



Emergency Contraception

A newsletter of the EC Network of the East European and Newly Independent States region

Issue 1, October 2004

Welcome to the Emergency Contraception Newsletter

Emergency contraceptive pills (ECPs) offer women an important second chance to prevent pregnancy when a regular contraceptive method fails, no method was used, or sex was forced. Despite endorsement of ECPs by major public health institutions such as the World Health Organization (WHO) and greater availability of dedicated ECPs (products labeled specifically for emergency contraception—EC), access remains limited for most women throughout the world. To some extent, limited access can be attributed to lack of knowledge, not lack of products. In the East European (EE) and Newly Independent States (NIS) region, for example, there is a product, Postinor[®], which has been widely available and used for many years as a regular, postcoital contraceptive. The current, more effective use of Postinor is for EC,* and the manufacturer, Gedeon Richter, Ltd., is now distributing it under the label Postinor and Postinor-2[®] as a dedicated ECP product. Greater awareness—among health providers as well as their clients—of EC as a

contraceptive option and of Postinor as an EC product can help prevent unintended pregnancies in the Eastern European and NIS region.

This newsletter aims to create greater awareness of ECPs by providing current, objective, and evidence-based information about this underutilized method. It contains news, resources, and lessons learned that could help program planners and health providers increase women’s access to ECPs.

The newsletter will be distributed electronically four times a year, in English and Russian, to a network of interested health providers, program managers, and decision makers in the EE and NIS region. It will link members of this network with EC advocates in other countries and it directs readers to Internet resources for further information about EC and other contraceptive methods.

One of the objectives of this newsletter is to promote information exchange and problem solving among network participants. The editor encourages readers to send news items regarding EC, as well as questions about provision and use of this method, to ecnetwork@path.org. To the extent possible, this information and responses to questions will be included in upcoming issues. Readers also are encouraged to share the newsletter with others who will find it of interest by sending their email addresses to ecnetwork@path.org so that they can be added to the distribution list. Readers who have questions about specific articles in the newsletter are encouraged to contact PATH directly at ecnetwork@path.org.

Contents

Questions and Answers About Emergency Contraceptive Pills	2
International EC news.....	3
EC programs: news from the EE/NIS region ..	5
Research results and technical updates.....	7
Publications.....	9
Meetings and events	10
Useful links.....	10
References.....	11

* The current formulation of Postinor is 0.75 mg levonorgestrel and the regimen for emergency contraception is two pills. Registrations are pending for a new EC formulation of 1.5 mg levonorgestrel, which will require only one pill.

The content of this newsletter is based in part on the “Emergency Contraception Newsletter” published twice a year by the International Consortium for Emergency Contraception (ICEC) and the American Society for Emergency Contraception (ASEC), and all articles are reprinted with permission of ICEC and/or ASEC. PATH is pleased to be able to adapt the newsletter to the East European (EE) and New Independent States (NIS) region and disseminate it to interested health providers, program managers, and decision makers.

About the ICEC

The mission of the International Consortium for Emergency Contraception and its members is to expand access to and ensure safe and locally appropriate use of EC worldwide within the broader context of family planning and reproductive health, with emphasis on developing countries. The Consortium maintains a global information network, issues internationally relevant normative materials about EC, including medical guidelines, and supports advocacy efforts at international, regional, and country levels. The Consortium now has 36 member agencies worldwide.



For more information, please visit www.cecinfo.org.

About the ASEC

The American Society for Emergency Contraception is a voluntary collaboration of organizations that promote the availability of EC for women. Founded in 1997, ASEC has four mandates: (1) to serve as a source of information for the media and others who want information on EC; (2) to serve as a watchdog for inaccurate or biased articles in the press and respond with accurate letters to the editor, and to watch for abuses of reproductive rights related to EC and draw attention to these problems; (3) to promulgate policies on EC and to support and disseminate the statements and guidelines of other organizations willing to endorse the method; and (4) to link its members, which are organizations working in the field of EC.

About PATH

PATH is an international, nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act. PATH’s work improves global health and well-being.



Headquartered in Seattle, Washington, PATH has 19 offices in 13 countries. PATH currently works in more than 100 countries in the areas of reproductive health; vaccines and immunization; HIV, AIDS, and tuberculosis; and children’s health and nutrition.

