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Companies commit to emergency contraception — Have you?

Plan B expands access, Gynétics' progestin-only ECP seeks approval

Good news on the emergency contraception (EC) front: A nationwide commercial launch is on the way for the first levonorgestrel pill, approval is pending on a second progestin-only product, and solid research shows that women who use emergency contraception do not intend to substitute it for regular pregnancy prevention methods.

Despite this positive news, family planning experts maintain that the awareness level of EC is still too low among patients and providers. At least one manufacturer has expressed willingness to spend $40 million to $50 million to raise awareness of EC among patients to the 50% level. Providers will need to up their efforts to expand knowledge of EC, once dubbed "the nation's best-kept secret."[1]

"During the first year on the market, promotion of Preven caused awareness of emergency contraception to increase from 11% to 15%," says **Sherry Bump**, executive director of marketing for Gynétics in

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Is emergency contraception still "the nation's best-kept secret?" Despite the efforts of the medical community as well as promotional efforts by the pharmaceutical companies that market the two products available to American women, relatively few women have heard of emergency contraceptives.

- Gynétics of Belle Mead, NJ, marketers of Preven, the first dedicated ECP product, plans to file a new drug application for a levonorgestrel ECP by the end of 1999, with an anticipated approval in the second half of 2000.
- Women's Capital Corp. of Bellevue, WA, marketer of Plan B, the first approved levonorgestrel ECP, is aiming for a national commercial launch of its product in the new year. While it is available through health care providers who dispense from their offices or clinics, Plan B is not available through retail pharmacies, except in western Washington state.

Belle Mead, NJ, the first company to launch a dedicated EC pill in the United States. "While this is an improvement, still far too many women are ignorant about emergency contraception — that pregnancy can be averted after sex, how EC works, and when EC should be used for greatest efficacy."

It will take $40 million to $60 million to move women's awareness levels from 15% to 50%, says Bump. Gynétics is willing to commit that level of funding to reach its audience with a mix of public relations and advertising messages. The company has enlisted the help of MTV's "Loveline" co-host Drew Pinsky to speak with the media and the public on the importance of emergency contraception.

"As we enter the new millennium, we will be reaching out to women through radio and television ads," says Bump.

Every effort needs to be directed to women to increase their knowledge and understanding of EC, she says. "Women have a tremendous need for EC, but they do not know solutions exist to prevent pregnancy after sex. Given that lack of knowledge, growth, acceptance, and usage will be slow."

Look for new ECP

Gynétics expects to file a new drug application with the U.S. Food and Drug Administration (FDA) for a levonorgestrel ECP by the close of 1999, with an anticipated approval in the second half of 2000, Bump reports. The company's first product, Preven, is stocked in nine out of the 10 top retail drug chains, which account for 75% of all prescription volume in the country.

(The top chains include Albertson's-American Stores of Boise, ID; CVS Corp. of Woonsocket, RI; Eckerd Corp. of Largo, FL; Kmart Corp. of Troy, MI; Kroger Co. of Cincinnati; Longs Drug Stores Corp. of Walnut Creek, CA; Medicine Shoppe International of St. Louis; Rite Aid Corp. of Camp Hill, PA; and Walgreen Co. of Deerfield, IL.) Wal-Mart of Bentonville, AR, continues its decision not to carry Preven. It is a decision Wal-Mart says was based on a variety of business considerations and not intended as a moral statement or judgment about the drug.[2]

"Initially, Gynétics' goal was to achieve distribution in six of the top 10 chains," Bump explains. "While we would like 10 out of 10 chains stocked, we are very pleased with this high level of distribution."

The lowdown on Plan B

There seems to be a considerable amount of misinformation circulating about the current and future product availability of Plan B, the new progestin-only ECP from Women's Capital Corp. of Bellevue, WA, according to **Sharon Camp**, PhD, company president.

[Plan B, which is packaged with two 0.75 mg levonorgestrel tablets, received FDA approval in July. **See *Contraceptive Technology Update,* September 1999, p. 108, for additional information on Plan B.**]

"Some people seem to be under the impression that there will be a gap in supply," reports Camp. "We definitely do not anticipate any such problem, despite some initial expiration dating issues."

The product now in distribution will expire at the end of January. The company intends to begin distributing the new drug product in January (it will expire in June) and has made a commitment to replace any expired product with the new product at no cost by means of a credit against new orders, Camp explains. The company encourages clinics to order what they believe they will need through January but not to order excessive amounts.

Women's Capital Corp. submitted additional information on the expiration dating issue to the FDA in October, along with a request for expedited review of the new data, Camp announces. "At the time of the national commercial launch next year, Plan B is expected to have an expiration date comparable to that for similar products, but a final decision on the new expiration

COMING IN FUTURE MONTHS

- What do new state laws mean for contraceptive coverage?
- New research in male contraceptive vaccine
- Disease management programs focus on women's health
- Detecting cervical cancer? Update on testing
- How chronic medical conditions influence contraceptive choices

dating may not be made by the FDA for several months," she says.

Other rumors erroneously have Plan B distribution restricted to Planned Parenthood clinics, Washington state, or to clinical trial sites, says Camp. Following its FDA approval, Women's Capital Corp. began distribution to health care providers who were able to dispense the drug directly from their clinics or offices, she explains. Plan B is now available in hundreds of clinics across the country, she says.

The product is not available through retail pharmacies, except in western Washington state, where pharmacists are dispensing emergency contraception under collaborative drug therapy agreements with local physicians and nurse practitioners. Women's Capital Corp. is testing a variety of marketing strategies in that area to ensure the success of the commercial launch in 2000, says Camp.

"Meanwhile, we have made an effort to concentrate supplies of Plan B in the health facilities currently providing the bulk of emergency contraception," she notes. "Our marketing efforts have focused on Planned Parenthood affiliates, Title X family planning clinics, campus health centers, and providers listed on the Emergency Contraception Hotline and Web site."

[The hotline number is (888) not-2-late. For information on the Web site, see resource box, below right.]

However, any provider who can dispense Plan B directly to clients may order the product by calling the company at (800) 330-1271, stresses Camp. Preferential pricing is available to qualified nonprofit providers. Introductory pricing has ended, and a new price schedule will be announced shortly.

Women will use EC, study shows

A great deal of education is needed for both providers and patients to get EC into the mainstream, says **Marie Harvey**, DrPH, director of research at the Center for the Study of Women in Society at the University of Oregon in Eugene.

