

POSITION PAPER

Provision of Emergency Contraception to Adolescents

Position Paper of the Society for Adolescent Medicine

Background

In 2000, adolescents in the United States had nearly 822,000 pregnancies despite improvements in the accessibility and range of contraceptive options available [1]. Eighty-five percent of pregnancies in adolescents were unintended, resulting in nearly 489,000 births and 235,000 abortions [1]. Timely use of emergency contraception could prevent up to 70% of abortions. In this Position Paper, emergency contraception refers to the use of estrogen and progestin-containing pills (combination emergency contraceptive pills or ECPs) or levonorgestrel-only pills (progestin-only ECPs) that are taken after unprotected intercourse to prevent pregnancy. ECP use is indicated any time sexual intercourse is unprotected (e.g., nothing is used to prevent pregnancy) or under-protected. Under-protection occurs in such instances when a condom breaks or slips, two or more combination oral contraceptive pills (OCP) are missed, one or more progestin-only pills is missed, a depot medroxyprogesterone acetate (Depo-Provera™) shot is 2 or more weeks late, the transdermal patch is detached for 24 hours or longer during the patch-on weeks, the vaginal ring is expelled or removed for 3 hours or longer during the ring-use weeks, vaginal spermicide is used alone, or a diaphragm or cervical cap is dislodged during intercourse.

ECPs reduce the risk of pregnancy after unprotected sex, preventing approximately 80% to 85% of pregnancies that would otherwise occur [2-4]. If used after all contraception failures, ECPs could prevent 50% of unintended pregnancies [5]. The efficacy of progestin-only ECPs is greater than that of combination ECPs; in one study, progestin-only

ECPs prevented 85% of pregnancies that would have been expected to occur without medication, whereas combination ECPs prevented 57% [6]. Though FDA-approved for use up to 72 hours after unprotected intercourse, ECPs have been shown to reduce the risk of pregnancy if taken up to 120 hours after intercourse [6,7]. Some studies demonstrate ECPs are more effective the sooner they are taken [4,8,9]. Delaying the first dose of ECPs by 12 hours from the time of unprotected intercourse increases the odds of pregnancy by almost 50% [9]; the risk of pregnancy continues to increase with the passage of time from unprotected intercourse up to 120 hours. Given the data that suggest ECPs are more effective the sooner they are used, it is of critical importance to improve adolescents' knowledge, use of, and access to ECPs. Adolescent health care providers play a vital role in helping adolescents prevent pregnancy through timely use of ECPs.

The established mechanisms of action of both combination and progestin-only ECPs include delaying or inhibiting ovulation, disrupting follicular development, and/or interfering with the maturation of the corpus luteum [10]. Clinical data have not verified other theorized mechanisms of action that may be involved, such as preventing implantation, altering sperm or egg transport, inhibiting the fertilization process, or changing cervical mucous. Accidental use of ECPs during pregnancy will neither interrupt a pregnancy after implantation nor be teratogenic [11-13]. The predominant side effects associated with use of combination ECPs are nausea (51%) and vomiting (19%) [7]. Less common side effects include fatigue, breast tenderness, headaches, dizziness, and abdominal pain. Compared with combination ECPs, progestin-only ECPs have signifi-

cantly fewer side effects, especially less nausea (23%) and vomiting (6%) [6].

There are virtually no contraindications to using ECPs in healthy adolescents. ECPs will not interrupt or harm an established pregnancy. Several studies involving the long-term use of OCPs have not shown any teratogenic effects on the fetus [11–13]. For combination ECPs, some health care providers use the same contraindications as for ongoing use of hormonal contraceptives containing estrogen such as history of thromboembolism, ischemic heart disease, uncontrolled hypertension, or hypersensitivity to any of the components. However, these conditions are rare among adolescents and many experts feel that a single course of combination ECPs does not carry the same risks as ongoing contraceptive use. Compared with combination ECPs, progestin-only ECPs have fewer theoretical medical risks; contraindications are limited to ongoing pregnancy, hypersensitivity to any component of the product (which is rare), and undiagnosed abnormal vaginal bleeding. However, if an adolescent has undiagnosed vaginal bleeding and requires ECPs, there is no reason to withhold the medication while the cause of the bleeding is being evaluated. Although both forms of ECPs are extraordinarily safe [14], progestin-only ECPs are preferred in women with a history of medical contraindications to estrogens such as venous thromboembolism [15].

Anticipatory Guidance

Adolescent health care providers are encouraged to routinely provide information and counseling about ECPs to adolescents, regardless of gender or current contraceptive method. Adolescent health care providers are encouraged to counsel adolescents about ECPs during visits for routine health care, as well as during visits for reproductive health care. Counseling should take into account the adolescent's age, developmental level, sexual orientation, and sexual history. Discussion of ECPs is especially important for adolescents with chronic illnesses whose current treatment may be teratogenic to the fetus or for whom pregnancy would severely compromise their health.