In 2002, PATH participated in developing and presenting a seminar on EC in Kyiv, Ukraine. One of a series presented by the Albert Schweitzer Institute with support from the Open Society Institute, the seminar brought together key EE and NIS policymakers, medical community leaders, and nongovernmental organizations (NGOs). These stakeholders subsequently became the core members of the EC Network of the EE and NIS. Following the EC seminar in Kyiv, PATH administered a small grants program that supported EC awareness-raising efforts of six organizations in Armenia, Lithuania, Macedonia, Moldova, Russia, and Uzbekistan.

For more information, please visit www.path.org.

Questions and Answers About Emergency Contraceptive Pills

What are ECPs?

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 EC involves taking ECPs, which are an elevated dose of hormonal contraceptive pills.* Prompt, easy, and affordable access to ECPs can reduce the rate of unwanted pregnancies and abortions. ECPs should be taken as soon as possible after unprotected sex. They are most effective the sooner they are taken—but can be used up to 120 hours after unprotected sex.†¹

ECPs containing only a progestin (levonorgestrel) or containing both estrogen (ethinyl estradiol) and progestin (levonorgestrel or norgestrel—the Yuzpe regimen) 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 a woman’s most fertile period, levonorgestrel-only ECPs reduce pregnancy risk by 89 percent, and the Yuzpe regimen reduces pregnancy risk by 75 percent.

Are ECPs safe?

ECPs are both safe and effective for women to use. WHO has stated that there are no contraindications to ECPs due to the small overall hormone dose and short duration of use.^{2,3} All women, even those women who for medical reasons cannot use birth control pills as a regular method of contraception, can use ECPs. The only condition restricting use of ECPs is an established pregnancy, defined as beginning with implantation, not because

* Another method of EC is insertion of an intrauterine device (IUD) into a woman’s uterus within seven days of unprotected intercourse.

† The 120-hour timeframe was recently established as the result of WHO research (see reference 1). ECP labeling may give the previous 72-hour timeframe and not currently reflect the new information.

ECPs are harmful, but because they will not work if a woman is already pregnant.⁴ Researchers have concluded that ECPs taken inadvertently during pregnancy will not harm a developing fetus.^{5,6}

What ECP products are available?

The two pharmaceutical companies that are the dominant suppliers of dedicated, levonorgestrel-only ECP products (i.e., products packaged and labeled specifically for EC) are Gedeon Richter Ltd. (their most well-known brand names are Postinor, Postinor-2, Plan B[®], Levonelle[®], Levonelle-2[®]) and Laboratoire HRA Pharma (brand names NorLevo[®], Vika[®], and Vikela[®]). Although these products have the same formulation (0.75 mg levonorgestrel), they are registered by different names in different countries. Health advocates and private ECP manufacturers are

actively working to achieve broader registration for ECPs in both developed and developing countries; at this writing, ECPs are registered in a total of 97 countries worldwide.⁷ There also are efforts by advocates in many countries, including the United States, to have ECPs given over-the-counter (OTC) status, which makes them available without prescription. In many countries of Western Europe, such as Belgium, Denmark, Finland, France, Norway, Sweden, and the United Kingdom,⁸ as well as in some states of the United States and several provinces of Canada, women can access levonorgestrel-only dedicated EC products either OTC or directly from pharmacists who provide EC screening and counseling services (called behind-the-counter or BTC access). In most countries of the EE and NIS region, Postinor and Postinor-2 are easily available through pharmacies.

International EC news

This section of the newsletter contains news items prepared by members of the International EC Consortium on their current activities related to registration, introduction, and promotion of ECPs, as well as discussion of issues related to regulatory status. This information can be useful to EE/NIS EC Network members as they develop awareness-raising strategies and consider the most effective ways to make ECPs accessible to women.

The issue of whether or not ECPs should be available without prescription is being debated in many parts of the world. In some countries, ECPs can be purchased OTC without prescription. In other countries ECPs are easily accessible in pharmacies where the pharmacist provides ECP screening and counseling services (this is called behind-the-counter or BTC).

Canada moves closer to allowing EC without a doctor's prescription

Canada is loosening restrictions on access to ECPs as they are considered to be safe and effective.