"It is clearly a lot of education for both women and providers to know that it is available and be able to request it and for providers to be able to offer it," Harvey explains. "I really hope that providers will start giving it to women who are using contraception as a backup method, just to have it available in case something goes wrong."

When emergency contraception is made available, women will use it, according to a recently-published acceptability study. A survey of 235 women's experiences with EC pills at 13 Kaiser Permanente medical offices in San Diego, the study shows that participants:

- were overwhelmingly accepting of the method — 91% were satisfied with EC pills, and 97% said they would recommend them to family and friends;
- found them easy to use — 99.6% reported no problems in usage;
- did not intend to substitute the method for regular contraception — 97% said they would use EC pills for emergencies only,[3] thus dispelling fears that women would forego use of ongoing contraception.

Seventy percent of the women who participated in the study were using a contraceptive method when they requested EC pills. When asked about the situation that led to unprotected intercourse, nearly one-half indicated it had been a condom failure.

Harvey, lead author of the study, says, "I'm a person who is concerned about women's reproductive health in general; while I want to prevent unintended pregnancy, I also want to prevent the spread of sexually transmitted diseases [STDs] and HIV. The important thing is to make sure as we counsel women about ECPs is to let them know that because they were unable to protect themselves against pregnancy, they also were unable to protect themselves against STDs and HIV."

References

1. Hatcher RA, Trussell J, Stewart F, et al. *Emergency Contraception: The Nation's Best-Kept Secret.* Atlanta: Bridging the Gap Communications; 1995.
2. Wal-Mart. Wal-Mart's Statement Concerning Preven. Bentonville, AR; July 21, 1999.
3. Harvey SM, Beckman LJ, Sherman C, et al. Women's experience and satisfaction with emergency contraception. *Fam Plann Perspect* 1999; 31. ■

RESOURCE

- The Emergency Contraception Web site, which received its 500,000th visit on Oct. 1, should be completely revamped by *Contraceptive Technology Update* press time. Check out the updated site at its new address: **www.not-2-late.com**.

Third-generation OCs safe, health officials say

The safety of third-generation oral contraceptives (OCs) is being affirmed by health experts around the globe following publication of a research paper showing that Danish hospital admissions for venous thromboembolism have increased 16% since the rise in prescriptions for third-generation pills.[1]

The British government, moving swiftly to avert a recurrence of what was termed the "pill scare" in 1995, released a statement to reassure women, stating "The risk of thromboembolism with oral contraceptives is very small and the Pill is a very effective method of contraception. Pregnancy itself carries a much greater risk of thromboembolism than using an brand of contraceptive pill."[2]

[See *Contraceptive Technology Update*, January 1996, p. 6, for an overview of the origins of the "pill scare," which arose following a warning from Britain's Committee on the Safety of Medicines (CSM) on the use of OCs containing gestodene and desogestrel. A firestorm of controversy ensued throughout Europe, which undermined general confidence in the pill.]

The British government's move comes as the second vote of confidence this year of its beliefs surrounding third-generation oral contraceptives. A review by the Medicines Commission, a British government advisory body, concluded in April that doctors can prescribe these pills as a first-line form of contraception.[3] The commission did confirm the CSM's concerns about increased risk of blood clots in users of third-generation pills. However, it said that as long as women were fully informed of the risks, which were small, the pills could be considered on equal footing with other contraceptive pills.

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Health officials moved quickly to quell concerns about third-generation oral contraceptives (OCs) following publication of a research paper showing that Danish hospital admissions for venous thromboembolism have increased 16% since the rise in prescriptions for third-generation pills.

- The British government has issued a statement affirming the safety of OCs after publication of the paper in a British medical journal. A national British medical committee earlier this year had stated its support of third-generation OCs as a first-line contraceptive choice.
- While the Danish researchers say the finding of an increase in the admission rate for venous thromboembolism among women supports their hypothesis that third-generation OCs increase the risk of venous thromboembolism to a larger extent than second-generation pills, they say the results should be interpreted with great caution and in context with other findings.

Look at the study

The just-published study looks at hospital admission rates for venous thromboembolism during the 1980s and the beginning of the 1990s, when use of third-generation OCs increased in Denmark.

According to **Lene Mellemkjær**, MSc, PhD, lead author of the study and research fellow at the Institute of Cancer Epidemiology in Copenhagen, Denmark, researchers wanted to examine venous thromboembolism risk among users of third-generation OCs in comparison to those using second-generation pills. The scientists also reviewed mortality from venous thromboembolism during that same time period.

"Previous epidemiologic studies[4,5,6] showing that risk of venous thromboembolism is higher among users of third-generation oral contraceptives compared to users of second-generation OCs have been criticized for being influenced by bias," observes Mellemkjær. "One proposed bias is that third-generation OCs may to a larger extent have been prescribed to women at high risk of venous thromboembolism, because third-generation OCs were thought to be safer."

If that is indeed the case, there should be no change in the incidence of venous thromboembolism during the time that the use of third-generation OCs increased, the Danish researchers say. This hypothesis is made under the assumption that there was no overall change in the use of OCs and no change in other risk factors for venous thromboembolism or diagnostic procedures, notes Mellemkjær.

"We studied admission rates for venous thromboembolism among Danish women and men at the ages 15 to 49 years during 1977-93 and mortality rates during 1977-95," says Mellemkjær. "Among women, the admission rates were quite constant through the 1980s but seemed to increase to a higher level in the beginning of the 1990s,

whereas the rates among men were quite constant throughout the period. There was no change in the mortality rates for either women or men."

The finding of an increase in the admission rate for venous thromboembolism among women supports the hypothesis that third-generation OCs increase the risk of venous thromboembolism to a larger extent than second-generation pills, but the results should be interpreted with great caution, states Mellemkjær.

"First, our study was a correlational study where we did not look at the individual woman admitted with venous thromboembolism to find out if she had used OCs, so changes in other risk factors or changes in diagnostic procedures may be alternative explanations for the increase in admission rates," Mellemkjær notes. "Secondly, the admission rates are based on small numbers, and the statistical variation of the increase in the admission rates is considerable."

Overall, the amount of information in the study is limited and does not justify any detailed analyses or strong conclusions; it must be viewed in context with the results of all the previous studies on the subject, Mellemkjær concludes.

Staying the course

American providers say their thinking is unchanged when it comes to the safety of third-generation birth control pills.

