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Price increase for IUD proves problematic for family planners

Providers review their options following Mirena price increase

Signs have been pointing toward a renaissance for intrauterine devices (IUDs). Since 2005, IUD use has gone up by 161%, according to SDI Health, a health care analytics firm in Plymouth Meeting, PA.[1] The birth control method is now making inroads on other preventive methods: IUD insertions increased 23% between January 2008 and January 2009, while during that same period, total contraceptive prescriptions fell by 2.6%.[1]

However, such increases might be impacted by the March 2010 announcement by Wayne, NJ-based Bayer HealthCare Pharmaceuticals to increase the list price of its levonorgestrel intrauterine system (LNG IUS), Mirena. According to company spokesperson Rose Talarico, the new list price of Mirena of $703.05 reflects the first price increase since September 2007, when the device listed for about $470 per unit.

Why was the increase instituted? The decision to increase the list price of the device "reflects the value that it offers to women who choose intrauterine contraception and over the long effective life of the product" of five years, Talarico says. At the new list price, over a five-year period, the average monthly cost of Mirena still is lower than the costs for branded

EXECUTIVE SUMMARY

Bayer HealthCare Pharmaceuticals announced in March 2010 that it was increasing the list price of its levonorgestrel intrauterine system, Mirena. The current price of $703.05 reflects the first price increase since September 2007, when the device listed for about $470 per unit.

- The manufacturer for the ParaGard Copper T 380A intrauterine device (IUD) says it will not increase its price from $392 a unit.
- Since 2005, intrauterine contraceptive use has gone up by 161%. Insertions increased 23% between January 2008 and January 2009, while total contraceptive prescriptions fell by 2.6%.

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oral contraceptives, she notes.

Mirena now carries an additional approved indication to treat heavy menstrual bleeding in women who use intrauterine contraception as their method of pregnancy prevention. The Food and Drug Administration (FDA) gave approval to the indication in October 2009, which made Mirena the first intrauterine device approved for this additional use. Does the company plan to offer increased assistance to women who cannot pay for the Mirena? According to Talarico, Bayer supports the ARCH Foundation, a not-for-profit foundation established to assist low-income patients who do not have insurance coverage for Mirena.

"Bayer is dedicated to women's health and committed to providing contraceptive options that are safe, effective, affordable, and well-matched to the needs of the women we serve," says Talarico. "We also provide our medications, including Mirena, to those in need and are committed to maintaining and improving access to Mirena through public health and patient support programs."

How about ParaGard?

Are similar price increases on the way for the other intrauterine contraceptive, the Copper T 380A intrauterine device (ParaGard Copper T 380A IUD, Duramed Pharmaceuticals, now Teva Women's Health, Woodcliff Lake, NJ)? No, says **George Jones**, group product manager for Teva Women's Health.

"The per unit Wholesale Acquisition Cost of ParaGard remains at $392 a unit," says Jones. "We want to reassure the reproductive health/family planning community that we currently have no plans to take the type of substantial price increase that Bayer has instituted with Mirena."

Are there any changes in pricing planned in light of recent U.S. health care reform legislation? No, says Jones. "Teva Women's Health values its relationship with reproductive health professionals and remains fully committed to bringing clinically important, cost-effective products to health care providers and patients," says Jones. "In this challenging economic environment, we will not put undue pressure on patients when it comes to family planning and long-acting contraceptive methods."

New LNG IUD?

The recently announced price increase for the Mirena IUD is "so discouraging," observes **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. However, there might be another levo-

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norgestrel IUD on the horizon, Hatcher notes. Medicines360, a San Francisco non-profit company, has joined forces with European women's health pharmaceutical company Uteron Pharma Operations in Liege, Belgium, to develop a long-acting LNG IUD. A Phase III trial is under way.[2]

"One can only hope that this generic LNG IUD will gain approval quickly," says Hatcher.

What is your response?

How will the Mirena price increase impact your clinical practice? For the nine physicians at Women's Health Group, a Thornton, CO, obstetrics and gynecology facility, Mirena insertions will drop sharply when the practice's stock of devices has been used, says Susan Lawrence, facility spokesperson. The physicians have been inserting an average of 50 Mirena IUSs per month; however, when Bayer announced Mirena's price increase, the practice alerted its patients that once its supply of Mirena devices is exhausted, it will no longer continue to stock the device, says Lawrence.

"In this time of excessive health care costs, there is simply no excuse for this attempt to raise prices just before health care reform potentially becomes a reality," states a bulletin issued by the facility. "This is just wrong and we need to stand up to this price gouging and reject it."

Women's Health Group will offer ParaGard as the intrauterine contraceptive option, or it will insert a Mirena if a patient brings it in herself, says Lawrence.

What has been the response to the clinic's action? "We got some positive feedback via e-mail the same day the announcement hit our e-mail list," says Lawrence. "Patients were happy to see a medical practice taking a stand and being an advocate for the patient."

Avoid Internet options

ParaGard is indicated for up to 10 years for intrauterine contraception; the Mirena is indicated for up to five years. While the cost of intrauterine contraception is very low when it is amortized over the average time of utilization, its initial cost often presents "sticker shock" for potential users.[3]

Clinicians might be tempted by lower-priced units advertised on web sites for their private patients who do not qualify for public assistance through such programs as the ARCH Foundation, states **Anita Nelson**, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School Of Medicine at the University of California in Los Angeles in a 2009 editorial published in Contraception. These units might pose problems for patients and providers, the editorial states.

