



CONTRACEPTIVE TECHNOLOGY

U P D A T E®

A Monthly Newsletter for Health Professionals

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Women's health issues included in managed care report card

HEDIS 2000 includes chlamydia screening, menopause counseling

How do managed health care plans rate when it comes to provision of women's services? A clearer picture will become evident this year as data are collected on two important areas of care: chlamydia screening and management of menopause.

The National Committee for Quality Assurance (NCQA) in Washington, DC, a nationwide organization charged with measuring and reporting on managed care quality, has included the two measures in its Health Plan Employer Data and Information Set (HEDIS) 2000.

Why should providers be concerned about NCQA and HEDIS? Organizations such as NCQA are grading managed care plans on many aspects of care and making the results public, as evidenced in NCQA's annual "State of Managed Care Quality" report and its Quality Compass database. Many employers and consultants use the database, which contains performance data from hundreds of health plans, as

EXECUTIVE SUMMARY

This year marks the inclusion of two important women's health issues — chlamydia screening and management of menopause — in the Health Plan Employer Data and Information Set (HEDIS) 2000, managed care guidelines developed by the National Committee for Quality Assurance.

- Public and private purchasers of health care use HEDIS to compare the quality of care and services provided by managed care organizations.
- The chlamydia screening measure assesses the percentage of sexually active women ages 15 to 25 who are screened for the disease. The management of menopause measure, based on a survey of a sample of women between ages 45 and 55, captures information about the quality of menopause counseling received by women from their providers.

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a decision support tool to help select or negotiate care with their health plan partners. Health plans, in turn, evaluate providers on their ability to demonstrate acceptable levels of care on measures monitored through HEDIS.

The two women's health issues joined two other items, controlling high blood pressure and appropriate medications for people with asthma, as additions to HEDIS 2000, according to **Brian Schilling**, NCQA spokesman. Information from the four new measures will not be reported until 2001, he says. "You won't see any data in 2000 at all because the first year is sort of a run-in period where we make sure that the measures work."

Why chlamydia screening?

The chlamydia screening measure assesses the percentage of sexually active women ages 15 to 25 who are screened for chlamydia. Chlamydia is now the nation's most common sexually transmitted disease (STD), affecting about 3 million people annually, most of whom show no symptoms, according to NCQA. Consequences of the disease can include infertility and ectopic pregnancy. Fortunately, cure rates approach 97%, and treatment costs average under \$10, NCQA reports.

Chlamydia screening is a simple yet powerful step. Researchers at Group Health Cooperative, a Seattle-based HMO, documented a 56% reduction in the incidence of pelvic inflammatory disease in high-risk women who were screened and treated for chlamydia.¹

Public health officials say the new measure will be significant in focusing managed care providers and purchasers on the importance of screening and treating a disease that ordinarily is rarely on the radar screen for private providers, notes **Judith Wasserheit**, MD, MPH, director of the Division of STD Prevention in the National Center for HIV, STD, and TB Prevention at the Atlanta-based Centers for Disease Control and Prevention.

"We hope that since what is measured is what gets done, this measure will focus managed care

providers a lot more on chlamydia in particular and, through that, on STDs and, more broadly, their impact on women," she states.

It is important to include managed care in prevention efforts against such STDs, says **Thomas Eng**, MD, president of the Institute for Interactive Health Communications in Washington, DC. Eng served as co-editor of *The Hidden Epidemic: Confronting Sexually Transmitted Diseases*, a 1996 Institute of Medicine report that called for the inclusion of STD-related performance measures in HEDIS to improve quality-assurance monitoring of STDs. Because plans will be evaluated on their performance in screening for chlamydia, they now have a direct interest in screening the targeted population, he notes.

Because chlamydia screening traditionally has been the expertise of public health personnel, health departments that also have such expertise should contact their local managed care plans to explore how they can work together to achieve HEDIS goals, says Eng. He chaired a two-day workshop that examined barriers impeding managed care organizations from providing comprehensive public health services and collaborating with health agencies.²

"I think to be serious about this, you need both direct clinical patient efforts, which the managed care plans would do, and also population-based outreach efforts, which most public health people are the best at doing," observes Eng. "I think that the two obviously need to talk to each other and try to think about how they can cooperatively intervene on both the community level and the individual patient level."

Counsel on menopause

The management of menopause measure, which is collected through patient surveys, is designed to capture information about the quality of menopause counseling women receive from their providers. The measure, based on a survey of a sample of women between ages 45 and 55, will examine the following three areas:

- **content:** to examine whether the patient

COMING IN FUTURE MONTHS

■ Impact of abstinence-only educational programs

■ Benefits of oral contraceptive use in perimenopause

■ Treatment strategies for persistent and resistant vaginitis

■ How to develop a menopause discussion group

■ Management strategies for OC breakthrough bleeding

RESOURCE

For more on the National Committee for Quality Assurance and HEDIS 2000, contact:

- **National Committee for Quality Assurance**, 2000 L St. N.W., Suite 500, Washington, DC 20036. Telephone: (202) 955-3500. Web: www.ncqa.org.

received counseling and was presented with a variety of treatment options;

- **personalization:** to determine the extent to which the patient received “personalized” counseling that included not only her medical history, but also her values and concerns;
- **quality:** to assess the patient’s overall satisfaction with the counseling and to determine whether the counseling was incorporated in her treatment or lifestyle.

Physician counseling and recommendations are likely to figure strongly in women’s decisions to begin hormone replacement therapy. Yet, just more than one-third of women ages 50 and older had physician counseling on this issue in the past year, according to a report issued by the Commonwealth Fund.³ Women with low incomes or less than a college education were the least likely to report physician counseling on hormone therapy options, survey results showed.

