

A supplement to

DRUG TOPICS®

February 2006



For 2 CE Credits

Emergency Contraception

A Clinical Review

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This continuing education activity was sponsored by The University of Florida College of Pharmacy, produced by *Drug Topics*, a publication of Advanstar Medical Economics, and made possible by an unrestricted educational grant from **Duramed Pharmaceuticals, Inc.**

Program Release Date: February 20, 2006

Program Expiration Date: February 29, 2008

Target Audience:

All pharmacists will benefit from this program.

Program Completion Time:

The approximate time to complete this program is 2 hours.

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Faculty Disclosure:

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Universal Program Number 012-999-05-267-H01. Expires February 29, 2008.

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Emergency Contraception: A Clinical Review

Kathleen Besinque, Pharm.D., MEd., FCSHP, FASHP

Introduction

Emergency contraception (EC) is a safe and effective method to reduce the rate of unintended pregnancy after unprotected intercourse or contraceptive failure. The term “Emergency Contraception” refers to the use of medications or devices (IUD) after unprotected intercourse to prevent pregnancy. An unintended pregnancy is defined as a pregnancy that was unplanned or unwanted at the time of conception and includes pregnancy occurring in women using contraceptives. An unplanned pregnancy has both personal and public health consequences. The public health consequences are a lost opportunity to prepare for pregnancy in ways that reduce fetal and maternal morbidity and mortality such as: folic acid supplementation, management of preexisting conditions, and changes in lifestyle such as avoidance of alcohol or tobacco. Personal consequences include all of the issues related to an unplanned pregnancy, including birth or pregnancy termination.

Approximately one-half of all pregnancies occurring in the United States each year are unintended.¹ More than

Learning Objectives

After completing this continuing education article, the pharmacist will be able to:

1. Describe pharmacists’ role in increasing access to Emergency Contraception (EC)
2. Discuss the role of EC in preventing unplanned pregnancy.
3. Compare EC regimens available in the United States.
4. Describe the pharmacology and clinical indications for EC.
5. Explain the importance of access and timing of doses to the effectiveness of EC.
6. Discuss the potential side effects and safety issues related to EC.
7. Assist and counsel a woman seeking EC regarding how to use the therapy.

half of the 3 million unintended pregnancies in the United States are terminated by elective abortion; therefore increasing the use of EC has the potential to reduce not only the rate of unintended pregnancy but the number of abortions as well. It has been estimated that the use of EC may reduce the rate of unintended pregnancy by as much as 50%.¹ Although the unintended pregnancy rate is highest among teens, the problem is not limited to young women. Women ages 30-34 have an unintended pregnancy rate of 33%. Women over age 40 have the highest percentage of unintended pregnancies terminated by abortion (almost 65%).² The average woman in the United States will experience 1.4 unintended pregnancies by the time she reaches age 45.³ Access to EC is important for women of all ages as unintended pregnancy is common and can occur in any woman of childbearing age.

Emergency contraception has been described by numerous authors as the “best-kept secret” in women’s health.⁴ Unfortunately, despite media campaigns targeting consumers and healthcare providers, EC remains an underutilized contraceptive method. A survey of women aged 15-44 conducted in California by the Kaiser Family Foundation in 2003 found that while 81% of the women recognized the term “emergency contraception”, fewer than half of those recognizing the term knew that it referred to a contraceptive method used after intercourse and only 8% of the women had ever used EC.⁵ EC has been extensively studied since the 1970s worldwide. After more than three decades of use, the effectiveness of the method in preventing pregnancy (up to 89% reduction in pregnancy) is well documented. Unfortunately, a lack of public awareness along with misconceptions about how EC works and its safety continue. In 1997 the FDA published an announcement in the Federal Register describing EC or “post-coital contraception” as an important strategy to address the public health crisis of unintended pregnancy in the U.S. The FDA announcement cited EC regimens as safe and effective and invited the pharmaceutical industry to apply for approval of EC products.⁶ Currently only one FDA-approved product, Plan B® (levonorgestrel 0.75 mg tablets), is marketed in the U.S. as an emergency contraceptive. Plan B® is currently available only by prescription and is indicated for use in preventing pregnancy up to 72 hours after intercourse. The FDA Advisory Committees on Reproductive Health Drugs and Nonprescription Drugs voted on December 16, 2003, to support a request by the manufacturer of Plan B® to move the product to non-prescription status. The FDA, however, ruled on May 16, 2004, that the request was “non-approvable.” Duramed Pharmaceuticals, the manufacturer of Plan B®, has submitted additional data for reconsideration. At press time,

the FDA has not reached a decision on approval of Plan B® for non-prescription status because of unresolved issues relating to the marketing of a product in a single package sold as either prescription or OTC depending on the age of the patient.⁷

Pharmacists, as the “most accessible” healthcare provider, play a crucial role in providing access to EC. As a trusted member of the healthcare team, the pharmacist can provide EC to women directly in states with pharmacist direct access programs, refer women inquiring about EC to healthcare providers in states where direct access is not permitted, counsel women receiving EC on its proper use, and most critical of all keep EC products on the pharmacy shelf. Direct access to EC from a pharmacist is currently permitted in Washington, California, Hawaii, New Mexico, Alaska, Maine, New Hampshire, and Massachusetts.⁸ The time-limiting nature of EC (it is most effective within 72 hours of unprotected intercourse and may be more effective the sooner it is taken) means that ready access is essential. Having a supply of EC in the pharmacy reduces delays in starting therapy, improves outcomes, and serves the public health. Pharmacists, therefore, play a key role in ensuring women have access to this important therapy.

This article will provide pharmacists with a detailed description of EC, its mechanism, clinical use, safety, and information regarding changes in the regulatory status of Plan B® that will affect pharmacy practice.

