AMERICAN HEALTH CONSULTANTS®

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

INSIDE

Inserted in this issue:
CTU Annual Contraception Survey

APRIL 2001

VOL. 22, NO. 4 (pages 37-48)

Clinical quandary: Is it PMS or PMDD? Find answer by listening to patients

New drug therapies help women overcome challenges

Forget all the jokes about premenstrual syndrome (PMS). For women with severe forms of the condition, the symptoms are no laughing matter. Depression, feelings of hopelessness, or self-deprecating thoughts; marked anxiety or tension; feeling "keyed up" or "on edge"; wide mood swings; and physical symptoms such as breast tenderness, headache, joint or muscle pain, bloating, or weight gain are just some of the indications that a diagnosis of PMS or premenstrual dysphoric disorder (PMDD) may be in order.

But how do you distinguish between PMS and PMDD? First, determine the patient's symptoms, then understand how those symptoms are impacting her life, advises **Steven Sondheimer**, MD, professor of obstetrics and gynecology at the University of Pennsylvania Medical Center in Philadelphia, and co-director of its premenstrual syndrome treatment program.

PMS is common, and its symptoms can range in severity from barely noticeable to severe, explains **Jean Endicott**, PhD, professor of clinical psychology in the department of psychiatry in the college of physicians and surgeons at New York City-based Columbia University. Endicott also serves as chief of the department of research assessment and

EXECUTIVE SUMMARY

While as many as 85% of menstruating women report one or more symptoms of premenstrual syndrome (PMS), only 5% to 10% of women experience symptoms that are debilitating.

- While PMS has no universally accepted definition, temporality and severity are crucial to the diagnosis. Symptoms must appear during the woman's luteal phase, which begins with ovulation, and decrease greatly or disappear with the onset of menstruation or shortly thereafter.
- Premenstrual dysphoric disorder (PMDD) is severe PMS characterized by marked premenstrual problems with dysphoric mood and other clinical characteristics and clinically significant impairment in psychosocial functioning. Treatment alternatives include Sarafem (fluoxetine hydrochloride).

training in the department of psychiatry, and director of the premenstrual evaluation unit at Columbia Presbyterian Medical Center, also in New York City. PMDD is the name given to severe PMS that is characterized by marked premenstrual problems with dysphoric mood and other clinical characteristics and clinically significant impairment in psychosocial functioning, states Endicott. Approximately 3% to 7% of women have PMDD, she notes.

Chart the symptoms

While there is no universally accepted definition or set of diagnostic criteria for PMS, most experts agree that temporality and severity are key to an on-target diagnosis.[1]

To qualify as PMS, symptoms must appear during the woman's luteal phase, which begins with ovulation, and decrease greatly or disappear with the onset of menstruation or shortly thereafter. Symptoms that persist throughout the cycle, even if they increase or diminish, do not fit into a diagnosis for PMS.

Common PMS symptoms include, among others, abdominal bloating, irritability, mood swings, headache, weight gain, fatigue, food cravings, tension, and breast swelling. Although as many as 85% of menstruating women report one or more symptoms of PMS, only 5% to 10% of women experience symptoms severe enough to be debilitating.[2]

Listen to your patient to understand what kind of relief she is seeking, suggests Sondheimer. A patient who presents with premenstrual breast tenderness might simply fear she has breast cancer. Once it is determined her breast exam is normal, she might not have any desire for any treatment for her symptoms, he explains.

Symptoms of PMS must be severe enough to cause trouble. To understand the impact of symptoms and devise an effective treatment plan, have women keep a daily symptom chart where they note what symptoms occur, when they occur, and how disruptive each one is. A diary kept for two or more cycles might indicate another medical condition, such as depression, anxiety, endometriosis, or diabetes, which may be the real cause of a woman's symptoms.

When is it PMDD?

While PMS usually is not particularly troublesome for a woman, by definition, PMDD impairs her functioning and has an impact not only on her life, but also can negatively impact the lives of others with whom she interacts, states Endicott. Unlike PMS, PMDD is characterized as a psychiatric disorder, with its criteria defined by the Washington, DC-based American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV).*

"The distinction between severe premenstrual problems with mood and the more common forms of PMS was always important, but now that we have widely accepted diagnostic criteria for PMDD, and effective treatments for PMDD have been identified, the distinction has taken on additional significance because women with PMDD can now obtain the help they need," Endicott explains.