For products that are temperature sensitive, such as the LNG-IUS, conditions during transport might substantially impact product efficacy, states the editorial. If an item is ordered online from the United Kingdom or Canada, the product might be shipped in the hull of an airplane or allowed to rest on a warehouse platform in the heat. In such variable environments, the product destabilizes and might not deliver the drug as desired.[3]

Legal problems have arisen from use of foreign intrauterine contraceptives, the editorial states. In California, providers placed foreign units in patients and billed the state under its Medicaid programs for reimbursement. This practice was termed as Medicaid fraud since providers did not use FDA-approved products. One physician has settled his case, while another physician is at risk for jail time, the editorial states.[3]

"As a result of the misguided altruism (or greed) of a few clinicians, all IUD providers in the state programs must now retain a patient-specific invoice for at least three years for each IUD they place," states the editorial.[3]

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RESOURCE

To obtain more information about the ARCH Foundation Patient Assistance Program for Mirena, visit iwww.archfoundation.com. The patient application form is available in English and Spanish. Click on "Application." Providers may call (877) 393-9071 weekdays 8:30 a.m. to 5 p.m. Eastern. Callers may leave a confidential message for a patient case coordinator 24/7. Patient case coordinators are available to address callers with specific language needs.

Science eyes OCs for ovarian endometriomas

While surgery is the most accepted method for treating ovarian endometriomas, recurrence often is recorded. Results from newly published research, which evaluates use of cyclic and continuous administration of oral contraceptives post surgical removal, indicate that Pill use can effectively reduce and delay endometrioma recurrence. [1]

If the use of an oral contraceptive pill (OCP) is considered to reduce the risk of recurrence of an endometrioma after laparoscopic cystectomy, treatment should be given for at least two years, advises **Neil Johnson**, MD, associate professor at the University of Auckland in New Zealand and medical director of Fertility Plus, an Auckland fertility clinic. Johnson is co-author of a review of the current study's results.[2]

Ovarian endometriomas may develop from ovarian corpus luteum formation;[3] by inhibiting ovulation with Pill use after surgical removal, the risk of developing further endometrioma may be reduced, says Johnson.

Andrew Kaunitz, MD, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine – Jacksonville, says, "This report adds to the literature indicating the benefits of hormonal management in women who have undergone surgery for endometriosis. The same group has previously shown that postoperative use of continuous oral contraceptives reduces dysmenorrhea in women who have undergone surgery for endometriosis."[4]

To perform the study, researchers looked at 239 patients who were scheduled to undergo laparoscopic excision of an ovarian endometrioma of at least 4 cm in size on ultrasound. Women included in the study were nulliparous, ages 20-40, and not attempting to conceive for at least two years post-surgery. Following the surgical intervention, women were randomized into one of three groups:

- those who were not prescribed any medical treatment (defined as the non-user group);
- those taking cyclic OCPs;
- those taking continuous pills.

Of the 239 women enrolled in the study, 217 completed the study (69 non-users, 75 cyclic users, and 73 continuous users). Follow-up was performed for at least 24 months, where recurrence, recurrence rate, recurrence-free survival, and size and rate of growth of recurrent cysts were documented.

The scientists recorded 37 endometrioma recurrences during follow-up, with 29% in the non-users, 14.7% in the cyclic OCP users, and 8.2% in the continuous OCP users. The results indicate a "significant" reduction in recurrence-free survival in users versus non-users, with no significant differences detected between the cyclic and continuous groups for the whole follow-up period.[2] The mean diameter of endometriomas was significantly smaller and the endometrioma growth was reduced in the OCP users compared to non-users, reviewers note.[2]

What is the most effective period for Pill use for postoperative results following endometrioma removal? Studies to date provide conflicting results on postoperative OCP use, reviewers note.[2]

Researchers in previous trials have looked at shorter duration of pill administration. In a prospective, randomized trial of 70 patients ages 20-35 who were not attempting to conceive, underwent laparoscopic excision of ovarian endometriomas, followed by postoperative administration of low-dose cyclic oral contraceptives for six months or no treatment on the basis of a computer-generated sequence. At three and six months after surgery and then at six-month intervals, both groups underwent ultrasonographic examination for possible evidence of endometrioma recurrence and for evaluation of the absence, persistence, or recurrence of pain symptoms. No benefit was found in the long-term recurrence rates at both 24 and 36 months, but a positive effect was seen at 12 months.[5]

Scientists who designed a retrospective study looked at Pill use for 9.5 months.[6] The study included 224 patients who had a minimum of two years of post-operative follow-up after laparo-

EXECUTIVE SUMMARY

Results from newly published research, which evaluates use of cyclic and continuous administration of oral contraceptives post surgical removal of ovarian endometriomas, indicate that Pill use can effectively reduce and delay endometrioma recurrence.

- Ovarian endometriomas may develop from ovarian corpus luteum formation. By inhibiting ovulation with Pill use after surgical removal, the risk of developing further endometrioma may be reduced, data suggests.
- If the use of an oral contraceptive is considered to reduce the risk of recurrence of an endometrioma after laparoscopic cystectomy, treatment should be given for at least two years, according to a new review of the research.

scopic ovarian endometrioma excision. While no benefit was seen, researchers hypothesized that a longer-term treatment period might be useful. Results from a cohort study published in 2008 supported this hypothesis.[3] Scientists saw a reduction in recurrence at 36 months follow-up.