The Women’s Health Measurement Advisory Panel of NCQA strongly recommended the menopause counseling measurement in HEDIS 2000, says **David Archer**, MD, a panel member and professor of obstetrics and gynecology and director of the Clinical Research Center at the Eastern Virginia Medical School in Norfolk. Women should have appropriate counseling and preventive health screening in their 40s and as they experience the menopausal transition, he notes.

“It is important to counsel all postmenopausal women on lifestyle and behavioral modification, along with performing an assessment of their risk factors for cardiovascular, osteoporotic, and neoplastic diseases,” he says. “This assessment requires annual updating because of new medical information becoming available.”

The amount of time required for the counseling session varies, says Archer. That flexibility must take into consideration the need for physician/patient interaction to address all the patient’s concerns, as well as the time constraints of managed health care, he says.

“We don’t offer specific guidelines saying, ‘This is exactly how the consultation must be performed, and these are the things you need to cover,’” Schilling of NCQA concurs. “We give the health plans and providers latitude in determining how they are going to track, promote, and execute any given intervention, whether it is counseling for menopause, chlamydia, or controlling high blood pressure.”

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Duramed Pharmaceuticals targets women’s health

New Apri offered as OC ‘value brand’

Family planners now have three alternatives when prescribing a desogestrel and ethinyl estradiol oral contraceptive (OC): Ortho-Cept from Ortho-McNeil Pharmaceutical of Raritan, NJ; Desogen from Organon of West Orange, NJ; and the newest addition, Apri from Duramed Pharmaceuticals of Cincinnati. The new OC is being marketed as a “value brand” and should be available at a savings of approximately 30% below the retail cost of comparable pills, according to **Ellen Knight**, Duramed spokeswoman.

Apri is the first substitutable product equivalent to Ortho-Cept and Desogen, both of which offer 30 mcg of ethinyl estradiol and 150 mcg of desogestrel. Apri received Food and Drug Administration (FDA) approval in August 1999 and began shipment in October, according to Knight.

The OC represents Duramed’s first birth control pill, but providers should be prepared to see similar products from the company in the future, she notes. Duramed has nine other OCs in its product development program.

Apri also marks the first product launch from Duramed’s product-development alliance with

EXECUTIVE SUMMARY

The Food and Drug Administration has approved Apri, a new oral contraceptive from Duramed and the first substitutable product equivalent to Ortho-Cept and Desogen. Duramed is marketing it at an estimated 30% savings over comparable brands.

- Duramed, a longtime manufacturer of generic products, gained approval for four women's health products in 1998. It has nine oral contraceptives in its product development program.
- The company received approval last March for Cenestin, a conjugated estrogens drug product whose synthetic components are chemically derived from a compound obtained from plant material. It has an approved indication for short-term use in treating such vasomotor symptoms as hot flashes and sweating associated with menopause.

Gedeon Richter Ltd., a Hungarian pharmaceutical company and one of the major suppliers of bulk active raw materials for OC products worldwide.

A longtime manufacturer of generic pharmaceuticals, Duramed has gained FDA approval for the following products in the last two years:

- **Medroxyprogesterone acetate tablets**, therapeutically interchangeable with Provera tablets manufactured by Pharmacia & Upjohn of Bridgewater, NJ, for the treatment of secondary amenorrhea and abnormal uterine bleeding due to hormonal imbalance. Manufacturing of the product had begun as of Dec. 2, and Duramed said distribution is expected to commence within 60 days.

- **Estropipate tablets**, comparable to Ogen tablets, also manufactured by Pharmacia & Upjohn. Estropipate may be used in estrogen replacement therapy (ERT) to treat moderate to severe vasomotor symptoms of menopause and help prevent osteoporosis. Duramed's products are available in 0.75 mg, 1.5 mg, and 3 mg strengths.

- **Estradiol tablets**, comparable to Estrace tablets manufactured by Bristol-Myers Squibb of Princeton, NJ. Duramed's products are available in 0.5 mg, 1 mg, and 2 mg strengths and are indicated in ERT. In addition, the FDA granted Duramed the rights to market a 1.5 mg estradiol tablet, a strength that is unavailable from any other source.

Duramed's largest foray into women's health care began in 1994, when it began to pursue a

generic equivalent to Premarin, a conjugated estrogens drug product from Wyeth-Ayerst Laboratories of Philadelphia. The FDA ruled that a synthetic version of Premarin could not be approved because the active ingredients of the drug had not been adequately defined. Duramed moved to develop a separate product, Cenestin, which gained regulatory acceptance in March 1999.

Cenestin is made of nine synthetic estrogen components. Those synthetic components are chemically derived from a compound obtained from plant material. The product is available in two dosage strengths: 0.625 mg and 0.9 mg.

As *Contraceptive Technology Update* went to press, Duramed anticipated receiving regulatory approval for the 1.25 mg tablet strength of Cenestin by the close of 1999, and consent for the 0.3 mg tablet strength in mid-2000.

Short-term use approved

The FDA has determined that Cenestin is safe for short-term use in the treatment of such vasomotor symptoms as hot flashes and sweating. It has not been approved for long-term use, such as the prevention of osteoporosis; however, the company is conducting research to gain a long-term indication, confirms Knight.

One important element of the clinical trials — the bone marker study — is complete, Knight says. Although results have not been published, preliminary results are favorable and show a reduction in bone markers, indicating a bone preservation effect. The company anticipates beginning the full osteoporosis clinical study this year to confirm the beneficial results indicated by the bone marker study.