Emergency Contraception: General Description

Oral emergency contraceptives, sometimes referred to as the “morning after pill,” are the use of the same contraceptive hormones found in some birth control pills to prevent pregnancy after unprotected intercourse. With EC the hormone regimen is slightly different than with ongoing birth control (two individual doses versus daily use) and the dose is higher than the dose used in oral contraceptives. There are two types of EC oral regimens currently utilized in the U.S., one containing levonorgestrel alone (Plan B®) and the Yuzpe regimen which is a combination of ethinyl estradiol and levonorgestrel. Both regimens have been FDA approved for pregnancy prevention when initiated within 72 hours of unprotected intercourse. EC is not the same as “the abortion pill” RU-486 (Mifiprex®).

The Yuzpe regimen (formally available as Preven® ethinyl estradiol 50mcg and levonorgestrel 0.25 mg tablets) was FDA approved in 1998. It has been in worldwide use since the 1970s. The Yuzpe regimen consists one dose (2 to 5 tablets) of a combined oral contraceptive product containing norgestrel or levonorgestrel (Table 1 contains a list of these products) followed by a second

TABLE 1**Brands and Doses of Dedicated Products and Oral Contraceptive Pills Used For Emergency Contraception**

Brand	Manufacturer	Dose	Ethinyl Estradiol per Dose (mcg)	Levonorgestrel per Dose (mg)*
One-Dose Regimen* (not FDA approved)				
Dedicated Emergency Contraception				
Plan B®	Duramed	2 tablets	0	1.5
Two-Dose Regimens (administered immediately and 12 hours later)				
Plan B®	Duramed	1 tablet per dose	0	0.75
Oral Contraceptive Pills				
Levora™	Watson	4 white tablets per dose	120	0.60
Levlen®	Berlex	4 light-orange tablets per dose	120	0.60
Lo/Ovral®	Wyeth	4 white tablets per dose	120	0.60 **
Low-Ogestrel®	Watson	4 white tablets per dose	120	0.60 **
Nordette®	Duramed	4 light-orange tablets per dose	120	0.60
Allesse®	Wyeth	5 pink tablets per dose	100	0.50
Aviane™	Duramed	5 orange tablets per dose	100	0.50
Levlite®	Berlex	5 pink tablets per dose	100	0.50
Ogestrel®	Watson	2 white tablets per dose	100	0.50 **
Ovral®	Wyeth	2 white tablets per dose	100	0.50 **
Tri-Levlen®	Berlex	4 yellow tablets per dose	120	0.50
Triphasil®	Wyeth	4 yellow tablets per dose	120	0.50
Trivora®	Watson	4 pink tablets per dose	120	0.50

*Two-Dose Regimens" is adapted from RA Hatcher, *et al*, *Contraceptive Technology: Seventeenth Revised Edition*. New York NY: Ardent Media, 1998. Updated by Felicia Stewart, MD, 2001.

* Recent WHO data (*Lancet* 2002; 360:1830-1880) for levonorgestrel showed that a 1.5 mg single-dose can substitute two 0.75 mg doses 12h apart. This simplifies the use of levonorgestrel without an increase in side effects. Pregnancy rates were slightly lower for the single dose regimen, but not statistically significant. Similar findings on single dose efficacy were obtained by Arowojulu *et al* (*Contraception* 2002; 66:269-273).

** The progestin in Ovral, Lo/Ovral, Low-Ogestrel, Ogestrel and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

Adapted with permission from Pharmacy Access Partnership, Oakland, California

dose taken 12 hours later. The regimen is highly effective when taken within 72 hours of intercourse (75% reduction in the rate of pregnancy). Several recent studies have evaluated the use of the Yuzpe regimen up to 120 hours after unprotected intercourse.^{9,10,11} The studies have concluded that treatment up to 120 hours after unprotected intercourse significantly reduced the rate of pregnancy. Although Yuzpe may be effective up to 120 hours, women should be encouraged to seek treatment as soon as possible to maximize efficacy.

Plan B[®] (levonorgestrel 0.75 mg tablets) is a progestin-only EC regimen with fewer side effects and higher efficacy than the Yuzpe regimen. Introduced in the U.S. in 1999, Plan B[®] consists of two doses of levonorgestrel 0.75mg taken 12 hours apart within 72 hours of unprotected intercourse. The levonorgestrel-only regimen has a higher efficacy rate (89% reduction in expected pregnancies ver-

sus 75% for Yuzpe¹²) and a lower incidence of nausea and vomiting when compared with the Yuzpe regimen. Recently studies have also evaluated the use of Plan B[®] up to 120 hours after intercourse with positive results.^{13,14} Efficacy is highest when Plan B[®] is administered as soon as possible; therefore women should be encouraged to initiate treatment as soon as possible.

Indications and contraindications

EC is indicated when contraceptive failure or unprotected intercourse have occurred and the woman does not want to become pregnant.¹⁵ Indications may include but are not limited to: contraceptive failure (condom slipped or broke), when a woman is late for a contraceptive injection, failure to use contraception, sexual assault, or post-coital exposure to a toxic or teratogenic agent. EC can be used when two or more doses of an oral contraceptive have

TABLE 2**Adverse Effects of Emergency Contraception**

Side Effect	Percent with Symptoms		P value
	Yuzpe (n=979)	Levonorgestrel (n=977)	
Nausea	50.5	23.1	<0.01
Vomiting	18.8	5.6	<0.01
Dizziness	16.7	11.2	<0.01
Fatigue	28.5	16.9	<0.01
Headache	20.2	16.8	0.06
Breast tenderness	12.1	10.8	0.40
Low abdominal pain	29.9	17.6	0.07
All other ADE	16.7	13.5	0.06

From: 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* 352:431, 1998

been missed, a contraceptive patch has fallen off for more than 24 hours, or a contraceptive ring was left out for more than 3 hours resulting in an increased risk of pregnancy. The absence of regular monthly menstrual cycles does not preclude the use of EC. Situations such as breastfeeding, a history of irregular cycles, and a number of other causes of amenorrhea should not prevent a woman from receiving EC. EC is indicated within 120 hours of intercourse not adequately protected by a contraceptive method including failure to use a method or failure of the method itself (i.e., condom breaking).

