increase the likelihood of repeat use.

Graham, A., Moore, L., Sharp, D., et al. Improving teenagers' knowledge of emergency contraception: cluster randomized controlled trial of a teacher-led intervention. *British Medical Journal* 324:1179 (2002).

This paper presents the results of a cluster randomized controlled trial undertaken to assess the effectiveness of a teacher-led intervention to improve teenagers' knowledge about emergency contraception. Participants in the trial included 1,974 boys and 1,820 girls aged 14 to 15 years of age from 24 mixed-sex secondary schools in England. Teachers were instructed on how to teach students about emergency contraception and then gave students

a single lesson on emergency contraception. Questionnaires were given to students as a baseline and at six months. Information gathered via the questionnaire included knowledge of the correct use of ECPs as well as time limits for ECPs and IUDs as emergency contraception. It also included sexual activity, use of emergency contraception, and intention to use emergency contraception in the future. Results showed that those in the intervention group showed higher levels of knowledge of emergency contraception than those in the control group and there were no differences between the two groups in terms of those who had never had sex, had used emergency contraception, or intended to use it in the future. The authors concluded that the intervention did not change participants' sexual activity or increase use of emergency contraception, but that it did significantly improve the proportion of students who knew the correct timing of emergency contraception for both the IUD and ECPs.

Hapangama, D., Glasier, A.F., and Baird, D.T. The effects of peri-ovulatory administration of levonorgestrel on the menstrual cycle. *Contraception* 63(3):123-129 (2001).

This article discusses the results of a study conducted to test the hypothesis that levonorgestrel (LNG) acts as an ECP by disrupting the preovulatory lutenizing hormone (LH) surge which causes a delay in ovulation. Twelve women using nonhormonal contraceptive methods or practicing abstinence enrolled in the study. Each woman was observed for four menstrual cycles, one acting as a prestudy cycle to familiarize the women with the methods of detecting LH surge and days of high fertility with a monitor. The women were divided into two groups; both groups received either LNG or a placebo during the first and third cycles (six women took LNG in the first cycle and six took it in the third cycle), and all women received a placebo during the second. Results showed that all 12 women took LNG before the LH peak and most likely ovulation. Researchers concluded that there is reason to believe that LNG taken immediately before ovulation can delay ovulation and therefore act as an emergency contraceptive. However, there may be other explanations for the mechanism of action of LNG such as altering the endometrium, interfering with sperm motility, and altering cervical mucous.

Jones, R.K., Darroch, J.E., and Henshaw, S.K. Contraceptive use among U.S. women having abortions in 2000-2001. *Perspectives on Sexual and Reproductive Health* 34(6):294-303 (2002).

Based on a review of contraceptive use patterns among 10,683 women in the United States who received abortion services during 2000 and 2001, this study suggests that more than 50,000 abortions were averted by use of ECPs in 2000. Of the women in this review, 1.3 percent reported having taken ECPs to prevent the pregnancy. Estimates by other researchers suggest that for each pregnancy that occurs after use of ECPs, three pregnancies are prevented. The authors conclude that the increased use of ECPs in the United States may account for a significant part of the recent reduction in abortions nationally. Interestingly, 46 percent of women did not use a contraceptive method in the month they became pregnant, mainly because of perceived low risk of pregnancy and concerns about contraception. The authors suggest that women and men need more opportunities to discuss issues such as when and whether to have sexual intercourse in a relationship, methods of pregnancy prevention, and appropriate timing of childbearing.

Lovvorn, A. et al. Provision of emergency contraceptive pills to spermicide users in Ghana. *Contraception* 61(4):287-293 (2000).

This study evaluated the effect of advance provision and on-demand provision services on ECP use and unprotected intercourse among women using spermicide for contraception. Two hundred and eleven women at four family planning clinics in Accra, Kumasi, Takoradi, and Nkawkaw were enrolled in the study; all were counseled on the importance of correct spermicide use, and each was given at least forty spermicide tablets. At two of the clinics (advance clinics), women were given one packet of ECPs to take home and use if unprotected intercourse occurred and they were instructed to return to the clinic if the pills were used, lost, or given away. At the other two clinics (on demand clinics), women were counseled about ECPs and advised to return to the clinic within three days of unprotected intercourse if they should need ECPs. In all of the clinics, women used ECPs after 78 percent of unprotected sexual acts, but ECPs were used more promptly by women who had the pills at home. The data did not suggest that the availability of ECPs affected the frequency of unprotected intercourse.

Marions, L. et al. Emergency contraception with mifepristone and levonorgestrel: mechanism of action. *Obstetrics and Gynecology* 100(1):65-71 (2002).

This study examined the effects of levonorgestrel and mifepristone on ovarian function, endometrial development, and markers of endometrial receptivity to determine their mechanisms of action. Six women were treated with a single dose of mifepristone (10 mg) and six women were treated with two doses of levonorgestrel (0.75 mg) 12 hours apart. Treatment with both mifepristone and levonorgestrel before ovulation inhibited the luteinizing hormone surge, showing no significant differences between the means of luteinizing hormone measurements. The results conclude that both regimens are effective methods of emergency contraception. The authors note that ECPs may be used on any day of the menstrual cycle but it is only when sexual intercourse takes place during a 6-day period that ends on the estimated day of ovulation that there is a risk of pregnancy. Additionally, the data indicates that the 10 mg mifepristone treatment delayed the development of the follicle or inhibited ovulation and the levonorgestrel treatment inhibited the luteinizing hormone peak. It is emphasized that mifepristone may be used up to 120 hours after intercourse, but administration of levonorgestrel should be started very soon after intercourse. The authors conclude that the primary mechanism of action for both mifepristone and levonorgestrel is inhibition of ovulation rather than inhibition of implantation. However, the effect on the endometrium and the fallopian tubes may also contribute to the mifepristone's effectiveness.

Muller, A.L., Llados, C.M., and Croxatto, H.B. Postcoital treatment with levonorgestrel does not disrupt postfertilization events in the rat. *Contraception* 67(5):415-419 (2003).

This paper presents the results of a study conducted to determine the effect of acute treatment with levonorgestrel (LNG) on ovulation, fertilization, and implantation in the rat. The main interventions were administration of LNG relative to ovulation, mating, and fertilization. Results showed that LNG, depending on time of treatment and/or dosage, either totally or partially inhibited ovulation. LNG had no effect on fertilization or implantation when given either shortly before or after mating, or before implantation. The authors conclude that LNG, when administered in doses much higher than those used in women, had no postfertilizaiton effects in the rat.

Norris Turner, A. and Ellertson, C. How safe is emergency contraception? *Drug Safety* 25(10):695-706 (2002).

This article reviews the safety information available about emergency contraception using direct and indirect biomedical and social science literature, the extensively documented safety profile of regular oral contraceptives, and over 30 years clinical experience with hormonal emergency contraception. The effectiveness, dosage, and timing of the Yuzpe regimen, progestin-only pills, copper-bearing IUDs, and mifepristone are included in this discussion. Research indicating that hormonal contraceptives may be effective up to 120 hours after intercourse is included. Concerns about several safety issues (including venous disease, arterial disease, future fertility, potential birth defects, adverse side effects, and drug interactions associated with emergency contraception) are allayed using research from long-term use of regular oral contraceptives. Public health concerns that increased access to emergency contraception will result in abandonment of ongoing contraception and repeat use and encourage promiscuity and unsafe sexual practices are also challenged using data from published studies. The authors conclude that emergency contraception is safe both from the individual and public health perspectives and that increased availability and use should be encouraged.

Piaggio, G. et al. Timing of emergency contraception with levonorgestrel of the Yuzpe regimen. *Lancet* 353(9154):721 (1999).

In this letter, authors of the study *Randomized Controlled Trial of Levonorgestrel versus the Yuzpe Regimen of Combined Oral Contraceptives for Emergency Contraception* responded to a letter suggesting that randomization itself could not account for the discrepancy between this study and an earlier study showing no decline in efficacy with delay in treatment time. The authors reviewed the results of their study and adjusted the estimate of the odds ratio successively for age, weight, body mass index, gravidity, cycle length, day of the cycle in which unprotected intercourse took place, and previous use of ECPs. The results of this adjustment gave almost the same results as the original analysis. The authors concluded, based on the statistically significant effect seen with both regimens, the consistency of results from their trial and that of a previous trial, and biological plausibility, that the effect of delayed treatment on efficacy is real. Moreover, delaying the first dose of ECPs by 12 hours increased the odds of pregnancy by nearly 50 percent.

Raymond, E.G. et al. Effect of the Yuzpe regimen of emergency contraception on markers of endometrial receptivity. *Human Reproduction* 15(11):2351-2355 (2000).

The purpose of this study was to determine if the Yuzpe regimen altered endometrial integrity expression or other markers of uterine receptivity in order to determine the contraceptive action of the Yuzpe regimen. Conflicting studies have indicated that the regimen may inhibit implantation of the fertilized ovum due to a disrupted endometrium. Nineteen women were followed after taking 100 mg of ethinyl oestradiol and 1 mg of norgestrel on the day of a luteinizing hormone surge and repeating this dose 12 hours later. Investigators found that treatment at this timing in a woman's cycle did not prevent ovulation, alter endometrial structure, or affect endometrial proteins. The authors postulated that the regimen may affect endometrial function in ways undetectable by the tests performed in the study.

Rodrigues, I., Grou, F., and Joly, J. Effectiveness of emergency contraceptive pills between 72 and 120 hours after unprotected sexual intercourse. *American Journal of Obstetrics and Gynecology.* 184(4):531-537 (2002).

This article discusses the results of the first study undertaken to determine the effectiveness of the Yuzpe regimen as an emergency contraceptive when taken between 72 and120 hours after unprotected intercourse. Three hundred and seventeen women were included in the final analysis, with 131 receiving treatment within 72 hours and 169 receiving treatment between 72 and 120 hours after unprotected intercourse. Results showed that the pregnancy rate was 0.8 percent for the group that received treatment within 72 hours and 1.8 percent for those who received it between 72 and 120 hours. Effectiveness rates (reduction in pregnancy rate attributable to treatment) decreased from 87 to 90 percent for those receiving it within 72 hours to 72 to 87 percent for those who received it between 72 and 120 hours. There was a statistically significant reduction in pregnancy for both groups. Results indicate that although women should be counseled to receive ECPs as soon after unprotected intercourse as possible, ECPs can still prevent pregnancy after 72 hours and up to 120 hours.

Skibiak, J.P. et al. *Testing Strategies to Improve Access to Emergency Contraception Pills: Prescription vs. Prophylactic Distribution.* Population Council (1999).

This publication describes the results of a study conducted in Zambia to compare two approaches to ECP provision. Three groups of women were selected to receive either: a pack of ECPs for future use (intervention), an advanced prescription for ECPs that could be redeemed at a participating health center (intervention), or information and counseling about ECPs only (control). The strategies were compared in terms of their effectiveness at communicating information about ECPs, reducing wastage, facilitating timely access to ECPs, and limiting the use of ECPs to emergencies only. Results indicated that neither approach had significant differences in communicating information, but advanced provision dramatically reduced the time between unprotected intercourse and administration of treatment. There also was an indication that advanced provision led women to be more likely to use ECPs, which was attributed to two major factors. First, given that women in the study had a very poor contraceptive use rate overall, advance supplies may have affected women's desire to use routine hormonal contraceptive methods. Second, having advance supplies of ECPs may have altered women's ability to negotiate condom use with her partner. The authors concluded that advance provision is safe and effective and should be further explored, but that greater provider awareness, information, and training about the correct use and potential negative effects of advance provision are needed.

Trussell, J., Ellertson, C., and Dorflinger, L. Effectiveness of the Yuzpe regimen of emergency contraception by cycle day of intercourse: implications for mechanism of action. *Contraception* 67(3):167-171 (2003).

This paper presents the results of a literature review aimed at providing evidence about the mechanism of action of the Yuzpe regimen. It includes studies that reported women treated by the Yuzpe regimen and their resulting pregnancies by cycle day of intercourse relative to expected day of ovulation. The authors found that effectiveness was significantly higher when intercourse occurred on or before the second day before ovulation. The investigators concluded that inhibiting implantation of a fertilized egg cannot be the primary mechanism of action. If it were, one would not expect effectiveness to be so much lower when ECPs are taken after intercourse that occurs later in the cycle.

Trussell, J. and Raymond, E.G. Statistical evidence concerning the mechanism of action of the Yuzpe regimen of emergency contraception. *Obstetrics and Gynecology* 93(5 Pt 2):872-876 (1999).

An analysis of published studies on the statistical evidence on the effectiveness of the Yuzpe regimen was conducted to learn more about its mechanism of action. Studies included in the analysis were those with information on effectiveness, number of women treated on each cycle day and the outcome of the treatment, probability of conception by menstrual cycle day, and occurrence of ovulation in women treated with the Yuzpe regimen. Forty estimates of the actual effectiveness of the Yuzpe regimen were compared with the maximum theoretical effectiveness if the regimen worked only by preventing or delaying ovulation. The researchers concluded that the Yuzpe regimen could not be as effective as other studies indicate if it worked only by preventing or delaying ovulation. Further investigation needs to be carried out in order to determine more fully the mechanisms of action of this regimen.

von Hertzen, H. et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomized trial. *Lancet* 360(9348):1803-1810 (2002).

This randomized, double-blind clinical trial among 4,136 women in 15 clinics in 10 countries compared the efficacy and side effects of three regimens for emergency contraception taken within five days of unprotected intercourse: a single 10 mg dose of mifepristone, two 0.75 mg doses of levonorgestrel taken 12 hours apart, and a single dose of 1.5 mg levonorgestrel. All three regimens are very effective at preventing pregnancy if taken within five days (120 hours) of unprotected intercourse, though the study showed a significant trend towards a lower efficacy the longer the delay between treatment and unprotected intercourse. Side effects were mild and did not differ significantly between the groups. The finding that a single dose of 1.5 mg levonorgestrel is as effective in reducing the risk of pregnancy as two 0.75 mg doses taken 12 hours apart has important implications for a simplified emergency contraception regimen.

World Health Organization. *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use*. 2nd ed. Geneva: Reproductive Health and Research, World Health Organization (2000). WHO/RHR/FPP/00.02.

This ground-breaking document summarizes the main recommendations of two scientific working group meetings held at WHO in March 1994 and May 1995 on the medical eligibility criteria for use of various contraceptives. It was updated in 2000. It includes numerous tables clarifying how various health conditions and behaviors should be considered when providing contraceptives. This document is designed for use by policy makers, family planning program managers, and the scientific community in the preparation of guidelines for service delivery of contraceptives.

World Health Organization Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 352(9126):428-433 (1998).

WHO conducted a double-blind, randomized trial of 1,998 women who requested emergency contraception after one unprotected coitus. Approximately half received levonorgestrel-only ECPs (0.75 mg, repeated 12 hours later), and half received the Yuzpe regimen (100 µg

ethinyl estradiol plus 0.5 mg levonorgestrel, repeated 12 hours later). The crude pregnancy rate was 1.1 percent with the levonorgestrel-only regimen and 3.2 percent with the Yuzpe regimen. The incidence of side effects was significantly lower with the levonorgestrel-only regimen, particularly nausea (23.1 percent vs. 50.5 percent) and vomiting (5.6 percent vs. 18.8 percent). The study also found that the effectiveness of emergency contraception decreased as the interval between administration and intercourse increased.

World Health Organization Task Force on Postovulatory Methods of Fertility Regulation. Efficacy and side effects of immediate post coital levonorgestrel used repeatedly for contraception. *Contraception* 61(5):303-308 (2000).

In order to evaluate the acceptability, safety, and side effects of repeat use of postcoital levonorgestrel, researchers enrolled 295 women with infrequent coitus (defined as 1 to 4 occurrences per month) at six sites. The women were instructed to take a single 0.75mg dose of levonorgestrel orally postcoitally for six months as their only form of contraception. Participants kept a diary of intercourse acts, tablet ingestion, and side effects. The overall probability of pregnancy per treated intercourse act was 1.4 per 1,000, and the calculated Pearl index failure rate was 6.8 pregnancies per 100 woman-years of use (95 percent CI 3.1-12.9). Nearly one-third of women discontinued the study before the six-month period, mainly because of bleeding problems associated with the treatment. Seventy percent of the women had menstrual problems. Other complaints included nausea, breast tenderness, weakness, dizziness, headache, abdominal bloating, loss of libido, depression, and vomiting. Researchers concluded that high-dose, postcoital administration of levonorgestrel pills is suitable for emergency contraception and back-up to the failure of other methods but is unsuitable for use as regular contraceptive methods.

Key Facts About Emergency Contraception

What is emergency contraception?

The term emergency contraception refers to methods used by women within a few hours or a few days after unprotected intercourse to prevent pregnancy before it happens. The most common method of emergency contraception involves taking emergency contraceptive pills (ECPs), which are an elevated dose of hormonal contraceptive pills, as soon as possible after unprotected intercourse and within no than than five days (120 hours). Another emergency contraceptive method is insertion of the intrauterine device (IUD) into a woman's uterus within seven days of unprotected intercourse to prevent pregnancy.

What types of ECPs are used for emergency contraception and how effective are they?

ECPs containing only a progestin (levonorgestrel) or containing both estrogen (ethinyl estradiol) and progestin (levonorgestrel or norgestrel) can be used as contraception after intercourse to reduce the risk of unintended pregnancy. Research demonstrates that the levonorgestrel-only regimen has fewer side effects and is more effective than the combined regimen. Either regimen of ECPs can be taken up to 120 hours after unprotected intercourse, but the sooner after unprotected intercourse that a woman takes ECPs, the lower her risk of pregnancy. If used during the most fertile period, there is a 75 percent and 89 percent reduction in pregnancy risk respectively for women using the Yuzpe and levonorgestrel-only regimens within 72 hours.

Why do women need emergency contraception?

The Global Health Council estimates that nearly 60 million unintended pregnancies occur worldwide each year. Emergency contraception has the potential to prevent millions of these pregnancies. Emergency contraception can be used anytime a woman has unprotected intercourse but does not want to become pregnant. ECPs, which are safe and can be made easily accessible, provide an important opportunity for women who do not wish to become pregnant to prevent pregnancy if contraception fails, sex is forced, or contraception is not used.

Who can use emergency contraception?

All women, even those women who for medical reasons cannot use birth control pills as a regular method of contraception, can use ECPs.

How does emergency contraception work?

ECPs work by interrupting a woman's reproductive cycle. ECPs are effective only before a pregnancy is established (clinically defined as implantation of a fertilized egg in the uterus).* They cannot work after a fertilized egg has been implanted. ECPs primary mechanism of action is the inhibition or delay of ovulation (or the release of an egg from a woman's ovaries).

* The definition provided above is provided within a medical/clinical context. Individuals may have their own beliefs about when a pregnancy begins.

Does emergency contraception cause an abortion?

Medical science considers that a pregnancy has begun once implantation of a fertilized egg in the lining of a woman's uterus is complete. The process of implantation begins six days after fertilization and is completed about one week later. ECPs used during this period prevent pregnancy from occurring before implantation, which is contraception and not abortion. Based on medical definitions, emergency contraception is prevention of pregnancy because it works before implantation. Emergency contraceptives are ineffective once implantation has begun. They cannot cause an abortion if the woman is already pregnant.

Are ECPs safe?

The World Health Organization has stated that there are no absolute contraindications to the use of emergency contraceptive pills due to the small overall hormone dose and short duration of use. ECPs do not have the same contraindications as daily oral contraceptives. Researchers have concluded that no evidence exists to suggest that ECPs will harm a developing fetus.

Is repeat use of ECPs harmful?

Repeat use of ECPs poses no health risks. Experience with ECPs suggests that repeat use within the same cycle is uncommon. Use of levonorgestrel-only ECPs as frequently as four times a month did not reveal negative health risks. While repeat use is not a reason to deny a woman access to ECPs, it is an indication that a woman needs further counseling on routine contraceptive methods, as all other methods are more effective. Women who have regular intercourse (more than four times per month) are not advised to use ECPs as a regular contraceptive method because it is not as effective as regular contraception.

Do ECPs prevent sexually transmitted infections?

ECPs do not protect against HIV/AIDS or other sexually transmitted infections like syphilis, gonorrhea, chlamydia, and herpes.

This material was developed by PATH.

Module B

Cost Considerations

Objective

To demonstrate how ECPs can reduce the public-sector costs associated with unintended pregnancy in a developing-country context.

Considerations for Decision Makers

- Low-cost provision of ECPs, through nonclinical staff for example, can lead to cost savings in unintended pregnancy costs per woman having unprotected sex.
- Increased cost of ECP provision (such as clinical consultation or examination) reduces these cost savings.
- The larger the price differential between the cost of providing ECPs and the cost of pregnancy outcomes, the more cost-effective the use of ECPs will be.
- Countries with high maternal health care costs are likely to accrue large benefits from making ECPs available.

In advocating for large-scale provision of ECPs, it is important to demonstrate how ECPs can reduce the public-sector costs associated with unintended pregnancies in developing countries. Provided here is a simple model that assesses the cost-effectiveness of providing ECPs through developing-country public-sector services. The results highlight considerations for making decisions about incorporating emergency contraceptive pills into the broader package of family planning options available to women in low-resource settings. These considerations are summarized above.

Introduction

Every year, nearly 60 million unintended pregnancies occur worldwide. From 1995 to 2000, nearly 700,000 women died as a result of unintended or unwanted pregnancy.[1] Maternal morbidity and mortality associated with unintended pregnancy incur incalculable social costs and personal costs to families. Unintended pregnancy also imposes an economic burden on a country's health care system because of the increased maternal health care costs associated with antenatal care, births, abortions, and postabortion care. Emergency contraception, as the only easily accessible, safe, and effective postcoital contraceptive method, has an important role to play in preventing unintended pregnancy. Consider that if 1,000 women who do not want to become pregnant have unprotected intercourse, an estimated 75 will become pregnant. If all 1,000 women use levonorgstrel-only ECPs, the number of pregnancies can be reduced to 11—an 89 percent reduction in unintended pregnancy.

Background

Severely limited health budgets require funds be allocated to interventions that not only have an important health impact, but also make the most of scarce resources. Cost-effectiveness analysis can provide helpful information for making decisions about incorporating new health interventions, health technologies, or treatments into existing health systems. Cost-effectiveness analysis compares the costs and outcomes of two or more alternatives, making it possible to see how a new intervention would compare with the status quo. When looking at the implications of widespread access to ECPs, critical costs include those associated with provision of the ECPs; pregnancy, delivery, and related complications; abortion and abortion complications; and maternal morbidity and mortality. Increased access to ECPs will result in fewer pregnancies and abortions, resulting in lower direct medical costs, which can be captured as cost savings. It is more difficult to capture the cost savings to the health sector and society associated with reduced maternal morbidity and mortality.

The published literature to date provides evidence of the cost-effectiveness of ECPs in the United States and Canada.[2,3,4] These studies found that emergency contraception was either cost-effective or resulted in cost savings to the public payer, managed care, or third-party insurer, when used after an act of unprotected intercourse, or when obtained in advance to be used as needed. These studies focused primarily on the direct medical costs associated with induced abortion, birth, spontaneous abortion, and ectopic pregnancies. In Canada and the United States, where the average cost of births and pregnancy-related outcomes is high, especially when compared to the low price of ECPs, use of emergency contraception reduced the expenditures on medical care through the prevention of unintended pregnancies.

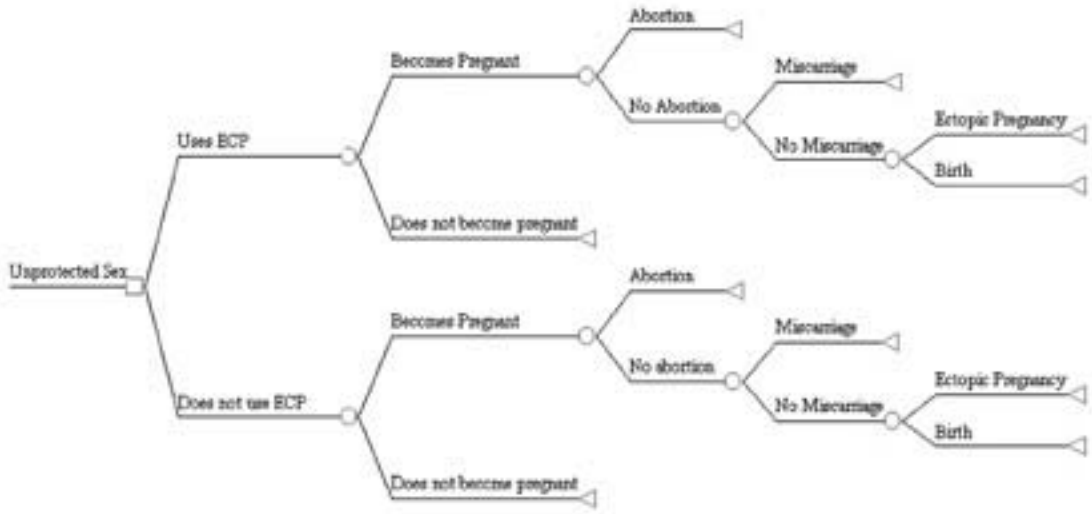
There is very little information on the costs or cost-effectiveness of the use of emergency contraception as part of family planning programs in developing countries. The evidence on the costs and outcomes from developed-country settings is not directly transferable to developing countries for several reasons. First, the health service delivery systems and cost structures in developing countries are more labor-intensive and less technology-intensive than in developed countries, resulting in lower health care costs compared to developed countries. Second, the product cost of the ECPs is relatively inexpensive in high-income countries, such as Canada and the United States. This is not the case in low- and middle-income countries, where the product cost of ECPs may be high relative to per capita health expenditures and the cost of services. Third, abortion services may be illegal in developing countries and not available through the public sector.

Assessing the Cost-Effectiveness of ECPs in Developing-Country Settings

There are a number of challenges in developing a rigorous and comprehensive cost-effectiveness analysis around the provision of ECPs in a developing-country setting, but even a simple approach can provide useful illustrative information to help guide decision making. This section describes the results of a relatively simple cost-effectiveness analysis that models the costs and outcomes associated with provision of ECPs. The analysis described below examines the costs to a public health system of a set of expected

outcomes related to women's using or not using ECPs after unprotected intercourse. The costs included in this analysis are representative of health services provided by the public-sector clinics. The model uses an existing framework[4] that describes a specific set of possible outcomes occurring as the result of unprotected intercourse. These include: pregnancy, induced abortion, spontaneous abortion, or miscarriage, ectopic pregnancy, and birth (see Figure 1). Using this model, it is possible to apply probabilities of pregnancy and outcomes, drawn from published literature, as well as country-specific data on unintended pregnancy, abortion, and health system costs.

Figure 1. Decision model for use or nonuse of emergency contraceptive pills



Model and Assumptions

The probability that a woman becomes pregnant following an unprotected act of intercourse is estimated at 7.5 percent.[5] The use of a levonorgestrel-only ECP reduces that risk of pregnancy by 85 percent. The risk of pregnancy in women who are using ECPs based on these probabilities is 1.125 percent. The model assumes that if a woman becomes pregnant, there is a 13 percent chance she will experience a spontaneous abortion,[*] and a 1.1 percent risk of an ectopic pregnancy.[6] The probability of induced abortion varies by country and is estimated at 48 percent in Cambodia, 59 percent in Peru, 67 percent in Uganda, and 73 percent in Ghana.[1]

The analysis also relies on data from four developing countries: Cambodia, Ghana, Peru, and Uganda. These four countries were selected because they demonstrate both geographic and economic differences. Appendix 1 provides maternal health care cost estimates in the four countries. Socio-demographic and reproductive health indicators for each country are included in Appendix 2. Data on the costs of maternal health care services are scarce, and even more difficult to determine are the costs associated with abortion and postabortion care, especially in countries where abortion is illegal. The four countries also were selected because of the availability of cost data through published literature (Uganda and Ghana), personal communication (Cambodia) and through a rapid MOH survey (Peru). The survey is included in Appendices 3, 4 and 5.

[*] Estimated from an unpublished internet source: http://www.umanitoba.ca/womens_health/global-r.htm.

The model assumes that all women who become pregnant receive maternal health care services in public-sector clinics or hospitals. Cost estimates for birth include antenatal care visits. Abortion costs are difficult to obtain, and where not available these costs are assumed to be 75 percent of birth costs.** ECPs are assumed to be procured by the program at a cost of $0.25 per unit,† and are provided to clients free of charge.

The cost of an unintended pregnancy represents the "net cost" equal to the total cost of the treatment (i.e., ECPs) minus the total costs that would have been incurred had the woman become pregnant. It is calculated as the weighted average of the costs of abortion, spontaneous abortion, ectopic pregnancy and birth, with the weights equal to the probabilities of each outcome for unintended pregnancies.

To provide a range of cost estimates, the model estimates costs for four scenarios that include clinical consultative services and higher abortion costs.

The model used four scenarios:

Scenario 1:

- ECPs can be obtained from a public health clinic or dispensary without an office visit.
- No costs associated with an office visit.

Scenario 2:

- ECPs can be obtained from a public health clinic or dispensary without an office visit.
- No costs associated with an office visit.
- Abortion costs are 25 percent higher than birth costs.

Scenario 3:

- ECPs are obtained from a public health clinic with a required clinical consultation.
- The cost of a consultative office visit is included.

Scenario 4:

- ECPs are obtained from a public health clinic with a required clinical consultation.
- The cost of a consultative office visit is included.
- Abortion costs are 25 percent higher than birth costs.

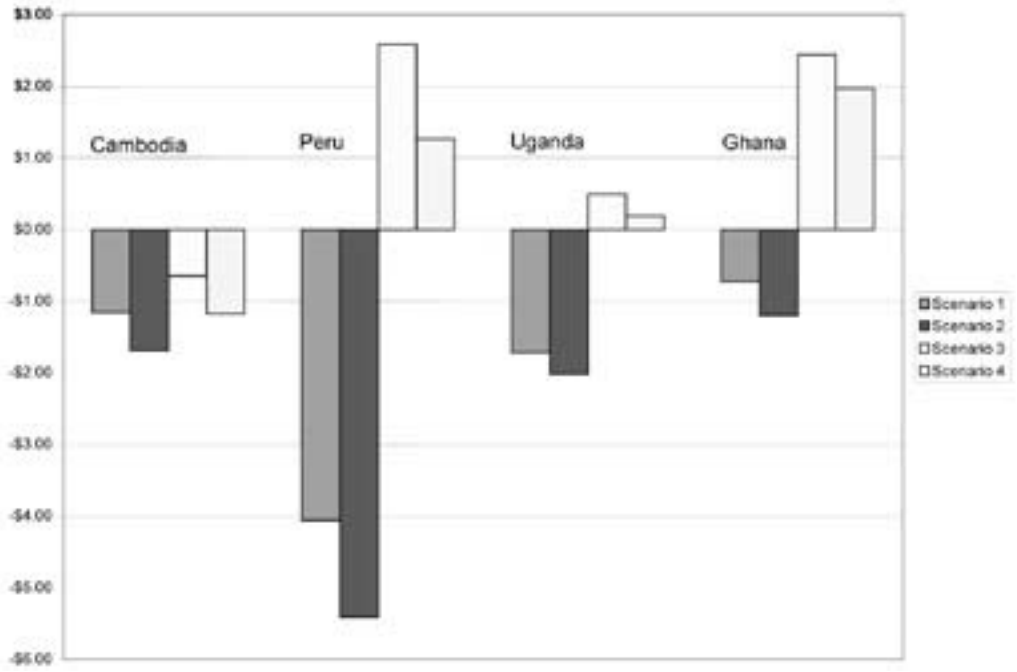
** In Cambodia, where abortion is legal and services are provided by the public sector, the cost estimate is for the provision of abortion services. In Peru, Ghana, and Uganda, where abortions are permitted only under certain conditions (e.g. to save the life of the woman in Uganda), the cost of abortion is the estimated average cost to the public sector for postabortion complication costs. These complication costs have been estimated at $66.00 per complication for Peru and Ghana and $35.00 for Uganda (Levin et al. 2000).

† This is the current price for levonorgestrel-only pills procured through UNFPA. (See information in the tools section of Module F on Regulation, Procurement and Distribution of a Progestin-Only ECP on procurement through international procurement services.) The per unit cost is exclusive of shipping costs, which will raise the per unit cost by 40 percent to over 200 percent, depending upon the size of the order.

Findings

Under the assumptions of Scenario 1, the provision of ECPs is cost-saving in all countries. (See Figure 2 below for an illustration of the cost savings (in $U.S.) versus the cost increases under the four scenarios.) For example, in Peru, the average cost of an unintended pregnancy was $5.10 per woman. The use of ECPs reduces that cost by $4.06—an 80 percent reduction. In Uganda, costs were reduced by 75 percent ($2.31 reduced by $1.72); in Cambodia, by 44 percent ($2.65 reduced by $1.16); and in Ghana, by 63 percent ($1.15 reduced by $0.73). Under Scenario 1, if 500,000 women experienced unintended pregnancy in a single year in Peru and half of these women received ECPs from a public health dispensary, $1 million would be saved in unintended pregnancy costs within the public sector. This level of cost savings is particularly noteworthy because of the need to treat all women at risk of unintended pregnancy with ECPs, even though only a portion of them would likely become pregnant from a single act of intercourse.

Figure 2. Savings or costs (in $U.S.) per woman to public payer to avoid an unintended pregnancy resulting from unprotected sex in Cambodia, Peru, Uganda, and Ghana under four ECP provision scenarios‡



As might be anticipated, even greater cost savings are realized across all countries when the cost of abortion is 25 percent higher than the cost of a birth and when ECPs are accessible without a clinical consultation (Scenario 2). When a required clinical consultation is included (Scenario 3), the cost of providing ECP increases—with the result that in three of the four countries (Cambodia is the exception), the costs incurred in providing ECPs appear to outweigh the cost savings gained from prevention of unintended pregnancy. In Scenario 4, where abortion costs are increased and ECPs are obtainable only with a clinical consultation, ECP provision still appears cost-effective in Cambodia, almost neutral in Uganda, and higher in Peru and Uganda.

‡ Costs below the line represent savings and costs above the line represent expenditures.

Discussion

The results of this analysis suggest that emergency contraceptive pills can be cost-saving to the public sector when the cost of providing the ECPs is kept low. The cost can be kept low if ECPs are available at a subsidized price to the government, if women are informed about ECPs, and if they are easily available without a clinical consultation. The safety profile of ECPs has led a number of countries to increase ECP access by making them available over-the-counter or through pharmacies.[§] Public health systems could emulate this easy-access approach.

The results of the analysis also demonstrate that the extent of cost savings or of additional costs incurred will depend upon many factors, including the extent of unintended pregnancy and resulting abortions, costs of pregnancy outcomes, cost of ECPs, and in particular, how ECPs are delivered to women. The higher the costs associated with both abortion and birth relative to the cost of providing ECPs, the greater the cost savings to the public payer. The costs and potential savings will also vary depending on the model assumptions, completeness of the cost data, and data accuracy.

The four scenarios in the model did not include variation in any of the probabilities associated with pregnancy outcomes and only included some variation in costs. Additionally, the model most likely underestimated costs associated with unintended pregnancy because it did not include costs related to pregnancy complications or complete societal costs, such as the indirect costs associated with losses in labor productivity and maternal deaths. Finally the model assumes all costs are borne within the public health care system. This may not be the case if a woman accesses ECPs, maternal health services, or abortion services through other sectors (for example through an NGO or the private sector).

Finally, although the focus of this analysis was cost-effectiveness, direct medical costs are not the only factor policy makers must consider when making decisions about allocating scarce resources. A significant proportion of unintended pregnancies (ranging from 50 percent in Cambodia to 75 percent in Ghana) end in abortion. Unintended pregnancies also lead to maternal deaths. Based on data from the Global Health Council, the following table provides an estimated number of abortions and maternal deaths that could be prevented if 100,000 women at risk of unintended pregnancy in each of the four countries used ECPs.[1]

Table 1. Unintended pregnancies, abortions, and maternal deaths averted through use of ECPs after unprotected intercourse by 100,000 women in Cambodia, Peru, Uganda, and Ghana[1]

	Cambodia	Peru	Uganda	Ghana
Unintended pregnancies	6375	6375	6375	6375
Abortions	3060	3761	4271	4718
Maternal deaths	25	9	60	30

[§] The Emergency Contraception Newsletter reports that as of Spring/Summer 2003, ECPs are available direct from a pharmacist in Albania, Belgium, Benin, Cameroon, Congo, Denmark, Finland, France, Gabon, Guinea-Bissau, Israel, Ivory Coast, Lithuania, Madagascar, Mali, Mauritius, Namibia, Portugal, Senegal, South Africa, Sri Lanka, Switzerland, Thailand, Togo, Tunisia, United Kingdom, and parts of United States and Canada. They are available over-the-counter in Norway and Sweden.

The significant number of negative outcomes averted through the use of emergency contraception illustrated in the table above demonstrates an additional critical benefit of the use of emergency contraception in developing-country settings. The costs associated with maternal deaths are not reflected in this analysis, but the issue should certainly be considered when assessing the costs associated with integrating emergency contraception into the public sector.

Appendix 1. Cost estimates ($US)

	Country			
	Cambodia	**Peru**	**Uganda**	**Ghana**
ECP	$0.25	$0.25	$0.25	$0.25
EC office visit	$0.51	$6.67	$2.21	$3.17
Induced abortion	$20.00	$66.00	$32.25	$14.84
Spontaneous abortion	$5.00	$53.00	$33.90	$14.60
Ectopic pregnancy	$45.00	$36.00	$33.90	$14.60
Birth	$30.00	$81.00	$37.81	$19.79

Appendix 2. Selected socio-demographic and reproductive health indicators for the period 1995-2000

	Country			
	Cambodia	**Peru**	**Uganda**	**Ghana**
Total Population (2002)	12,487,190	26,749,000	23,395,170	20,070,910
GDP per capita (2002)	$325	$2,404	$367	$432
Number of women aged 15-44	2,579,293	6,005,502	4,297,124	4,120,553
MM rate	590	240	1,100	590
Maternal deaths	14,192	9,741	71,515	2,1387
Pregnancies	3,558,236	7,153,365	8,892,312	5,340,873
Births	2,405,472	4,058,911	6,501,377	3,624,982
Unintended pregnancies	1,292,562	3,433,953	1,570,701	1,241,011
Abortions	619,030	2,021,452	1,057,093	914,763
Unintended births	673,532	1,412,501	513,608	326,248

Source: Global Health Council. *Promises to Keep: The Toll of Unintended Pregnancies on Women's Lives in the Developing World.* 2002.

Appendix 3. Guidelines for collecting information on birth, abortion, and abortion-related costs

Try to meet with individuals who can provide information on public hospitals and health centers and NGO health centers. You may also be interested in private hospital or clinics, since these presumably cover costs and may be more realistic of true resource use. It would be useful to get urban and rural estimates.

Explain to whoever you meet that you are interested in getting estimates of costs for

1. An office visit to obtain ECPs.
2. Antenatal care (average cost per woman).
3. Uncomplicated vaginal delivery.
4. Ectopic pregnancy or complicated delivery (as a proxy).
5. Abortions using MVA and surgical procedures.
6. Costs associated with abortion complications.

It would be easiest to get ***average per patient costs***, but these costs should include labor, materials, and indirect costs used in providing any service to women. A source of information may be insurance, hospital, or clinic user-fees manuals or fee schedules.

If you receive a user-fee manual or fee schedule, ask if these fees cover the full cost of service. If not, ask what percentage of the full cost do the user fees represent.

Two tables are provided to help collect and organize cost data.

Appendix 4 is a more detailed table that can be used for a single facility.

Appendix 5 is a summary table that can be used to enter average cost estimates that you may be able to collect across different types of facilities.

Appendix 4. Cost data by facility

Try to fill in the following information. Fill in one of these tables for each facility as needed.

1. Name of facility:_____
2. Location:_____
3. Type of facility: Public Private NGO (circle one)

	Charges per patient (from user fees)		Cost per patient (other source—full cost of providing service in local currency)	Average number of hours or days in clinic or hospital (hours or days)
	Local currency	% of full cost		
Office visit (20-minute)				
Antenatal care				
Birth				
Vaginal delivery				
Complicated delivery				
Induced abortion				
MVA				
Surgical				
Ectopic pregnancy				
Spontaneous abortion				
Postabortion complications				
Optional				
Daily bed charges				
Ob/gyn consultation				

Note: We are interested in the full cost to the provider for each of these services. If not available, we can use patient charges or user fees (that is, what the patient pays) as a proxy and try to estimate how much those costs are subsidized in public health settings.

Appendix 5. Summary of costs*

	Hospitals		Health Centers		
	Public Hospital	Private Hospital	Public Health Center	NGO or Mission Health Center	Private Clinic
Office visit to pick up ECPs (20-minute visit)					
Antenatal care					
Birth					
Vaginal delivery					
Induced abortion					
MVA					
Surgical					
Ectopic pregnancy					
Spontaneous abortion					
Postabortion complications					

* Local currency. Provide exchange rate $US 1.00 = _____

References

[1] Global Health Council. *Promises to Keep: The Toll of Unintended Pregnancies on Women's Lives in the Developing World*. New York: Global Health Council (2002).

[2] Trussell, J., Koenig, J., Ellertson, C., and Stewart, F. Preventing unintended pregnancy: the cost-effectiveness of three methods of emergency contraception. *American Journal of Public Health* 87:932-937 (1997).

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[4] Marciante, K., Gardner, J., Veenstra, D., and Sullivan, S. Modeling the cost and outcomes of pharmacist-prescribed emergency contraception. *American Journal of Public Health* 91(9):1443-1445 (2001).

[5] WHO Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 352:428-433 (1998).

[6] Awojob, O.A. and Ogunsina, S. Ectopic pregnancy in a rural practice. *Niger Journal of Medicine* 10:139-140 (2001).

Module C

Raising Public Awareness

Objective

To generate public support for large-scale provision of emergency contraceptive pills (ECPs).

Building community support and creating demand for ECPs are important steps in preparing for their introduction into a large-scale family planning program. In order for an ECP program to be effective, potential clients need to be aware that the option exists, understand when ECPs are appropriate, and know where to obtain ECPs when they need them. By educating the community about emergency contraception and involving all stakeholders in planning for ECP introduction, ECP advocates can help to create broad awareness and support for the method that will lead to client demand.

The following topics are discussed in this module:

- Social Context and Financial Resources
- Key Audiences
- Framing Key Messages
  - Women's rights and human rights approach
  - ECPs and public health messages
  - Web-based resources for rights and public health messages
- Choosing Effective Channels to Communicate Messages
  - Community resources
  - Media
- Awareness-Raising Approaches
  - Informational workshops for the media
  - Networking with advocates

This module is closely related to Module A: Information for Policy Makers, and Module D: Informing Clients. The tools provided in these modules can be used across all three areas of activities. The tools are presented as examples and should be adapted according to local needs.