"Based on the overall evidence, my perspective is that when prescribing OCs formulated with 35 mcg estrogen or less, concerns regarding thromboembolism do not form a basis for preferring a given estrogen dose or progestin type," says **Andrew Kaunitz**, MD, professor and assistant chair of the OB/GYN department at the University of Florida Health Science Center in Jacksonville.

David Grimes, MD, vice president of biomedical affairs at Family Health International in Research Triangle Park, NC, co-authored a review of the major research surrounding the third-generation pills, which concluded that "modern combined oral contraceptives are safer than earlier formulations with respect to cardiovascular disease, which occurs rarely in young women."[7]

"All I have to say about the third-generation issue is in [that] review," Grimes comments. "Nothing published since then has changed my assessment."

References

1. Mellemkjær L, Sorensen HT, Dreyer L, et al. Admission for and mortality from primary venous thromboembolism in women of fertile age in Denmark, 1977-95. *BMJ* 1999; 319: 820-821.
2. BBC. Government plays down fresh pill worry. London, England; Sept. 24, 1999.
3. BBC. U-turn over pill scare. London, England; April 7, 1999.
4. World Health Organisation Collaborative Study on Cardiovascular Disease and Steroid Hormone Contraception. Venous thromboembolic disease and combined oral contraceptives: Results of international multicentre case-control study. *Lancet* 1995; 346:1,575-1,582.
5. Jick H, Jick SS, Gurewich V, et al. Risk of idiopathic cardiovascular death and nonfatal venous thromboembolism in women using oral contraceptives with differing progestagen components. *Lancet* 1995; 346:1,589-1,593.
6. Spitzer WO, Lewis MA, Heinemann LAJ, et al. Third generation oral contraceptives and risk of venous thromboembolic disorders: An international case-control study. *BMJ* 1996; 312:83-88.
7. Rosenberg L, Palmer JR, Sands MI, et al. Modern oral contraceptives and cardiovascular disease. *Am J Obstet Gynecol* 1997; 177:707-715. ■

Meeting the challenge of caring for Hispanic women

Hispanic women access reproductive health care less often and need it more, national figures show. More than one in three Hispanic women polled in a 1999 survey said they had not received a routine gynecological or prenatal exam in the last year. Nearly a quarter had not gone for such checkups in at least two years. And more than one in 10 said they had never had such an exam.[1]

Such lack of care is troubling when given the following statistics:

- Cervical cancer rates among Hispanic women are nearly double those of the general population, according to a recent report by the National Cancer Institute in Bethesda, MD, and the American Cancer Society and Centers for Disease Control and Prevention (CDC), both in Atlanta.[2]
- In slightly more than a decade, the proportion of all AIDS cases reported among adult and adolescent women more than tripled, from 7% in 1985 to 23% in 1998. The epidemic has increased most dramatically among women of color: African-American and Hispanic women

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More than one in three Hispanic women polled in a 1999 survey said they had not received a routine gynecological or prenatal exam in the last year, with nearly a quarter not accessing such care in at least two years and more than one in 10 never having such an exam.

- Cervical cancer rates among Hispanic women are nearly double those of the general population, national data show. Along with African-American women, Hispanic women represent less than one-fourth of all U.S. women, yet they account for more than three-fourths (77%) of AIDS cases reported to date among women in America.
- Socioeconomic barriers, cultural beliefs, and behavioral risk factors all play into Hispanic women's use of reproductive health care services. Public health officials are addressing the issue as Hispanic women represent an increasing presence in the U.S. population.

together represent less than one-fourth of all U.S. women, yet they account for more than three-fourths (77%) of AIDS cases reported to date among women in America.[3]

A number of factors come into play when looking at the need for increased use of reproductive health care among Hispanic women. According to the 1999 survey, 66% of the Hispanic women surveyed said they either delayed or did not get needed gynecological care because of one of these reasons:

- It cost too much or they did not have health insurance.
- They didn't have a regular doctor or didn't know where to go for care.
- It took too long to get an appointment or a needed referral.[1]

Social factors, such as lack of transportation, scarcity of after-hours clinics, and language and education barriers also hinder Hispanic women from accessing health care services, says **Rodrigo Cardenas**, MD, president of La Salud Hispana, a public health organization based in Englewood Cliffs, NJ.

When it comes to health, Hispanic women are more committed to their family's well-being than their own, notes Cardenas. But unlike most other women, Hispanics tend to focus only on the health of their husbands and children, totally disregarding their own.

"When diagnosed with a disease, many accept it as a judgment or punishment for something they have done," Cardenas observes. "They also believe that as good wives and mothers, they must not complain but must accept the burden of illness."

This belief that destiny is out of one's hands and events are inevitable is known as fatalism. Various factors, including immigration and educational level, are strongly associated with a fatalistic view among Hispanic women, especially those who are immigrants.[4] Such beliefs can keep women from accessing such routine care as breast cancer screenings and Pap smears.[5,6]

Reaching women at risk

To reach Hispanic and other underserved women, the CDC offers breast and cervical cancer screening services through its National Breast and Cervical Cancer Early Detection Program. By October 1997, more than 1.5 million screening tests had been provided through the CDC-sponsored program.

One such CDC-funded program, the New Jersey Breast and Cervical Control Initiative in Trenton, works with a number of programs across the state to provide education and screening to women with limited health insurance or no health insurance who are at or below 250% of the poverty level, with a special emphasis on racial-ethnic minority populations and the disabled. Since the program began in 1996, 14,000 women — 31% Hispanic — have been screened for breast or cervical cancer.[7]

Having printed patient information in Spanish is not enough when it comes to providing prevention education materials, says **Doreleena Sammons-Posey**, state project director. One approach to delivering the prevention message is a play, "El Secreto de Marta" (Martha's Secret), used by the Camden County Screening Project. The play focuses on Martha, a Hispanic woman who shares news of a lump in her breast with a friend, who then calls on a breast cancer survivor to talk with Martha about the importance of following through with screening and treatment. Humor and a light-hearted approach serve to dispel many fears and myths surrounding Hispanic women's beliefs about the disease. Hispanic moderators are used to field questions and offer answers on women's health issues following the production. **(See resource listing, p. 143, to order a video of the production.)**

Focus group participants have told program organizers they feel more comfortable when

they see and hear people of their own culture, says **Evelyn Robles-Rodriguez**, RN, MSN, Camden County project coordinator. One facility in Elizabeth meets this request by offering special clinic days just for Hispanic women, using appropriate educational videos in the waiting rooms and scheduling a number of Hispanic translators and providers to staff the event, notes Sammons-Posey. The New Jersey initiative also has developed a resource directory to list agencies that provide services, including translators, to different racial/ethnic/minority populations to guide women to appropriate care.