For a PMDD diagnosis, the patient must have:

- five or more of the following symptoms during most menstrual cycles in the past year: irritability, tension, depressed mood, mood swings, decreased interest in usual activities, difficulty concentrating, lethargy, marked change in appetite, insomnia or hypersomnia, sense of being overwhelmed, and physical symptoms such as breast tenderness and bloating. One or more of those symptoms must be depressed mood, tension, mood swings, or irritability.
- a disturbance that significantly interferes with social or occupational functioning.
- symptoms that are not an exacerbation of another disorder, such as major depressive disorder.[3]

Make sure the symptom diaries you provide patients with contain the items needed to make the diagnosis of PMDD, says Endicott. Women should be told to consider each item and rate the severity with which it was experienced during the past 24 hours, she suggests.

The daily ratings will help determine the pattern of premenstrual problems (which occur first and can be used as "early warning signs"), the timing of onset and offset of specific problems (which can be of importance in planning the timing of medication), as well as the relative severity of the problems during different phases of the menstrual cycle, says Endicott. In addition, sometimes just charting the symptoms and being cognizant of when they occur gives patients a sense of power over what is going on, states Sondheimer.

Look at new therapies

For women with mild to moderate PMS, getting adequate sleep, eating a healthy diet, exercising regularly, and eliminating nicotine and alcohol may help in easing troublesome symptoms, says Sondheimer. While there have been no studies to ascertain their effectiveness against the affective symptoms of PMS, combined oral contraceptives do offer some women relief while providing effective birth control, he notes.

For women with PMDD, recent clinical research has led to increased use of selective serotonin reuptake inhibitors. In July 2000, the Food and Drug Administration approved Sarafem (fluoxetine hydrochloride, Eli Lilly, Indianapolis) as the first prescription medication indicated for the treatment of PMDD.

Clinicians might recognize the drug as Prozac, which has been in use for several years under approved indications for depression, obsessive-compulsive disorder, and bulimia. The company sought the additional trademark since depression and PMDD are distinct disorders with different diagnostic and treatment approaches.

Fluoxetine's effectiveness for the treatment of PMDD was established in two double-blind placebo-controlled trials.[4] Common side effects were similar to those experienced by other fluoxetine users and included nausea, tiredness, nervousness, dizziness, and difficulty concentrating.[4]

Scientists are conducting ongoing research on several psychotropic drugs in efforts to identify more treatments and thus provide more choices, says Endicott. Drugs under review include sertraline hydrochloride (Zoloft, Pfizer, New York City), paroxetine hydrochloride (Paxil, SmithKline Beecham Pharmaceuticals, Philadelphia), and venlafaxine hydrochloride (Effexor, Wyeth-Ayerst Laboratories, Philadelphia).

"I think there is a potential that newer birth control pills with different progestational agents may have the potential of being helpful," adds Sondheimer. "There is some evidence that PMS can be helped by calcium supplementation in some patients."

Check new guidelines

While much of the research on the diagnosis and treatment of PMDD has been conducted in mental health settings, since dysphoric mood is the primary complaint, women usually bring up the condition and the desire for treatment in an OB/GYN setting, states Endicott. The Washington, DC-based American College of Obstetricians and Gynecologists revised its practice bulletin on premenstrual syndrome in 2000 to guide its members in appropriate treatment of the condition.

"The recently published guidelines are likely to be seen by many, if not most, obstetricians and gynecologists," says Endicott. "Hopefully, this will result in more women obtaining appropriate treatment for PMDD."

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The 'acne pill' might see competition

You might have to reformulate your response to patients' request for the "acne pill" if the Food and Drug Administration (FDA) approves Philadelphia-based Wyeth-Ayerst Laboratories' request to add an acne indication to its Alesse combined oral contraceptive (OC).

Wyeth-Ayerst has submitted a New Drug Application to the federal agency to receive an indication for use of the drug to "treat moderate acne vulgaris in women of reproductive age with no known contraindications to oral contraceptive therapy, who desire contraception, and are unresponsive to topical anti-acne medications."[1] The data were accepted by the FDA in January 2001,

EXECUTIVE SUMMARY

Alesse, a combined oral contraceptive (OC) marketed by Philadelphia-based Wyeth-Ayerst Laboratories, is seeking approval to add acne treatment to its approved indication. If approved, the drug will become the first 20 mcg OC to gain the indication.

- Ortho Tri-Cyclen, a 35 mcg phasic pill marketed by Ortho-McNeil Pharmaceuticals of Raritan, NJ, received approval in 1996 for the same indication. It now is the most prescribed OC in the United States.
- According to a 2000 survey, controlling acne and regulation of menstrual periods were the two benefits listed most frequently by survey respondents.

according to a company press release.