Tools Provided at the End of This Module

- Agenda for a Media Workshop on Emergency Contraception
- Emergency Contraception Radio Script
- Emergency Contraception Telephone Hotline Script
- Posters
- Postcards

Social Context and Financial Resources

When developing strategies for raising public awareness, it is vital to understand the social and cultural environment of the country. Another important consideration is the availability of resources. Some strategies for raising public awareness, such as television advertisements, can be very costly; others, such as holding workshops and meetings with women's groups, can be fairly inexpensive. Rarely do people have the luxury of implementing all of the strategies they would like. Instead, resources must be weighed against potential outcomes. It is important to be clear about the audiences that will be targeted in assessing the most cost-effective strategies to implement. Knowing the financial resources available as well as the organizational capacity to carry out advocacy efforts will help determine the direction of the strategy. Some questions that may be helpful in working through this process include:

- What are the social, cultural, and religious attitudes toward family planning and reproductive health issues in the country, and how will they affect the messages and mechanisms of awareness-raising?
- What financial resources are available to conduct an awareness-raising campaign?
- Given the organization's staff expertise and capacity to conduct an awareness campaign, what other resources will be needed?
- Given the social context (and the accompanying political currents), as well as the resources available, should advocacy efforts focus on a large-scale campaign or a more targeted approach?

For information on potential sources of financial resources that may be available, see the section on resources in Module A: Information for Policy Makers.

Key Audiences

Given the resources and constraints identified above, the next step is to determine the key audience(s) who are the most important to reach. Awareness-raising can be effectively carried out at the grassroots level, as well as at the national level. The strategy will depend on the availability of ECPs in the country, financial resources, and the geographical reach of the organization carrying out the advocacy work. The following questions will help identify the critical target audiences.

- Who will have the most interest in messages about ECPs?
- Who has the greatest need for this method?
- Are there organized groups through which these people can be reached effectively?
- Which groups will have the greatest impact in terms of helping spread the message about ECPs?

Successful ECP advocacy campaigns around the world have been aimed at the following audiences:

- Women's groups
- Organizations of health professionals
- Clients of public health clinics
- Youth-serving organizations
  - General public
  - NGOs (both local and international NGOs and their affiliates)
  - Community-based health organizations and community-based distributors
  - Media, including journalists

Framing Key Messages

When developing a public awareness campaign, key messages are often communicated within an overall framework, or approach, designed to appeal to a specific audience. Examples of frameworks that have been used when advocating for ECPs in different political and cultural environments include women's rights and human rights, as well as public health. The framework must be appropriate for the social and political context and resonate with the public if the campaign is to be successful. Regardless of the messages selected, it is important to pretest them with members of the target audience. Some framing approaches that have been used successfully are described below.

Women's rights and human rights approach

The rights-based approach for reproductive and sexual health has been highlighted at several international conferences during the past two decades, including the International Conference on Population and Development (ICPD) in 1994 and the Fourth World Conference on Women in 1995. The ICPD Programme of Action clearly puts access to contraception within the framework of human rights, stating, "Reproductive rights embrace certain human rights that are already recognized in national laws, international human rights documents and other consensus documents. These rights rest on the recognition of the basic right of all couples and individuals to decide freely and responsibly the number, spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health."[1] ECPs are a unique contraceptive method and as such need to be put in the context of the right to contraceptive choice.

A useful resource for considering a rights-based approach in the context of reproductive health is the recent issue of PATH's publication, *Outlook*: A Rights-Based Approach to Reproductive Heath[2]: http://www.path.org/resources/pub_outlook.htm

ECPs, Human Rights, and Women's Rights in Latin America

- In Colombia, Profamilia faced an uphill battle to integrate ECPs into the family planning system due to strong opposition by conservative forces, including local Catholic religious leaders. Several elements were crucial to Profamilia's success in registering a dedicated levonorgestrel-only ECP product in 2001. Profamilia framed ECPs first and foremost as an important rights and legal issue. By highlighting access to ECPs as a sexual and reproductive right as stated by the Programme of Action of the ICPD, which Colombia signed in 1994, the responsibility of the Colombian government to ensure access to the widest range of contraceptive methods was reiterated. Additionally, Profamilia publicized the fact that the Ministry of Health standards already included ECPs, which meant they were sanctioned as part of the family planning program. Profamilia staff championed the cause of ECP access and helped build alliances with the media, women's groups, medical associations, and youth networks. The groups within these alliances proved to be key allies with Profamilia when the local religious leaders mounted a campaign opposing the registration of a dedicated ECP product. In the end, it was the support of these groups and the understanding on the part of the government and the public that ECPs should be an integral option in family planning programs that helped secure registration and women's access to a dedicated ECP product. More information on Profamilia's experience can be found in both English and Spanish at: http://www.ippfwhr.org/publications/download/serial_issues/spotEC1_s.pdf.

  For additional information, contact Profamilia at: Asociacion Pro-Bienstar de la Familia Colombiana, Calle 34 No 14-52, Santa Fe de Bogotá, Bogotá, Colombia; or email: info@profamilia.org.co.

- Linking ECP access to human and women's rights issues has been particularly successful in the Latin American region. Since 1999, the Pacific Institute for Women's Health (PIWH) has used this approach to advocate for ECPs in Mexico and Nicaragua in a project titled "Emergency Contraception as a Woman's Right." PIWH has collaborated closely with other groups in these countries to provide training and advocacy about ECPs, stressing that it is an important option for any woman wanting to avoid or delay pregnancy and that it is a woman's right to decide when and if she will have children. More information on PIWH's approach and work can be found on their website: http://www.piwh.org/latinamerica.html#ecright.

- The rights-based approach has also been successful in the initiatives undertaken by the Latin American Consortium for Emergency Contraception (LACEC). Advocacy efforts of LACEC member organizations focus on integrating ECPs into family planning programs and norms within a sexual and reproductive rights framework, emphasizing the fact that ECPs are a female-controlled method and that this method empowers women to decide whether and when they will become pregnant. It has been a cornerstone of the work done by LACEC groups and has been cited as a key element of their success.[3]

ECPs and public health messages

Unintended pregnancy

By preventing pregnancy before it happens, ECPs help reduce the number of unintended pregnancies and pregnancy-related maternal deaths, which can have a devastating effect on the lives of women and families in the world's poorest countries.

- The United Nations estimates that 200 million women become pregnant each year, and one-third of those pregnancies are unintended.[4]
- Every year, 8 to 30 million women experience contraceptive failure.[3,4]
- The stress and risks related to carrying a pregnancy to term and delivering a child are extremely high in countries where family planning services are limited. In fact, a woman delivering a child is twice as likely to die as a woman undergoing an abortion.[5]
- The Global Health Council calculates that from 1995 to 2000 nearly 700,000 women died as a result of an unintended or unwanted pregnancy.[6]

Abortion

Greater access to ECPs could reduce not only the number of unintended pregnancies, but also the number of abortions and associated maternal mortality.

- Worldwide, abortion-related complications are the cause of 14 percent of all maternal deaths.[6]
- Many unintended pregnancies in the developing world result from a lack of access to adequate family planning services. Women who decide to terminate their pregnancies are often faced with undergoing unsafe abortions, which severely threatens their lives. In the report *Promises to Keep: The Toll of Unintended Pregnancies on Women's Lives in the Developing World*, the Global Health Council notes that every year nearly 60 million unintended pregnancies occur, resulting in approximately 43 million abortions. Of these 43 million abortions, approximately 75,000 result in the death of the mother.[6] These deaths occur not because abortion is an inherently unsafe procedure, but because of the poor and unsafe conditions in which abortions often take place in countries where adequate family planning services are not available and access to safe abortion is restricted.

Optimal birth spacing

Access to ECPs would enable women to achieve the optimal spacing of three years between births—which has shown to improve the health of both mothers and children.

- Over 50 percent of nonfirst births in developing countries occur with less than three years spacing, which can have serious adverse effects on the health of both mothers and children.[7]
- Infants and children born less than three years apart are significantly more likely to die than their counterparts born more than three years apart.[7] Children born with birth spacing intervals of 36 to 41 months show a 26 percent, 43 percent, and 51 percent reduction in neonatal, infant, and under-five deaths, respectively, compared to those children born just 24 to 29 months apart.[7]

- Longer birth intervals are also associated with improved nutritional status of children. Data show that birth intervals of 36 to 41 months show a 28 percent reduced rate of stunting and a 29 percent reduction in underweight children.[7,8]
- Longer birth intervals also showed significantly reduced risks in terms of maternal mortality in a study conducted using data from nineteen Latin American countries.[9]

Web-based resources for rights and public health issues

Listed below are websites offering information and resources that can be used for advocating for ECP access based on the issues of rights and public health. These websites are also included in the website resources appendix, which lists websites and other resources for creating advocacy messages.

Global Health Council: http://www.globalhealth.org

The Global Health Council website contains information on international public health issues and news from around the world as well as publications useful for advocates. The Global Health Council report *Promises to Keep: The Toll of Unintended Pregnancies on Women's Lives in the Developing World* (http://www.globalhealth.org/assets/publications/PromisesToKeep.pdf) contains global and regional statistics on unintended pregnancy and abortion and related maternal mortality, as well as links to other data sources.

The Center for Reproductive Rights: http://www.crlp.org/

The Center for Reproductive Rights website contains updated information on global issues and events related to reproductive health and rights. It includes links to other sites, publications, news, and information on advocacy, human rights, legal issues, contraception, abortion, adolescents, equality, and safe pregnancy.

PIWH: http://www.piwh.org, http://www.piwh.org/latinamerica.html

Information for media and advocacy efforts and descriptions of PIWH programs and publications can be found on this site.

Catalyst Consortium: http://www.rhcatalyst.org/

This site contains information about Catalyst Consortium projects and focus program areas, including optimal birth spacing, postabortion care, south-to-south collaboration, adolescence, empowerment, and HIV/AIDS/STI prevention.

Choosing Effective Channels to Communicate Messages

To educate the public and raise awareness about emergency contraception, it will be necessary to decide which channels will be most effective, as well as how to tailor key messages for the target audiences. Answering the following questions can help determine which channels and messages would be most effective:

- Is the audience in a rural or urban area?
- What is the literacy level of the audience?
- Does the audience have access to mass media such as newspapers, magazines, and radio?

- Can the audience be targeted as a group, or would person-to person contact be more feasible and effective?

The following approaches have been used successfully for ECP advocacy.

Community resources

- Enlisting local champions such as educators, students, women's advocates, community workers, NGO staff, and factory union representatives to conduct advocacy about emergency contraception. With training, these individuals can spread the message through mechanisms of their own choosing such as holding meetings and discussions at workplaces, community gathering halls, and schools; putting up posters; passing out information; and sharing information with friends and family.
- Holding information sessions at women's group meetings, schools, offices, factories, and other workplaces.

Media

Mass media can be an excellent method of raising public awareness. Paid advertising tends to be an expensive approach; however, messages can also be integrated into television or radio programming, incorporated into the themes of story lines, or delivered through public service announcements. Press briefings can provide journalists with information that they use to write their own stories about ECPs. Media outlets to consider include:

- Radio
- TV
- Newspapers, press releases
- Magazines
- Traditional folk media, theater
- Soap operas

Awareness-Raising Approaches

Informational workshops for the media

Workshops that prepare journalists to report accurately and effectively on issues related to emergency contraception help ensure that correct information is communicated to a large audience—including potential users, providers, advocates, and even opponents. The Population Council in Mexico conducted successful workshops for journalists in both Mexico and Honduras that provided background on reproductive health issues and key information about emergency contraception. Emergency contraception advocates found that this approach not only raised awareness, but also helped to neutralize a misinformation campaign mounted by several opposition groups in Mexico. The agenda of the Population Council's journalist workshop is provided as a tool at the end of this section. The emergency contraception fact sheet provided as a tool in Module A: Information for Policy Makers can be distributed to workshop participants to take with them as a reference for informing the public about emergency contraception in the media.

Networking with advocates

Networking with groups that provide reproductive health information and services can strengthen the base of support for emergency contraception advocacy. Holding workshops or forming local emergency contraception alliances can be effective mechanisms for sharing emergency contraception information and advocacy materials, which can be disseminated more broadly. Groups that would be effective networking advocates include:

- Women's groups
- Youth advocacy groups
- Academic and health institutions
- Government sector
- ECP manufacturer or distributor

Developing Local Champions

Working with local networks and community groups, as well as encouraging active local champions, were successful strategies for increasing access to emergency contraception in Mexico. The Population Council in Mexico enlisted the help of grassroots organizations such as youth groups, whose members helped raise awareness of emergency contraception—especially among adolescents—by handing out flyers at fairs and concerts. The Population Council also worked with two highly respected physicians who were strongly supportive of increased access to ECPs. The physicians conducted numerous ECP training sessions for Ministry of Health clinicians and because of this were able to become a catalyst for change within the health system. The two physicians also became very involved in providing information about ECPs to the public through the media, participating in interviews on radio and television. By identifying and working with individuals like these two physicians who actively championed the cause of greater access to ECPs, it was possible to make progress within the government systems and circumvent the barriers created by political pressures and the multiple concerns faced by government officials.

References

[1] ICPD Program of Action. Paragraph 7.3 (1996).

[2] PATH. A Rights-Based Approach to Reproductive Health. *Outlook* 20(4):1-7 (2004).

[3] Pacific Institute for Women's Health website (www.piwh.org) (accessed September 2003).

[4] United Nations Population Fund. *The State of World Population* 1997. New York: UNFPA (1997).

[5] Segal, S.J. and LaGuardia, K.D. Termination of pregnancy—a global view. *Baillieres Clinical Obstetrics and Gynaecology* 4(2):235-247 (1990).

[6] Global Health Council. Promises to Keep: The Toll of Unintended Pregnancies on Women's Lives in the Developing World. New York: Global Health Council (2002).

[7] Setty-Venugopal, V. and Upadhyay, U.D. Birth Spacing: Three to Five Saves Lives. Population Reports Series L, No. 13. Baltimore: Johns Hopkins University Bloomberg School of Public Health, Population Information Program (2002).

[8] Rutstein, S. "Effects of Birth Interval on Mortality and Health: Multivariate Cross-Country Analysis." Presentation at the OBSI Champions Meeting, Washington, D.C. (May 2000).

[9] Conde-Agudelo, A. and Belizan, J.M. Maternal morbidity and mortality associated with interpregnancy interval: cross-sectional study. *British Medical Journal* 321(7271):1255-1259 (2000).

Module C Tools List

Agenda for a Media Workshop on Emergency Contraception

The Population Council conducted successful workshops for journalists in both Mexico and Honduras, which provided background on reproductive health issues and key information about emergency contraception to encourage accurate reporting on the issues. A sample agenda from these meetings is provided here to assist in implementing such a workshop in other settings.

Emergency Contraception Radio Script

Outreach through mass media can be very effective. Profamilia Colombia used radio stations to air messages tailored to different demographic groups in the country. Profamilia strategically aired messages at different times throughout the day to cover the various target audiences. For TV or radio advertising, a series of messages that change frequently can more effectively retain peoples' attention than a single message. Using multiple messages also makes it possible to cover multiple issues. A transcription of a radio spot developed by Profamilia in Colombia is provided here.

Emergency Contraception Telephone Hotline Script

Hotlines are telephone services individuals can call to receive information or to request help with an emergency or a problem requiring immediate attention. Hotlines, usually toll-free, have proven to be useful tools for increasing access to emergency contraception information. They can provide information about what emergency contraception is, how it works, its advantages and disadvantages, where to get it, and how to take it. Some hotlines provide recorded information; others are staffed by trained operators who speak directly with callers about their concerns and provide information about how and where to obtain ECPs.

An emergency contraception hotline, set up by the Population Council, was successful in Mexico, receiving over 10,000 calls a month at its peak. The Population Council in Mexico has documented this success in two articles.[1,2] The hotline received a great deal of attention from journalists and received good coverage in the media, raising awareness of ECPs and helping the efforts of advocates.

When developing an emergency contraception hotline, it is critical to ensure that women receive accurate and objective information. This tool is adapted from a transcript of information provided to women calling the 1-888-Not-2-Late automated emergency contraception hotline in the United States, developed and operated by the Office of Population Research at Princeton University and the Association of Reproductive Health Professionals. It provides information about ECPs and also directs callers to providers who have said they are willing and licensed to prescribe ECPs. It is an example of the kind of ECP information that can be provided through an emergency contraception hotline.

Posters

Posters placed strategically in places frequented by women are another effective way to raise awareness about emergency contraception. Women's centers, health centers, night spots such as bars or discos, universities, and public transportation such as buses, subways, and trains are just some of the places where posters advocating emergency contraception can be placed. Examples of posters used in Zambia and South Africa are provided here to stimulate ideas. All messages and visual presentations should be tested with audiences to ensure they will work well.

Postcards

The Population Council in Mexico used advertising postcards in efforts to educate women about emergency contraception. Staff placed postcards in cafes, bars, restaurants, on public transportation, at bridal shows, and other areas where young women might have the chance to see them. Sample postcards from the Mexico campaign are provided here.

[1] Ellertson, C. et al. Information campaign and advocacy efforts to promote access to emergency contraception in Mexico. *Contraception* 66:331-337 (2002).

[2] Heimburger, A. et al. Practices among providers and potential clients after a 3-year introduction effort. *Contraception* 66:321-329 (2002).

Agenda for a Media Workshop on Emergency Contraception (EC)

General Objective:

Inform members of the media about the importance of emergency contraception.

Specific Objectives:

(a) Learn the legal standard (or framework) for the introduction of EC in Honduras.

(b) Learn the most important medical aspects of EC.

(c) Determine the role of mass media in reporting on and promoting EC.

Target Audience: members of the media

Date: November 6

Location: Tegucigalpa

Agenda:

9:00–9:15 a.m.	Welcome	Dr. Sandra García, Population Council. Dr. Carlos Morlacchi, Executive Director, Ashonplafa.
9:15–9:45 a.m.	What is EC? History and medical aspects of EC.	Dr. Guillermina Mejía, Consultant, Population Council, Mexico.
9:45–10:15 a.m.	Experiences from EC introduction in other countries.	Lic. Patricia Merlo, IMIFAP, Mexico
10:15–10:30 a.m	Presentation of the EC project in Honduras, and presentation of research results in Ashonplafa clinics.	Mtra. Suyapa Pavón, Ashonplafa, Honduras Dr. Diana Lara, Population Council, Mexico.
10:30–10:50 a.m.	Legal framework for EC introduction in Honduras, and strategy of introduction in Ashonplafa.	Dr. Marielos Barahona, Ashonplafa, Honduras.
10:50–11:10 a.m.	The role of mass media in reporting on and promoting EC. Results of a review of various types of media.	Mtro. Vladimir López Recinos.
11:10–11:45 a.m.	Questions and answers	
11:45–12:00 p.m.	Closing	Dr. Carlos Morlacchi, Ashonplafa.
12:00–1:00 p.m.	Lunch	

Emergency Contraception Radio Script

Emergency Contraception

You had sex.

But there was no protection.

You were forced or the method failed.

Look, I will give you the solution.

Although it is better to use family planning, there are emergency methods.

Call: _____ or log onto: _____for more information.

This material, originally developed in Spanish, was reproduced with permission from Profamilia.

Emergency Contraception Telephone Hotline Script

Application Voice Script

English Greeting

Welcome to the Emergency Contraception Hotline, now managed by the Association of Reproductive Health Professionals. If you are calling from a rotary phone, please get ready to write down the names and phone numbers of the providers near you. If you have a touchtone phone, please press 1 to hear more in English.

Introduction

Emergency contraceptives are birth control methods that can prevent pregnancy after sex. Emergency contraception does not protect against sexually transmitted infections.

This hotline tells you about emergency contraception and gives the names and phone numbers of places nearby where you can get emergency contraceptives. Do not use emergency contraception except under the care of a health care provider who is licensed to prescribe. This hotline is not tied to any companies that make or sell emergency contraceptives.

You will now hear a menu of six choices. To return to this menu at any time, press the star key.

Menu

For information on where you can get emergency contraception press 1.

For more information on emergency contraceptive pills, press 2.

For more information on emergency insertion of a Copper-T IUD, press 3.

For guidelines on making calls to providers, press 4.

If you are a provider who would like to be included in the directory or your directory information has changed, or if you are a consumer who would like to comment on the hotline, press 5.

For more information about emergency contraception and where to obtain it anywhere in the country, please visit our website. Our address is (insert web address) If you would like additional written information about emergency contraception, ask your health care provider or press 6.

Providers

This directory lists hospitals, private doctors, family planning clinics, pharmacies, and others who can tell you about emergency contraceptives and who have said they are willing and licensed to prescribe emergency contraception. As with all health care choices, take care when choosing a provider of emergency contraception. The operators of this hotline make no claims about the quality or cost of the services offered. If you have a regular health care provider, you may wish to call the provider first.

If you have had sex that was not protected by birth control, or if your method failed in the

past few days and you do not wish to become pregnant, call a provider as soon as you can and tell the person who answers the phone that you need emergency contraception.

You will now hear the name, location, and phone number of five clinics near you. Have a pen and paper ready. If you find an error in the names and phone numbers listed, please call the hotline again and press 5 to let us know.

The five providers nearest you are:

Repeat Option

To return to the main menu, press the star key. To repeat this message, press the pound key.

Emergency Contraceptive Pills

There are two types of emergency contraceptive pills. One type is nothing more than ordinary birth control pills that contain hormones called estrogen and progestin. The brand name of the combined birth control specially packaged and labeled for emergency use in (insert name of country) is (insert brand name). About 50 percent of women who use this type get nauseated and 20 percent vomit. Use of this type of pill cuts the chance of pregnancy by 75 percent. The other type of emergency contraceptive pill contains only the hormone called progestin. This type is specially packaged and labeled for emergency use as the brand name (insert brand name). It is more effective than the first type, and the risk of nausea and vomiting is also lower.

Some people call emergency contraceptive pills "morning after" pills. But you do not have to wait until the morning after. You can start the pills right away or up to five days after you have had unprotected sex—that is sex during which you did not use birth control or your birth control may have failed. Your health care provider will tell you to take the first dose within 120 hours after unprotected sex. The provider will tell you to take the second dose 12 hours after the first dose. Each dose is 1, 2, 4, or 5 pills, depending on the brand. Not all brands of birth control pills can be used for emergency contraception. Emergency contraceptive pills require a prescription. Do not use them except under the care of someone licensed to prescribe.

Most women can safely use emergency contraceptive pills, even if they cannot use birth control pills as their regular method of birth control.

To return to the main menu, press the star key. To repeat this message, press the pound key.

Emergency Insertion of a Copper-T IUD

An IUD, or intrauterine device, is a small device that is placed into the uterus, also called the womb. You can get the emergency Copper-T IUD inserted up to seven days after unprotected sex—that is sex during which you did not use birth control or your birth control may have failed. IUDs require a prescription. A provider will tell you the advantages and disadvantages of using an IUD.

For medical reasons, the IUD is not the best option for many women who need emergency

contraception. The IUD is the most expensive emergency contraceptive, but it may be left in place to provide highly effective contraception for up to 10 years after insertion. The copper-T IUD is the most effective emergency contraceptive. An emergency insertion of the Copper-T IUD cuts the chance of pregnancy by more than 99 percent.

To return to the main menu, press the star key. To repeat this message, press the pound key.

Send a Message

If you are a consumer with comments about this hotline or a provider whose information has changed, you may either write in your comments or leave a voice-mail message. Consumers should write to (provide address for written correspondence). Providers should write to (provide address for written correspondence). Please stay on the line to leave a voice-mail message. Questions about individual medical problems will not be answered. Please consult a clinician for those questions.

Tips for Calling Providers

If you need emergency contraception, chances are you are feeling worried, maybe even panicked. When you call to make an appointment, ask any questions you may have about emergency contraception or about what will happen when you come in for an appointment. Many providers are happy to take the time to give more information when asked. By seeking out information and services to avoid an unintended pregnancy, you are acting responsibly. The following tips may help you get the most out of your calls to hotline providers.

Be aware that the directory of providers is not 100 percent failproof. If a hotline provider cannot help you, we strongly encourage you to let us know by leaving a message on the hotline (option 5 on the main menu).

Keep in mind that the cost of services will vary. Be sure to ask how much a visit will cost and check to see if there is a sliding scale fee depending on your income.

If the receptionist does not have information emergency contraception or thinks it is not provided there, ask to speak to a nurse or physician if possible.

If you call a site with a specific clinician listed and that clinician is unavailable, ask if there is someone else there who will prescribe emergency contraception, or ask for a referral to another provider.

Ask whether the clinician can phone in an emergency contraception prescription to your local pharmacist.

Be prepared to answer questions regarding the start date of your last period, when unprotected intercourse took place, your medical history, and your last pelvic exam.

If you are concerned you will run out of time before a provider can see you, try your local emergency room.

To return to the main menu, press the star key. To repeat this message, press the pound key.

Request Phone Number

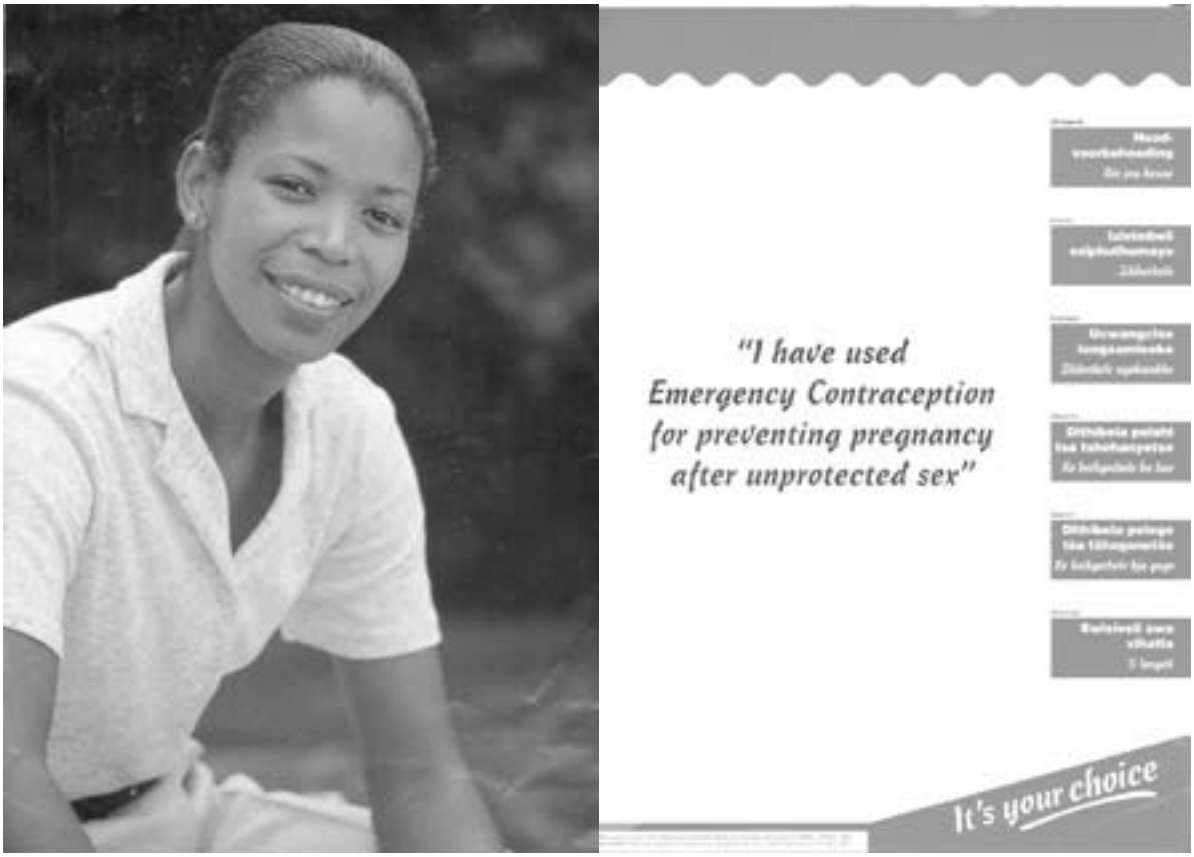
In order to connect you to the emergency contraception hotline, please enter your ten digit telephone number, beginning with the area code first. Please enter now.

Goodbye

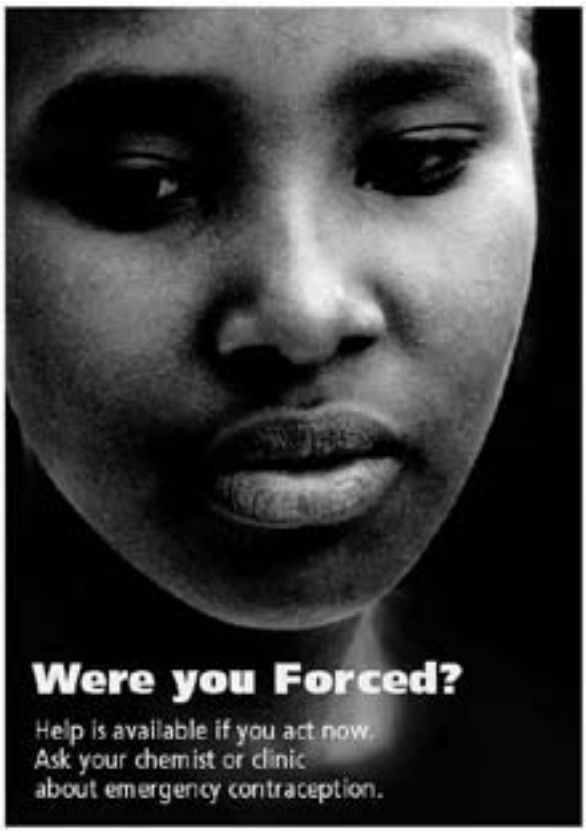
Thank you and good-bye.

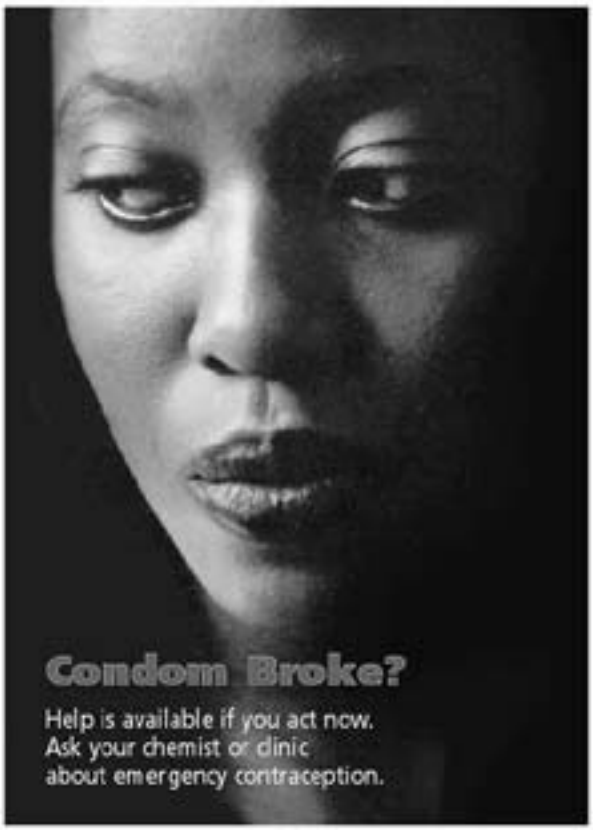
Content and format adapted with permission from Association of Reproductive Health Professional's (ARHP) Emergency Contraceptive Hotline Application Voice Script.

Posters



This material was reprinted with permission from the Reproductive Health Research Unit of the University of Witwatersrand, South Africa.





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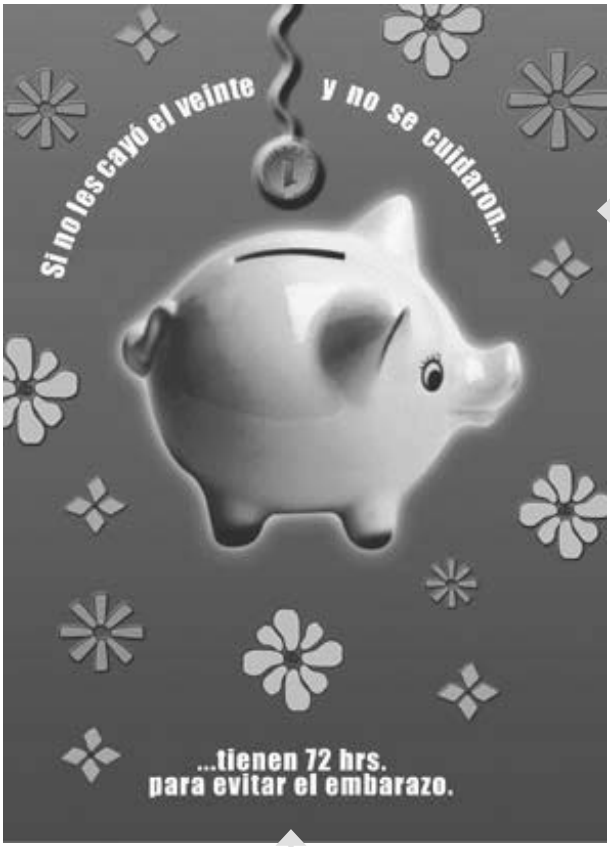
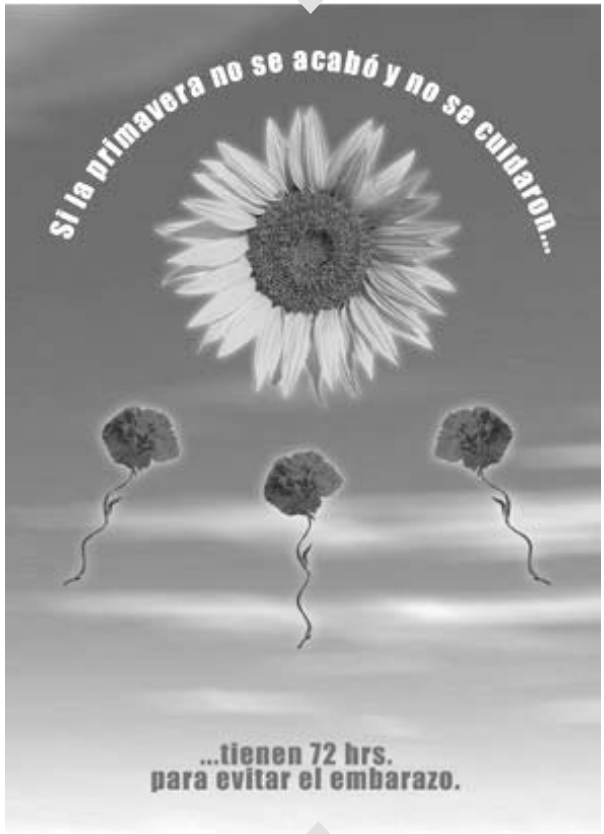
Postcards



If you forgot to save for a rainy day

…you have 72 hours to avoid pregnancy.

If spring isn't over yet and you didn't take precautions…



…you have 72 hours to avoid pregnancy.

These materials were reprinted from the Population Council.

If you ate the whole pie…

…you have 72 hours to avoid pregnancy

01-800-363-3427
in three days
Your call is confidential
www.inthreedays.org.mx

These materials were developed and translated by the Population Council of Mexico and reprinted here with their permission.

If love was sugar sweet and you didn't take precautions…

Consult your physician.

Module D

Informing Clients

Objective

To educate clients about the availability of emergency contraceptive pills (ECPs) and ensure correct use.

When ECPs have been successfully incorporated into a family planning program, it is important to provide adequate information about this contraceptive option so that clients can make an informed decision about whether or not to use ECPs—and if they choose to use them, to ensure they do it correctly. Many women do not know about ECPs, and many who have heard about them through advocacy campaigns may have questions and concerns about the method. This module discusses development of client materials that provide essential information and answer specific questions women may have about ECPs. In developing client materials, it is important to avoid overburdening the client with information, yet still provide enough so that she feels confident and safe taking ECPs. The following topics are discussed in this module:

- Identifying Key Audiences
- Developing Informational Materials for Clients
- Channels for Communicating ECP Messages to Clients

This module is closely related to Module A: Information for Policy Makers and Module C: Raising Public Awareness. The tools provided in these modules can be used across all three areas of activities. The tools are presented as examples and should be adapted according to local needs.

Tools Provided at the End of This Module

- Sample Text for Brochures
- Brochure in Three Formats
- South Africa Brochure

Additional tools that may be useful for providing information for clients can be found in the tools section of Module F: Regulation, Procurement, and Distribution of a Progestin-Only ECP and Module G: The Option of Providing Combined Oral Contraceptives (COCs) as Nondedicated Emergency Contraceptive Pills (ECPs).

The approaches used for informing ECP clients and potential ECP users will depend on a number of factors including resources available and the social and cultural environments of the clients. The main objective is to reach as large a number of potential clients as possible with correct, concise information about ECPs.

Identifying Key Audiences

Women who may need emergency contraception include sexually active adolescents, contraceptive users who experience a method failure or do not use their method consistently (condom users may experience breakage or slippage, oral contraceptive pill users may miss pills), women who have intercourse infrequently, those who are not using regular ongoing contraception methods, and those who want to space births, among others. A starting point in developing ECP materials for clients is to conduct an assessment of client information needs. A discussion of the assessment process, along with several assessment tools—including a client knowledge, attitudes, and practices questionnaire-are provided in Module E: Assessment.

Developing Informational Materials for Clients

In countries where ECPs have been successfully integrated into large-scale family planning programs, client materials typically provide factual information that clients need in order to make informed choices about using emergency contraception. Below are key facts that women may need or want to know. It is important to use language that is easy for clients to understand and to pre-test messages to be sure they are understood.

Key facts and messages

- ECPs work by preventing a pregnancy before it happens; ECPs will not work if a woman is already pregnant. Pregnancy is defined as implantation, when the fertilized egg attaches to the uterus.[1,2 *]
- ECPs cannot interrupt an established pregnancy.[1]
  - If a woman is already pregnant and takes ECPs, they will not harm the developing fetus.[1]
- Although no studies have been conducted on ECPs and future fertility, studies conducted on oral contraceptives to determine their effect on fertility have shown that they have no effect on long-term fertility. Researchers have thus concluded that hormonal emergency contraception has no effect on future fertility.[3]
- Levonorgestrel-only ECPs and combined progestin-estrogen ECPs are not the same as mifepristone, which is commonly known as the abortion pill (RU 486).[4]
- ECPs are safe. There is no evidence that taking ECPs harms a woman or causes ill health effects.[5,6]
- ECPs cannot protect against sexually transmitted infections (STIs) or HIV/AIDS. While ECPs can protect against pregnancy after unprotected intercourse, this method cannot replace condoms for protection against STIs or HIV/AIDS.
- ECPs are easy to use.
- ECPs are conveniently available. (*Providers should make sure that client outreach materials provide information on where women can go to get ECPs).*
- ECPs are not recommended for use as a regular contraceptive; other methods are more effective for regular use.

*The definition provided above is provided within a medical/clinical context. Individuals may have their own beliefs about when a pregnancy begins.

Key technical information for developing client information

- There are two options for emergency contraception: doses of the hormones used in oral contraceptives and insertion of an IUD. Hormonal contraception used as emergency contraception is effective for up to 5 days (120 hours) after unprotected sex. Insertion of the IUD is effective as emergency contraception for up to 7 days after unprotected intercourse.
- ECPs should be taken as soon as possible, but not later than 120 hours or five days after unprotected intercourse. It is important to take the pills as soon as possible, because their effectiveness decreases over time. There are two types of oral contraceptive hormones used for emergency contraception:
  - Progestin-only ECPs: One 1.5 mg dose (2 tablets) taken as soon as possible after unprotected intercourse, ideally within 120 hours or five days.* When used correctly, progestin-only ECPs reduce the risk of pregnancy by 85 percent for a single act of unprotected intercourse.** Progestin-only ECPs have fewer side effects than combined oral contraceptives used for EC.
  - Combined Estrogen/Progestin ECPs: The first dose should be taken as soon as possible after unprotected intercourse and the second dose 12 hours later. The pills should be taken as soon as possible after unprotected intercourse, as effectiveness decreases over time, but they can be used up to 120 hours or five days later. When used correctly, combined oral contraceptives taken for emergency contraception reduce the risk of pregnancy by 75 percent for a single act of unprotected intercourse.[6]**

Other sources of information for clients

Emergency contraception materials should direct clients to other resources where they can get more information about ECPs. Examples include hotline numbers, websites, and organizations that provide ECP services.

Advice for developing messages for clients

- Keep messages short, clear, and easy to understand.
- Use innovative language and a presentation style that is eye catching and appealing.
- Be sensitive to ethnic, cultural, and regional perspectives on topics related to sex and reproductive health.
- Consider translation of emergency contraception information into local dialects and multiple languages, if needed, to cover the wide spectrum of clients to be served.

*The single-dose regimen may differ from product labeling, due to the publication in 2002 of the results of a study indicating that a single dose of 1.5 mg of levonorgestrel can substitute for two 0.75 mg of levonorgestrel.

**These estimates of reduction in the risk of pregnancy following ECP use are based on studies that evaluated ECP use within a 72-hour time frame.

Channels for Communicating Emergency Contraception Messages to Clients

Health care and family planning clinics have proven to be very effective channels for communicating emergency contraception information. Providers can use their clients' regular visits for contraceptive and other health services as opportunities to discuss emergency contraception—and, where possible, to distribute ECPs in advance of need to clients at risk of unintended pregnancy. This is particularly important for clients receiving birth control methods such as oral contraceptives, condoms, hormonal injections, or other methods that can fail or be used incorrectly. Clinics also can distribute brochures and wallet cards, which clients can take home with them for future reference. It is also important to update brochures on other contraceptive methods such as oral contraceptives, condoms, hormonal injections, and others to include accurate and updated information about emergency contraception.

References

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[2] Hughes, E.C. and Committee of Terminology of the American College of Obstetricians and Gynecologists. *Obstetrics-Gynecologic Terminology*. Philadelphia: F.A. Davis (1972).

[3] Norris Turner, A. and Ellertson, C. How safe is emergency contraception? *Drug Safety* 25(10):695-706 (2002).

[4] Glasier, A. Emergency contraception. *Best Practice & Research Clinical Obstetrics and Gynecology* 16(2):181-191 (2002).

[5] Ho, P.C. and Kwan, M.S. A prospective randomized comparison of levonorgestrel with the Yuzpe regimen in post-coital contraception. *Human Reproduction* 8(3):389-392 (1993).

[6] WHO Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 352(9126):428-433 (1998).

Module D Tools List

Sample Text for Brochures

This is key text that PATH has used in its brochures. This is an example of the information that can be included in client materials. This text can be modified and adapted for local settings depending on the needs and knowledge level of clients.

Brochure in Three Formats

This pocket-sized brochure is designed to be carried in a wallet or purse and can be accessed for easy reference. It provides abbreviated information about ECPs and refers clients to other resources for information such as an emergency contraception hotline. The covers of three different versions developed by PATH to reach women from diverse language and ethnic communities in the United States are shown here.

South Africa Brochure

This full-page, tri-fold brochure was developed by the Reproductive Health Research Unit of the University of Witwatersrand in South Africa and has been useful for providing clients with information about ECPs.

Sample Text for Brochures

Emergency Contraceptive Pills

What are emergency contraceptive pills (ECPs)?

- ECPs are a safe and effective method of birth control that can prevent pregnancy after sex.
- You should start ECPs within 120 hours (5 days) after unprotected sex if you don't want to become pregnant.
- ECPs are more effective the sooner after sex they are taken.
- ECPs are not abortion pills. They will not work if you are already pregnant.

When do I use emergency contraceptive pills?

ECPs can be used if you had unprotected sex in the last 5 days. Use ECPs if:

- You didn't use any birth control.
- The condom broke.
- You missed 3 or more birth control pills or started your pack late.
- Your diaphragm slipped.
- You missed your birth control shot.
- You were forced to have sex.