Health Minister Pierre Pettigrew announced on May 18, 2004, that Health Canada was moving forward with allowing access to levonorgestrel without a doctor's prescription. Health Canada has proposed to amend the Food and Drug Regulations by removing the levonorgestrel-only ECP, Plan B (the same product as

the Postinor product available in the EE and NIS region), from prescription-only status. The National Drug Scheduling Advisory Committee has recommended BTC status, which would require professional intervention from the pharmacist at the point of sale.

Plan B is expected to be marketed BTC in Canada approximately six months after the publication of the proposed amendment in the Canada Gazette, Part I, which took place in May 2004. In English Canada (Common Law), there will be no limit of age for access to EC in pharmacies. It is up to the provider to verify if the teenager understands all required instructions. In French Canada (Civil Code), the lower limit of age for access to EC in pharmacies is 14 years. Under this age, parental consent is necessary.

NorLevo to be available without a prescription in Dutch pharmacies

In November 2003, the Contraception Foundation in the Netherlands started a project to allow women to download a prescription for levonorgestrel-only ECPs at no charge that they could take to any pharmacist to obtain NorLevo. Between the start of the project and mid-April 2004, over 1,700 prescriptions were downloaded. Following a two-month evaluation procedure, the Dutch evaluation committee approved the switch from prescription-only to non-prescription status. The change was approved

with very few conditions, which included a slight modification of the summary of product characteristics with regards to vomiting, and the requirement of a more patient-friendly version of the package insert. The implementation of both of these changes shall take place by the end of 2004. If this decision is validated by the medical agency, women in the Netherlands will have wider access to the treatment at pharmacies with no prior prescription needed.

Implementing a global strategy to increase access to EC—the Belgian experience

NorLevo has been available in Belgium since September 2000. In June 2001, following scientific experts' advice, the Belgian Health Authorities decided to remove the requirement for a medical prescription to obtain NorLevo, thus facilitating access to and provision of EC. Also, since May 2004, women under 21 years old have had free access to the treatment. These measures were supported by a targeted and widespread information campaign conducted in schools and via pharmacists and family planning providers, youth magazines, and internet websites such as www.72.be (a user-friendly site that shows the hectic life of the spermatozoid and provides accurate information about the “morning-after pill”) and www.norlevo.be.

Advance provision of NorLevo could optimize its use, efficiency and access. Available data on risky sexual behavior suggest that good knowledge of EC reinforces regular contraception use and does not encourage its abuse. Since April 2004, an active strategy was implemented to recommend prescribing levonorgestrel-only ECP conjointly with a regular oral contraceptive, to provide information on the preventive aspect and occasional side effects of the product, and to answer women's concerns.

Update on application for OTC status for Plan B in the United States

The U.S. distributor of Plan B has applied to the U.S. Food and Drug Administration (USFDA) for OTC status.

Barr Laboratories, distributor of the levonorgestrel-only ECP, Plan B, in the U.S., submitted an application to the USFDA for OTC status in February 2004. The USFDA's external advisory panel and its own scientific staff recommended approval of OTC status. However, in May, the acting head of the USFDA made the rare move

of going against these recommendations and refused to grant OTC status to Plan B. The reason cited for this decision was that there was not sufficient information about the effects of ECPs on young adolescents. This action has brought widespread criticism. Critics, including most major health and physician organizations, say that this decision was influenced by political, not health, considerations. Barr Laboratories has resubmitted their OTC application proposing prescription-only status for women under the age of 16.

Two organizations, the Reproductive Health Technologies Project (RHTP) and NARAL Pro-Choice New York, are coordinating the campaign for OTC approval for Plan B. RHTP provides fact sheets and talking points in support of OTC status on their website at: www.backupyourbirthcontrol.org.

The following descriptions of ECP promotion efforts are examples of approaches for raising awareness of ECPs among key groups.

Promoting NorLevo in Western African countries

The first dedicated levonorgestrel-only ECP in Senegal, NorLevo was made available in the private sector in February 2002, under BTC status, with the initial objective of providing access to the product to women who face unwanted pregnancy following unprotected intercourse. Active promotion was undertaken among every target group directly concerned, with the aim of emphasizing their role in the provision of the treatment. These target groups included:

- Pharmacists, to ensure accessibility of the product and direct information to women.
- Midwives and nurses, to include one of the major sources of information and health services for women.
- Doctors and gynecologists, to encourage implementation of EC into the range of occasional contraceptive options.
- Women, to inform about the indication of the treatment and the way to get timely access to the treatments when needed.