Wyeth-Ayerst filed the request based on clinical data collected in trials intended to justify the indication, says **Doug Petkus**, a company spokesman.

"Other OCs manufacturers have the indication, so there are competitive and clinical reasons why we pursued it," states Petkus. If the new indication is approved, Alesse would be the first oral contraceptive containing 20 mcg of estrogen indicated for the treatment of acne.

Indication ups sales

Ortho Tri-Cyclen, marketed by Ortho-McNeil Pharmaceuticals of Raritan, NJ, has seen sales triple in a three-year span since it was approved in late 1996 for treatment of moderate acne vulgaris.[2] **(See *Contraceptive Technology Update,* March 1997, p. 25, for news of FDA's approval.)**

"Since February 1998, it's been the most prescribed birth control pill in the U.S.," states **Mark Monseau**, an Ortho-McNeil spokesman. "In addition to being the only birth control pill clinically proven and approved by the FDA to help reduce moderate acne in women, it's also well-tolerated and demonstrates excellent cycle control with low incidence of nuisance side effects."

Ortho Tri-Cyclen has enjoyed sustained popularity among providers, according to *CTU's* annual Contraception Survey. Respondents to the 2000 poll named the pill as their first choice for 21-year-old nonsmoking women. Ortho Tri-Cyclen was the top choice in both formulary and nonformulary categories, with about 33% of survey respondents naming it as their first choice when not under formulary restrictions, and about 37% selecting it as the top choice in formulary plans. **(See *CTU,* September 2000, p. 101, for complete survey results.)**

However, the trend may be slipping, as both Alesse and another 20 mcg pill, Mircette (Organon, West Orange, NJ), moved up to capture more than 21% of top-choice selections in the 2000 survey. The two pills accounted for fewer than 10% of 1999 responses in the same category. **(See *CTU,* June 2000, p. 72, for coverage of the increased popularity of 20 mcg pills.)**

Data to be published

Alesse is a monophasic pill with 100 mcg levonorgestrel and 20 mcg ethinyl estradiol. Ortho Tri-Cyclen offers a steady dose of 35 mcg of ethinyl estradiol and a triphasic dose of norgestimate.

Efficacy data on Ortho Tri-Cyclen's impact on acne vulgaris have been published.[3,4]

There are no published or presented data yet available on Alesse, says Petkus.

"The announcement we made is that the FDA 'accepted' our data submission, and now they are reviewing the information," he states. "Once they render a final decision, we will be able to share the clinical data they are currently evaluating."

A 2000 survey published by the Washington, DC-based American College of Obstetricians and Gynecologists shows more women are starting to rely on the Pill for its noncontraceptive benefits.[5] Acne treatment and regulation of menstrual periods were the two benefits listed most frequently by survey respondents.

Oral contraceptives have proven to be an excellent option for pregnancy prevention, but they also offer many important noncontraceptive health benefits for the women who use them, notes **Wayne Shields**, president and CEO of the Washington, DC-based Association of Reproductive Health Professionals (ARHP). Those health benefits include reduced risk of some reproductive cancers and beneficial effects on fibroids.

"ARHP supports the efforts of pharmaceutical companies to study noncontraceptive health benefits of OCs — and other hormonal methods as well," Shields comments. "This positive action can raise the standard of health care for women by helping us better understand the benefits and risks associated with OC use."

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Bone mineral density and DMPA: reassuring news

Recent research on the effect of the contraceptive injectable depot medroxyprogesterone acetate (DMPA, Depo-Provera, Pharmacia Corp., Peapack, NJ) on bone mineral density (BMD) offers reassurance regarding long-term use of the drug.

Questions about DMPA's impact on BMD arose with the publication of a New Zealand cross-sectional study of 30 long-term DMPA users.[1] This retrospective study found a difference of about 7% in bone density between DMPA users ages 25 and 51 and other premenopausal users. A subsequent study of some of the original DMPA users who discontinued the method found that bone density tended to increase after the method was stopped.[2] **(Discussion of these studies and others examining DMPA's impact on BMD can be found in *Contraceptive Technology Update,* January 1998, p. 1.)**

Results from a just-published longitudinal cohort study of 59 Chinese women have led its researchers to conclude DMPA can be used on a long-term basis without fear of linear bone loss leading to early osteopenia and osteoporosis.[3]

Two recent cross-sectional studies,[4,5] which indicate DMPA's effect on BMD is small and reversible, offer reassurance to women who choose the injectable contraceptive, says **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center in Jacksonville.