It is becoming increasingly important to get the word out to Hispanic women about health risks, especially about those risks that have a greater impact on them, says Cardenas. One in four American women will be of Hispanic origin by the year 2030, according to U.S. Census data.

References

1. Kaiser Family Foundation. *A National Survey of Women's Reproductive Health Care.* Menlo Park, CA: 1999.
2. Wingo PA, Ries LAG, Giovino GA, et al. Annual report to the nation on the status of cancer, 1973-1996, with a special section on lung cancer and tobacco smoking. *J Natl Cancer Inst* 1999; 91:675-690.
3. Centers for Disease Control and Prevention. *HIV/AIDS Among US Women: Minority and Young Women at Continuing Risk.* Atlanta; August 1999.
4. Chavez LR, Hubbell FA, Mishra SI, et al. The influence of fatalism on self-reported use of Papanicolaou smears. *Am J Prev Med* 1997; 13:418-424.
5. Hubbell FA, Chavez LR, Mishra SI, et al. From ethnography to intervention: Developing a breast cancer control program for Latinas. *J Natl Cancer Inst Monogr* 1995; 18:109-115.
6. Hubbell FA, Chavez LR, Mishra SI, et al. Beliefs about sexual behavior and other predictors of Papanicolaou smear screening among Latinas and Anglo women. *Arch Intern Med* 1996; 156:2,353-2,358.
7. Alvarado M, Mestel R. Latino women neglect check-ups. *Bergen Record.* Bergen, NJ; Aug. 23, 1999. ■

RESOURCE

"El Secreto de Marta" breast cancer prevention video is in production, and the price has not been set, but project coordinator Evelyn Robles-Rodriguez, RN, MSN, says the price will be low. For more on the video, contact:

- **Camden County Cancer Screening Project**, 3 Cooper Plaza, Suite 220, Camden, NJ 08103. Telephone: (856) 968-7315.

ASK THE EXPERTS

Does smoking affect efficacy of the pill?

Contraceptive Technology Update reader **Sharon Swain**, RN, a public health nurse with the Peel Health Department in Brampton, Ontario, asks, "Is there any documentation supporting reduced efficacy of oral contraceptives [OCs] in women who smoke?"

These *CTU* editorial advisory board members addressed this question:

✔ **Michael Rosenberg**, MD, MPH, clinical professor of obstetrics and gynecology and epidemiology at the University of North Carolina at Chapel Hill and president of Health Decisions, a private research firm;

✔ **Andrew Kaunitz**, MD, professor and assistant chair of the department of obstetrics and gynecology at the University of Florida Health Sciences Center in Jacksonville, FL;

✔ **Susan Wysocki**, RNC, BSN, NP, president of the National Association of Nurse Practitioners in Women's Health in Washington, DC.

Rosenberg: There are two lines that suggest that the anti-estrogenic effect of smoking diminishes the effectiveness of OCs. First, several studies of cycle control indicate that, after control for other factors affecting spotting and bleeding, smokers experience a higher frequency of such problems.[1,2] A single study of the contraceptive efficacy of OCs in smokers indicates a slightly diminished effectiveness in smokers.[2] Second, laboratory work indicates that estrogen increases the catabolism of estrogen, providing a rationale for these observed effects.

The interesting import of this is that the traditional treatment of smokers, which is to use a lower-estrogen preparation, may bear re-examination. The use of low-dose pills in smokers is driven more by safety than efficacy concerns, since smoking acts synergistically with age and other risk factors to increase the chances of thrombosis. This concern has been recognized by the fact that one preparation, Loestrin 1/20 (Parke-Davis, Morris Plains, NJ), has been marketed to smokers for more than a decade.

The bottom line is that although relevant information is sparse, it suggests that OCs may be less effective in smokers. Especially with the increasing use of lower-dose OCs (20 mcg preparations), there is a need to balance the safety and efficacy risks. Clinically, in a younger smoker without risk factors for thrombosis, I would be tempted to start with a 20 mcg preparation and move up to 30 if cycle control problems occurred. A similar approach for other smokers who lack risk factors probably also is reasonable. However, in the infrequent patients at risk for thrombosis, I believe that lower estrogen should be more important.

Kaunitz: As shown by Rosenberg, OC users who smoke experience more breakthrough bleeding.[1] I am not aware of data, however, that demonstrates higher OC failure rates among smokers.

Wysocki: We know that smoking decreases estrogen levels; hence, smokers have a higher incidence of irregular bleeding on the pill. This is the reason that smokers are at higher risk for osteoporosis in later years. One important point to remember is that the efficacy of OCs largely depends on the progestin, so it may be possible to have pills that are even lower than 20 mcg of estrogen. The estrogen in combination OCs, for the most part, is for cycle regularity.

References

1. Rosenberg MJ, Waugh MS, Stevens CM. Smoking and cycle control among oral contraceptive users. *Am J Obstet Gynecol* 1996; 174:628-632.

2. Baron JA, Greenberg ER. "Cigarette smoking and estrogen related disease in women." In: Rosenberg MJ, ed. *Smoking and Reproductive Health.* Boston: PSG, 1987:149-160. ■

GUEST COLUMN

7 facts you should know from national meetings

By **Robert A. Hatcher**, MD, MPH
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The following information is from the Washington, DC-based Association of Reproductive Health Professionals meeting and the New York City-based Planned Parenthood Federation of America's National Medical Committee session, both held recently in Dallas:

1. Plan B, the progestin-only emergency contraceptive pill (ECP), is available.

Distribution of Plan B (Women's Capital Corp., Bellevue, WA) to drugstores is hampered by expiration date problems. The same problem plagued Preven (Gynétics, Belle Mead, NJ). **Sharon Camp**, PhD, president of Women's Capital Corp., is optimistic the date will be changed. In several European countries, exactly the same preparation (0.75 mg of levonorgestrel) is approved for five years.

While progestin-only contraception has fewer failures than combined oral contraceptives (OCs) used for emergency contraception, the failure rate goes up with each 12-hour delay. This rate emphasizes the importance of actually getting Plan B into the hands of each sexually active woman who hopes not to become pregnant at this time in her life.