How do emergency contraceptive pills work?

ECPs prevent pregnancy by:

- Temporarily stopping an egg from being released.
- Stopping fertilization of the egg.
- Stopping a fertilized egg from attaching to the wall of the uterus.

ECPs do not protect against sexually transmitted infections, including HIV/AIDS.

Are there side effects?

ECPs make some women feel sick to their stomach or vomit. Some women may have sore breasts or headaches. These side effects last about one day. ECPs can also cause some women's periods to come a little early or late. They do not affect a woman's ability to become pregnant in the future.

How do I take emergency contraceptive pills?

- For the progestin-only regimen, take a single dose of 1.5 mg levonorgestrel as soon as possible within 120 hours after unprotected sex.
- For the estrogen and progestin regimen, take the first dose as soon as possible within 120 hours after unprotected sex and take the second dose 12 hours later.
- Keep a packet of ECPs at home to use when you need them.

Are there different types of ECPs?

- Yes, different types of ECPs have different levels of effectiveness.
- Taken in special doses, some regular birth control pills can be used as emergency contraception.

Sometimes you need a second chance.

You have 120 hours to act.

For emergency contraceptive pills:

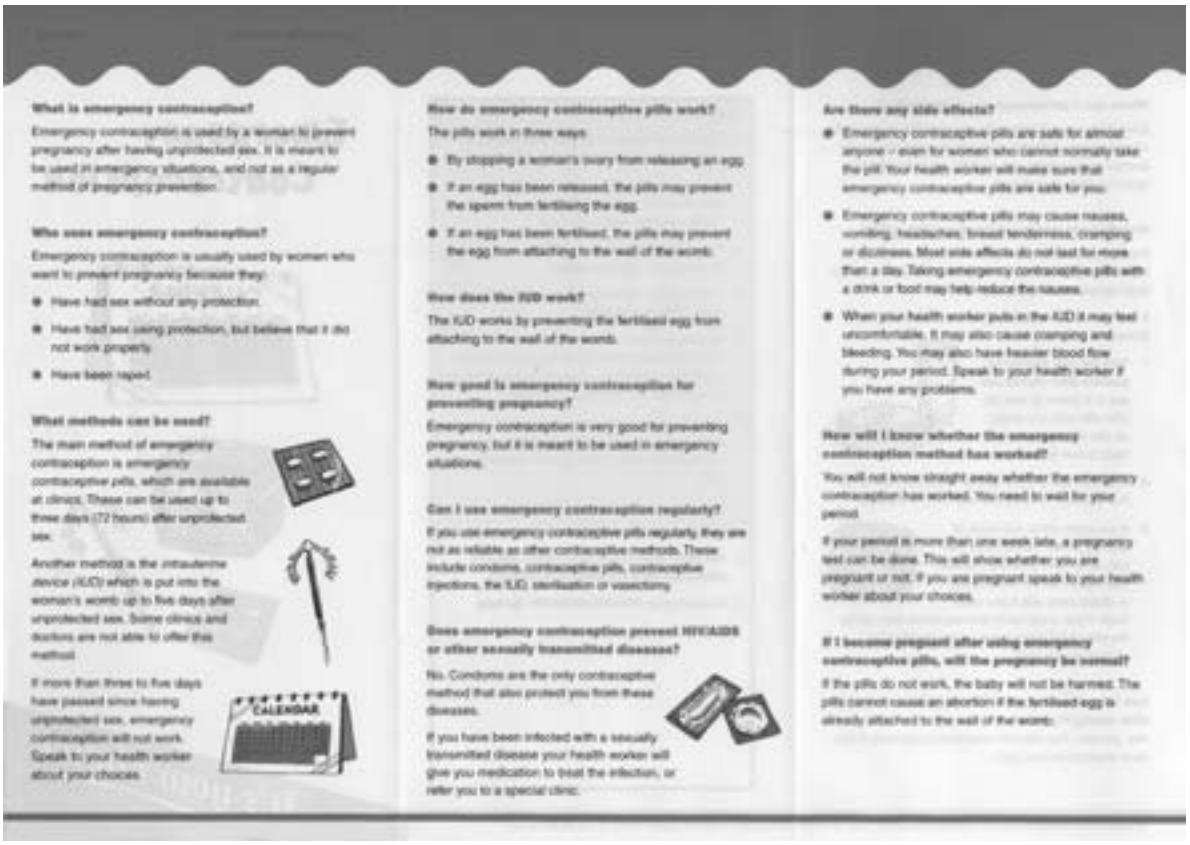
- Call your doctor or clinic.
- Visit the emergency contraception website www.not-2-late.com.

Brochure in Three Formats

These tri-fold brochures include information about ECPs on the inside.

This material was developed by PATH.

South Africa Brochure



What is emergency contraception?

Emergency contraception is used by a woman to prevent pregnancy after having unprotected sex. It is meant to be used in emergency situations, and not as a regular method of pregnancy prevention.

Who uses emergency contraception?

Emergency contraception is usually used by women who want to prevent pregnancy because they:

- Have had sex without any protection.
- Have had sex using protection, but believe that it did not work properly.
- Have been raped.

What methods can be used?

The main method of emergency contraception is emergency contraceptive pills, which are available at clinics. These can be used up to three days (72 hours) after unprotected sex.

Another method is the *intrauterine device (IUD)* which is put into the woman's womb up to five days after unprotected sex. Some clinics and doctors are not able to offer this method.

If more than three to five days have passed since having unprotected sex, emergency contraception will not work. Speak to your health worker about your choices.

How do emergency contraceptive pills work?

The pills work in three ways:

- By stopping a woman's ovary from releasing an egg.
- If an egg has been released, the pills may prevent the sperm from fertilising the egg.
- If an egg has been fertilised, the pills may prevent the egg from attaching to the wall of the womb.

How does the IUD work?

The IUD works by preventing the fertilised egg from attaching to the wall of the womb.

How good is emergency contraception for preventing pregnancy?

Emergency contraception is very good for preventing pregnancy, but it is meant to be used in emergency situations.

Can I use emergency contraception regularly?

If you use emergency contraceptive pills regularly, they are not as reliable as other contraceptive methods. These include condoms, contraceptive pills, contraceptive injections, the IUD, sterilisation or vasectomy.

Does emergency contraception prevent HIV/AIDS or other sexually transmitted diseases?

No. Condoms are the only contraceptive method that also protect you from these diseases.

If you have been infected with a sexually transmitted disease your health worker will give you medication to treat the infection, or refer you to a special clinic.

Are there any side effects?

- Emergency contraceptive pills are safe for almost anyone – even for women who cannot normally take the pill. Your health worker will make sure that emergency contraceptive pills are safe for you.
- Emergency contraceptive pills may cause nausea, vomiting, headaches, breast tenderness, cramping or dizziness. Most side effects do not last for more than a day. Taking emergency contraceptive pills with a drink or food may help reduce the nausea.
- When your health worker puts in the IUD it may feel uncomfortable. It may also cause cramping and bleeding. You may also have heavier blood flow during your period. Speak to your health worker if you have any problems.

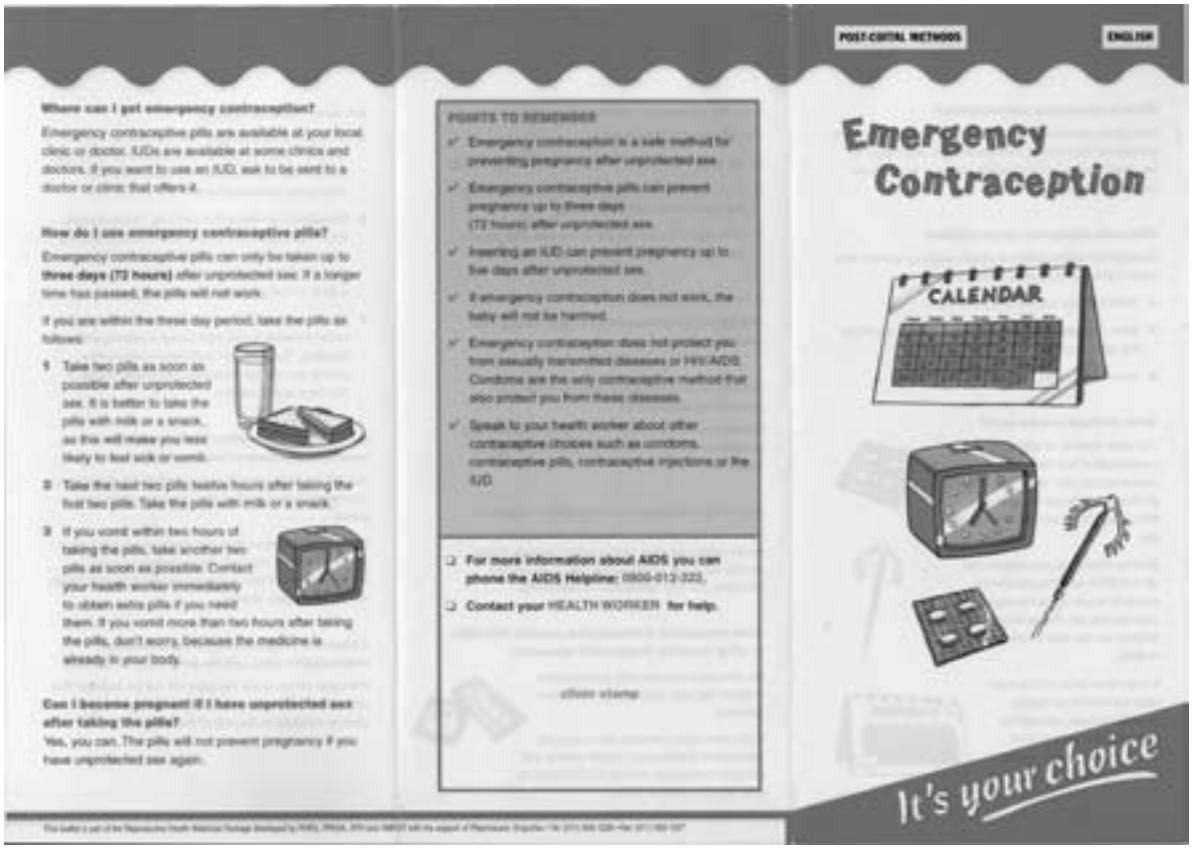
How will I know whether the emergency contraception method has worked?

You will not know straight away whether the emergency contraception has worked. You need to wait for your period.

If your period is more than one week late, a pregnancy test can be done. This will show whether you are pregnant or not. If you are pregnant speak to your health worker about your choices.

If I become pregnant after using emergency contraceptive pills, will the pregnancy be normal?

If the pills do not work, the baby will not be harmed. The pills cannot cause an abortion if the fertilised egg is already attached to the wall of the womb.



POST-COITAL METHODS ENGLISH

Where can I get emergency contraception?

Emergency contraceptive pills are available at your local clinic or doctor. IUDs are available at some clinics and doctors. If you want to use an IUD, ask to be sent to a doctor or clinic that offers it.

How do I use emergency contraceptive pills?

Emergency contraceptive pills can only be taken up to **three days (72 hours)** after unprotected sex. If a longer time has passed, the pills will not work.

If you are within the three day period, take the pills as follows:

1. Take two pills as soon as possible after unprotected sex. It is better to take the pills with milk or a snack, as this will make you less likely to feel sick or vomit.
2. Take the next two pills twelve hours after taking the first two pills. Take the pills with milk or a snack.
3. If you vomit within two hours of taking the pills, take another two pills as soon as possible. Contact your health worker immediately to obtain extra pills if you need them. If you vomit more than two hours after taking the pills, don't worry, because the medicine is already in your body.

Can I become pregnant if I have unprotected sex after taking the pills?

Yes, you can. The pills will not prevent pregnancy if you have unprotected sex again.

POINTS TO REMEMBER

- ✓ Emergency contraception is a safe method for preventing pregnancy after unprotected sex.
- ✓ Emergency contraceptive pills can prevent pregnancy up to three days (72 hours) after unprotected sex.
- ✓ Inserting an IUD can prevent pregnancy up to five days after unprotected sex.
- ✓ If emergency contraception does not work, the baby will not be harmed.
- ✓ Emergency contraception does not protect you from sexually transmitted diseases or HIV/AIDS. Condoms are the only contraceptive method that also protect you from these diseases.
- ✓ Speak to your health worker about other contraceptive choices such as condoms, contraceptive pills, contraceptive injections or the IUD.

❑ **For more information about AIDS you can phone the AIDS Helpline:** 0800-012-322.

❑ **Contact your** HEALTH WORKER **for help.**

clinic stamp

Emergency Contraception

CALENDAR

It's your choice

This material was reprinted with permission from the Reproductive Health Research Unit of the University of Witwatersrand, South Africa.

Module E

Assessment

Objective

To gather information for guiding the integration of emergency contraceptive pills (ECPs) into large-scale family planning or health programs.

An important step in developing a successful emergency contraception program is to gain an understanding of the existing context, including the perceptions of clients, providers, program planners, and decision makers. This understanding will provide the basis for developing appropriate ECP introduction strategies and will ensure that ECP information and services are tailored to local needs. The following topics are discussed in this module:

- Assessment of Existing Program
- ECP Introduction Assessment
- Key Questions and Considerations for An Assessment
- Effective Ways to Gather Information
- Moving from Assessment to Action
- Using and Adapting Assessment Tools

Tools Provided at the End of this Module

- Client Knowledge, Attitudes, and Practices Questionnaire
- Provider Knowledge, Attitudes, and Practices Survey on Emergency Contraceptive Pills
- In-Depth Interview Guide for Key Reproductive Health Authorities
- Mystery Shopper Survey Guidelines

Assessment of Existing Program

The World Health Organization (WHO) publication, *Making Decisions about Contraceptive Introduction: A Guide for Conducting Assessments to Broaden Contraceptive Choice and Improve Quality of Care*,[1] is a useful tool that can help program planners prepare for introduction of a new contraceptive method by assessing user perspectives as well as the quality of family planning services currently being delivered. It addresses three questions:

1. Is there a need to improve the provision of currently available contraceptive methods?
2. Is there a need to remove any methods from a given setting?
3. Is there a need to introduce new contraceptive methods?

When this WHO assessment process was undertaken in Zambia, beginning in 1995, one recommendation that emerged was to introduce emergency contraception into the Zambian national family planning program. Following this recommendation, ECP service delivery support systems were developed and tested together with several alternative strategies for improving access to and the quality of emergency contraception services.[2]

ECP Introduction Assessment

Once the decision has been made to introduce ECPs into a large-scale program, an assessment specific to ECP introduction will provide information that can be used to design an introduction plan. The first step in undertaking this assessment is to identify what information is needed and how it will be used. The assessment tools should directly relate to these information needs, in order to obtain appropriate and targeted information.

Prior to developing an assessment plan it will be important to identify:

- The priority groups/informants from whom information should be gathered to help shape ECP introduction strategies (e.g., ministry of health officials, social marketing groups).
- The information that is available and information gaps (the gaps will determine the key questions).

Key Questions and Considerations for an Assessment

The following questions, outlined by the International Consortium for Emergency Contraception, can help stimulate thinking on issues that need to be addressed in emergency contraception introduction.[3] This list of key questions can provide a start for determining what information is already known and what gaps will need to be addressed through the assessment process.

Regulatory system requirements

- Is a post-coital contraceptive or specially packaged ECP product registered for use? If not, what requirements must be met for registration approval?
- What are the procedures for changing the labeling for existing products?
- Can medical providers prescribe combined oral contraceptives for off-label uses?
- Are pharmacists and other nonmedical health professionals authorized to distribute contraceptives? If so, does that authorization also apply to ECPs?

Service delivery capabilities

- What is the current overall knowledge among providers of family planning methods in general and ECPs in particular?
- Do providers perceive a need for ECPs?
- What standards of care would be required for ECP services?
- What are providers' capabilities with regard to ECP information and services?

- What mechanisms exist for the distribution of regular oral contraceptives (clinics, hospitals, pharmacies, social marketing, and community-based and commercial distribution systems)?
- What is the capacity of these distribution channels to take on an additional, closely related product?
- What is the capacity of non-family planning/reproductive health care providers (e.g., hospital emergency rooms, maternal and child health clinics, and sexual assault crisis centers) to supply ECPs?
- What level of provider training would be required to ensure high-quality services?
- What training and information mechanisms are preferred by providers?
- What do providers consider to be barriers to providing quality ECP services?

Client needs and perspectives

- Are potential clients aware of family planning in general and the method in particular?
- When told about the method, do potential clients perceive a need for it?
- What questions do they have about it?
- Are rumors or misinformation about the method widespread?
- Which population groups report the greatest need for ECP services?
- What distribution mechanisms would be most convenient and acceptable to potential clients?
- What are user perceptions of existing services through which ECPs might be provided?
- What information channels (both formal and informal) are preferred by potential clients?

Effective Ways to Gather Information

There are a number of useful information gathering methods to help ECP introduction. It is important to think about how the information will be used in determining which methods are best in a particular setting. Consider how scientific the information gathering process needs to be and whether relatively simple, inexpensive, and quick methods of gathering information will meet the program needs for assessment.

The following table summarizes characteristics of data gathering methods and issues to consider in determining which methods will be used as part of the ECP assessment.

Data Gathering Method	Issues to Consider
Knowledge, attitude, and practice (KAP) surveys	• Are used when it is important to determine what percentage of people in a community or particular group know or believe certain things or act in specific ways. • Are useful for assessing client and provider perspectives about ECPs. • Can use close-ended or open-ended questions or both. However, open-ended questions are more difficult to collect and analyze. • Require participants randomly selected from various parts of the community and can be expensive and time consuming. Consider whether it is necessary to know what proportion of people believe something, or whether it is enough to know what kinds of things people believe. In the latter case, quicker and less expensive qualitative research techniques may be more appropriate.
In-depth interviews	• Provide detailed insight into people's thoughts, feelings, and behaviors. • Are a good method for gathering information from hard-to-reach or influential target audience members such as policy makers. • Require more time to analyze because they contain many open-ended questions.
Focus group discussions (FGDs)	• Are in-depth discussions, usually one to two hours in length, in which six to ten representatives of the target audience, under the guidance of a facilitator, discuss topics of particular importance to the forthcoming program. • Produce qualitative results: they are an exploration of knowledge, beliefs, concerns, and attitudes. • Are often the method of choice for audience research geared toward developing print materials.
Desk research	• Is collecting data from secondary sources, which can be a useful first step in an ECP assessment process. • Can identify existing information on relevant topics such as demographic or regulatory information. • May be possible to frame the issue of ECP provision in a broader sociocultural, economic, and political environment based on existing information.
Mystery shoppers or clients	• Are researchers (or members of the research team) who pose as clients to assess how services are being provided (e.g., a mystery shopper walks into clinic and tells the provider that she had sex and does not want to get pregnant and documents the provider's response). • Can be used to provide a measure of whether and how ECP information and services are provided. • Need to ensure that mystery client surveys are handled ethically and that results are used constructively.

Source: Information on KAP surveys, in-depth interviews and FGDs adapted from: Zimmerman, M., Newton, N., Frumin, L., Wittet, S. *Developing Health and Family Planning Materials for Low-Literate Audiences: A Guide (revised ed.).* Washington, D.C.: PATH (1996).

Moving from Assessment to Action

The most important aspect of an assessment is ensuring that the information gathered is used to guide and inform the program development decision making process. Before undertaking the assessment, it is generally helpful to develop a plan for analyzing and interpreting the data that will be gathered. It may be useful to organize the assessment findings in a matrix according to the original research questions, the central findings from the assessment, and programmatic recommendations that come out of the findings.

The matrix below, based on an initial assessment in Sri Lanka demonstrates how assessment findings can inform programmatic decisions. Program planners in Sri Lanka completed a baseline survey, a postal questionnaire of medical service delivery personnel, in-depth interviews with community leaders, and group discussions with family health workers (midwives) selected from different parts of the country. The introduction plan informed by this assessment was successful. The new method was well received by both providers and clients and ECP use has continued to expand over time.

Assessment Questions	Key Findings	Programmatic Recommendations
What are provider attitudes about ECPs?	• Doctors and midwives willing to distribute ECPs. • Concerns expressed that some people would resort to ECP use in place of regular contraceptive methods. • Concerns expressed about possible spread of STIs and HIV/AIDS due to increased sexual activity without condoms (since pregnancy protection available through ECPs).	• Train clinic staff and telephone operators on how ECP information should be provided to possible users. • Train clinicians willing to introduce ECPs in clinics. • In provider training, address concerns regarding use of ECPs as a regular contraceptive method and possible decrease in condom use. (Studies have provided evidence that these concerns are not borne out—see a discussion of this issue in Module A: Information for Policy Makers.) • Train providers to use ECP provision as an opportunity to discuss its correct use and encourage clients to adopt regular contraceptive methods.
How will the public respond to an ECP product?	• Subject is new to the general public. • Idea of ECP well accepted by both married and unmarried men and women. • Perception that ECP can be used to cause an abortion.	• An aggressive educational and publicity campaign should be implemented. • Educational activities and materials should be aimed at preventing the misconception that ECP would be abortifacient. (See Module A: Information for Policy Makers.)
What are the issues regarding marketing of a branded ECP?	• Brand name should be given wide publicity to maximize public awareness. • Service providers would be happy to popularize such a product. • Government restrictions prevent media advertising of drugs that require a doctor's prescription.	• Given that publicity of the brand name is not possible, due to government restrictions, promotional campaign should focus on the concept of emergency contraception.

Source: Matrix adapted from assessment findings described in Abeywickrema, D., Basnayake, S., Subasinghe, C., and Bamunusinghe, J. *An evaluation report on the marketing of Postinor 2 in Sri Lanka.* Family Planning Association of Sri Lanka (March 2000).

Developing recommendations from assessment findings can be a difficult process. Including partners and community members in the development of recommendations is a way of ensuring that appropriate solutions to issues are identified. It is important to consider available resources, the feasibility of proposed solutions, and program priorities when determining how to best translate the data collected into the actions required for a successful program.

Using and Adapting Assessment Tools

The assessment tools included in this module are adaptations of instruments that have been used in a variety of field settings around the world. They are intended to serve as examples of the multiple ways that assessments can be performed. These tools are not intended to be used for operations research, but rather are geared toward shaping program development to meet local needs. If more academic research is the objective, it will be important to seek help from local experts to meet that need.

Tool adaptation and pretesting

These instruments (or portions of them) may be translated and freely adapted as needed for use in particular settings. It will be important to pretest the tools that are developed prior to producing the final version, to make sure that the questions are clear and culturally appropriate for the setting in which they will be used and that they will effectively yield the information sought.

Data entry and analysis

It is useful to develop a plan for data entry and analysis before tools are finalized to ensure that the instruments are designed to facilitate these processes as much as possible. Make sure that the assessment team includes staff with experience designing databases and analyzing the type of data that will be collected.

Data collection

If multiple interviewers will participate in the data collection process, it may be helpful to develop a guide that explains each question and details any special instructions for the interviewers (such as whether they are supposed to prompt the interviewee by reading each possible response or record only the responses offered by the interviewee). It is also useful to hold a training session for interviewers (or mystery shoppers) to review the interview guide and to standardize the way in which the questions are asked and data is recorded.

References

[1] World Health Organization. Making Decisions about Contraceptive Introduction: A Guide for Conducting Assessments to Broaden Contraceptive Choice and Improve Quality of Care. Available at: http://www.who.int/reproductive-health/publications/rhr_02_11_contraceptive_introduction/ci-guide.pdf. Accessed November 2003.

[2] World Health Organization. The Strategic Approach to Improving Quality of Care in Reproductive Health Services. Available at: http://www.who.int/reproductive-health/strategic_approach/zambia.en.html Accessed November 2003.

[3]: International Consortium for Emergency Contraception. *Expanding Global Access to Emergency Contraception: A Collaborative Approach to Meeting Women's Needs* (October 2000).

Module E Tools List

Client Knowledge, Attitudes, and Practices Questionnaire

This structured interview guide was developed by the Population Council in Mexico as a follow-up to a baseline survey evaluating the introduction of ECPs in Mexico. It was implemented by interviewing clients at a family planning clinic. The questions, however, are relevant for use as part of a preliminary assessment of client KAP, though they should be adapted for and pretested in the setting in which they will applied. The format of the tool could also be adapted for use as a paper survey (if a paper survey is appropriate for the literacy level of the client population).

Provider Knowledge, Attitudes, and Practices Survey on Emergency Contraceptive Pills

This provider KAP survey was adapted from different provider surveys developed by PATH, the Population Council in Mexico, and the Family Planning Association of Sri Lanka. It is formatted as a paper survey that could be mailed or distributed to providers (perhaps at a meeting or conference); however, the questions could be adapted for use in a different format (such as an interview) if a paper survey is not practical.

In-Depth Interview Guide for Key Reproductive Health Authorities

This in-depth interview guide was developed by PATH for use with high-level reproductive health medical authorities. It is geared toward learning about reproductive health authorities' attitudes toward ECPs, their perceptions of the need for ECPs and barriers to providing high-quality ECP services, and their opinions about training needs of their staff and the best mechanism to expand ECP information.

Mystery Shopper Survey

This mystery shopper survey was adapted from mystery shopper surveys developed by PATH and the Reproductive Health Research Unit of the University of Witwatersrand, South Africa. It is intended as a measure of whether and how ECP information and services are provided in a pharmacy setting. In this tool the primary scenario includes a woman posing as a secret shopper and walking into a pharmacy and telling the pharmacist, "*Yesterday I had sex and didn't use any method of contraception. I am worried about getting pregnant and I would like to know if there is something I can do to prevent pregnancy.*" Immediately following the pharmacy visit, another member of the research team interviews the woman who visited the pharmacy and documents her experience in the pharmacy on the recording sheet. While this tool was developed for use in a pharmacy setting, the questions could be adapted for use in clinical settings.

Client Knowledge, Attitudes, and Practices Questionnaire

Follow-up on Emergency Contraceptive Pills

Questionnaire for Family Planning Users

I. Identification Data

1.1 Date of interview: _____
Day/Month/Year

1.2 User's sex:
Female ☐
Male ☐

1.3 Time interview began: _____
Hours: Minutes

1.4 Time interview finished: _____
Hours: Minutes

1.5 Place:

1.6 Interviewer initials:

Introduction

This interview is part of a study to evaluate the introduction on a larger scale of a contraceptive method. As a follow-up to a survey, we are now interviewing clients of some family planning clinics. We expect the interview to take about 15 minutes. You do not need to provide your name, none of the information collected through this interview will be included in your clinical record. If you prefer not to respond, your decision will not affect in any way the services you are receiving at the clinic. Please be assured that all the information gathered will be kept strictly confidential. Are you willing to participate in our study?

Yes ☐ ***Skip to 2.1***
No ☐

Thank you anyway.

Have a nice day.

II. Background Information

The first questions are to obtain general information.

2.1 How old are you?

Does not respond ..... ☐

2.2 What is the highest level of education you attained?

Primary ..... ☐

Secondary ..... ☐

Technical not leading to secondary degree ..... ☐

Preparatory ..... ☐

Technical leading to secondary degree ..... ☐

University ..... ☐

Postgraduate studies ..... ☐

Degree obtained: _____ Years: _____

Does not know/not respond ..... ☐

No studies at all ..... ☐

2.3 Have you ever had sexual relationships?

Yes ..... ☐

No ..... ☐ ***Skip to 3.1***

2.4 Have you (or your partner) ever been pregnant?

Yes ..... ☐

Yes, I am pregnant right now ..... ☐

No ..... ☐

2.5 **(In the case of a male user)** Have you ever gotten a partner pregnant?

Yes ..... ☐

No ..... ☐

N/A ..... ☐

2.6 Do you (or your partner) use a contraceptive method? **(In case the client is pregnant—Were you or your partner using a method before you got pregnant?)**

Yes ..... ☐

No ..... ☐ ***Skip to 3.1***

2.7 Which contraceptive method or methods are you using?
(Read and check those methods mentioned and then prompt: Any other?)

Pills ..... ☐

Injectables ..... ☐

Condoms ..... ☐

IUD ☐
Tubal ligation ☐
Vasectomy ☐
Withdrawal (your husband takes care of you) ☐
Calendar (rhythm) ☐
Other ☐ Specify: _____

III. Knowledge About Emergency Contraception

3.1 Have you ever heard about emergency contraception or the morning-after pill?

Yes ☐
No ☐ ***Skip to 4.1***

3.2 When was the first time you heard something about emergency contraception?

Less than 6 months ago ☐
6-11 months ago ☐
1-5 years ago ☐
> 5 years ago ☐
Does not remember ☐

3.3 Where did you hear about it? **(Read and check those methods mentioned and then prompt: Somewhere else?)**

At this clinic ☐
At a different clinic/health center ☐
Through friends' or relatives' comments ☐
Through the news, in magazines ☐
Through the radio ☐
Television ☐
Course or formal lecture ☐
Telephone line ☐
Internet page ☐
Other ☐ Specify: _____
Does not remember ☐

3.4 Do you know where a woman can obtain emergency contraceptive pills?
(Read and check those methods mentioned and then prompt: Somewhere else?)

Hospital/health center/clinic ☐
Social worker/community worker ☐
Private clinic ☐
Pharmacy ☐
Supermarket ☐
Other ☐ Specify: _____
It is not possible to obtain them ☐
Does not know ☐

3.5 Would emergency contraceptive pills work if there is a menstrual delay?

Yes ☐
No ☐
Does not know ☐

3.6 How long after unprotected sex should emergency contraceptive pills be taken?

Immediately after sex ☐
Within 24 hours ☐
Within 120 hours (5 days) ☐
Within one week ☐
At any time before the first day of the next menses ☐
Other ☐
Does not know ☐ Specify: _____

3.7 Which drug do you believe is contained in emergency contraceptive pills:
(Read and check responses mentioned.)

The same as in normal contraceptive pills ☐
The same one, but stronger ☐
A completely different drug ☐
Does not know ☐

3.8 Did the person or media (for example, television, radio, etc.) from which you obtained information about EC explain to you: **(Read and circle those methods mentioned.)**

	YES	NO	N/R
Which methods can be used?	1	2	3
How often you can use them?	1	2	3
Where they can be obtained?	1	2	3
That it would be advisable to talk about the method with your partner?	1	2	3
That you would not have any problem to become pregnant in the future?	1	2	3
That after using emergency contraception it would be advisable to start using a different contraceptive method?	1	2	3

3.9 How effective are emergency contraceptive pills in preventing a pregnancy? **(Read and check those methods mentioned)**

Almost always (99%) ..... ☐
Three out of four (75%) ..... ☐
Half of the times (50%) ..... ☐
Less than the third part (30%) ..... ☐
Not sure ..... ☐

IV. Quality of Care

4.1 Have you received during the last year (lately) information about emergency contraception at this center?

Yes ..... ☐
No ..... ☐ ***Skip to 5.1***
Does not remember ..... ☐

4.2 Who provided this information?

Doctor ..... ☐
Psychologist ..... ☐
Social worker ..... ☐
Group talk ..... ☐
Poster ..... ☐
Brochures ..... ☐
Video ..... ☐
Other ..... ☐ Specify: _____
Does not remember ..... ☐

V. Use of Emergency Contraceptive Method

5.1 Have you (or your partner) ever used emergency contraceptive pills?

Yes ..... ☐

No ..... ☐ **Skip to 6.1**

5.2 How many times have you used this method during the last year? _____

Does not remember ..... ☐

5.3 Who recommended it? **(Read if the person does not respond)**

A friend ..... ☐

Partner (male) ..... ☐

Telephone line ..... ☐

Web page ..... ☐

Radio program ..... ☐

Television program ..... ☐

Other ..... ☐ Specify: _____

Does not remember/know ..... ☐

5.4 Why did you use it? **(Read and check those methods mentioned.)**

You do not use a contraceptive method ..... ☐

The timing was miscalculated (rhythm) ..... ☐

The condom broke or slipped ..... ☐

You missed pills ..... ☐

You were forced to have sex ..... ☐

The withdrawal failed ..... ☐

Other ..... ☐ Specify: _____

Does not remember ..... ☐

5.5 After you (or you partner) used emergency contraception, did you start using a regular method of birth control or one different from the method you were using?

Yes ..... ☐

No ..... ☐ **Skip to 6.1**

Does not remember ..... ☐ **Skip to 6.1**

Does not know ..... ☐ **Skip to 6.1**

5.6 Which method did you start using?

Pills ☐
Injectables ☐
Condoms ☐
IUD ☐
Tubal ligation ☐
Vasectomy ☐
Withdrawal ☐
Calendar (rhythm) ☐
Other ☐ Specify: _____
Does not remember ☐

VI. Attitudes Toward Emergency Contraception

Let me define briefly what emergency contraceptive pills are. They are traditional contraceptive pills, those that are taken daily, but administered in higher doses and for a short time. Women can use them after having had unprotected sex and as a way to help them prevent a pregnancy. This method is sometimes called the "morning-after pill," but the woman actually has up to five days after intercourse to get protected.

Emergency contraceptive pills must be taken as soon as possible within the first 120 hours after unprotected sex. If taken within 72 hours, and with the correct doses, they prevent about 3 out of 4 pregnancies that would have otherwise occurred. Some women who have taken them have experienced nausea or vomiting. The ingredient in these pills is the same as the one in normal contraceptive pills, but in higher doses. This method is used in case of emergency; it is not recommended for routine use.

6.1 What do you think about this method?

Adequate for women ☐
Inadequate for women ☐
Adequate for some women ☐
You would like to have more information ☐
Other ☐
Does not know ☐ Specify: _____

6.2 Do you have any questions or concerns about this method?

Yes ☐
No ☐ **Skip to 6.4**

6.3 Which are your concerns?

It may cause health problems ☐
It may hurt the baby in case it does not work ☐
It may result in complications to get pregnant in the future ☐
It is abortifacient ☐
Its use may be illegal ☐
It will result in more women suffering from STI and even AIDS ☐
If men know that this method exists they would exert pressure on women to use it ☐
Some women may use it frequently instead of using regular contraceptives ☐
Other ☐ Specify: _____
I do not have enough information ☐

6.4 Where do you think this contraceptive method should be provided? **(Read and check those methods mentioned.)**

Public hospitals ☐
Private hospitals ☐
Institutional health centers ☐
Community health centers ☐
At midwives' houses ☐
Pharmacies ☐
Any shop where drugs are expended ☐
Schools ☐
Vending machines ☐
Other ☐ Specify: _____

6.5 Who should provide it? **(Read and check those methods mentioned.)**

Doctors ☐
Nurses ☐
Social workers ☐
Sex Counselors ☐
Community health workers ☐
Psychologists ☐
Midwives ☐
Pharmacists ☐
Other ☐ Specify: _____

6.6 From what you have learnt about emergency contraception, do you think you would ever use it or recommend it to a friend or relative in case of need?

Yes ..... ☐
No ..... ☐
Not sure ..... ☐

6.7 Do you believe your partner would accept that you use this method? (Or would you accept that your partner uses it?)

Yes ..... ☐
No ..... ☐
Not sure ..... ☐

6.8 According to you, which would be the best ways to inform people about emergency contraception? (**Read and check those methods mentioned.)**

At the clinic ..... ☐
Group talks ..... ☐
Brochures ..... ☐
Posters ..... ☐
Radio ..... ☐
Television ..... ☐
Magazines/newspapers ..... ☐
Schools ..... ☐
Telephone line ..... ☐
Internet page ..... ☐
Other ..... ☐ Specify: _____
Does not know ..... ☐

VII. Distribution

In some countries, providers supply women in advance with kits containing emergency contraceptive pills. Thus, women can easily resort to them in case of need, without having to return to the clinic.

7.1 What do you think about this idea?

Adequate ..... ☐
Has doubts ..... ☐
Inadequate ..... ☐

7.2 Why? _____

7.3 Some pharmaceutical companies have developed something called "a dedicated product" for emergency contraceptive pills. This dedicated product contains the exact dose, but it consists of two pills only and has fewer side effects; the cost of the product, however, is higher than that of using regular oral contraceptive pills for emergency contraception. Would you prefer this dedicated product?

Yes ..... ☐
No ..... ☐
It depends ..... ☐
Does not know ..... ☐

7.4 Why? _____

7.5 How much would you be willing to pay for this product? US $ _____

US$0-3 ..... ☐
US$3-5 ..... ☐
US$6-10 ..... ☐
US$10 -20 ..... ☐
US$20-50 ..... ☐
US$50-100 ..... ☐
More than US$100 ..... ☐
Does not know/respond ..... ☐

We have come to the end. But before we finish:

We would like to mention that emergency contraceptive pills do not protect against sexually transmitted infections, including HIV, the virus which causes AIDS. Condoms are believed to be the most effective method to protect against these diseases.

Do you have any further doubts about emergency contraception?

User's questions:

(1) _____
_____
_____
_____

(2) _____
_____
_____
_____

(3) _____
_____
_____
_____

(4) _____
_____
_____
_____

Write the time the interview finished: ___Hours: ___Minutes

Write this same time on the first page of the questionnaire.

Thanks again for participating in this project.

This survey was originally developed in Spanish by the Population Council of Mexico. It was translated and adapted with permission from the Population Council of Mexico by PATH.

Provider Knowledge, Attitudes, and Practices Survey on Emergency Contraceptive Pills

Our organization,_____, is seeking to learn about medical providers' knowledge of and perceptions of the need for emergency contraceptive pills (ECPs), as well as barriers to providing high-quality ECP services. The information you provide will be used to design training curricula and materials about ECPs and other contraceptive methods. Your answers will not be released to anyone and will remain anonymous. Your name will not be written on the questionnaire or be kept in any other records. **Please return the survey by** ____ to ___.

Thank you for your help.

Please check below:

- Obstetrician/Gynecologist ☐
- Nurse ☐
- Psychologist ☐
- Other _____

Please check below:

- Female ☐
- Male ☐

Region where you work

- Urban ☐
- Rural ☐

Do you agree that unintended pregnancies and, as a result, induced abortions are serious problems in our country?

- Yes ☐
- No ☐

How long does a typical appointment with your client last?

- Less than 15 min. ☐
- 15-20 min. ☐
- 20-30 min. ☐
- More than 30 min. ☐

Does a typical appointment include a discussion of family planning? *Please check **one***

- Always ☐
- Most of the time ☐
- Sometimes ☐
- When the client requests information ☐
- Never ☐

What are the contraceptive methods available at your clinic or health center?
*Please check **all** that apply*

Hormonal methods

Oral contraceptive pills ..... ☐
Emergency contraceptive pills ..... ☐
Contraceptive injection..... ☐
Contraceptive implant ..... ☐

Barrier methods

Male condom..... ☐
Female condom ..... ☐
Diaphragm..... ☐

Other methods

Vaginal spermicides..... ☐
Safe period (rhythm) ..... ☐
Withdrawal ..... ☐
Sterilization ..... ☐
IUD..... ☐

Do you have concerns about the methods listed below? ***Check only*** *where you have a concern*

	Not effective	Unsafe	Other
Hormonal methods			
Oral contraceptive pills	☐	☐	☐
Emergency contraceptive pills	☐	☐	☐
Contraceptive injection	☐	☐	☐
Contraceptive implant	☐	☐	☐
Barrier methods			
Male condom	☐	☐	☐
Female condom	☐	☐	☐
Diaphragm	☐	☐	☐
Other methods			
Vaginal spermicides	☐	☐	☐
Safe period (rhythm)	☐	☐	☐
Withdrawal	☐	☐	☐
Sterilization	☐	☐	☐
IUD	☐	☐	☐

If for any method you checked "*other,*" please explain:

_____

_____

What contraceptive methods would you like to learn more about?

_____

_____

_____

What advice/treatment would you give to a woman who came to you with a history of a missed or delayed period?

_____

_____

_____

What advice or treatment would you give to a woman who came to you with concerns about contraceptive failure (condom breakage, missed pills, missed injection)?

_____

_____

_____

Do you agree or disagree with the following statement, "ECPs are primarily a form of contraception"?

Agree (*skip to question 14*) ..... ☐

Disagree (*go to question 13*) ..... ☐

Do you agree or disagree with the following statement, "ECPs are primarily a form of abortion"?

Agree ..... ☐

Disagree ..... ☐

When you or someone at your clinic discuss family planning, do you include a discussion of emergency contraception? *Please check **one***

- Always ☐
- Most of the time ☐
- Sometimes ☐
- When the client requests information ☐
- Never ☐

Have you ever prescribed ECPs?

- Yes ☐
- No (*skip to question 16)* ☐

If *yes*, please check ***one*** of the following:

In the last year, how many times have you prescribed ECPs?

- 0 times ☐
- 1-10 times ☐
- 11-20 times ☐
- 21-30 times ☐
- More than 30 times ☐

How familiar are you with the use of ECPs?

- Very familiar ☐
- Somewhat familiar ☐
- Not at all familiar ☐

What advantages do you believe this method has?

- None ☐
- Prevents unintended pregnancy ☐
- Ideal when no contraception was used ☐
- Accessible ☐
- Easy to manage (dose) ☐
- Not necessary to use a routine contraceptive ☐
- Women can self-prescribe ☐
- Low cost ☐
- Effective ☐
- Few contraindications ☐
- No important side effects ☐
- Can be managed by the woman without the man's participation ☐
- Other (*please describe*)_____

What concerns do you have about ECPs? *Please check **all** that apply*

- No concerns ☐
- Moral or religious objection ☐
- Women will rely on ECPs as a regular form of contraception ☐
- Side effects—nausea and vomiting ☐
- Ineffective in preventing pregnancy ☐
- Safety of fetus if ECPs are not effective in preventing pregnancy ☐
- Not safe ☐
- Does not protect against sexually transmitted infections ☐
- Insufficient time for adequate patient counseling/education ☐
- Encourages irresponsible behavior ☐
- Other (*please describe*)_____

What would you like to learn more about emergency contraception? *Please check **all** that apply*

- Types of emergency contraception ☐
- Mechanism of action of emergency contraception ☐
- Effectiveness ☐
- IUD as emergency contraception ☐
- Safety of EC and hormonal contraceptives ☐
- Possible side effects ☐
- Advance distribution ☐
- Other (*please describe*) _____

Where do you believe ECPs should be offered? *Please check **all** that apply*

- Government hospitals ☐
- Private hospitals ☐
- Government health centers ☐
- Private clinics ☐
- Community health centers ☐
- Midwives ☐
- Pharmacies ☐
- Supermarkets ☐
- Schools ☐
- Vending machines ☐
- Other (*please describe*)_____

Who do you think should offer ECPs? *Please check **all** that apply*

- Doctors ☐
- Nurses ☐
- Social workers ☐
- Community health promoters ☐
- Psychologists ☐
- Midwives ☐
- Pharmacists ☐
- Other (*please describe*)_____

How satisfied are you with current guidelines governing ECP use in this country?

- Very satisfied (*skip to question 24)* ☐
- Somewhat satisfied (*skip to question 24)* ☐
- Not at all satisfied ☐

If you answered, *"Not at all satisfied"* to the previous question, what official documentation would make it easier for you to provide EC information to women? *Please check **all** that apply*

- Health authorities guidelines ☐
- Professional association recommendations ☐
- Other (*please describe*) _____

Please check the statement that best describes your clients:

- "All of my clients know that there is a contraceptive method that can prevent pregnancy after unprotected sex." ☐
- "Some of my clients know that there is a contraceptive method that can prevent pregnancy after unprotected sex." ☐
- "Few of my clients know that there is a contraceptive method that can prevent pregnancy after unprotected sex." ☐

To which clients do you offer the method? *Please check **all** that apply*

- Adolescents ☐
- Married or partnered women ☐
- Rape cases ☐
- Clients who used a contraceptive method ☐
- Commercial sex workers ☐
- Other (*please describe*)_____

Do you have any materials for clients that discuss emergency contraception?