"In my opinion, concerns regarding BMD should not discourage otherwise appropriate candidates or their clinicians from using this convenient, highly effective contraceptive," states Kaunitz.

EXECUTIVE SUMMARY

While recognizing its effectiveness as a contraceptive, family planning providers continue to follow research on depot medroxyprogesterone acetate (DMPA, also known as Depo-Provera) and its impact on bone density.

- A just-published study offers reassurance regarding long-term use of the drug.
- Two recent cross-sectional studies indicate DMPA's effect on bone mineral density is small and reversible.

Assess the impact

DMPA is the third most popular form of birth control among Hong Kong women, says **Grace Tang**, MD, professor at the University of Hong Kong, and a co-author of the study. In order to get a broader view of the drug's impact on BMD, the Chinese research group did a cross-sectional study on DMPA users (ranging from five to 15 years in use) and published the results in 1999.[6]

"We made an estimate of the likely rate of bone loss," Tang observes of the 1999 research. "We then proceeded to verify the results in a longitudinal follow-up of this cohort to see if our projection was correct."

The longitudinal cohort study revealed the study subjects' annual rate of bone loss at three sites was substantially less than the projected values in the cross-sectional study, which had demonstrated a reduction in BMD in DMPA users.

"We have plans to do a prospective study from point zero," reports Tang. "The concern is the recruitment time needed to get adequate number of subjects; in our study, the subject number was only 67."

Why have questions continued on DMPA's impact on bone health?

"In my opinion, the variable results may be related to 1) sample demographic differences; 2) lack of baseline values of BMD, meaning that subjects may start with very different BMD levels in different populations; and 3) varying periods of time in making the observations in BMD in different studies, and the BMD loss may not be linear in nature," observes Tang.

The benefits of DMPA continue to outweigh the concerns about BMD, says Kaunitz. He points to the results of the Orr-Walker and Petitti cross-sectional studies, which assessed women who

were former users of DMPA. Both found that long-term after DMPA use, BMD in former users is similar to that of never-users.

"This is strikingly similar to picture with BMD and lactation, since BMD declines during lactation, then goes back to normal after baby is weaned," notes Kaunitz. "Taken together, these studies suggest that the BMD declines seen in current DMPA users may be transient, and without long-term clinical significance."

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Meet 'Joe Partner': New STD treatment plan

How do you get treatment for partners of your patients who test positive for chlamydia? Meet "Joe Partner," San Francisco Health Plan's approach to attacking the spread of the sexually transmitted disease (STD).

The recently enacted California Senate Bill 648, dubbed the "Ortiz Bill" after its sponsor, Sen. Deborah Ortiz of Sacramento, authorizes providers who diagnose chlamydia in a patient to prescribe or provide prescription antibiotic drugs to that patient's sex partner or partners without prior examination. Taking advantage of this new legislation, San Francisco Health Plan, a not-for-profit health plan that provides affordable health coverage to lower-income San Franciscans, soon will begin paying for the treatment of partners of members with chlamydia in a bold step to reduce the number of recurring infections.

EXECUTIVE SUMMARY

San Francisco Health Plan, a not-for-profit health plan that provides affordable health coverage to lower-income San Franciscans, soon will begin paying for the treatment of partners of members with chlamydia in a bold step to reduce the number of recurring infections.

- The move comes with recently enacted legislation that authorizes providers who diagnose chlamydia in a patient to prescribe or provide prescription antibiotic drugs to that patient's sex partner or partners without prior examination.
- In developing a formulary for the universal "Joe Partner," Health Plan providers can write two prescriptions, one for the patient and one for the unseen partner. The new practice also will create two dispensing fees, which also will be covered by the health plan.

Chlamydia remains the most frequently reported infectious disease in the United States, according to the Atlanta-based Centers for Disease Control and Prevention (CDC).[1] While almost 660,000 cases of chlamydia were reported in 1999, the CDC estimates that 3 million new cases of the STD occur in the United States each year.[1] In women, untreated chlamydia may lead to pelvic inflammatory disease, one of the most common causes of ectopic pregnancy and infertility.

Karen Smith, MD, medical director for San Francisco Health Plan, estimates about 5% of the plan's members in the high-risk 15-25 age group are infected with the disease, and that many of the plan members have silent (asymptomatic) infections. Even if patients do present with symptoms and receive treatment, they may return two months later with a similar infection, since their partners fail to receive treatment.

"We know that 40% of the time, the treated member comes back reinfected two months later," observes Smith.