EC can also be used as “back-up” contraception. Women do not need to wait for an “emergency situation” to occur to receive a supply of or a prescription for EC. The American College of Obstetrics and Gynecology (ACOG) adopted an initiative encouraging healthcare providers to discuss EC with and offer an advance prescription for EC to every woman at every visit. Providing EC in advance of need, to keep at home “just in case,” may be the best indication for prescribing EC.¹⁶

The Planned Parenthood Federation of America, the World Health Organization (WHO), and the prescribing information for Plan B® cite no absolute contraindications for EC pills except pregnancy.^{17,18} Pregnancy is considered a contraindication because EC has no benefit (is ineffective) when a woman is already pregnant. The use of EC will NOT cause harm to or disrupt an existing pregnancy.¹⁵

A physical examination and extensive medical history are not required for the initiation of EC because it has no

clinically significant impact on conditions such as cardiovascular disease, angina, acute focal migraine, or severe liver disease.¹⁹ Contraindications to the use of ongoing hormonal contraceptives should not be applied to EC regimens as the literature does not support this. Worldwide use of EC over three decades has not produced evidence of serious adverse effects from the use of EC or worsening of the medical conditions considered contraindications to ongoing hormonal contraceptive use.²⁰

Mechanism of Action

The mechanism or mechanisms of action by which EC prevent pregnancy are thought to be similar to those of oral contraceptives. There is good evidence that EC prevents or delays ovulation as the primary mechanism of action.^{21,22,23} EC regimens, however, work throughout the menstrual cycle, which means that additional mechanisms may be involved. Ongoing hormonal methods of contraception have been shown to act by the following mechanisms: alter the endometrial lining, alter cervical mucous, interfere with fertilization, or disrupt transport of an egg or prevent the implantation of a fertilized egg in the womb.²⁴ A study using levonorgestrel (LNG) that examined the effects of LNG on ovarian function and endometrial development found that when women were given EC prior to ovulation, a significant delay in the leutinizing hormone peak occurred resulting in no ovulation in 80% of women and delayed ovulation in the remaining 20%²¹. In the same study, when EC was given after ovulation, only minor effects on ovarian function occurred. No significant

changes in endometrial activity were found, suggesting that the primary mechanism of action for Plan B® is due to the inhibition of ovulation and not to inhibition of implantation. A similar study using the Yuzpe regimen demonstrated that ovulation did not occur in a significant proportion of women who had been given the Yuzpe regimen for up to 5 days after administration²². The study also concluded that delay, or inhibited ovulation is the primary mechanism of action for the Yuzpe regimen. The International Consortium for Emergency Contraception in a 2003 Policy Statement on the mechanism of action for EC reports that EC pills inhibit, delay or interfere with ovulation and that EC *may* interfere with fertilization or implantation, although there are no direct clinical data to support mechanisms other than the inhibition, delay or alteration of ovulation.²⁵ The use of EC does not cause an abortion or interfere with an established pregnancy. If EC is inadvertently taken by a woman who is pregnant, the pregnancy will not be affected.²⁵

Efficacy

Emergency contraceptives significantly reduce the expected rate of pregnancy when used up to 5 days after unprotected intercourse or contraceptive failure. The reduction in expected pregnancies (efficacy of the method) is estimated as follows. A single act of unprotected intercourse in the second or third week of the menstrual cycle has an expected pregnancy rate of 8 per 100 women. This expected pregnancy rate is an estimate that may vary depending on the woman's age or inherent fertility. Using this baseline for fertility, studies find that when 100 women are given Plan B® after unprotected intercourse, only one of the 100 women become pregnant (an 89% reduction in the number of expected pregnancies).^{13,14,26} The efficacy rate for Plan B® has been extensively studied and varies from 75%-90%.¹³ The Yuzpe regimen reduces the risk of pregnancy by approximately 75% (range 56%-89%).^{9,10,26}

Dosing

Emergency contraception using Plan B® (levonorgestrel 0.75mg tablets) is FDA approved for use (first dose) within 72 hours of unprotected intercourse. Efficacy of EC for both the Yuzpe and Plan B® regimens is highest when initiated within 72 hours of unprotected intercourse. It has been reported that even within the 72-hour time frame, the sooner a regimen is initiated, the more effective it may be. In one study of the Yuzpe regimen that has not been repeated, a linear relationship was found between the time EC was initiated and the subsequent pregnancy rate.²⁷ A pregnancy rate of 0.5% (2/386) was reported when EC was initiated within 12 hours of intercourse versus 4.1%

(6/146) when initiated 61-72 hours after intercourse. The FDA-approved dosing regimen for Plan B® is for the first dose to be taken within 72 hours of unprotected intercourse, followed by a second dose taken 12 hours later. Although there is evidence of efficacy as late as 120 hours after intercourse, women should be encouraged to seek treatment as soon as possible, preferably within the 72-hour timeframe. Since the time required from intercourse or ovulation to implantation is approximately six to seven days; the use of EC beyond 120 hours is not likely to be effective.²⁵

Studies have also examined the potential to administer the regimen as a single dose of levonorgestrel 1.5 mg (two tablets).^{13,14} The single-dose regimen may improve compliance and simplify EC regimens. Preliminary evidence suggests the single-dose regimen is effective, possibly more effective than a two-dose regimen. The use of Plan B® after 72 hours and the use of a single 1.5mg dose of levonorgestrel for emergency contraception is not currently FDA approved.

Safety and Side Effects

Emergency contraception has an excellent safety profile in nearly all women.^{16,17,20} The FDA and the WHO have both made statements attesting to the safety of EC.^{6,17} Oral contraceptives, which contain the same hormonal compounds found in EC, have an excellent safety record after more than 40 years of use. In fact, the health consequences of pregnancy are greater than any individual risk from the use of EC¹⁶.