The 9th International Medical Vision Conference (VIM), held in Dakar early April 2004, was the appropriate opportunity to provide accurate medical information to health care providers who were attending the event. HRA Pharma conducted three conferences detailing

the core medical information, including single-dose administration as well as frequently asked questions and recommended answers. Enthusiasm and interest were shown by many of the gynecologists and midwives, who were willing to actively share their experiences as providers of EC.

ECP sales and use boosted in Jamaica in award-winning “ACE” campaign

The Futures Group, an American NGO, created a social marketing program* that promoted abstinence, condom use, and ECPs as sequential options (in order of preference) for sexually active Jamaican youth under the Commercial Market Strategies (CMS) project. The Futures Group has defined this triple message campaign as the “ACE” (abstinence, condoms, and EC) approach to describe an appropriate prevention strategy for youth. Despite extremely limited funds and a short duration, the social marketing campaign nearly doubled ECP sales over the previous year, increased knowledge of ECPs as a method to avoid pregnancy from 28 percent to nearly 50 percent among girls and from 17 percent to 32 percent among boys ages 15 to 19, and increased use of ECPs after unprotected sex from baseline 2 percent to nearly 8 percent among girls ages 15 to 19. The ECP product that was available both before and during the project was a full priced, nonsubsidized, commercial product. During the project, condom sales also increased. The campaign was awarded the Population Institute’s Global Media Award for “Best Commercial Advertising Campaign” in 2003.

Registration of Postinor-1 underway

PROSALUD INTER-AMERICANA, a Latin American social marketing group, is pleased to announce that its network partners PROSALUD (Venezuela) and

PROSALUD (Peru) have started the registration process for Postinor-1, a one-pill presentation of Postinor-2. With the WHO finding that a single dose of both tablets of Postinor-2 offered the same benefits as taking the two pills 12 hours apart¹ (see page 7 for the summary of the study), the manufacturer of Postinor decided to offer a single dose. The registration is expected to take 90 to 120 days. Postinor-1 will improve compliance. PROSALUD plans to gradually discontinue the availability of Postinor-2 in favor of the newer presentation.

EC programs in Argentina, Ecuador set to begin

PROSALUD INTER-AMERICANA is pleased to announce that its network partner PROSALUD (Argentina) will commence activities in August. Funded in part by donations from Bergstrom Foundation, Population Services International (PSI), and PROSALUD INTER-AMERICANA, the program will replicate the PSIA model that has been successful in both Venezuela and Peru. Postinor-2 has been registered in Argentina since September 2003 and will be commercialized by a well-established importer/distributor of pharmaceutical products.

PROSALUD INTER-AMERICANA is also pleased to announce that its network partner COPPRENDE will commence activities in Ecuador in August. Funded in part by donations from Bergstrom Foundation, Population Services International, Compton Foundation, Conservation, Food and Health, and PROSALUD INTER-AMERICANA, the program will replicate the PSIA model that has been successful in both Venezuela and Peru. The registration of Postinor-2 will be completed in July and will be commercialized by a well-established importer/distributor of pharmaceutical products.

EC programs: news from the EE/NIS region

Success story—launch of NorLevo in Baltics

NorLevo was launched in two Baltic countries—Estonia and Latvia—in spring 2003, becoming the first levonorgestrel-only dedicated ECP in those countries to be granted OTC status. In order to secure successful entrance into the market, Nycomed communicated to end consumers and providers the simple message—“New emergency contraceptive!” The launch campaign mainly consisted of:

- Use of media channels: TV (sponsoring Youth TV Reality Show), print media, and the internet.
- Use of youth organizations to distribute information and special gimmicks, e.g. condoms packed in NorLevo branded pack to teenagers.
- Promotions targeting end consumers with the message, “Buy NorLevo, get condom free of charge.”

* Social marketing programs use commercial marketing techniques and systems for social benefit. They seek to influence social behaviors not to benefit the marketer, but to benefit the target audience and general society.

- Visits by sales people to gynecologists and pharmacists.