Get partners treated

The Ortiz bill provides the necessary legal language for health care providers.

"What it does is give very exact language to physicians allowing them to write for that partner, sight unseen, if it is medically indicated," explains Smith. "Normally, that is considered

potentially malpractice."

According to Smith, providers had been meeting the public health challenge of partner treatment by doubling the amount of medication and instructing the patient to split it with the partner or by writing a separate second prescription for the patient, dated a day or two later, which then could be given to the partner.

With the new language in hand, San Francisco Health Plan officials made the commitment to provide the chlamydia treatment prescriptions of patients' partners at no charge. However, they faced two challenges. Women often are reluctant to identify their partners, so how could providers write the necessary prescriptions? Plus, how could they track the number of prescriptions for partners?

Enter 'Joe Partner'

San Francisco Health Plan is in the process of creating a second formulary that consists of just two drugs — doxycycline and azithromycin — for just one member, whose name is "Joe Partner." Now providers can write two prescriptions, one for the patient and one for the unseen partner. The new practice also will create two dispensing fees, which also will be covered by the health plan.

Final touches on the new program were being refined as of *Contraceptive Technology Update's* press time, confirms **Lucy Saldana**, PharmD, a clinical pharmacist for San Francisco Health Plan. By being able to see the number of "Joe Partner" prescriptions, the plan will have a clearer picture of partner treatment, she predicts.

"We have added the option that doctors can write only one prescription, double the dose, and write 'partner Rx' somewhere on the prescription, and the pharmacist will create two packaged prescriptions," reports Smith. "That is slightly less work than two prescriptions; either will achieve the same result."

Costs are offset

The health plan is a small one, consisting of some 31,000 members, says Saldana. In developing the partner treatment program, it looked at a number of variables, including the number of prescriptions written for doxycycline and azithromycin in 1999. Plan officials believe the costs of paying for the partner's prescription and dispensing fee will be offset by the cost savings associated with reduced retreatment.

To raise provider awareness about chlamydia, San Francisco Health Plan recently held a series of programs for the 400 primary care physicians in its network. The presentations included information on chlamydia screening, CDC guidelines, and the HEDIS (Health Plan Employer Data and Information Set) 2000 chlamydia screening measure. The HEDIS screening measure, developed by the Washington, DC-based National Committee for Quality Assurance, assesses the percentage of sexually active women aged 15-25 who are screened for the disease in managed care settings. **(See *CTU*, February 2000, p. 17.)**

Patient education sheets on chlamydia treatment also are being distributed to providers, reports Smith. Written in English and Spanish, the sheets include information on the infection, the drugs used, and potential side effects.

Education of pharmacists is key

One of the keys to the program's success will be the pharmacy network education, says Saldana. There are approximately 3,000 pharmacies in San Francisco, so plan officials want to make sure pharmacists know how to properly process the partner prescriptions. Information will be faxed to every pharmacy with a detailed description of the partner treatment program and how to process the prescriptions.

"The key with this population is that you don't want to make an extra call, do an extra fax, or have them wait extra time, because they get very suspicious in terms of 'What's going on? Are you reporting me?'" says Saldana. "We understand that; so to encourage people to go for treatment and make them feel like there are no strings attached, we thought this approach was a really good process by which to get their needs met."

The health plan will perform monthly audits to track the program's process and obtain feedback from those involved during regularly scheduled town hall meetings. By doing its homework in advance, health plan officials believe the introduction of "Joe Partner" will be well-received.

"What we want to do is threefold: Provide the treatment, make it safe, and make it easy on both the provider and the patients," says Smith.

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'Question Mark' program is answer to HIV testing

Maryland has the fourth highest rate of new cases of HIV / AIDS in the United States.[1] The problem is particularly severe in the city of Baltimore, where AIDS is the leading cause of death among those age 15-40.[1] How can the issue be addressed?

One answer lies in the Red Ribbon Question Mark Campaign, a multimedia social marketing campaign intended to promote HIV testing in Baltimore, specifically in the three zip codes with the highest HIV seroprevalence in the city. Designed for the Maryland AIDS Administration by the Johns Hopkins University Center for Communication Programs and Eisner Communications, all in Baltimore, the campaign's intended audience includes women of childbearing age, men and women engaged in risky behaviors, and health care providers.