Nausea is the most common adverse effect encountered by women using EC.¹⁰ Nausea is usually reported only with the first dose, and is more common with the use of the Yuzpe regimen. Overall, the Plan B® (levonorgestrel-only) regimen is associated with a lower incidence of nausea (23% vs. 50%) and vomiting (6% vs. 19%) than the Yuzpe regimen.^{28,29} Other adverse effects reported with the use of EC are: dizziness, breast tenderness, headache, changes in menstrual bleeding during the next cycle (26.3%), abdominal pain, and fatigue (Table 2). These reported side effects are mild and subside after the regimen has been completed. Providing women with an anti-emetic such as meclizine, metoclopramide, or diphenhydramine has been shown to reduce the incidence of nausea and vomiting from the Yuzpe regimen. However, there are additional side effects from doing so³⁰. An anti-emetic can be administered about 30 minutes to one hour before the first dose of the Yuzpe regimen. Side effects from the anti-emetic regimens include: drowsiness, dry mouth, and blurred vision. The use of Plan B® regimen significantly lowers the incidence of nausea and vomiting; therefore,

TABLE 3

Pharmacist Requirements to Dispense Emergency Contraception

	Alaska	California	Hawaii	Maine	Massachusetts	New Hampshire	New Mexico	Washington
Beginning of Pharmacy Access to EC	Regulations approved Nov 2001.	Effective Jan. 1, 2002 by legislative statute.	Effective Dec. 25, 2004 by legislative statute.	Effective July 1, 2004 by legislative statute.	Effective December 15, 2005 by legislative statute.	Effective Aug. 16, 2005 by legislative statute.	1992 and 2001: Pharmacists given prescriber status. 12/02: EC regulations 5/03	1997.
Authorized Prescriber	MD, Nurse Practitioner.	MD or State Board of Pharmacy and Board of Medicine.	MD only.	MD, DO, PA, Nurse Practitioner, Nurse-Midwife	MD only.	Not available.	State Pharmacy Board.	MD, Nurse Practitioner.
Protocol for Collaborative Therapy Agreements	Individually determined. Protocol permits distribution up to 120 hours after sex. Protocol requires Board approval. Must be renewed every 2 years	Individually determined or statewide protocol. Protocol permits distribution up to 120 hours after sex with both tablets given at the same time. No renewal or Board approval of protocols.	Model Board of Pharmacy collaborative agreement or individually approved. Protocol permits distribution up to 120 hours after sex. Protocols must be approved by Board of Pharmacy	Individually determined. Protocol permits distribution up to 120 hours after sex with both tablets given at the same time.	Individually determined. Protocols to be filed with Board of Pharmacy.	Individually determined. Protocols require Board of Pharmacy approval.	Statewide protocol. May also use individual collaborative protocols. No filing of protocols with Board is required.	Individually determined. Must be renewed every 2 years. Protocols required to be in file with Board of Pharmacy.
Components of Pharmacy Assessment	Informed consent form; screening checklist.	Mandated EC fact sheet.	Informed consent form; screening checklist.	Informed consent form; EC fact sheet.	Not yet determined	To be determined.	Informed consent form; EC fact sheet; assessment form; pregnancy prevention counseling.	Informed consent form; screening checklist.
Pharmacist Training Requirements	"Adequate training" is required.	One hour of continuing education is required	Training is required. May be ACPE, curriculum-based if provided by an ACPE accredited school of pharmacy, health department or other local approved course	Board approved course	Training is required. May be ACPE continuing education or curriculum-based. Training to include: referral, quality assurance and documentation.	To be developed by the Board of Pharmacy	Initial training requires a board approved training course followed by a live 2 hours course every 2 years.	No specific training requirement
Payment	EC rarely covered under insurance plans. Medicaid covers Plan B.	EC product covered by Medical. HMOs offering prescription drug coverage required to cover EC.	EC product covered by two of the largest insurance companies in the state. Pharmacist consultation covered by Medicaid (Med-QUEST).	Medicaid (MaineCare) covers Plan B.	NA	Not available.	EC product is covered by several insurance companies and Medicaid.	EC product and services covered by medical coupons, welfare, Uniform Medical Plan (option for state employees), Medicaid DSHS.
Pharmacist Participation	~15 currently working.	~3,000 currently trained. Many graduating pharmacy students trained.	~150+ currently trained; 82 currently working.	~ 200 currently trained. 17 providing service.	Pending implementation. Many pharmacists have been trained.	Not available.	160 pharmacists; 54 technicians All pharmacy students. New Mexico	~1200 community pharmacists; 90% of graduating pharmacy students trained.
Pharmacy Participation	18 pharmacies, including two chains, several independents, and Native corporations.	~ 1200 participating pharmacies, half of which are chain stores. 85% of counties have EC pharmacies.	~ 40+ participating pharmacies, including Longs, Times, and Kaiser Permanente systems.	~ 10 pharmacies. Hannaford, Rite Aid, and CVS are expected to participate.	Not available	Not available.	36 participating pharmacies (~24%), including several chains. Access in 18 communities.	~ 660 participating pharmacies.
Contact Information	Alaska EC Project (www.alaskaec.org)	www.ec-help.org; toll free Hotline (800-EC-Help);				Not available.		

Acronyms

- CBO - Community Based Organization
- MD - Medical Doctor
- DSHS - Department of Social and Health Services
- PA - Physician's Assistant
- ER - Emergency Room
- DO - Doctor of Osteopathic Medicine
- HMO - Health Maintenance Organization
- HMHBB - Healthy Mothers Healthy Babies