What is the next step in research? Scientists in the current 2010 study say that further studies are required, especially to look at the effect of oral contraceptive use on the recurrence of symptoms, as well as weigh the potential advantages that continuous OCP use might have over cyclical Pill administration.[2]

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Is it time to bring OCs over the counter?

Research recently conducted in the area around El Paso, TX, and Juarez, Mexico, suggests there is demand in the United States for over-the-counter birth control pills.[1]

As part of the study, researchers interviewed more than 1,000 El Paso women, about half of whom obtained their birth control pills across the border at Mexican pharmacies and half of whom went to U.S. clinics to get their pills. Researchers report that women of different ages, parities, and educational levels likely would take advantage of an OTC option were oral contraceptives available at low cost.[1]

One group already is working on the possibility of such access, says study co-author **Daniel Grossman**, MD, senior associate at Ibis Reproductive Health, a non-profit research organization based in Cambridge, MA, and Oakland, CA. Since 2004, the Working Group on Oral Contraceptives Over-the-Counter has brought together researchers, advocates and clinicians to review existing data and identify information gaps, reached out to provider organizations, synthesized existing data and conducted new analyses to establish the rationale for an over-the counter (OTC) switch, states Grossman.

"Our aim is to ensure that all these efforts move forward with a clear focus on providing more options to women who currently face barriers accessing contraception," Grossman observes. "The cost of an OTC OC [oral contraceptive] product is a critical piece of this."

Convenience key factor

In conducting the current study, researchers found that older women and those who were born and educated in Mexico were more likely to buy their pills in Mexican pharmacies. Women who received public assistance from such federal programs as Women, Infant and Children (WIC) were more likely to go to the U.S. clinics.

Among both groups, most of the women said they believed the facility where they obtained the pills was cheaper and more convenient than the options on the other side of the border. About 90% of the women who obtained oral contraceptives on the U.S. side say they trusted their clinic to give them good information (compared to 46% of Mexican pharmacy consumers), and that they liked the other health services provided there. About 90% of the women who bought pills from the Mexican pharmacies said they wanted to bypass a doctor's prescription and be able to send family or friends to pick up the pills.

Lead author **Joseph Potter**, PhD, professor in the Sociology Department and Population Research Center at the University of Texas at Austin, said, "Our team's next steps will be to further analyze the experience of the women enrolled in the El Paso study to see how well the OTC pharmacy

EXECUTIVE SUMMARY

Research recently conducted in the area around El Paso, TX, and Juarez, Mexico, suggests there is demand in the United States for over-the-counter (OTC) birth control pills.

- Researchers interviewed more than 1,000 women, about half of whom obtained their birth control pills across the border at Mexican pharmacies and half of whom went to U.S. clinics to get their pills. Women of different ages, parities, and educational levels would likely take advantage of an OTC option were oral contraceptives available at low cost, researchers report.
- The Working Group on Oral Contraceptives Over-the-Counter is focusing its efforts on establishing the rationale for an OTC switch. It is looking to first take a progestin-only pill over the counter.

users compare to the family planning clinic users with respect to A, continuation, B, screening for contraindications, and C, use of preventive health services."

POP to come first

Are oral contraceptives suitable for over-the-counter status? According to the working group, the substantial literature available on the Pill confirms it meets most of the Food and Drug Administration's (FDA) criteria for OTC status:

- the drug's benefits outweigh the risk for women of reproductive age;
- the potential for misuse or abuse is low;
- a consumer can easily self-diagnose the condition for which the pills are indicated;
- directions for use are straightforward.[2]

Because the FDA officials also want to know that health care practitioners are not needed for the safe and effective use of an OTC product, the outstanding safety question is whether women can self-screen appropriately for contraindications to OC use, including hypertension, states the working group. Experience indicates that in countries where OCs already are obtainable without prescription, women use them safely without prior screening by a health care professional, the working group maintains.[2]

Over the past year, working group members have focused efforts on first moving a progestin-only pill (POP) over the counter, which Grossman sees as an interim step toward an eventual OTC switch for combined pills. Given the fewer and rarer contraindications for POPs, as well as the precedence of an OTC switch for a progestin-only emergency contraception product, an over-the-counter switch for POPs is likely more feasible, says Grossman. In addition, by not affecting the much larger population of current combined Pill users, whose pills would remain on prescription, it seems less likely that many women would lose insurance coverage for an OTC POP and have to pay more after the OTC switch, says Grossman.

"Still, we are concerned about the cost of an OTC POP product, and the working group is exploring how best to ensure an accessible price," states Grossman.

What will it take to bring over-the-counter access to combined oral contraceptives? To bring about an OTC switch, a company would need to submit an application to the FDA, says Grossman. Several types of studies would be required as part of that application, including an actual use study and a label comprehension study, he explains.

"The working group has developed a draft OTC label for an OTC POP, as well as protocols for actual use and label comprehension studies, and we are now beginning to reach out to both for-profit and non-profit pharmaceutical companies to gauge their interest in exploring the possibility of an OTC switch with the FDA and moving forward with this research," states Grossman.