Duramed recently filed an Investigational New Drug application with the FDA to study the effects of medroxyprogesterone acetate administered cyclically with Cenestin. Duramed anticipates initiating the related Phase III clinical trials in the coming months and filing a New Drug Application upon completion of those trials.

While Cenestin and Premarin are conjugated estrogens drug products, Cenestin is a synthetic product chemically derived from a compound obtained from plant material, and Premarin is made from the urine of pregnant mares.

Cenestin has the advantage of being derived from plant sources, and therefore offers an alternative to Premarin for individuals who have ethical or emotional problems with use of equine

RESOURCE

- **Duramed Pharmaceuticals**, 7155 E. Kemper Road, Cincinnati, OH 45249. Telephone: (513) 731-9900. Fax: (513) 731-5270. Web: www.duramed.com. For more on Cenestin, go to www.cenestin.com.

urine sources, says **James Simon**, MD, clinical professor of OB/GYN at George Washington University in Washington, DC. Simon, who practices in a private OB/GYN practice in Washington, DC, also runs the Women's Health Research Center in Laurel, MD, an independent research center. He developed the protocol for Cenestin's approval for vasomotor symptoms.

"It is another alternative, one that is chemically and pharmacokinetically similar to Premarin, and so people have yet another alternative," Simon remarks of Cenestin. "The more alternatives, the better, since this class of compounds seems to be underutilized based on the number of women who are menopausal and the number of women who are candidates for ERT." ■

Male vaccine studied; shot not yet a reality

"Thanks to one biotech company, the promise of a Pill-style prophylactic for men may finally take off," proclaims a popular men's magazine article.¹ For those involved in such research, however, that promise is not yet a product.

Even the most favorable experimental male contraceptives are at least a decade away from general use, according to a 1998 review of methods under research.² Progress has been slow in part due to the challenge of controlling the male reproductive system. While a woman produces one egg a month, a man generates hundreds of millions of sperm daily. And while a woman's fertility ends at menopause, a man continues to produce sperm throughout his adult life.

Scientists are looking at a variety of hormonal and nonhormonal approaches to suppress sperm production, but the process in question pertains to the inhibition of the sperm's fertilizing ability. (*Contraceptive Technology Update* offered a review of methods under research in its February 1998 issue; see p. 22.)

Immucon, a Montreal, Quebec-based firm, has filed a U.S. patent based on its claim that it can use a fragment of a protein to neutralize the sperm's fertilizing capacity acquired at the level of the epididymis.

In tests on rodents, scientists affiliated with Immucon have found that the protein P26h is responsible for informing sperm cells when they have reached the surface of an egg.³ This protein is very important for the binding to the ovum, says **Alain Bossé**, Immucon president. If it is not there or if its action is blocked by immunocontraception, fertilization does not occur, he explains. "What we have done is to take a segment of this protein and inject it into the hamster's body, and antibodies are developed against this P26h" he says. "They bind themselves to the sperm head, and when the sperm goes out, it cannot fertilize."

Immucon researchers have identified P34H in humans as the target protein.⁴ Clinical trials will have to be conducted to determine whether the principle holds true in men. "We are about to begin the monkey studies," says Bossé. "We hope to be in Phase I studies about two to 2½ years from now."

Immucon, which maintains its own Web site (www.immucon.com), has received much interest from men seeking the experimental method, says Bossé. "Everybody is asking [about the contraceptive method] and telling about their personal case, about their partner is having trouble with female contraceptives."

The need for that market isn't being met, he says. "People are asking if they can't have it now, then they are willing to use it in clinical trials."

Paul Primakoff, PhD, professor in the department of cell biology at the School of Medicine at

EXECUTIVE SUMMARY

The inhibition of the sperm's fertilizing ability is the focus of research efforts aimed at male contraception. While preliminary results are promising, it will be some time before such methods are available to the general population.

- Immucon, a Montreal, Quebec-based firm, has filed a U.S. patent based on its claim that it can use a fragment of a protein to neutralize the sperm's fertilizing capacity acquired at the level of the epididymis.
- Scientists at the University of California-Davis also have identified and studied proteins on the surface of sperm required for fertilization.

RESOURCE

- **Immucon**, 1224 Stanley, Suite 313, Montreal, Quebec, Canada H3B 2S7. Telephone: (514) 878-1591. Fax: (514) 878-0035. E-mail: info@immucon.com.

University of California-Davis Medical School, and members of his research team have identified and studied other proteins on the surface of sperm that are required for fertilization. One protein, identified as PH-20, helps a sperm cell penetrate the outer layer of cells that surrounds the egg. It also appears to help a sperm cell adhere to the egg coat, which lies between the cumulus cell layer and the egg cell membrane. Another protein, identified as PH-30 or fertilin, is required for a sperm cell to bind and fuse to the egg cell membrane.

In rodent studies, UC-Davis researchers have found the proteins to be extremely effective contraceptive vaccines. When they inject preparations of one or both proteins into rodents, the animals respond by synthesizing antibodies specific to the proteins. The antibodies then bind to the proteins as they appear on the surface of sperm cells. Thus, they prevent the proteins from participating in the events of fertilization.

Creating infertility

Taking their research a step further, scientists studied the activity of sperm in mice lacking the gene for fertilin-beta.⁵ Sperm from the mutant mice looked and moved normally, but most of them failed to attach to the egg. Those sperm fused with the plasma membrane, which encases the egg, at just half the rate of sperm from normal mice.

"That is another kind of proof of concept that if you can delete the activity of a single sperm protein, then you can create this infertility," observes Primakoff. "Then the question becomes, 'When you want to make this into a contraceptive method, how do you delete this protein? Can you really do it with antibodies, or are there possible approaches through a pharmaceutical?'"