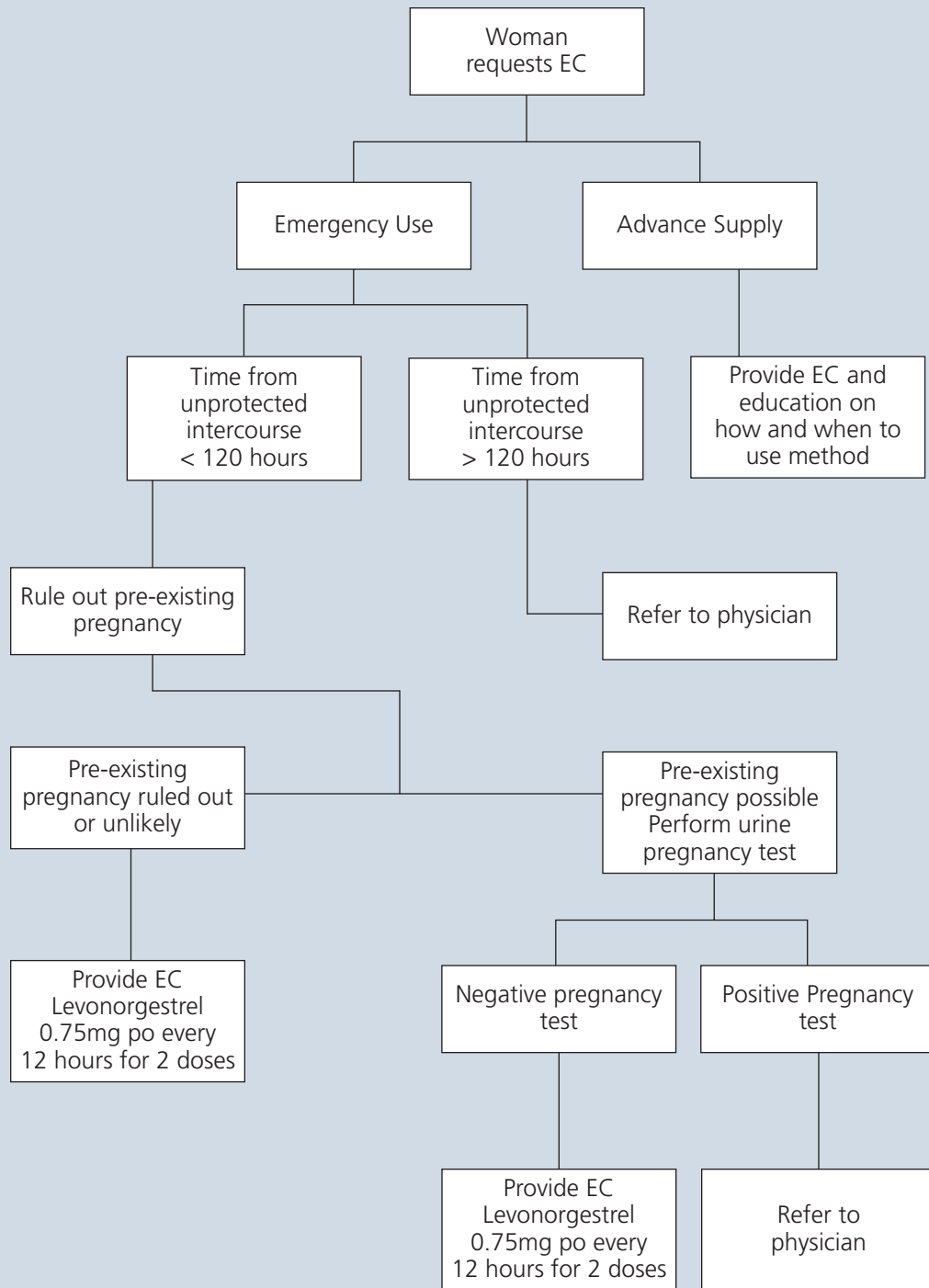
Notes

- Preven™ combined emergency contraception product is no longer being manufactured in the United States, but may still be available in limited quantities in pharmacies.
- Some protocols permit pharmacists to dispense oral contraceptives (used according to the Yuzpe Regimen) if Plan B is not available. California protocols also permit dispensing condoms to Family PACT and Medi-Cal clients.
- For copies of this grid and additional information about states with pharmacy access programs and other states working to increase pharmacy access to EC, visit www.GO2EC.org or call 510-272-0150

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FIGURE 1

Algorithm for Providing Emergency Contraception



the use of routine anti-emetics is not recommended.

Initiation of EC

The standard of care for providing oral emergency contraceptives does not require a physical examination.¹⁹ The information required to assess the need for EC may be obtained through an interview or using a self-administered form or questionnaire. An algorithm for providing EC may be helpful (Figure 1). Pharmacists may be called upon to assist women in determining if EC is indicated in their situation. The essential requirement for initiating EC including both cases of consensual intercourse and sexual assault is the exposure of the woman to unprotected or inadequately protected intercourse.¹⁵⁻¹⁹ Questions to establish the likelihood of efficacy such as the time lapse between initiation of treatment and intercourse should be asked. The timing and nature (normal versus abnormal) of the last menstrual period may be included in the EC screening tool but are not essential. If a woman thinks she is already pregnant, a urine pregnancy test can be performed. If the result is negative, then EC can be given. If the urine pregnancy test is positive, then EC will not be effective and should not be given. There are no dosage adjustments or guidelines for modification of doses with respect to potential drug interactions in the U.S. In the UK the Faculty of Family Planning and Reproductive Health recommend a single dose of 2.25mg levonorgestrel for emergency contraception in women using enzyme-inducing drugs.³¹ Current recommendations in the U.S. are, once a regimen is selected, the dosing is the same for all women.¹⁹

Repeat Use of Emergency Contraception

Concerns regarding the repeat use of or reliance on emergency contraception as a primary method of contraception have been raised. The currently available evidence indicates that EC is safe and effective even when used multiple times.^{20,32,33} The WHO guidelines on EC services state that “repeated use {of EC} poses no health risks and should never be cited as a reason for denying women access to treatment” (WHO guidelines 1998). Studies that have examined the repeat use of EC in Europe have reported lifetime EC use rates of 12%-19.9%.³³ The number of women using EC on three or more occasions falls to 0.8%-3.4%. Given the high failure rate of many contraceptive methods (condoms breaking, diaphragms slipping, or missed doses of birth control pills) and the high frequency of unprotected intercourse, repeat use of EC can be expected to occur and repeat use would be appropriate.³³ In fact, the repeat use rates found in current literature may be too low and reflect the need to increase provider and

public education about the relative safety of EC and situations where EC would be indicated. There is little research on how often within a menstrual cycle a woman can use EC. However, there is no evidence that EC cannot be used more than once during a menstrual cycle if needed. The repeat use of EC during a year or a lifetime has not been reported to cause adverse effects. Studies which have evaluated the effects of providing EC in advance have shown that while the use of EC is higher in women receiving advance supplies, the women do not increase risk taking or abandon other methods of contraception when provided EC. The high degree of safety and the lack of contraindications to EC suggest that EC should be given “as often as needed.”³³