OTC status of NorLevo has increased the availability of hormonal EC, as well as knowledge about reproductive health and contraception for every woman.

EC Small Grant projects

In 2002, PATH participated in developing and presenting a seminar on EC in Kyiv, Ukraine. One of a series presented by the Albert Schweitzer Institute with support from the Open Society Institute (OSI), the seminar brought together key EE and NIS policymakers, medical community leaders, and NGOs. For the seminar materials, please see <http://health.osf.lt/en/archive/2002/index.php?id=1736&no=0&gid>. Following the EC seminar, PATH administered a one-time-only small grants program, funded by OSI, that supported EC awareness-raising efforts by six organizations in Armenia, Lithuania, Macedonia, Moldova, Russia, and Uzbekistan. Three of these efforts are described below.

Increasing awareness of and access to EC in Moldova Republic

The Women's Health Care Center "Dalila" (WHCD) implemented a project to raise awareness of and increase access to EC in three big cities in Moldova (Chisinau, Drochia, and Cahul). Working closely with the Ministry of Health of Moldova, the Medical University of Moldova, the Medical Republican College, the Women's Health Care Centers in Drochia and Cahul, and the local NGO, "Partners for Community," WHCD conducted



EC Seminar for Journalists - Chisinau

one-day EC training sessions to a total of 43 family planning doctors, 74 family doctors, and 81 nurses in three regions of Moldova.

Recognizing the importance of providing accurate information on EC to women, WHCD conducted an EC seminar that was attended by 27 journalists who represented 18 major media organizations in Moldova, including radio, television, and printed media. In collaboration with the radio "Antena C," WHCD launched a weekly radio show for youth dedicated to family planning issues. The program, which included discussion of EC, covered 80 percent of the territory of Moldova. In addition to dissemination of EC information through mass media, WHCD developed, pretested, and printed 40,000 EC brochures for women in Russian. These materials were distributed through 53 family planning centers, abortion centers, pharmacies, and other organizations throughout the country. The extensive reach of WHCD's EC project demonstrated that a great deal can be accomplished with limited resources.

EC awareness promotion in Armenia

Adventist Development and Relief Agency (ADRA) carried out a four-month awareness-raising campaign in the area surrounding the city of Goris. The campaign included community meetings, training of medical personnel, and dissemination of printed materials. EC information meetings in seven villages of the area (Shinuhair, Khot, Halidzor, Tatev, Khndzoresk, Nerqin Khndzoresk, and Tegh) reached 137 women of reproductive age in those communities. Using the training materials provided by PATH at the Schweitzer EC Seminar in Kyiv, ADRA conducted a one-day EC seminar for 31 health care providers (6 ob/gyns and 25 nurses) of the Family Health Center in Goris.

ADRA translated into Armenian and printed 2,000 copies of an EC brochure that Gedeon Richter, Ltd., the manufacturer of Postinor, had made available in Russian. In addition, ADRA developed and printed 500 flyers on EC. These EC materials were widely distributed through the community meetings and the trainings and were provided to other NGOs working in reproductive health field.

ADRA also addressed the issue of ECP product supply. Although ECPs are readily available in the cities, women have limited access to ECPs in rural areas. To introduce the product in the rural areas and generate demand,

ADRA supplied the government-run women's health clinic with 162 boxes of Postinor-2 for distribution to women free of charge.



EC training materials and Postinor provided to seminar participants

Uzbekistan EC project “For a new generation”



Uzbekistan Health Institute, a Branch of Kashkadyr Oblast (UHIBKO), conducted 24 one-day EC seminars for teenagers, medical college students, and women in five raions of Kashkadyr Oblast (Guzan, Kasan, Shakhrisabz, Kasbi, Mubarek, and Karshi City). With the logistical support of the local government, UHIBKO reached 300 young people and 300 women of reproductive age with information about family planning, including EC.

UHIBKO also disseminated information about EC through printed materials and the media. They developed, printed, and distributed 10,000 EC brochures in Uzbek and published an article in the national medical newspaper, *Health Care of Uzbekistan*, which reaches most of the medical providers in the country.

Research results and technical updates

Updated regimen for levonorgestrel-only ECP

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, and levonorgestrel is effective up to 120 hours (five days) after unprotected intercourse.

von Hertzen H, et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomized trial. *The Lancet*. 2002; 60:1803-1810.