2. ECP provision by pharmacists in Washington state has had an immense impact.

In the year prior to pharmacist provision of ECPs without a prescription, 140 pharmacies filled 10 prescriptions. The same 140 pharmacies provided ECPs to 9,700 women in the year after women could obtain ECPs from those same pharmacies without a provider's prescription, according to **Don Downing**, RPh, pharmaceutical care provider with Washington State University in Pullman and the University of Washington and the Washington State Pharmacists Association, both in Seattle.

3. Watch the upswing of prescriptions for third-generation OCs.

"Now we are pretty close to saying that the data suggesting a 100% increase in venous thromboembolism in women on desogestrel and gestodene pills [compared to older pills] were wrong," states **Felicia Stewart**, MD, assistant adjunct professor in the department of obstetrics and gynecology in the School of Medicine at the University of California, San Francisco. In Britain, the media are calling the reversal of prescriptions of desogestrel and gestodene the "pill U-turn."

4. Teen pregnancy rates are dropping.

Use of Depo-Provera (depot medroxyprogesterone acetate or DMPA) contraceptive injections

and Norplant implants by U.S. teens rose from 0% in 1988 to 13% in 1995 (Norplant 3%, DMPA 10%). This shift toward more effective contraception accounts for 80% of the fall in pregnancies in teens ages 15 to 19, while 20% of the drop in teen pregnancies may be ascribed to abstinence, according to **Jacqueline Darroch**, PhD, senior vice president at the Alan Guttmacher Institute in New York City.

5. Nulligravid women may be appropriate candidates for IUDs.

Nulligravid women are appropriate candidates for intrauterine devices (IUDs), suggests research co-authored by David Hubacher, PhD, senior research associate at Family Health International in Research Triangle Park, NC, and Roger Lara, MD, head of the department of family planning of the National Perinatology Institute in Mexico City. Use of IUDs among 663 women with primary tubal infertility was compared to IUD use by 341 infertile women without tubal pathology and 251 primigravid women in their first or second trimester of pregnancy. Prior use of a copper IUD was not associated with an increased risk for infertility in this retrospective case control analysis.

6. There is no cure — yet — for human papilloma virus (HPV).

"As far as I know at this time, even if warts disappear completely, there is nothing that cures human papilloma virus," says **Mary Rubin**, RNC, PhD, CRNP, director of clinical education for Education Programs Associates in Campbell, CA.

7. Look for U.S. introduction of Lunelle, the combined injectable contraceptive.

Lunelle, the once-a-month injection of 25 mg of DMPA and 5 mg of estradiol cypionate from Pharmacia & Upjohn of Bridgewater, NJ, is closer to being an option for U.S. women. In U.S. trials, there were no pregnancies in the 872 women studied, says **Andrew Kaunitz**, MD, professor and assistant chair of the department of obstetrics and gynecology at the University of Florida Health Sciences Center in Jacksonville, FL. **(See *CTU*, November 1999, p. 125, for more on Lunelle.)** Only 6.3% discontinued because of menstrual irregularities. Researchers did note a several-pound weight gain in the first year of use.

Return of fertility is faster than with every-three-months Depo-Provera injections. In more than 10,000 users, there has not been a case of deep vein thrombosis, pulmonary embolism, or death. These are still small numbers, but positive. Lab studies demonstrate that the medication is not thrombophilic. ■

Mid-Years WOMEN'S HEALTH

Transdermal estrogen replacement: The pros

By **Ivy M. Alexander**, MS, C-ANP
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(Editor's note: This is the first of a two-part series on transdermal estrogen replacement therapy. In this issue, we explore the potential benefits. Next month, we'll discuss the potential risks and disadvantages.)

As more women experience and live beyond menopause, interest in risks and benefits associated with estrogen replacement therapy (ERT) has increased. Initially, interest focused on relief of menopausal symptoms. Now that more research and experiential data are available, systemic effects related to estrogen deficiency and replacement are being recognized. Systemic benefits associated with ERT include reducing osteoporosis and coronary heart disease (CHD) and possibly some protection from colorectal cancer, Alzheimer's disease, and senile dementia.[1,2]

Estrogen can be administered via oral, parenteral, intravaginal, and transdermal routes. Oral administration is most common, followed by the transdermal route.[1] The purpose of this column is to review the advantages of transdermal estrogen delivery systems.

The most common reason for estrogen administration is relief of menopausal symptoms. Transdermal therapy effectively reduces hot flashes, night sweats, headaches, mood changes, irritability, insomnia, and subjective sleep disturbances.[1-5] Likewise, genitourinary symptoms such as vaginal dryness, pruritis, stress incontinence, urinary frequency, and dyspareunia are decreased with transdermal ERT. Potential benefits include:

- **Offers hepatic effects.**

In addition to relieving classic menopausal symptoms, transdermal ERT offers several other

systemic benefits. The transdermal route of delivery bypasses the liver, so serum estradiol and estrone levels are closer to the 1:1 ratio seen before menopause.[1] Additionally, transdermal estrogen does not affect angiotensin, sex hormone-binding globulin, or thyroid binding globulin, all of which are increased with oral estrogen administration.[1,6] Finally, oral estrogens can affect bile composition and increase the risk of lithogenesis. Since transdermal estrogen does not appear to affect bile composition, it may be a safer option for women at risk for gallbladder disease.[1]

• **Improves lipid profile and cuts CHD risk.**

Transdermal estrogens affect the lipid profile differently than orally administered estrogens. Both decrease total cholesterol and low-density lipoproteins (LDL) and increase high-density lipoproteins (HDL). The changes seen with oral administration are greater than those occurring with transdermal delivery. Conversely, triglyceride levels increase with oral therapy and decrease with transdermal administration.[1,2,5] With either type of administration, CHD risks may be reduced through improved lipid profile, reduced fasting insulin levels, increased left ventricular function, decreased vascular resistance, and reduced LDL oxidation.[1,2,5]

Despite the general belief that ERT is cardioprotective, a recent study found no benefit and a small increase in CHD during the first year of combination oral therapy in women who had cardiac disease prior to initiating HRT. Long-term treatment appeared to offer some benefit.[2]

• **Lessens osteoporosis risk.**

Osteoporosis risk is decreased with transdermal and oral ERT. This benefit is conferred by decreasing the rate of bone resorption and slowing turnover. Oral and transdermal delivery systems have been equally effective in reducing osteoporosis and reducing fracture risk.[1,2]

• **Is easy to use.**

Several estrogen and estrogen / progesterone combination patches are available. Patches are placed on the lower abdomen or buttock and replaced once or twice weekly.[6] Studies indicate higher compliance in women using transdermal delivery as compared with oral estrogen.[1]

References

1. Connell EB. Transdermal estrogen therapy. *Postgrad Med* 1997;101-130.

2. Wenger NK. HRT and coronary heart disease: Answers to your top 12 questions. *Women's Health in Primary Care* 1999; 2:305-321.