Primakoff says he is often questioned on a possible timetable for contraceptive products, but he says it is too early to make any predictions. "Being involved in it, and seeing how the science goes, it is really hard to say, but I don't believe it is close," he remarks. "I don't think anyone has really figured out how to do this."

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Promote National Condom Week: Ideas you can use

Events include a contest, dinner dance

What is your clinic's message this year for National Condom Week, Feb. 14 -21? A roundup of ideas from three Planned Parenthood affiliates may provide inspiration for encouraging your patients to use condoms consistently.

The year 2000 marks the 22nd observance of the event, according to **David Silberman**, MPH, project director at Pharmacists Planning Service Inc. (PPSI) of San Rafael, CA. PPSI, a nonprofit organization that promotes public health education and awareness campaigns, sponsors National Condom Week with the Condom Resource Center of Oakland, CA, a nonprofit organization dedicated to providing outreach education, technical assistance, and print and audiovisual materials on condom

EXECUTIVE SUMMARY

The 2000 observance of National Condom Week, Feb. 14-21, gives family planners a unique opportunity to encourage consistent condom use in the community.

- A two-day scientific symposium and a condom couplet contest are some of the activities planned by Pharmacists Planning Service of San Rafael, CA, which sponsors the week with the Condom Resource Center of Oakland, CA.
- Family planners have used a literary reading, a "Love Carefully" dinner dance, and a "Safer Sex Gazette" to promote the condom message.

use. About 650 school and college campuses will host special activities in conjunction with the week, he estimates.

Winners of the National Condom Couplet Contest will be announced by PPSI during the week. The contest encourages submission of a rhymed couplet (two lines of verse with the same number of syllables, and rhyming last syllables). Light-hearted verses such as "When you rise . . . condomize" are then used to further promote the condom message.

Also on tap is a two-day scientific symposium cosponsored by the University of California Berkeley School of Public Health and the New York University School of Education's department of health studies. Such events help underscore the need for increased education and awareness of condom use, says Silberman.

Planned Parenthood of Lincoln (NE) partners with the Nebraska AIDS Project's Lincoln affiliate in sponsoring a "Love Carefully" dinner dance at a local Unitarian church. The two organizations split the responsibilities of hiring a disc jockey, coordinating food items through the church's social action committee, promoting the event through a flier inserted in Planned Parenthood's newsletter, and assembling items for a silent auction, according to **Linda Hellerich**, director of development.

Tickets for the event are under \$20 and food costs are kept low. Planned Parenthood buys the food, which is prepared by church committee members. Items sold at the auction, which range from Valentine's Day-themed items such as flow-ers and candy to movie passes, are donated. The 1998 event raised almost \$3,000 before expenses, with \$800 garnered from the auction, she reports.

A table is set up to display small cloth bags filled with condoms and safer-sex printed material, but the prevention message is low-key, says Hellerich. The event, which has been held for about five years, attracts many families, who use the church's nursery for child care during the dance. It also has attracted some untoward attention as well. Picketers who oppose dissemination of sex education materials marched outside during the 1999 event. Organizers are undeterred in planning this year's dance, says Hellerich.

Want to provoke a thoughtful discussion about condoms? Planned Parenthood of Southeastern Pennsylvania hosted a reading from the book, *Getting It On: A Condom Reader* (Soho Press, New York City). The book, a literary collection of short stories, poems, and novel excerpts, made its

publishing debut during the 1999 observation of National Condom Week.

Cynthia Baughman, a professor of screenwriting at Temple University in Philadelphia, read her short story, "Safety Speech," from the book, which was followed by an audience discussion on safer sex. Packets of condoms and information were distributed following the event.

Planned Parenthood used fliers to get out the word, says **Tamela Luce**, public affairs coordinator. Fliers were mailed to newsletter recipients, placed in clinics, and posted in such community areas as coffeehouses. Information also was posted on the affiliate's Web site, as well as printed in newspaper calendar listings.

While turnout was relatively light, organizers were pleased with the event, says Luce. The affiliate is considering teaming with a local college or university to boost activity during the 2000 observance of National Condom Week.

Use a safer sex gazette

Get the word out on the importance of condoms with a "Safer Sex Gazette," such as the one published by the Planned Parenthood of South Carolina in Columbia. The gazette, an 8.5 x 11 inch handout printed on both sides, uses a newsletter format and a catchy style to convey its message, says **Jane Emerson**, affiliate chief executive officer. The handout covers the history of National Condom Week and offers information about how to use condoms and how to talk to partners about them.

The gazette, developed in-house and printed inexpensively, was distributed not only during National Condom Week, but at health fairs and other community events throughout the year, says Emerson. During National Condom Week, the affiliate used graduate students from local universities to set up tables in local bars to pass out the gazettes and offer free condoms.

"We have used it for the past three or four years," says Emerson. "We distribute them at health fairs, especially with young people." ■

RESOURCE

- **Pharmacists Planning Service Inc.**, 101 Lucas Valley Road, Suite 210, San Rafael, CA 94903. Telephone: (415) 479-8628. Fax: (415) 479-8608. E-mail: ppsi@aol.com.

Weighing the risks of transdermal ERT

By Ivy M. Alexander, MS, C-ANP
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New Haven, CT

(Editor's note: This is the conclusion of a two-part series on transdermal estrogen replacement therapy. The first installment, which reviewed potential benefits, appeared in the December 1999 Contraceptive Technology Update, p. 145.)