Other EC regimens

Oral Contraceptives and other progestins

The use of oral contraceptives, containing norgestrel or levonorgestrel, for EC has been extensively studied. Prior to the availability of Plan B® and Preven® in the U.S., EC was prescribed extensively using standard oral contraceptive products. The use of a dedicated product such as Plan B® for emergency contraception is preferred to minimize errors in dosing or administration (Figure 1). Current recommendations are that only oral contraceptive products containing levonorgestrel should be used for EC. Norethindrone has been studied in combination with ethinyl estradiol as an emergency contraceptive and has been found to be less effective than levonorgestrel-containing regimens. If a dedicated product is not available or would delay treatment, or insurance coverage requires the use of a combination oral contraceptive product, the pharmacist should provide the product-specific dosing requirements for EC, preferably repackaged to reduce the potential for errors. It is important to make sure the placebo tablets from combination OC pill packs are not used in error. A list of products and doses of oral contraceptives that can be used for EC can be found in Table 1.

Single-dose levonorgestrel

Two recent studies investigated the use of single-dose treatment with levonorgestrel 1.5 mg for EC.^{13,14} Efficacy was similar or slightly improved with the single-dose regimen. Efficacy was reduced for both regimens by delayed initiation of therapy (treatment after 72 hours). Side effects from both regimens were mild; however, women taking the single dose reported more headache, breast tenderness, and heavy menstrual flow than did women who took the two-dose regimen. Results of these studies support the use of a single-dose regimen of levonorgestrel as safe and effective.

The Yuzpe regimen has not been studied for single-dose

use and should only be given as a two-dose regimen due to the likelihood of nausea and vomiting from estrogen exposure.

Use of EC between 72 and 120 hours

Several studies have documented the efficacy of EC regimens (Yuzpe and Plan B®) when used between 72 and 120 hours of unprotected intercourse.^{9,10,11,29} Results indicate that Plan B® when taken between 72 and 120 hours of unprotected intercourse reduced the risk of pregnancy significantly.^{13,14,28} There was a relationship between the timing of EC and intercourse noted—the sooner the EC was taken, the higher the efficacy.¹⁴ Since the time required from fertilization to implantation is approximately six to seven days; the use of EC beyond 120 hours is not likely to be effective.²⁵

The options for preventing pregnancy between 72 and 120 hours after intercourse are few. They include only the emergency IUD insertion or the use of oral EC regimens beyond the 72 hour approved time-frame. Given the literature evidence of efficacy after the 72 hour time-frame and the high degree of safety of oral EC as compared with emergency IUD insertion, the use of oral EC regimens as late as 120 hours after unprotected intercourse can be recommended. Women should be informed that the efficacy of EC may be reduced when used after the 72 hour time-frame and encouraged to start EC as soon as possible after unprotected intercourse.

Pharmacists' Role

Pharmacists are a unique healthcare provider because they are accessible and available during hours that other healthcare providers are often not. Pharmacists can provide general information about EC and answer questions or provide referrals when needed. In several states, pharmacists can provide EC directly to women under collaborative practice agreements or through enhanced scope-of-practice functions.⁸ Numerous studies have documented the acceptability and feasibility of direct access to EC from pharmacists.³⁴⁻⁴⁰ In addition to serving as a resource, pharmacists should have a supply of emergency contraception products available in the pharmacy to minimize delay in initiation of treatment. Pharmacists are encouraged to provide information regarding EC to all women at risk for pregnancy (age 15-44) and make EC available to women “in advance.”

Pharmacists have an important opportunity to improve access to EC for women by maintaining an inventory of EC. Studies of pharmacies in the eastern U.S. and southwest found that most (65%-89%) pharmacies could not fill a prescription for EC in the same day, and only some

could fill a prescription for EC the next day^{36,42}. In order to provide adequate health care to women, EC must be available when needed. EC is more effective the earlier it is taken and should be available to women quickly and without delay to women who require it. Pharmacists should be encouraged to contact local healthcare providers to let them know that EC is in stock.

Counseling

Counseling by pharmacists for women receiving EC should include information about the efficacy of EC, possible side effects and the need to obtain follow-up care if menses does not occur as expected. When counseling a woman regarding what to expect from EC, the pharmacist should include information on when to expect her next menstrual period. Most women (10%-15%) will have menses within one week of the originally expected date, some earlier and some later.^{10,12,24} If menses does not occur within this time frame, a pregnancy test or follow-up with her healthcare provider is recommended. Changes in menstrual bleeding are common and may include: lighter than expected menses (13%) or heavier-than-usual bleeding (14%) and in some women spotting (harmless) within a few days after taking EC. The pharmacist should reassure women receiving EC that changes in menses are common and self-limiting. Follow-up care is indicated if menses does not occur within 7 days of the expected onset date in order to rule out pregnancy or within 3 weeks of EC treatment (in women with irregular or unpredictable menses).²⁴

The pharmacist should provide information regarding the other possible side effects from EC. The most common side effects: nausea, dizziness, fatigue, headache, and breast tenderness are mild and do not occur in all women taking EC. Side effects, if they occur, do not require treatment and resolve when the treatment regimen is completed.

Nausea and vomiting are the most common side effects from EC. Nausea and vomiting, if present, generally occur only with the first dose of EC. Nausea is significantly less common with Plan B® as compared with the Yuzpe regimen. Although vomiting has been reported from the Yuzpe regimen, it is infrequent with Plan B®. The risk of both nausea and vomiting can be reduced by co-administration of an anti-emetic such as meclizine, diphenhydramine, or metoclopramide with the first dose of EC. The routine use of the anti-emetic is not recommended for women receiving Plan B® because the overall incidence of vomiting is so low. Women should be informed that if vomiting does occur after taking EC, they may need to repeat the dose of EC. Vomiting within 1 hour of taking an EC dose requires a repeated dose. Between 1 and 2 hours after EC, there are conflicting recommendations regarding

the need to repeat the dose. Women who report vomiting 2 or more hours after taking EC do not need to repeat their EC dose.