3. Lubbert H, Nauert C. Continuous versus cyclic transdermal estrogen replacement therapy in postmenopausal women: Influence on climacteric symptoms, body weight, and bleeding pattern. *Maturitas* 1997; 28:117-125.

4. Polo-Kantola P, Erkkola R, Irjala K, et al. Effect of short-term transdermal estrogen replacement therapy on sleep: A randomized, double-blind crossover trial in postmenopausal women. *Fertil Steril* 1999; 71:873-880.

5. Rozenberg S, Ylikorkala O, Arrenbrecht S. Comparison of continuous and sequential transdermal progestogen with sequential oral progestogen in postmenopausal women using continuous transdermal estrogen: Vasomotor symptoms, bleeding patterns, and serum lipids. *Int J Fertil Womens Med* 1997; 42(Suppl 2):376-387.

6. Anderson B, Mattesson LA. The effect of transdermal estrogen replacement therapy on hyperandrogenicity and glucose homeostasis in postmenopausal women with NIIDM. *Acta Obstet Gynecol Scand* 1999; 78:260-261. ■

Contraceptive coverage laws proliferate in 1999

By **Cynthia Dailard**
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On Sept. 29, President Clinton signed the Treasury and General Government Appropriations Act, which ensures that federal employees will continue to have access to contraceptives for a second year in a row. The law — enacted on an annual basis to fund specific branches of the government — renews a provision requiring health plans participating in the Federal Employees Health Benefits Program (FEHBP) to provide coverage of prescription contraceptives approved by the Food and Drug Administration (FDA) on par with coverage for all other prescription drugs.

While Congress now has created a two-year tradition of providing comprehensive contraceptive coverage for its employees, many individuals insured through private-sector employers do not enjoy such coverage. In fact, research by the Alan Guttmacher Institute shows that while virtually all traditional fee-for-service plans cover prescription drugs, only half cover prescription

contraceptives and only one-third cover oral contraceptives, the most popular form of reversible contraception among U.S. women.

In response to this disparity, Sens. Olympia Snowe (R-ME) and Harry Reid (D-NV), along with Reps. Jim Greenwood (R-PA) and Nita Lowey (D-NY), introduced the Equity in Prescription Insurance and Contraceptive Coverage Act (EPICC), which is federal legislation requiring contraceptive coverage in private-sector, employment-based health plans. The bill has 38 cosponsors in the Senate and 119 cosponsors in the House; its sponsors are hopeful for passage in the year 2000.

9 states pass laws

Such optimism is based on the enormous momentum building in favor of contraceptive coverage at the state level. Between April and September, nine states enacted EPICC-like contraceptive coverage laws: California, Connecticut, Georgia, Hawaii, Maine, Nevada, New Hampshire, North Carolina, and Vermont — joining Maryland, which approved the first such law in 1998.

All of those laws require private insurance coverage of FDA-approved contraceptive drugs and devices, and all but those enacted in California, Connecticut, and Georgia require coverage of contraceptive services. Notably, North Carolina's law is the first and only law in the country to explicitly exclude coverage for the abortifacient "RU-486" (mifepristone) and for Preven, an emergency contraceptive pill. (When the bill was enacted, Preven was the only formulation of oral contraceptives on the market specifically packaged for "emergency," or postcoital, use.)

'Sweet victory' in California

The recent signing of California's law on Sept. 27 by Gov. Gray Davis marked a particularly sweet victory for family planning advocates in the state and across the country. Pioneering the first contraceptive coverage bill in the nation back in 1995, the California legislature passed such legislation four times over the ensuing years — with three bills vetoed by then-governor Pete Wilson — before seeing contraceptive coverage become a reality.

In most states, and in the FEHBP, resolving difficult questions over the scope of an exemption for entities that object to covering contraceptives was central to the bill's ultimate success. Indeed, seven of the 10 states that have enacted contraceptive coverage laws included some form of "conscience clause." Those states are Maryland, Maine, Nevada, Connecticut, North Carolina, Hawaii, and California. Those state-crafted provisions typically specify which employers should be entitled to claim a conscientious objection to providing contraceptive coverage to their employees and what grounds should form the basis of such an exemption.

While these exemptions typically allow entities that qualify as a "religious employer" to opt out of the coverage requirement when covering contraception would conflict with the employer's bona fide religious beliefs, practices, or tenets — depending on the state — the real question determining the scope of such an exemption is how each law defines "religious employer."

The California law, for example, contains a rather narrow conscience clause and exempts only those nonprofit organizations that have as their primary purpose the inculcation of religious values and that primarily employ and

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serve people who share those religious beliefs. The law thus appears to exempt churches, synagogues, and religious schools in California, but not religiously-affiliated hospitals. In sharp contrast, Maryland's law does not define the term at all. This potentially allows any entity that self-identifies as a religious organization to claim an exemption.

To date, Hawaii has the only law that protects enrollees from being disadvantaged when their employer claims a religious exemption. The law specifies that when an employer opts out on religious grounds, the enrollee is entitled to purchase coverage for contraceptives directly from the plan. The cost to the enrollee must be no more than the price the employee would have paid had the employer not been exempted.

As the sponsors of EPICC and state legislators continue to press for contraceptive coverage, they will invariably confront similar questions involving religious exemptions. While such debates are often difficult and contentious, there now exists a handful of models in state laws that can help guide such future debates. ■

CE objectives

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After reading *Contraceptive Technology Update,* the participant will be able to:

• Identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services. **(See "Third-generation OCs safe, health officials say," p. 140, and "Testing strategy gives look at HIV incidence,"** ***STD Quarterly,*** **p. 3.)**

• Describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area.

• Cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. **(See "Transdermal estrogen replacement: The pros," p. 145.)** ■

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S·T·D QUARTERLY™

Expanding HIV prevention programs in African-American communities

1 in 160 African-American women infected

While African-Americans represent only an estimated 12% of the total U.S. population, they comprise almost 37% of all AIDS cases reported in this country.[1] Take a closer look at the epidemic's impact on African-American women, and you'll know that your job as a reproductive health care provider becomes that much more significant in educating these women about HIV prevention.