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Give good information to debunk web myths

While you might provide correct information to your adolescent patients when it comes to teen sexual health topics, results of a recent study indicate many popular health web sites do not.[1]

Adolescents go to the Internet for their health information, says the study's lead researcher **Sophia Yen**, MD, MPH, a board-certified specialist in adolescent medicine at Lucile Packard Children's Hospital and a clinical instructor of

pediatrics at Stanford University, both in Palo Alto, CA. Many web sites, even trusted portals such as WebMD, have incorrect information and do not update their information according to the latest guidelines, she states.

Yen's team identified leading teen sexual health myths regarding emergency contraception, intrauterine contraception, oral contraceptives, Pap smears, and herpes by 35 well-trafficked health web sites, and presented its findings at the 2009 annual meeting of the Society for Adolescent Medicine in Los Angeles. The researchers studied web sites that appeared among the first 10 to 15 hits on Google searches of terms such as "birth control," "morning after pill" and "sexually transmitted disease."

About half of the web sites failed to provide accurate, complete information about emergency contraception, researchers found. For instance, many sites did not correct the myth that emergency contraception causes an abortion. Many sites also did not give the World Health Organization's current recommendations for how to use the dedicated emergency contraceptive pill (1.5 mg of levonorgestrel as a single dose). When used within five days after unprotected intercourse, the regimen reduces a woman's chance of pregnancy by 60-90%. The regimen is more effective the sooner after intercourse it is taken.[2]

Sixty percent of the web sites said the birth control pill causes weight gain, despite research showing modern oral contraceptives do not affect body weight.[3] Less than 20% of the web sites made it clear that intrauterine devices (IUDs) are safe for use in adolescents. Although 74% of web sites with IUD pages were updated in 2008, few reflect published research and a 2007 American College of Obstetrics and Gynecology (ACOG) recommendation that say adolescents can safely use IUDs.[4-6]

Forty percent of web sites surveyed did not provide accurate information about the timetable for the first Pap exam, researchers report. According to 2009 ACOG guidelines, women should have their first cervical cancer screening at age 21. Most women younger than 30 should undergo cervical screening once every two years instead of annually, and those age 30 and older can be rescreened once every three years, according to 2009 guidance.[7]

Give good information

What do you tell teens about health information on the Internet? The most reliable sites identified by Yen's team include:

- **Go Ask Alice**, www.goaskalice.columbia.edu, a question-and-answer service maintained by Columbia University;
- **Center for Young Women's Health**, www.youngwomenshealth.org, an educational effort of Children's Hospital Boston;
- **TeensHealth, kidshealth.org/teen**, a part of the KidsHealth family of web sites operated by the nonprofit Nemours Center for Children's Health Media;
- **Teen Wire**, www.teenwire.com, an educational site for teens maintained by Planned Parenthood Federation of America.

Yen also recommends the book, *Our Bodies, Ourselves* (Boston Women's Health Book Collective, 2005) to her patients.

EXECUTIVE SUMMARY

While clinicians might provide correct information to adolescent patients when it comes to teen sexual health topics, results of a recent study indicate many popular health web sites do not.

- About half of frequently accessed health web sites failed to provide accurate, complete information about emergency contraception. Sixty percent of the web sites said the birth control pill causes weight gain, despite research showing modern oral contraceptives do not affect body weight.
- To help teens obtain the best information, guide them toward web sites associated with academic medical centers, where site review committees are more likely to include a board-certified adolescent medicine specialist.

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Get ready to 'SWAP' educational material

[This is the second part of a two-part series on electronic media resources. Last month we discussed the California STD/HIV Prevention Training Center's Youth Social Marketing Toolkit.]

Need a good online source of educational material? The California STD/HIV Prevention Training Center (CAPTC) has developed an online database containing more than 175 educational and promotional materials focusing on sexually transmitted diseases (STDs)/HIV and related issues. The site, known as SWAP, contains a collection of fact sheets, posters, palm cards, presentations, and public service announcements. *(Visit the California STD/HIV Prevention Training Center web site, www.stdhivtraining.org. Click on "Resources" on the menu bar to access the SWAP link.)*

All materials are free, downloadable, and reviewed for medical accuracy. The search function is user-friendly and categorizes materials by publication type, audience, specific disease, language, and other key words.

What led to the development of the web resource? SWAP evolved from the observation that many local health providers were developing excellent materials while others were reinventing the wheel or did not have the resources to do so, says Smith.

"The willingness of agencies to share materials exemplifies a public health ideal of cooperation," notes **Amy Smith**, MPH, health promotion and health education unit chief in the STD Control Branch of the California Department of Public Health and the CAPTC. "This resource is particularly useful during financially restricted times and in an environment with growing reliance on electronic communication."

From its Sept. 1, 2007, kickoff through Feb. 15, 2010, SWAP has elicited 15,154 unique page views and 38,673 downloads of materials, says Smith. The number has grown consistently over time; in the past 12 months, SWAP averaged more than 650 unique page views a month, she notes. After the first year of existence, a monthly feature was instituted. The feature focuses on a new campaign or an STD related issue and provides related resources. An announcement linking to the monthly feature keeps SWAP visible and timely, says **Joyce Lisbin**, EdD, health communication coordinator at the STD Control Branch and the CAPTC.