In addition to information about the medication and possible side effects, pharmacists should inform women that EC does not provide protection against sexually transmitted infections (STIs) such as syphilis, gonorrhea, or AIDS and should provide information regarding the symptoms of STIs. The pharmacist should be prepared to make referrals to clinics or physicians that provide testing and treatment for sexually transmitted infections if requested. The use of condoms for protection from sexually transmitted infections should be encouraged if applicable.

EC is not as effective as other methods of contraception and should not be considered as a routine method of contraception. The pharmacist should provide information about the resumption or initiation of routine contraceptive use during counseling. Women requiring EC due to the failure of a condom may benefit from a demonstration of the proper use of condoms. Women using condoms should continue to use them during future acts of intercourse. Women already using a hormonal contraceptive who have missed doses of their hormonal method can resume the method right away (back up must be used for at least 7 days after missing doses). If a woman wants to start hormonal contraception, she can begin either after her next menses or start immediately (using back up for at least 7 days). If requested, the woman should be provided information regarding the selection or use of an ongoing method of contraception and given a referral to a provider.

Advance Prescribing

Providing EC to women in advance of need may further increase utilization and provide the best form of access. Women using diaphragms or condoms for contraception may choose to keep EC at home “just in case.” Studies have demonstrated that having EC readily available at home results in lower rates of unintended pregnancy.³³ Advance prescribing of EC does not reduce the use of other methods of contraception, does not increase risk taking (unprotected intercourse), or result in repeated use of EC.^{33,34} Pharmacists are encouraged to provide information regarding EC to all women at risk for pregnancy (age 15-44) and make EC available to women “in advance”.

Pharmacists have an important opportunity to improve access to emergency contraception for women by maintaining an inventory of EC products. Many factors, including a lack of prescriptions received for EC, have been cited by pharmacists as reasons for not stocking EC. Pharmacists

should be encouraged to contact local healthcare providers, including family planning clinics and let the providers know that EC is in stock at their pharmacy as a means to increase prescriptions for EC.

Pharmacist Access

Direct access to emergency contraception from a pharmacist is currently permitted in eight states (California, Maine, Massachusetts, Alaska, Hawaii, New Mexico, Washington and New Hampshire) and in many countries worldwide. Legislation has been introduced to expand the role of the pharmacist to include providing EC in several additional states. Providing EC directly by the pharmacist can be an effective mechanism to reduce delays associated with getting a prescription and allow women to access EC during evening and weekend hours when other healthcare providers may be unavailable. Studies have demonstrated that women will go to the pharmacist for EC and are satisfied with the services of the pharmacist.^{34,40} Each state permitting pharmacists to initiate EC has specific requirements for participation related to training and protocols (see Table 3). Most states permitting pharmacists to initiate EC have a training requirement prior to participation. The pharmacist must also have a collaborative drug therapy protocol with a physician or authorized prescriber in most states. California and New Mexico have developed statewide protocols available to all qualified pharmacists. The availability of a statewide protocol removes the barrier of finding a collaborative protocol prescriber and simplifies the process of becoming an EC provider pharmacist in those states. Information on the current status of EC legislation in your state or on becoming an EC provider is available at www.go2EC.org.

Over-The-Counter Access

Several well-respected medical organizations, including the American College of Obstetricians and Gynecologists (ACOG) and the American Medical Association (AMA) have passed resolutions calling for emergency contraceptives to be made available over the counter (OTC) in the U.S.⁶ An application for OTC status for Plan B® was filed with the FDA by Duramed Pharmaceuticals and is currently under review. The FDA advisory committees have endorsed the proposal for OTC status. Arguments in favor of OTC status for EC include: emergency contraceptive regimens are safe, women are capable of determining the need for EC, the oral regimen is easy to administer, the dose does not need to be adjusted in any women, and overdose has never been documented.²¹ Arguments against OTC status include fear that ease of obtaining EC will result in an increase in risk-taking among teenagers (a

fact that has not been documented in the published literature) and that women may be unable to safely determine the need for EC (a fact also not supported by available literature). In some countries in Europe EC is readily available OTC. In British Columbia and Quebec, Canada, women have access to EC from pharmacies through a third class of drugs mechanism. Countries with OTC availability of EC have not reported complications from increased access.

Summary and Conclusions

Emergency contraception is a safe and effective method to prevent unintended pregnancy. It is currently underutilized despite numerous efforts to increase awareness and access. Pharmacists play a critical role in providing

information regarding the safety and efficacy of EC to the communities they serve. The pharmacist can help to dispel myths and misinformation surrounding EC. In states where collaborative practice allows the pharmacist to provide EC directly to women, pharmacists can become certified/qualified providers to further improve access. Having access directly from the pharmacist reduces delays in obtaining a prescription and is convenient for many women. Keeping EC in stock for use when needed is critical. Delays in treatment reduce the effectiveness of treatment and can be avoided by having a supply of EC products available for use. Pharmacists can play an important role in promoting public health by ensuring ready access to EC for women on a timely basis. ■

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Self-Assessment Questions

Write your answers on the answer form appearing on page 16 (photocopies of the answer form are acceptable) or on a separate sheet of paper. Mark the most appropriate answer.