As more women experience and live beyond menopause, interest in risks and benefits associated with estrogen replacement therapy (ERT) has increased. Estrogen can be administered via oral, parenteral, intravaginal, and transdermal routes. Oral administration is the most common, followed by the transdermal route.¹ The purpose of this column is to examine the disadvantages of transdermal estrogen delivery systems. They include:

- **Breast cancer risk.** Although generally safe, several potential risks or disadvantages accompany ERT and transdermal delivery systems. One issue that concerns many women is the risk of breast cancer. Although still controversial, it appears that if any association exists between ERT and breast cancer, the association is very small.^{1,2}
- **Endometrial hyperplasia.** Hyperplasia of the endometrial lining is a risk for women with an intact uterus receiving unopposed ERT. The risk is minimized by administering cyclical or continuous progesterone. Continuous administration is preferred by many women because menstrual flow usually ceases after the first few months of therapy.^{1,3} Combination therapy is available in patch form or can be achieved by daily oral progesterone administration.⁴ Progesterone patches are being studied but are not yet commercially available.³
- **Dose-related side effects.** Systemic dose-related side effects are comparable with oral and

transdermal delivery systems. Some women who experience nausea or headache while taking oral preparations may have fewer side effects with transdermal delivery.¹

- **Weight gain.** Reports on weight gain are controversial. Although some weight increase during initial therapy has been noted, most research studies have not identified an increase in weight attributable to HRT with long-term therapy.⁵ However, changes in fat mass and distribution have been identified. Those changes may differ according to route of administration. One study reported increased fat mass and decreased lean body mass with oral administration as compared with transdermal therapy.⁶

- **Deep-vein thrombosis.** The risk of thromboembolism while on oral ERT is generally highest in the first year of therapy. Because few data are available on risk among women receiving transdermal estrogen, the interaction between embolic risk and transdermal administration is uncertain. However, the absolute risk for venous thromboembolism with oral estrogen administration is low.²

- **Rash at administration site.** The most common problem associated with transdermal ERT is developing a skin rash at the site of administration. That can be reduced by rotating patch locations and not using the same site in succession. Additionally, removing the patch for swimming or bathing can be helpful because moisture under the patch appears to increase irritation.¹

Overall, benefits associated with ERT tend to outweigh risks. Careful screening to identify women at heightened risk for negative outcomes is appropriate. Clear discussion on advantages and disadvantages can help a woman decide. ERT is clearly associated with reduced menopausal symptoms and improved overall quality of life.^{1,2,5} Once a woman experiences relief of vasomotor symptoms, she may be more inclined to consider long-term ERT and reap additional systemic benefits.

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Teens on the Web: Take a look at these 6 sites

(Editor's note: Beginning in this month's issue, Contraceptive Technology Update is highlighting Web sites and listservs that will be helpful to you and/or your patients. If you'd like to submit a Web site or listserv you think would interest your peers, please use the form enclosed in this issue.)

Does your practice include an abundance of adolescent patients? Here are some Internet Web sites that offer good information for teens or for those who care for them:

1. National Campaign to Prevent Teen Pregnancy. Address: www.teenpregnancy.org.

The Washington, DC-based National Campaign to Prevent Teen Pregnancy, founded in February 1996, is a nonprofit, nonpartisan initiative organized around one major goal: to reduce the U.S. teen pregnancy rate by one-third between 1996 and 2005.

The Web site offers free, easy-to-download fact sheets for every state, four territories, and the District of Columbia that include comprehensive teen pregnancy and birth statistics, race/ethnicity and age breakdowns, state rankings and comparisons to national statistics, and rates of teen sexual activity and contraceptive use. It also includes Spanish-language translations of the campaign's tips for parents, teens, and faith communities and a fact sheet on teen pregnancy and childbearing among Hispanics in the United States. A special section designed for teens, "Teen In-Site," covers adolescent issues with a weekly teen survey.

2. Advocates for Youth. Address: www.advocatesforyouth.org.

Advocates for Youth, also based in Washington, DC, promotes the health of adolescents worldwide with a focus on the prevention of unintended teenage pregnancy and the spread of sexually transmitted diseases (STDs), including HIV/AIDS, through access to health services and information. The organization's popular fact sheet series is now available on the Web. These one-page fact sheets cover essential statistics, emerging trends, and resources in a concise and easy-to-use format. Topics include adolescent contraceptive use, adolescent pregnancy and childbirth, adolescent HIV/AIDS and STDs, and other issues. Programs that use peer educators may want to check out the Peer Education Webring, which links peer education Web sites from around the globe.

3. American Social Health Association's "I Wanna Know." Address: www.iwannaknow.org.

This teen health and awareness Web site has been created by the Research Triangle Park, NC-based nonprofit organization in response to the worsening STD statistics among U.S. adolescents. It is aimed at providing fingertip access to dynamic and reliable sexual health information for teens and offers a parents' guide to help adults discuss sensitive matters with teens. A unique feature is "South Treybourne Diaries," the daily chronicles of several fictional characters who deal with real-life issues in a soap opera format.

4. Planned Parenthood Federation of America's "Teenwire." Address: www.teenwire.com.

This teen health and awareness Web site, created by the New York City-based reproductive health organization, offers teens a private place on the Internet where they can get information and news about teen sexuality, sexual health, and relationships. Check out "Hothouse," an electronic "e-zine" written by teens for teens, and "Yikes!" a page set up to help answer such questions as "Have I got a sexually transmitted infection?"