Yes ☐
No ☐
Do not know ☐

Are there any written guidelines that you use for emergency contraception?

Yes ☐
No ☐
Do not know ☐

What information would make it easier for you to provide EC information to women?
*Please check **all** that apply*

Written materials and resources designed for medical providers ☐
Written materials and resources for women ☐
Data/studies on emergency contraception effectiveness and safety ☐
Comprehensive emergency contraception training ☐
Other *(please describe)* _____

What are the obstacles to increased access to this method in this country in general?
*Please check **all** that apply*

None ☐
Religious opposition ☐
Health center politics ☐
Opposition for health reasons ☐
Opposition from civil groups ☐
Opposition from medical personnel ☐
Lack of awareness on the part of clients ☐
Cost ☐
Availability ☐
Legal restrictions ☐
Other (*please describe*)_____

Do you have any ideas about how to overcome these obstacles? *Please check **all** that apply*

- Training courses ☐
- Clarifying erroneous preconceptions ☐
- Government norms ☐
- Information to the general population ☐
- Incorporation into counseling on family planning methods ☐
- Offer it at a low cost ☐
- Provision in appropriate doses ☐
- Dedicated product ☐
- Over-the-counter provision ☐
- Easy access to the method ☐
- Other (*please describe*)_____

What barriers exist for your clients to access emergency contraception?
*Please check **all** that apply*

- Lack of awareness about ECPs ☐
- Fear of side effects ☐
- Fear of effects on fetus if already pregnant ☐
- Cultural barriers ☐
- Cost ☐
- Other providers' reluctance to refer clients for ECPs ☐
- Clinic or pharmacy hours ☐
- Transportation ☐
- Client fear or embarrassment about discussing the need for ECPs ☐
- Other (*please describe*) _____

In your community, is emergency contraception information easily available for women?

- Yes ☐
- No ☐

In your community, what organizations or information sources can most effectively reach women with information on health and lifestyle issues? *Please check **three***

- Medical institutions ☐
- Media (radio, TV, newspapers) ☐
- Nongovernmental Organizations ☐
- Women's organizations (*please specify*)_____
- Printed materials (posters, brochures, booklets) ☐
- Hotline ☐
- Other (*please describe*) _____

Which health providers do you consider are most important to reach with information about emergency contraception? *Please number in order from most important (1) to least important (5)*

Obstetricians/gynecologists

Nurses

Hospital emergency rooms

Other medical providers (*please specify*) _____

Family planning counselors

This material was adapted from provider surveys developed by PATH, Population Council of Mexico, and the Family Planning Association of Sri Lanka.

In-Depth Interview Guide for Key Reproductive Health Authorities

Date (day/month/year):_____ Time interview began:_____

Name of facilitator: _____ Time interview ended:_____

Introduction

Introduce yourself and explain the purpose of the interview. If a notetaker is present, introduce the notetaker (it is often helpful to have a notetaker working in collaboration with the interviewer).

Our organization [insert the name of organization here] **is seeking to learn about reproductive health authorities' attitudes toward emergency contraceptive pills (ECPs), their perceptions of the need for ECPs and barriers to providing high-quality ECP services, and their opinion on training needs of their staff and the best mechanism to expand ECP information. The information you provide will be used to design training curricula and materials on emergency contraception and other contraceptive methods.**

Let the interviewee know that if at any time he/she does not feel comfortable with a topic, he/she is not required to respond. There are no wrong or right answers.

Ask interviewee to complete the background information form, then proceed with the interview guide.

Background Information Form for Key Reproductive Health Medical Authorities

(This form is to be filled out by the reproductive health medical authority before the interview begins.)

1. Please check: Female ☐ Male ☐
2. How many staff are employed by your institution? _____
3. How many staff do you directly supervise? _____
4. Which contraceptive methods does your staff recommend most often?
   *Check **up to five** methods*

Hormonal methods

- Oral contraceptive pills ☐
- Emergency contraceptive pills ☐
- Contraceptive injection ☐
- Contraceptive implant ☐

Barrier methods

- Male condom ☐
- Female condom ☐
- Diaphragm ☐

Other methods

- Vaginal spermicides ☐
- Safe period (rhythm) ☐
- Withdrawal ☐
- Sterilization ☐
- IUD ☐

5. Do you have concerns about the methods listed below?
   ***Check only** where you have a concern*

	Not effective	Unsafe	Other
Hormonal methods			
Oral contraceptive pills	☐	☐	☐
Emergency contraceptive pills	☐	☐	☐
Contraceptive injection	☐	☐	☐
Contraceptive implant	☐	☐	☐

	Not effective	Unsafe	Other
Barrier methods			
Male condom	☐	☐	☐
Female condom	☐	☐	☐
Diaphragm	☐	☐	☐

	Not effective	Unsafe	Other
Other methods			
Vaginal spermicides	☐	☐	☐
Safe period (rhythm)	☐	☐	☐
Withdrawal	☐	☐	☐
Sterilization	☐	☐	☐
IUD	☐	☐	☐

If for any method you checked "*other*", please explain:

_____

_____

6. What concerns do you have about ECPs? *Please check **all** that apply*

No concerns ☐
Moral or religious objection ☐
Women will rely on ECPs as a regular form of contraception ☐
Side effects—nausea and vomiting ☐
Ineffective in preventing pregnancy ☐
Safety of fetus if ECPs are not effective in preventing pregnancy ☐
Not safe ☐
Does not protect against sexually transmitted infections ☐
Insufficient time for adequate patient counseling/education ☐
Encourages irresponsible behavior ☐
Other (*please describe*)_____

7. In your opinion, what aspects related to emergency contraception should be included in the training for medical providers? *Please check **all** that apply*

Types of emergency contraception ☐
Mechanism of action of emergency contraception ☐
Effectiveness ☐
IUD as emergency contraception ☐
Safety of emergency contraception and hormonal contraceptives ☐
Possible side effects ☐
Advance distribution ☐
Other (*please describe*) _____

Interview Guide for Key Reproductive Health Medical Authorities

Note: When possible it is best to have two people attend the interview, an interviewer and a note taker. The interviewer should begin by saying:

Today I would like to discuss with you some issues that are important to women in [insert your country here]**. As a key medical authority, your opinions and experience are important to us and will help us to design training curriculum and materials for medical providers.**

Emergency Contraception Service Provision, Perceptions, and Attitudes

What do you think about the rate of unintended pregnancies and abortion rate?

Probe: Do you think something should be done to lower those rates?

What do you and your staff do to make it happen?

What do women do if they need to get help with preventing pregnancy after unprotected sex?

Probe: Do medical providers of your medical institution offer emergency contraception to the women?

If yes, who are their potential emergency contraception clients?

When is emergency contraception is offered?

How often do they discuss emergency contraception with their clients?

Is emergency contraception information currently available to women in your medical institution?

In what form?

What do you think about emergency contraception?

Probe: In your opinion, are ECPs primarily a form of contraception or a form of abortion? Why?

What are your concerns about ECPs?

What is the current overall knowledge among providers regarding ECPs?

In your medical institutions, what are medical providers' perceptions of a need for ECPs?

Barriers to Providing High-Quality Emergency Contraception Services

What barriers, if any, might prevent your staff from routinely providing emergency contraception information and services to women? Why? ***(don't read list)***

- Personal, moral, or religious objection
- Women will rely on ECPs as a regular form of contraception
- Side effects—nausea and vomiting
- Ineffective in preventing pregnancy
- Safety of fetus if ECPs is not effective in preventing pregnancy
- Not safe
- Does not protect against sexually transmitted infections
- Insufficient time for adequate patient counseling/education
- Encourages irresponsible behavior
- Lack of support or opposition from local board of health

What standards of care might affect provision of emergency contraception?

Probe: Are you satisfied with current guidelines governing ECP use in this country?

What political or other concerns might limit more extensive development of Emergency contraception services or information dissemination in the communities you serve?

What financial or staff constraints could limit the expansion of emergency contraception information provision and services in your medical institution?

What do you see as the most effective mechanisms to expand emergency contraception information and services to women in your medical institutions? ***(don't read list)***

- Staff training
- Materials
- Funding
- ECP product availability
- Authority for staff to provide ECPs
- Other?

What is the capacity of nonfamily planning/reproductive health personnel (pharmacists, feldshers, teachers, etc.) to supply ECP information?

Probe: Who are the most important providers to be reached with ECP information?

Contraception Provision

Which contraceptive methods are recommended to women most often in your medical institution? Why? ***(don't read list)***

- Hormonal methods
- Barrier methods
- Other methods?

Information/Training Needs

What information would be most helpful in enabling you and your staff to provide emergency contraception information and services to women? ***(don't read list)***

- Written materials and resources designed for medical providers
- Written materials and resources for clients
- Data/studies on ECP effectiveness and safety
- Comprehensive ECP training for service providers
- Other?

In your medical institutions, what are medical provider training needs in family planning and contraception? Why?

How would you organize this training? How long should it be?

What issues on ECPs and other contraceptive methods should be included in the training?

In your opinion, which medical providers should be trained on ECPs first of all?

Where do you feel most women get information about family planning? ***(don't read list)***

- Friends or coworkers
- Family members or spouse
- Medical provider
- TV
- Radio
- Billboards
- Magazines
- Newspapers
- Brochure or printed matter
- Other

What source of information do you think women can trust the most, and why?

In your opinion, what informational materials do women need first of all?

Probe If you were to have educational materials on Emergency Contraception or other contraceptive methods to give to women, what would make them interesting?

From what source would you like women to learn more about Emergency Contracetpion and other contraceptives?

If media, what kind of media? If people, what people?

If printed materials, what kind? (describe)

Why do you prefer this source of information? What makes this source trustworthy?

What messages on ECPs are most important to pass to the women?

Conclusion

We will close today's interview with some final thoughts. We want to thank you for sharing your ideas and opinions today. Do you have anything you would like to add?

How do you feel about our discussion? Do you have any suggestions for improving the interview process?

Here is contact information in case you have any more questions or comments you wish to share after the interview.

The interviewer should thank the interviewee and tell them that their contribution has been very valuable. Emphasize that this information is being used develop training and information materials on ECPs and other contraceptives.

After the Interview

Immediately after the discussion:

- Facilitator and notetaker debrief together.
- Make a note of suggested changes in the way the interview is conducted or in the technical aspects of the logistics.
- Revise, edit, and complete notes.

That afternoon or evening (notetaker and/or facilitator)—do not delay this step:

- Review the notes; make clarification notes as necessary.
- Complete and correct the notes in accordance with the recording.
- Summarize important themes or points made in the summary section of the interview.
- Send the tape and the clarification notes to be transcribed.
- Meet with the other project staff to discuss how the interviews are going. Share suggestions for changes to the guide or about the interviews.

Mystery Shopper Survey

Guidelines

Note: This page is for use in preparing for the pharmacy visit. It should not be used while in the pharmacy.

The following are two scenarios (one for a female shopper, one for a male shopper) for use in the pharmacy. The attached page is to be used by the interviewer who will interview the mystery shopper after he/she has finished his/her visit.

Female Mystery Shopper: *Yesterday I had sex and didn't use any method of contraception. I am worried about getting pregnant and I would like to know if there is something I can do to prevent pregnancy.*

Male Mystery Shopper: *I had sex two days ago. We always use condoms, but this time the condom broke. I am worried that my girlfriend will get pregnant. Is there anything we can do to prevent this?*

If the counter staff person or pharmacist says YES:

After the employee has told you about what you can do to prevent pregnancy, ask the following two questions to help initiate a discussion about sexually transmitted infections and ongoing contraception. If the pharmacy staff member provides this information without being asked, there is no need to ask the prompting questions:

- What else can happen to me (or my girlfriend, if mystery shopper is male)?
- Is there anything else I need to know?

If the counter staff person or pharmacist says NO, continue by saying:

I had a friend who said there were pills I (my girlfriend) could take; do you know anything about that?

Or: I see the poster in your window that says something about emergency contraception. What is that?

If the frontline staff member or pharmacist STILL says NO, ask:

Do you know from whom or where I may get information/help?

Note: Mystery shopper should be sure to emphasize he/she is interested in PREVENTING pregnancy, to avoid any potential confusion with abortifacients.

Mystery Shopper Recording Sheet

Name of mystery shopper_____ Date_____

Name of interviewer _____

1. Name of pharmacy	
2 Address of pharmacy	
3. Sex of person spoken to in pharmacy	Male Female
4. What was the general attitude of the person who attended you at the BEGINNING of the visit?	Positive (friendly, welcoming, attentive) Indifferent Negative (judgmental, impatient, rude)
5. What was the general attitude of the person who attended you at the END of the visit?	Positive (friendly, welcoming, attentive) Indifferent Negative (judgmental, impatient, rude)
6. If the staff person had a poor attitude are there reasons or things you observed that might have affected his/her attitude? **Circle all that are mentioned.**	Other customers Many customers Embarrassed Too many questions Didn't know how to answer questions Bored Other _____ **Specify** Don't know Not applicable
7. How long was the interaction with the staff person?	_____ minutes
8. Were you asked when you had your (your girlfriend had her) last menstrual period?	Yes No

9. Were you asked whether the period was normal in length and timing?	Yes No
10. Were you offered any treatments or medications?	Yes No
11. What were you offered?	Emergency contraception dedicated product *[insert site specific name]* _____ Oral contraceptives for use as emergency contraception Other _____ **Specify brand name**

12. How much did it cost?	_____
13. Did the staff person explain what the product was for?	Yes No
14. Did the staff person explain how effective the product was?	Yes No
15. Did the staff person give you instructions on how to take it?	Yes No
16. What were the instructions?	**Please describe below** _____ _____ _____ _____
17. Did the staff person discuss side effects?	Yes No
18. If yes, what side effects were discussed?	Nausea Vomiting Irregular bleeding Other _____ **Specify**

19. Did you observe any printed materials about emergency contraception, sexually transmitted infections, contraception, or other reproductive health issues? **If YES, write down what you saw.** _____ _____ _____	Yes No
20. Did the staff person talk to you about sexually transmitted infections?	Yes No
21. Did the staff person recommend the use of a family planning method for future use?	Yes No **Skip to Q23**
22. What method was recommended?	_____ **Specify method**
23. Did the staff person offer you a referral?	Yes No **Skip to Q26**
24. Why were you referred?	Didn't have the product/or information Pregnancy test Sexually transmitted infection exam Other _____ **Specify**
25. Where were you referred?	Another pharmacy Specific doctor's office or clinic Hospital Doctor affiliated with pharmacy Counseling center Other _____ **Specify**
26. Did the pharmacy staff person ask you if you had any questions?	Yes No

27. Did the pharmacy staff person give you any other information or advice?	Yes No **Please describe below** _____ _____ _____ _____

Content and format for this tool were adapted from mystery shopper surveys developed by PATH and the Reproductive Health Research Unit of the University of Witwatersrand, South Africa.

Module F

Regulation, Procurement, and Distribution of a Progestin-Only ECP

Objective

To secure and distribute an adequate supply of a high-quality progestin-only emergency contraceptive pill (ECP) product.

The following topics are discussed in this module:

- Project Regulation
  - National regulatory authority (NRA)
  - Product registration
- Product Procurement
  - Estimating initial quantity of ECPs
  - Ongoing monitoring of ECP demand
  - Role of program staff in procurement cycle
  - Managing the procurement process
  - Ensuring product quality
  - Monitoring supplier performance
- Distribution
  - Distribution systems
  - Service delivery options

Tools Provided at the End of This Module

- Potential Market for ECPs: A Basic Demand Model
- Information to Include in a Levonorgestrel-Only ECP Package Insert
- Sample Procurement Specification: Levonorgestrel-Only ECPs
- Preferential Pricing for Public-Sector Agencies
- Procurement Through International Procurement Services

Progestin-only ECPs containing levonorgestrel are the preferred product for family planning programs because they are more effective, can be taken in one dose, and have fewer side effects than combined estrogen/progestin ECPs. In 2003, the World Health Organization (WHO) revised the Essential Drugs List to recommend a single dose of 1.5 mg levonorgestrel for emergency contraception instead of two doses of the combined oral contraceptive ethinyl estradiol/levonorgestrel.[1] This module provides information, as well as specific tools, to help a family planning program prepare for routine provision of a progestin-only ECPs. Regulation, procurement, and distribution are critical steps in the process of incorporating emergency contraception into a program. Program planners must understand and support these steps to ensure timely provision, adequate quantities, and high quality of the ECP product they plan to provide.

Progestin-Only Dedicated ECPs

Formulation (per pill)	Common Brand Names	Single Dose* (number of tablets)
LNG 0.75 mg	Levonelle-2, NorLevo, Plan B, Postinor-2, Vikela	2

*Manufacturers may introduce a single dose tablet for emergency contraception; in this event, the dose would be one 1.5 mg tablet.

Product Regulation

In most countries, all medicines, including contraceptives, are subject to national regulatory requirements. These requirements are based on national legislation that identifies the registration, licensing, market authorization, and inspection requirements with which products must comply. The overall purpose of regulatory requirements is to ensure the safety, efficacy, and quality of all medicines provided to the public. Following is a brief summary of the regulatory function, followed by a description of the registration process. What is presented here is the generally accepted model for these functions and processes; in any specific country they will vary, according to national policy and legislative requirements. In addition, the degree of oversight and enforcement depends on the resources available.

National regulatory authority (NRA)

In most countries, an NRA is established by national legislation to serve as an administrative agency, to ensure that regulatory requirements are properly implemented and enforced. In general, major NRA authority typically includes:

- Oversight of product manufacturer, importer, and distributor licenses.
- Registration of drugs, medicines, and other health products for use in country.
- Approval of product labeling, the package insert, and use instructions that accompany a product to ensure they are accurate, complete, and balanced.

- Determination of whether a product will be provided by physician prescription only, or will be widely available over-the-counter (i.e., with no prescription required).
- Postmarketing surveillance to monitor problems with adverse reactions and product quality.

Product registration

Product registration is one of the critical functions that almost all NRAs perform. The process of registering a product varies according to national requirements, but certain clinical, manufacturing, and distribution information is typically required. The most commonly required information is contained in the manufacturer's product dossier, which covers:

- Product formulation
- Manufacturing process
- Packaging requirements
- Clinical research results
- Product quality tests
- Other product-specific information

In most cases, the product manufacturer, working with its local distributor, is responsible for registering its product with the NRA and will submit the required documents to the NRA for product registration.

Facilitation of the Registration Process

Program planners interested in introducing a new ECP into a family planning program can help facilitate the registration process by:

- Contacting the manufacturer and its in-country distributor or helping to identify a distributor where none exists, to demonstrate that a market for the ECP product exists.
- Building support among those who influence policy, such as community leaders and medical providers and those who influence registration of new drugs—in particular, decision makers at the ministry of health and the NRA—by including them in initial advocacy and planning activities. Their participation is critical, as their advice and collaboration can help ensure timely progress through the registration process.
- Providing key information about ECPs to leaders and decision makers: for example, the role ECPs can play in preventing unintended pregnancy and abortion, the mechanism of action of ECPs, evidence-based information on the safety and efficacy of ECPs, and the fact that progestin-only ECPs are included in WHO's Essential Drugs List. This information is provided in Module A: Information for Policy Makers

Prescriptive or over-the-counter (OTC) status

The issue of whether a dedicated ECP product should be provided by prescription only or available OTC in pharmacies has been decided differently in various countries. Progestin-only ECPs are available without prescription in many countries in the European Union, including Belgium, France, Italy, Norway, and the United Kingdom. An application for OTC status—i.e., exemption from prescription-dispensing requirements—for a progestin-only dedicated ECP is currently under consideration by the U.S. Food and Drug Administration. The criteria that determine OTC status focus on safety—and the fact that ECPs have gained OTC status in many countries—speak to the safety of this contraceptive method, specifically in regard to the following key issues:

- ECPs are safe for self-medication, as there are no serious side effects[2] and an overdose or inappropriate use could not cause serious harm.[3]
- Studies have shown that women are able to follow the instructions and self-administer the treatment correctly.[4]
- Medical intervention is not necessary to ensure safe and correct use of ECPs because there are no documented medical contraindications for emergency contraception[5] and women can independently determine whether they need to use ECPs.[6]
- Contraindications relevant to frequent, long-term use listed in the package labeling of regular oral contraceptives are sometimes included on ECP packaging—but this is without justification, as ECP treatment is of short duration, ECPs are not toxic, and they have no important drug interactions. [2, 4]
- If a woman who was already pregnant took ECPs, it would not harm the fetus.[7]

Product labeling

Regulatory authorities require a product's primary package to be properly labeled before it can be approved for registration and in-country use. Product package labeling requirements will vary from country to country; however, for ECP products the most common labeling information required for the individual blister pack should include the following:

- Product/brand name
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name or symbol
- Contents and quantity

Package insert sheet and client use instructions

Regulatory authorities require that drugs, medicines, and contraceptives packaged for consumer use contain printed materials with information about the product. The manufacturer therefore provides a package insert sheet with each consumer unit package. The insert sheet usually contains the following information:

- Active ingredient
- Other ingredients (excipients)
- Precautions and contraindications for use
- Use instructions
- Side effects
- Storage instructions

The package insert sheet should be easy for clients to read and understand. Information that should be included in a levonorgestrel-only ECP package insert is provided in the tools section of this module.

Product Procurement

Procurement is the process by which ECP products are requested and obtained from manufacturers and distributors. Regardless of whether the requesting institution is a nongovernmental organization or a government agency, the standard procurement process is traditionally managed by dedicated procurement personnel and includes:

1. Confirming the quantity required.
2. Managing the procurement process.
3. Ensuring product quality.
4. Monitoring supplier performance.

Program planners support this process by providing information on program requirements, such as quantities, delivery schedule, and other specific program needs. This module provides extensive information about procurement. Much of this information will actually be used only by those involved in the procurement process. However, this information also can be useful as an overview for decision makers of what is involved in supplying a program with this contraceptive method, which differs from other methods due to its irregular use by clients.

Estimating initial quantity of ECPs

Because ECPs are not intended for regular use, traditional techniques for estimating demand are likely not to be appropriate. There currently does not appear to be a consistently used method for forecasting demand, partly due to the fact that dedicated ECP products have only recently begun to be widely available.

When initiating provision of ECPs, the experience of a social marketing organization has indicated that a simple calculation can be useful. The organization purchases initial supplies of ECPs based on an estimate of 5 to 10 percent of the volume of oral contraceptives regularly sold in the country—adjusting toward the low or high end, depending on how well-known ECPs are in the country and the country's statistics on contraceptive prevalence by method. As this initial supply of ECPs is used, staff record data on the number of clinics or pharmacies supplied and the number of ECP packets in the dispensers sold to these locations. These sales data are then used for forecasting future demand.

Initial demand estimation

A spreadsheet for estimating the quantity of ECPs a program should initially purchase is included in the tools section of this module (Potential Market for ECPs: A Basic Demand Model). The spreadsheet enables the user to calculate an estimated maximum that could be needed and then to refine this first estimate to produce a more realistic estimate of ECP supply required for an initial order.

Ongoing monitoring of ECP demand

Once an initial supply of ECPs has been received, it is important to monitor use and stock depletion over time. Careful monitoring is critical for both avoiding stockouts and compiling data that can be used to forecast future demand. Funding cycles may make reordering before the next procurement cycle difficult; however, if it is feasible, ECP product should be reordered even before the next cycle if monitoring indicates that the initial supply was inadequate and a stockout is possible. Monitoring and recording use over one year will establish demand data that can be used in forecasting future requirements. Monitoring use should include noting trends, such as increased use due to campaigns for increased awareness of the method; these trends should be quantified and factored into the resupply process. Projections can be based on the patterns of ECP consumption and extrapolations of those patterns for the time period covered by the next procurement cycle. As the procurement unit plans for the next procurement cycle, program managers are responsible for providing them with a forecast of ECP product needed.

Role of program staff in procurement cycle

Program staff play an important role in the procurement cycle. In addition to identifying program requirements and delivery schedule needs, they also serve as a technical resource in assisting procurement staff to promptly respond to product and delivery schedule changes requested by the supplier. Program staff also provide information on product problems encountered in the field. The procurement unit will document this information and use it in evaluating supplier performance as they consider suppliers for the next cycle of procurement. For these reasons, it is important for program staff to establish and maintain a continuous, collaborative working relationship with procurement personnel responsible for ECP procurement.

Managing the procurement process

The procurement process a family planning program will use to ensure an ECP product supply depends on several factors, including the funding source and relevant requests governing use of funds (e.g., whether it is donor-provided or government funded), the number of manufacturers, and the program delivery schedule requirements (when the product is needed). These factors also affect the length of time it will take to complete the entire procurement cycle, from initial identification of requirements to final delivery of product. It is therefore important, for planning purposes, for program staff to work closely with procurement personnel to obtain accurate estimates of the procurement cycle time. Some of the key factors that determine the procurement method to be used are briefly discussed below.

Funding source

Donor-provided: When EC products are directly provided by a donor, the procurement process is shortened, because several steps in the process are eliminated (requesting quotes, negotiating contracts with suppliers, etc.). If the donor provides direct funding to the responsible government procurement agency, these steps will have to be included, the process will take more time, and any special procurement requirements imposed by the donor must be complied with. Donor agencies vary in their approach to emergency contraception, as seen in the policies of two of the major contraceptive donor agencies, the United States Agency for International Development (USAID) and the United Nations Population Fund (UNFPA). Both USAID and UNFPA endorse country programs' routine provision of ECPs as one of the contraceptive options offered in the method mix. Through 2003, USAID, however, has not provided a dedicated progestin-only ECP product to country programs. UNFPA provides dedicated ECPs to requesting countries. Module A: Information for Policy Makers discusses the ECP support available through these agencies. UNFPA also offers a service under which they procure and ship dedicated ECPs to support a country program for a fee. Information on UNFPA procurement services is provided in the tools section of this module.

Government-funded: Government-funded procurement must comply with national procurement requirements, which in most cases follow a traditional public-sector process that includes: identifying requirements; obtaining budget approval; preparing bidding documents (which include specifications, quality assurance and inspection requirements, proposed terms and conditions); requesting bids or quotes; evaluating bids or quotes; negotiating and awarding contract; arranging for shipment; and product inspection. As mentioned above, program planners support this process by providing procurement managers with specific information on program requirements.

Number of product manufacturers

When there are multiple manufacturers of a product, there is a competitive environment—which can result in a lower price. In a competitive environment, as is the case for combined oral contraceptives, donors' and national procurement policy often will require open or limited international bidding—a formal process requiring a lead time of several months. In the case of progestin-only dedicated ECP products, the number of suppliers currently is limited. The two pharmaceutical companies that are the dominant suppliers of dedicated, progestin-only ECP products (i.e., products packaged and labeled specifically for emergency contraception) are Gedeon Richter Ltd. and Laboratoire HRA Pharma. Their ECP products, Postinor-2 (Gedeon Richter Ltd.) and NorLevo (Laboratoire HRA Pharma) are registered in many countries. There are other manufacturers of levonorgestrel, principally in China and India, that have significant local market shares and that could become suppliers of a dedicated levonorgestrel-only ECP in the future. Product and contact information of additional suppliers will be made accessible on the website of the International Consortium for Emergency Contraception, when they enter the international market. As of 2003, however, because Gedeon Richter Ltd. and Laboratoire HRA Pharma are the only two major suppliers, the procurement agency can issue a request for quote directly to each manufacturer, rather than requesting bids from multiple manufacturers, which will streamline the procurement process and shorten the procurement cycle. Contact information for both Gedeon Richter Ltd. and Laboratoire HRA Pharma is contained in the tools section of this module.

Requests for a quote can be based on procurement specifications or the manufacturer's brand name. If using procurement specifications to request quotes, a sample generic procurement specification for levonorgestrel-only ECPs can be found in the tools section at the end of this module. The procurement agency can use this sample to develop its own product specification.

The procurement agency should always ensure that only products registered through the NRA are purchased for use in country. This is traditionally addressed in the request for bid documents by including a requirement that the supplier be responsible for registering its product in-country before it can be considered for a contract award.

Product availability

Information about the availability of ECP products, drawn from the International Planned Parenthood Federation (IPPF) 2002 Directory of Hormonal Contraceptives, is accessible on the website: http://ec.princeton.edu/worldwide/default.asp.

This website provides a searchable database of oral contraceptives available worldwide—both combined oral contraceptive pills and progestin-only contraceptive pills—that can be used for emergency contraception. The database can be searched by country or by product. In addition, the International Consortium for Emergency Contraception website provides a list of countries in Africa, Asia, and Latin America with information about the status of dedicated ECP products. The list, which is updated annually, can be accessed at: http://www.cecinfo.org/files/ecstatusavailability.pdf.

Factors that affect the procurement price of a product

Cost impact on the supplier: The purchaser can improve the chances of obtaining favorable prices by trying to minimize the costs incurred by the supplier in filling the order. A program can realize savings by:

- Maximizing the volume of a single order. The volume of product ordered is a factor that most manufacturers will consider when determining the price they will charge a customer. The greater the volume of product ordered, the greater savings a manufacturer may be able to achieve through such measures as bulk procurement of raw materials. These savings are often then passed on to the purchaser by offering a lower price for the product.
- Limiting special requests. Any time a manufacturer has to change or adapt a standard process to accommodate a purchaser's special request, an additional cost is incurred. For example, if a purchaser requests special packaging requirements (for example, requesting four products per box when the norm is six per box) the manufacturer must order different size boxes and adjust its standard packaging process. The additional costs incurred are most often passed on as higher prices to the purchaser.
- Minimizing the number of shipments for the order. The more frequent the number of shipments the purchaser requests, the greater the administrative cost incurred by the purchaser. This increase in administrative costs can be passed on to the purchaser in the form of higher prices.

Preferential pricing: If a governmental or public-sector agency is conducting the procurement, it is possible to request preferential public sector pricing directly from the manufacturer. Both Gedeon Richter Ltd. and Laboratoire HRA Pharma offer public-sector pricing (see Preferential Pricing for Public Sector Agencies in the tools section for these manufacturers' contact information and more details.)

Ensuring product quality

As mentioned in the section above on product regulation, the NRA has the responsibility of ensuring the quality of drugs and medicines by establishing inspection and quality assurance testing requirements. However, it is the responsibility of the procurement unit to ensure compliance with these requirements. This is traditionally accomplished by including appropriate certification, inspection, and testing requirements in the technical specifications and special conditions of contracts issued to suppliers.

Commonly requested certification requirements for pharmaceutical contraceptives can be found in sections 1.3 through 1.7 of the Sample Procurement Specification: Levonorgestrel-Only ECPs contained in the Tools section of this module. Common inspection and testing requirements are also included in this sample procurement specification.

Monitoring supplier performance

Once the elements described above have been considered and the process for procuring an emergency contraception product has been determined, the procurement process can be set in motion. Managing this process involves preparing appropriate documents, establishing contract terms that ensure product quality, arranging for product shipment, ensuring adherence to contract terms, and monitoring the supplier's performance. Information that will help in carrying out this process is found in the Sample Procurement Specification: Levonorgestrel-Only ECPs in the tools section of this module. This document is provided to illustrate the level of detail that is required for a specification that addresses product quality, inspection, and testing issues. The procurement specification is an important component of managing the process because, along with appropriate contract terms and conditions, it helps to ensure that products provided to the program are of acceptable quality.

Distribution

Because ECPs are most effective when taken as soon as possible after unprotected sex, and should be taken within 120 hours, easy access to this method is of particular importance.

Barriers to ECP access have included:

- Client embarrassment in requesting ECPs (because they have to admit that they had sex without protection).
- Provider biases against ECPs or certain users.
- Restrictive hours of service delivery.

Distribution systems

The table below describes some of the advantages and disadvantages associated with three broad categories of distribution systems: public sector, family planning nongovernmental organizations, commercial pharmacies, and social marketing or franchising.

Distribution System	Advantages	Disadvantages
Public sector (clinics, hospitals, special services for sexual assault or sexually transmitted infections)	• Large clientele • Organizational structure may provide for effective quality control of services and counseling • Potential for linking clients to other reproductive health services • Low or no cost to clients	• May have restricted hours • May not have the flexibility to respond quickly to ECP needs • Locations may not be easily accessible to clients • May present challenges for youth or unmarried women or couples requesting ECPs • May be difficult to incorporate ECPs into programs that have not traditionally provided family planning
Family planning NGOs	• Specialized family planning services may make it easier to integrate ECPs into systems • Organizational structure may provide for effective quality control of services and counseling • Potential for linking clients to other reproductive health services • May provide low-cost services to clients	• May have restricted hours • Locations may not be easily accessible to clients
Commercial pharmacies	• Easy access, open long hours, weekends • Attractive to youth and other populations less comfortable with clinics • Can make ECP distribution self-sustaining	• Pricing generally higher than through public distribution mechanisms and therefore less accessible to low-income clients • Pharmacy staff providing ECPs to clients may not have correct information about indications for use or dosage • Pharmacies that lack separate counseling setting may be intimidating to some potential users • Do not always provide a link to other needed services
Social marketing/ social franchising	• Potential for low cost to client • Includes advertising and awareness-raising • Typically uses training to improve service quality • Can make ECP distribution self-sustaining	• Often requires ongoing subsidy for product and/or advertising • Distribution staff may not have correct information about indications for use or dosage • Does not always provide a link to other needed services

Service delivery options

Given the time-sensitive nature of ECP use, program planners should develop awareness-raising systems to ensure that women know about ECPs and where to access them. Information about ECPs can be delivered in a variety of venues, including public-sector clinics, where providers can routinely mention ECPs during family planning visits, and social service and other public-sector or NGO nonclinical service points. Mass media campaigns are another mechanism for raising awareness. (See Module C: Raising Public Awareness for more detailed discussion of these issues.) One approach for ensuring timely access to ECPs is to provide women with an advance supply (along with instructions for use) or an advance prescription that can be filled if needed. Advance provision of ECPs has been found to reduce unintended pregnancies without increasing repeated use or encouraging women to abandon other methods of contraception.[8]

It may be possible to integrate ECP products, as well as information and counseling, into specialized service delivery options beyond the categories described above. These might include:

- Community-based distribution programs
- School nurses
- University health centers
- NGO programs
- Social services
- Factories with many young female workers
- Private-sector medical providers
- Sexual assault services

Regardless of the distribution system implemented, it is important to ensure a consistent supply of the ECP product.

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Module F Tools List

Potential Market for ECPs: A Basic Demand Model

Because ECPs are used on an irregular and unexpected basis, forecasting the need and planning the supply process will differ from regular contraceptive pills. This tool will help program managers plan for an initial supply of ECPs.

Information to Include in a Levonorgestrel-Only ECP Package Insert

Regulatory authorities require that drugs, medicines, and contraceptives packaged for consumer use contain printed materials with information about the product. It is important to ensure that this information sheet uses clear language and is easy for clients to understand. The package insert should be designed to meet regulatory requirements and provide clients with key information that they will need for using the pills. This tool provides essential information for pill users as well as optional additional information that can be considered, if space permits.

Sample Procurement Specification: Levonorgestrel-Only ECPs

Procurement units can use this sample format as a guide, adding country-specific information where appropriate. The sample specification is designed to be used in conjunction with bidding and contract documents. The specification also can be useful as an overview of the kind of information that will be needed for procurement purposes.

Preferential Pricing for Public-Sector Agencies

Contact information is provided for two manufacturers of a dedicated levonorgestrel-only ECP who offer public-sector pricing.

Procurement Through International Procurement Services

Organizations with limited procurement capacity or wanting to procure small quantities of ECPs may find that ordering through a reputable international procurement agency is advantageous. Information about this option is provided.

Potential Market for ECPs: A Basic Demand Model

This model is a tool to help program managers use generally available statistics and data to define the potential market for ECPs in their service area—both the maximum demand per year and the realistic demand per year. The maximum demand is the total number of ECPs that could potentially be needed by the target population based on estimates of unprotected sex acts. The realistic demand reduces this estimate by taking into account issues of ECP knowledge, accessibility, and women's ability to pay for the pills.

In the beginning, when ECPs are just being introduced, the maximum demand will be much higher than the realistic demand. But over time, by increasing client awareness and provider training, the total realistic demand will grow because of increased knowledge and increased access, and will therefore more closely match the maximum demand.

Model Description, Data, and Assumption

Maximum demand per year

The first section of the model estimates the maximum demand per year for ECPs. This is calculated by combining estimates of the maximum number of coital acts that could require ECPs for women using contraceptives and women not using any contraception. The estimate for women using contraception is calculated by computing the total number of women of reproductive age using traditional methods, male condoms, and oral contraceptive pills; estimating the total number of theoretically protected coital acts per year; and then, based on observed departure from effective use of contraception, calculating the number of coital acts that require pregnancy prevention.

Traditional methods, condoms, and pills are the only contraceptives included in the model because they are the methods for which a woman would be aware of a departure from effective use and would perceive the need for ECPs (sexual relations outside of the safe period, partner failing to withdraw, inconsistent condom use, or missed oral contraceptive pills). Users of other methods of contraception such as sterilization and intrauterine devices are not likely to need ECPs. To calculate the total number of coital acts in this population, the model uses the world average of 106 coital acts per year.[1] The observed departure from effective use of contraception is included in the model as a fixed rate of 20 percent, based on estimates of observed departure from effective use of contraception (the percentage of coital acts that contraceptive users would **know** they did not actually use their contraception effectively). The 20 percent estimate is based on data indicating that an average of 22 percent of women knowingly miss more than 2 pills per cycle;[2] approximately 19 percent of coital acts by condom users are knowingly unprotected;[3] and failure rates of withdrawal and rhythm methods are 20 percent and 19 percent, respectively.[4] While the failure rate of traditional methods is not parallel to the data for condoms or pills, the assumption is that most failure of traditional methods would be clearly observed (either because women following their cycle had intercourse during their fertile period or their partner did not withdraw in time). Furthermore, since unprotected acts do not always lead to pregnancy, the observed rate would not be any lower than actual failure rate.

The estimate for women not using any contraception is calculated by computing the total number of sexually active women of reproductive age not using contraception, estimating the total number of unprotected coital acts per year, and then—based on the estimate of the proportion of women who would prefer to avoid a pregnancy—calculating the total number of coital acts among women not using any contraception that would require pregnancy prevention.

The proportion of women not using contraception who would prefer to avoid pregnancy is based on data indicating that about 17 percent of married women in the developing world would prefer to avoid a pregnancy but are not using any form of contraception.[5]

Realistic demand per year

The second section of the model estimates a more realistic demand for ECPs by calculating a subset of the maximum demand by determining the number of those women who would have knowledge of ECPs, live in an area where ECPs are accessible, and have the ability to pay. These percentages are estimated based on local knowledge of the population and will vary by country.

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Content and format for this tool were adapted from a forecasting model developed by AltaCare. PATH greatly appreciates contributions made to the model by the Deliver Project at John Snow, Inc. and Population Services International.

Potential Market for ECPs: A Basic Demand Model

MAXIMUM DEMAND PER YEAR

(Maximum number of coital acts for which women may question their pregnancy status immediately after intercourse)

Women Using Contraception

(a) Total population	
(b) Percentage of women of reproductive age	
(c) Total number of women of reproductive age = (a)x(b)	-
(d) Contraceptive prevalence rate—traditional methods (withdrawal, rhythm) (%)	
(e) Contraceptive prevalence rate—male condoms (%)	
(f) Contraceptive prevalence rate—oral contraceptive pills (%)	
(g) Total contraceptive prevalence rate of traditional methods, condoms and pills (%) = (d)+(e)+(f)	-
(h) **Total number of women of reproductive age using traditional methods, condoms, or pills** = (c)x(g)	-
(i) Average number of coital acts per year	106
(j) **Total number of theoretically PROTECTED coital acts/year** = (h)x(i)	-
(k) Observed departure from effective use of contraception (%)i.e., missed oral contraceptive pills, unprotected coital acts by condom users)	20%
(l) **Total number of coital acts among women using traditional methods, condoms, and pills requiring pregnancy prevention/year** = (j)x(k)	-

Women NOT Using Any Contraception

(m) Total number of sexually active women of reproductive age	
(n) Rate of non-contraceptive use (%)	
(o) **Total number of sexually active women of reproductive age not using contraception** = (m)x(n)	-
(p) Average number of coital acts per year	106
(q) **Total number of theoretically UNPROTECTED coital acts / year** = (o)x(p)	-
(r) Proportion of women not using any contraception who prefer to avoid pregnancy (%)	17%
(s) **Total number of coital acts among women not using any contraception requiring pregnancy prevention/year** = (q)x(r) (Maximum opportunity)	-
(t) TOTAL MAXIMUM DEMAND PER YEAR = (l)+(s)	**-**

REALISTIC DEMAND PER YEAR

(Subset of coital acts from maximum opportunity of women that have knowledge of ECPs, live in area where ECPs are accessible, and have ability to pay)

(u) Total number of coital acts requiring pregnancy prevention per year =(total maximum demand from (t) above)	**-**
(v) % of women with knowledge of ECPs	
(w)% of women who live in areas where ECPs are accessible	
(x) % of women who have ability to pay for ECPs	
(y) **Total % of women who may seek ECPs** = (v)x(w)x(x)	**-**
(z) TOTAL REALISTIC DEMAND PER YEAR **Number of coital acts for which women may seek ECPs = (u)x(y)**	**-**

The shaded boxes are calculated automatically in the electronic version of this document.

References included in model description.

Instructions for Using the Basic Demand Model to Assess the Potential Market for ECPs

Maximum Demand per Year

Women using contraception

(a) Enter the total number of women in the population. Individual country data is available online from the Population Reference Bureau website http://www.worldpop.org/datafinder.htm, the United Nations World Contraceptive Use 1998 website http://www.un.org/esa/population/pubsarchive/wcu/wcu.htm, and the Measure Demographic and Health Surveys website http://www.measuredhs.com/countries/start.cfm.

(b) Enter the percentage of women of reproductive age. Country-specific data may be available on the websites described in (a) above.

(c) Multiply (a)x(b) to find the total number of women of reproductive age.

(d) Enter the contraceptive prevalence rates for traditional methods (i.e., withdrawal and rhythm) as a percentage (%). Country specific data may be available on the websites described in (a) above.

(e) Enter the contraceptive prevalence rates for male condoms as a percentage (%). Country-specific data may be available on the websites described in (a) above.

(f) Enter the contraceptive prevalence rates for oral contraceptive pills as a percentage (%). Country-specific data may be available on the websites described in (a) above.

(g) Add (d)+(e)+(f) for the total contraceptive prevalence rate of traditional methods, condoms, and pills.

(h) Multiply (c)x(g) to find the total number of women of reproductive age using traditional methods, condoms, or pills as their contraceptive method.

(i) There is no need to enter anything here. The average number of coital acts per year around the world is estimated to be 106. This is a fixed number. However, it can be substituted with a number more reflective of local conditions, if local data are available.

(j) Multiply (h)x(i) for the total number of theoretically PROTECTED coital acts per year for traditional methods, condoms, and pills.

(k) There is no need to enter anything here. This is a fixed rate of 20 percent based on estimates of observed departure from effective use of contraception (the percentage of coital acts that contraceptive users would KNOW they did not actually use their contraception effectively).