A 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 EC 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 (the levonorgestrel product was the same as Postinor). All three regimens are very effective at preventing pregnancy if taken within five days (120 hours) of unprotected intercourse, although the study showed a significant trend towards a lower efficacy the longer the delay between treatment and unprotected intercourse. The study also found that the levonorgestrel regimens were not only as effective as

mifepristone, but that the women who used mifepristone were more likely to get pregnant if they had further acts of unprotected intercourse than those who used levonorgestrel. 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 EC regimen.

Analysis of DIAL EC data complete, published in *Contraception*

In most states in the United States, ECPs are available only by prescription. To facilitate timely access to this time-sensitive method, ECP advocates in several states have established a telephone line that women can call to obtain prescriptions. Analysis of one such program is described below.

Raymond EG, Spruyt A, Bley K, Colm J, Gross S, Robbins LA. The North Carolina DIAL EC Project: Increasing Access to Emergency Contraceptive Pills by Telephone. *Contraception*. 2004; 69:367-372.

Family Health International has completed an analysis of data collected by the DIAL EC Project, which was initiated

in February 2001 at Planned Parenthood of Central North Carolina. The results of the analysis were published in *Contraception*. The project enabled North Carolina residents to obtain prescriptions for ECPs by telephone. In the first 29 months of the project, we issued 9,745 prescriptions to 7,774 callers. Forty percent of callers were teens. Only 16 percent of callers received more than one prescription. The service was initially free, but in the last six months, most callers were asked to pay \$40 per prescription. The fee resulted in a decline in the number of prescriptions issued, but the service became financially self-sustaining. This service proved to be an effective and efficient means for increasing access to ECPs in underserved areas.

Study evaluates impact on risk-taking behaviors among adolescents receiving advance provision of EC

One approach for ensuring that women have access to ECPs is to provide them in advance of need. Questions have been raised as to whether this approach would increase irresponsible sexual activity, in particular among teens. Following is a description of the results of a study looking into this issue.

Gold MA, Wolford JE, Smith KA, Parker AM. The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. *Journal of Pediatric and Adolescent Gynecology*. 2004;17(2):87-96.

A randomized trial was conducted at an urban, hospital-based adolescent clinic in Pittsburgh, PA, from June 1997 to June 2002. The objective of this study was to determine whether adolescents given advance EC have higher sexual and contraceptive risk-taking behaviors compared to those obtaining it on an as-needed basis. Three hundred and one predominantly minority, low-income, sexually active adolescent women, ages 15 to 20, not using long-acting contraception, participated in the study. At both one and six-month follow-up interviews, there were no differences between advance EC and control groups in reported unprotected intercourse within the past month or at last intercourse. At six-months, more advance EC participants reported condoms use in the past month compared to control group participants (77 percent versus 62 percent, $p=0.02$), and at last intercourse (advance EC 83 percent versus control 78 percent, $p=0.34$). There were no significant differences by group in hormonal contraception use reported by advance EC or control groups in the past month (44 percent versus 53 percent, $p=0.19$) or at last intercourse (48 percent

versus 58 percent, $p=0.20$). At the first follow-up, the advance group reported nearly twice as much EC use as the control group (15 percent versus 8 percent, $p=0.05$) but not at the final follow-up (8 percent versus 6 percent, $p=0.54$). Advance EC group participants began their EC significantly sooner (11.4 hours versus 21.8 hours, $p=0.005$). Providing advance EC to adolescents is not associated with more unprotected intercourse or less condom or hormonal contraception use. In the first month after enrollment, adolescents provided with advance EC were nearly twice as likely to use it, and they began EC sooner, when it is known to be more effective.

Review of EC data: mechanisms of action of levonorgestrel and mifepristone when used for EC

Gemzell-Danielsson K, Marions L. Mechanisms of action of mifepristone and levonorgestrel when used for emergency contraception. *Human Reproduction Update*. 2004;10(4):341-348.