Since the program's inception, testing is up 9.6% statewide, and 48% and 30% at sentinel testing sites. The campaign has reached a 76% awareness level and boosted "intent to get tested" by 19 percentage points. Calls to the First Call for Help referral hotline have increased 1,500% after the campaign began, with 62% of callers crediting the campaign as the impetus for their request.[2]

EXECUTIVE SUMMARY

The Red Ribbon Question Mark Campaign, a multimedia social marketing campaign under way in Baltimore, has shown good results in raising awareness levels and encouraging at-risk individuals to get tested for HIV.

- Since the program's inception, testing is up 9.6% statewide, and 48% and 30% at sentinel testing sites. The campaign has reached a 76% awareness level and boosted "intent to get tested" by 19 percentage points. Calls to the local referral hotline have increased 1,500%, with 62% of callers crediting the campaign as the impetus for their request.
- Designed for the Maryland AIDS Administration by the Johns Hopkins University Center for Communication Programs and Eisner Communications, the campaign's intended audience includes women of childbearing age, men and women engaged in risky behaviors, and health care providers.

With new breakthroughs in clinical care, it is important for patients to know their HIV status early enough to take advantage of available treatment, as well as to learn how to protect themselves and others from transmission, says **Liza Solomon**, DrPH, director of the Maryland AIDS Administration. The Red Ribbon Question Mark campaign addresses these topics through its theme line, "Live Long. Live Strong. Get Tested."

Keep message positive

The key to any successful social marketing program is to know the audience, says **Jim Williams**, associate director of Johns Hopkins' Center for Communication Programs. Formative research was conducted through focus groups, with neighborhood community outreach workers targeting such hard-to-reach populations as intravenous drug users.

"One of the things that came through very clearly is that [people] are tired of being threatened with death for HIV; they wanted something that was positive and encouraging, something that would reduce the anxiety level, which is a barrier for people getting tested," observes Williams.

With this information in hand, program officials pretested the theme line, creative concepts, and logo design (the AIDS red ribbon in the shape of a question mark) prior to use in the media campaign.

"We wanted to make sure we weren't turning our audience off or creating another barrier to testing," Williams explains. "Especially when trying to communicate with hard-to-reach audiences, you don't want to give any excuse not to get tested."

The comprehensive media campaign includes radio and television advertising, as well as print ads on buses, subway cars, billboards, and clinic posters. Estimated costs total about $450,000, which includes the pre- and post-testing surveys, advertising, and production charges, says Solomon.

The initial campaign, which kicked off in December 1999, used a popular on-air personality at the No. 1 urban-format radio station as the "voice" for the radio spots. This approach lent street credibility with the intended audience, who were already familiar with the disc jockey, says Williams.

Providers also were factored into the program, receiving calendars, notepads, mouse pads, pens, and coffee mugs with the red ribbon question mark logo, as well as posters echoing the images in the print campaign. Lapel pins, worn by providers,

RESOURCES

For more information on the Red Ribbon Question Mark Campaign, contact:

- **Liza Solomon**, DrPH, Maryland AIDS Administration, 500 N. Calvert St., Baltimore, MD 21202. Telephone: (410) 767-5013.
- **Jim Williams**, Johns Hopkins University Center for Communication Programs. Telephone: (410) 659-6273. E-mail: jwilliam@jhuccp.org.

were used as "ice-breakers" to help providers raise the subject of testing with patients.

Research showed some providers were uncomfortable in asking about testing, with patients equally hesitant to bring up such a sensitive subject, explains Williams. The buttons, when worn by providers, would prompt patients to ask "What's that?" so providers could respond, "It's to ask you if you've been tested for HIV. Have you?"

"We know that providers are critical in terms of what a patient will be interested in," says Solomon. "We really wanted to engage the provider in making the first touch."

Provider survey results indicate 40% of respondents felt the campaign helped them speak to patients about HIV testing, says Williams. Two-thirds of respondents noted they were using the campaign material in their practices.

Campaign lives on

The campaign received three awards in a national competition, sponsored by the Marietta, GA-based National Public Health Information Coalition, open to public health departments from all states. The logo design also captured an 1999 Addy Award from the Advertising Association of Baltimore.

The media program was reinitiated in February 2001 with a tie-in to Black History Month. Other programs have inquired about use of the Red Ribbon Question Mark Program, with the Georgia Department of Health scheduled to begin its own version of the campaign as of *Contraceptive Technology Update* press time, says Williams.

"We think this is a pretty universal issue for those of us who work in the HIV field," Solomon observes. "If anything we have done can be of use to another public health entity, then we're thrilled." **(See the resource box, above, for contact information. Review the campaign at the following Web page: www.jhuccp.org/hiv_campaign/index.stm.)**

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Challenge: How to uncover 'invisible men'

Take a look at the list of patients who have entered your examination room in the last five days. Are any of them young men?