5. American Medical Association's "Adolescent Health On-Line." Address: www.ama-assn.org/adolhlth/adolhlth.htm.

The Chicago-based American Medical Association's (AMA) Program on Child and Adolescent

Health sponsors this Web site for providers, with resources for information on adolescent health issues and the AMA's Guidelines for Adolescent Preventive Services program. Providers can order such resources as "The Parent Package," which includes 15 reproducible tip sheets to help primary care providers share important information about adolescence with parents.

6. Kaiser Family Foundation and Children Now's "Talking With Kids." Address: www.talkingwithkids.org.

This Web site is part of a national initiative by Oakland, CA-based Children Now and the Kaiser Family Foundation of Menlo Park, CA, to encourage parents to talk with their children earlier and more often about difficult issues such as sex, HIV/AIDS, violence, alcohol, and drug abuse. Information is available in English and Spanish. ■



Capitol Hill forecast: What's on tap for 2000

By **Cynthia Dailard**
Senior Public Policy Associate
Alan Guttmacher Institute, Washington, DC

While only time will tell what this legislative year has in store for family planning programs, one thing is clear: On a wide range of social issues — including but not limited to family planning — partisan lines will be drawn more sharply than ever as Democrats and Republicans position themselves in preparation for the 2000 presidential and congressional elections. As a result, 2000 promises to be a year more about political posturing than thoughtful policy debates.

Interestingly, 1999 was a year of major legislative developments, both positive and negative, for domestic and international family planning programs. To some extent — particularly on the domestic front — social conservatives refrained from promoting their anti-family planning agenda.

Historically, social conservatives have attempted to attach hostile amendments to the

Title X family planning program designed to impair the program's ability to deliver contraceptive services to low-income women and teenagers in need of subsidized care. Two perennial favorites have included a requirement that Title X clinics obtain parental consent before dispensing contraceptives to minors and prohibiting Title X funds from going to clinics that perform abortions with their own funding.

Funding hikes for abstinence programs

In 1999, House Republican leaders asked Title X opponents to refrain from offering those and other controversial policy "riders" that often bog down the annual funding bill for the Department of Health and Human Services. In exchange for doing so, House conservatives demanded that funding for abstinence-only education programs under the Adolescent and Family Life program (AFL) be more than tripled and earmarked that funding for programs teaching that "sexual activity outside the context of marriage is likely to have harmful psychological and physical effects."

When the final bill emerged from a joint House-Senate conference, it doubled funding for AFL, raising the funding level from \$17.7 million to \$39.7 million (although \$20 million will not be available until Oct. 1, 2000). And despite the Senate's proposal to increase Title X funding by \$7 million (above its existing level of \$215 million), the House leaders also insisted on eliminating any increase for the Title X program.

President Clinton vetoed the initial version of the bill and cited insufficient funding for family planning among his many reasons. Ultimately, a revised version of the bill emerged from negotiations between the administration and congressional appropriators with a dramatic change. Funding for the Title X program was raised to \$239 million — just \$1 million short of the president's request of \$240 million and the largest funding increase in more than two decades. The AFL funding increase, however, remained intact.

After conservatives in 1998 cut off all U.S. funding for the United Nations Population Fund (UNFPA), the largest multilateral population assistance agency in the world, family planning advocates began a concerted campaign early in 1999 to reverse the move. Much to the surprise of both sides, proponents of family planning in Congress ultimately succeeded in restoring \$25 million in funding for UNFPA.

International family planning programs funded through the United States Agency for International Development (USAID), however, did not fare nearly as well. For five years, family planning opponents had attempted unsuccessfully to reimpose the "Mexico City" gag rule policy, in place throughout the Reagan and Bush administrations but revoked by President Clinton during his first days in office. The policy would block foreign nongovernmental organizations (NGOs) that — with their own funds — provide abortion services or lobby on abortion from receiving U.S. funds for family planning.

In 1999, however, family planning opponents held hostage \$1 billion in back dues owed by the United States to the United Nations until the Clinton administration finally agreed to the Mexico City policy. While the president was given authority under this agreement to waive the restriction and ultimately did so, it came at a significant price: \$12.5 million was deducted from the \$385 million appropriated for USAID's population aid program, and no more than a total of \$15 million may go to foreign NGOs that provide legal abortions or engage in legal lobbying on abortion.

What will happen to funding?

Clearly, recent developments in domestic and international family planning have significance beyond the 1999 budget cycle. On the domestic front, presidential candidate and Republican frontrunner George W. Bush has stated in his campaign that promoting abstinence is the only way to reduce teen-age pregnancy, and he has promised that his administration would boost funding significantly for abstinence-only programs.

Additionally, Secretary of State Madeleine Albright, in a highly unusual move, announced within days of the Mexico City agreement that the Clinton administration will ask that funding for USAID's program be \$542 million — a 40% increase. Together, those actions set the stage not only for 2000 budget battles, but the presidential campaign as well. ■

RESOURCE

- **Association of Professors of Gynecology and Obstetrics**, 409 12th St. S.W., Washington, DC 20024. Telephone: (202) 863-2507. Fax: (202) 863-2514. Web: www.apgo.org.

Educational module targets hyperlipidemia

The in Association of Professors of Gynecology and Obstetrics in Washington, DC, has developed an educational monograph, "Managing Hyperlipidemia in Women," as part of its Educational Series on Women's Health Issues. The teaching module includes the monograph; case studies with clinical setting scenarios, discussion points, and management suggestions; and slides with study guide information. A teaching module with case studies, slide set, and lecture guide is \$150 for members, \$250 for nonmembers; the monograph only is \$5 for association members, \$7 for nonmembers. The module is approved for three hours of Category 1 continuing medical education credit. ▼

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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 "Male vaccine studied; shot not yet a reality," p. 21.)
- Describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area. (See "Women's health issues included in managed care report card," p. 17.)
- Cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. (See "Weighing the risks of transdermal ERT," p. 24, and "Duramed Pharmaceuticals targets women's health," p. 19.) ■

Dedicated ECPs move into Canada

Canadian family planners are seeing the emergence of dedicated emergency contraceptive pills (ECP), with one now on the market and another under regulatory review by Canadian health officials.