Almost two-thirds (62%) of all women reported with AIDS in 1998 were African-American.[1] It is now estimated that one in 160 African-American women is HIV-infected, notes **Janet Cleveland**, MS, special assistant to the director for HIV prevention at the Atlanta-based Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention, Intervention Research and Support.

Although AIDS-related deaths among women are now decreasing, largely as a result of recent advances in HIV treatment, HIV/AIDS remains among the leading causes of death for U.S. women ages 25 to 44. Among African-American women in this same age group, AIDS results in more deaths than from any other cause.[2]

EXECUTIVE SUMMARY

Almost two-thirds (62%) of all women reported with AIDS in 1998 in the United States were African-American, and it is now estimated that one in 160 African-American women is HIV-infected.

- While AIDS-related deaths among women are decreasing, largely as a result of recent advances in HIV treatment, HIV/AIDS remains among the leading causes of death for U.S. women ages 25 to 44. Among African-American women in this same age group, AIDS results in more deaths than from any other cause.
- African-American leaders and the Congressional Black Caucus were instrumental in obtaining an additional $156 million for prevention programs in 1998, with $39 million administered by the Atlanta-based Centers for Disease Control and Prevention this fall.

Why the gap?

Race and ethnicity in the United States are not risk factors for HIV infection, but they correlate with other more fundamental issues such as poverty, access to quality health care, health care seeking behavior, illicit drug use, and living in communities with high prevalence of sexually transmitted diseases (STDs), says the CDC.[3]

Acknowledging the disparity in HIV and STD rates by race or ethnicity is one of the first steps in empowering affected communities to organize and focus on the problem.

While AIDS has taken its toll on African-Americans, the Hispanic population has been affected as well, Cleveland notes. African-American and Hispanic women together represent less than one-fourth of all U.S. women, yet they account for more than three-fourths (77%) of AIDS cases reported to date among women in

the United States.[2] **(See story, p. 141 in this month's *Contraceptive Technology Update*, for an overview of reproductive health needs for Hispanic women.)**

In response to HIV's rapid spread among African-Americans, the CDC has worked in partnership with national, local, and regional minority organizations to build its prevention efforts, increasing funding levels from nearly $11 million in 1988 to more than $120 million in 1999.

African-American leaders and the Congressional Black Caucus were instrumental in obtaining an additional $156 million for prevention programs in 1998, with $39 million administered by the CDC this fall. The money represents a 50% increase over 1998 funding earmarked for HIV prevention programs in African-American communities.[4]

Targeting women at risk

Reaching at-risk women with group education and prevention case management in 12 transitional and homeless shelters in Chicago is the focus of one CDC-funded program: Shelter Women's AIDS Project. A service of the South Side Help Center, a Chicago not-for-profit organization, the project is now in its third year of CDC funding. It offers a series of eight educational group sessions over a four-month period to help women in the shelters learn about HIV and how to protect themselves from it.

The program also provides a weekly support group to further disseminate the prevention message, says **Elayne Owens**, prevention case manager and prevention specialist. A variety of educational approaches are used, including games and role-playing, as well as videos and informational speakers. "I bring in speakers who are HIV-positive to put a face on the disease, so they see the reality," notes Owens. "I also have females who are either a family member or friend who is impacted with the virus to speak so they realize that this virus is really here."

The eight educational sessions are about two hours in length and cover such information as methods of HIV transmission and correct male/female condom use. The courses are set on a four-month cycle as women move out of the shelters and new ones enter the program.

Women served by the program are provided referrals for mental health services, substance abuse treatment, medical care, and other social and health services. By addressing women's immediate needs, such as planning for long-term housing, program staffers help remove barriers to allow women to receive the prevention message.

In addition to education and counseling, the program offers HIV testing. The program leaders direct women to convenient neighborhood testing sites operated by the local board of health or provide transportation to satellite testing sites operated by South Side Help Center. Owens stays in touch with the women for a year and serves as a stable resource for those who find themselves in transition.

"I tell them, 'We're just struggling here together, so let me know where you are and what you're doing,'" says Owens. "It gives them the opportunity if they are having some problems, they have somebody they can call. That is very important."

Teen WISE (Women Informed Seeking Empowerment), a CDC-funded program in Detroit, focuses its efforts at African-American young women between ages 12 and 19. Also in its third year of CDC funding, the program is operated by Neighborhood Service Organization of Detroit, a private nonprofit organization.

Workshops, support groups, and street outreach are the main vehicles for reaching the teens, says **Janice Cross**, Teen WISE coordinator and program coordinator for community health services at Neighborhood Service Organization. The workshops can be presented as a one-time session for a church or group, a set of three to four workshops, or a series of nine workshops for a school. Support groups can follow, set up on a weekly, biweekly, or monthly basis. Street outreach moves education out into bus stops, parks, and other community gathering areas, where condoms and safer sex kits are distributed.

One popular approach to reaching teens is the "Pamper Party," which group educators coordinate with local cosmetology colleges. A small group of adolescent women gather for a one-hour HIV-prevention message, then may choose to have their hair or nails done by cosmetology students.

For Valentine's Day, program staffers coordinate a "Love Yourself First" party, with a decorated cake and grab bags filled with inexpensive hand lotions and other personal grooming products. A workshop is presented on HIV prevention, followed by group discussion.

A communitywide activity includes Teen WISE's outreach picnics, held during the summer at Belle Isle, a public park and a popular teen gathering. Teen WISE collaborates with other programs to sponsor a picnic with entertainment from local musical and dance groups, combined with education from peer outreach educators, counseling, and testing services.

Peer educators play a large role in Teen WISE's success, says Cross. Training and a trial presentation allow program coordinators to select qualified teens, who then go on the program payroll. Training sessions are held several times a year to keep educator slots filled.

"Our peer educators are to be role models because kids will listen to other kids," says Cross. "Even our outreach workers, who are in their 30s, are thought to be too old. Kids listen to other kids, which is the whole point of where this program is going."