About 650 hours of staff time was recorded in developing the SWAP site, collecting its material, and promoting the site, says Lisbin. The ongoing maintenance of collecting and adding new materials to the database, as well as the time to develop and distribute the monthly feature, requires about one day a month, she says. ■

GUEST COLUMN

What's in a name when it comes to birth control?

By **Robert Hatcher**, MD, MPH
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Several descriptive phrases are now being coined when family planning providers discuss such highly effective reversible methods as intrauterine contraception (ParaGard Copper T 380A intrauterine device, Duramed Pharmaceuticals, and the Mirena levonorgestrel intrauterine system, Bayer HealthCare Pharmaceuticals) and the contraceptive implant (Implanon, Schering-Plough Corp.).

In attending the recent 2010 Contraceptive Technology conferences in Boston and San Francisco, I was struck by the number of different phrases that providers are using to discuss these highly effective methods.

One such phrase that succinctly captures the outstanding effectiveness of these contraceptive options is "top-tier" or "top-of-the-line" methods. These phrases stem from a chart developed from material from the World Health Organization's

Medical Eligibility Criteria for Contraceptive Use.[1] The chart shows the different "tiers" of contraceptives, ranked by effectiveness. A panel of global family planning experts developed the graphic chart to present all contraceptive methods on a continuum of effectiveness. Research indicates this simple counseling chart can improve women's understanding of contraceptive effectiveness better than more complex tools.[2] It is recreated on page 26 in the latest edition of *Contraceptive Technology,*[3] as well as in at the Family Health International web site. *(To access the handout, go to www.fhi.org. Select "Publications," "Reproductive Health," "Service Delivery Tools," and "Comparing the Effectiveness of Family Planning Methods." The chart is also available in Spanish and French.)*

When saying that something is "top of the line," it is self-explanatory. Just as when someone describes a BMW as a top-of-the-line auto, it is clearly evident that such an item is indeed at the top of its class. With rates at less than one pregnancy per year per 100 women, both forms of intrauterine contraception and the contraceptive implant definitely qualify as top-of-the-line methods.

Other names to know

When thinking about long-acting methods, also consider the term HER-C, which stands for **h**ighly **e**ffective **r**eversible **c**ontraception. This phrase was used by 2010 Contraceptive Technology conference speaker **Eleanor Bimla Schwarz,** MD, MS, assistant professor in the departments of medicine and obstetrics, gynecology and reproductive medicine at the University of Pittsburgh School of Medicine.[4] Another way to think about these methods is to term them as "you-can't-forge- me" methods, because women do not have to take a daily pill or insert a device prior to sexual activity, says Schwarz.

Many family planning research scientists, such as **Jeffrey Peipert,** MD, MPH, MHA, professor of obstetrics and gynecology at the Washington University School of Medicine in St. Louis, refer to long-acting methods as "LARC"— long acting reversible contraception. Peipert is leading a cohort study of 10,000 women in the St. Louis region and is looking at use of these methods through the Contraceptive Choice Project. The project is providing birth control at no cost to all participants for three years; 70% of women are choosing long-acting methods.

"Reversible sterilization" is a term used by **David Grimes,** MD, FACOG, FACPM, vice president of biomedical affairs at the Research Triangle Park, NC-based Family Health International and clinical professor in the Department of Obstetrics and Gynecology at the Chapel Hill, NC-based University of North Carolina School of Medicine. This phrase tells you two things about these methods in one fell swoop: they are reversible, and like sterilization, they are very effective.

So which phrase is best when talking about the Copper T-380A intrauterine device (IUD), the levonorgestrel intrauterine system (LNG IUS), and the contraceptive implant? Each has its own merit. When discussing the subject with university family planning students, I talk about how each phrase can teach people something about these extraordinary methods.

The important thing about long-acting reversible contraceptives is to include them in every counseling session regarding birth control options. With more awareness of their benefits, more women might be willing to consider them for pregnancy prevention.

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See June online issue for condom fit and feel scale

The Condom Fit and Feel Scale developed by the Sexual Health Research Working Group at Indiana University Bloomington was discussed in the *Contraceptive Technology Update* story, "Study shows condom fit impacts its usage," June 2010, p. 64. That scale is available with the online June issue.

For assistance accessing that scale, contact customer service at (800) 688-2421 or customerservice@ahcmedia.com. ■

WASHINGTON WATCH

How can drug discounts be improved for clinics?

By **Adam Sonfield**
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Washington, DC

With drug manufacturers retreating in recent years from voluntary discounts to family planning and other public clinics, providers increasingly rely on federally mandated discounts. The 340B Drug Pricing Program, established in 1992 and run by the federal Office of Pharmacy Affairs, creates a "price ceiling," calculated quarterly for every drug, that caps how much drug companies can charge eligible safety-net providers, including Title X–supported family planning centers and community health centers. The Prime Vendor Program, run by a private contractor, Apexus of Irving, TX, seeks to negotiate even steeper discounts for drugs, as well as for products not covered by 340B, such as medical devices and pharmacy-related services.

Family planning centers piece together these discounts with those from other sources. Larger nonprofit and public agencies, such as Planned Parenthood Federation of America in New York City, negotiate their own contracts with manufacturers, as do private cooperatives, such as the Family Planning Cooperative Purchasing Program (a nationwide effort for Title X–supported centers run by the Los Angeles-based California Family Health Council) and purchasing programs designed for community health centers. Many of these programs also negotiate discounts for condoms, medical and office supplies, and lab work.