Preven, the ethinyl estradiol/levonorgestrel ECP from Gynetics of Belle Mead, NJ, has been launched for Canadian marketing by Roberts Pharmaceutical Canada of Toronto. It received Canadian regulatory clearance in March 1999.

Paladin Labs of Montreal, Quebec, has exclusive Canadian distribution rights from Women's Capital Corp. of Bellevue, WA, for Plan B, the company's levonorgestrel ECP. Plan B is under regulatory review by Canadian health authorities. ■

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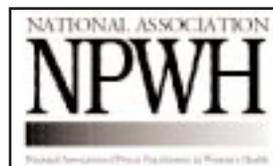
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Teen-agers and HIV testing: Removing barriers to care

Provider recommendation and free, confidential testing strong motivators

Are you talking with sexually active teens about HIV testing? You should be. A recommendation from a health care provider has been identified as a strong motivator among teens at high risk for infection to seek testing.¹

While much has been accomplished in the field of HIV/AIDS prevention, more must be done among young people and people of color, in whom infection is taking an especially firm hold, says **Victor Barnes**, acting deputy director for the Division of HIV/AIDS Prevention at the Atlanta-based Centers for Disease Control and Prevention's (CDC) National Center for HIV, STD, and TB Prevention.

Young people are disproportionately affected by the epidemic, notes Barnes. In the United

States, the CDC estimates that half of all new HIV infections are among people under 25, and the majority of young people are infected through sexual transmission.²

About half of all new AIDS cases among 13- to 19-year-olds are among women.³ In a study of 25 states, African-Americans account for 23% of HIV infections among those ages 13 to 24.⁴ Yet only 25% of sexually experienced teens ages 15 to 17 report ever having been tested for HIV.⁵

State laws allow tests

While entry age may vary from state to state, minors in every state are allowed to consent for diagnosis and treatment for sexually transmitted diseases. Since the mid-1980s, many states have enacted HIV-specific laws, including statutes that govern consent for HIV testing and treatment, to augment such legislation.⁶ At least 13 states — Arizona, California, Colorado, Connecticut, Delaware, Iowa, Maine, Michigan, Montana, New Mexico, New York, Ohio, and Wisconsin — have statutes that explicitly allow minors to consent to HIV testing or to receive a test without the consent of their parents.

In addition, counseling and informed consent have been incorporated as integral parts of the HIV testing process. Most states have enacted laws requiring informed consent for HIV testing, and federal legislation (the Ryan White CARE Act) requires counseling and informed consent for HIV testing performed in any facility receiving

EXECUTIVE SUMMARY

Young people have been disproportionately affected by the HIV/AIDS epidemic. Half of all new HIV infections in the United States are among people under 25, and the majority is infected through sexual transmission, according to the Centers for Disease Control and Prevention.

- A health care provider's recommendation is a strong motivator among teens at high risk for infection to seek testing. Access to confidential, convenient, and caring youth health care centers that are viewed as "teen-friendly" also helps.
- Many teens do not see themselves at risk for HIV, so they do not seek testing. Fear of being stigmatized also stands in the way.

Ryan White funds, whether or not the testing is paid for with federal monies.⁶

If HIV testing is available to teens, why don't they seek knowledge of their HIV status? A survey of at-risk youth in Miami, Houston, New York City, and Newark, NJ, found that many teens do not see themselves at risk for the disease.¹ Even though many knew someone in their neighborhood who was HIV-positive or who had died from AIDS, those surveyed did not link community infection rates with their own risk.

A fear of being labeled and stigmatized by families, friends, and communities also was named as a deterrent to testing. Perceptions of the consequences of living with HIV and the psychological hurdle of admitting mistakes and "incorrect" behavior also kept many from learning their HIV status.

Since many teens do not receive routine health exams, they only go for care when it is symptom-driven. This is especially true among adolescent males; unless they need physicals to play sports at school or are sick, young men reported that they rarely see a doctor. Lack of knowledge about the location of "teen-friendly" testing facilities also kept many teens from going for testing, according to survey results.

Lack of access for teens

There are very few specific places for teens to get HIV testing, and those places are not usually known, asserts **Robert Johnson**, MD, director of the Division of Adolescent and Young Adult Medicine (DAYAM) at the New Jersey Medical School in Newark. For those teens who may opt to visit their regular health care provider, access may not be what it should, he notes.

"I'm very sad to say that most health care providers who take care of teens don't think about this as a test that should be done, even when it is appropriate to do it," notes Johnson. "For example, kids can get a [sexually transmitted disease], and the health care provider may not even mention the fact that an HIV test should be done, or the health care provider may not be equipped to do the test."

According to the teens participating in the 1999 Kaiser Family Foundation survey, the key factors that motivate teens to seek HIV testing are:

- fear of exposure to HIV;
- presence of STD symptoms;
- recommendations of health professionals, parents, partners, and select peers;
- access to confidential, convenient, and caring youth health care centers;
- "teen-friendly" test sites.

"The key motivators for teens to seek HIV testing are knowing someone who has been tested and can walk them through the process; the testing facility/staff is non-threatening, nonjudgmental, approachable, and, most important, confidential; and the overwhelming need to know if they have been exposed," says **Edwidge Jourdain Thomas**, RN, MS, ANP, adult primary care provider and director of clinical services at Columbia University School of Nursing in New York City.