References

1. Centers for Disease Control and Prevention. *HIV/AIDS Among African Americans.* Atlanta; August 1999.
2. Centers for Disease Control and Prevention. *HIV/AIDS Among US Women: Minority and Young Women at Continuing Risk.* Atlanta; August 1999.
3. Centers for Disease Control and Prevention. *HIV Continues to Exact Toll on African Americans.* Atlanta; Aug. 30, 1999.
4. Kim LL. Funds for preventing HIV in minorities raised. *Atlanta Journal Constitution*; Oct. 6, 1999: C1. ■

EXECUTIVE SUMMARY

A new testing technology, the Serologic Testing Algorithm for determining Recent HIV Seroconversion (STARHS), is giving researchers a better look at the leading edge of the HIV/AIDS epidemic.

- The STARHS strategy uses two separate HIV antibody tests. The first test is the standard antibody test, the enzyme-linked immunosorbent assay, which is used to detect the presence of HIV just six to eight weeks after infection. The second test is a less sensitive form of the standard test. If a person tests positive on the sensitive test, and negative on the less sensitive tests, scientists know the infection is in its early stages.
- The ability to determine early HIV infection means the identification and notification of previous sexual and needle-sharing partners can be enhanced. The testing strategy also may have positive implications for medical treatment and strengthen HIV epidemiological surveillance.

Testing strategy gives look at HIV incidence

When it comes to distinguishing new HIV infections from longstanding infections, public health officials are looking to the STARHS — the Serologic Testing Algorithm for determining Recent HIV Seroconversion.

Developed by scientists at the Atlanta-based Centers for Disease Control and Prevention (CDC) along with other colleagues, the STARHS technology allows researchers to determine whether infection occurred in the last four to six months. With this testing strategy, public health officials can begin to know which populations are becoming HIV-infected today and how to help stem further spread of the disease.

"First and foremost, it is most useful as a tool to help us measure incidence," says **Sandra Schwarcz**, MD, MPH, director of AIDS surveillance with the San Francisco Department of Public Health. "What is particularly exciting about it is that it allows us to measure incidence in a cross-sectional survey, at a single point in time, and that has not been possible before."

The STARHS strategy uses two separate HIV antibody tests. The first test is the standard antibody test, the enzyme-linked immunosorbent assay (EIA). It is used to detect the presence of HIV just six to eight weeks after infection.

The second test is a less sensitive, or detuned, form of the standard antibody test. Because people who have been infected recently (those who have seroconverted within the previous four months) have lower levels of antibody, they will test seropositive on the standard, sensitive EIA and seronegative on the less sensitive EIA. People with long-standing infections (defined as those who have seroconverted sometime before the previous four months) will have antibody levels sufficiently high to test positive on both of the assays.[1]

The ability to determine early HIV infection means the identification and notification of previous sexual and needle-sharing partners can be

enhanced, say public health officials.[1] Early detection also may have positive implications for medical treatment and may strengthen HIV epidemiological surveillance.

For some time, CDC researchers had been looking at easy ways to measure HIV incidence and measure new infections, says **Robert Janssen**, MD, deputy director of the Division of HIV / AIDS Prevention — Surveillance and Epidemiology. This had proven to be no simple task, as scientists were unable to use a number of markers to determine new infections.

At the same time, researchers were examining methods to confirm the safety of the blood supply. CDC mathematical statistician Glen Satten, PhD, came upon the idea of using older, less sensitive assays to identify people early in infection, Janssen recalls.

"Even though they [the older assays] were pretty good, there was still a period during which someone would be reactive on the new assay but not reactive on the old assay," Satten explains. "Presumably, the first assays were made to be as good as possible [making the time interval as small as possible], so I wondered, could we make a 'bad' assay — one that could detect HIV as late as possible but still reliably detect HIV?"

To achieve this goal, scientists modified three elements — sample dilution, sample incubation time, and conjugate incubation time — of the present 3A11 assay (Abbott Laboratories, Abbott Park, IL) to produce the less sensitive assay.

In a large multi-population study, researchers were able to show the validity of the dual-testing algorithm. They stated, "The sensitive / less sensitive testing strategy provides accurate diagnosis of early HIV-1 infection, provides accurate estimates of HIV-1 incidence, can facilitate clinical studies of early HIV-1 infection, and provides information on HIV-1 infection duration for care planning."[2]

Since the study was published, researchers from the CDC have spent much time standardizing the testing strategy, says Janssen.

"It is a test that is simple in principle, and even the lab techniques are simple in principle," he notes. "Making the dilutions can be difficult."

The protocol has since been refined so the testing strategy may be reproduced easily. Several testing sites are working under an investigational new drug application with the U.S. Food and Drug Administration, says Janssen, and a number of researchers are using the dual-testing algorithm strategy to enroll patients in their studies of early HIV.

Scientists also are looking at the application of the STARHS technology in international testing situations, Janssen confirms. Further work is needed to refine the test for the various subtypes of HIV found in other countries.

Incidence still high

Results from applying the STARHS technology in high-risk settings were presented recently at the recent National HIV Prevention Conference in Atlanta, which was convened by the CDC and 17 other sponsoring organizations. The findings indicate that HIV incidence continues at high levels in the United States.[3-6] The highest rates of infection in the four presentations were found among gay and bisexual men and people coinfected with other sexually transmitted diseases.[7]

"This new testing technique provides us with a snapshot of the epidemic's leading edge," says Janssen. "We can now better identify new epidemics while they are still emerging, and intervene before infection spreads more broadly."

References

1. Schwarcz S. A new HIV test to detect recent infections. *FOCUS* 1999; 14(3).

2. Janssen RS, Satten GA, Stramer SL, et al. New testing strategy to detect early HIV-1 infection for use in incidence estimates and for clinical and prevention purposes. *JAMA* 1998; 280:42-48.

3. McFarland W. HIV incidence among clients at anonymous sites in San Francisco. Presented at the National HIV Prevention Conference. Atlanta; Aug. 30, 1999.

4. Weinstock H. HIV sero-incidence among high risk heterosexuals and men who have sex with men in the U.S. using a dual EIA testing strategy. Presented at the National HIV Prevention Conference. Atlanta; Aug. 30, 1999.

5. Valleroy L. HIV incidence among young men who have sex with men in seven U.S. metropolitan areas. Presented at the National HIV Prevention Conference. Atlanta; Aug. 30, 1999.

6. Schwarcz-Kaplan S. Trends in HIV incidence among STD clients in the San Francisco Health Department — 1989-98. Presented at the National HIV Prevention Conference. Atlanta; Aug. 30, 1999.

7. National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention. *New Data Show Decline in AIDS Deaths Slowing Down.* Centers for Disease Control and Prevention, Atlanta; Aug. 30, 1999. ■

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