(l) Multiply (j)x(k) for the total number of coital acts using traditional methods, condoms, and pills requiring pregnancy prevention per year.

Women NOT using any contraception

(m) Enter the total number of sexually active women of reproductive age. Country-specific data may be available on the websites described in (a) above.

(n) Enter the rate of noncontraceptive use. Find this rate by subtracting the total percent of contraceptive use from 100 to get the noncontraceptive use rate. The total contraceptive use rate can be found at the Population Reference Bureau, the United Nations World Contraceptive Use 1998, or the Measure Demographic and Health Surveys websites described in (a) above.

(o) Multiply (m)x(n) for the total number of women not using contraception.

(p) There is no need to enter anything here. The average number of coital acts per year around the world is estimated to be 106. This is a fixed number. However, it can be substituted with a number more reflective of local conditions, if local data are available.

(q) Multiply (o)x(p) for the total number of theoretically UNPROTECTED coital acts per year.

(r) There is no need to enter anything here. This number is based on the estimate that 17 percent of married women in the developing world would prefer to avoid a pregnancy but are not using any form of contraception. This is a fixed number.

(s) Multiply (q)x(r) for the total number of coital acts requiring pregnancy prevention per year.

(t) Add (l)+(s) for the total maximum demand per year.

Realistic demand per year

(u) Enter the total number of coital acts requiring pregnancy prevention per year. This is the total maximum demand per year from (t) above.

(v) Estimate the percentage (%) of women with knowledge of ECPs. Knowledge, attitudes, and practices studies about ECPs performed locally may provide this information.

(w) Estimate the percentage (%) of women who live in areas where ECPs are (or will be) accessible. For example if ECPs are only available in urban areas, use the percentage of the population living in urban settings.

(x) Estimate the percentage (%) of women with the ability to pay for ECPs. This estimate may depend on whether ECPs are available at a subsidized price

(y) Multiply (v)x(w)x(x) for the total percentage (%) of women who may seek ECPs.

(z) Multiply (u)x(y) for the total number of coital acts for which women may seek ECPs. **This is the realistic demand per year.**

Content and format for this tool were adapted from a forecasting model developed by AltaCare. PATH greatly appreciates contributions made to the model by the Deliver Project at John Snow, Inc. and Population Services International.

Information to Include in a Levonorgestrel-Only ECP Package Insert

Essential information for clients

- Brief instructions:
  - ECPs are medicine to prevent pregnancy after unprotected sexual intercourse. Use ECPs if you do not want to become pregnant, if you think your contraceptive method failed, or if you were raped.
  - Take a single dose of 1.5 mg levonorgestrel as soon as possible within 120 hours after unprotected sex. ECPs are more effective the sooner they are taken.
  - ECPs can be used anytime in the menstrual cycle.
- Brief information about side effects:
  - Most women do not feel anything after taking ECPs. Some women have sore breasts and headaches. Some women have their period a little later or a little earlier than usual. Some women feel sick to their stomach, and some women even vomit after taking ECPs.
  - If you vomit within 1 hour after taking ECPs (it may mean you have vomited up the ECPs), you should try to take another dose immediately.
  - If you vomit more than one hour after taking ECPs, you do not need to take extra pills.
  - These ECP side effects may be uncomfortable, but they are not harmful and usually last for only one day or less.
  - It is normal for your next period to begin a few days earlier or later than expected.
- Sexually transmitted infections (STIs): ECPs do not protect STIs or HIV. If you think you may have contracted an STI or HIV, visit your health or STI clinic.

Optional additional information

- ECPs do not work if you are already pregnant.
- ECPs are effective contraception, but they do not work every time. If your period does not start within 3 weeks after taking ECPs, you may be pregnant. Have a pregnancy test to know for sure.
- As soon as possible, begin using a birth control method you will be able to use on an ongoing basis. ECPs are intended for emergency protection. They are not as effective as other forms of birth control.
- After using ECPs:
  - Use a barrier method, like a condom, each time you have sex until you begin your next menstrual period. After that time you may continue using your birth control method or begin a new one.

Or

– If you were using oral contraceptives pills, you should continue taking the tablets starting on the day after you took the ECPs until the end of the cycle. You should then use a condom or other barrier contraceptive method for at least seven days after restarting oral contraceptive pills.

Sample Procurement Specification: Levonorgestrel-Only ECPs

The following sample format can be used in developing procurement specifications for emergency contraceptives. In developing a procurement specification it is important to thoroughly review national regulatory and registration requirements for the product to ensure that appropriate product requirements are incorporated into the specification. In this sample, examples of product specifications are in italics: when preparing a procurement specification, appropriate product specifications can be substituted for the italicized examples. The sample procurement specification is designed to be used in conjunction with bidding and contract documents.

Notes (for submission of sample of product):

The sample emergency contraceptives pills submitted by the bidder in response to this solicitation must be exactly the same as would be supplied if a contract were awarded to the bidder. In other words, samples should have same tablet shape, color, weight, ingredients, and identification imprint; same blister pack size, material, text, and identification markings; same inner box size, material, text, and identification markings.

1. Requirements

1.1 Emergency Contraceptive Tablets in Accordance with the Following Specifications:

Two-tablet package consisting of two emergency contraceptive levonorgestrel-only tablets.

Each tablet shall contain 0.75 milligrams of levonorgestrel.

Product and Brand Names:

Product Name: _____

Brand Names: _____

1.2 Raw Materials

Emergency contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor. A typical validation includes, but is not limited to, these areas.[1]

- Manufacturing records and procedures for the raw material synthesis, processing, packing, and storage.
- Quality control records and procedures for the raw material, in-process, and final product.
- Plant certification by local regulatory authorities (such as Commerce, Industry, Health, Environment) as required.

[1] Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, good manufacturing practices require that manufacturers validate vendors for all raw materials.

- Certification of workers' training in good manufacturing practices and safety protection.
- Records demonstrating raw materials with the required physical and chemical characteristics.

1.3 Registration Requirements

Emergency contraceptives offered under this purchase description shall be currently registered in the country of destination and approved by _____ (local regulatory authority).

1.4 Certificate of Licensing Status

Emergency contraceptives offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offeror(s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Certification Scheme.[2]

1.5 No Objection Certificate

In the case of goods of foreign origin, emergency contraceptives offered under this purchase description shall have been awarded a No Objection Certificate by _____(local regulatory authority) on behalf of any local manufacturer(s) of the importing country.

1.6 Compliance with Good Manufacturing Practices

The Supplier must be able to provide certification that the emergency contraceptives are manufactured according to WHO good manufacturing practices (GMP). Such certification can be found in the WHO Certification Scheme "Certificate of a Pharmaceutical Product." Supplier also must be able to provide copies of its annual GMP audit reports.

1.7 WHO Certification—Movement in International Commerce

The Supplier must be able to provide documentation indicating manufacturer of the product has received confirmation from the Ministry of Health of the country of manufacture that the pharmaceutical meets the requirements in the WHO Certification Scheme.

1.8 Shape and Dimensions

Tablets shall be of the shape and dimensions of the Bidder's normal, standard commercial tablet.

1.9 Colors

Emergency contraceptive tablets shall be similar to Bidder's normal, standard commercial tablets.

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[2] WHO Certification Scheme for the Quality of Pharmaceutical Products Moving in International Commerce. For additional information see www.who.int/medicines/library/qsm/who-edm-qsm-2000-2/certifscheme.shtml.

1.10 Tablet Marking

Each tablet shall bear the identifying imprint of its manufacturer if such imprint is provided on the Bidder's normal, standard commercial tablet.

1.11 Packaging

1.11.1 Presentation

Each individual tablet shall be enclosed in a transparent blister pack of thermoformed polymer with a foil backing. The supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer's stability test data to validate the product's stated shelf life at ambient temperature 32 degrees C or above and relative humidity of 85 percent. Variations must be proven scientifically comparable by means of stability data.

The size of the package shall not be less than 65 mm (2.6 inches) x 27 mm (1.08 inches). Thicker polymer or foil or the addition of a card to either the front or back of the package (in addition to the minimum polymer or foil) is acceptable.

1.11.2 Mounting

Tablets shall be mounted two (2) tablets per package.

1.12 Identification Markings on Individual Blister Packs

1.12.1 Each individual blister pack shall have the following information:

- Product/brand name
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name or symbol
- Contents and quantity
- Product use and storage instructions (accompanying the blister pack)

1.12.2 Printing and layout

On the back of each blister package the trade or brand name of the product shall be printed in precision full registration.

The month and year of expiration, and the lot/batch control number shall be shown on each individual blister pack. Debossing is acceptable for these numbers.

The tablet formulation and/or the international nonproprietary name shall be printed on the individual packet and may be printed on the reverse side (smallest type no less than one mm high).

1.13 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability, or detract from their appearance.

1.14 Lots Per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.15 Shelf Life

The shelf life of the product provided under this solicitation shall be ___ (_) years from the date of manufacture when stored under tropical conditions such as those prevailing in _____*(recipient country name).* The Supplier shall be able to provide to the satisfaction of registration/national quality control authorities manufacturer's stability test data substantiating this ___year shelf life at ambient temperatures 32 degrees C or above and relative humidity of 85 percent in the proposed blister package.

At the time of inspection or acceptance for delivery to the country of destination, no more than ___ (__) months shall have expired since the date of manufacture shown on the batch release or Certificate of Analysis.

1.16 Test Data

Chemical and physical test data for raw materials, components, in-process, and finished product testing must be on record for each lot shipped and must be available to Purchaser's representatives when requested.

2. Quality Assurance Provisions

2.1 Compliance

The Supplier shall guarantee that the products as packed for shipment comply with all provisions of the specification and related documents.

2.2 Documentation

2.2.1.

The Supplier shall provide evidence[3] of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the "Manufacturer's Batch Certificate" under the WHO Certification Scheme.

[3] Including quality control and manufacturing records, in-process control records, and final product certificate of analysis.

2.2.2.

The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.

2.2.3.

The Supplier shall provide a copy of the Certificate of Analysis to the Purchaser for each lot intended for shipment.

2.2.4.

The Supplier shall provide to the Purchaser a copy of the approval of each component for each lot intended for shipment.

2.3 Inspection by the Purchaser

The Purchaser reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Specification and Special Conditions of Contract to ensure that the goods conform to prescribed requirements.[4] The Purchaser reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to shipment of the goods and to draw samples from the Supplier's factory and/or warehouse. Except as otherwise specified in the contract or purchase order, prior to shipment the Purchaser will sample or cause to be sampled the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.[5]

The Purchaser may have some or all of the tests specified in Section _____of the contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on pharmaceutical products according to _____Pharmacopoeia.

2.4 Sampling Procedures

The Purchaser or the Purchaser's representative shall select the required samples from the lot according to Section ____ of the Special Conditions of Contract. If the order is to be filled using more than one production lot, each production lot shall be separately sampled and tested.

Where an inspection lot is smaller than 10,001 units, it will be deemed to be 10,001 for determination of sample sizes.

The normal, tightened, and reduced inspection provisions of ISO 2859 (Inspection by Attributes) may be used for visual inspection. Sampling for analytical testing shall be done in accordance with pharmacopoeial requirements.

All sampled boxes and shipping cartons shall be so marked and shall include the date and initials of sampler.

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[4] In some cases, Special Conditions of Contract are added to the governing contract. These terms accommodate any special needs not otherwise covered, such as requirements to remedy non-conforming product, time limitations on inspections, or the use of specific inspection agencies.

[5] Depending on the tests required, sampling may be conducted according to the standards of the International Organization for Standardization (ISO 2859: Inspection by Attributes), or as dictated by local or international pharmacopoeiae. Following recognized sampling procedures helps to ensure that the products tested are representative of the whole. For information on obtaining ISO 2859: Inspection by Attibutes, see www.iso.ch/iso/en/CatalogueDetailPage.

2.5 Sample Retention

The Supplier shall retain a sample of ten blister packages, or the equivalent required to perform three complete chemical assays, from each lot shipped, for a period of one year after the printed expiration date.

3. Packing

3.1 Inner Boxes

3.1.1

Products sealed in individual packages as specified in Section 1.11 shall be packed in inner boxes of ___ (__) *packages* per inner box. Inner boxes shall be made of *light fiberboard (white)* of a size sufficient to contain the specified number of packages. The overall dimensions should be such that the product does not get damaged during transportation and storage.

3.1.2

For inner boxes, the Bidder shall fill in the blanks provided below:

The products in each inner box will be ___ (__) individual *packages;* the overall dimension of a box will be ___cm x ___cm x ___cm.

3.2 Exterior Shipping Cartons

3.2.1.

Product and printed materials, packaged and packed as specified above, shall be contained in exterior shipping cartons of strong, export quality material able to withstand rough handling and the prevailing climatic conditions during transport and storage.

3.2.2

The Bidder shall fill in the following blanks:

The exterior shipping carton will contain ____ inner boxes; the overall dimensions of a carton will be _ cm, x __ cm x __ cm and the gross weight of one shipping carton will be ___ kg.

A standard 20 foot (6.096 meter) container will accommodate _____ exterior shipping cartons.

4. Markings

4.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner that is acceptable to the Purchaser.[6]

[6] The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country if importation.

- Product/brand name
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name, address
- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions for storage and handling

4.2 Exterior Shipping Cartons

The following information shall be stenciled or labeled on the exterior shipping cartons on two opposing sides in bold letters at least __ mm high with waterproof ink in a clearly legible manner that is acceptable to the Purchaser:[7]

Regulatory Information (on two opposing sides of carton)

- Product/brand name
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name, address
- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions and symbols (see below) for storage and handling
- Notice of need to protect from exposure to water and extreme heat or extreme cold

Customs/Shipping Information (on two opposing sides of carton)

- Made in _____
- Supplier's name and address (if different from manufacturer)
- Consignee's address in full
- Gross weight of each carton (in kg)
- Port of entry
- Contract number
- Quantity of goods
- Carton ___ of ___

[7] The smallest type shall be no less than ten mm high, unless otherwise specified by the commercial laws of the country of importation.

5. Printed Materials—Product Information Sheets

5.1 Consumer information and directions for use shall be printed in English and/or in _____ and provided as package inserts, one copy for each consumer unit.

5.2 Information for Physicians' Use shall be printed in English and/or in _____. Two copies of such information shall be provided for each 100 blister packages and shall be placed in each exterior shipping carton.

Preferential Pricing for Public-Sector Agencies

In consideration of the need and the public good, manufacturers may decide to offer a preferential price to public-sector or nonprofit programs.

Gedeon Richter Ltd. (Postinor-2) and Laboratoire HRA Pharma (Norlevo), the two major international pharmaceutical companies that currently manufacture and distribute levonorgestrel-only products packaged and labeled specifically for emergency contraception, have both indicated a willingness to provide their product to qualified governmental organizations and public-sector agencies at preferential prices. Requests for preferential public-sector pricing should be issued directly to the companies at the following addresses:

Gedeon Richter Ltd.
1103 Budapest
Gyomroiu. 19-21
Hungary
Attention:
Ms. Agnes Hazslinszky, Area Manager, International, Dosage Form Products (a.hazslinszky@richter.hu)
Tel: 36-1-431-4406 Fax: 36-1-261-9641

AltaCare, on behalf of Laboratoire HRA Pharma
19, rue Frederick Lemaitre
75020 Paris, France
Attention:
Mr. Saad Harti, Managing Director (saad.harti@altacare.fr)
Mrs. Sophie Godefroy, Brand Manager (godefroy@altacare.fr)
Tel: 33-143-49-6133 Fax: 33-143-49-6179

The companies may request information that confirms the organization is a bona fide governmental organization or public-sector agency. They may request information on the plans for successfully introducing emergency contraception into the existing family planning/reproductive health program. Other information that the companies may request includes:

- Quantity of ECP dosages required.
- Delivery date for shipment.
- Shipping instructions and shipping document requirements.
- Inspection or testing requirements.
- Registration, licensing, and quality assurance documentation required to register and import product.
- Name and contact information for follow-up questions.

Since procurement personnel are traditionally responsible for contacting manufacturers and suppliers to request pricing and detailed product information, program planners should work closely with their procurement staff to provide the information that the manufacturers may request.

Procurement Through International Procurement Services

An organization would want to use the services of a reputable international procurement agency to obtain levonorgestrel-only emergency contraceptive pills if the organization has limited procurement capacity or the value of an order is small. Two international agencies with experience in procuring and providing levonorgestrel-only ECPs are UNFPA and IPPF, which have provided the general ordering and contact information below.

UNFPA

UNFPA has considerable experience in the international procurement and shipment of dedicated ECPs and its procurement services are available to government ministries, multilateral and bilateral agencies, and NGOs. General ordering requirements for UNFPA procurement services are as follows.

For orders of 20,000 packs or more of levonorgestrel-only ECP, delivery time is an average of two to three months after the purchase order is issued.

UNPFA is currently able to fill orders of fewer than 20,000 packs. The delivery time for small orders is a period of several days.

UNFPA payment terms are net 30 days and there is a service fee charge of 5 percent of the cost of insurance and freight value of the goods to cover UNFPA expenses to process the order.

Requests for UNFPA procurement services and general inquiries should be issued directly to UNFPA at the following address:

Ms. Nana Essah, Sr. Procurement Officer
Procurement Services Section
United Nations Population Fund (UNFPA)
220 East 42nd Street
New York, New York 10017, USA
Tel: 212-297-5384
Fax: 212-296-4916
Email: essah@unfpa.org

*For planning purposes, the approximate order value of 20,000 packs is US$5,000 at a current price of US$0.25 per pack of two tablets. The gross weight of a shipment of 20,000 packs of Postinor 2 is approximately 137 kilograms

International Planned Parenthood Federation (IPPF)

IPPF, working through a subsidiary, ENET, provides international procurement and shipment of dedicated levonorgestrel-only ECPs to its member associations and third-party customers.

Organizations placing orders through IPPF must guarantee that their levonorgestrel-only ECP products (examples of which are Postinor-2 and Norlevo) will be exclusively distributed through family planning clinics and youth centers, where the end users will receive the ECPs either free of charge or for a minimal fee to cover costs. Member associations and third party customers who can comply with this requirement must submit an official letter to IPPF confirming that the product will be distributed through the public sector or an NGO. The letter should also identify the annual quantity of ECPs required. Within two weeks of receipt of the above letter, IPPF will study the possibilities of supplying within that country and a decision will be taken. IPPF's ability to supply the product is conditioned by several factors, including whether or not the product is registered in a country and IPPF's agreement with ECP manufacturers. IPPF will notify the requesting party of its ability to supply product, including information on any conditions of provision that would be required.

For those requests for ECP that have been approved, IPPF currently has a minimum order quantity requirement of 10,000 packs of levonorgestrel-only ECPs. The approximate price for ECP ranges from US$0.25 to US$0.60, depending upon the manufacturer supplying the product. The time required to process an order for ECPs is approximately 2 to 3 months after the purchase order has been received by IPPF. IPPF payment terms are 30 days and there is a service fee charge of 4.5% of the CIF (cost of insurance and freight) value of the goods to cover IPPF expenses to process the order.

Requests for IPPF procurement services should be issued directly to IPPF at the following address:

Mrs. Vanessa Gerbron, Services Provider
E-mail: vgerbron@ippf.org
or
Carl Foissey, Business Analyst
E-mail: cfoissey@ippf.org
International Planned Parenthood Federation (IPPF)
Regent's College
Inner Circle, Regent's Park
London NW1 4NS
United Kingdom
Telephone: +44 (0)20 7487 7926
Fax: +44 (0)20 7487 7950

This material was developed by PATH.

Module G

The Option of Providing Combined Oral Contraceptives (COCs) as Non-Dedicated Emergency Contraceptive Pills (ECPs)

Objective

To guide decision making and program planning when provision of combined oral contraceptives for emergency contraception is being considered.

There are two types of ECPs: progestin-only pills containing levonorgestrel and COCs. This module briefly discusses issues to consider when looking at the option of providing COCs for emergency contraception. The following topics are discussed:

- Provision of COCs for Emergency Contraception
- Approaches for Providing COCs as Non-Dedicated ECPs
- Pros and Cons of Providing COCs as Non-Dedicated ECPs
- Planning for Product Supply

Tools Provided at the End of This Module

- Prototype Package Format
- COCs for Emergency Contraception: Example of the Repackaging Format Used by the Family Guidance Association of Ethiopia
- Information to Include When Providing COCs for Emergency Contraception
- Provision of a One-Month Supply of COCs for Emergency Contraception

Provision of COCs for Emergency Contraception

As described in the World Health Organization (WHO) publication Emergency Contraception: A Guide for Service Delivery, there are two kinds of products that can be used as emergency contraceptive pills: (1) progestin-only pills containing levonorgestrel and (2) COCs, containing progestin and estrogen, which are widely used for regular contraception.[1] The progestin-only pills have a higher effectiveness rate for emergency contraception and have fewer side effects than COCs when taken for emergency contraception.[2] In addition, progestin-only pills can be taken in one dose.[3] For these reasons, progestin-only pills are considered the preferred emergency contraceptive product for family planning programs.

In 2003, the WHO Model List of Essential Medicines was revised to include only the progestin-only pills for emergency contraception. There are two manufacturers that widely distribute a dedicated progestin-only ECP—that is, an ECP labeled and packaged specifically for emergency contraception.*

In some countries, however, the option of providing a dedicated progestin-only ECP is not feasible or progestin-only pills may be registered but access may be limited. Family planning programs in this situation have found that providing COCs may be the only viable way to routinely offer emergency contraception to clients. They have done this by cutting up regular COC packets and repackaging the pills in the correct dosage for emergency contraception or by providing an entire cycle of pills with instructions for emergency contraceptive use. Although these approaches have been used successfully, there are trade-offs with regard to cost and quality. Most importantly, offering COCs means offering a less effective product. The table below shows the formulations and most common brand names of the COCs that are used for emergency contraception. Additional information about the availability of COC and ECP products, drawn from the International Planned Parenthood Federation 2002 Directory of Hormonal Contraceptives, is accessible on the website: http://ec.princeton.edu/worldwide/default.asp. This website provides a searchable database of oral contraceptives available worldwide—both COCs and progestin-only contraceptive pills—that can be used for emergency contraception. The database can be searched by country or by product.

Combined Oral Contraceptives

Formulation	Common Brand Names	First dose: Number of tablets	Second dose: Number of tablets
EE 50 mcg + LNG 0.25 mg or EE 50 mcg + LNG 0.50 mg	Eugynon 50, Fertilan, Neogynon, Noral, Nordiol, Ovidon, Ovral, Ovran, PC-4, Preven	2	2
EE 30 mcg + LNG 0.15 mg or EE 30 mcg + NG 0.30 mg	Lo/Femenal, Microgynon 30, Nordette, Ovral L, Rigevidon	4	4

Abbreviations: EE = ethinyl estradiol LNG = levonorgestrel NG = norgestrel

For all regimens, the first dose should be taken as soon as possible after intercourse, but optimally within 120 hours, and the second dose should be taken 12 hours after the first dose.

Source: Adapted from Expanding Global Access to Emergency Contraception. International Consortium for Emergency Contraception (October 2000), p. 47.

*Gedeon Richter Ltd. and Laboratoire HRA Pharma. Contact information is provided in Module F: Regulation, Procurement, and Distribution of a Progestin-Only ECP.

Approaches for Providing COCs as Non-Dedicated ECPs

Because COCs generally come in one-month supply packets, providers distributing COCs for emergency contraception develop various approaches for delivering the pills to clients. Frequently used approaches for delivering COCs as nondedicated ECPs include the following:

- Providing a month's cycle of pills to the client with verbal instructions on how to take them.
- Cutting up cycles as needed and giving the pills to the clients with verbal instructions.
- Cutting up COCs in advance on site (at a health care facility) and inserting them in envelopes along with some form of written instructions.
- Repackaging COCs in a centralized, supervised facility and inserting printed instructions.

Although each of these approaches has advantages, there are also disadvantages, which means there is a trade-off as to safety/risk or cost savings/increased expense, as discussed below.

Pros and Cons of Providing COCs as Non-Dedicated ECPs

There are several factors to address when considering whether provision of COCs as non-dedicated ECPs is an appropriate choice. These include the political situation regarding emergency contraception, regulatory requirements, the scale of the program, cost-saving opportunities, donor provision of appropriate COC products and possible donor restrictions on use of those products, and costs of repackaging and quality assurance. Program planners must evaluate all of these elements carefully before making a decision about repackaging COCs for EC.

Reasons why programs would choose the option of providing COCs as nondedicated ECPs

1. Potential opposition: If there are sectors or groups in a country whose sensitivities toward emergency contraception might delay registration, procurement, and distribution of a progestin-only ECP, provision of COCs for emergency contraception—a low-profile approach—may be the best alternative, helping avoid controversy and making it possible to move ahead and incorporate emergency contraception into a program in a timely way. Provision of a month's cycle of pills, in particular, has the potential advantage of being more anonymous, in that no one will know how the client intends to use the pills.
2. Availability: Because COCs are widely used for regular contraception, they are registered and easily available in most countries.
3. Access: If COCs are donor-provided, it may be easier for a program to use some of the product for emergency contraception, rather than to procure an additional product.
4. Cost: Providing a month's cycle of pills or cutting up cycles as needed and giving them to the client with verbal instructions on how to take them would be a low-cost approach.

Reasons why programs would not choose to provide COCs as nondedicated ECPs

1. Effectiveness: COCs are less effective for emergency contraception than progestin-only formulations, and they have more side effects.
2. Regulatory constraints: There may be regulatory barriers to cutting up COC packets and using the pills for any purpose other than that for which they were originally registered. A program considering this approach should be aware of the National Regulatory Authority (NRA) requirements. In the United States, for example, the Food and Drug Administration allows a repackaging/relabeling process when it is done on an individual basis for clients, but requires a manufacturer's license for large-scale repackaging. In many countries where there is not a dedicated emergency contraception product, however, family planning organizations informally cut up COC packets for emergency contraception, without seeking special NRA approval.
3. Quality control: The farther one gets from a centralized product quality control system, the greater the risks for error in packaging or in providing instructions for use. Possibilities for error include provision of the wrong product, the incorrect number of pills, and incorrect or incomplete instructions. Quality control can be difficult when cutting up pill packs by hand at multiple sites. A particular risk is that the integrity of the blister packs that protect each pill could be destroyed. Providing a month's cycle of pills or cutting up cycles as needed and giving them to the client with verbal instructions would entail greater risk of error and lack of quality control than cutting up COCs in advance on site and inserting them in envelopes along with written instructions or repackaging the COCs in a centralized, supervised facility and inserting printed instructions. Quality control problems could undermine an emergency contraception program.
4. Cost: The cost of cutting up COCs in advance and inserting them in envelopes along with some form of written instructions could, depending on the scale, be as high as the cost of providing a dedicated, levonorgestrel-only ECP.
5. Potential for incorrect administration: When providing a month's cycle of COCs with instructions on the number of pills to take for emergency contraception, the burden for correct administration is placed entirely on the client. The risk of error is high, especially for low-literate clients.
6. Mixing of different packets and batches: COC packets may not divide into the correct number of ECP doses, which means that pills from different packets and perhaps different manufacturing batches or lots could be repackaged together. This could result in an inaccurate expiry date or difficulty in tracing pills if a product recall were necessary.

Planning for Product Supply

When cutting up COC packets for emergency contraception, it will be necessary to determine how many packets of COCs will be needed to yield the desired number of EC cycles. In Zambia, where 21-pill packets of Microgynon are used, the practice is always to provide EC in segments of 4 pills, as smaller segments could too easily be lost. Since there are 2.5 EC cycles (of 8 pills each) in one packet of Microgynon, this practice means wasting 1 pill from each cycle. The wastage should be factored in when deciding on the number of packets to order.

References

[1] World Health Organization. Emergency Contraception: A Guide for Service Delivery. WHO/FRH/FPP/98.19. Geneva:WHO (1998).

[2] WHO Task Force on Postovulatory Methods of Fertility Regulation. Randomized controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 352:428-433 (1998).

[3] von Hertzen, H. et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. *Lancet* 360(9348):1803-1810 (2002).

PATH greatfully acknowledges the contributions of John Skibiak of the Population Council Nairobi to the development and the content of this module.

Module G Tools List

Prototype Package Format

A package format that can be adapted as needed.

COCs for Emergency Contraception: Example of the Repackaging Format Used by the Family Guidance Association of Ethiopia

An illustration of a repackaging format used for repackaged COCs for emergency contraception.

Information to Include When Providing COCs for Emergency Contraception

Essential information that should be provided either on the package or on a package insert and additional, optional information.

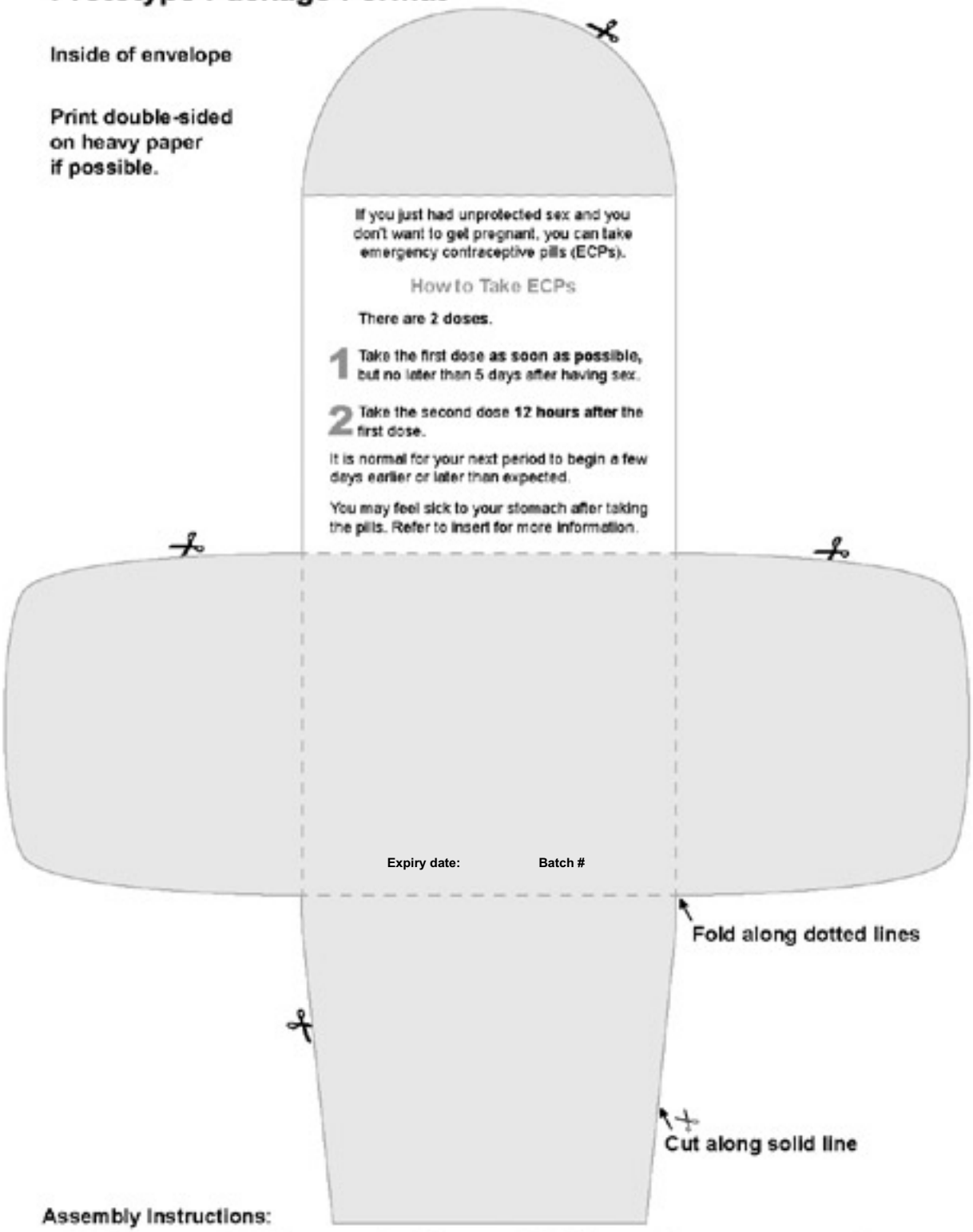
Provision of a One-Month Supply of COCs for Emergency Contraception

Suggested instructions to provide when dispensing a month's supply of oral contraceptives for the indication of emergency contraception.

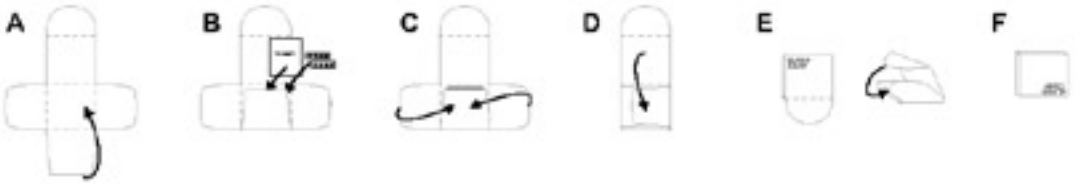
Prototype Package Format

Inside of envelope

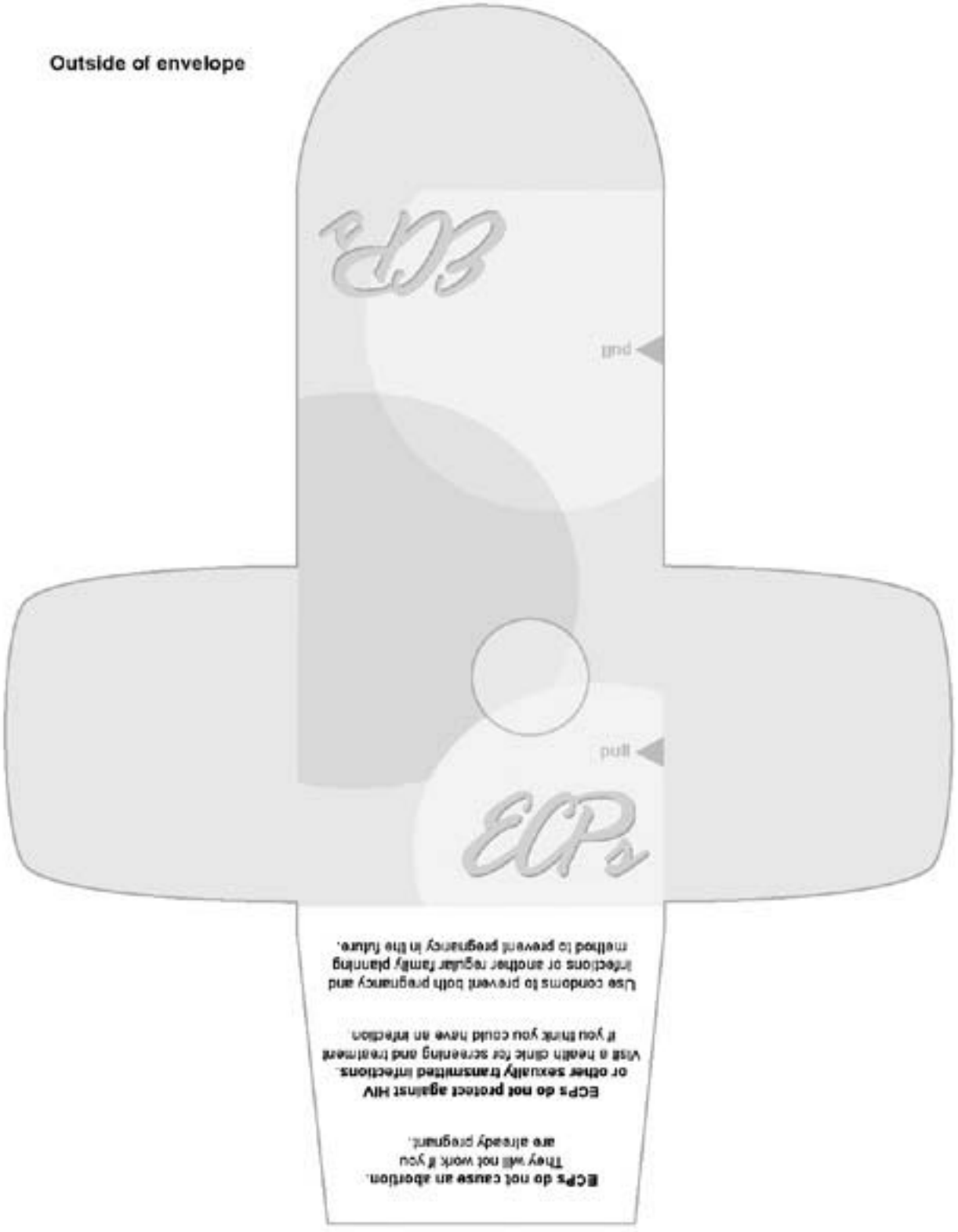
Print double-sided
on heavy paper
if possible.



Assembly Instructions:



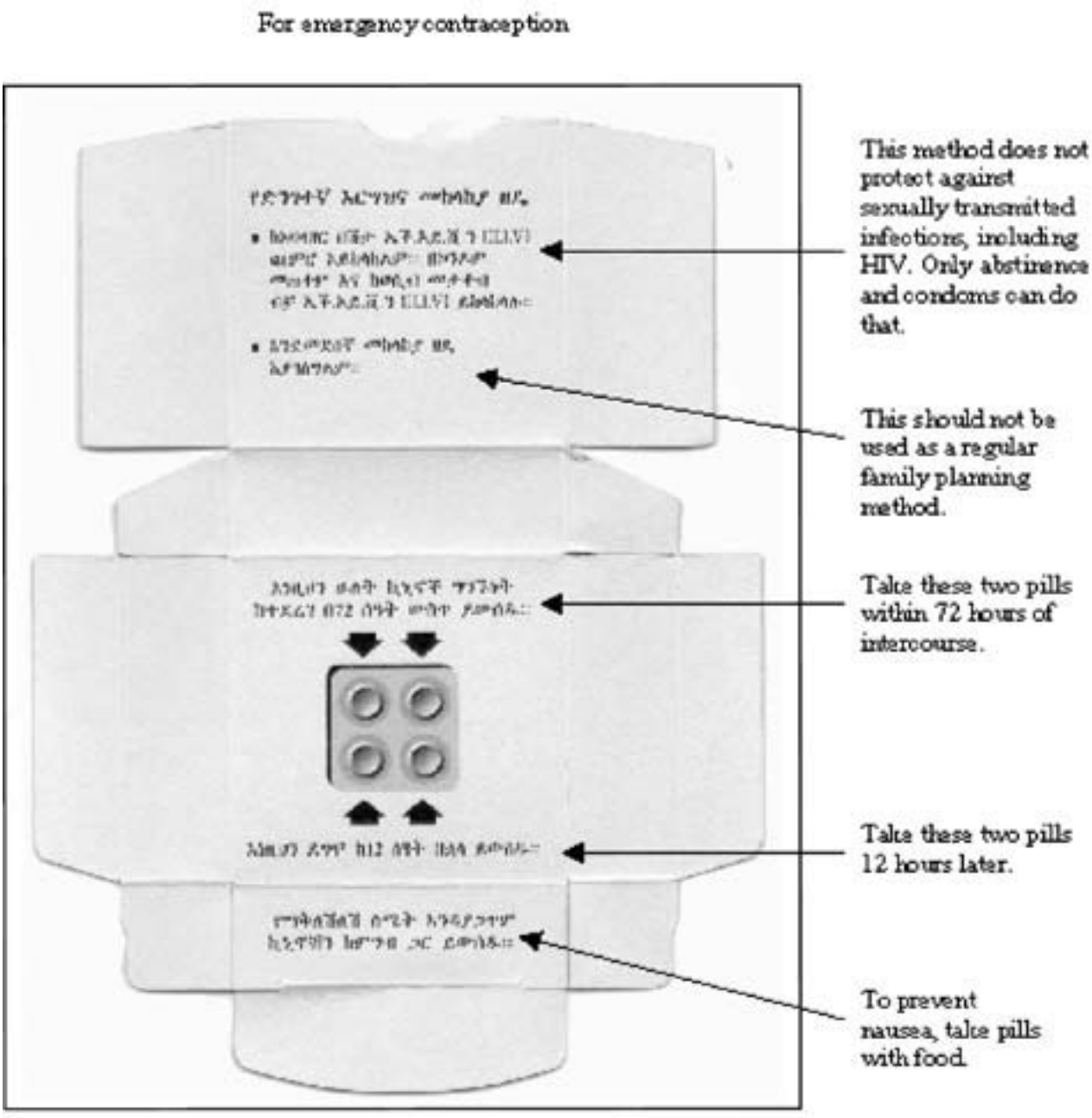
Outside of envelope

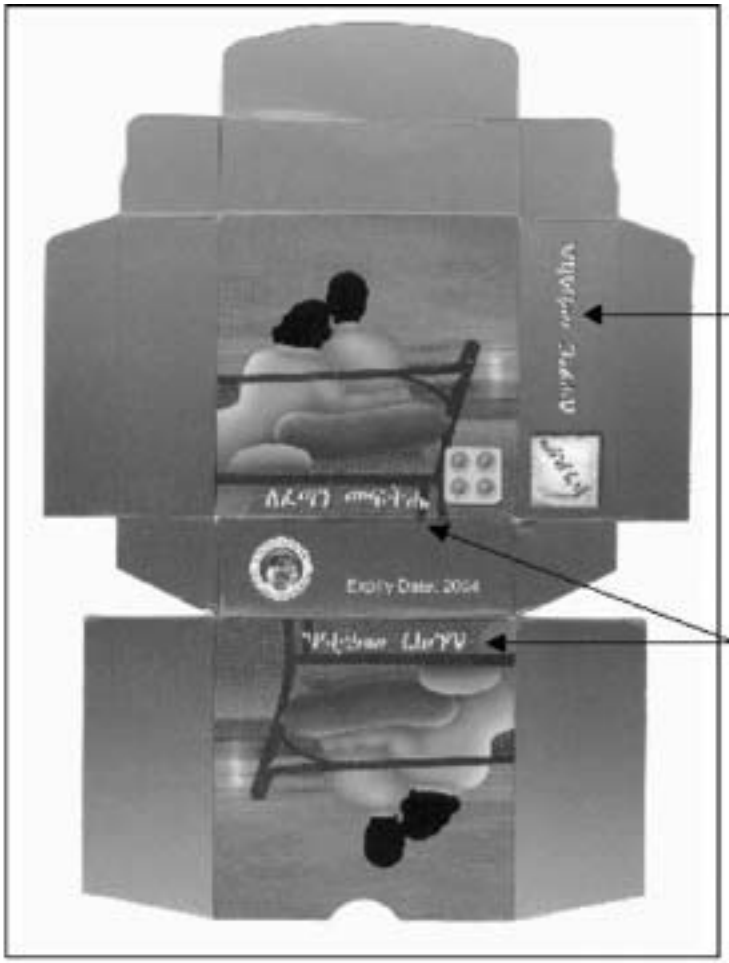


This format was developed by PATH

COCs for Emergency Contraception:

Example of the Repackaging Format Used by the Family Guidance Association of Ethiopia





The Family Guidance Association of Ethiopia developed this package format in collaboration with the Modern Center for Business Services in Dubai and with the Population Council. It was reprinted with permission.

Information to Include When Providing COCs for Emergency Contraception

Essential Information

There are two kinds of essential information: product information and information for the user. This information should be provided either on the package or on a package insert.