- 1. Which of the following best describes the percentage of pregnancies in the U.S. that are unintended?**
 - a. Greater than 70%
 - b. 60% - 70%
 - c. 45% - 55%
 - d. Less than 40%
- 2. Unplanned pregnancy is a problem limited to teenagers and women who do not use contraceptives.**
 - a. True
 - b. False
- 3. Indications for EC include which of the following:**
 - a. A condom breaks during intercourse
 - b. A woman forgets to take 2 or more of her oral contraceptive tablets
 - c. A woman has been the victim of a sexual assault.
 - d. All of the above are indications for EC.
- 4. Which of the following EC regimens can be recommended?**
 - a. Levonorgestrel 0.75mg tablets #2 Take one now and one 12 hours later
 - b. Lo-Orval®. Take two tablets now and two tablets 12 hours later
 - c. OrthoNovum 1/35®. Take 4 tablets now and 4 tablets 12 hours later
 - d. A and B
 - e. All of the above
- 5. The primary mechanism of action by which Plan B® prevents pregnancy is:**
 - a. Inhibition or delay of ovulation
 - b. Disruption of an implanted embryo
 - c. Changes to cervical mucus
 - d. All of the above are primary mechanisms
- 6. Plan B® has been shown to be 89% effective, which means that if 100 women take Plan B® after having unprotected intercourse, only 11 of them will become pregnant:**
 - a. True
 - b. False
- 7. Which of the following must be done prior to prescribing EC:**
 - a. A complete physical examination including a PAP smear
 - b. Obtain a detailed medical history to rule out medical contraindications to oral contraceptives.
 - c. Counseling on how and when to take EC
 - d. All of the above
- 8. Which of the following are contraindications to receiving EC therapy:**
 - a. Migraine headaches
 - b. Pregnancy
 - c. Age over 40
 - d. All of the above
- 9. The use of EC products between 72 and 120 hours after unprotected intercourse**
 - a. Has been shown to be unsafe
 - b. Is possibly less effective than use up to 72 hours
 - c. Has not demonstrated efficacy
 - d. Is illegal
- 10. Which of the following is/are true regarding the repeat use of EC**
 - a. It is safe
 - b. It may be appropriate for some women
 - c. It should not be a reason to deny EC
 - d. All of the above are true
- 11. Studies evaluating the "advance prescribing" of EC have shown**
 - a. That women stop using their other contraceptive methods
 - b. An increase in the frequency of unprotected intercourse
 - c. A reduction in the rate of unplanned pregnancy
 - d. A high rate of repeated use

12. A single oral dose of levonorgestrel 1.5mg for EC has been shown to be at least as effective as the traditional regimen.

- a. True
- b. False

13. Common side effects from Plan B® include which of the following:

- a. Severe nausea and vomiting
- b. Breast discomfort
- c. Fatigue
- d. B and C
- e. All of the above

14. The pharmacist should inform a woman receiving EC that her next menstrual period will

- a. Be at least 1 week later than expected
- b. Begin 2 days after completing her EC
- c. Most likely be within one week of when it is expected
- d. Be missed

15. Which of the following would be an appropriate suggestion to a woman who has experienced nausea and vomiting with EC drug therapy in the past:

- a. Because nausea and vomiting worsens with each dose of EC, women who experience nausea and vomiting should avoid EC in the future
- b. An antiemetic such as meclizine taken 30 minutes before the first dose has been shown to reduce EC related nausea and vomiting
- c. If vomiting occurs more than 2 hours after the dose was taken, the dose should be repeated
- d. All of the above are appropriate

16. Counseling points for women receiving EC include:

- a. EC will protect her from sexually transmitted diseases and pregnancy
- b. EC is not as effective as regular ongoing birth control
- c. EC will protect her from pregnancy during the next 7 days
- d. All of the above

17. Non-prescription (OTC) status for Plan B®

- a. Has been requested by the manufacturer
- b. Has the potential to increase access to EC
- c. Is supported by the AMA and ACOG
- d. All of the above

18. Direct access to EC from a pharmacist

- a. Is available in 7 states as of 2005
- b. Has been shown to be well accepted by women
- c. Increases the availability of EC
- d. All of the above

19. Which of the following are ways a pharmacist can improve access to EC for women in their community?

- a. Maintaining an inventory of EC products in the pharmacy
- b. Providing information about EC to the public
- c. Becoming an EC provider pharmacist in states where pharmacist access is permitted
- d. All of the above

20. Which of the following should the pharmacist do when counseling a patient on EC:

- a. Keep the counseling session private
- b. Review possible side effects
- c. Recommend starting EC as soon as possible after unprotected intercourse
- d. All of the above

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Answer Sheet and Evaluation

Continuing Education Accreditation

This continuing education activity was sponsored by The University of Florida College of Pharmacy, produced by *Drug Topics*, a publication of Advanstar Medical Economics, and made possible by an unrestricted educational grant from Duramed Pharmaceuticals, Inc.



The University of Florida College of Pharmacy has been accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity has been approved for 2.0 hours (0.2 CEU) of continuing pharmacy education credit; 012-999-05-267-H01. To receive credit you must achieve a score of 70% on the quiz and complete the evaluation. The University of Florida College of Pharmacy will mail statements of credit within four weeks after receipt of a successful quiz.

Answer Form

February 20, 2006 UPN 012-999-05-267-H01. Test questions start on page 14.

Emergency Contraception: A Clinical Review

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|---|---|--|---|
| 11. <input type="radio"/> a. <input type="radio"/> b. <input type="radio"/> c. <input type="radio"/> d. | 6. <input type="radio"/> a. <input type="radio"/> b. | 11. <input type="radio"/> a. <input type="radio"/> b. <input type="radio"/> c. <input type="radio"/> d. | 16. <input type="radio"/> a. <input type="radio"/> b. <input type="radio"/> c. <input type="radio"/> d. |
| 2. <input type="radio"/> a. <input type="radio"/> b. | 7. <input type="radio"/> a. <input type="radio"/> b. <input type="radio"/> c. <input type="radio"/> d. | 12. <input type="radio"/> a. <input type="radio"/> b. | 17. <input type="radio"/> a. <input type="radio"/> b. <input type="radio"/> c. <input type="radio"/> d. |
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Please circle the number that reflects your opinion of the following statements, using the rating scale below, and return with your answer form. 1 = Strongly agree 2 = Agree 3 = Disagree 4 = Strongly disagree

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