Counseling about ECPs should include a description of the method, the mechanisms of action, indications for use, efficacy, safety, common side effects, time limits for use, and where and how to obtain the method. In addition, adolescent health care providers should provide information about other, more

effective methods of contraception when providing information about ECPs. Counseling should emphasize that ECPs and other hormonal methods of contraception do not prevent sexually transmitted infections (STI). Adolescent health care providers are encouraged to provide information about ECPs in the office or clinic through a variety of modalities, including written brochures, wallet cards, posters, websites, and informational hotlines. In the United States, adolescents can obtain telephone information about ECPs by calling the toll free number: 1-888-NOT-2-LATE.

The Provision of ECPs

During clinical encounters, adolescent health care providers are encouraged to ask each sexually active female adolescent when she last had vaginal intercourse, what she used for pregnancy prevention, and if there was any known failure of the method(s). When an episode of unprotected vaginal intercourse is reported within the past 120 hours, ECPs should be offered and, when possible, provided on site. All female adolescents receiving health care related to sexual assault in emergency departments and other health care settings should be counseled about ECPs and provided with a complete course of ECP treatment at the time of assessment, if desired by the adolescent. Provision of ECPs should not be contingent on an adolescent's receiving comprehensive health care. Providers should be aware that requiring office visits, pregnancy testing, pelvic examination, Pap smear or STI testing before prescribing or dispensing ECPs can pose significant barriers to timely access to ECPs and are rarely indicated. Adolescent health care providers and pharmacists should maintain the same degree of confidentiality when providing ECPs as they do when providing other reproductive health care.

Current evidence suggests that progestin-only ECPs have the most favorable balance of safety, side effects, and efficacy [6]. Given that progestin-only ECPs are associated with less nausea and vomiting and are more effective in preventing pregnancy than combination ECPs, progestin-only ECPs are the preferred regimen to provide for emergency contraception. However, if progestin-only ECPs are not available, adolescent health care providers should provide a combination ECP regimen with which they are familiar. Anti-emetics taken 1 hour before taking the combination ECPs can decrease the incidence of gastrointestinal side effects; providers are encour-

aged to offer anti-emetics in conjunction with combination ECPs. When progestin-only ECPs are prescribed, adolescents should be instructed to take both tablets at once (rather than the current FDA-approved label instructions to take the first tablet as soon as possible after unprotected or under-protected intercourse and the second tablet 12 hours later). Taking both tablets at once is an easier regimen to follow and there is evidence that this is just as effective as splitting the dose in two. This single, two-tablet dose of progestin-only ECPs is not associated with more side effects when compared with other standard progestin-only ECP regimens [4].

Adolescents should be counseled to follow up with their health care provider 2 weeks after they use ECPs to ensure that they did not become pregnant, to consider testing for sexually transmitted infections, and to discuss their future plans for effective contraception. Adolescents should be instructed to follow up for a pregnancy test if they do not get a menses within 3 weeks of using ECPs.

Adolescent health care providers are encouraged to offer all female adolescents an advance prescription or advance course of ECPs to have in the event of a future episode of unprotected intercourse or contraceptive failure. When a prescription is given, clinicians are encouraged to provide the adolescent with a list of local pharmacies confirmed to have ECPs in stock. Adolescent health care providers are encouraged, whenever possible, to prescribe ECPs over the telephone and are encouraged to develop protocols for telephone triage, and standing orders to facilitate ready access to ECPs as soon as possible.

Access to ECPs

Adolescent health providers and pharmacists are encouraged to establish written protocols to avoid undue delay, embarrassment, or transportation burdens for adolescent patients trying to obtain ECPs. This will ensure access to ECPs for all adolescents and will prevent the personal convictions of an individual health care provider or pharmacist from interfering with ECP provision and use [16]. Numerous medical and women's advocacy organizations support a change in the status of ECPs from prescription-only to over-the-counter (OTC). On December 16, 2003, members of the FDA Nonprescription Drugs and Reproductive Health Drugs Advisory Committees overwhelmingly recommended the approval of the application to make progestin-only ECPs (Plan B™) available over-the-counter. The

committee voted 23 to 4 in favor of the switch, agreeing that Plan B™ is safe and effective enough for use without medical supervision and that the labeling provides sufficient information to ensure safe and effective over-the-counter use. The consensus of most medical, public health, consumer, and advocacy organizations is that there is a tremendous need for ECPs to be made available OTC. The FDA's decision on the application has been postponed and is still pending. As a result of current controversy over making ECPs OTC, the FDA has been considering approving OTC status but with an age restriction. An age restriction would seriously limit adolescents' access to ECPs. Restrictions to OTC access have been opposed by numerous health and advocacy organizations. In addition, concerns have been expressed about the political pressures that may be influencing this delay in decision-making to switch Plan B to OTC status [17].