Product information

- Label: Emergency Contraceptive Pills (or ECPs).
- Expiry date of pills, including month, day, and year.
- Manufacturer's batch or lot number.
- Locally mandated information (required by government agencies).

Information for the user

- Brief instructions:
  - ECPs can **prevent** pregnancy after unprotected sexual intercourse. Use ECPs if you do not want to become pregnant, if you think your contraceptive method has failed, or if you were raped.
  - The first dose should be taken as soon as possible after sex, but can be taken up to 5 days (120 hours) after sex. ECPs are more effective the sooner they are taken.
  - The second dose should be taken 12 hours after the first dose.
  - Try to take the first dose so that the timing of the second dose (12 hours later) is practical for you (i.e., during waking hours).
  - ECPs can be used anytime in the menstrual cycle.
- Brief information about side effects:
  - Some women have sore breasts, headaches, or feel nauseous. Some women even vomit after taking ECPs.
  - If you vomit within one hour after taking ECPs, take another dose immediately.
  - If you vomit more than one hour after taking ECPs, you do not need to repeat the dose.
  - The side effects of ECPs may be uncomfortable, but they are not harmful and usually last for only one day or less.
  - It is normal for your next period to begin a few days earlier or later than expected.
- Sexually transmitted infections (STIs): ECPs do not protect against STIs or HIV. If you think you may have contracted an STI or HIV, visit your health or STI clinic.
- Locally mandated information (required by government agencies).

Optional Additional Information

If the program is providing a package insert, the following additional information could be included.

- ECPs do not work if you are already pregnant.
- ECPs are effective contraception, but they do not work every time. If your period does not start within 3 weeks after taking ECPs, you may be pregnant. Have a pregnancy test to know for sure.
- As soon as possible, begin using a birth control method you will be able to use on an ongoing basis. ECPs are intended for emergency protection. They are not as effective as other forms of birth control.
- After using ECPs
  - Use a barrier method, like a condom, each time you have sex until you begin your next menstrual period. After that time you may continue using your contraceptive method or begin a new one; or
  - If you were using oral contraceptives pills, you should continue taking the tablets starting on the day after you took the ECPs until the end of the cycle. You should then use a condom or other barrier contraceptive method for at least seven days after restarting contraceptive pills.

ECPs and Condoms: Packaging for Dual Protection

ECPs are sometimes packaged with condoms as dual protection, since ECPs do not protect against STIs, including HIV/AIDS. In such cases, there will be two expiry dates—one for the pills and one for the condom. It will be important, when planning distribution, to use the earlier of the two expiry dates. There also may be some additional client information provided with the package when two products are provided.

Provision of a One-Month Supply of COCs for Emergency Contraception

In a few countries, programs have chosen to distribute the entire one-month supply of COCs, along with instructions on the number of pills to take for EC. While it may be easier to dispense EC using this approach, of the four approaches outlined in this module, this one entails the most risk because it places the burden for correct dosage squarely on the client. The risk of incorrect dosage is greatly enhanced if literacy is low, if there is no way to confirm that the client thoroughly understands the instructions she has been given, if multiple pill brands are available in the country, and/or if the pack contains iron pills or placebos in addition to the birth control pills. The following instructions could be given to clients when providing them with a month's supply for EC, in addition to providing use instructions such as those printed on the prototype package in the tools section of this module.

- For emergency contraception, pills can be taken from a whole packet of regular oral contraceptive pills. Do not mix brands. Take the two doses from the same packet.
- If you have a complete packet of 28 regular oral contraceptive pills, the last 7 pills should not be used. EC doses should be taken using pills from the first 21 pills in the packet.

This material was developed by PATH.

Module H

Provider Training

Objective

To provide techniques and materials for training medical and nonmedical personnel who will be distributing emergency contraception to clients.

Training health care providers to screen and counsel clients for emergency contraceptive pills (ECPs) will help ensure successful introduction of the method and its correct use. The substance of this module is a prototype training curriculum that can be adapted to different kinds of health providers. As an introduction to the curriculum, the following topics are discussed:

- Provider Training
- Target Audiences for Training
- How to Use the Emergency Contraception Curriculum

Tools Provided at the End of This Module

- Emergency Contraception Curriculum
- Pre- and Post-Session Questionnaire
- Handout 1: Key Messages for Emergency Contraceptive Pill Clients
- Handout 2: Sample Emergency Contraceptive Pill Screening Checklist
- Handout 3: Counseling for Emergency Contraceptive Pill Clients
- Handout 4: Counseling Skills Observer Checklist
- Training Aid 1: Grab Bag—Key Messages for Emergency Contraceptive Pill Clients
- Training Aid 2: Demonstration Role-Play
- Training Aid 3: Emergency Contraceptive Pill Client Situation Role-Plays

Provider Training

For more than 30 years, emergency contraception has been known to be an effective method for preventing pregnancy after unprotected sexual intercourse. However, it is only within the past ten years that emergency contraception has received widespread attention as a contraceptive option, and dedicated ECPs have only recently become available. As a result, information about screening and counseling ECP clients is not yet included in many training programs for health providers. Emergency contraception is unique in that it is a postcoital method, women need it due to unexpected circumstances, and it must be taken within a short time frame. Provider training can help ensure quality of services. Pre-service training, as

part of the curriculum in university schools of medicine and pharmacy, can ensure long-term sustainability of provider training. For example, in Cambodia, provider training has been institutionalized by the University of Health Science Faculty of Pharmacy. The Faculty of Pharmacy adapted and—in collaboration with the Pharmacists Association of Cambodia—integrated PATH's pharmacy personnel training curriculum into the final year of studies.

Target Audiences for Training

Providers of emergency contraception will differ in each country, depending on the laws, regulations, and the sociocultural situations. Groups in both the public and private sectors that have been instrumental in providing emergency contraception information and services to women include:

- Nurses
- Physicians
- Trained health workers, such as community health volunteers and midwives
- Community-based distributors
- Pharmacists and pharmacy counter staff
- Peer educators such as youth leaders at factories*
- Domestic and sexual abuse and rape survivor counselors and advocates

Training should be adapted to meet the specific needs of the training participants. Assessment work can help guide training. Some important questions to ask when determining participants for training include:

- At what stage of introduction is emergency contraception currently?
- What is the educational background of participants?
- Which provider groups are most accessible to potential users of emergency contraception?
- Which provider groups will be able to reach the largest number of women?
- Which provider groups are the most motivated?

How to Use the Emergency Contraception Curriculum

This training curriculum can be adapted and used for a range of providers with differing levels of knowledge. For example, the emphasis on technical information or the time spent on interactive exercises can be modified and adapted to meet the needs of specific groups. This curriculum has been adapted and used successfully in several countries. Various adaptations have been incorporated into the curriculums of schools of pharmacy, as well as continuing education programs of health professional organizations. Efforts to

* Peer educators can play a critical role in raising awareness among women who might not otherwise receive information; however, they do not typically distribute ECPs or provide the kind of technical information contained in this module.

include emergency contraception in the curriculums of health provider training programs can help to ensure widespread provider knowledge about emergency contraception. Providers who are already trained in emergency contraception will benefit from periodic "refresher" training sessions that emphasize key elements of ECP service delivery as well as updated service delivery guidelines based on current medical evidence.

The curriculum guides the trainer through essential information about ECPs, related reproductive health issues such as sexually transmitted infections (STIs), and counseling issues such as continued contraception and referral. It is important for the trainer to become familiar with all of the material in this curriculum; however, it is not intended to be read aloud or used as a lecture script. The curriculum is formatted to create an interactive learning environment, and questions and activities are included to promote discussion. The activities aim to help the trainees improve their skills in providing ECPs and other reproductive health services. The curriculum and training materials presented here were drawn from a number of existing curricula and training resources.

Training techniques used throughout the curriculum include:

- Small and large group discussions
- Presentation of material by the trainer
- Role-play
- Brainstorming
- Games
- Working in small groups or pairs

The training tools are designed as a generic model for training various types of providers including clinicians and pharmacists. Consider including additional information specific to the level of provider that will be trained and the setting in which they will be providing ECPs to clients. Some topics for consideration include:

Clinicians

- Providing information (both verbal and written depending on the woman's need) about other ongoing family planning methods including the intrauterine device.
- Providing information about STIs including HIV/AIDS management and treatment.
- Providing information to women in a clinic setting; ensuring a private and supportive environment.
- Providing ECPs in advance of need to women at risk of unintended pregnancy.

Pharmacists

- Ensuring privacy in pharmacy settings.
- Providing women with appropriate verbal and printed instructions for using ECPs.
- Referring women to other health care providers for family planning methods and STI management/treatment.

The training session is scheduled to last for approximately five and a half hours depending on how many breaks are included.

Each section begins on a new page. **The trainer/presenter is encouraged to adapt and modify the training curriculum to best meet the needs of the audience and country situation.** Suggestions for the amount of time needed to conduct each session are also provided, but the trainer should adjust the time as appropriate for the audience. The type of training technique (e.g., role-play or group discussion) used for each section is also included after the section title. The trainer may change the methodology used for each section according to the audience—for instance, a group discussion could be changed to a presentation. In addition, depending on local realities and needs, there are certain activities or sections that might only be used for certain groups. Regardless of the techniques used, participants should be encouraged to share their thoughts, ideas, and experiences throughout the training.

Key points are included at the end of each section. The trainer should ensure that these messages are covered during the training. The training curriculum includes training aids (TAs), which are referenced throughout the curriculum.

Trainers should provide each training participant with a packet of materials to reinforce key points covered in the training. The packet of materials should include photocopies of handouts (HOs) and reference materials included in the curriculum notebook as well as any other materials deemed appropriate by the trainer or presenter. At the beginning of each session, the trainer is provided with a list of TAs and HOs used for that module. The trainer is also provided with a list of country-specific information needed for each module. The trainer should collect this information and insert it into the curriculum prior to conducting the training workshop. Technical references are listed at the end of the curriculum.

Once participants have completed the training, certificates of completion should be given.

Additional Resources for Developing Training Sessions

A resource for developing training sessions for pharmacists is: *Youth-Friendly Pharmacy Program Implementation Kit: Guidelines and tools for implementing a youth-friendly reproductive health pharmacy program* (PATH, 2003). This is also available on the internet at:

http://www.path.org/files/RH_PPIK_1.pdf ; http://www.path.org/files/RH_PPIK_2.pdf ; http://www.path.org/files/RH_PPIK_3.pdf ; http://www.path.org/files/RH_PPIK_4.pdf ; http://www.path.org/files/RH_PPIK_5.pdf.

Resources for developing clinician focused training sessions can be found at: http://www.path.org/resources/ec_diverse-communities-proj.htm#notebook.

The International Consortium for Emergency Contraception's *Emergency Contraception Pills: Medical and Service Delivery Guidelines* provides medical guidelines that can serve as a standard of care for implementing a service protocol around ECPs. It can be found in the appendix. It is also available on-line at:

http://www.cecinfo.org/html/res-downloadable-mtrls.htm.

Module H Tools List

Emergency Contraception Curriculum

A curriculum for training providers of emergency contraception with information on unintended pregnancy, background on emergency contraception, regimen effectiveness, mechanism of action, safety and use, common side effects, counseling, screening and education, follow-up, and awareness and increasing awareness of ECPs. The tools listed below are to be used in conjunction with the curriculum.

Pre- and Post-Session Questionnaire

Questionnaires to be used both before and after the training to help the trainer understand and measure participant knowledge level and awareness.

Handout 1: Key Messages for Emergency Contraceptive Pill Clients

This tool has a list of key topics and issues that should be discussed with the client when providing ECPs. Alternatively, if privacy cannot be assured, the handout can be given to the client to take home.

Handout 2: Sample Emergency Contraceptive Pill Screening Checklist

This tool is designed to help providers remember what to ask a client when screening her for ECP provision.

Handout 3: Counseling for Emergency Contraceptive Pill Clients

This tool helps train providers to counsel women in a manner that is respectful of the client and responsive to her needs for information and counseling.

Handout 4: Counseling Skills Observer Checklist

This tool can be used both in training and as a reminder for providers on the best ways to counsel women for ECP use.

Training Aid 1: Grab Bag—Key Messages for Emergency Contraceptive Pill Clients

These statements are intended to be used as training tools for providers. The pieces can be drawn from a bag or hat and act as prompts for what a provider should tell a client about ECPs.

Training Aid 2: Demonstration Role-Play

This role-play is a tool that can help providers prepare for a variety of situations in which many different types of women may request ECPs.

Training Aid 3: Emergency Contraceptive Pill Client Situation Role-Plays

These role-plays are tools that can help providers prepare for the many different types of situations and women that may request ECPs.

Emergency Contraception Curriculum for {insert group} in {insert country}

Overview

Learning objectives

By the end of this training, participants will be able to:

- Describe the history and expanding role of emergency contraception in pregnancy prevention.
- Describe key facts about emergency contraception including different regimens, effectiveness, mechanism of action, safety, and side effects.
- Exhibit good emergency contraceptive counseling skills.
- Identify mechanisms for raising awareness of emergency contraception within the client population.
- Increase their awareness of emergency contraception resources in [*insert country*].

Time

Approximately 5 hours and 30 minutes (depending on length and frequency of breaks).

Agenda

1. Introduction and Pre-Session Questionnaire (15 min.)
2. Unintended Pregnancy (30 min.)
3. Background on Emergency Contraception (25 min.)
4. Effectiveness of Two Emergency Contraceptive Pill Regimens (20 min.)
5. Description of Emergency Contraceptive Pill Regimens (15 min.)
6. Emergency Contraceptive Pill Mechanism of Action (20 min.)
7. Emergency Contraceptive Pill Safety and Use (15 min.)
8. Common Side Effects (15 min.)
9. Emergency Contraception Screening and Communication (20 min.)
10. Counseling for Emergency Contraceptive Pill Clients (45 min.)
11. Follow-Up and Referral for Clients (15 min.)
12. Increasing Awareness of Emergency Contraception (30 min.)
13. Review, Conclusion, and Post-Session Questionnaire (20 min.)

Handouts and training aids

Pre- and Post-Session Questionnaire

HO 1: Key Messages for Emergency Contraceptive Pill Clients

HO 2: Sample Emergency Contraceptive Pill Screening Checklist

HO 3: Counseling for Emergency Contraceptive Pill Clients

HO 4: Counseling Skills Observer Checklist

TA 1: Grab Bag—Key Messages for Emergency Contraceptive Pill Clients

TA 2: Demonstration Role-play

TA 3: Emergency Contraceptive Pill Client Situation Role-Plays

Preparation

You will need the following materials:

- Flip chart, overhead, or chalkboard
- Markers or chalk

Local data on the following issues can be used:

- Number of unintended pregnancies by year for the past several years.
- Number of pregnancies in girls under 15 years of age for the past several years.
- Number of abortions by year.
- Number of abortions to girls under 15 years of age by year.
- Emergency contraception availability.
- Status of dedicated emergency contraceptive pill product.
- Emergency contraception awareness or use.
- Local brands of antiemitics (i.e., antinausea drugs).

Content and format for this curriculum were adapted from:

- *Diverse Audiences Emergency Contraception Clinical Provider Training Curriculum*. Seattle, WA: PATH (2000).
- *Comprehensive Reproductive Health and Family Planning Training Curriculum* (Module 5: Emergency Contraceptive Pills). Watertown, MA: Pathfinder International (revised 2000).
- *Special Report on Emergency Contraception: The Pharmacist's Role*. American Pharmaceutical Association (2000).
- *Expanding Global Access to Emergency Contraception: A Collaborative Approach to Meeting Women's Needs*. Seattle, WA: International Consortium for Emergency Contraception (2000).

Introduction and Pre-Session Questionnaire

(15 Minutes)

1. **Introduce trainer and participants.**
2. **Review objectives of this session (write out on flip chart paper, overhead, or chalkboard).**
3. **Establish time frame for this session.**

See **Overview** for objectives. Emphasize practical approach of training.

This training is designed to build knowledge of emergency contraception (EC) by providing accurate, up-to-date information. The session is scheduled to last for approximately five hours and thirty minutes. During the session participants will share their thoughts, ideas, and experiences in discussions, small group work, role-plays, and large group discussions. Encourage participants to ask questions when they have them.

4. **Distribute pre-session questionnaire. Allow participants approximately ten minutes to complete the questionnaire.**

Unintended Pregnancy

(30 Minutes)

Discussion, presentation, pair work, and brainstorming

1. **Ask participants "What is unintended pregnancy? How common is it?" List participants' responses on a flip chart, overhead, or chalkboard.**
2. **Using the participant responses, define unintended pregnancy and its consequences. Present information below if necessary.**
3. **Link this information to the need for EC, citing data on need from [insert country]**

Definition: *Unintended pregnancy* is "a pregnancy that is unwanted or mistimed at conception." Unintended pregnancy **does not** mean unwanted births or unloved children. However, it **does** mean less opportunity to prepare and less time for:

- Prepregnancy risk identification.
- Management of preexisting conditions.
- Changes in diet and vitamins.
- Avoidance of alcohol, toxic exposure, and smoking.
- Ensuring the financial resources needed to deliver and support a new child.

Each year in the world:

- Seventy-five million women experience an unintended pregnancy.[1]
- Thirty million women experience contraceptive failure.[2]
- Approximately 43 million abortions occur, of which twenty million are unsafe.[3,4]

4. **Ask participants to work in pairs for five minutes. Each pair should make a list of their responses to the question: "What are the consequences of unintended pregnancy?"**
5. **Ask several volunteers to offer items from their list. Present information below as summary.**

Consequences of unintended pregnancies can be significant.

Possible responses include:

- Health risks to mother.
- Reliance on abortion to end pregnancy.
- Discontinuation of schooling (for adolescents).
- Emotional distress.
- Economic hardship.
- Disapproval from the community, especially for young, unmarried women.
- Possible health risks to infants, including birth injuries, lower birth weight, and a lower chance of survival.[5]

Where abortion is illegal or restricted by age, women may seek an illegal provider who may be unskilled or may practice under unsanitary conditions. Unsafe abortion represents a high

proportion of the maternal deaths. Nearly 14 percent of all maternal deaths are the result of abortion complications.[4] [*Insert country-specific data on unsafe abortion.*]

6. Briefly introduce EC using the information below.

Emergency contraception is the only currently available contraceptive method that **prevents** pregnancy **after** sexual intercourse and **before** implantation. Because there is no perfect form of contraception and there are very few perfect contraceptive users, it is important to remember that even those couples using contraception faithfully and correctly can experience contraceptive failure.

7. Ask participants "Why or when would someone need EC?" List participants' responses on a flip chart, overhead, or chalkboard.

8. Discuss and complement participant responses with the information below.

There are different reasons a client might need EC. Those reasons are:

- If a couple recently had sex without using contraception.
- If a condom broke or slipped.
- If a woman using oral contraceptive pills missed three or more pills.
- If a woman using contraceptive injections was late for her shot.
- If a woman thinks that her diaphragm or cervical cap slipped.
- If a woman experienced an IUD expulsion.
- If sex was forced (rape).

Summary of key points

- [*Insert country-specific data to demonstrate the magnitude of the problem of unintended pregnancy.*]
- EC has a very strong potential role in reducing unintended pregnancy.
- The health and social consequences of unintended pregnancy are significant.
- Use of EC after contraceptive failure or when no contraception was used represents a responsible choice to prevent pregnancy.

Background on Emergency Contraception

(25 Minutes)

Brainstorming and presentation

1. **Ask participants "What do you know or what have you heard about EC?"**
2. **List participants' responses on flip chart, overhead, or chalkboard. Tell participants that while some of the things they have heard or believe about EC may not be completely correct, the training session today will clarify points of confusion and correct any misinformation.**
3. **Highlight the history of EC introduction with specific information about EC introduction and availability in [insert country].**

Emergency contraception is not new.

- High-dose estrogens were used for EC in the 1960s.
- In the mid-1970s, Dr. Albert Yuzpe's research on high-dose estrogen regimens led to the current regimen utilizing available combined oral contraceptive products. Also in the 1970s, research began on the use of progestin-only pills.
- Regulatory authorities throughout the world (including France, the United Kingdom, and the United States) have approved EC products. Emergency Contraceptive Pills (ECPs) are on the World Health Organization Model Essential Medicine List. (See the appendix for a list of website resources and a link to the WHO Essential Medicine List. This list also provides a link to the International Consortium for Emergency Contraception's list of other countries with registered EC products.)
- [Insert relevant country-specific data on EC introduction and availability.]
- With these developments, the use of EC is increasing and likely will continue to expand. It is important that providers be prepared to help women use it effectively.

4. **Explain the two types of EC.**

There are **two types of EC:** ECPs and IUD insertion.

ECPs

ECPs are higher doses of the same hormones found in ordinary birth control pills. ECPs should be initiated as soon as possible within **5 days** (120 hours) after unprotected sex. ECPs are more effective the sooner they are taken.[6] *Women should be encouraged to take the ECPs as soon as possible within 120 hours, but they should understand that the effectiveness of the pills is lessened the longer one waits after intercourse to take them.*[6]

ECPs are sometimes referred to as the "morning after pill," despite the longer window of opportunity for their use. Recommended dosing differs depending on the type of ECP that is taken.

ECPs are not the same as misoprostol, mifepristone, or RU486 (the French abortion pill), and they cannot cause an abortion.

ECPs can be provided to women **before** they need them. We know that contraceptives fail and sometimes women are unable to use a contraceptive method. Therefore, it may be important for

women to have ECPs available at home in the event that they have unprotected intercourse and do not want to get pregnant. Having ECPs at home will help ensure that they are easily available and can be used soon after intercourse when they are most effective.

IUD Insertion

IUD insertion within **7 days** of unprotected sex also is an effective form of EC and has the added benefit of providing the client with a long-term contraceptive method. Providers not trained in IUD insertion can refer women to health care providers for this procedure. However, this must occur within the time frame above.

A copper-T IUD used for EC reduces the risk of pregnancy after unprotected intercourse by 99 percent.[7]

If inserted for EC, IUDs can be retained for up to 10 years or removed during the client's next menstruation.

Screening for an IUD as an EC method should follow regular IUD screening criteria. In addition, the provider should ascertain that the unprotected intercourse occurred within 7 days of seeking treatment.

NOTE: If asked about the mechanism of action, the trainer may explain that the copper on the IUD can prevent fertilization or inhibit implantation.

5. Note to participants that the training will focus on ECPs because they are accessible through a variety of providers, whereas IUDs can only be inserted by physicians.

Summary of key points

- EC has been in use for over 30 years and many international regulatory bodies approve it.
- There are two types of EC: ECPs and IUD insertion. ECPs are the focus of the training since they are the most easily accessible and available.
- EC is increasingly being recognized as a standard of care for prevention of pregnancy after unprotected intercourse.

Effectiveness of Two Emergency Contraceptive Pill Regimens

(20 Minutes)

Presentation

Introduce the two types of ECP regimens, review their effectiveness, and discuss the dosage requirements. Use the information below.

There are two types of ECPs currently in use that will be discussed in this training. Each type or regimen is defined by the type of hormone or active ingredients used.

- The **progestin-only regimen** consists of 1.5mg levonorgestrel (or 3.0 norgestrel) taken in a single dose as soon as possible after unprotected intercourse. It can be taken up to 120 hours or five days after unprotected intercourse. *It is important to take the pills as soon as possible because their effectiveness decreases over time.*
- **Estrogen and progestin** (the **combined regimen**, or the Yuzpe regimen), is ethinyl estradiol plus levonorgestrel (or norgestrel). Take the *first dose as soon as possible* after unprotected intercourse and the **second dose 12 hours later**. It can be taken up to 120 hours or five days after unprotected intercourse. *It is important to take the pills as soon as possible because their effectiveness decreases over time.*

Note: The two doses of the combined ECP regimen should NOT be taken at one time because of the increased risk of nausea and vomiting.

The differences in both effectiveness and side effects between the two methods are significant and substantial. **The progestin-only method is both more effective and produces fewer side effects.**

Regimen	Effectiveness	Side effects
Progestin-only	Reduces the risk of pregnancy by **89 percent**.*	**Nausea** in 23 percent of women and **vomiting** in 6 percent.[8]
Combined estrogen/ progestin	Reduces the risk of pregnancy by **75 percent**.*	**Nausea** present in 43 percent of women using this regimen and **vomiting** in 16 percent.[9]

If vomiting occurs within one hour after taking a dose, take another dose as soon as possible. If vomiting occurs more than one hour after taking ECPs, you do not need to repeat the dose.

Neither method will work if a woman is already pregnant.

Research has demonstrated that the efficacy of ECPs decreases as the time increases between intercourse and use of ECPs.[9] This means that women must have ready access to ECPs in order to maximize their effectiveness.

Almost all other contraceptive methods are more effective than ECPs for *regular ongoing use*. ECPs are not 100 percent effective. Women who use them on a regular basis repeatedly expose themselves to the risk of method failure. ECPs reduce the risk of pregnancy by 75 to 89 percent. That is to say that, if 100 women have unprotected intercourse during their most fertile times of the month and take:

- A progestin-only EC regimen, then 1 will become pregnant, a 89 percent reduction in pregnancy risk.
- A combined estrogen/progestin EC regimen, then 2 will become pregnant, a 75 percent reduction in pregnancy risk.[8]

*These estimates of reduction in the risk of pregnancy following ECP use are based on studies that evaluated ECP use within a 72-hour time frame.

The more times a woman uses the method, the more times she exposes herself to pregnancy risk. Additionally, regular ECP use (four or more times a month) causes bleeding irregularity. While not necessarily a health risk, irregular bleeding is unacceptable to most women.

Summary of key points

- There are two ECP regimens: progestin-only and combined estrogen and progestin.
- The progestin-only regimen is more effective and has fewer side effects.
- Both ECP regimens are more effective the sooner they are taken.
- The **progestin-only** regimen (1.5mg dose of levonorgestrel) can be safely and effectively taken at one time, rather than 12 hours apart.
- ECPs are not intended for regular use; almost all other contraceptive methods are more effective.

Description of Emergency Contraceptive Pill Product Regimens

(15 Minutes)

Presentation and discussion

1. **Explain that ECPs are available in many countries as a dedicated (specifically packaged) product. Discuss the availability of a dedicated product in [*insert country*].**

Both the progestin-only and combined regimens are available in some countries as dedicated ECP products—those packaged and labeled specifically for use as ECPs. If it is available and affordable, the progestin-only regimen is recommended over the combined regimen. The progestin-only regimen is more effective and has fewer side effects. The combined regimen, however, is better than no ECPs at all.

[*Insert country-specific data on status of dedicated product. Include information on the brand name, the cost and whether the product is available in pharmacies.*]

2. **Ask participants if they have heard of regular oral contraceptive pill packets being used for EC. Ask, "How can regular oral contraceptive pills be used as EC?"**
3. **Explain the different ways EC may be provided with regular oral contraceptive pills using the information provided below. Have participants follow the discussion using the table in HO 1: Key Messages for Emergency Contraceptive Pill Clients.**

Regular oral contraceptive pills can be used for EC. The doses of combined oral contraceptives approximate the amount of the estrogen and the progestin used in the Yuzpe regimen. Most of the brands listed in the table 5 on the third page of HO 1: *Key Messages for Emergency Contraceptive Pill Clients* (and the next page) require taking 2 or 4 pills for the first dose and 2 or 4 pills for the second dose. Because these are combined (estrogen and progestin) pills, they cannot be taken in a single dose.

ECP Formulations

	Formulation (per pill)	Common Brand Names	First Dose (number of tablets)	Second Dose (number of tablets)
Progestin-only Regimen	LNG 0.75 mg	Levonelle-2, NorLevo, Plan B, Postinor-2, Vikela	2 **(Single Dose)**	0
Combined Regimen	EE 50 mcg + LNG 0.25 mg or EE 50 mcg + NG 0.50 mg	Eugynon 50, Fertilan, Neogynon, Noral, Nordiol, Ovidon, Ovral, Ovran, PC-4, Preven	2	2
	EE 30 mcg + LNG 0.15 mg or EE 30 mcg + NG 0.30 mg	Lo/Femenal, Microgynon 30, Nordette, Ovral L, Rigevidon,	4	4

Abbreviations: EE = ethinyl estradiol LNG = levonorgestrel NG = norgestrel

For all regimens, the first dose should be taken as soon as possible after intercourse, but optimally within 120 hours. The second dose of the combined regimen should be taken 12 hours after the first dose. The progestin-only regimen doses may be taken all at one time.

Adapted from: *Expanding Global Access to Emergency Contraception.* International Consortium for Emergency Contraception (October 2000), p. 47.

Information in this table has been updated to reflect current research:
von Hertzen, H. et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomized trial. *Lancet* 360(9348):1803-1810 (2002).

To help the client avoid mistakes in taking the regimen, the provider or staff should cut up oral contraceptive pill packets and give only the specific number of tablets needed. Using sharp scissors helps ensure that the blister package is cleanly cut so that seals around individual tablets are not broken. If it is not possible or acceptable to cut the packet, it is preferable to prescribe and dispense a 21-day pack (rather than a 28-day pack with inert/placebo tablets) so that the client will not take the inert tablets in error.

When low-dose progestin-only pills are used as ECPs, it is important to emphasize that *it is correct and safe* to take the 20 (or 25, depending on the brand used) tablets for each dose.

It is critical to ensure the client understands the dosage. When oral contraceptive pills are prescribed and dispensed for use as ECPs, it is important that the product is identified clearly, and that the women are instructed carefully about the number and color of the tablets required for each dose. To help ensure compliance with the regimen when using regular oral contraceptives, provide written information. Manufacturers of oral contraceptives do not provide patient information about EC.

High-dose oral contraceptive combinations (pills containing more than 50 µg of estrogen) and triphasic formulations* **should not be used** as ECPs.

Summary of Key Points

- There are dedicated ECP products in many countries.
- Dedicated ECP products are preferred because they are packaged and labeled specifically for use as ECPs and because there is less chance for error.
- Where no dedicated product is available, regular oral contraceptive pills can be used for EC.
- When COCs are repackaged as ECPs, provide clear product identification and client instructions.
- ECP availability in [insert country].

*Triphasic formulation of OCs alter the dosage of estrogen and progestin throughout the monthly regimen to alter steroid levels in an effort to minimize metabolic effects and breakthrough bleeding and amenorrhea. They should not be used as ECPs.

Emergency Contraceptive Pill Mechanism of Action

(20 Minutes)

Brainstorming, discussion, and presentation

Note to Trainer: You may wish to have a physician or other clinician present during the discussion on ECP mechanism of action to help explain the process of pregnancy and how hormonal contraceptives work.

1. **Ask participants "How do ECPs prevent pregnancy?" Confirm or correct participants' responses.**
2. **Note the content of participants' responses related to ECPs' mechanism of action on a flip chart, overhead, or chalkboard.**
3. **Provide the information below if it is not covered through the question and answers.**

ECPs work the same way regular oral contraceptive pills work. These pills may work in more than one way. We clearly understand some of these ways; others are possible but not yet proven.

- Statistical evidence suggests that ECPs must work through more than one mechanism of action or they could not be as effective as they are.[10]
- Research has shown that ECPs can inhibit or delay ovulation.[11,12,13]
- ECPs may prevent implantation (i.e., the implanting of the fertilized egg in the lining of the uterus) by altering the endometrium (the lining of the uterus). However, the evidence for endometrial effects of ECP treatment is mixed, and it is not clear that the endometrial changes would inhibit implantation.[12, 13,14,15,16,]
- It is possible that ECPs inhibit fertilization—through thickening of the cervical mucous resulting in trapping of sperm or alterations in the tubal transport of sperm or egg—but no data exist regarding confirmation of this possible mechanism of action.

Timing plays a key role in how ECPs work. Of particular importance is:

- Cycle day on which intercourse occurred.
- Cycle day on which treatment is used.[17]

ECPs' role in preventing pregnancy:

- It takes about **6 days** after ovulation for a fertilized egg to begin to implant. **Therefore, intervention within 120 hours or up to 5 days cannot result in abortion.**
- As mentioned earlier, ECPs will not work if implantation has occurred and a woman is already pregnant.

ECPs do not interfere with an established pregnancy. Studies of oral contraceptives taken inadvertently in early pregnancy show no increased risk of miscarriage or congenital abnormalities.[18,19]

Women may want to know how ECPs work in order to make an informed choice about ECP use. Therefore, it is important that the provider understand and be able to describe how ECPs work.

Important points to communicate to clients about the mechanism of action are that ECPs:

- Work through various mechanisms.
- Will not interrupt or harm an established pregnancy (i.e., it is NOT a medical abortion).

- Are not the same as mifepristone (RU486, the "Abortion Pill"), which is used to terminate an established pregnancy.

Summary of Key Points

- ECPs are thought to work in several ways. We have more clinical evidence on some of these ways than on others. ECPs work the same way regular oral contraceptive pills work.
- ECPs will not cause an abortion.
- Timing plays a key role in how ECPs work.
- If a woman takes ECPs and still becomes pregnant, the pregnancy will not be harmed by the ECP use.
- ECPs will not affect a woman's ability to become pregnant in the future.

Emergency Contraceptive Pill Safety and Use

(15 Minutes)

Brainstorming, discussion, and presentation

1. **Ask participants "Do you think ECPs are safe?" and "Are there health conditions that would prevent you from providing ECPs to a woman?" Confirm or correct participants' responses.**
2. **Use a flip chart to record responses.**
3. **Highlight the points on safety provided below.**

According to the World Health Organization and the International Planned Parenthood Federation, there are no contraindications for ECPs because the amount of hormone is too small to have a clinically significant impact and the duration of use is very short.[20,21]

Many of the contraindications for daily oral contraceptives are based on the presumption of long-term use. The World Health Organization states that ECPs have no clinically significant impact on conditions such as cardiovascular disease, angina, acute focal migraine, or severe liver disease.[21]

Repeated use of ECPs is not harmful for most women. For some women who have sexual intercourse infrequently (defined as four or less times per month) and who are not at risk of sexually transmitted infections (STIs) or HIV, ECPs may be an appropriate method. For a woman who has regular intercourse (multiple times within a cycle), frequent use of ECPs is not recommended because other methods are more effective at preventing pregnancy. Additionally, frequent ECP use may be more expensive than using regular contraceptive methods. As mentioned earlier, repeated use of ECPs within the same cycle may cause bleeding disturbances, which while not harmful, are likely to be unacceptable to a woman. However, a woman should not be denied ECP services because she is a repeat user, unless she is someone for whom oral contraceptives are contraindicated. In this situation, nonjudgmental counseling about other methods is an important part of good service. If a woman regularly uses ECPs, it is important to try to determine why the woman is not using regular contraception and to counsel her about ongoing contraception.

There are no known drug interactions with ECPs. Given the short duration of treatment, it is unlikely that drug interactions that affect oral contraceptive use also affect ECP use. However, women taking drugs that may reduce the efficacy of oral contraceptives (including Rifampin and certain anticonvulsant drugs) should be advised that the efficacy of ECPs may be reduced.

Summary of key points

- ECPs can be safely used by women.
- Frequent ECP use (multiple times within one cycle) does not present a health risk, but is not recommended because it is not as effective as other methods.

Common Side Effects

(15 Minutes)

Brainstorming, discussion, and presentation

1. **Ask participants "What are the common side effects of ECPs and how can they be managed?"**
2. **Write responses on a flip chart.**
3. **Confirm or correct responses using the information below.**

ECPs sometimes cause side effects such as nausea, vomiting, headaches, dizziness, cramping, fatigue, or breast tenderness. These side effects usually go away within 1 to 2 days after taking the ECPs. ECPs also may cause irregular bleeding until the woman's next period, and her period may come early or late. However, in more than 90 percent of cases, menses will be of normal duration for the woman.[23] As mentioned earlier, the progestin-only regimen causes fewer of these side effects.

If a woman's period has not resumed within 4 weeks after taking the ECPs, she may be pregnant. It is important that women understand this and either return to the ECP provider for referral information or go to a clinic. This is especially important for women who take ECPs more than 120 hours after unprotected intercourse.

- The progestin-only regimen is preferred because it has fewer side effects than the combined regimen.
- Nausea and vomiting are common side effects of the combined regimen.

Regimen	Nausea	Vomiting	Recommendations
Progestin-only	Occurs in about 23 percent of women.	Occurs in only about 6 percent of women.[8]	Routine use of an antiemetic is not recommended before women take a dose of the progestin-only regimen.
Combined estrogen/progestin	Occurs in about 43 percent of women.	Occurs in about 16 percent of users.[9]	Prophylactic use of an antiemetic such as dimenhydrinate (Dramamine® or [*insert local brand name*]) is routinely recommended to reduce the risk of nausea and vomiting with the combined regimen.[9]

- If vomiting occurs within one hour after taking a dose, the woman should repeat the dose. This means she may need to return to the ECP provider or pharmacy for another dose. If vomiting occurs more than one hour after taking a dose, the pills already have been absorbed and the woman does not need to repeat the dose.

Insert side effect information for locally available dedicated product, if applicable.

Summary of key points

- Nausea and sometimes vomiting are potential side effects of ECP use. They are not dangerous and are far more common among women who use the combined ECP regimen.
- The progestin-only regimen is better tolerated.
- If a woman vomits within one hour after taking ECPs, she should repeat the dose.

- Antiemetics can reduce the frequency of nausea and vomiting with the combined regimen.
- If a woman's menstrual period is more than 4 weeks late, she may be pregnant and may need further counseling or referral services. It is especially important that women who take ECPs more than 120 hours after intercourse be informed about the possibility of pregnancy or ECP failure.

Emergency Contraception Screening and Communication
(20 Minutes)

Brainstorming, pair work, presentation, and discussion

1. **Ask participants "What key screening questions should a woman be asked when providing her with ECPs for recent unprotected intercourse?"**
2. **List responses on a flip chart, overhead, or chalkboard. Correct or complement participants responses with the questions listed below. This information is also provided in HO 2: Sample Emergency Contraceptive Pill Screening Checklist. Make sure participants understand that ECPs also can be provided before a woman needs them. For example, condom users may wish to keep a packet of ECPs at home in case of condom breakage.**

The important screening questions for ECP use following recent unprotected intercourse are:

- Do you want to prevent pregnancy?
- Have you had unprotected sex during the last 5 days (120 hours)?
- If "yes" then the client may be eligible for ECPs. Effectiveness will be lower the longer a woman takes to take ECPs.
- Was the last menstrual period less than 4 weeks ago?
- Was this period normal in both its length and timing?
- If "yes" to the previous two questions, ECPs may be provided.
- Is there reason to believe you may be pregnant?
- If the client is not pregnant, ECPs may be given. If the client's pregnancy status is unclear, ECPs may still be given, with the explanation that the method will not work if she is already pregnant.

3. **Tell participants we will now do an exercise to help them answer common questions clients who seek ECPs may have.**
4. **Cut up a copy of TA 1: *Grab Bag—Key Messages for Emergency Contraceptive Pill Clients* so that each question is on a separate strip of paper.**
5. **Place folded questions in a bag and shake to distribute them within the bag.**
6. **Invite one participant at a time to pick a question from the bag, read it aloud, and answer it. If the participant is unable to answer the question, it can be passed to another participant.**
7. **If the question cannot be answered by the second participant, answer the question and assist participants to understand it. Confirm or correct answers using the information below and in HO 1: *Key Messages for Emergency Contraceptive Pill Clients*.**

After a woman is screened for ECPs and given instructions on how to use them, it is important to ask if she has any further questions about ECPs. Some women will have many questions while others will have few, if any, but it is important to be able to answer women's questions when asked. Because not all women will need or want all of the information provided below in the key messages, it is recommended that it be used only when women ask for it. These messages are provided below and in HO 1: *Key Messages for Emergency Contraceptive Pill Clients.*

What are emergency contraceptive pills?

ECPs are pills that you can take after sex to prevent pregnancy. ECPs are useful if you have had sex without using contraception or if you had a contraceptive failure (such as a broken condom).

ECPs contain the same ingredients as pills used for regular contraception, but in higher amounts. They are effective and safe.

How do emergency contraceptive pills work?

Depending on when you use ECPs during your monthly cycle, ECPs may:

- Stop or delay an egg from being released from the ovary.
- Stop a fertilized egg from attaching to your uterus.
- Prevent the sperm from getting to the egg.

ECPs will not work once a pregnancy has started (a fertilized egg has implanted).

How effective are emergency contraceptive pills?

ECPs prevent most pregnancies, but they are not 100 percent effective.

When can I use ECPs?

ECPs can be used within five days of unprotected intercourse but are most effective the sooner they are used.

What if I had unprotected sex more than 5 days ago?

If more than 5 days have passed since you had unprotected sex, the ECPs may still have some effect but it is important to take them as soon as possible.

Do emergency contraceptive pills cause side effects?

ECPs sometimes cause nausea, vomiting, and less frequently, headaches, dizziness, cramping, fatigue, or breast tenderness. These side effects usually go away within a few days after you take the ECPs. ECPs also may cause irregular bleeding until your next period, and your period may come early or late.

What should I do after using emergency contraceptive pills?

You will not see any immediate signs showing whether the ECPs worked. Your menstrual period may come on time, or it may be early or late. If your period has not started within 4 weeks of taking ECPs, you might be pregnant. If you are pregnant, you need to consider what your options are. If you have any cause for concern, see your health care provider or pharmacist.

If the emergency contraceptive pills do not work and I become pregnant, will the pregnancy be normal?

Based on available evidence, there is no reason to believe that the pregnancy would be abnormal or that the fetus would be hurt in any way.

What if I have unprotected sex again after taking the emergency contraceptive pills?

If you have unprotected sex *after* using ECPs, they will not protect you. Use a regular contraceptive method to prevent pregnancy in the future.

Can I use emergency contraceptive pills every time I have sex?

No. ECPs should not be used routinely to prevent pregnancy because they are less effective and frequently more expensive than other family planning methods and may cause irregular bleeding.

Do emergency contraceptive pills prevent sexually transmitted infections?

No. ECPs do not protect against HIV/AIDS or other STIs like syphilis, gonorrhea, chlamydia, and herpes. If you are worried about whether you have an infection, talk to your health care provider or pharmacist about your concerns, and ask how you can get treatment and protect yourself in the future.

What if I had sex multiple times before taking emergency contraceptive pills?

ECPs are more effective the sooner after sex they are taken. Protection is greatest if sex occurred within 120 hours. Use the most recent act of unprotected intercourse to determine if you should take ECPs. While you may be pregnant from a previous act of unprotected intercourse, taking ECPs will not harm a developing fetus, and if you are not pregnant, using ECPs may still prevent pregnancy from the most recent act of unprotected intercourse.

Can I have a packet of emergency contraceptive pills to keep at home in case I need them?

Yes. ECPs are more effective the sooner they are used. It may be appropriate for some people, condom users for example, to keep a packet of ECPs at home to use in the event of unprotected sex. This will help ensure you can use ECPs as soon as possible after sex when they are most effective.

How do I use emergency contraceptive pills?

[This section will vary depending on country context and product availability.]

For the progestin-only regimen, take a single dose of 1.5 mg levonorgestrel as soon as possible within 120 hours after unprotected intercourse.

For the estrogen and progestin regimen, take the first dose as soon as possible within 120 hours after unprotected intercourse and take the second dose 12 hours later.

Summary of key points

- Key screening questions determine whether ECPs are an appropriate method for a client.
- Providers should be prepared to answer clients' questions about ECPs and provide them with key information to use ECPs correctly.
- ECPs can be provided to women and couples **before** they are needed, as a back up to condom use for example.