Nearly all Title X–supported providers are enrolled in 340B, and most are also a part of Prime Vendor, according to a 2009 study commissioned by the Office of Population Affairs and conducted jointly by The Lewin Group of Falls Church, VA, and the New York City-based Guttmacher Institute.[1] Nevertheless, providers reported a wide range of problems in making use of these programs.

Family planning centers reported that they do not have a central source of information to gauge their drug purchasing options, work within program rules, and learn about and compare prices across products and sources. Instead, they rely on a patchwork of information from purchasing programs, drug manufacturers and distributors, and family planning programs, grantees, associations, and advocates.

Little of this information is appropriately tailored to their specific needs and level of understanding. Moreover, drug manufacturers tightly control information on pharmaceutical pricing, and the formulas underlying the 340B price ceilings prevent providers from predicting changes in advance. Taken together, these issues mean that family planning centers are forced to spend substantial resources attempting to track down the best prices for the best mix of drugs and devices.

Discounts too small and unstable

The second major set of problems reported by study participants is that, despite their best efforts, the discounts they were finding were neither large enough nor stable enough to meet their needs. The 340B ceiling prices are in most cases only marginally lower than the actual average prices manufacturers offer to private-sector customers, although the newly enacted health care reform legislation will increase those discounts significantly. In addition, the price ceilings are adjusted quarterly and without advance notice, creating an instability in prices that may force providers to switch the products they stock and force clients to adjust to a new drug and dosage. Providers sometimes find better or more stable prices through Prime Vendor or other purchasing arrangements, but manufacturers are not required to negotiate with these programs.

Finally, family planning centers reported numerous administrative problems in dealing with 340B and Prime Vendor. Rising and unstable prices posed serious problems for maintaining a budget, and they often force providers to seek additional funding or

COMING IN FUTURE MONTHS

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cut back in services midyear. Shifting drug prices also raise issues for how frequently Title X–supported centers must recalculate their sliding-fee scale. Under that scale, clients are assessed a fee based on their income that is equal to a percentage of the provider's actual per-client costs. Similarly, health centers serving clients on Medicaid must face complicated inventory and billing issues to ensure that drug companies are not forced to provide duplicate discounts — first to the provider, and then to the state Medicaid agency in the form of rebate. They also must deal with the bureaucracy and payment delays common to state Medicaid programs and Medicaid managed care plans.

What can be done?

Although the Lewin-Guttmacher study was not designed to look for potential solutions to these problems, provider representatives volunteered numerous suggestions, particularly for the Office of Population Affairs.[2]

The agency could serve as a centralized information source for family planning centers on available discounts, program rules, current prices, and best practices. It could pull together information in a way that best fits the needs and understanding of Title X–supported providers. It also could coordinate efforts with 340B, Medicaid, and other government programs to identify ways in which program rules conflict and how best to respond. The agency could go further, even — for example, by gathering and analyzing purchasing data and providing technical assistance — to help its provid-

continued on page 84

CNE/CME INSTRUCTIONS

Physicians and nurses participate in this continuing nursing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the December issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CNE OBJECTIVES/QUESTIONS

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 services and patient care;
- integrate practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts;
- provide practical information that is evidence-based to help clinicians deliver contraceptives sensitively and effectively.

1. What is the Food and Drug Administration-approved indication for the ParaGard Copper T 380A IUD?
   A. Up to three years for intrauterine contraception
   B. Up to five years for intrauterine contraception
   C. Up to seven years for intrauterine contraception
   D. Up to 10 years for intrauterine contraception

2. What is the most accepted method for treating ovarian endometriomas?
   A. Surgery
   B. Chinese herbs
   C. Ethanol sclerotherapy
   D. Thalidomide

3. What are the World Health Organization's current recommendations for how to use the dedicated emergency contraceptive pill?
   A. 1 mg of levonorgestrel as a single dose.
   B. 1.5 mg of levonorgestrel as a single dose.
   C. 2 mg of levonorgestrel as a single dose.
   D. 1.5 mg of mifepristone as a single dose.

4. According to a new analysis released at the 2010 STD Prevention conference, what is the rate of new HIV diagnoses among men who have sex with men?
   A. More than 10 times that of other men and more than 20 times that of women
   B. More than 30 times that of other men and more than 40 times that of women

C. More than 44 times that of other men and more than 40 times that of women
D. More than 50 times that of other men and more than 60 times that of women

Answers: 1. D 2. A 3. B 4. C

continued from page 83

ers leverage their collective purchasing power to negotiate better prices with manufacturers. The most expansive solutions, however, would require action by Congress, to go beyond its limited efforts under health care reform to improve the discounts required of drug manufacturers. For example, Congress could expand the list of providers and supplies included in the 340B program or increase the stability and predictability of the 340B price ceilings.

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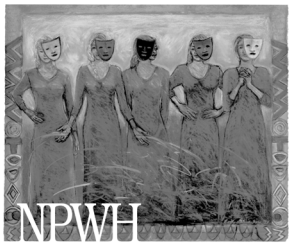
Contraceptive Technology Update is endorsed by the National Association of Nurse Practitioners in Women's Health and the Association of Reproductive Health Professionals as a vital information source for health care professionals.