Be 'teen-friendly'

Most teens participating in the Kaiser survey say they go to public clinics for their medical care. Their impressions of the clinic staff were an important factor in whether they followed professional advice and returned for follow-up care, survey results showed.

The more teen-focused the facility, the more likely teens were to trust the individuals working there, the survey revealed. While some teens said providers' recommendations to be HIV tested made them "very nervous," they were responsive to such advice.

The underlying concerns for all age groups when it comes to health care are competence, consumer friendliness, and confidentiality, says Thomas, who is affiliated with Columbia Advanced Practice Nurse Associates (CAPNA) in New York City. CAPNA offers primary care to all age groups through advanced practice providers.

"We, including front office and practitioners, facilitate and coordinate — in partnership with our patients — their health care, and encourage them to call us with questions and concerns that we address promptly," notes Thomas. "We allow for one hour on our initial visits to establish a rapport with our patients and help them understand that our philosophy is that we are available to assist them through their illness/ill health or help them maintain their present level of wellness and/or to obtain a higher level."

Teens who visit a DAYAM clinic, whether it's for a cold, eating disorder, or orders from juvenile court, undergo a complete evaluation that includes a determination of their sexual health, says Johnson.

"If they are sexually active, then we ask the about the pattern of sexual activity, then we always do STD testing and offer HIV testing," reports Johnson. "One hundred percent of the time, the kids ask for and want an HIV test." (See story below for counseling tips and outreach ideas to encourage HIV testing for your adolescent patients.)

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Talking to teens about HIV testing

How can you encourage HIV testing among adolescents? First, take a quick look around your facility and see if it qualifies as a "teen-friendly" place. A 1999 study prepared for the Kaiser Family Foundation determined that a teen-friendly clinic offers:

- **Respect for teens who are sexually active.** Teens expect to be treated professionally and with respect by clinical and support staff.
- **Free or low-cost testing.** Because teens lack financial or insurance resources or wish to avoid

involving parents in sensitive health care matters, cost is a prime consideration when seeking testing.

- **A clinical environment.** Teens expect facilities to be clean, neat, and well-organized, with an air of professionalism.
- **A broad range of teen health services.** When a wide range of services are offered at a facility, teens know that anyone who sees them there will never know why they are there.
- **Confidentiality.**
- **Options for oral or blood-drawn HIV testing.** Fear of needles may keep some teens from seeking HIV testing.
- **Convenient access to public transportation or locations within walking distance to schools.** Many teens lack private transportation. Access to clinics via bus, rail, or easy walking distance aids in overcoming barriers to testing.
- **Fewer questions and paperwork.** Reducing the number of questions and paperwork, or at least explaining the need for them, helps alleviate teens' natural impatience. For gay and bisexual youth, standard questions that assume heterosexuality are particularly annoying.¹

Ask the question

If your facility meets the definition of teen-friendliness, then it's time to assess your own approach when it comes to the issue of HIV testing.

Felicia Guest, MPH, CHES, associate director for training at the Southeast AIDS Training and Education Center at the Emory University School of Medicine in Atlanta, suggests this line of questioning: "For all of my patients who are having sexual experiences with another person, I always recommend that they get an HIV test. Have you had one yet?"

This approach makes it clear the patient is not being singled out, the provider views HIV testing as a routine recommendation, and knowing one's HIV status is routine, not "weird," says Guest.

Once the question has been asked, present teens with four or five options about testing, she suggests. First, explain the difference between anonymous testing, where no name is associated with the results, and confidential testing, where a person's name is recorded along with the test outcome.

Guest suggests free or sliding-scale anonymous testing as a first-choice testing option for teens. If teens are in a small town and fear exposure from local testing, they may opt to go to the next county, she notes. A third option is to use the Home Access Express HIV-1 Test System manufactured by Home Access Health Corp. of Chicago, the only home collection diagnostic test approved by the Food and Drug Administration (FDA). **(For more information, see resource box at right.)**

"This test avoids venipuncture; it's just done with a fingerstick," says Guest. "For teens who can afford it, it is in the range of a little less or more than \$50, depending on how you want to do the rapid return [of test results], and it can be done anonymously."

If teens choose to seek testing away from your facility, remind them to ask for the availability of oral HIV testing because avoidance of needles plays a large role in fear of testing. Steer teens from choosing to donate blood as a way to learn their HIV status because it is not anonymous and runs the risk of exposing others to early infection, says Guest. Tell teens to avoid at-home tests marketed on the Internet that are not approved by the FDA.

Promote testing

The Division of Adolescent and Young Adult Medicine (DAYAM) at the New Jersey Medical School in Newark has developed a variety of specialized programs that respond to the health and psychosocial needs of more than 1,500 high-risk youth, says **Robert Johnson, MD**, division director.

DAYAM uses trained peer outreach workers (who are themselves high-risk teens) to deliver HIV risk reduction outreach messages to youth in schools and on the streets. Street outreach educators use a mobile testing van and the Orasure oral testing method from Epitope of Beaverton, OR. The van workers set appointments for teens to receive their test results.

"We realized early on that we could not just wait for kids to come in off the street for our services," Johnson says. "If we really wanted to tackle this issue, we had to go out into the community where teen-agers were and offer testing to them."

RESOURCE

For more information on the Home Access HIV test kit, contact:

- **Home Access Health Corp.**, 2401 W. Hassell Road, Suite 1510, Hoffman Estates, IL 60195-5200. Telephone: (847) 781-2500. E-mail: kj@homeaccess.com. Web site: www.homeaccess.com.

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