Counseling for Emergency Contraceptive Pill Clients

(45 Minutes)

Presentation, demonstration, role-playing, and discussion

1. Remind participants that counseling is an important part of ECP service delivery. Refer participants to HO 3: *Counseling for Emergency Contraceptive Pill Clients* and review the key points described there (also provided below).

As with any contraceptive method, ECPs should be provided in a manner that is respectful of the client and responsive to her needs for information and counseling. This is especially true for young women. As noted in HO 1: *Key Messages for Emergency Contraceptive Pill Clients*, this means maintaining a supportive, reassuring, participatory, and confidential environment.

Reassure all clients, regardless of age or marital status, that all information will be kept confidential.

Be supportive of the client's choices and refrain from making judgmental comments or indicating disapproval through body language or facial expressions while discussing ECPs with clients. Supportive attitudes will help set the stage for follow-up counseling about regular contraceptive use and STI prevention.

Actively involve the client in the counseling process. This may be more effective in ensuring compliance than simply providing her with information. This active involvement may include:

- Asking her what she has heard about ECPs.
- Discussing her experience with other contraceptive methods.
- Validating or correcting her ideas as appropriate.

Maintain privacy by ensuring that counseling is conducted in a private and supportive environment to the greatest extent possible. When it is difficult to maintain privacy, give the method to the client with appropriate verbal and printed instructions about both ECPs and other forms of regular contraceptive methods. If in a nonclinic setting, advise her to attend a clinic or contact a health care or family planning provider for counseling about regular contraceptive methods. Reassure the woman that all information will be kept confidential, including the fact that she has received ECPs.

2. Introduce the counseling steps of GATHER described below. Explain that this is a way of remembering the essential steps in counseling.

Greet.
Ask questions.
Tell client about specific reproductive health topics.
Help client make decision that is best for her/him.
Explain what to do.
Refer or schedule return visit, if appropriate.

3. Ask for a volunteer to play the part of client in a role-play to demonstrate effective counseling. The trainer plays the role of the provider. Give the participant TA 2: *Demonstration Role-Play* to read quickly.

4. **The other participants will observe, filling out a checklist to take note of what effective behaviors have been demonstrated by the trainer. Distribute HO 4: *Counseling Skills Observer Checklist*. Participants should also refer back to HO 2: *Sample Emergency Contraceptive Pill Screening Checklist* for additional questions to ask when screening clients for ECPs.**
5. **Discussion: Ask several participants to summarize what counseling steps they observed in the role-play. Process the activity with the following questions: "What did you like about the way the provider dealt with this client?" "What could he/she have done to make the interaction more effective?" "What have you learned from this exercise?"**
6. **Go over the summary of the basic steps of the client-provider interaction as provided below.**

In the role-play, the trainer should be sure to show a respectful attitude. Ask open-ended questions to invite the clients to communicate their needs openly. Screen briefly and confirm the confidential nature of these services. Ask if clients have questions, and listen to their concerns.

Summary of the basic steps of the client-provider interaction:

- Greet client, introduce yourself, and ask what she needs.
- Ask questions, screen client.
- Tell client about ECPs; give clear information about use, side effects, and follow-up.
- Help client make decisions. Provide written or pictoral instructions, if available.
- Explain what the options are, what the client should do. Discuss options for on-going contraception with client.
- Refer to other health care provider if necessary.

7. **Ask participants to work in pairs. Each pair will work for ten minutes to prepare a short role-play to demonstrate client counseling.**
8. **Give each pair one of the case studies on TA 3: *Emergency Contraceptive Pill Client Situation Role-Plays*. Request that participants do their best to demonstrate effective client service skills in the role-play.**
9. **Ask each pair to present their role-play. The other participants will observe.**
10. **When all the groups have presented, process the activity with the following questions:**
    (a) "What did you like about the way the he/she dealt with this client?"
    (b) "Did he/she provide correct information about ECPs and their use?"
    (c) "What could he/she have done to make the interaction more effective?"
    (d) "What have you learned from this exercise?"
11. **Ask participants what challenges they might encounter in providing good-quality services. Ask the group to brainstorm ways to meet these challenges.**

Summary of key points

- Treatment of clients, regardless of age or marital status, should always be courteous, respectful, nonjudgmental, and helpful.
- When possible, the regular use of contraceptive methods should be emphasized.
- When appropriate, assessment of STI risk should be made.
- When pharmacists and other nonclinical staff are providing ECPs, they should refer clients to health care clinics for further treatment (e.g., for STIs or possible pregnancy) and information and counseling about regular contraceptive methods.
- Women should never be denied access to ECPs to prevent pregnancy.

Follow-Up and Referral for Clients

(15 Minutes)

Presentation and brainstorming

1. **Ask participants "In what instances would it be good for a provider to follow up with a client after ECP provision?" and "In what instances would it be good for a provider to refer a client?"**
2. **Complement participants' responses with the information provided below.**

In some cases, it is important to provide follow-up care/evaluation after providing ECPs. The situations below represent possibilities for follow-up and referral:

- If the client reports no menses within 4 weeks of ECP use, she may be pregnant. It is normal for a woman's menses to begin a few days earlier or later than usual after taking ECPs. If a woman does not have a period within 4 weeks, she should be referred to a health care provider to discuss her next options.
- A client should be encouraged to return to her provider or the nearest health care facility if she has concerns or problems.
- Providers who offer routine contraceptive methods can dispense these at the time of ECP service or, if unavailable, the client may be referred to a pharmacy or other health care provider.
- Assessing STI risk and providing or referring the client for diagnosis or treatment is a critical part of EC services.
- Women who have been forced to have sex or have been sexually assaulted or raped may seek advice or services from you. As providers of EC, it is important to be attentive to the possibility that these women may be unaware that there is any method available that can prevent pregnancy after sexual assault. Seeking health services may be a stressful experience after the trauma of a sexual assault. Providers should be supportive and sensitive to the emotional turmoil that women in this situation may be experiencing. Women who have been sexually assaulted are also in need of diagnosis and possible treatment for STIs and should be offered treatment or referral to a sexual assault center or emergency treatment facility for a comprehensive evaluation and possible prophylactic STI treatment.

3. **Highlight need for ongoing contraceptive management and explain when this is appropriate according to the list below.**

Whenever possible, ECP counseling should include discussion of a long-term contraceptive plan. The following table clarifies the timeline for initiating regular contraceptive use after ECP use depending on the method selected.

Contraceptive method	Initiate use
Condom	immediately
Diaphragm	immediately
Oral contraceptives	immediately or after next menses*
Injectable/implant	within 7 days after next menses*

(*Use back-up method until menses occurs)

ECPs do not protect against STIs or HIV. People requesting EC may have been exposed to an STI. Providers play a pivotal role helping clients determine whether they are at risk of an STI, and if so, referring the client to a clinic for a check-up or providing services as necessary. Key questions that help clients assess their risk include:

- Do I have a new sexual partner?
- Do I have more than one sexual partner?
- Does my partner have more than one partner?
- Has my partner been diagnosed with a STI?
- Do I use intravenous drugs?
- Do I have any symptoms of STIs? Some common symptoms include:
  - Abnormal vaginal discharge
  - Genital sores or ulcers
  - Swollen nodes
  - Acute or chronic lower abdominal pain
  - Fever

Given the sensitive nature of these questions, it may be more appropriate to provide clients with a list of these questions.

Summary of key points

- Follow-up and referral are critical to good service.
- Women may have been exposed to STIs and need to assess their risk and be diagnosed and treated or referred, as appropriate.
- Women who have been sexually assaulted and abused should be referred to violence or rape relief resources.
- ECP discussions can lead to a long-term contraceptive plan.
- ECPs **DO NOT** protect against STIs. Providers should assess STI risk and make referrals as part of ECP provision.

Increasing Awareness of Emergency Contraception
(30 Minutes)

Small group work and discussion

1. **Ask participants to work in groups of five and answer two questions:**
   (a) "What are the greatest barriers to EC use?"
   (b) "What can you do specifically to increase awareness of EC in your community?"
2. **Let participants discuss in small groups for ten minutes. Ask each group to prepare their list of answers on a flip chart, overhead, or chalkboard and present to the group.**
3. **Encourage participants to include ideas about raising awareness within their communities or among their colleagues.**
4. **After all the groups have presented, allow time for large group discussion.**
5. **Highlight lack of awareness of EC in [*insert country*] based on information below and gathered in baseline assessment.**

In [*insert country*], one of the greatest barriers to the use of EC is lack of awareness. Because the public is largely uninformed about the method, there are obstacles to the widespread provision of EC.

[*Insert country-specific data on EC awareness from assessment (if there is one).*]

Women's (especially young women's) awareness of EC remains low; therefore, the method remains underused. Some of the reasons clients find it difficult to discuss EC are:

- Shame about improper use of, or lack of use of, contraception.
- Discomfort discussing topics related to sexuality.
- Cultural issues related to provider/client relationship.
- Fears about confidentiality (particularly with adolescents).

Without knowledge about EC, clients are unable to make informed contraceptive choices. It is important that clients have access to this information from a highly valued source. As providers, you play a pivotal role in expanding women's awareness of, and access to, this critical contraceptive option. Education about EC is important both for couples who do not use a contraceptive method at all and for those who use a method that fails, because EC can act as a backup. The knowledge that a backup exists may encourage couples to adopt the use of condoms as a method of preventing HIV infection and STIs. **Providers can play a number of important roles in the provision of EC**. These include:

- Counseling clients to explain or reinforce key points about EC use.
- Educating clients about EC.
- Creating an environment that encourages people to seek ECP services.

All providers should be aware of key issues involving EC, such as the need to begin therapy as soon as possible, preferably within 120 hours after unprotected intercourse.

Thus far, training has focused on providing ECPs after unprotected sexual intercourse. **However, advance distribution and prescribing of ECPs can greatly improve the convenience of the method and help ensure that women have access to treatment as soon as they need it.** This is particularly important in view of research that demonstrates improved efficacy with earlier ECP use. Transportation can be a significant barrier for access to ECPs; advance prescribing, when appropriate, helps to control for this barrier. Providers should dispense ECPs to women who may wish to keep them at home to use in the event of unprotected intercourse.

Some providers raise concerns about whether providing ECPs to women ahead of time will make them more likely to use them irresponsibly. Research has not found this to be true.

Summary of key points

- Many women are not informed about EC.
- Providers can help expand knowledge and use of this important contraceptive method.
- Advance distribution can improve client access to and effective use of ECPs.

Review, Conclusion, and Post-Session Questionnaire
(20 Minutes)

Presentation and discussion

1. **Review the session's objectives and ask for final questions and comments.**
2. **Make recommendations on how providers can help increase awareness of EC using the information below.**

The most important thing providers can do to improve the consistent and appropriate use of EC is to talk about it with clients. Providers have a crucial role to play in reducing unintended pregnancy by educating clients about EC and providing it when appropriate.

Reaching women with EC information and services poses special challenges. Some women may find it difficult to access reliable information and services because they:

- Are unaware of the availability of ECPs.
- Lack confidence or are embarrassed to ask for ECPs.
- Are unaware that some providers can help them.
- Are anxious about judgmental attitudes of providers.

The following recommendations can help increase adolescent clients' awareness of EC:

- Routinely advise clients about ECPs as a backup to contraceptive accidents.
- Make EC informational materials available and actively refer clients to them.
- Encourage clients to obtain advance-of-need ECPs, if appropriate.
- Display youth-friendly posters, signs, or other logos.

3. **Distribute post-session questionnaire. Allow participants approximately ten minutes to complete the questionnaire.**
4. **Collect the post-session questionnaire and then go over it, asking participants to call out the correct answers.**
5. **Thank everyone for their participation in the training.**

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Pre- and Post-Session Questionnaire

Emergency Contraceptive Pills (ECPs)

Respondent Background:

I am: ___ Male ___ Female
I am: ___ Pharmacist ___ Doctor ___ Nurse ___ Midwife
___ Other, specify:_____

Mark the following statements as true or false.	True	False
1. Progestin-only emergency contraception pills (ECPs) reduce the risk of pregnancy by 89 percent.		
2. ECPs may be used up to 120 hours (5 days) after unprotected intercourse.		
3. There are no contraindications to ECP use.		
4. ECPs provide protection against HIV/AIDS and other sexually transmitted infections.		
5. Depending on local regulations, ECPs can be provided safely by properly trained doctors, nurses, pharmacists, and pharmacy staff.		
6. ECPs are an effective, regular contraceptive method.		
7. Condoms and other barrier methods may be started immediately following ECP use.		
8. ECPs cannot cause an abortion.		
9. The most common side effects of ECPs are nausea and vomiting.		
10. All clients should undergo a full pelvic exam before receiving ECPs.		
11. ECPs can be used safely by adolescent girls.		
12. ECPs are more effective the sooner they are taken after intercourse.		
13. ECPs should not be provided to clients before they need them.		
14. Regular oral contraceptive pills cannot be used for EC.		

Pre- and Post-Session Questionnaire

Emergency Contraceptive Pills (ECPs)

Answer Key

Mark the following statements as true or false.	True	False
1. Progestin-only emergency contraception pills (ECPs) reduce the risk of pregnancy by 89 percent.	X	
2. ECPs may be used up to 120 hours (5 days) after unprotected intercourse	X	
3. There are no contraindications to ECP use.	X	
4. ECPs provide protection against HIV/AIDS and other sexually transmitted infections.		X
5. Depending on local regulations, ECPs can be provided safely by properly trained doctors, nurses, pharmacists, and pharmacy staff.	X	
6. ECPs are an effective, regular contraceptive method.		X
7. Condoms and other barrier methods may be started immediately following ECP use.	X	
8. ECPs cannot cause an abortion.	X	
9. The most common side effects of ECPs are nausea and vomiting.	X	
10. All clients should undergo a full pelvic exam before receiving ECPs.		X
11. ECPs can be used safely by adolescent girls.	X	
12. ECPs are more effective the sooner they are taken after intercourse.	X	
13. ECPs should not be provided to clients before they need them.		X
14. Regular oral contraceptive pills cannot be used for EC.		X

Handout 1:
Key Messages for Emergency Contraceptive Pill Clients

What are emergency contraceptive pills?

- Emergency contraceptive pills (ECPs) are pills that you can take after sex to prevent pregnancy. ECPs are useful if you had sex without using contraception or if you had a contraceptive failure (such as a broken condom).
- ECPs contain the same ingredients as some pills used for regular contraception, but in higher amounts. They are effective and safe for almost all women.

How do emergency contraceptive pills work?

Depending on when you use ECPs during your monthly cycle, ECPs may:

- Stop or delay an egg from being released from the ovary.
- Stop a fertilized egg from attaching to your uterus.
- Prevent the sperm from getting to the egg.

ECPs will not work once a pregnancy has started.

How effective are emergency contraceptive pills?

- ECPs prevent most pregnancies, but they are not 100 percent effective.

When can I use ECPs?

- ECPs can be used within five days of unprotected tercourse but are most effective the sooner they are used.

What if I had unprotected sex more than 5 days ago?

- If more than 5 days have passed since you had unprotected sex, the ECPs may still have some effect but it is important to take them as soon as possible.

Do emergency contraceptive pills cause side effects?

- ECPs sometimes cause nausea, vomiting, headaches, dizziness, cramping, fatigue, or breast tenderness. These side effects usually go away within a few days after you take the ECPs. ECPs also may cause irregular bleeding until your next period, and your period may come early or late.

What should I do after using emergency contraceptive pills?

- You will not see any immediate signs showing whether the ECPs worked. Your menstrual period may come on time, or it may be early or late. If your period has not started within 4 weeks of taking ECPs, you might be pregnant. If you are pregnant, you need to discuss your options with a health care provider. If you have any cause for concern, see your health care provider or pharmacist.

If the emergency contraceptive pills do not work and I become pregnant, will the pregnancy be normal?

- Based on available information, there is no reason to believe that the pregnancy would be abnormal or that the fetus would be hurt in any way.

What if I have unprotected sex again after taking the emergency contraceptive pills?

- If you have unprotected sex *after* using ECPs, they will not protect you. You will need to repeat the treatment. Use a regular contraceptive method to prevent pregnancy in the future.

Can I use emergency contraceptive pills every time I have sex?

- **No.** ECPs should not be used routinely to prevent pregnancy because they are less effective and frequently more expensive than other family planning methods and may cause irregular bleeding.

Do emergency contraceptive pills prevent sexually transmitted infections?

- **No.** ECPs do not protect against HIV/AIDS or other sexually transmitted infections (STIs) like syphilis, gonorrhea, chlamydia, and herpes. If you are worried about whether you have an infection, talk to your health care provider or pharmacist about your concerns and ask how you can get treatment and protect yourself in the future.

What if I had sex multiple times before taking emergency contraceptive pills?

- You can still use ECPs if the last time you had sex is within 5 days. If you are already pregnant from an earlier act of unprotected sex, the ECPs will not have any effect. ECPs are more effective the sooner after sex they are taken.

Can I have a packet of emergency contraceptive pills to keep at home in case I need them?

- **Yes.** ECPs are more effective the sooner they are used. It may be appropriate for some people, condom users for example, to keep a packet of ECPs at home to use in the event of unprotected sex. This will help ensure you can use ECPs as soon as possible after sex when they are most effective.

How do I use emergency contraceptive pills?

- For the progestin-only regimen, take a single dose of 1.5 mg levonorgestrel as soon as possible within 120 hours after unprotected sex.
- For the estrogen and progestin regimen, take the first dose as soon as possible within 120 hours after unprotected sex and take the second dose 12 hours later.

Specific information about the ECP formulations is provided in the table below.

[This section depends on country context and product availability.]

ECP Formulations

	Formulation (per pill)	Common Brand Names	First Dose (number of tablets)	Second Dose (number of tablets)
Progestin-only Regimen	LNG 0.75 mg	Levonelle-2, NorLevo, Plan B, Postinor-2, Vikela	2 **(Single Dose)**	0
Combined Regimen	EE 50 mcg + LNG 0.25 mg or EE 50 mcg + NG 0.50 mg	Eugynon 50, Fertilan, Neogynon, Noral, Nordiol, Ovidon, Ovral, Ovran, PC-4, Preven	2	2
	EE 30 mcg + LNG 0.15 mg or EE 30 mcg + NG 0.30 mg	Lo/Femenal, Microgynon 30, Nordette, Ovral L, Rigevidon,	4	4

Abbreviations: EE = ethinyl estradiol LNG = levonorgestrel NG = norgestrel

For all regimens, the first dose should be taken as soon as possible after intercourse, but optimally within 120 hours. The second dose of the combined regimen should be taken 12 hours after the first dose. The progestin-only regimen doses may be taken all at one time.

Adapted from: *Expanding Global Access to Emergency Contraception.* International Consortium for Emergency Contraception (October 2000), p. 47.

Information in this table has been updated to reflect current research:
von Hertzen, H. et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomized trial. *Lancet* 360(9348):1803-1810 (2002).

Content and format were adapted from *Special Report on Emergency Contraception: The Pharmacist's Role.* American Pharmaceutical Association (2000).

Handout 2:
Sample Emergency Contraceptive Pill Screening Checklist

1. Do you want to prevent pregnancy?	**Yes**	**No**
2. Have you had unprotected sex during the last 5 days (120 hours)?	**Yes**	**No**

If "**Yes**", then the client may be eligible for ECPs. It is important to take them as soon as possible after uprotected sex. After 120 hours (5 days) ECPs can no longer be considered to be effective.

3. Was the last menstrual period less than 4 weeks ago?	**Yes**	**No**
4. Was this period normal in both its length and timing?	**Yes**	**No**

If "**Yes**" to the previous two questions, ECPs may be provided.

5. Is there reason to believe that the you may be pregnant?	**Yes**	**No**

If the client is not pregnant, ECPs may be given. If the client's pregnancy status is unclear, ECPs may still be given, with the explanation that the method will not work if she is already pregnant and will not harm the fetus.

Content and format for this checklist were adapted from *Comprehensive Reproductive Health and Family Planning Training Curriculum* (Module 5: Emergency Contraceptive Pills). Watertown, MA: Pathfinder International (revised 2000).

Handout 3:
Counseling for Emergency Contraceptive Pill Clients

As with any contraceptive method, ECPs should be provided in a manner that is respectful of the client and responsive to her needs for information and counseling.

During counseling, providers should:

Reassure all clients, regardless of age or marital status, that all information will be kept confidential.

Be supportive of the client's choices and refrain from making judgmental comments or indicating disapproval through body language or facial expressions while discussing ECPs with clients. Supportive attitudes will help set the stage for follow-up counseling about regular contraceptive use and STI prevention.

Actively involve the client in the counseling process. This may be more effective in ensuring compliance rather than simply providing her with information. This active involvement may include:

- Asking her what she has heard about ECPs.
- Discussing her experience with other contraceptive methods.
- Validating or correcting her ideas as appropriate.

Maintain privacy by ensuring that counseling is conducted in a private and supportive environment to the greatest extent possible. When it is difficult to maintain privacy, give the method to the client with appropriate verbal and printed instructions about both ECPs and other forms of regular contraceptive methods. If in a nonclinic setting, advise her to attend a clinic or contact a health care or family planning provider for counseling about regular contraceptive methods. Reassure the client that all information will be kept confidential, including the fact that she has received ECPs.

Content and format for this handout were adapted from *Comprehensive Reproductive Health and Family Planning Training Curriculum* (Module 5: Emergency Contraceptive Pills). Watertown, MA: Pathfinder International (revised 2000).

Handout 4:
Counseling Skills Observer Checklist

Counseling skill observed	Yes	No	Comments
1. Greets client in friendly and helpful way.			
2. Introduces self.			
3. Asks client why he/she has come to you or what makes him/her think he/she needs ECPs.			
4. Ensures confidentiality.			
5. Screens client for date of unprotected sex and last menstruation.			
6. Tells client about ECPs (how they work, effectiveness, possible side effects).			
7. Allows client to ask questions and asks client if he/she has any questions.			
8. Explains correct use of ECPs and asks client to summarize instructions.			
9. Shows ECPs to client and gives client correct number of pills.			
10. Explains how to manage possible side effects and tells client to return or go to a clinic or hospital if there are any problems or concerns.			
11. Tells client the menstrual period is likely to be within one week before or after the normal expected date.			
12. Asks client about ongoing contraceptive method, and asks if he/she would like to discuss other contraception options.			
13. Explains to the client that he/she and his/her partner may be at risk of an STI.			
14. Provides referral information for community health services.			
15. Demonstrates a nonjudgmental attitude and respect for client.			

Content and format for this checklist were adapted from *Comprehensive Reproductive Health and Family Planning Training Curriculum* (Module 5: Emergency Contraceptive Pills). Watertown, MA: Pathfinder International (revised 2000).

Training Aid 1:
Grab Bag—Key Messages for Emergency Contraceptive Pill Clients

What are emergency contraceptive pills?

✂----------

How do ECPs work?

✂----------

How effective are ECPs?

✂ ----------

What if I had unprotected sex more than 5 days ago?

✂ ----------

Do ECPs cause side effects?

✂ ----------

What should I do after using ECPs?

✂ ----------

If the ECPs do not work and I become pregnant, will the pregnancy be normal?

✂ ----------

What if I have unprotected sex again after taking the ECPs?

✂ ----------

Can I use ECPs every time I have sex?

✂ ----------

Do ECPs prevent sexually transmitted infections?

✂ ----------

What if I had sex multiple times before taking ECPs?

✂ ----------

Can I have a packet of ECPs to keep at home in case I need them?

✂ ----------

How do I use ECPs?

✂ ----------

Content and format for this training aid were adapted from *Comprehensive Reproductive Health and Family Planning Training Curriculum* (Module 5: Emergency Contraceptive Pills). Watertown, MA: Pathfinder International (revised 2000).

Training Aid 2:
Demonstration Role-Play

You have volunteered to play the part of a client seeking ECPs in a role-play to demonstrate effective counseling techniques.

You are a 21-year old woman who is seeking ECPs today. You had unprotected sex with your new boyfriend the night before last, and your best friend told you to go to a provider and ask about pills that can prevent you getting pregnant. The first day of your last menstrual period was two weeks ago. You are healthy and do not smoke. You usually use condoms, but this time you didn't have any around and hadn't expected to have sex. You'd like to know if the provider can give you some of these pills to keep at home in case this ever happens to you again.

Content and format for this training aid were adapted from *Comprehensive Reproductive Health and Family Planning Training Curriculum* (Module 5: Emergency Contraceptive Pills). Watertown, MA: Pathfinder International (revised 2000).

Training Aid 3:
Emergency Contraceptive Pill Client Situation Role-Plays

GROUP 1 Role-play:

You are a young woman. Several days ago you were assaulted and raped, and you think you may need EC to prevent you from getting pregnant. You go to the (insert: family planning clinic, pharmacy, or other provider setting) to find out more information. The provider asks screening questions. You begin to feel nervous, but finally share with the provider that you were raped.

✂ ----------

GROUP 2 Role-play:

You have heard about EC from friends and think you might need it, but you are scared to try it because you think it might make you infertile and that it might not be safe because you smoke. You had unprotected sex last night (you were not expecting to have sex with your new boyfriend and did not have any contraceptive protection nearby). Your last menstrual period ended 5 days ago and was normal. You are a smoker and have herpes but no other health problems. You have been pregnant once before and had an abortion and are scared of having another one. You have not been sexually active for a while but are starting a new relationship. You are interested in learning more about the pill for ongoing contraception.

✂ ----------

GROUP 3 Role-play:

You are seeking ECPs at your local (insert: family planning clinic, pharmacy, or other provider setting). You had unprotected sex yesterday and knew you could get pills that would be likely to prevent you from getting pregnant. The provider has asked you some questions and shown you how to take birth control pills for EC. You want to pay for the pills, but you don't have any money right now. You are interested in finding out about ongoing contraceptive options, but you are not sure where to go for this information. You would also like to know if you can get condoms.

✂ ----------

GROUP 4 Role-play:

A man comes to you and tells you that when he was having sex with his girlfriend last night, the condom broke.

✂ ----------

GROUP 5 Role-play:

A young woman comes to you and tells you she has missed at least 3 of her birth control pills. She is wondering what she should do.

✂ ----------

GROUP 6 Role-play:

You have a patient requesting EC. You have no private counseling area and there are many other patients waiting to be served. You look closely at her, and she appears to have a black eye.

✂ ----------

GROUP 7 Role-play:

A young woman comes in requesting EC. You recognize her because this is the third time she has come in asking for EC.

✂ ----------

GROUP 8 Role-play:

A young woman for whom you prescribed EC comes back and tells you that the method didn't work and now she is pregnant.

Content and format for this training aid were adapted from *Comprehensive Reproductive Health and Family Planning Training Curriculum* (Module 5: Emergency Contraceptive Pills). Watertown, MA: Pathfinder International (revised 2000).

Module I

Evaluation

Objective

To measure achievement of objectives and to document the impact of interventions.

A systematic evaluation of a program or project objectively measures change—what it has accomplished in terms of process, outcomes, and less commonly, impact. This module on evaluation discusses the following topics:

- Relationship between Assessment and Evaluation
- Evaluation Functions
- Characteristics of Good Evaluation
- Choice of Evaluation Method
- Evaluation Plan Development
- Links to Evaluation Resources

Tools Provided at the End of this Module

- Example Results Framework for an Emergency Contraception Project
- Example Outline of an ECP Program Evaluation Report

Relationship Between Assessment and Evaluation

To measure change, it is necessary to have a starting point, before the program's activities or interventions begin, when specific targets of the program interventions—or indicators—are measured. This starting point, or baseline, can be documented as part of assessment activities. (Please refer to Module E: Assessment and the assessment tools, which are closely tied to this module on evaluation.) The same indicators used for the baseline can be monitored and recorded throughout the evaluation period—making it possible, at the end of the evaluation period, to document the changes that have taken place in the indicators.

Evaluation Functions

Evaluation of emergency contraceptive pill programs fulfills four key functions:

1. It *enables program managers and staff to guide and improve their own work*, by providing systematic and objective feedback on what is and is not working and why, so that systems for providing ECP product and information can be improved.

2. It *demonstrates to others the effectiveness of strategies and approaches of ECP integration*, so that program managers can decide whether and how to adapt or replicate them, expanding the impact and reach of the ECP program.
3. It *demonstrates to decision makers or donors the effective use of their resources* for the intended purposes—a critical element of reports on completed projects, as well as of requests for future support.
4. It *increases the knowledge base about effective interventions and the factors that affect program success*, providing data that will facilitate making ECPs more available in the future.

Characteristics of Good Evaluation

Following is a list of characteristics of a strong evaluation process that should be kept in mind as a new evaluation strategy is developed:

- Project goals (and objectives) are well defined and measurable.
- Data are collected and analyzed in a systematic and unbiased way, with proper regard for the interests and safety of all participants.
- Stakeholders are involved at all stages to enhance relevancy and accuracy.
- Resources are prudently used.
- Results are shared in a timely and understandable manner with appropriate parties.
- Findings are applied to future programs or policies.

Choice of Evaluation Method

The methods used to evaluate a project will depend on:

- **The size of the program.** Small pilot projects may lend themselves to more in-depth evaluation using qualitative approaches. (See qualitative data-collection tools, provided in Module E: Assessment.) Larger programs may allow more effective use of quantitative approaches with more generalizable results such as using contraceptive commodity distribution records to demonstrate the number of ECPs distributed monthly and the number of sites where ECPs are available.
- **The nature of the work that is being evaluated.** For example, if the project is focused on provider training, changes in provider knowledge, attitudes, and practices (KAP) may be central to the evaluation. If the focus of the work is on client information and education, the number of calls to an emergency contraception hotline, or number of women requesting ECPs may be more important.
- **Resources available.** It is important to build evaluation activities into the budgets. Clearly ECP introduction efforts with limited budgets must carefully match evaluation activities to the scope of the project activities. It will be important to determine what other resources are available, such as existing systems for gathering data for indicators. If it is possible to tap into existing data collection systems that collect relevant data, this can significantly reduce the resources required for obtaining information.

Evaluation Plan Development

Build in evaluation from the beginning

It is important to include the evaluation plan as part of the ECP introduction process and to work in collaboration with partners and others who will be interested in the outcome of the evaluation in order to ensure that the evaluation results provide useful, relevant information.

Link your expected results to the planned activities

In developing an evaluation plan, link the expected results of the project to planned activities. To do this, be explicit about goals and objectives of the project and define where, in the process of integrating ECPs, data could be collected to measure whether the project has been successful. Data that are used to measure success can also be called indicators. A results framework can be an effective way of developing an evaluation plan. An example of a results framework is included at the end of this module to demonstrate how a framework like this can apply to an emergency contraception program evaluation.

Select indicators that will indicate change brought about by the project interventions

The indicators should be part of the baseline data, providing a measurement of the status before the project. At the end of the project, later data on the same indicators can be compared with the baseline data to show changes that may have resulted from the project activities. For each indicator, determine where or how the information will be obtained. Data for a single indicator should be collected from more than one source. Cross-checking the data from several sources will increase accuracy and credibility. The following table shows the indicators to include.

Aspect of ECP Integration	Indicator
Policy level	• Stated support for ECPs from ministry of health (for example resources allocated for ECPs or standard of care guidelines • Stated support from medical association leaders (for example, a published statement or a public announcement in support of ECPs) • Commitment to collaborate by local partner organizations
Service delivery	• Number of women requesting ECPs • Number of ECPs sold/distributed monthly • Number of personnel authorized to provide ECPs • Number of people trained to provide ECPs • Number of sites where ECPs are available
Service quality	• Positive change in provider attitudes toward ECPs • Positive change in client experience accessing ECPs • Percentage of ECPs clients also counseled about sexually transmitted infections • Percentage of ECPs clients also referred to source of ongoing contraceptive method
Awareness raising	• Number of calls to emergency contraception hotline • Percentage of public who know what ECPs are or where to get them

Choose methods for data collection

Module E: Assessment provides guidance regarding data collection methods that can be used for assessment, including knowledge, attitudes and perceptions (KAP) surveys, in-depth interviews, focus group discussions, and mystery shopper techniques, as well as issues to consider in data collection, entry, and analysis. These methods can all be used as part of an evaluation to verify successful results. For evaluation, however, it is especially important to also consider issues of avoiding bias, controlling quality, and ensuring sample sizes large enough to detect the changes the project hopes to observe. For example, if only a selection of service delivery sites are to be evaluated, it is better to randomly select the sites rather than picking sites that are easy to reach or that are friendly to program organizers, as it is important that the sites selected be representative of all project/program sites. Plans for ensuring the quality of both the data collection and data entry processes should be in place before the data collection begins. This can include providing standardized forms, training the staff that will collect the data on the use of the forms, and including mechanisms for confirming accurate data entry in the computer software developed for entering data forms. If quantitative data is to be collected and the evaluation goal is to show a statistically significant change (for example, in provider attitudes toward ECPs), it is important to consult with a statistician in determining the sample size (in this case, number of providers to include in the study) that will be necessary to demonstrate the change that the project/program hopes to achieve.

Links to Evaluation Resources

The MERLIN Virtual Library is a comprehensive collection of both print and electronic resources to assist in the monitoring and evaluation of health and population services. Developed by the USAID-funded MEASURE *Evaluation* Project, it is available on the Internet at ttp://www.cpc.edu/measure/merlin/merlin.html.

Module I Tools List

Example Results Framework for an Emergency Contraception Project

This is a general overview covering key elements of an introduction strategy. In a real ECP integration effort, each section would need to be fleshed out more fully. This results framework is intended solely to demonstrate how a program can link results, activities, and indicators, as well as specify prospectively how information will be obtained to verify whether results were achieved.

Example Outline of an ECP Program Evaluation Report

This outline provides an example of how a program evaluation report of an ECP program could be structured.

Example Results Framework for an Emergency Contraception Project

Overall Goal: To improve women's awareness of and access to emergency contraception through public-sector programs so that women can make informed choices regarding emergency contraceptive use.

Aspect of ECP integration	Desired result	Activities aiming to achieve this result	Indicators	Means of verification
Policy level	Support from ministry of health (MOH), medical associations, and local partner organizations for integrating ECPs into public-sector systems.	• Meetings with key representatives from MOH, medical associations, and local partner organizations	• Stated support from MOH • Stated support from medical association leaders • Commitment to collaborate by local partner organizations • Development of action plan	• Meeting minutes • Letter of commitment • Implementation of action plan
Service delivery	Increased capacity of public-sector clinicians to provide ECP information and prescriptions to clients. Increased provision of ECPs through public-sector systems	• Public-sector clinician training • Regular meetings with providers to learn from one another and openly discuss concerns and problems • Distribution of ECPs through public-sector programs	• Number of public-sector clinicians who are trained to provide ECPs • Positive change in provider attitudes toward ECPs • Number of ECPs distributed monthly • Number of sites where ECPs available	• Training records • Pre- and post-training provider KAP survey • Mystery client surveys • Client satisfaction surveys Contraceptive commodity distribution records
Service quality	ECPs provided to clients as part of an integrated response to unprotected sex.	• Public-sector clinician training includes information about ongoing family planning methods and sexually transmitted infections	• Percentage of clients provided with ECPs counseled on sexually transmitted infection • Percentage of clients provided with ECPs referred to ongoing contraceptive methods	• Pre- and post-training provider KAP survey • Mystery client surveys • ECP clients' clinical records
Awareness raising	Increased awareness of ECPs for women of reproductive age.	• Background workshop for journalists • Development of hotline with information about ECPs • Develop IEC materials such as brochures, posters, and radio spots	• Number of articles about ECPs in mainstream media • Number of calls to ECP hotline • Number of women requesting ECPs	• Media tracking • Hotline tracking • Sentinel clinic tracking of ECP requests

Example Outline of an ECP Program Evaluation Report

I. Introduction
   A. Background on emergency contraceptive pills (ECPs)
      1. ECPs as a unique form of contraception that can be used after sex to prevent pregnancy
      2. Ideally ECPs should be used within 120 hours of unprotected sex and are significantly more effective the sooner they are taken
   B. Description of local advocacy framework
      1. Rates of unintended pregnancy
      2. Negative consequences of unintended pregnancy for both family and child
      3. ECPs can help prevent unintended pregnancy, reduce abortion rates, and reduce maternal mortality
   C. Description of the program's integration of ECPs into the public-sector systems
      1. Program goals and objectives
      2. Program implementation
      3. Collaborating partners

II. Evaluation Methods: Overview of Evaluation Strategy
   A. Description of methods (for example, KAP survey, in-depth interview, focus group discussion) and participants (policy makers, providers, clients) used to evaluate program success
      1. Study populations, setting, and locations where data collected
      2. Participant recruitment
      3. Sampling: how participants were selected, rationale for number of participants, analysis methods used, including statistical tests (if applicable)

III. Description of evaluation results
   A. Policy level
      1. Indications of support at the policy level
      2. Service delivery
         a. Capacity of providers to provide ECP information and prescription
         b. Provision of ECPs through public-sector system
         c. Providers' satisfaction
      3. Service quality
         a. ECP provision as part of an integrated response to unprotected sex
         b. Client satisfaction
      4. ECP Awareness raising
         a. Increase in level of awareness about ECPs
         b. Media reports on ECPs

IV. Discussion of the evaluation findings and their implications
   A. Summarize central findings
   B. Discuss effectiveness of strategies and approach

V. Provision of recommendations, based on evaluation results, for improvement and next steps possible

This material was developed by PATH.

Appendix A

Emergency Contraceptive Pills: Medical and Service Delivery Guidelines

Emergency Contraceptive Pills:

Medical and Service Delivery Guidelines

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Emergency Contraceptive Pills: Medical and Service Delivery Guidelines

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2003

International Consortium for Emergency Contraception

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FOREWORD

Offering emergency contraception is an important way for family planning and other reproductive health programs to improve the quality of their services and better meet the needs of their clients. Emergency contraception is needed because no contraceptive method is 100 percent effective, and few people use their method perfectly every time they have intercourse. Furthermore, emergency contraception is useful in cases of sexual assault.

Emergency contraceptive pills (ECPs), the most commonly used and most convenient form of emergency contraception, are not difficult to provide. Specially packaged ECPs or supplies of regular oral contraceptives that can be used for ECPs are readily available in most places. Providers can be trained easily in the correct use, counseling, and follow-up related to ECPs. Nevertheless, providing ECPs does entail unique service delivery issues, such as the need to ensure rapid access to the method to maximize efficacy and the importance of conveying information about additional, ongoing methods to prevent both pregnancy and sexually transmitted infections after the ECPs are used.

An essential component of programs providing emergency contraception is education, informing women about this important option before they need it. Because the time frame for treatment is short — efficacy declines with each day or even hour of delay — women need to be aware that emergency contraception is an option, know where they can seek services, and understand that treatment should be started as soon as possible after unprotected or inadequately protected intercourse. Providing emergency contraceptive information and, if practical, supplies of ECPs at the time of a regular family planning or medical visit is one way of ensuring that women have the resources they need to protect themselves from pregnancy in the event of unprotected intercourse or a contraceptive failure.

The organizations that make up the International Consortium for Emergency Contraception have compiled these service delivery guidelines to give family planning and other reproductive health programs and practitioners the information they need to provide ECPs safely and effectively. The recommendations in these guidelines reflect the latest available research on emergency contraception and have been reviewed by internationally recognized reproductive health experts. Local programs should adapt these guidelines as necessary to comply with national or other requirements.

SUMMARY SERVICE PROTOCOL FOR EMERGENCY CONTRACEPTIVE PILLS

Emergency contraceptive pills (ECPs) are an important option for women who recently have had unprotected intercourse or a contraceptive failure and who do not want to become pregnant. ECPs have been shown to be safe and effective in studies conducted over the past three decades.

Indication

To prevent pregnancy after unprotected or inadequately protected intercourse.

Regimens

The two regimens discussed in these guidelines are:

- **Levonorgestrel-only regimen:** 1.50 mg levonorgestrel in a single dose or in two doses of 0.75 mg taken up to 12 hours apart.
- **Combined estrogen-progestin regimen:** two doses of 100 mcg ethinyl estradiol plus 0.50 mg of levonorgestrel taken 12 hours apart.

Treatment with either regimen should be initiated as soon as possible after intercourse because data suggest that efficacy declines substantially with time. Both regimens have been shown to be effective through five days (120 hours) after intercourse. Longer delays have not been investigated.

In some locations, both regimens are available as products formulated and labeled specifically for use as ECPs. Alternatively, ECPs can be formulated from a variety of regular oral contraceptive pills (see Table 1 or www.cecinfo.org).

The levonorgestrel-only regimen is preferred because it is more effective and is associated with a lower incidence of side effects.

Mode of Action

The exact mode of action of ECPs in any given case cannot be known. ECPs have been shown to inhibit or delay an egg from being released from the ovary when taken before ovulation. They may also prevent sperm and egg from uniting or stop a fertilized egg from attaching to the uterus. The two ECP regimens discussed in these guidelines do not interfere with an established pregnancy.

Effectiveness

Various studies have shown that the levonorgestrel-only regimen reduces the risk of pregnancy by 60 percent to 93 percent or more after a single act of intercourse, and the combined regimen reduces it by 56 percent to 89 percent. In direct comparisons, the levonorgestrel regimen has been shown to be substantially more effective than the combined regimen. Both regimens appear to be more effective the sooner after intercourse they are used. ECPs are not as effective as consistent and correct use of most modern contraceptive methods.

Side Effects

Side effects of both regimens include nausea, vomiting, abdominal pain, fatigue, headache, dizziness, breast tenderness, and irregular vaginal spotting or bleeding. The levonorgestrel-only regimen is associated with a significantly lower chance of nausea and vomiting than the combined regimen. In most women, menses following treatment will occur within a week before or after the expected time.

Prevention and Management of Nausea and Vomiting

The best way to minimize nausea and vomiting is to use the levonorgestrel-only regimen instead of the combined regimen whenever possible. Pretreatment with the antiemetic drugs meclizine or metoclopramide can prevent these symptoms in users of the combined regimen. If vomiting occurs within two hours after either dose, repeat the dose, if feasible. In cases of severe vomiting, vaginal administration of ECPs may be effective.

Precautions

There are no known medical conditions that preclude the use of ECPs. ECPs are not indicated in women with confirmed pregnancy because they will have no effect. However, ECPs may be given without pregnancy testing or when pregnancy status is unclear, as there is no evidence suggesting harm to a pregnant woman or to her pregnancy.

Screening

Because ECPs are not dangerous under any known circumstances, routine screening via examination or laboratory tests is unnecessary prior to treatment. The client herself can determine whether ECPs are indicated after written or oral instruction. A pregnancy test may be helpful in ruling out pregnancy if the client has missed a menstrual period. However, treatment should not be delayed in order to perform any screening procedures.

Special Situations

- **Breastfeeding:** There is no evidence that ECPs will harm a breastfeeding woman or her infant, although some authorities recommend feeding immediately before taking the pills and then expressing and discarding the breast milk for the six hours afterwards.
- **Coital act(s) more than 120 hours in the past:** ECPs may be used, but clients should be informed that efficacy has not been studied. Emergency intrauterine device (IUD) insertion should be considered.
- **More than one prior unprotected act:** One ECP treatment may be used to cover all unprotected or inadequately protected acts within the past 120 hours.
- **Repeated ECP use:** ECPs may be used as frequently as requested, but clients should be informed that ongoing, correct use of other contraceptive methods provides more effective protection over time.
- **Use of ECPs before intercourse:** No data are available on how long the contraceptive effect of ECPs persists after the pills have been taken. Clients should be encouraged to use a contraceptive method other than ECPs whenever possible.
- **Unprotected intercourse during the "infertile period":** Because it is often difficult to define the infertile period with certainty, ECPs are recommended any time that unprotected or inadequately protected intercourse occurs and the client is concerned that she is at risk for pregnancy.
- **Concurrent use of other drugs:** Clients should be counseled about the possibility of drug interactions and managed accordingly (see Section 2.7).
- **Use of other formulations:** Combined estrogen-progestin pill formulations containing the progestin norethindrone in place of levonorgestrel can be used when the regimens described herein are not available.