One of the main barriers to widespread use of ECPs is concern about the mechanism of action. Recently, treatment with either 10 mg mifepristone or 1.5 mg of levonorgestrel has emerged as the most effective hormonal method for EC with very low side effects. However, the knowledge of the mechanism of action of levonorgestrel and mifepristone in humans, when used for contraceptive purposes and especially for EC, remains incomplete. The objective of this review was to summarize available data on the effects of mifepristone and levonorgestrel on female reproductive functions relevant to the emergency use of the compounds. When summarized, available data from studies in humans indicate that the contraceptive effects of both levonorgestrel and mifepristone, when used in single-low doses for EC, involve either blockade or delay of ovulation, due to either prevention or delay of the LH surge, rather than to inhibition of implantation.

Research on mechanism of action of levonorgestrel: results of two animal studies

Muller AL, Lladós CM, and Croxatto HB. Postcoital treatment with levonorgestrel does not disrupt postfertilization events in the rat. *Contraception*. 2003; 67(5):415-419.

Croxatto HB, Oritz ME, Muller AL. Mechanisms of action of emergency contraception. *Steroids*. 2003; 68(10-13):1095-1098.

In the articles cited above, the results of two key animal studies are discussed, as well as results of several other studies undertaken to determine exactly how ECPs 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 levonorgestrel 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 (see citation above). A similar study on Cebus monkeys was conducted to test the effect of acute levonorgestrel treatment on ovulation in nonmated cycles and on the pregnancy rate in mated cycles. Levonorgestrel 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 levonorgestrel treatment had no postfertilization effects in the Cebus monkeys.

Society for Adolescent Medicine issues position statement on EC

The Society for Adolescent Medicine has recently written a position statement on EC. The statement includes support for both advance prescription and OTC availability for adolescents. The statement was published in the July 2004 issue of the *Journal of Adolescent Health* (Volume 35, pages 66-70). It can be accessed on the internet at http://www.adolescenthealth.org/html/PositionPaper_EmergencyContraception.pdf.

Publications

ICEC evidence-based materials on EC available online (English, French, and Spanish)

ICEC has issued a set of five statements with accurate, up-to-date information on improving access, EC and medical abortion, repeat use, mechanism of action, and timing and dosage. They can be accessed online at <http://www.cecinfo.org/html/res-downloadable-mtrls.htm>. Single copies of these publications can also be requested free of charge from the International Consortium.

The Consortium has also published *Medical and Service Delivery Guidelines for Emergency Contraceptive Pills* for use in training programs or for distribution to clinical staff. The updated version of these guidelines incorporating recent revisions on ECPs dosage and timing can be accessed online at <http://www.cecinfo.org/html/res-downloadable-mtrls.htm>. Single copies are available free of charge. Multiple copies can be purchased.

PATH's new publication, Resources for Emergency Contraceptive Pill Programming: A Toolkit (English and Spanish)

The purpose of this toolkit is to help policymakers, program planners, donors, and family planning providers integrate ECPs into family planning and reproductive

health programs in developing countries. The toolkit has been introduced in national workshops in Indonesia, Kenya, Bolivia, Paraguay, and Nicaragua through collaborations with CISTAC, PROMESA, the Latin American Consortium for Emergency Contraception, and ECafrique. The toolkit is available online at http://www.path.org/resources/ec_resecpprog-toolkit.htm in English and http://www.path.org/resources/ec_resecpprog-toolkit-sp.htm in Spanish. To order a copy of the CD-ROM, please send a message to publications@path.org.

PPFA has updated online EC fact sheets (English)

The Katharine Dexter McCormick Library at Planned Parenthood Federation of America has recently updated its four key fact sheets on EC. They can be accessed on the internet at <http://www.plannedparenthood.org/ec/>.

The titles are:

- Emergency Contraception
- A Brief History of Emergency Contraception
- Obstructing Access to Emergency Contraception in Hospital Emergency Rooms
- The Difference Between Emergency Contraception and Medical Abortion

Meetings and events

There have been many meetings held in Europe, the United States, and Latin America during the past year. In the United States, issues discussed included provision of EC for victims of sexual assault, specifically in regard to the need for legislation mandating provision of ECPs by emergency rooms in hospitals; expanding access to ECPs through multiple state government programs, including social services as well as health services; OTC status of Plan B, and how it would affect provision of Plan B by state programs. Presentations on EC were made at a meeting of the Ecuadorian Federation of the Gynecology and Obstetrics Societies (FESOG) in Ecuador, and at the International Federation of Professional Abortion and

Contraception Associates meeting in Vienna, Austria.