If not, perhaps you may want to examine your center's approach to attracting this underserved population. Critical gaps exist in reproductive health services for young men, particularly when it comes to sexually transmitted diseases (STD), contends **Harlan Rotblatt**, adolescent services director for the Los Angeles (CA) County Department of Health Services — Public Health STD Program.

"The focus of traditional reproductive health services on women has contributed to the lack of care for males, creating in turn a persistent reservoir of undetected male cases," state Rotblatt and associates in a poster presentation at the 2000 national meeting of the Washington, DC-based American Public Health Association.[1] "These undetected cases increase the likelihood of both female reinfection and sequelae in males."

This problem is reflected in imbalances in STD reporting in Los Angeles County, Rotblatt notes.

EXECUTIVE SUMMARY

The challenge of reaching men, particularly male adolescents, is one faced by all facilities providing reproductive health services.

- Los Angeles (CA) County hosted a summit on the subject with representatives from more than 40 agencies, including family planning providers, community clinics, managed care organizations, government agencies, and schools. A working group arose from the summit and is planning strategies to meet male reproductive health needs.
- Take a look at your facility to see if it is "male-friendly." Consider use of urine-based screening for sexually transmitted diseases to expand services outside clinic walls.

Males accounted for only 18% of nearly 16,000 reported chlamydia cases in 1998 in Los Angeles County among ages 10-24.

Teen-agers remain at high risk for STD infection. According to the Atlanta-based Centers for Disease Control and Prevention (CDC), teens account for a significant proportion of the 15 million STD infections in the United States.[2] Forty percent of chlamydia cases are reported among young people ages 15-19.[2]

The opportunity to educate teens about pregnancy and STD prevention is often missed in routine physical exams, note CDC researchers. Among surveyed high school students who received a routine checkup during the previous year, only about 40% of females and 25% males had discussed the subjects with their health care provider.[3]

To address the challenge, the Los Angeles County STD Program hosted a summit on young men and reproductive health. It was attended by about 70 representatives from more than 40 agencies, including family planning providers, community clinics, managed care organizations, government agencies, schools, and other youth-serving agencies.

Program participants identified the following needs in enhancing male services:

- increased funding, not only for male health services, but also for the agency staff necessary to deliver them;
- more attention and support on the issue from state and local health department officials;
- assistance for community agencies in accessing existing funding sources for male clients;
- provision of early reproductive health education to boys and girls;
- the development of guidelines for conducting urine-based STD screening for male clients in various settings;
- collaborations between agencies to create community testing events.[4]

Since the summit, a working group of representatives from public and private agencies has met regularly to plan strategies to meet male reproductive health needs. The group is looking at these strategies:

- education of managed care organizations, traditional family planning clinics, and other health providers;
- trainings to foster STD urine screening by community agencies;
- resources to facilitate access to services and funding streams;
- promotion of positive perceptions of young men and policy advocacy.

While change is slow, more young men are accessing care, reports **Julie Kirk**, director of adolescent services at Westside Women's Health Center in Santa Monica. The nonprofit community clinic sponsors a teen clinic for young men and women each Monday and Thursday. The number of male patients has grown since the clinic's inception, she notes.

Apart from nurse practitioners and supervisors, the clinic is run by teens for teens, using the clinic's trained peer educators. Young men can get urine screening for chlamydia and gonorrhea; blood screening for hepatitis B, HIV, and syphilis; testicular cancer checks; as well as general medical care.

A sign on the front door specifically states that the clinic is for young men and women, and a male peer educator is one of the first people viewed when patients walk in the door, says Kirk. The clinic is walk-in by design, which further reduces the stress for young men who might be hesitant to access the clinic. Word of the program is spread by the center's regular presentations at area high schools, notes Kirk.

To further reflect its growing umbrella of services, the center is changing its name to Westside Family Health Center this summer, says Kirk.

With the advent of urine-based nucleic acid amplification tests for STDs, young men also may be reached through community outreach efforts, notes Rotblatt.

"Urine-based nucleic acid amplification tests offer new opportunities for large-scale, nonclinic-based STD screening for males; yet these opportunities remain largely unexplored," he notes**.**

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Teen sites: Check these cyber guides for info

Teens need credible information on sexual health. Add these to your current list, and check the February 2000 issue of *Contraceptive Technology Update,* p. 25, for additional sites.