ECPs and Advocacy

Health care providers, pharmacists, and patients still have misconceptions and inadequate information about ECPs that interfere with patient access to and use of ECPs [18–20]. Educators of adolescent health providers should be a resource for providing medically accurate information. After lack of information, cost is a primary barrier for adolescents who require ECPs. Adolescent health care providers should urge pharmaceutical companies to set affordable pricing and to charge reasonable fees for pharmacist counseling regarding ECPs so that cost is not a barrier to adolescents accessing ECPs. Another common barrier to timely access to ECPs is pharmacies not maintaining a supply of ECPs for immediate provision. Large retail pharmacy chains should be encouraged to keep ECPs in stock. Adolescent health care providers are encouraged to advocate for their state legislatures and relevant regulatory bodies to authorize measures to permit collaborative practice agreements that would allow trained pharmacists to dispense ECPs with a pre-approved protocol, rather than by prescription. Adolescent health providers with prescriptive authority are encouraged to create and authorize standing orders for ECP provision by nurses, pharmacists, and other authorized health care providers.

Position Statement

The prevention of unintended adolescent pregnancy requires a multifaceted approach that includes pri-

mary and secondary prevention methods. Adequate information about and access to ECPs are essential components of secondary prevention efforts. The Society for Adolescent Medicine (SAM) asserts its support for increasing awareness of and improving timely access to ECPs with the following positions:

Provision of ECPs

- Adolescent health care providers are encouraged to counsel all adolescents about ECPs during visits for acute as well as routine health care.
- All female adolescents being treated for sexual assault in emergency departments or other health care settings should be counseled about ECPs and offered a complete course of ECP treatment at the time of assessment.
- ECPs should be offered, and preferably provided at the site where adolescents receive health care, whenever an episode of unprotected vaginal intercourse or contraceptive failure is reported within the past 120 hours. Although FDA-approved for use up to 72 hours, ECPs are effective and should be provided to adolescents up to 120 hours after unprotected intercourse. Provision of ECPs should not be contingent on an adolescent's receiving pregnancy testing, pelvic examination, Pap smear or STI testing.
- Adolescent health care providers should prescribe progestin-only ECPs as the ECP regimen of choice because of higher efficacy and lower side effects. When progestin-only ECPs are prescribed, adolescents should be instructed to take both tablets at once and as soon as possible after unprotected intercourse (rather than the current FDA approved label instructions to take the first tablet as soon as possible after unprotected or under-protected intercourse and the second tablet 12 hours later).
- Adolescent health care providers and pharmacists should maintain the same degree of confidentiality when providing ECPs as they do when providing other reproductive health care.

ECP Accessibility and Advocacy

- To reduce barriers to accessing ECPs, SAM strongly supports efforts to change the status of ECPs from prescription-only to over-the-counter without an age restriction.
- Until the FDA approves ECPs for over-the-counter status, adolescent health care providers should offer all female adolescents an advance ECP pre-

scription or ECP medication to take home for future use.

- Adolescent health providers and pharmacists are encouraged to establish written protocols to avoid barriers to obtaining ECPs irrespective of the individual health care provider's or pharmacist's personal attitudes and beliefs.
- Adolescent health providers and their professional organizations should develop and disseminate medically accurate, age-appropriate educational materials about ECPs and should advocate for distribution of these materials by state and local Departments of Health.
- Adolescent health care providers are encouraged to advocate for parity of insurance coverage for all contraceptive methods, including ECPs.

Note: The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

Prepared by:

Melanie A. Gold, D.O.
Associate Professor of Pediatrics
Division of Adolescent Medicine
University of Pittsburgh School of Medicine
Children's Hospital of Pittsburgh
Pittsburgh, Pennsylvania

Gina S. Sucato, M.D., M.P.H.
Assistant Professor of Pediatrics
Division of Adolescent Medicine
University of Pittsburgh School of Medicine
Children's Hospital of Pittsburgh
Pittsburgh, Pennsylvania

Lee Ann E. Conard, R.Ph., D.O., M.P.H.
Adolescent Medicine Assistant Professor
Department of Pediatrics
West Virginia University
School of Medicine
Morgantown, West Virginia

Paula J. Adams Hillard, M.D.
Professor of Obstetrics and Gynecology
Professor of Pediatrics
Division of Adolescent Medicine
University of Cincinnati College of Medicine
Cincinnati, Ohio

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