Information for Clients

Information about ECPs and related issues may be provided in person, over the telephone, in writing, or by a combination of these approaches. At a minimum, the following messages should be conveyed:

- The client should start treatment as soon as possible after intercourse.
- Following ECP use, if the client's menstrual period has not come within a week after it was expected, she should seek evaluation and care for possible pregnancy.
- If the client has irregular bleeding and lower abdominal pain, she should contact a health care provider for possible evaluation for ectopic pregnancy.
- The client should use another form of contraception after using ECPs. ECPs are not suitable for ongoing contraception.
- ECPs do not protect against HIV or other sexually transmitted infections (STIs).

Ideally, the client should also be given information about efficacy, side effects, mechanism of action, other contraceptive methods, and methods to prevent STIs. She should be offered a temporary method, such as condoms, for use in the immediate future, and referrals to facilities where she can obtain any needed follow-up services. All counseling should be nonjudgmental and supportive.

Follow-up

Advise the client to see a health care provider if she experiences irregular bleeding combined with lower abdominal pain or if she has any questions or reason for concern.

EMERGENCY CONTRACEPTIVE PILLS: MEDICAL AND SERVICE DELIVERY GUIDELINES

1 Introduction

Despite the availability of highly effective methods of contraception, many pregnancies are unplanned and unwanted. These pregnancies carry a higher risk of morbidity and mortality, often due to unsafe abortion. Many of these unplanned pregnancies can be avoided using emergency contraception.[1,2]

1.1 Definition

Emergency contraceptive pills (ECPs) are hormonal methods of contraception that can be used to prevent pregnancy after an unprotected or inadequately protected act of intercourse.

ECPs sometimes are referred to as "morning-after" or "postcoital" pills. The term "emergency contraceptive pills" is preferred because it conveys the important message that the treatment should not be used as an ongoing contraceptive method, and it avoids giving the mistaken impression that the pills must be taken on the morning after intercourse.

These guidelines address medical and service delivery issues related to two regimens of ECPs, one containing a progestin only (levonorgestrel), and the other containing a combination of a progestin (levonorgestrel) and an estrogen (ethinyl estradiol).

A brief overview of the use of intrauterine devices (IUDs) for emergency contraception is included in the Appendix.

1.2 Indications

ECPs are indicated to prevent pregnancy after unprotected or inadequately protected sexual intercourse, including:

- when no contraceptive has been used;
- when there is a contraceptive failure or incorrect use, including:
  - — condom breakage, slippage, or incorrect use
  - — two or more consecutive missed combined oral contraceptive pills
  - — progestin-only pill (minipill) taken more than three hours late
  - — more than two weeks late for a progestin-only contraceptive injection (depot-medroxyprogesterone acetate or norethisterone enanthate)
  - — more than seven days late for a combined estrogen-plus-progestin monthly injection
  - — dislodgment, delay in placing, or early removal of a contraceptive hormonal skin patch or ring
  - — dislodgment, breakage, tearing, or early removal of a diaphragm or cap
  - — failed coitus interruptus (e.g., ejaculation in vagina or on external genitalia)
  - — failure of a spermicide tablet or film to melt before intercourse
  - — miscalculation of the periodic abstinence method or failure to abstain on fertile day of cycle
  - — IUD expulsion; or
- in cases of sexual assault when the woman was not protected by an effective contraceptive method.

2 Emergency Contraceptive Pills

2.1 ECP Regimens

Two ECP regimens are discussed in these guidelines:

- **Levonorgestrel-only regimen:** 1.50 mg levonorgestrel in a single dose or in two doses of 0.75 mg taken up to 12 hours apart.
- **Combined estrogen-progestin (Yuzpe) regimen:** two doses of 100 mcg ethinyl estradiol plus 0.50 mg of levonorgestrel taken 12 hours apart.

Note that levonorgestrel plus an equal amount of a related but inactive compound is called norgestrel; therefore, these regimens can also be formulated by substituting double the amount of norgestrel as is indicated for levonorgestrel.

Treatment with either regimen should be initiated as soon as possible after unprotected or inadequately protected intercourse, because efficacy declines substantially with time.[3,4] Early data showed that both regimens are effective when used up to 72 hours after intercourse.[5,6] Consequently, some product package instructions and older guidelines advise use only within that time frame. However, more recent studies indicate that the regimens continue to be moderately effective if started between 72 and 120 hours.[4,7] No data are available on efficacy if treatment is started more than 120 hours after intercourse.

Both regimens are available in some locations as products formulated and labeled specifically for use as

ECPs. They also can be made up from a variety of regular oral contraceptive pills (see Table 1 or www.cecinfo.org). The levonorgestrel-only regimen is preferred because it is more effective and is associated with a lower risk of nausea and vomiting.[5]

2.2 Mode of Action

Like all hormonal contraceptives, ECPs may work in a variety of ways. The precise mechanism of action of ECPs in a particular case cannot be determined and probably depends on the time in a woman's menstrual cycle when intercourse occurred and when ECPs were taken.[8,9] Several studies have provided direct evidence that when taken before ovulation, both the combined regimen and the levonorgestrel regimen can act by preventing or delaying ovulation.[10-14] Some studies have shown changes in histologic and biochemical features of the endometrium after treatment with combined ECPs, suggesting that they may act by impairing endometrial receptivity to implantation of a fertilized egg.[6,14,15] However, other studies have shown no such effects with both the combined and levonorgestrel-only regimens,[10,11,13,16,17] and it is not clear that the observed changes would be sufficient to prevent implantation. Additional possible mechanisms include interference with sperm transport or penetration[18,19] and interference with corpus luteum function.[14,20] To date, no direct clinical data exist regarding these possibilities. Nevertheless, statistical evidence on the effectiveness of ECPs suggests that they could not be as effective as data indicate if they only worked by interfering with ovulation.[21]

ECPs have often been confused with medical abortion. ECPs are effective only in the first few days following intercourse before a pregnancy is established, while medical abortion is a nonsurgical option for terminating a pregnancy. At least five days elapse between intercourse and the establishment of a pregnancy, defined as implantation of a fertilized egg in the lining of a woman's uterus. ECPs work in this interval to prevent pregnancy. They are ineffective once implantation has begun. Data from studies of high-dose oral contraceptives indicate that neither of the two ECP regimens discussed here will interrupt an established pregnancy or harm a developing embryo.[22]

2.3 Efficacy

The statistic commonly used to express the efficacy of most contraceptive methods indicates the proportion of women who become pregnant while using the method over a fairly long period of time. This statistic is not meaningful for ECPs, which are intended for one-time use. Instead, the contraceptive efficacy of ECPs is commonly expressed in terms of the "prevented fraction," which is the proportion of expected pregnancies averted by the treatment. Determining this fraction is not straightforward; it involves many assumptions that are difficult to validate. Therefore, the reported efficacy figures presented below may not be precise. Yet, precise estimates of efficacy may not be highly relevant to many women who have had unprotected intercourse, since ECPs are often the only available treatment. A more important consideration for most ECP clients may be the fact that ECPs (specifically, the levonorgestrel regimen) are certainly more effective than nothing.[23]

Four studies of the levonorgestrel regimen that included a total of almost 5,000 women reported prevented fractions between 60 percent and 93 percent; that is, this regimen reduced a woman's chance of pregnancy by that amount.[4,5,24,25] A meta-analysis of eight studies of the combined regimen including more than 3,800 women concluded that the regimen prevents about 74 percent of expected pregnancies; the proportion ranged from 56 percent to 89 percent in the different studies.[26] A large randomized trial that directly compared the two regimens showed that the levonorgestrel regimen is significantly more effective than the combined regimen. The relative risk of pregnancy in this study was 0.36, indicating that the chance of pregnancy among women who received the levonorgestrel regimen was about one third of the chance among those who received the combined regimen.[5]

Multiple studies have indicated that both regimens are more effective the sooner after intercourse the pills are taken.[4,5,25,27] Some older studies of the combined regimen did not show this time effect,[28] but they may not have been as rigorously conducted as more recent research. No data are available establishing efficacy if ECPs are taken more than 120 hours after intercourse.

ECPs are inappropriate for regular use as an ongoing contraceptive method for several reasons. First, ECPs are less effective than most modern methods over the long term. The prevented fraction statistic used to express efficacy of ECPs after a single use cannot be directly compared to published failure rates of other contraceptives used for prolonged periods of time. However, if ECPs were used as an ongoing method, the cumulative risk of pregnancy during a full year of use would likely be higher than the risk associated with regular hormonal contraceptives, male condoms, and other barrier methods. In addition, very frequent ECP use would result in more side effects (such as menstrual irregularities) and exposure to a higher total hormone dose than would regular use of either combined oral contraceptive pills or progestin-only pills. Data are not available on the incidence of medical complications (if any) in women who use current regimens of ECPs frequently over a long period of time.

2.4 Side Effects, Prevention, and Management

No deaths or serious complications have been causally linked to emergency contraception.[29] Side effects that are medically minor but troublesome to clients do occur, however.

Nausea and vomiting

Nausea occurs in about 18 percent of women and vomiting occurs in about 4 percent of women using levonorgestrel-only ECPs.[4,5,24,25] Nausea and vomiting occur in about 43 percent and 16 percent, respectively, of clients using the combined regimen.[30] In studies directly comparing the two regimens, the levonorgestrel regimen has been shown to cause significantly and substantially less nausea and vomiting than the combined regimen.[5,25] If they occur, these symptoms are usually limited to the first three days after treatment.[31]

Prevention

The best way to minimize nausea and vomiting is to use the levonorgestrel-only regimen instead of the combined regimen whenever possible. Nausea and vomiting are uncommon enough with the levonorgestrel-only regimen that prophylactic administration of an antiemetic drug is not routinely warranted. However, if the combined regimen is used, antiemetic pretreatment may be considered, depending on program and client resources. A single dose of meclizine (50 mg), taken one hour before the first dose of the regimen, reduces the risk of nausea by about 30 percent and the incidence of vomiting by about 60 percent. Clients who use meclizine should be warned that it might cause drowsiness.[30] Metoclopramide, 10 mg taken one hour before each dose of the combined regimen, also reduces the incidence of nausea.[32] Lower doses of these drugs and other antiemetics also may prevent nausea and vomiting, but they have not been studied. It is not possible to predict which ECP users will have nausea or vomiting or which women will benefit from antiemetic pretreatment. Taking ECPs with food has not been shown to alter the risk of nausea.[30,33]

Management

If vomiting occurs within two hours of taking an ECP dose, many experts believe that the dose should be repeated. In cases of severe vomiting, ECPs can be administered vaginally. Studies of regular oral contraceptive pills administered by this route suggest that the hormones are well absorbed through the vaginal mucosa.[34,35]

Delay in menses

Clients should be informed that ECPs do not necessarily bring on menses immediately (a potential misperception among ECP users); the menstrual period usually occurs within one week before or after the expected time.

Management

After using ECPs, if the menstrual period has not come by a week after it was expected, the client should be advised to consider the possibility that she may be pregnant and to seek appropriate evaluation (such as a pregnancy test) and care.

Irregular vaginal bleeding

Some women may experience irregular bleeding or spotting after taking ECPs. The proportion with this side effect varies substantially in different studies; for example, trials of the LNG regimen found that between 0 percent and 17 percent of women reported non-menstrual bleeding in the first week after use.

Management

Irregular bleeding due to ECPs is not dangerous and will resolve without treatment. However, it is important not to discount the possibility that irregular bleeding after ECP use may be due to another more serious cause, such as ectopic pregnancy. Consideration should be given to evaluating this symptom with a pregnancy test and other appropriate tests if the woman has other symptoms of ectopic pregnancy, such as lower abdominal pain.

Other side effects of ECPs

Other side effects may include abdominal pain, breast tenderness, headache, dizziness, and fatigue. These side effects usually do not occur more than a few days after treatment, and they generally resolve within 24 hours.[31]

Management

A nonprescription pain reliever can be used to reduce discomfort due to headaches or breast tenderness.

Effects on pregnancy

Results from studies of high-dose oral contraceptives suggest that neither the pregnant woman nor the fetus will be harmed if ECPs are inadvertently used during early pregnancy.[36] Available evidence suggests that ECPs do not increase the chance that a pregnancy following ECP use will be ectopic; in fact, like all contraceptive methods, ECPs reduce the absolute risk of ectopic pregnancy by preventing pregnancy in general.[37]

2.5 Precautions

No evidence exists to indicate that ECPs are dangerous under any known circumstances or in women with any particular medical condition. Although some product

package inserts list precautions similar to those associated with continuous use of combined oral contraceptives and levonorgestrel-only pills, experts believe that these precautions do not apply to ECPs because the treatment is so short. Women with previous ectopic pregnancy may use ECPs.

ECPs are not indicated for a woman who has a confirmed pregnancy because they will have no effect. However, if an evaluation for pregnancy has not been performed or if pregnancy status is unclear, ECPs may be provided, as there is no evidence suggesting harm to the woman or to an existing pregnancy. In the absence of pregnancy evaluation, though, the client should understand that she could already be pregnant, in which case ECP treatment will not be effective.

2.6 Screening

Because ECPs are safe for all women, and clients can determine for themselves whether they have had unprotected or inadequately protected intercourse, the only purpose of screening is to identify situations when ECPs are clearly not needed (e.g., the client is already pregnant) or when an emergency contraceptive treatment other than ECPs (i.e., an IUD) should be considered. This screening can be done by a clinician or other trained provider or by the client herself after written or oral instruction.[38] Clinical assessments (e.g., pregnancy test, blood pressure measurement, laboratory tests, pelvic exam) are not required but can be offered if medically indicated for other reasons and desired by the client. A pregnancy test may be helpful in detecting pregnancy if the client has missed a menstrual period.

ECPs should not be withheld or delayed in order to carry out screening procedures.

2.7 Special Issues

Use in breastfeeding women

A woman who is less than six months postpartum, is exclusively breastfeeding, and has not had a menstrual period since delivery is unlikely to be ovulatory and therefore is unlikely to need ECPs. However, a woman who is providing supplemental feeding to her infant or who has had menses since delivery may be at risk for pregnancy. A single treatment with ECPs is unlikely to have an important effect on milk quantity or quality. An unknown amount of hormone may pass into the breast milk. Some authorities recommend that nursing women should feed the baby immediately before taking ECPs and then express and discard the breast milk for the next six hours, but the need for this practice is not proven.

Use after coital act(s) more than 120 hours in the past

No data are available on efficacy if treatment is started more than 120 hours after intercourse. However, since ECPs apparently pose no danger either to the woman or to the embryo if the ECPs fail, it is reasonable to provide them if the client is fully counseled about the possibility of pregnancy. A more effective approach would be to insert a copper IUD (see Appendix), if the earliest unprotected act occurred within the past seven days and the woman is otherwise a candidate for emergency IUD insertion.

Use after more than one unprotected act

ECPs should not be withheld if the client has had more than one unprotected or inadequately protected act of intercourse, unless she is known to be already pregnant. However, clients should be informed that the efficacy of the ECPs will decline as the interval between the earliest coital act and the use of the ECPs lengthens. Clients should be encouraged to use ECPs as promptly as possible after an act of unprotected intercourse and not to wait until they have had a series of unprotected acts. Only one ECP treatment should be given at a time, regardless of the number of prior unprotected acts.

Repeated use

ECPs are not intended for repeated use (see Section 2.3) and no direct data are available about the effects of frequent use of current regimens. However, experience with similar regimens[39] and with high-dose oral contraceptives suggests that the likelihood of harm from limited repeat use is low. ECPs should not be denied just because the woman has used them before, even within the same menstrual cycle. All women who use ECPs, especially those who use them repeatedly, should be given information about other forms of contraception and counseling about how to avoid future contraceptive failures. Certainly repeated use of ECPs is safer than pregnancy, in particular when the pregnancy is unintended and women do not have access to safe abortion services.

Use of ECPs before intercourse

No data are available about how long the contraceptive effect of ECPs persists after the pills have been taken. Presumably ECPs taken immediately before intercourse are as effective as ECPs taken immediately afterwards. However, if a woman has the opportunity to plan to use a contraceptive method before intercourse, a method other than ECPs, such as condoms or another barrier method, is recommended.

Use of ECPs during the "infertile period"

Studies have shown that fertilization can result from intercourse only during a five- to seven-day interval around the time of ovulation.[40] Theoretically, ECPs should not be needed if unprotected intercourse occurs at other times of the cycle, because the chance of pregnancy even without ECPs would be zero. However, in practice, it is often impossible to determine for certain whether a specific act of intercourse occurred on a fertile or infertile cycle day. Therefore, ECPs generally should be provided any time unprotected or inadequately protected intercourse occurs and the client is concerned that she is at risk for pregnancy. In situations when the unprotected act is extremely unlikely to result in pregnancy, the client's anxiety level and the availability of program and client resources should be taken into account in making the decision.

Drug interactions

No specific data are available about the interactions of ECPs with other drugs that the client may be taking. However, it seems reasonable that drug interactions would be similar to those with regular oral contraceptive pills. A full discussion of this matter is beyond the scope of these guidelines, but several excellent references on the subject are available.[41-45] Women taking drugs that may reduce the efficacy of oral contraceptives (including but not limited to rifampicin, certain anticonvulsant drugs, and Saint John's wort) should be advised that the efficacy of ECPs may be reduced. Consideration may be given to increasing the amount of hormone administered in the ECPs, either by increasing the amount of hormone in one or both doses, or by giving an extra dose.

Use of other formulations

One study has shown that a combined estrogen-progestin pill formulation containing the progestin norethindrone offered an efficacy and side effect profile similar to the standard combined pill regimen containing levonorgestrel.[33] These results suggest that oral contraceptive pills containing progestins other than levonorgestrel may be used for emergency contraception in situations when the two standard regimens are not available.

2.8 Information for the Client

Relevant information can be provided to ECP clients in person, over the telephone, in writing (e.g., in a pamphlet or product package insert), or by a combination of these methods. This information should include at least the following key messages:

- The client should take ECPs as soon as possible after intercourse to maximize efficacy. She should not take extra doses unless she vomits within two hours after a dose.
- After taking ECPs, if the next menstrual period has not come by a week after it was expected, the client should consider the possibility that she may be pregnant and seek evaluation and care.
- If the client has irregular bleeding and lower abdominal pain, she should contact a health care provider for possible evaluation of ectopic pregnancy.
- ECPs are not suitable for ongoing contraception. The client should use a standard method of contraception to prevent pregnancy from coital acts in the future.
- ECPs do not protect against HIV or other sexually transmitted infections (STIs). The act of intercourse that prompted the request for ECPs may have put the client at risk for these infections, and she should consider getting tested.

Ideally, the client should also be given information about efficacy, side effects, and mechanism of action of ECPs, as well as information about other contraceptive methods to use in the future and methods for preventing STIs. Whenever feasible, a regular method such as condoms should be offered for her to use in the immediate future. Depending on the situation, the client should be referred to facilities where she can obtain pregnancy care in case of treatment failure, tests for STIs and HIV, and other needed services.

However, clients should not be overwhelmed with so much information that they cannot absorb it all. In addition, some clients may not want counseling on certain topics (such as information on other contraceptive methods or on the mechanism of action of ECPs) at the time they receive ECPs. Providers should not deny ECPs to women who refuse more than the minimum information needed to ensure that they use ECPs correctly.

2.9 Counseling

Two studies have suggested that most women do not need any interaction with a health care provider in order to use ECPs safely and effectively.[38,46] However, counseling can serve to reinforce any messages given in writing and may lead to better overall outcomes. Counselors should be mindful of possible unique sources of anxiety among women requesting ECPs: embarrassment at failing to use contraception effectively; rape-related trauma; concern about STIs, including HIV, due to condom failure or non-use; and hesitation due to a misperception that ECPs cause abortion.

Counselors should be as supportive as possible of the client's choices and refrain from making judgmental comments or indicating disapproval through body language or facial expressions while discussing ECPs with clients. Supportive attitudes will help set the stage for follow-up counseling about regular contraceptive use and prevention of STIs. When possible, give clients written as well as oral instructions for taking the ECPs. Pictorial instructions may help clients whose literacy may be limited.

Actively involving the client in the counseling process is encouraged. For example, a provider might ask her what she has heard about ECPs, discuss her experience with other contraceptive methods (particularly the incident that led to the ECP request), and explore her current approach to protecting herself from STIs. Validating or correcting her ideas as appropriate may be more effective in ensuring compliance than simply providing her with information.

Whenever possible, ensure that counseling is conducted in private. In situations where privacy is inadequate (for instance, in many pharmacies), advise clients to contact a health care or family planning provider for additional information and counseling about regular contraceptive methods. Reassure all clients, regardless of age or marital status, that all information that they give to the provider, as well as the fact that they have received treatment, will be kept confidential.

2.10 Follow-up

No scheduled follow-up is required after ECP use unless the client identifies a problem or question. However, the client should be advised to seek follow-up care if she:

- needs ongoing contraceptive counseling or a contraceptive method;
- has not had a menstrual period by a week after it was expected;
- has irregular bleeding and lower abdominal pain;
- suspects she may be pregnant;
- needs other services, such as evaluation for STIs; or
- has other reasons for concern.

2.11 If the Client Becomes Pregnant

A woman who has used ECPs may later find herself to be pregnant because the ECPs have failed, because she was already pregnant before taking the ECPs, or because coital acts after taking the ECPs led to pregnancy. In any of these cases:

- Advise the client about all available options, and let her decide which is most appropriate for her situation. Respect and support her decision. Refer her to other service providers as appropriate.
- If she decides to continue the pregnancy, reassure her that there is no evidence of any teratogenic effect following ECP use. Available data suggest that ECPs do not increase the likelihood that a subsequent pregnancy will be ectopic.

2.12 Starting or Resuming Regular Contraception after ECP Use

Whenever possible, clients receiving ECPs should be given contraceptive counseling and provided with an ongoing contraceptive method, such as condoms, for at least immediate future use. However, such counseling may not be appropriate in all situations or may not be desired by clients at the time of ECP provision, and it should not be a prerequisite for providing ECP services. Clients who need or desire counseling but who do not receive it at the ECP visit should be referred for a follow-up appointment at the earliest convenient time.

Clients may wish to restart their previous contraceptive method after taking ECPs, or they may prefer to initiate a new method. If the reason for requesting ECPs is because the regular contraceptive method failed (for example, the condom broke or the client missed taking oral contraceptive pills), discuss with the client the reasons for failure and how it can be prevented in the future. In some cases, the need for ECPs may be an indication that a change of methods should be considered.

ECP clients, particularly those with risk factors for STIs, such as young age, multiple partners, or residence in a location where STIs are especially prevalent, should ideally receive counseling on how to prevent STIs as well as pregnancy by using condoms in addition to or as the primary contraceptive method.

Guidelines for initiating or restarting contraceptive use after using ECPs

Male or female condom

Can be used immediately.

Diaphragm or cervical cap

Can be used immediately.

Spermicidal foam, tablets, jelly, cream, or film

Can be used immediately.

Oral contraceptives, hormonal contraceptive patch, or vaginal ring

Two options are offered. Many experts recommend the first as preferable because the method is initiated sooner, which may reduce subsequent pregnancy risk.

a. The client may begin using the method the day after taking the ECPs. If she is newly starting the method, she should begin with a new pill pack, patch, or ring. If she was previously using the method (e.g., the ECPs were indicated because of missed pills or dislodgement of the patch or ring), she may resume using the pill pack, patch, or ring that she was previously using. In this case, she should be reminded that the patch or ring will not be effective past the original date on which it was scheduled to be removed. All clients starting hormonal methods immediately after using ECPs should use a barrier method if they have intercourse in the next seven days after starting or restarting the method. Clients may have some irregular bleeding until the onset of menses.

b. The client may wait until the beginning of her next menstrual cycle and then start the method according to the standard instructions for that method. In this case, she should be advised to use a barrier contraceptive method or abstain from intercourse for the remainder of the current cycle.

Injectables

Initiate progestin-only injectables and combined monthly injectables within seven days after the beginning of the next menstrual cycle. The client should use a barrier contraceptive or abstain from intercourse until she receives the injection.

Implants

Insert within seven days after the beginning of the next menstrual cycle. Use a backup method or abstain from intercourse until the implants are inserted.

IUD

Insert after the start of the next normal menstrual period. The client should use a barrier contraceptive or abstain from intercourse until the IUD is inserted.

NOTE: If the client intends to use an IUD as a long-term method and meets IUD screening criteria, emergency insertion of a copper-bearing IUD may be a good alternative to ECP use (see Appendix).

Natural family planning

Natural family planning may be initiated after the first normal menstrual period following ECP use. If intercourse occurs in the interim, an alternate contraceptive method (such as condoms) or abstinence should be used.

Female or male sterilization

Perform the operation only after informed consent can be ensured. It is not recommended that clients make this decision under the stressful conditions that often surround ECP use. Defer female sterilization until after the client's first menstrual period, to ensure that she is not pregnant. Use a backup method or abstain from intercourse until the sterilization procedure is performed.

3 ECP Service Delivery Systems

Given that ECPs appear to be most effective when taken soon after intercourse, every effort should be made to ensure that women know about ECPs before they need them. This can be accomplished by:

- routinely informing women about ECPs at the time of regular medical or family planning visits;
- including information about ECPs on Web sites or telephone answering machines;
- distributing written information about ECPs with other contraceptive supplies or medications;
- including information about ECPs within sexual education programs; or
- instituting mass-media informational campaigns and advertising ECP services.

Information about ECPs is particularly relevant to adolescents who are not yet sexually active; to women who are using contraceptive methods that are often used inconsistently or incorrectly, such as barrier methods, oral contraceptives, or natural family planning; and to other high-risk women, such as youth, migrant workers and their spouses, and victims of sexual assault.

It is also critical that women be able to obtain ECPs quickly when the need arises. Because the instructions for use of ECPs are simple and medical screening is not necessary, the requirement for an immediate visit to a doctor is not necessary for safe and effective use[38] and may create barriers to access. Some approaches to facilitating access are:

- providing women with an advance prescription or supply of ECPs;[47]
- prescribing ECPs by telephone without seeing the client;
- training nurses, midwives, pharmacists, or nonclinical individuals such as community health workers and

sexual assault counselors to provide ECPs, if allowed by local regulations;

- ensuring that nonclinical staff in health facilities, whom clients may contact before seeing a clinician, are aware of the availability of ECPs;
- distributing ECPs through nonclinical settings, such as through community-based services, schools, social marketing programs, and the commercial sector (e.g., pharmacies); or
- distributing ECPs over the counter.[48]

All ECP providers should be given appropriate training and follow clear service delivery guidelines. Training should include information on indications for ECP use, recommended ECP regimens, mode of action, efficacy, side effects and their management, precautions and screening, client information and counseling needs, and follow-up procedures. In addition, because ECPs are a backup method, the training also should include information about other contraceptive methods, if necessary for the audience. The training often is most effective if it is participatory in nature and includes exercises to build participant skills in the areas of screening, counseling, and follow-up. To obtain provider-training curricula, please contact the International Consortium for Emergency Contraception or visit the Consortium's Web site at www.cecinfo.org.

3.1 Youth

Reaching adolescents with emergency contraceptive information and services poses special challenges to programs. Young women may find it difficult to access relevant information about or services for emergency contraception because they:

- are unaware of the availability of ECPs;
- lack confidence or are embarrassed to visit a family planning clinic;
- do not know of the existence of the clinic;
- find the clinic hours inconvenient;
- fear a pelvic examination; or
- are anxious about judgmental attitudes of the providers.

Programs should work to ensure that clinics serving adolescents are youth-friendly (for example, by ensuring privacy and confidentiality, accessible facilities, reasonably priced services, and flexible hours — particularly during evenings and weekends).

3.2 Women Who Have Been Sexually Assaulted

Reaching women who have been forced to have intercourse also poses special challenges. ECP providers should be attentive to the possibility that these women may be:

- unaware that something can be done to prevent pregnancy after sexual assault;
- unwilling to report the assault and therefore unwilling to seek services;
- concerned they will be blamed for the assault by the medical provider; or
- also in need of diagnosis and treatment for STIs.

Program managers and providers should ensure that police stations, emergency health care centers, and other facilities where women may seek help after an assault can provide clients with ECPs, if appropriate, or at least with information about where to obtain ECPs and other needed treatments as promptly as possible.

TABLE 1 ECP Formulations

	Formulation (per pill)	Common Brand Names	Dose
Levonorgestrel-only Regimen	LNG 1.50 mg	(registrations pending)	1 tablet
	LNG 0.75 mg	Imediat N, Levonelle-2, NorLevo, Plan B, Post-day, Postinor-2, Vika, Vikela	2 tablets at once **OR** 1 tablet, followed by 1 more 12 hours later
Combined Regimen	EE 50 mcg + LNG 0.25 mg **OR** EE 50 mcg + NG 0.50 mg	E-Gen-C, Eugynon, Fertilan, Imediat, Neogynon, Nordiol, Ogestrel, Ovral, Ovran, Preven, Tetragynon	2 tablets, followed by 2 more 12 hours later
	EE 20 mcg + LNG 0.10 mg	Alesse, Levlite, Aviane, Loette	5 tablets, followed by 5 more 12 hours later
	EE 30 mcg + LNG 0.15 mg **OR** EE 30 mcg + NG 0.30 mg	AnNa, Levlen, Levora, Lo/Femenal, Lo/Ovral, Low-Ogestrel, Microgynon 30, Nordette, Rigevidon	4 tablets, followed by 4 more 12 hours later

Abbreviations:
EE = Ethinyl Estradiol LNG = Levonorgestrel NG = Norgestrel

When using oral contraceptive pill packs containing 28 pills, the last seven pills should not be used. For all regimens, pills should be taken as soon as possible after intercourse but optimally within 120 hours.

This table was prepared in October 2003. An updated table may be found on the Consortium Web site at: www.cecinfo.org.

APPENDIX: USE OF IUDS FOR EMERGENCY CONTRACEPTION

Copper-bearing IUDs can be used as a method of emergency contraception. They are most appropriate for women in stable relationships who wish to retain the IUD for long-term contraception and who meet the screening requirements for regular IUD use. When inserted within seven days after intercourse, copper-bearing IUDs are the most effective method of emergency contraception; they reduce the risk of pregnancy by more than 99 percent.[49,50]

However, emergency IUD insertion requires a much higher degree of training and clinical oversight than administration of ECPs. Clients must be screened to exclude those who are already pregnant, those who have pelvic inflammatory disease or another reproductive tract infection, and those who are at high risk for STIs. In many instances, the act of intercourse that led to the request for emergency contraception might put the woman at increased risk for STIs, in which case the IUD is not an optimal contraceptive choice.

For further information about use of IUDs for emergency contraception, consult the *IPPF Medical and Service Delivery Guidelines*. The most recent edition, which contains information about emergency contraception, is available from IPPF, Regent's College, Inner Circle, Regent's Park, London NW1 4NS, UK; Web site: www.ippf.org.

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ABOUT THE INTERNATIONAL CONSORTIUM FOR EMERGENCY CONTRACEPTION

The mission of the International Consortium for Emergency Contraception is to expand access to and ensure safe and locally appropriate use of emergency contraception worldwide within the broader context of family planning and reproductive health, with emphasis on developing countries.

The seven founding members of the Consortium initially focused on introducing a dedicated emergency contraceptive pill product in selected "demonstration" countries. As interest in emergency contraception and the Consortium grew, the Consortium expanded its membership to include a wide range of organizations working to ensure that women have access to all forms of emergency contraception. The specific objectives of the Consortium are to:

- serve as an authoritative source of information about emergency contraception;
- be a voice for expanded access to and safe and appropriate use of emergency contraception;
- serve as a strategic planning forum for emergency contraception service delivery and information, education, and communication efforts;
- facilitate information sharing and networking among Consortium members and other groups working to broaden knowledge of and access to emergency contraception;
- encourage partnerships between public-sector organizations and private industry that are designed to make high-quality products for emergency contraception for large numbers of women worldwide at an affordable price; and
- seek and promote new emergency contraceptive methods that are safe and effective.

The Consortium welcomes applications for membership from noncommercial agencies that share the Consortium's overall goal of expanding access to emergency contraceptive products and services in developing countries. Interested applicants should contact the Consortium Coordinator. The Consortium and the American Society for Emergency Contraception also jointly produce an electronic update of emergency contraception activities worldwide. If you would like to subscribe or contribute an article to this update, please contact the Consortium at the following address or the American Society for Emergency Contraception at Amsocec@aol.com.

Consortium Coordinator
International Consortium for Emergency Contraception
E-mail: info@cecinfo.org
Web site: www.cecinfo.org

The International Consortium encourages the formation of regional networks or consortia in order to better address specific issues and local barriers to EC access. For information on these organizations, please contact the following addresses:

- **Africa:** EC Afrique. Web site: www.ec-afrique.org; E-mail: ec-afrique@pcnairobi.org; Mail: ECafrique Secretariat, Population Council, PO Box 17643, 00500 Nairobi, Kenya.
- **Latin America:** Latin American Consortium for Emergency Contraception (LACEC)/Consorcio Latinoamericano de Anticoncepcion de Emergencia (CLAE). Web site: www.clae.info; E-mail: vschiappa@icmer.org; Mail: Instituto Chileno de Medicina Reproductiva (ICMER), Jose Victorino Lastarria 26, Depto. 21, Santiago, Chile.
- **Asia (Southeast):** Asia Pacific Network on Emergency Contraception (APNEC). Web site: N/A; E-mail: equintillan@piwh.org; Mail: Pacific Institute for Women's Health, 3450 Wilshire Boulevard, Suite 1000, Los Angeles, CA 90010 USA.
- The Consortium maintains two listings of individuals and organizations working in the **Arab** and **East European/NIS/Balkan** regions. To join either region's listserve, please e-mail the following addresses: Arab region: arabregion@cecinfo.org. East Europe, the Balkans, and the NIS region: europeregion@cecinfo.org. Additional information and updated contact information are available on the Consortium Web site: www.cecinfo.org.

INTERNATIONAL CONSORTIUM FOR EMERGENCY CONTRACEPTION

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Appendix B

Website Resources

- **ACOG's Emergency Contraceptive Practice Bulletin**

  The American College of Obstetricians and Gynecology's (ACOG) Practice Bulletin contains clinical management guidelines on emergency oral contraception for clinicians. Information contained in this document is based on evidence-based research and findings on emergency contraception. It includes information on what emergency contraception is and the mechanism of action and information on safety, efficacy, risks, and benefits. In addition, clinical recommendations for prescribing and dispensing emergency contraception to patients is included with information on side effects and both dedicated products and use of oral contraceptives as emergency contraception. Recommendations are made based on scientific evidence as well as expert opinion. The Practice Bulletin on Emergency Contraception, which has useful and accurate information, is available at: http://www.acog.org.

- **ACOG News Release Supporting Over-the-Counter Provision of ECPs**
  http://www.acog.org/from_home/publications/press_releases/nr02-28-01-2.cfm.

- **Catalyst Consortium Website**

  Information about Catalyst Consortium's projects and their focus program areas including optimal birth spacing, postabortion care, south-to-south collaboration, adolescence, empowerment, and HIV/AIDS and sexually transmitted infection prevention. http://www.rhcatalyst.org/.

- **Center for Reproductive Rights Website**

  The Center for Reproductive Rights' website contains updated information on global issues and events related to reproductive health and rights. It includes links to other sites; publications; news; and information on advocacy, human rights, legal issues, contraception, abortion, adolescents, equality, and safe pregnancy. http://www.crlp.org/.

- **Consortium for Emergency Contraception in India's Website**

  This site contains information on the consortium meeting that was held in India in January 2001 and India's efforts to introduce emergency contraception. http://www.ecindia.org.

- **Emergency Contraception and the Global Gag Rule—An Unofficial Guide**

  A publication by Population Action International (PAI) which provides information about the global gag rule can be accessed at the PAI website:
  http://www.populationaction.org/resources/publications/globalgagrule/GagRule_download.htm.

- **Family Health International (FHI)**

  This site includes information about emergency contraception in five languages, English, French, Spanish, Russian and Arabic. It also includes training materials for both individual and group emegency contraception trainings. http://www.fhi.org/en/Topics/ECP.htm

- **Global Health Council Website**

  The Global Health Council's website contains information on international public health issues and news from around the world, as well as publications useful for advocates. http://globalhealth.org

  The Global Health Council's Report, "Promises to Keep: The Toll of Unintended Pregnancies on Women's Lives in the Developing World," contains global and regional statistics on unintended pregnancy and abortion and related maternal mortality, as well as links to other data sources. http://www.globalhealth.org/assets/publications/PromisesToKeep.pdf

  Useful data for ECP advocacy from the Global Health Council can be accessed at http://www.globalhealth.org/news/article/2319.

- **International Consortium for Emergency Contraception (ICEC) Website**

  Provides useful information about emergency contraception. http://www.cecinfo.org.

  Among the information available at this site is a list of countries in Africa, Asia, and Latin America where emergency contraception is available with information about the status of dedicated ECP products. The list, which is updated annually, can be accessed at: http://www.cecinfo.org/files/ecstatusavailability.pdf.

- **ICEC "Emergency Contraception Pills: Medical and Service Delivery Guidelines"**

  This resource provides medical guidelines that can serve as a standard of care for implementing a service protocol around ECPs. http://www.cecinfo.org/html/res-downloadable-mtrls.htm.

- **ICEC Policy Statements on ECPs**

  Updated and accurate information published by the ICEC including five statements on medical abortion, mechanism of action, timing and dosage, repeat use, and access. http://www.cecinfo.org/html/res-downloadable-mtrls.htm.

- **International Planned Parenthood Federation (IPPF) Website**

  The IPPF has made its Directory of Hormonal Contraceptives available online. This user-friendly, searchable database of hormonal contraceptives used worldwide is available in English, French, and Spanish. Users can search by composition, brand name, type, or manufacturer. http://www.contraceptive.ippf.org/.

  The IPPF's statement on emergency contraception can be found at: http://mirror.ippf.org/medical/imap/statements/eng/2000_05b.htm.

- **Latin American Consortium for Emergency Contraception Website**

  This resource can be accessed through the Pacific Institute for Women's Health website at: http://www.piwh.org/latinamerica.html#consortium.

- **Measure Demographic and Health Surveys Website**

  Individual country data can be accessed at: http://www.measuredhs.com/countries/start.cfm.

- **MERLIN Virtual Library—Monitoring and Evaluation Resources**

  A comprehensive collection of both print and electronic resources to assist in the monitoring and evaluation of health and population services. Developed by the United States Agency for International Development-funded MEASURE *Evaluation* Project, it is available on the Internet at: http://www.cpc.unc.edu/measure/merlin/merlin.html.

- **National Contraception Policy Guidelines, Republic of South Africa**

  A model for a dual protection approach (an approach that promotes strategies that prevent both unwanted pregnancy and STI/HIV infection) is provided by the National Contraception Policy Guidelines issued by the Republic of South Africa's Department of Health. In discussing barrier methods, these guidelines state, "In the event of condom failure, access to emergency contraception should be promoted more extensively." http://www.doh.gov.za/docs/factsheets/guidelines/contraception/contraception01.pdf.

  http://www.doh.gov.za/docs/factsheets/guidelines/contraception/contraception02.pdf.

- **Not-2-Late Website**

  This site provides information in English, Spanish, and Arabic about emergency contraception. Information on this site includes: ECPs available worldwide, promotional materials developed by other organizations worldwide, questions and answers, emergency contraception news, and references.
  http://www.not-2-late.com and http://ec.princeton.edu/.

  Specific information about the availability of combined oral contraceptives and ECP products, drawn from IPPF 2002 Directory of Hormonal Contraceptives, is accessible on the website: http://ec.princeton.edu/worldwide/default.asp.

- **Pacific Institute for Women's Health (PIWH) Website**

  This website has extensive information about women's and reproductive rights in Latin America. http://www.piwh.org. http://www.piwh.org/latinamerica.html.

- **PATH's Youth-Friendly Pharmacy Program Implementation Kit: Guidelines and Tools for Implementing a Youth-Friendly Reproductive Health Pharmacy Program**

  A resource for developing training sessions for pharmacists.

  http://www.path.org/files/RH_PPIK_1.pdf.

  http://www.path.org/files/RH_PPIK_2.pdf.

  http://www.path.org/files/RH_PPIK_3.pdf.

  http://www.path.org/files/RH_PPIK_4.pdf.

  http://www.path.org/files/RH_PPIK_5.pdf.

- **PATH's Emergency Contraception for Diverse Communities Project**

  This includes resources for developing clinician-focused training sessions.
  http://www.path.org/resources/ec_diverse-communities-proj.htm#notebook.

- **Population Council Website**

  This site provides useful information on their efforts to promote emergency contraception. http://www.popcouncil.org/rhfp/ec.html.

- **Population Reference Bureau Website**

  This website links to additional data resources, *Measure* and PopNet. http://www.prb.org/

  Individual country data is available at http://www.worldpop.org/datafinder.htm. and the Measure Demographic and Health Surveys website can be accessed at http://www.measuredhs.com/countries/start.cfm.

- **Profamilia Colombia Website**

  Profamilia is the IPPF affiliate in Colombia. Information on their programs and work can be found on this website, including links to information on their emergency contraception efforts. http://www.profamilia.org.co/.

- **United Nations World Contraceptive Use Website (1998)**

  This website provides individual country data.
  http://www.un.org/esa/population/pubsarchive/wcu/wcu.htm.

- **World Health Organization (WHO) Database Reports**
  The ICEC's website links to the WHO Database Reports, which list current scientific literature regarding emergency contraception compiled by WHO/HRP. Full citations and some abstracts are provided.
  http://www.cecinfo.org/html/res-downloadable-mtrls.htm.

- **WHO Emergency Contraception—A Guide for Service Delivery**

  Millions of unwanted pregnancies and abortions could be avoided if emergency contraceptives were easily accessible. This booklet provides technical and managerial advice on how to introduce emergency contraception into family planning programs This booklet explains how available methods are effective, easy to use, and safe for the majority of women who may need them. http://www.who.int/reproductivehealth/publications/FPP_98_19/FPP_98_19_abstract.en.html.

- **WHO Essential Medicines List**
  http://www.who.int/medicines/organization/par/edl/expcom13/list_apr2003.doc.

- **WHO Making Decisions about Contraceptive Introduction: A Guide for Conducting Assessments to Broaden Contraceptive Choice and Improve Quality of Care**

  This is a useful tool that can help program planners prepare for introduction of a new contraceptive method by assessing user perspectives, as well as quality of family planning services currently being delivered.
  http://www.who.int/reproductive-health/publications/rhr_02_11_contraceptive_introduction/ci-guide.pdf.

- **Women's Global Network for Reproductive Rights (WGNRR) Website**

  The WGNRR is an autonomous network of groups and individuals who aim to achieve and support reproductive rights for women. Their website contains useful information on many subjects that will be useful to those advocating for increased access to ECPs.

  http://www.wgnrr.org/.

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