S·T·D
QUARTERLY™

Report outlines impact of syphilis and HIV in U.S. gay and bisexual men

Rate of new HIV diagnoses among MSM is 44 times that of other men

An analysis presented at the 2010 National STD Prevention Conference gives a chilling look at impact of HIV and syphilis among U.S. gay and bisexual men.[1] The rate of new HIV diagnoses among men who have sex with men (MSM) is more than 44 times that of other men and more than 40 times that of women. The rate of primary and secondary syphilis among MSM is estimated at more than 46 times that of other men and more than 71 times that of women.

"While the heavy toll of HIV and syphilis among gay and bisexual men has been long recognized, this analysis shows just how stark the health disparities are between this and other populations," said **Kevin Fenton**, MD, director of the Centers for Disease Control and Prevention's (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, upon the release of the new information. "It is clear that we will not be able to stop the U.S. HIV epidemic until every affected community, along with health officials nationwide, prioritize the needs of gay and bisexual men with HIV prevention efforts."

While CDC data have shown for several years that gay and bisexual men make up most new HIV and new syphilis infections, the new rates reflect estimates based on the size of the U.S. population of gay and bisexual men. Because disease rates account for differences in the size of populations being compared, the new rates provide a reliable method for assessing health disparities between populations.

The analysis is just a first step in outlining the scope of the challenge, says **Jennifer Horvath**, a CDC spokesperson. The federal agency also is developing further breakdowns of MSM rates by race and age, as well as estimates for other populations significantly affected by HIV, such as injection drug users, she notes.

Look at the numbers

To determine the rates of disease for men who have sex with men, CDC researchers first estimated the size of the gay and bisexual male popu-

EXECUTIVE SUMMARY

A new analysis reveals the impact of HIV and syphilis among U.S. gay and bisexual men.

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- The rate of primary and secondary syphilis among MSM is estimated at more than 46 times that of other men and more than 71 times that of women.
- While national data have shown for several years that MSM make up most new HIV and new syphilis infections, the new rates reflect estimates based on the size of the U.S. population of gay and bisexual men.

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lation in the United States, which is defined as the proportion of men who reported engaging in same-sex behavior within the past five years. By analyzing nationally representative surveys, the researchers conclude that MSM comprise 2.0% (range: 1.4-2.7%) of the overall U.S. population ages 13 and older, or 4% of the U.S. male population (range: 2.8-5.3%).

Disease rates per 100,000 population then were calculated using 2007 surveillance data on HIV and primary/secondary syphilis diagnoses and U.S. Census data for the total U.S. population.[1] The analysis reports the range of new HIV diagnoses in MSM was 522-989 cases per 100,000, versus 12 per 100,000 other men and 13 per 100,000 women. The rate of primary and secondary syphilis among MSM was calculated at more than 46 times that of other men and more than 71 times that of women. The range was 91-173 cases per 100,000 MSM versus 2 per 100,000 other men and 1 per 100,000 women.

"These data underscore the significant disparities in HIV and syphilis among gay and bisexual men, and this new analysis calls for the need to intensify efforts to address the diverse profile of HIV in the gay community," says Horvath. "These results should also prompt a wake-up call that we will not be able to stop the U.S. HIV epidemic until every community more fully addresses the prevention needs of gay and bisexual men."

What's the next step?

The CDC recently has announced the expansion of its successful HIV testing initiative to reach more gay and bisexual men with HIV testing services.

Funding for the new phase of the initiative is expected to total about $142.5 million over the next three years. It will be provided to state and local health departments across the country to increase access to testing and early diagnosis of HIV. While the initiative originally was designed to increase testing and knowledge of HIV status primarily among African-American men and women, the program now will reach more U.S. jurisdictions and populations at risk. These include gay and bisexual men, as well as male and female Latinos and injection drug users. Public health officials are focusing the funding on areas across the nation where these populations are hardest hit. *(Federal officials set a June 3, 2010, deadline for funding applications. Go to the CDC web page www.cdc.gov/hiv/topics/funding/PS10-10138/index.htm for more information.)*

"Far too many Americans with HIV -- more than 200,000 people -- are unaware of their infection and may be unknowingly transmitting the virus to others," said **Jonathan Mermin**, MD, director of CDC's Division of HIV/AIDS Prevention, in an announcement of the program expansion. "The expansion of this initiative reflects CDC's continued commitment to ensure that far more Americans are tested for HIV, especially among vulnerable men and women most in need of HIV services."

To address the challenge of syphilis's impact in the gay and bisexual male community, the CDC is looking to increase access to syphilis screening for MSM, especially among those with HIV infection, says Horvath. The agency also continues to implement its updated National Syphilis Elimination Plan to address increases in syphilis diagnoses among MSM and prioritize prevention in cities where such men have been hardest hit, she notes. (*For more about the program, see the* Contraceptive Technology Update *article, "Syphilis rates continue to climb in the U.S.," May 2008, p. 57, and the STD Quarterly supplement article, "Syphilis rate on the increase in gay, bisexual men in the U.S.," July 2007, p. 1.)*

"CDC provides funding to the health departments with the greatest burden of syphilis cases, which in turn focus their efforts on the populations most impacted by the disease in their local areas," says Horvath. "CDC is also partnering with health departments and community-based organizations to expand testing, treatment, and prevention among MSM."

Multiple avenues eyed

Many factors come into play when looking at the high rates of HIV and syphilis among gay and bisexual men, research suggests.