1. Center for Young Women's Health: www.youngwomenshealth.org/healthinfo.html. Recognizing the urgent need for education, clinical care, research, and health care advocacy for adolescent girls and young women, Children's Hospital of Boston has created its Center for Young Women's Health Web site. The Web address above offers a listing of patient information sheets written especially for teens on such topics as "Taking Oral Contraceptives for Irregular Periods and Acne" and "A Guide to Polycystic Ovary Syndrome." Many of the information sheets are available in English and Spanish.

2. Go Ask Alice! www.goaskalice.columbia.edu. Go Ask Alice! is the health question-and-answer Internet site produced by "Alice!" from Columbia University's Health Education Program, a division of the New York City-based Columbia University Health Service. It has three primary features: new questions and answers, updated each week; a search engine, which references the thousands of questions answered since the site's inception; and the "ask" section, which allows questions to be posted to the site. The site defines its mission as "to provide factual, in-depth, straight-forward, and nonjudgmental information to assist readers' decision making about their physical, sexual, emotional, and spiritual health." It is supported by a team of Columbia University health educators and health care providers, along with information and research specialists from health-related organizations worldwide.

3. It's Your Sex Life: www.itsyoursexlife.com. A public education project of the Henry J. Kaiser Family Foundation of Menlo Park, CA, this Web site offers information for teens on pregnancy and contraception, sexually transmitted diseases, and communication.

4. Teen Advice Online: www.teenadvice.org. The mission of Teen Advice Online is to provide support for teen-age problems through a network of peers from around the globe. Comprised of a team of nonprofessionals ages 13 and older, the site offers articles written by peer counselors, as well as an archive of previously answered questions. ■

Contraceptive Technology Update® (ISSN 0274-726X), including **STD Quarterly**™, is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodical postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Contraceptive Technology Update**®, P.O. Box 740059, Atlanta, GA 30374.

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Statement of financial disclosure: To reveal any potential bias in this publication, and in accordance with the Accreditation Council for Continuing Medical Education guidelines, we disclose the following: Dr. Hatcher (chairman of the editorial advisory board and peer reviewer) reports being on the speaker's bureau for Organon, Wyeth-Ayerst Laboratories, Ortho-McNeil Pharmaceuticals, and Parke-Davis. Dr. Nelson (board member) serves on the speaker's bureau for Berlex Laboratories, Gynetics, Eli Lilly and Co., 3M Pharmaceuticals, Ortho-McNeill, Organon, Parke-Davis, Pfizer, Pharmacia & Upjohn Co., and Wyeth Ayerst; she conducts research for Ortho-McNeil and Pharmacia & Upjohn. Dr. Rosenfield (board member) is a stockholder and board member of Biotechnology General Corp. Dr. Rosenberg (board member) is a consultant for Organon; serves on the speaker's bureau for Organon, Wyeth-Ayerst, and Parke-Davis; and conducts research for Organon, Wyeth-Ayerst, Ortho-McNeil, and Parke-Davis. Dr. Kaunitz (board member) conducts research for Merck, Pfizer, Pharmacia & Upjohn, RW Johnson Pharmaceutical Research Institute, and Solvay; he is a consultant for Ortho-McNeil, Parke-Davis, and Pharmacia & Upjohn; he is a stockholder in Johnson & Johnson; and he does CME presentations and publications for Merck, Organon, Pharmacia & Upjohn, and Wyeth-Ayerst.

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Suspect Norplant lots still undergoing tests

What is the status of the product stability tests for suspect lots of Norplant contraceptive implants? Implant marketer Wyeth-Ayerst Pharmaceuticals of Philadelphia continues to work with the Food and Drug Administration in conducting evaluation tests, and company officials hope to have an update soon, states **Doug Petkus**, company spokesman.

Wyeth-Ayerst Laboratories issued an advisory in August 2000 that alerted providers that routine shelf-life stability laboratory tests indicated product from certain specified lots might not release enough levonorgestrel to deliver effective, ongoing contraception.

"For now, it is important for your readers [to know] that women who began using Norplant before Oct. 20, 1999, are not affected by this situation, and their Norplant system remains an effective long-term contraceptive option," states Petkus. "Women who received Norplant from the affected lots are advised to use a backup nonhormonal contraceptive method; upon request, the company will cover the costs of backup birth control until more conclusive info is available." ■

CE objectives

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.
- 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 *Clinical quandary: Is it PMS or PMDD? Find answer by listening to patients,* p. 37; *The 'acne pill' might see competition,* p. 39; and *Meet 'Joe Partner': New STD treatment plan,* p. 42.)** ■

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