The International Consortium for EC Annual Meeting was held on September 30, 2004, in New York City. In the upcoming issues of the EE and NIS Newsletter, information about the proceedings of this meeting will be provided.

For future issues of this newsletter, we hope that EE and NIS EC Network members will send us information about meetings on EC that have taken place in their countries. Please send this information by email to ecnetwork@path.org.

Useful links

Medical Eligibility Criteria for Contraceptive Use, 3rd Edition, 2004 (English)

World Health Organization (WHO) has updated the second edition of its publication, *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use*, which was published in 2000. It summarizes the main recommendations of an expert Working Group meeting held at the WHO, Geneva, October 21-24, 2003. The document provides recommendations for appropriate medical eligibility criteria based on the latest clinical and epidemiological data and is intended to be used by policymakers, family planning program managers, and the scientific community.

The document covers the following family planning methods: low-dose combined oral contraceptives (COCs), combined injectable contraceptives (CICs), combined patch (P), combined vaginal ring (R), progestogen-only pills (POPs), depot medroxyprogesterone acetate (DMPA), norethisterone enantate (NET-EN), levonorgestrel (LNG) and etonogestrel (ETG) implants, ECPs, copper intrauterine devices (Cu-IUDs), levonorgestrel-releasing IUDs (LNG-IUDs), copper-IUD for EC (E-IUD), barrier methods (BARR), fertility awareness-based methods (FAB), lactational

amenorrhoea method (LAM), coitus interruptus (CI), and female and male sterilization (STER). It can be accessed online at: http://www.who.int/reproductive-health/publications/RHR_00_2_medical_eligibility_criteria_3rd/.

PATH's RHO website: Fall 2004 edition (English)

The Reproductive Health Outlook (RHO) website (www.rho.org) is designed for reproductive health program managers and decision makers. RHO provides up-to-date summaries of research findings, program experience, and clinical guidelines related to key reproductive health topics. RHO contains 14 sections:

1. Adolescent Reproductive Health
2. Cervical Cancer Prevention
3. Contraceptive Methods
4. Family Planning Program Issues
5. Gender and Sexual Health
6. Harmful Health Practices
7. HIV/AIDS
8. Infertility
9. Information and Communication Technologies
10. Men and Reproductive Health

11. Refugee Reproductive Health
12. Reproductive Health Needs of Older Women
13. Reproductive Tract Infections
14. Safe Motherhood

RHO also provides links to the best in-depth reproductive health information on the internet.

Comprehensive Counseling for Reproductive Health: An Integrated Curriculum, EngenderHealth, 2003 (English)

This is a curriculum designed to put the concept of integrated reproductive health services into practice by helping all levels of service providers develop the communication and counseling skills needed to assess and address their clients' comprehensive sexual and reproductive health needs. It can be accessed at: <http://www.engenderhealth.org/res/offc/counsel/ccrh/index.html>.

References

1. von Hertzen H, et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a World Health Organization (WHO) multicentre randomized trial. *The Lancet*. 2002; 360 (9348): 1803-1810. (See abstract in Research Results and Technical Updates section of this newsletter.)
2. 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. *The Lancet*. 1998; 352(9126):428-433.
3. Ho CC and Kwan MS. A prospective randomized comparison of levonorgestrel with the Yuzpe regimen in postcoital contraception. *Human Reproduction*. 1993; 8(3):389-392.
4. WHO. *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use*. 2nd ed. Geneva: Reproductive Health and Research, WHO; 2000.
5. Norris TA and Ellertson C. How safe is emergency contraception? *Drug Safety*. 2002;25(10):695-706.
6. Raman-Wilms L., et al. Fetal genital effects of first-trimester sex hormone exposure: a meta-analysis. *Obstetrics and Gynecology*. 1995; 85(1):141-149.
7. The International Consortium for Emergency Contraception provides a listing of the registration status of ECP products in countries around the world on its website at <http://www.cecinfo.org>.
8. Allan Guttmacher Institute. Issues in Brief 2003 Series N. 3. (Accessed 10/25/2004 at http://www.guttmacher.org/pubs/ib_3-03.html)