These factors include high prevalence of HIV and other sexually transmitted diseases among MSM, which increases the risk of disease exposure, and limited access to prevention services. Other factors are complacency about HIV risk, particularly among young gay and bisexual men; difficulty of consistently maintaining safe behaviors with every sexual encounter over the course of a lifetime; and lack of awareness of syphilis symptoms and how it can be transmitted, such as in oral sex.[2] Additionally, factors such as homophobia and stigma can prevent gay and bisexual men from seeking prevention, testing, and treatment services, research indicates.

There is no single or simple solution for reducing HIV and syphilis rates among gay and bisexual men, says Fenton.

"We need intensified prevention efforts that are as diverse as the gay community itself," he says. "Solutions for young gay and bisexual men are especially critical, so that HIV does not inadvertently

become a rite of passage for each new generation of gay men."

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Community groups can perform HIV intervention

Researchers originally developed program

An approach designed to reduce HIV and sexually transmitted diseases (STDs) in adolescents previously used exclusively by academic researchers now has been shown to be successfully implemented by community-based organizations (CBOs).[1]

Adolescents are at heightened risk for STDs. The Centers for Disease Control and Prevention estimates that about 19 million new infections occur each year in the United States, with almost half of them among young people ages 15-24.[2]

The program, "Be Proud! Be Responsible!" originally was developed by researchers at the University of Pennsylvania. The current study was designed to evaluate the program outside the research setting, says program co-developer **John Jemmott III**, PhD, professor of communication in psychiatry and of communication at the University of Pennsylvania's School of Medicine and Annenberg School for Communication.

The "Be Proud! Be Responsible!" curriculum consists of six culturally appropriate, hour-long modules that address facts, attitudes, and beliefs surrounding HIV and AIDS. Condom use skills and negotiation-refusal techniques are included in the curriculum. The intervention is designed to be informative and entertaining and includes group discussion, games, mini-lectures, videos, condom demonstrations, role-plays, and other interactive activities.

To perform the current study, interventions were led by 86 community-based organizations with a total of 1,707 adolescent participants divided into a control group and an HIV/STD risk-reduction group. The intervention was designed to give adolescents the knowledge, motivation, and skills necessary to reduce their risk of STDs, including HIV. The teens reported in at three, six, and 12 months following the intervention. The study's primary outcome was consistent condom use in the three months prior to each follow-up assessment, averaged over the follow-up assessments.

Results indicate that HIV/STD-intervention participants were more likely to report consistent condom use [odds ratio (OR) = 1.39; 95% confidence interval (CI) = 1.06, 1.84] than were control-intervention participants.[1] The HIV/STD-intervention participants also reported a greater proportion of condom-protected intercourse (beta = 0.06; 95% CI = 0.00, 0.12) than did the control group.

The study also looked at the impact of extended training and found that CBO facilitators who received more training were no more effective than those who received a basic intervention packet alone. Results suggest that the training of CBO facilitators does not need to be "extraordinarily extensive or expensive" to achieve desired results, according to researchers.[1]

"We were pleased to find that effective interventions can retain their beneficial effects when implemented by CBOs outside of tightly controlled research settings," says program co-developer **Loretta Jemmott**, PhD, RN, professor of nursing at the University of Pennsylvania School of Nursing. "This has important implications for ways that future interventions can be rolled out."

Two extended versions of the "Be Proud! Be Responsible!" curriculum exist. "Making Proud Choices!" is the safer-sex-based extension, while "Making a Difference!" is the abstinence-based extension. The Jemmott research team continues to research abstinence interventions. Results from their theory-based, abstinence-only intervention appear to be associated with a lower rate of sexual involvement among African American sixth- and seventh-graders.[3] *(*Contraceptive Technology Update *reported on the study. See "New data on abstinence*

EXECUTIVE SUMMARY

An approach designed to reduce HIV and sexually transmitted diseases (STDs) in adolescents previously used exclusively by academic researchers now has been shown to be successfully implemented by community-based organizations
• The program, "Be Proud! Be Responsible!" originally was developed by researchers at the University of Pennsylvania. The program addresses facts, attitudes, and beliefs surrounding HIV and AIDS. Condom use skills and negotiation-refusal techniques are included in the curriculum.
• The Centers for Disease Control and Prevention estimates that approximately 19 million new STD infections occur each year in the United States, with almost half of them among young people ages 15-24.

— What do they mean for teen pregnancy prevention? April 2010, p. 37.)

The "Be Proud! Be Responsible!" program is one of several "best-evidence" HIV behavioral interventions evaluated by the Centers for Disease Control and Prevention's HIV/AIDS Prevention Research Synthesis Project. Interventions that are listed in the project's Compendium of HIV Prevention Interventions with Evidence of Effectiveness have been rigorously evaluated and have shown significant effects in eliminating or reducing sex- or drug-related risk behaviors, reducing the rate of new HIV/STD infections, or increasing HIV-protective behaviors. Interventions in the compendium meet the efficacy criteria for best evidence and are considered to provide the strongest scientific evidence of efficacy.[4] More than 60 evidence-based individual-level, group-level, and community-level HIV behavioral interventions are now listed in the resource. *(To see a list of the programs, go to cdc.gov/hiv/topics/research/prs/evidence-based-interventions.htm.)*

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